JSS ACADEMY OF HIGHER EDUCATION & RESEARCH
(DEEMED TO BE UNIVERSITY) MYSURU

JSS ACADEMY OF HIGHER EDUCATION AND RESEARCH, MYSURU

(Deemed to be University - Accrediated 'A+' Grade By NAAC)

JSS COLLEGE OF PHARMACY, OOTY

(An ISO 9001:2015 Certified Institution)
(Ranked 9th in India by NIRF - 2020)
(QS 3 Star in Pharmacy Program)

ACADEMIC CALENDAR

2020 - 2021

CONTENTS

1. EXCERPT FROM JSS ACADEMY OF HIGHER EDUCATION & RESEARCH REGULATIONS

Medium of instruction and examinations
Medium of instruction and examination shall be in English.

Working days in each semester
Each semester shall consist of not less than 100 working days. The odd semesters shall be conducted from the month of June/July to November/December and the even semesters shall be conducted from December/January to May/June in every calendar year.

Attendance and progress
A candidate is required to put in at least 80% attendance in individual courses considering theory and practical separately. The candidate shall complete the prescribed course satisfactorily to be eligible to appear for the respective examinations.

Program/Course credit structure
As per the philosophy of Credit Based Semester System, certain quantum of academic work viz. theory classes, tutorial hours, practical classes, etc. are measured in terms of credits. On satisfactory completion of the courses, a candidate earns credits. The amount of credit associated with a course is dependent upon the number of hours of instruction per week in that course. Similarly the credit associated with any of the other academic, co/extra-curricular activities is dependent upon the quantum of work expected to be put in for each of these activities per week.

Credit assignment
Theory and Laboratory courses
Courses are broadly classified as Theory and Practical. Theory courses consist of lecture (L) and Practical (P) courses consist of hours spent in the laboratory. Credits (C) for a course is dependent on the number of hours of instruction per week in that course, and is obtained by using a multiplier of one (1) for lecture and a multiplier of half (1/2) for practical (laboratory) hours. Thus, for example, a theory course having four lectures per week throughout the semester carries a credit of 4. Similarly, a practical having four laboratory hours per week throughout semester carries a credit of 2.
The contact hours of seminars, assignments and research work shall be treated as that of practical courses for the purpose of calculating credits. i.e., the contact hours shall be multiplies by ½. Similarly, the contact hours of journal club, research work presentations and discussions with the supervisor shall be considered as theory course and multiplied by 1.

Minimum credit requirements
The minimum credit points required for award of M Pharm degree by JSS AHER, Mysore is 95. However based on the credit points earned by the students under the head of the co-curricular activities, a student shall earn a maximum of 100 credit points. These credits are divided into theory courses, Practical, Seminars, Assignments, Research work, Discussions with the

supervisor, Journal club and Co-Curricular activities over the duration of four semesters. The credits are distributed semester wise. Courses generally progress in sequence, building competencies and their positioning indicates certain academic maturint on the part of learners. The learners are expected to follow the semester-wise schedule of courses given in the syllabus.

Academic work

A regular record of attendance both in Theory, Practical, Seminar, Assignment, Journal club, Discussion with supervisor, Research work presentation and dissertation shall be maintained by the Department/teaching staff of respective courses.

Course of study

The course of study for I M Pharm shall include Semester wise Theory & Practical as given in Table – I to X. The number of hours to be devoted to each theory, tutorial and practical course in any semester shall not be less than that shown in Table – I to X.

Table – I: Course of study for semester I & II (Pharmaceutics)

Course code	**Name of the course**	**No. of hours**	**Credit points**
Semester I			
MPH101T	Modern Pharmaceutical Analytical Techniques	4	4
MPH102T	Drug Delivery System	4	4
MPH103T	Modern Pharmaceutics	4	4
MPH104T	Regulatory Affair	4	4
MPH105T	Pharmaceutics Practical I	12	6
	Seminar/Assignment	07	4
Total		**35**	**26**
Semester II			
MPH201T	Molecular Pharmaceutics (Nano Tech and Targeted DDS)	4	4
MPH202T	Advanced Biopharmaceutics & Pharmacokinetics	4	4
MPH203T	Computer Aided Drug Delivery System	4	4
MPH204T	Cosmetic and Cosmeceuticals	4	4
MPH205T	Pharmaceutics Practical II	12	6
	Seminar/Assignment	7	4
Total		**35**	**26**

Table – II: Course of study for semester I & II (Industrial Pharmacy)

Course code	Name of the course	No. of hours	Credit points
Semester I			
MIP101T	Modern Pharmaceutical Analytical Techniques	4	4
MIP102T	Pharmaceutical Formulation Development	4	4
MIP103T	Novel drug delivery systems	4	4
MIP104T	Intellectual Property Rights	4	4
MIP105P	Industrial Pharmacy Practical I	12	6
	Seminar/Assignment	07	4
Total		**35**	**26**
Semester II			
MIP201T	Advanced Biopharmaceutics and Pharmacokinetics	4	4
MIP202T	Scale up and Technology Transfer	4	4
MIP203T	Pharmaceutical Production Technology	4	4
MIP204T	Entrepreneurship Management	4	4
MIP205P	Industrial Pharmacy Practical II	12	6
	Seminar/Assignment	7	4
Total		**35**	**26**

Table – III: Course of study for semester I & II (Pharmaceutical Chemistry)

Course code	Name of the course	No. of hours	Credit points
Semester I			
MPC101T	Modern Pharmaceutical Analytical Techniques	4	4
MPC1012T	Advanced Organic Chemistry -I	4	4
MPC103T	Advanced Medicinal chemistry	4	4
MPC104T	Chemistry of Natural Products	4	4
MPC105P	Pharmaceutical Chemistry Practical I	12	6
	Seminar/Assignment	07	4
Total		**35**	**26**
Semester II			
MPC201T	Advanced Spectral Analysis	4	4
MPC202T	Advanced Organic Chemistry -II	4	4
MPC203T	Computer Aided Drug Design	4	4
MPC204T	Pharmaceutical Process Chemistry	4	4
MPC205P	Pharmaceutical Chemistry Practical II	12	6
	Seminar/Assignment	7	4
Total		**35**	**26**

Table – IV: Course of study for semester I & II (Pharmaceutical Analysis)

Course code	Name of the course	No. of hours	Credit points
Semester I			
MPA101T	Modern Pharmaceutical Analytical Techniques	4	4
MPA102T	Advanced Pharmaceutical Analysis	4	4
MPA103T	Pharmaceutical Validation	4	4
MPA104T	Food Analysis	4	4
MPA105P	Pharmaceutical Analysis Practical I	12	6
	Seminar/Assignment	07	4
Total		**35**	**26**
Semester II			
MPA201T	Advanced Instrumental Analysis	4	4
MPA202T	Modern Bioanalytical Techniques	4	4
MPA203T	Quality Control and Quality Assurance	4	4
MPA204T	Herbal and Cosmetic analysis	4	4
MPA205P	Pharmaceutical Analysis Practical II	12	6
	Seminar /Assignment	7	4
Total		**35**	**26**

Table – V: Course of study for semester I & II (Pharmaceutical Quality Assurance)

Course code	Name of the course	No. of hours	Credit points
Semester I			
MQA101T	Modern Pharmaceutical Analytical Techniques	4	4
MQA102T	Quality Management System	4	4
MQA103T	Quality Control and Quality Assurance	4	4
MQA104T	Product Development and Technology Transfer	4	4
MQA105P	Pharmaceutical Quality Assurance Practical I	12	6
	Seminar/Assignment	07	4
Total		**35**	**26**
Semester II			
MQA201T	Hazards and Safety Management	4	4
MQA202T	Pharmaceutical Validation	4	4
MQA203T	Audits and Regulatory Compliance	4	4
MQA204T	Pharmaceutical Manufacturing Technology	4	4
MQA205P	Pharmaceutical Quality Assurance Practical II	12	6
	Seminar/Assignment	7	4
Total		**35**	**26**

Table – VI: Course of study for semester I & II (Pharmaceutical Regulatory Affairs)

Course code	Name of the course	No. of hours	Credit points
Semester I			
MRA101T	Good Regulatory Practices	4	4
MRA102T	Documentation and Regulatory writing	4	4
MRA103T	Clinical Research Regulations	4	4
MRA104T	Pharmaceutical Regulations and IPR	4	4
MRA105P	Pharmaceutical Regulatory Affairs Practical I	12	6
	Seminar/Assignment	07	4
Total		**35**	**26**
Semester II			
MRA201T	Regulatory Aspects of Drugs and Cosmetics	4	4
MRA202T	Regulatory Aspects of Herbals and Biologics	4	4
MRA203T	Regulatory Aspects of Medical Devices	4	4
MRA204T	Regulatory Aspects of Food and Nutraceuticals	4	4
MRA205P	Pharmaceutical Regulatory Affairs Practical II	12	6
	Seminar/Assignment	7	4
Total		**35**	**26**

Table – VII: Course of study for semester I & II (Pharmaceutical Biotechnology)

Course code	Name of the course	No. of hours	Credit points
Semester I			
MPB101T	Modern Pharmaceutical Analytical Techniques	4	4
MPB102T	Microbial and Cellular Biology	4	4
MPB103T	Bioprocess Engineering and Technology	4	4
MPB104T	Advanced Pharmaceutical Biotechnology	4	4
MPB105P	Pharmaceutical Biotechnology Practical I	12	6
	Seminar/Assignment	07	4
Total		**35**	**26**
Semester II			
MPB201T	Proteins and protein Formulation	4	4
MPB202T	Immunotechnology	4	4
MPB203T	Bioinformatics and Computer Technology	4	4
MPB204T	Biological Evaluation of Drug Therapy	4	4
MPB205P	Pharmaceutical Biotechnology Practical II	12	6
	Seminar/Assignment	7	4
Total		**35**	**26**

Table – VIII: Course of study for semester I & II (Pharmacy Practice)

Course code	Name of the course	No. of hours	Credit points
Semester I			
MPP101T	Clinical Pharmacy Practice	4	4
MPP102T	Pharmacotherapeutics - I	4	4
MPP103T	Hospital & Community Pharmacy	4	4
MPP104T	Clinical Research	4	4
MPP105P	Pharmacy Practice Practial I	12	6
	Seminar/Assignment	07	4
Total		**35**	**26**
Semester II			
MPP201T	Principles of Quality Use of Medicines	4	4
MPP202T	Pharmacotherapeutics - II	4	4
MPP203T	Clinical Pharmacokinetics and Therapeutic Drug Monitering	4	4
MPP204T	Pharmacoepidemiology & Pharmacoeconomics	4	4
MPP205P	Pharmacy Practice Practial II	12	6
	Seminar/Assignment	7	4
Total		**35**	**26**

Table – IX: Course of study for semester I & II (Pharmacology)

Course code	Name of the course	No. of hours	Credit points
Semester I			
MPL101T	Modern Pharmaceutical Analytical Techniques	4	4
MPL102T	Advanced Pharmacology-I	4	4
MPL103T	Pharmacological and Toxicological Screening Methods-I	4	4
MPL104T	Cellular and Molecular Pharmacology	4	4
MPL105P	Pharmacology Practical I	12	6
	Seminar/Assignments	07	4
Total		**35**	**26**
Semester II			
MPL 201T	Advanced Pharmacology II	4	4
MPL 202T	Pharmacological and Toxicological Screening Methods-II	4	4
MPL 203T	Principles of Drug Discovery	4	4
MPL 204 T	Clinical Research and Pharmacovigilance	4	4
MPL 205P	Pharmacology Practical II	12	6
	Seminar/Assignment	7	4
Total		**35**	**26**

Table – X: Course of study for semester I & II (Pharmacognosy)

Course code	Name of the course	No. of hours	Credit points
Semester I			
MPG 101T	Modern Pharmaceutical Analytical Techniques	4	4
MPG102T	Advanced Pharmacognosy I	4	4
MPG103T	Phytochemistry	4	4
MPG104T	Industrial Pharmacognostical Technology	4	4
MPG105P	Pharmacognosy Practical I	12	6
	Seminar/Assignment	07	4
Total		**35**	**26**
Semester II			
MPG 201T	Medicinal Plant Biotechnology	4	4
MPG 202T	Advanced Pharmacognosy II	4	4
MPG 203T	Indian Systems of Medicine	4	4
MPG 204T	Herbal Cosmetics	4	4
MPG 205P	Herbal Cosmetics Practical II	12	6
	Seminar/Assignment	7	4
Total		**35**	**26**

End semester examinations

The End Semester Examinations for each theory and practical course through semesters I to II shall be conducted by the university. (Table XI -Table XX)

Table – XI: Pharmaceutics

Course code	Name of the course	Internal Assessment				End Semester Exams		Total Marks
		Continuous Mode	Sessional Exams		Total	Marks	Duration	
			Marks	Duration				
Semester I								
MPH101T	Modern Pharmaceutical Analytical Techniques	10	15	1Hr	25	75	3 Hrs	100
MPH102T	Drug Delivery System	10	15	1Hr	25	75	3 Hrs	100
MPH103T	Modern Pharmaceutics	10	15	1Hr	25	75	3 Hrs	100
MPH104T	Regulatory Affair	10	15	1Hr	25	75	3 Hrs	100
MPH105T	Pharmaceutics Practical I	20	30	6 Hrs	50	100	6 Hrs	150
	Seminar/Assignment*	-	-	-	-	-	-	100
Total								**650**
Semester II								
MPH201T	Molecular Pharmaceutics (Nano Tech and Targeted DDS)	10	15	1Hr	25	75	3 Hrs	100
MPH202T	Advanced Biopharmaceutics & Pharmacokinetics	10	15	1Hr	25	75	3 Hrs	100
MPH203T	Computer Aided Drug Delivery System	10	15	1Hr	25	75	3 Hrs	100
MPH204T	Cosmetic and Cosmeceuticals	10	15	1Hr	25	75	3 Hrs	100
MPH205T	Pharmaceutics Practical II	20	30	6 Hrs	50	100	6 Hrs	150
	Seminar/Assignment*	-	-	-	-	-	-	100
Total								**650**

* The subject experts at college level shall conduct examination

Table – XII: Industrial Pharmacy

Course code	Name of the course	Internal Assessment				End Semester Exams		Total Marks
		Continuous Mode	Sessional Exams		Total	Marks	Duration	
			Marks	Duration				
Semester I								
MIP101T	Modern Pharmaceutical Analytical Techniques	10	15	1Hr	25	75	3 Hrs	100
MIP102T	Pharmaceutical Formulation Development	10	15	1Hr	25	75	3 Hrs	100
MIP103T	Novel drug delivery systems	10	15	1Hr	25	75	3 Hrs	100
MIP104T	Intellectual Property Rights	10	15	1Hr	25	75	3 Hrs	100
MIP105P	Industrial Pharmacy Practical I	20	30	6 Hrs	50	100	6 Hrs	150
	Seminar/Assignment*	-	-	-	-	-	-	100
Total								**650**
Semester II								
MIP201T	Advanced Biopharmaceutics and Pharmacokinetics	10	15	1Hr	25	75	3 Hrs	100
MIP202T	Scale up and Technology Transfer	10	15	1Hr	25	75	3 Hrs	100
MIP203T	Pharmaceutical Production Technology	10	15	1Hr	25	75	3 Hrs	100
MIP204T	Entrepreneurship Management	10	15	1Hr	25	75	3 Hrs	100
MIP205P	Industrial Pharmacy Practical II	20	30	6 Hrs	50	100	6 Hrs	150
	Seminar/Assignment*	-	-	-	-	-	-	100
Total								**650**

* The subject experts at college level shall conduct examination

Table – XIII: Pharmaceutical Chemistry

Course code	Name of the course	Internal Assessment				End Semester Exams		Total Marks
		Continuous Mode	Sessional Exams		Total	Marks	Duration	
			Marks	Duration				
Semester I								
MPC 101T	Modern Pharmaceutical Analytical Techniques	10	15	1Hr	25	75	3 Hrs	100
MPC 1012T	Advanced Organic Chemistry -I	10	15	1Hr	25	75	3 Hrs	100
MPC 103T	Advanced Medicinal chemistry	10	15	1Hr	25	75	3 Hrs	100
MPC 104T	Chemistry of Natural Products	10	15	1Hr	25	75	3 Hrs	100
MPC 105P	Pharmaceutical Chemistry Practical I	20	30	6 Hrs	50	100	6 Hrs	150
	Seminar/Assignment*	-	-	-	-	-	-	100
Total								**650**
Semester II								
MPC 201T	Advanced Spectral Analysis	10	15	1Hr	25	75	3 Hrs	100
MPC 202T	Advanced Organic Chemistry -II	10	15	1Hr	25	75	3 Hrs	100
MPC 203T	Computer Aided Drug Design	10	15	1Hr	25	75	3 Hrs	100
MPC 204T	Pharmaceutical Process Chemistry	10	15	1Hr	25	75	3 Hrs	100
MPC 205P	Pharmaceutical Chemistry Practical II	20	30	6 Hrs	50	100	6 Hrs	150
	Seminar/Assignment*	-	-	-	-	-	-	100
Total								**650**

* The subject experts at college level shall conduct examination

Table – XIV: Pharmaceutical Analysis

Course code	Name of the course	Internal Assessment				End Semester Exams		Total Marks
		Continuous Mode	Sessional Exams		Total	Marks	Duration	
			Marks	Duration				
Semester I								
MPA101T	Modern Pharmaceutical Analytical Techniques	10	15	1Hr	25	75	3 Hrs	100
MPA102T	Advanced Pharmaceutical Analysis	10	15	1Hr	25	75	3 Hrs	100
MPA103T	Pharmaceutical Validation	10	15	1Hr	25	75	3 Hrs	100
MPA104T	Food Analysis	10	15	1Hr	25	75	3 Hrs	100
MPA105P	Pharmaceutical Analysis Practical I	20	30	6 Hrs	50	100	6 Hrs	150
	Seminar/Assignment*	-	-	-	-	-	-	100
Total								**650**
Semester II								
MPA201T	Advanced Instrumental Analysis	10	15	1Hr	25	75	3 Hrs	100
MPA202T	Modern Bioanalytical Techniques	10	15	1Hr	25	75	3 Hrs	100
MPA203T	Quality Control and Quality Assurance	10	15	1Hr	25	75	3 Hrs	100
MPA204T	Herbal and Cosmetic analysis	10	15	1Hr	25	75	3 Hrs	100
MPA205P	Pharmaceutical Analysis Practical II	20	30	6 Hrs	50	100	6 Hrs	150
	Seminar/Assignment*	-	-	-	-	-	-	100
Total								**650**

* The subject experts at college level shall conduct examination

Table – XV: Pharmaceutical Quality Assurance

Course code	Name of the course	Internal Assessment				End Semester Exams		Total Marks
		Continuous Mode	Sessional Exams		Total	Marks	Duration	
			Marks	Duration				
Semester I								
MQA101T	Modern Pharmaceutical Analytical Techniques	10	15	1Hr	25	75	3 Hrs	100
MQA102T	Quality Management System	10	15	1Hr	25	75	3 Hrs	100
MQA103T	Quality Control and Quality Assurance	10	15	1Hr	25	75	3 Hrs	100
MQA104T	Product Development and Technology Transfer	10	15	1Hr	25	75	3 Hrs	100
MQA105P	Pharmaceutical Quality Assurance Practical I	20	30	6 Hrs	50	100	6 Hrs	150
	Seminar/Assignment*	-	-	-	-	-	-	100
Total								**650**
Semester II								
MQA201T	Hazards and Safety Management	10	15	1Hr	25	75	3 Hrs	100
MQA202T	Pharmaceutical Validation	10	15	1Hr	25	75	3 Hrs	100
MQA203T	Audits and Regulatory Compliance	10	15	1Hr	25	75	3 Hrs	100
MQA204T	Pharmaceutical Manufacturing Technology	10	15	1Hr	25	75	3 Hrs	100
MQA205P	Pharmaceutical Quality Assurance Practical II	20	30	6 Hrs	50	100	6 Hrs	150
	Seminar/Assignment*	-	-	-	-	-	-	100
Total								**650**

* The subject experts at college level shall conduct examination

Table – XVI: Pharmaceutical Regulatory Affairs

Course code	Name of the course	Internal Assessment				End Semester Exams		Total Marks
		Continuous Mode	Sessional Exams		Total	Marks	Duration	
			Marks	Duration				
Semester I								
MRA101T	Good Regulatory Practices	10	15	1Hr	25	75	3 Hrs	100
MRA102T	Documentation and Regulatory Writing	10	15	1Hr	25	75	3 Hrs	100
MRA103T	Clinical Research Regulations	10	15	1Hr	25	75	3 Hrs	100
MRA104T	Pharmaceutical Regulations and IPR	10	15	1Hr	25	75	3 Hrs	100
MRA105P	Pharmaceutical Quality Assurance Practical I	20	30	6 Hrs	50	100	6 Hrs	150
	Seminar/Assignment*	-	-	-	-	-	-	100
Total								**650**
Semester II								
MRA201T	Regulatory Aspects of Drugs and Cosmetics	10	15	1Hr	25	75	3 Hrs	100
MRA202T	Regulatory Aspects of Herbals and Biologics	10	15	1Hr	25	75	3 Hrs	100
MRA203T	Regulatory Aspects of Medical Devices	10	15	1Hr	25	75	3 Hrs	100
MRA204T	Regulatory Aspects of Food and Nutraceuticals	10	15	1Hr	25	75	3 Hrs	100
MRA205P	Pharmaceutical Regulatory Affairs Practical II	20	30	6 Hrs	50	100	6 Hrs	150
	Seminar/Assignment*	-	-	-	-	-	-	100
Total								**650**

* The subject experts at college level shall conduct examination

Table – XVII: Pharmaceutical Biotechnology

Course code	Name of the course	Internal Assessment				End Semester Exams		Total Marks
		Continuous Mode	Sessional Exams		Total	Marks	Duration	
			Marks	Duration				
Semester I								
MPB101T	Modern Pharmaceutical Analytical Techniques	10	15	1Hr	25	75	3 Hrs	100
MPB102T	Microbial and Cellular Biology	10	15	1Hr	25	75	3 Hrs	100
MPB103T	Bioprocess Engineering and Technology	10	15	1Hr	25	75	3 Hrs	100
MPB104T	Advanced Pharmaceutical Biotechnology	10	15	1Hr	25	75	3 Hrs	100
MPB105P	Pharmaceutical Biotechnology Practical I	20	30	6 Hrs	50	100	6 Hrs	150
	Seminar/Assignment*	-	-	-	-	-	-	100
Total								**650**
Semester II								
MPB201T	Proteins and protein Formulation	10	15	1Hr	25	75	3 Hrs	100
MPB202T	Immunotechnology	10	15	1Hr	25	75	3 Hrs	100
MPB203T	Bioinformatics and Computer Technology	10	15	1Hr	25	75	3 Hrs	100
MPB204T	Biological Evaluation of Drug Therapy	10	15	1Hr	25	75	3 Hrs	100
MPB205P	Pharmaceutical Biotechnology Practical II	20	30	6 Hrs	50	100	6 Hrs	150
	Seminar/Assignment*	-	-	-	-	-	-	100
Total								**650**

* The subject experts at college level shall conduct examination

Table – XVIII: Pharmacy Practice

Course code	Name of the course	Internal Assessment				End Semester Exams		Total Marks
		Continuous Mode	Sessional Exams		Total	Marks	Duration	
			Marks	Duration				
Semester I								
MPP101T	Clinical Pharmacy Practice	10	15	1Hr	25	75	3 Hrs	100
MPP102T	Pharmacotherapeutics - I	10	15	1Hr	25	75	3 Hrs	100
MPP103T	Hospital & Community Pharmacy	10	15	1Hr	25	75	3 Hrs	100
MPP104T	Clinical Research	10	15	1Hr	25	75	3 Hrs	100
MPP105P	Pharmacy Practice Practial I	20	30	6 Hrs	50	100	6 Hrs	150
	Seminar/Assignment*	-	-	-	-	-	-	100
Total								**650**
Semester II								
MPP201T	Principles of Quality Use of Medicines	10	15	1Hr	25	75	3 Hrs	100
MPP202T	Pharmacotherapeutics - II	10	15	1Hr	25	75	3 Hrs	100
MPP203T	Clinical Pharmacokinetics and Therapeutic Drug Monitering	10	15	1Hr	25	75	3 Hrs	100
MPP204T	Pharmacoepidemiology & Pharmacoeconomics	10	15	1Hr	25	75	3 Hrs	100
MPP205P	Pharmacy Practice Practial II	20	30	6 Hrs	50	100	6 Hrs	150
	Seminar/Assignment*	-	-	-	-	-	-	100
Total								**650**

* The subject experts at college level shall conduct examination

Table – XIX: Pharmacology

Course code	Name of the course	Internal Assessment				End Semester Exams		Total Marks
		Continuous Mode	Sessional Exams		Total	Marks	Duration	
			Marks	Duration				
Semester I								
MPL101T	Modern Pharmaceutical Analytical Techniques	10	15	1Hr	25	75	3 Hrs	100
MPL102 T	Advanced Pharmacology-I	10	15	1Hr	25	75	3 Hrs	100
MPL103T	Pharmacological and Toxicological Screening Methods-I	10	15	1Hr	25	75	3 Hrs	100
MPL104T	Cellular and Molecular pharmacology	10	15	1Hr	25	75	3 Hrs	100
MPL105P	Pharmacology Practical– I	20	30	6 Hrs	50	100	6 Hrs	150
	Seminar/Assignment*	-	-	-	-	-	-	100
Total								**650**
Semester II								
MPL201T	Advanced Pharmacology II	10	15	1Hr	25	75	3 Hrs	100
MPL102T	Pharmacological and Toxicological Screening Methods-II	10	15	1Hr	25	75	3 Hrs	100
MPL203T	Principles of Drug Discovery	10	15	1Hr	25	75	3 Hrs	100
MPL204T	Clinical Research & Pharmacovigilance	10	15	1Hr	25	75	3 Hrs	100
MPL205P	Pharmacology Practicals –II	20	30	6 Hrs	50	100	6 Hrs	150
	Seminar/Assignment*	-	-	-	-	-	-	100
Total								**650**

* The subject experts at college level shall conduct examination

Table – XX: Pharmacognosy

Course code	Name of the course	Internal Assessment				End Semester Exams		Total Marks
		Continuous Mode	Sessional Exams		Total	Marks	Duration	
			Marks	Duration				
Semester I								
MPG 101T	Modern Pharmaceutical Analytical Techniques	10	15	1Hr	25	75	3 Hrs	100
MPG 102T	Advanced Pharmacognosy I	10	15	1Hr	25	75	3 Hrs	100
MPG 103T	Phytochemistry	10	15	1Hr	25	75	3 Hrs	100
MPG 104T	Industrial Pharmacognostical Technology	10	15	1Hr	25	75	3 Hrs	100
MPG 105P	Pharmacognosy Practical I	20	30	6 Hrs	50	100	6 Hrs	150
	Seminar/Assignment*	-	-	-	-	-	-	100
Total								**650**
Semester II								
MPG 201T	Medicinal Plant Biotechnology	10	15	1Hr	25	75	3 Hrs	100
MPG 202T	Advanced Pharmacognosy II	10	15	1Hr	25	75	3 Hrs	100
MPG 203T	Indian Systems of Medicine	10	15	1Hr	25	75	3 Hrs	100
MPG 204T	Herbal Cosmetics	10	15	1Hr	25	75	3 Hrs	100
MPG 205P	Herbal Cosmetics Practicals	20	30	6 Hrs	50	100	6 Hrs	150
	Seminar/Assignment*	-	-	-	-	-	-	100
Total								**650**

* The subject experts at college level shall conduct examination

Internal assessment: Continuous mode

The marks allocated for Continuous mode of Internal Assessment shall be awarded as per the scheme given below.

Table – XXI: Scheme for awarding internal assessment: Continuous mode

Theory	
Criteria	**Maximum Marks**
Attendance (Refer Table – VI)	8
Student – Teacher interaction	2
Total	10
Practical	
Attendance (Refer Table – VI)	10
Based on Practical Records, Regular viva voce, etc.	10
Total	20

Table – XXII: Guidelines for the allotment of marks for attendance

Percentage of Attendance	**Theory**	**Practical**
95 – 100	8	10
90 – 94	6	7.5
85 – 89	4	5
80 – 84	2	2.5
Less than 80	0	0

Sessional Exams

Two sessional exams shall be conducted for each theory / practical course as per the schedule fixed by the college(s). The scheme of question paper for theory and practical sessional examinations is given below. The average marks of two sessional exams shall be computed for internal assessment as per the requirements given in tables – V - VIII.

Question paper pattern for theory sessional examinations
(Answer all the questions)

I. Long Answers (Answer 1 out of 2) = 1 x 10 = 10
II. Short Answers (Answer 4 out of 5) = 4 x 5 = 20

Total = 30 marks

Question paper pattern for practical sessional examinations

I. Synopsis = 10
II. Experiments = 40
III. Viva voce = 10

Total = 60 marks

Promotion and award of grades

A student shall be declared PASS and eligible for getting gradein a course of B.Pharm.programme if he/she secures at least 50% marks in that particular course including internal assessment.

Carry forward of marks

In case a student fails to secure the minimum 50% in any Theory or Practical course as specified in 12, then he/she shall reappear for the end semester examination of that course. However his/her marks of the Internal Assessment shall be carried over and he/she shall be entitled for grade obtained by him/her on passing.

Improvement of internal assessment

A student shall have the opportunity to improve his/her performance only once in the sessional exam component of the internal assessment. The re-conduct of the sessional exam shall be completed before the commencement of next end semester theory examinations.

Reexamination of end semester examinations

Reexamination of end semester examination shall be conducted as per the schedule given below. The exact dates shall be notificed from time to time

Tentative schedule of end semester examinations

Semester	For Regular Candidates	For Failed Candidates
I	November / December	May / June
II	May / June	November / December

Allowed to keep terms (ATKT)

No student shall be admitted to any examination unless he/she fulfills the norms of the JSSAHER. The ATKT rules are applicable as follows:

A student shall be eligible to carry forward all the courses of I and II Semester till the III semester examinations. However, he/she shall not be eligible to attend the courses of IV semester until all the courses of I, II and III semesters are successfully completed.

A student shall be eligible to get his/her CGPA upon successful completion of the courses of I to IV semesters within the stipulated time period as per the norms.

Note: Grade AB should be considered as failed and treated as one head for deciding ATKT. Such rules are also applicable for those students who fail to register for examination(s) of any course in any semester.

Award of Ranks

Ranks and Medals shall be awarded on the basis of final CGPA. However, candidates who fail in one or more courses during the B.Pharm program shall not be eligible for award of ranks.Moreover, the candidates should have completed the B. Pharm program in minimum prescribed number of years, (four years) for the award of Ranks.

Award of degree

Candidates who fulfill the requirements mentioned above shall be eligible for award of degree during the ensuing convocation.

Annual Calendar

2020-21

MAY - 2020

Date	Day	Particulars
1	FRI	May Day - Holiday
2	SAT	
3	**SUN**	**Holiday**
4	MON	
5	TUE	
6	WED	
7	THU	
8	FRI	
9	SAT	
10	**SUN**	**Holiday**
11	MON	**III Sessional Examinations for I, II DPharm, I to IV PharmD & II Sessional Examinations for II, IV, VI & VIII Semester BPharm**
12	TUE	
13	WED	
14	THU	
15	FRI	
16	SAT	
17	**SUN**	**Holiday**
18	MON	**Commencement of Academic Session 2020 – 21 for III, V & VII Semester BPharm., II to V PharmD, III Semester MPharm and II DPharm.**
19	TUE	
20	WED	
21	THU	
22	FRI	
23	SAT	
24	**SUN**	**Holiday**
25	MON	Ramzan - Holiday
26	TUE	
27	WED	
28	THU	
29	FRI	
30	SAT	
31	**SUN**	**Holiday**

JUNE - 2020

Date	Day	Particulars
1	MON	
2	TUE	
3	WED	
4	THU	
5	FRI	
6	SAT	
7	**SUN**	**Holiday**
8	MON	
9	TUE	
10	WED	
11	THU	
12	FRI	
13	SAT	
14	**SUN**	**Holiday**
15	MON	
16	TUE	
17	WED	
18	THU	
19	FRI	
20	SAT	
21	**SUN**	**Holiday**
22	MON	
23	TUE	
24	WED	
25	THU	
26	FRI	
27	SAT	
28	**SUN**	**Holiday**
29	MON	
30	TUE	**Completion of Internship for VI PharmD**

JULY - 2020

Date	Day	Particulars
1	WED	**Commencement of Internship for VI PharmD (Academic Year 2020-21) & Doctor's Day Program at Govt. Medical College Hospital, Ooty**
2	THU	
3	FRI	
4	SAT	
5	**SUN**	**Holiday**
6	MON	
7	TUE	
8	WED	
9	THU	
10	FRI	
11	SAT	
12	**SUN**	**Holiday**
13	MON	**Commencement of Certificate Courses and PG Diploma Programs**
14	TUE	
15	WED	
16	THU	
17	FRI	
18	SAT	**Objective Structured Clinical Examination (OSCE) - Demonstration Session for V PharmD Students**
19	**SUN**	**Holiday**
20	MON	**I Sessional Examinations for III, V and VII Semester BPharm**
21	TUE	
22	WED	
23	THU	
24	FRI	
25	SAT	
26	**SUN**	**Holiday**
27	MON	**I Sessional Examinations for III, V and VII Semester BPharm**
28	TUE	
29	WED	**Program Committee meeting for III, V and VII Semester BPharm** **I Sessional Examinations for IV PharmD (PB)**
30	THU	**I Sessional Examinations for II DPharm, II to IV PharmD**
31	FRI	

AUGUST - 2020

Date	Day	Particulars
1	SAT	Bakrid – Holiday
2	**SUN**	**Holiday**
3	MON	**I Sessional Examinations for II DPharm, II to IV PharmD**
4	TUE	
5	WED	
6	THU	
7	FRI	
8	SAT	Ph.D. Scholars Journal Club / Synopsis Presentation by 12:30 p.m. **Program Committee meeting for II DPharm, II to V PharmD**
9	**SUN**	**Holiday**
10	MON	**Commencement of Classes for I DPharm, I BPharm, I MPharm, I PharmD and I PharmD (PB) (Tentative)** Safe Use of Medicines – OUT REACH PROGRAM
11	TUE	Krishna Jayanthi - Holiday
12	WED	
13	THU	
14	FRI	
15	SAT	Independence Day - Flag Hoisting Ceremony at 9.30 a.m.
16	**SUN**	**Holiday**
17	MON	
18	TUE	
19	WED	
20	THU	
21	FRI	
22	SAT	Vinayakar Chaturthi – Holiday
23	**SUN**	**Holiday**
24	MON	
25	TUE	
26	WED	
27	THU	
28	FRI	
29	SAT	**Jayanthi of His Holiness Jagadguru Rajaguru Tilaka Dr. Sri Shivarathri Rajendra Mahaswamiji – Holiday (Tentative)**
30	**SUN**	Muharam – Holiday
31	MON	**Special Pooja on the eve of Jayanthi Celebrations of His Holiness Jagadguru Rajaguru Tilaka Dr. Sri Shivarathri Rajendra Mahaswamiji by 4 PM - 6 PM**

SEPTEMBER - 2020

Date	Day	Particulars
1	TUE	National Nutrition Week – OUT REACH PROGRAM **Non-University Examinations for II Semester BPharm**
2	WED	**Non-University Examinations for II Semester BPharm**
3	THU	
4	FRI	**Commencement of University Theory Examinations for II, IV , VI, VIII Semester BPharm and II Semester MPharm (Tentative)**
5	SAT	Ph.D. Research audit by 12.30 p.m. Teachers' Day Celebrations
6	**SUN**	**Holiday**
7	MON	
8	TUE	
9	WED	
10	THU	
11	FRI	
12	SAT	Ph.D. Scholars Journal Club / Synopsis Presentation by 12:30 p.m.
13	**SUN**	**Holiday**
14	MON	
15	TUE	
16	WED	
17	THU	
18	FRI	
19	SAT	Ph.D. Research audit by 12.30 p.m.
20	**SUN**	**Holiday**
21	MON	
22	TUE	
23	WED	
24	THU	
25	FRI	**World Pharmacist Day Celebrations and Professional Activities in association with IPA Nilgiris Local Branch**
26	SAT	Ph.D. Scholars Journal Club / Synopsis Presentation by 12:30 p.m.
27	**SUN**	**Holiday**
28	MON	**Commencement of University Theory Examinations for I & II DPharm., and I to V PharmD (Tentative)**
29	TUE	World Heart Day – OUT REACH PROGRAM
30	WED	

OCTOBER - 2020

Date	Day	Particulars
1	THU	
2	FRI	Gandhi Jayanthi – Holiday
3	SAT	Ph.D. Research audit by 12.30 p.m.
4	**SUN**	**Holiday**
5	MON	
6	TUE	
7	WED	
8	THU	
9	FRI	
10	SAT	Ph.D. Scholars Journal Club / Synopsis Presentation by 12:30 p.m. World Mental Health Day – OUT REACH PROGRAM
11	**SUN**	**Holiday**
12	MON	
13	TUE	
14	WED	
15	THU	
16	FRI	
17	SAT	Ph.D. Research audit by 12.30 p.m.
18	**SUN**	**Holiday**
19	MON	
20	TUE	
21	WED	
22	THU	
23	FRI	
24	SAT	Ayutha Pooja - Holiday (Tentative)
25	**SUN**	Ayutha Pooja - Holiday
26	MON	Vijaya Dasami – Holiday
27	TUE	
28	WED	**II Sessional Examinations for I, III, V and VII Semester BPharm**
29	THU	
30	FRI	Milad-un-Nabi - Holiday
31	SAT	Ph.D. Research audit by 12.30 p.m. **Parents – Teachers –Students Meet at 10 a.m. (Issue of Sessional Marks)**

NOVEMBER - 2020

Date	Day	Particulars
1	**SUN**	**Holiday**
2	MON	**II Sessional Examinations for I, III, V and VII Semester BPharm and I Semester MPharm**
3	TUE	
4	WED	
5	THU	
6	FRI	
7	SAT	Ph.D. Research audit by 12.30 p.m. Objective Structured Clinical Examination (OSCE) - First Sessional for V PharmD Students
8	**SUN**	**Holiday**
9	MON	Program Committee meeting for I, III, V and VII Semester BPharm & I Semester MPharm
10	TUE	World Immunization Day – OUT REACH PROGRAM
11	WED	**Non-University Examinations (Theory) for BPharm Semester System**
12	THU	
13	FRI	Deepavali - Holiday (Tentative)
14	SAT	Deepavali - Holiday World Diabetes Day – OUT REACH PROGRAM
15	**SUN**	**Holiday**
16	MON	**Commencement of University Theory Examinations for I , III, V, VII Semester BPharm. and I Semester MPharm.**
17	TUE	
18	WED	**PhD Module I: Get, Set and Research - Biostatistics, Research Methodology, Communications and Ethics**
19	THU	
20	FRI	
21	SAT	Ph.D. Research audit by 12.30 p.m. **II Sessional Examinations for IV Year PharmD (PB)**
22	**SUN**	**Holiday**
23	MON	**II Sessional Examinations for I, II DPharm, I to IV PharmD**
24	TUE	
25	WED	
26	THU	
27	FRI	
28	SAT	Ph.D. Scholars Journal Club / Synopsis Presentation by 12:30 p.m.
29	**SUN**	**Holiday**
30	MON	**II Sessional Examinations for I, II DPharm, I to IV PharmD**

DECEMBER - 2020

Date	Day	Particulars
1	TUE	World AIDS Day – OUT REACH PROGRAM
2	WED	**57th National Pharmacy Week Celebrations – Inauguration & Release of College Magazine 'PHARMASAGA' – Vol. XXIX, Profesional Awareness programmes, Cultural events and Valedictory function.**
3	THU	
4	FRI	
5	SAT	
6	**SUN**	**Holiday**
7	MON	**Commencement of Classes for II, IV, VI and VIII Semester BPharm and IV Semester MPharm Students** **Program Committee meeting for I, II DPharm, I to V PharmD**
8	TUE	
9	WED	
10	THU	
11	FRI	
12	SAT	Ph.D. Scholars Journal Club / Synopsis Presentation by 12:30 p.m.
13	**SUN**	**Holiday**
14	MON	
15	TUE	
16	WED	
17	THU	
18	FRI	
19	SAT	Ph.D. Research audit by 12.30 p.m.
20	**SUN**	**Holiday**
21	MON	
22	TUE	
23	WED	
24	THU	**Commencement of Winter Vacation**
25	FRI	Christmas – Holiday
26	SAT	
27	**SUN**	**Holiday**
28	MON	
29	TUE	
30	WED	
31	THU	

JANUARY - 2021

Date	Day	Particulars
1	FRI	New Year - Holiday
2	SAT	Ph.D. Research audit by 12.30 p.m.
3	**SUN**	**Holiday**
4	MON	
5	TUE	
6	WED	
7	THU	
8	FRI	
9	SAT	Ph.D. Scholars Journal Club / Synopsis Presentation by 12:30 p.m.
10	**SUN**	**Holiday**
11	MON	
12	TUE	
13	WED	
14	THU	Pongal – Holiday
15	FRI	Thiruvalluvar Day – Holiday
16	SAT	Uzhavar Thirunal – Holiday
17	**SUN**	**Holiday**
18	MON	**Commencement of Classes after Winter Vacation**
19	TUE	
20	WED	
21	THU	
22	FRI	
23	SAT	Ph.D. Scholars Journal Club / Synopsis Presentation by 12:30 p.m.
24	**SUN**	**Holiday**
25	MON	
26	TUE	Republic Day - Flag Hoisting Ceremony at 9.30 am
27	WED	
28	THU	
29	FRI	
30	SAT	Ph.D. Research audit by 12.30 p.m
31	**SUN**	**Holiday**

Note: Government Holidays for the year 2021 are to be confirmed and subject to change

FEBRUARY - 2021

Date	Day	Particulars
1	MON	
2	TUE	
3	WED	
4	THU	World Cancer Day – OUT REACH PROGRAM
5	FRI	**Annual Sports Meet**
6	SAT	
7	**SUN**	**Holiday**
8	MON	
9	TUE	
10	WED	
11	THU	
12	FRI	
13	SAT	Ph.D. Scholars Journal Club / Synopsis Presentation by 12:30 p.m.
14	**SUN**	**Holiday**
15	MON	
16	TUE	
17	WED	
18	THU	
19	FRI	**I Sessional Examinations for II, IV, VI & VIII Semester BPharm**
20	SAT	Ph.D. Research audit by 12.30 p.m.
21	**SUN**	**Holiday**
22	MON	**I Sessional Examinations for II, IV, VI & VIII Semester BPharm**
23	TUE	**I Sessional Examinations for II, IV, VI & VIII Semester BPharm and II Semester MPharm**
24	WED	
25	THU	
26	FRI	
27	SAT	Ph.D. Scholars Journal Club / Synopsis Presentation by 12:30 p.m.
28	**SUN**	**Holiday**

MARCH – 2021

Date	Day	Particulars
1	MON	**Commencement of NSS special camp in a selected Village**
2	TUE	**Program Committee meeting for II, IV, VI and VIII Semester BPharm & II Semester MPharm**
3	WED	
4	THU	
5	FRI	
6	SAT	Ph.D. Research audit by 12.30 p.m. **Closing of NSS special camp in a selected Village** **Parents – Teachers –Students Meet at 10 a.m. (Issue of Sessional Marks)**
7	**SUN**	**Holiday**
8	MON	
9	TUE	
10	WED	**III Sessional Examinations for IV PharmD (PB)**
11	THU	Maha Shivarathri - Holiday
12	FRI	**III Sessional Examinations for I, II DPharm, I to IV PharmD**
13	SAT	Ph.D. Scholars Journal Club / Synopsis Presentation by 12:30 p.m. **Objective Structured Clinical Examination (OSCE) - Second Sessional for V PharmD Students**
14	**SUN**	**Holiday**
15	MON	**III Sessional Examinations for I, II DPharm, I to IV PharmD**
16	TUE	
17	WED	
18	THU	
19	FRI	
20	SAT	**Awards, Annual day celebrations and Alumni meet (AAA Function) & Release of College Magazine 'PHARMASAGA' – Vol. XXX**
21	**SUN**	**Holiday**
22	MON	
23	TUE	**Program Committee meeting for I, II DPharm, I to V PharmD**
24	WED	
25	THU	
26	FRI	
27	SAT	Ph.D. Scholars Journal Club / Synopsis Presentation by 12:30 p.m.
28	**SUN**	**Holiday**
29	MON	
30	TUE	
31	WED	

APRIL - 2021

Date	Day	Particulars
1	THU	**Commencement of University Theory Examinations for I & II DPharm., and I to V PharmD (Tentative)**
2	FRI	Good Friday - Holiday
3	SAT	Ph.D. Research audit by 12.30 p.m.
4	**SUN**	**Holiday**
5	MON	**Personality Development Program for I D.Pharm, I B.Pharm and I PharmD students at Sutturu Sri Kshethra (Tentative)**
6	TUE	
7	WED	
8	THU	
9	FRI	
10	SAT	Ph.D. Scholars Journal Club / Synopsis Presentation by 12:30 p.m. Safe Use of Medicine – OUT REACH PROGRAM
11	**SUN**	**Holiday**
12	MON	
13	TUE	
14	WED	Tamil New Year and Dr. B.R. Ambedkar Birthday – Holiday
15	THU	
16	FRI	
17	SAT	Ph.D. Research audit by 12.30 p.m.
18	**SUN**	**Holiday**
19	MON	
20	TUE	
21	WED	
22	THU	
23	FRI	**II Sessional Examinations for II, IV, VI & VIII Semester BPharm**
24	SAT	Ph.D. Scholars Journal Club / Synopsis Presentation by 12:30 p.m.
25	**SUN**	**Mahavir Jayanthi - Holiday**
26	MON	**II Sessional Examinations for II, IV, VI & VIII Semester BPharm**
27	TUE	**II Sessional Examinations for II, IV, VI & VIII Semester BPharm and II Semester MPharm**
28	WED	
29	THU	
30	FRI	

MAY - 2021

Date	Day	Particulars
1	SAT	May Day - Holiday
2	**SUN**	**Holiday**
3	MON	**Non-University Examinations for II Semester BPharm** Program Committee meeting for II, IV, VI and VIII Semester BPharm& II Semester MPharm
4	TUE	**Non-University Examinations for II Semester BPharm**
5	WED	
6	THU	
7	FRI	
8	SAT	Ph.D. Scholars Journal Club / Synopsis Presentation by 12:30 p.m.
9	**SUN**	**Holiday**
10	MON	**Commencement of University Theory Examinations for II, IV , VI, VIII Semester BPharm and II Semester MPharm (Tentative)**
11	TUE	Ramzan - Holiday
12	WED	
13	THU	
14	FRI	
15	SAT	Ph.D. Research audit by 12.30 p.m.
16	**SUN**	**Holiday**
17	MON	World Hypertension Day – OUT REACH PROGRAM
18	TUE	
19	WED	**PhD Module II: Get, Set and Research - Biostatistics, Research Methodology, Communications and Ethics**
20	THU	
21	FRI	
22	SAT	Ph.D. Scholars Journal Club / Synopsis Presentation by 12:30 p.m.
23	**SUN**	**Holiday**
24	MON	
25	TUE	
26	WED	
27	THU	
28	FRI	**Commencement of Summer Vacation (Tentative)**
29	SAT	Ph.D. Research audit by 12.30 p.m.
30	**SUN**	**Holiday**
31	MON	

JUNE - 2021*

Date	Day	Particulars
1	TUE	
2	WED	
3	THU	
4	FRI	
5	SAT	Ph.D. Research audit by 12.30 p.m.
6	**SUN**	**Holiday**
7	MON	
8	TUE	
9	WED	
10	THU	
11	FRI	
12	SAT	Ph.D. Scholars Journal Club / Synopsis Presentation by 12:30 p.m.
13	**SUN**	**Holiday**
14	MON	
15	TUE	
16	WED	**Commencement of academic session 2021 – 22 for III, V & VII Semester BPharm., II to V PharmD, III Semester MPharm and II DPharm.**
17	THU	
18	FRI	
19	SAT	Ph.D. Research audit by 12.30 p.m.
20	**SUN**	**Holiday**
21	MON	
22	TUE	
23	WED	
24	THU	
25	FRI	
26	SAT	Ph.D. Scholars Journal Club / Synopsis Presentation by 12:30 p.m.
27	**SUN**	**Holiday**
28	MON	
29	TUE	
30	WED	

***This month will be overlapping with the academic year 2021-22.**

M. PHARM
PHARMACEUTICS

SYLLABUS
SEMESTER I
MPH 101T-MODERN PHARMACEUTICAL ANALYTICAL TECHNIQUES (Theory)

SCOPE
This subject deals with various advanced analytical instrumental techniques for identification, characterization and quantification of drugs. Instruments dealt are NMR, Mass spectrometer, IR, HPLC, GC etc.

OBJECTIVES
After completion of course student is able to know about chemicals and excipients
 The analysis of various drugs in single and combination dosage forms
 Theoretical and practical skills of the instruments

Course Content:

THEORY **60 Hrs**

1. a. UV-Visible spectroscopy: Introduction, Theory, Laws, Instrumentation associated with UV-Visible spectroscopy, Choice of solvents and solvent effect and Applications of UV-Visible spectroscopy, Difference/ Derivative spectroscopy. b. IR spectroscopy: Theory, Modes of Molecular vibrations, Sample handling, Instrumentation of Dispersive and Fourier - Transform IR Spectrometer, Factors affecting vibrational frequencies and Applications of IR spectroscopy, Data Interpretation. c. Spectroflourimetry: Theory of Fluorescence, Factors affecting fluorescence (Characterestics of drugs that can be analysed by flourimetry), Quenchers, Instrumentation and Applications of fluorescence spectrophotometer. d. Flame emission spectroscopy and Atomic absorption spectroscopy: Principle, Instrumentation, Interferences and Applications.	12 Hrs
2 NMR spectroscopy: Quantum numbers and their role in NMR, Principle, Instrumentation, Solvent requirement in NMR, Relaxation process, NMR signals in various compounds, Chemical shift, Factors influencing chemical shift, Spin-Spin coupling, Coupling constant, Nuclear magnetic double resonance, Brief outline of principles of FT-NMR and 13C NMR. Applications of NMR spectroscopy.	12 Hrs
3. Mass Spectroscopy: Principle, Theory, Instrumentation of Mass Spectroscopy, Different types of ionization like electron impact, chemical, field, FAB and MALDI, APCI, ESI, APPI Analyzers of Quadrupole and Time of Flight, Mass fragmentation and its rules, Meta stable ions, Isotopic peaks and Applications of Mass spectroscopy.	12 Hrs
4. Chromatography: Principle, apparatus, instrumentation, chromatographic parameters, factors affecting resolution, isolation of drug from excipients, data interpretation and applications of the following: Thin Layer chromatography High Performance Thin Layer Chromatography Ion exchange chromatography Column chromatography	12 Hrs

□ Gas chromatography □ High Performance Liquid chromatography □ Ultra High Performance Liquid chromatography □ Affinity chromatography □ Gel Chromatography	
5. a. Electrophoresis: Principle, Instrumentation, Working conditions, factors affecting separation and applications of the following: a) Paper electrophoresis b) Gel electrophoresis c) Capillary electrophoresis d) Zone electrophoresis e) Moving boundary electrophoresis f) Iso electric focusing b. X ray Crystallography: Production of X rays, Different X ray methods, Bragg's law, Rotating crystal technique, X ray powder technique, Types of crystals and applications of X-ray diffraction.	12 Hrs
a. Potentiometry: Principle, working, Ion selective Electrodes and Application of potentiometry. b. Thermal Techniques: Principle, thermal transitions and Instrumentation (Heat flux and power-compensation and designs), Modulated DSC, Hyper DSC, experimental parameters (sample preparation, experimental conditions, calibration, heating and cooling rates, resolution, source of errors) and their influence, advantage and disadvantages, pharmaceutical applications. Differential Thermal Analysis (DTA): Principle, instrumentation and advantage and disadvantages, pharmaceutical applications, derivative differential thermal analysis (DDTA). TGA: Principle, instrumentation, factors affecting results, advantage and disadvantages, pharmaceutical applications.	12 Hrs

REFERENCES

1. Spectrometric Identification of Organic compounds - Robert M Silverstein, Sixth edition, John Wiley & Sons, 2004.
2. Principles of Instrumental Analysis - Doglas A Skoog, F. James Holler, Timothy A. Nieman, 5th edition, Eastern press, Bangalore, 1998.
3. Instrumental methods of analysis – Willards, 7th edition, CBS publishers.
4. Practical Pharmaceutical Chemistry – Beckett and Stenlake, Vol II, 4th edition, CBS Publishers, New Delhi, 1997.
5. Organic Spectroscopy - William Kemp, 3rd edition, ELBS, 1991.
6. Quantitative Analysis of Drugs in Pharmaceutical formulation - P D Sethi, 3rd Edition, CBS Publishers, New Delhi, 1997.
7. Pharmaceutical Analysis - Modern Methods – Part B - J W Munson, Vol 11, Marcel. Dekker Series
8. Spectroscopy of Organic Compounds, 2nd edn., P.S/Kalsi, Wiley estern Ltd., Delhi.
9. Textbook of Pharmaceutical Analysis, KA.Connors, 3rd Edition, John Wiley & Sons, 1982.
10. Textbook of Pharmaceutical Analysis, KA.Connors, 3rd Edition, John Wiley & Sons, 1982.

MPH 102T-DRUG DELIVERY SYSTEMS (Theory)

SCOPE

This course is designed to impart knowledge on the area of advances in novel drug delivery systems

OBJECTIVES

Upon completion of the course, student shall be able to understand

- The various approaches for development of novel drug delivery systems.
- The criteria for selection of drugs and polymers for the development of delivering system
- The formulation and evaluation of Novel drug delivery systems..

Course Content:

THEORY **60 Hrs**

1. Sustained Release(SR) and Controlled Release (CR) formulations: Introduction & basic concepts, advantages/ disadvantages, factors influencing, Physicochemical & biological approaches for SR/CR formulation, Mechanism of Drug Delivery from SR/CR formulation. Polymers: introduction, definition, classification, properties and application Dosage Forms for Personalized Medicine: Introduction, Definition, Pharmacogenetics, Categories of Patients for Personalized Medicines: Customized drug delivery systems, Bioelectronic Medicines, 3D printing of pharmaceuticals, Telepharmacy.	10 Hrs
2. Rate Controlled Drug Delivery Systems: Principles & Fundamentals, Types, Activation; Modulated Drug Delivery Systems;Mechanically activated, pH activated, Enzyme activated, and Osmotic activated Drug Delivery Systems Feedback regulated Drug Delivery Systems; Principles & Fundamentals.	10 Hrs
3. Gastro-Retentive Drug Delivery Systems: Principle, concepts advantages and disadvantages, Modulation of GI transit time approaches to extend GI transit. Buccal Drug Delivery Systems: Principle of muco adhesion, advantages and disadvantages, Mechanism of drug permeation, Methods of formulation and its evaluations.	10 Hrs
4. Occular Drug Delivery Systems: Barriers of drug permeation, Methods to overcome barriers.	06 Hrs
5. Transdermal Drug Delivery Systems: Structure of skin and barriers, Penetration enhancers, Transdermal Drug Delivery Systems, Formulation and evaluation.	10 Hrs
6. Protein and Peptide Delivery: Barriers for protein delivery. Formulation and Evaluation of delivery systems of proteins and other macromolecules.	08 Hrs
7. Vaccine delivery systems: Vaccines, uptake of antigens, single shot vaccines, mucosal and transdermal delivery of vaccines	06 Hrs

REFERENCES

1. Y W. Chien, Novel Drug Delivery Systems, 2nd edition, revised and expanded, Marcel Dekker, Inc., New York, 1992.

2. Robinson, J. R., Lee V. H. L, Controlled Drug Delivery Systems, Marcel Dekker,Inc., New York, 1992.
3. Encyclopedia of controlled delivery, Editor- Edith Mathiowitz, Published by WileyInterscience Publication, John Wiley and Sons, Inc, New York! Chichester/Weinheim
4. N.K. Jain, Controlled and Novel Drug Delivery, CBS Publishers & Distributors, New Delhi, First edition 1997 (reprint in 2001).
5. S.P.Vyas and R.K.Khar, Controlled Drug Delivery - concepts and advances, Vallabh Prakashan, New Delhi, First edition 2002

JOURNALS

1. Indian Journal of Pharmaceutical Sciences (IPA)
2. Indian drugs (IDMA)
3. Journal of controlled release (Elsevier Sciences) desirable
4. Drug Development and Industrial Pharmacy (Marcel & Decker) desirable

MPH 103T-MODERN PHARMACEUTICS (Theory)

SCOPE

Course designed to impart advanced knowledge and skills required to learn various aspects and concepts at pharmaceutical industries

OBJECTIVES

Upon completion of the course, student shall be able to understand

- The elements of preformulation studies.
- The Active Pharmaceutical Ingredients and Generic drug Product development
- Industrial Management and GMP Considerations.
- Optimization Techniques & Pilot Plant Scale Up Techniques
- Stability Testing, sterilization process & packaging of dosage forms

Course Content:

THEORY **60 Hrs**

1. a. Preformation Concepts – Drug Excipient interactions - different methods, kinetics of stability, Stability testing. Theories of dispersion and pharmaceutical Dispersion (Emulsion and Suspension, SMEDDS) preparation and stability Large and small volume parental – physiological and formulation consideration, Manufacturing and evaluation. b. Optimization techniques in Pharmaceutical Formulation: Concept and parameters of optimization, Optimization techniques in pharmaceutical formulation and processing. Statistical design, Response surface method, Contour designs, Factorial designs and application in formulation	20 Hrs
2. Validation : Introduction to Pharmaceutical Validation, Scope & merits of Validation, Validation and calibration of Master plan, ICH & WHO guidelines for calibration and validation of equipments, Validation of specific dosage form, Types of validation. Government regulation, Manufacturing Process Model, URS, DQ, IQ, OQ & P.Q. of facilities	10 Hrs
3. cGMP & Industrial Management: Objectives and policies of current good manufacturing practices, layout of buildings, services, equipments and their maintenance Production management: Production organization, , materials management, handling and transportation, inventory management and control, production and planning control, Sales forecasting, budget and cost control, industrial and personal relationship. Concept of Total Quality Management.	10 Hrs
4. Compression and compaction: Physics of tablet compression, compression, consolidation, effect of friction, distribution of forces, compaction profiles. Solubility.	10 Hrs
5. Study of consolidation parameters; Diffusion parameters, Dissolution parameters and Pharmacokinetic parameters, Heckel plots, Similarity factors – f2 and f1, Higuchi and Peppas plot, Linearity Concept of significance, Standard deviation , Chi square test, students T-test , ANOVA test.	10 Hrs

REFERENCES

1. Theory and Practice of Industrial Pharmacy By Lachmann and Libermann
2. Pharmaceutical dosage forms: Tablets Vol. 1-3 by Leon Lachmann.
3. Pharmaceutical Dosage forms: Disperse systems, Vol, 1-2; By Leon Lachmann.
4. Pharmaceutical Dosage forms: Parenteral medications Vol. 1-2; By Leon Lachmann.
5. Modern Pharmaceutics; By Gillbert and S. Banker.
6. Remington's Pharmaceutical Sciences.
7. Advances in Pharmaceutical Sciences Vol. 1-5; By H.S. Bean & A.H. Beckett.
8. Physical Pharmacy; By Alfred martin
9. Bentley's Textbook of Pharmaceutics – by Rawlins.
10. Good manufacturing practices for Pharmaceuticals: A plan for total quality control, Second edition; By Sidney H. Willig.
11. Quality Assurance Guide; By Organization of Pharmaceutical producers of India.
1. 12.Drug formulation manual; By D.P.S. Kohli and D.H.Shah. Eastern publishers, New Delhi.
12. How to practice GMPs; By P.P.Sharma. Vandhana Publications, Agra.
13. Pharmaceutical Process Validation; By Fra. R. Berry and Robert A. Nash.
14. Pharmaceutical Preformulations; By J.J. Wells.
15. Applied production and operations management; By Evans, Anderson, Sweeney and Williams.
16. Encyclopaedia of Pharmaceutical technology, Vol I – III.

MPH 104T-REGULATORY AFFAIRS (Theory)

SCOPE

Course designed to impart advanced knowledge and skills required to learn the concept of generic drug and their development, various regulatory filings in different countries, different phases of clinical trials and submitting regulatory documents : filing process of IND, NDA and ANDA

- To know the approval process of
- To know the chemistry, manufacturing controls and their regulatory importance
- To learn the documentation requirements for
- To learn the importance and

OBJECTIVES

Upon completion of the course, it is expected that the students will be able to understand

- The Concepts of innovator and generic drugs, drug development process
- The Regulatory guidance's and guidelines for filing and approval process
- Preparation of Dossiers and their submission to regulatory agencies in different countries
- Post approval regulatory requirements for actives and drug products
- Submission of global documents in CTD/ eCTD formats
- Clinical trials requirements for approvals for conducting clinical trials
- Pharmacovigilence and process of monitoring in clinical trials.

Course Content:

THEORY **60 Hrs**

1. a. Documentation in Pharmaceutical industry: Master formula record, DMF (Drug Master File), distribution records. Generic drugs product development Introduction , Hatch- Waxman act and amendments, CFR (CODE OF FEDERAL REGULATION) ,drug product performance, in-vitro, ANDA regulatory approval process, NDA approval process, BE and drug product assessment, in –vivo, scale up process approval changes, post marketing surveillance, outsourcing BA and BE to CRO. b. Regulatory requirement for product approval: API, biologics, novel, therapies obtaining NDA, ANDA for generic drugs ways and means of US registration for foreign drugs	12 Hrs
2. CMC, post approval regulatory affairs. Regulation for combination products and medical devices.CTD and ECTD format, industry and FDA liaison. ICH - Guidelines of ICH-Q, S E, M. Regulatory requirements of EU, MHRA, TGA and ROW countries.	12 Hrs
3. Non clinical drug development: Global submission of IND, NDA, ANDA. Investigation of medicinal products dossier, dossier (IMPD) and investigator brochure (IB).	12 Hrs
4. Developing clinical trial protocols. Institutional review board/ independent ethics committee Formulation and working procedures informed Consent process and procedures. HIPAA- new, requirement to clinical study process, pharmacovigilance	12 Hrs

safety monitoring in clinical trials.	

REFERENCES

1. Generic Drug Product Development, Solid Oral Dosage forms, Leon Shargel and IsaderKaufer,Marcel Dekker series, Vol.143
2. The Pharmaceutical Regulatory Process, Second Edition Edited by Ira R. Berry and Robert P.Martin, Drugs and the Pharmaceutical Sciences,Vol.185, Informa Health care Publishers.
3. New Drug Approval Process: Accelerating Global Registrations By Richard A Guarino, MD,5th edition, Drugs and the Pharmaceutical Sciences,Vol.190.
4. Guidebook for drug regulatory submissions / Sandy Weinberg. By John Wiley & Sons.Inc.
5. FDA regulatory affairs: a guide for prescription drugs, medical devices, and biologics/edited By Douglas J. Pisano, David Mantus.
6. Clinical Trials and Human Research: A Practical Guide to Regulatory Compliance By Fay A.Rozovsky and Rodney K. Adams
7. www.ich.org/
8. www.fda.gov/
9. europa.eu/index_en.htm
10.https://www.tga.gov.au/tga-basics

MPH 105P-PHARMACEUTICS PRACTICALS – I

1. Analysis of pharmacopoeial compounds and their formulations by UV Vis spectrophotometer
2. Simultaneous estimation of multi component containing formulations by UV spectrophotometry
3. Experiments based on HPLC
4. Experiments based on Gas Chromatography
5. Estimation of riboflavin/quinine sulphate by fluorimetry
6. Estimation of sodium/potassium by flame photometry
7. To perform In-vitro dissolution profile of CR/ SR marketed formulation
8. Formulation and evaluation of sustained release matrix tablets
9. Formulation and evaluation osmotically controlled DDS
10. Preparation and evaluation of Floating DDS- hydro dynamically balanced DDS
11. Formulation and evaluation of Muco adhesive tablets.
12. Formulation and evaluation of trans dermal patches.
13. To carry out preformulation studies of tablets.
14. To study the effect of compressional force on tablets disintegration time.
15. To study Micromeritic properties of powders and granulation.
16. To study the effect of particle size on dissolution of a tablet.
17. To study the effect of binders on dissolution of a tablet.
18. To plot Heckal plot, Higuchi and peppas plot and determine similarity factors.

SEMESTER II

MPH 201T-MOLECULAR PHARMACEUTICS (NANO TECHNOLOGY & TARGETED DDS) (NTDS) (Theory)

SCOPE

This course is designed to impart knowledge on the area of advances in novel drug delivery systems.

OBJECTIVES

Upon completion of the course student shall be able to understand

- The various approaches for development of novel drug delivery systems.
- The criteria for selection of drugs and polymers for the development of NTDS
- The formulation and evaluation of novel drug delivery systems.

Course Content:

THEORY **60 Hrs**

1 Targeted Drug Delivery Systems: Concepts, Events and biological process involved in drug targeting. Tumor targeting and Brain specific delivery.	12 Hrs
2. Targeting Methods: introduction preparation and evaluation. Nano Particles & Liposomes: Types, preparation and evaluation.	12 Hrs
3. Micro Capsules / Micro Spheres: Types, preparation and evaluation , Monoclonal Antibodies ; preparation and application, preparation and application of Niosomes, Aquasomes, Phytosomes, Electrosomes.	12 Hrs
4. Pulmonary Drug Delivery Systems : Aerosols, propellents, ContainersTypes, preparation and evaluation, Intra Nasal Route Delivery systems; Types, preparation and evaluation.	12 Hrs
5. Nucleic acid based therapeutic delivery system : Gene therapy, introduction (ex-vivo & in-vivo gene therapy). Potential target diseases for gene therapy (inherited disorder and cancer). Gene expression systems (viral and nonviral gene transfer). Liposomal gene delivery systems. Biodistribution and Pharmacokinetics. knowledge of therapeutic antisense molecules and aptamers as drugs of future.	12 Hrs

REFERENCES

1. Y W. Chien, Novel Drug Delivery Systems, 2nd edition, revised and expanded,Marcel Dekker, Inc., New York, 1992.
2. S.P.Vyas and R.K.Khar, Controlled Drug Delivery - concepts and advances, VallabhPrakashan, New Delhi, First edition 2002.
3. N.K. Jain, Controlled and Novel Drug Delivery, CBS Publishers & Distributors, NewDelhi, First edition 1997 (reprint in 2001).

MPH 202T-ADVANCED BIOPHARMACEUTICS & PHARMACOKINETICS (Theory)

SCOPE

This course is designed to impart knowledge and skills necessary for dose calculations, dose adjustments and to apply biopharmaceutics theories in practical problem solving. Basic theoretical discussions of the principles of biopharmaceutics and pharmacokinetics are provided to help the students' to clarify the concepts.

OBJECTIVES

Upon completion of this course it is expected that students will be able understand,

- The basic concepts in biopharmaceutics and pharmacokinetics.
- The use raw data and derive the pharmacokinetic models and parameters the best describe the process of drug absorption, distribution, metabolism and elimination.
- The critical evaluation of biopharmaceutic studies involving drug product equivalency.
- The design and evaluation of dosage regimens of the drugs using pharmacokinetic and biopharmaceutic parameters.
- The potential clinical pharmacokinetic problems and application of basics of pharmacokinetic

Course Content:

THEORY	**60 Hrs**
1 Drug Absorption from the Gastrointestinal Tract: Gastrointestinal tract, Mechanism of drug absorption, Factors affecting drug absorption, pH–partition theory of drug absorption. Formuulation and physicochemical factors: Dissolution rate, Dissolution process, Noyes–Whitney equation and drug dissolution, Factors affecting the dissolution rate. Gastrointestinal absorption: role of the dosage form: Solution (elixir, syrup and solution) as a dosage form ,Suspension as a dosage form, Capsule as a dosage form, Tablet as a dosage form ,Dissolution methods ,Formulation and processing factors, Correlation of in vivo data with in vitro dissolution data.Transport model: Permeability-Solubility-Charge State and the pH Partition Hypothesis, Properties of the Gastrointestinal Tract (GIT), pH Microclimate Intracellular pH Environment, Tight-Junction Complex	12 Hrs
2. Biopharmaceutic considerations in drug product design and In Vitro Drug Product Performance: Introduction, biopharmaceutic factors affecting drug bioavailability, rate-limiting steps in drug absorption, physicochemical nature of the drug formulation factors affecting drug product performance, in vitro: dissolution and drug release testing, compendial methods of dissolution, alternative methods of dissolution testing,meeting dissolution requirements,problems of variable control in dissolution testingperformance of drug products. In vitro–in vivo correlation, dissolution profile comparisons, drug product stability,considerations in the design of a drug product.	12 Hrs
3. Pharmacokinetics: Basic considerations, pharmacokinetic models, compartment modeling: one compartment model- IV bolus, IV infusion, extra-vascular. Multi compartment model:two compartment - model in brief, non-linear pharmacokinetics:	12 Hrs

cause of non-linearity, Michaelis – Menten equation, estimation of kmax and vmax. Drug interactions: introduction, the effect of proteinbinding interactions,the effect of tissue-binding interactions,cytochrome p450-based drug interactions,drug interactions linked to transporters.	
4. Drug Product Performance, In Vivo: Bioavailability and Bioequivalence: drug product performance, purpose of bioavailability studies, relative and absolute availability. methods for assessing bioavailability, bioequivalence studies, design and evaluation of bioequivalence studies, study designs, crossover study designs, evaluation of the data, bioequivalence example, study submission and drug review process. biopharmaceutics classification system, methods. Permeability: In-vitro, in-situ and In-vivo methods.generic biologics (biosimilar drug products),clinical significance of bioequivalence studies, special concerns in bioavailability and bioequivalence studies, generic substitution.	12 Hrs
5. Application of Pharmacokinetics: Modified-Release Drug Products, Targeted Drug Delivery Systems and Biotechnological Products. Introduction to Pharmacokinetics and pharmacodynamic, drug interactions. Pharmacokinetics and pharmacodynamics of biotechnology drugs. Introduction, Proteins and peptides, Monoclonal antibodies, Oligonucleotides, Vaccines (immunotherapy), Gene therapies.	12 hrs

REFERENCES

1. Biopharmaceutics and Clinical Pharmacokinetics by Milo Gibaldi, 4th edition,Philadelphia, Lea and Febiger, 1991
2. Biopharmaceutics and Pharmacokinetics, A. Treatise, D .M. Brahmankar and Sunil B. Jaiswal., VallabPrakashan, Pitampura, Delhi
3. Applied Biopharmaceutics and Pharmacokinetics by Shargel. Land YuABC, 2ndedition, Connecticut Appleton Century Crofts, 1985
4. Textbook of Biopharmaceutics and Pharmacokinetics, Dr. Shobha Rani R. Hiremath,Prism Book
5. Pharmacokinetics by Milo Gibaldi and D. Perrier, 2nd edition, Marcel Dekker Inc.,New York, 1982 6. Current Concepts in Pharmaceutical Sciences: Biopharmaceutics, Swarbrick. J, Leaand Febiger, Philadelphia, 1970
6. Clinical Pharmacokinetics, Concepts and Applications 3rd edition by MalcolmRowland and Thom~ N. Tozer, Lea and Febiger, Philadelphia, 1995
7. Dissolution, Bioavailability and Bioequivalence, Abdou. H.M, Mack PublishingCompany, Pennsylvania 1989
8. Biopharmaceutics and Clinical Pharmacokinetics, An Introduction, 4th edition,revised and expande by Robert. E. Notari, Marcel Dekker Inc, New York and Basel,1987.
9. Biopharmaceutics and Relevant Pharmacokinetics by John. G Wagner and M.Pemarowski, 1st edition, Drug Intelligence Publications, Hamilton, Illinois, 1971.
10. Encyclopedia of Pharmaceutical Technology, Vol 13, James Swarbrick, James. G.Boylan, Marcel Dekker Inc, New York, 1996.
11. Basic Pharmacokinetics,1 st edition,Sunil S JambhekarandPhilip J Breen,pharmaceutical press, RPS Publishing,2009.

12. Absorption and Drug Development- Solubility, Permeability, and Charge State, Alex Avdeef, John Wiley & Sons, Inc,2003.

MPH 203T-COMPUTER AIDED DRUG DEVELOPMENT (Theory)

SCOPE

This course is designed to impart knowledge and skills necessary for computer Applications in pharmaceutical research and development who want to understand the application of computers across the entire drug research and development process. Basic theoretical discussions of the principles of more integrated and coherent use of computerized information (informatics) in the drug development process are provided to help the students to clarify the concepts.

OBJECTIVES

Upon completion of this course it is expected that students will be able to understand,

- History of Computers in Pharmaceutical Research and Development
- Computational Modeling of Drug Disposition
- Computers in Preclinical Development
- Optimization Techniques in Pharmaceutical Formulation
- Computers in Market Analysis
- Computers in Clinical Development
- Artificial Intelligence (AI) and Robotics
- Computational fluid dynamics(CFD)

Course Content:

THEORY **60 Hrs**

1 a. Computers in Pharmaceutical Research and Development: A General Overview: History of Computers in Pharmaceutical Research and Development. Statistical modeling in Pharmaceutical research and development: Descriptive versus Mechanistic Modeling, Statistical Parameters, Estimation, Confidence Regions, Nonlinearity at the Optimum, Sensitivity Analysis, Optimal Design, Population Modeling b. Quality-by-Design In Pharmaceutical Development: Introduction, ICH Q8 guideline, Regulatory and industry views on QbD, Scientifically based QbD - examples of application.	12 Hrs
2. Computational Modeling Of Drug Disposition: Introduction ,Modeling Techniques: Drug Absorption, Solubility, Intestinal Permeation, Drug Distribution ,Drug Excretion, Active Transport; P-gp, BCRP, Nucleoside Transporters, hPEPT1, ASBT, OCT, OATP, BBB-Choline Transporter	12 Hrs
3. Computer-aided formulation development:: Concept of optimization, Optimization parameters, Factorial design, Optimization technology & Screening design. Computers in Pharmaceutical Formulation: Development of pharmaceutical emulsions, microemulsion drug carriers Legal Protection of Innovative Uses of Computers in R&D, The Ethics of Computing in Pharmaceutical Research, Computers in Market analysis.	12 Hrs
4. a. Computer-aided biopharmaceutical characterization: Gastrointestinal absorption simulation. Introduction, Theoretical background, Model construction, Parameter sensitivity analysis, Virtual trial, Fed vs. fasted state, In vitro dissolution and in	12 Hrs

vitroin vivo correlation, Biowaiver considerations b. Computer Simulations in Pharmacokinetics and Pharmacodynamics: Introduction, Computer Simulation: Whole Organism, Isolated Tissues, Organs, Cell, Proteins and Genes. c. Computers in Clinical Development: Clinical Data Collection and Management, Regulation of Computer Systems	
5. Artificial Intelligence (AI), Robotics and Computational fluid dynamics: General overview, Pharmaceutical Automation, Pharmaceutical applications, Advantages and Disadvantages. Current Challenges and Future Directions.	12 Hrs

REFERENCES

1. Computer Applications in Pharmaceutical Research and Development, Sean Ekins, 2006, John Wiley & Sons.
2. Computer-Aided Applications in Pharmaceutical Technology, 1st Edition, Jelena Djuris, Woodhead Publishing
3. Encyclopedia of Pharmaceutical Technology, Vol 13, James Swarbrick, James. G.Boylan, Marcel Dekker Inc, New York, 1996.

MPH 204T-COSMETICS AND COSMECEUTICALS (Theory)

SCOPE

This course is designed to impart knowledge and skills necessary forthefundamental need for cosmetic and cosmeceutical products.

OBJECTIVES

Upon completion of the course, the students shall be able to understand

- Key ingredients used in cosmetics and cosmeceuticals.
- Key building blocks for various formulations.
- Current technologies in the market
- Various key ingredients and basic science to develop cosmetics and cosmeceuticals
- Scientific knowledge to develop cosmetics and cosmeceuticals with desired Safety, stability, and efficacy.

Course Content:

THEORY	**60 Hrs**
1 Cosmetics – Regulatory : Definition of cosmetic products as per Indian regulation. Indian regulatory requirements for labeling of cosmetics Regulatory provisions relating to import of cosmetics., Misbranded and spurious cosmetics. Regulatory provisions relating to manufacture of cosmetics – Conditions for obtaining license, prohibition of manufacture and sale of certain cosmetics, loan license, offences and penalties.	12 Hrs
2. Cosmetics - Biological aspects : Structure of skin relating to problems like dry skin, acne, pigmentation, prickly heat, wrinkles and body odor. Structure of hair and hair growth cycle. Common problems associated with oral cavity. Cleansing and care needs for face, eye lids, lips, hands, feet, nail, scalp, neck, body and under-arm.	12 Hrs
3. Formulation Building blocks: Building blocks for different product formulations of cosmetics/cosmeceuticals. Surfactants – Classification and application. Emollients, rheological additives: classification and application. Antimicrobial used as preservatives, their merits and demerits. Factors affecting microbial preservative efficacy. Building blocks for formulation of a moisturizing cream, vanishing cream, cold cream, shampoo and toothpaste. Soaps and syndetbars. Perfumes; Classification of perfumes. Perfume ingredients listed as allergens in EU regulation. Controversial ingredients: Parabens, formaldehyde liberators, dioxane.	12 Hrs
4. Design of cosmeceutical products: Sun protection, sunscreens classification and regulatory aspects. Addressing dry skin, acne, sun-protection, pigmentation, prickly heat, wrinkles, body odor., dandruff, dental cavities, bleeding gums, mouth odor and sensitive teeth through cosmeceutical formulations.	12 Hrs
5. Herbal Cosmetics : Herbal ingredients used in Hair care, skin care and oral care. Review of guidelines for herbal cosmetics by private bodies like cosmos with respect to preservatives, emollients, foaming agents, emulsifiers and rheology modifiers. Challenges in formulating herbal cosmetics.	12 Hrs

REFERENCES

1. Harry's Cosmeticology. 8th edition.
2. Poucher'sperfumecosmeticsandSoaps,10th edition.
3. Cosmetics - Formulation, Manufacture and quality control, PP.Sharma,4th edition
4. Handbook of cosmetic science and Technology A.O.Barel, M.Paye and H.I. Maibach. 3 rd edition
5. Cosmetic and Toiletries recent suppliers catalogue.
6. CTFA directory.

MPH 205P-PHARMACEUTICS PRACTICALS - II

1. To study the effect of temperature change , non solvent addition, incompatible polymer addition in microcapsules preparation
2. Preparation and evaluation of Alginate beads
3. Formulation and evaluation of gelatin /albumin microspheres
4. Formulation and evaluation of liposomes/niosomes
5. Formulation and evaluation of spherules
6. Improvement of dissolution characteristics of slightly soluble drug by Solid dispersion technique.
7. Comparison of dissolution of two different marketed products /brands
8. Protein binding studies of a highly protein bound drug & poorly protein bound drug
9. Bioavailability studies of Paracetamol in animals.
10. Pharmacokinetic and IVIVC data analysis by WinnolineR software
11. In vitro cell studies for permeability and metabolism
12. DoE Using Design Expert® Software
13. Formulation data analysis Using Design Expert® Software
14. Quality-by-Design in Pharmaceutical Development
15. Computer Simulations in Pharmacokinetics and Pharmacodynamics
16. Computational Modeling Of Drug Disposition
17. To develop Clinical Data Collection manual
18. To carry out Sensitivity Analysis, and Population Modeling.
19. Development and evaluation of Creams
20. Development and evaluation of Shampoo and Toothpaste base
21. To incorporate herbal and chemical actives to develop products
22. To address Dry skin, acne, blemish, Wrinkles, bleeding gums and dandruff.

DETAILS OF SUBJECT TEACHERS – semester I

S.No	Name of the Subject	Name of the Teachers	Designation and Department	Mobile No.	e-mail
1.	Modern Pharmaceutical Analytical Techniques	Dr. N. Krishnaveni	Professor	9442083447	krisath@jssuni.edu.in
2.	Drug Delivery System	Dr V Senthil	Professor	9842650602	senthil.v@jssuni.edu.in
3.	Modern Pharmaceutics	Dr R Sureshkumar	Asst,Professor	9865064872	sureshcoonoor@jssuni.edu.in
4.	Regulatory Affair	Dr.K Gowthamarajan	Professor	9443089812	gowthansang@jssuni.edu.in

DETAILS OF SUBJECT TEACHERS – semester II

S.No	Name of the Subject	Name of the Teachers	Designation and Department	Mobile No.	e-mail
5.	Molecular Pharmaceutics (Nano Tech and Targeted DDS)	Dr R Sureshkumar	Asst. Professor	9952335392	sureshcoonoor@jssuni.edu.in
6.	Advanced Biopharmaceutics & Pharmacokinetics	Dr. N Jawahar	Asst. Professor	9486946314	jawahar.n@jssuni.edu.in
7.	Computer Aided Drug Delivery System	Dr Karri VVS Narayana Reddy	Lecturer	9952478866	narayana.reddy@jssuni.edu.in
8.	Cosmetic and Cosmeceuticals	Dr V Senthil	Professor	9842650602	senthil.v@jssuni.edu.in

Academic Plan
2020-21

SEMESTER 1

Name of the Subject	**Modern Pharmaceutical Analytical Techniques (Theory)**
Name of the Faculty	Dr. Krishna Veni N M.Pharm., Ph.D
Designation, Department	Professor & Head, Department of Pharmaceutical Analysis
Mobile Number	9442083447
e-Mail i.d.	krisath@jssuni.edu.in

Scope, Course Objectives and Course Outcomes

SCOPE

This subject deals with various advanced analytical instrumental techniques for identification, characterization and quantification of drugs. Instruments dealt are NMR, Mass spectrometer, IR, HPLC, GC etc.

OBJECTIVES

After completion of course student is able to know about

1. Chemicals and excipients
2. The analysis of various drugs in single and combination dosage forms
3. Theoretical and practical skills of the instruments

COURSE OUTCOMES (COS)

At completion of this course it is expected that the students will be able to

CO 1 : Explain the general principles and techniques of spectroscopy & Chromatography

CO 2 : Perform the assay of single and multiple component pharmaceuticals using various analytical techniques

CO 3 : Develop skills in selecting suitable techniques for the analysis of drugs and pharamceutials

CO 4 : Apply the knowledge learnt in developing newer analytical methods and procedures of their own design

CO 5 : Explore and learn the various instrumental techniques available for the analysis of organic substances

LECTURE PLAN – Abstract

Sessional	No. of Hours of Didactic Lecture	No of Hours of other Activities	Total No. of Lecture Hours
	Advanced Instrumentation Techniques		
I	30	1	31
II	30	--	30
Total No. of Hours	60	--	61

I SESSIONAL : 30 Lectures + 1 Activity

Lecture No.	Lecture Details	Hours
	Orientation of the subject	**01**
Unit-1:		**10**
UV Visible Spectroscopy		
1.	UV Visible Spectroscopy - Introduction, Theory, Laws	
2.	Instrumentation associated with UV Visible Spectroscopy, Choice of Solvents & Solvent Effects	
3.	Applications of UV visible spectroscopy, Difference/ Derivative Spectroscopy	
IR Spectroscopy		
4.	IR Spectroscopy - Theory, Modes of Molecular Vibrations, Samples handling	
5.	Instrumentation of Dispersive and Fourier Transform IR spectrometere	
6.	Factors affecting vibrational frequencies and applications of IR spectroscopy, Data Interpretation	
Spectroflourimetry		
7.	Spectroflourimetry - Theory of fluorescence, Factors affecting fluorescence	
8.	Quenchers, Instrumentation, Applications of Fluorescence Spectrophotometer	
Flame emission spectroscopy & Atomic abosrption spectroscopy		
9.	Principle, Instrumentation	
10.	Interferences and Applications	
Unit-2:		**10**
NMR Spectroscopy		
1.	NMR spectroscopy - Quantum numbers and their role in NMR, Principle	
2.	Instrumentation - Continous wave NMR instrument	
3.	Principle and Instrumentation of FT NMR	
4.	solvent requirements, Relaxation process	
5.	NMR signals in various compounds	
6.	chemical shift, factors influencing chemical shift	
7.	spin spin coupling, coupling constant	
8.	Nuclear magnetic double resonance	
9.	Applications of NMR Spectroscopy	

10.	Principles of 13C NMR	
Unit-3:		**10**
MassSpectrometry		
1.	Principle, theory	
2.	Instrumentation of Mass Spectroscopy - sample introduction techniques	
3.	Different types of ionization - electron impact, chemical	
4.	Different types of ionization - Field, FAB and MALDI	
5.	Different types of ionization - APCI, ESI, APPI	
6.	Analyzers of Quadrupole and Time of Flight	
7.	Mass fragmentation and its rules	
8.	Mass fragmentation and its rules	
9.	Meta stable ions, Isotopic peaks	
10.	Applications of Mass spectroscopy	

II SESSIONAL : 30 Lectures

Lecture No.	Lecture Details	Hours
Unit-4:		**10**
Chromatography - Principle, Apparatus, Instrumentation, Chromatographic Parameters, Factors influencing resolution, Isolation of drugs from excipients, data interpretation and applications of		
1.	Thin Layer Chromatography	
2.	High Performance Thin Layer Chromatography	
3.	Ion Exchange Chromatography	
4.	column Chromatography	
5.	Gas Chromatography	
6.	Gas Chromatography	
7.	HPLC	
8.	HPLC	
9.	Ultra high Performance Liquid Chromatography	
10.	Affinity Chromatography, Gel Chromatography	
Unit-5:		**10**
Electrophoresis - Principle, Instrumentation, Working, Factors affecting separation and applications		
1.	Paper Electrophoresis	
2.	Gel Electrophoresis, Zone Electrophoresis	
3.	Capillary Electrophoresis	
4.	Capillary Electrophoresis	
5.	Moving Boundray Electrophoresis	
6.	Iso Electric Focussing	
X Ray Crystallography		
7.	Production of X Rays, Braggs Law	
8.	Different X Ray diffraction methods - Rotating Crystal Technique	
9.	X Ray Powder technique, Types of Crystals	
10.	Applications of X Ray Diffractions	
Unit-6:		**10**
Immunological Assays		

1.	Potentiometry - Principle, working	
2.	Ion selective Electrodes and other electrodes used in potentiometry	
3.	Applications of potentiometry	
Thermal Techniques		
4.	Differential Scanning Colorimetry - Principle, Thermal transitions	
5.	DSC - Instrumentation (Power compensated, heat flux designs),	
6.	Modulated DSC, Hyper DSC	
7.	Experimental Parameters - sample preparation, experimental conditions, calibration, heating and cooling rates, resolution, source of errors), Their influence, advantages, disadvantages and applications	
8.	Differential Thermal Analysis (DTA) - Principle instrumentation, Advantages & Disadvantages, Pharmaceutical Applications	
9.	Derivative Differential Thermal Analysis	
10.	Thermogravimetric Analysis (TGA) - Principle, instrumentation, factors affecting results, advantages & disadvantages, Pharmaceutical Applications	

Text Books

1. Spectrometric Identification of Organic compounds - Robert M Silverstein, Sixth edition, John Wiley & Sons, 2004.
2. Principles of Instrumental Analysis - Doglas A Skoog, F. James Holler, Timothy A. Nieman, 5th edition, Eastern press, Bangalore, 1998.
3. Instrumental methods of analysis – Willards, 7th edition, CBS publishers.
4. Practical Pharmaceutical Chemistry – Beckett and Stenlake, Vol II, 4th edition, CBS Publishers, New Delhi, 1997.
5. Organic Spectroscopy - William Kemp, 3rd edition, ELBS, 1991.
6. Quantitative Analysis of Drugs in Pharmaceutical formulation - P D Sethi, 3rd Edition, CBS Publishers, New Delhi, 1997.
7. Pharmaceutical Analysis - Modern Methods – Part B - J W Munson, Vol 11, Marcel. Dekker Series
8. Spectroscopy of Organic Compounds, 2nd edn., P.S/Kalsi, Wiley estern Ltd., Delhi.
9. Textbook of Pharmaceutical Analysis, KA.Connors, 3rd Edition, John Wiley & Sons, 1982.

Reference Books

1. Introduction to Spectroscopy; by Donald L Pavia

Name of the Subject	**Drug Delivery System (Theory)**
Course/ Semester	M.Pharm,, Ist Semester
Name of the Faculty	Dr V.Senthil, M.Pharm, Ph.D,
Designation, Department	Professor, Pharmaceutics
Mobile Number	9842650602
e-Mail i.d.	senthil.v@jssuni.edu.in

Scope, Course Objectives and Course Outcomes

SCOPE

This course is designed to impart knowledge on the area of advances in novel drug delivery systems.

OBJECTIVES

Upon completion of the course, student shall be able to understand

- The various approaches for development of novel drug delivery systems.
- The criteria for selection of drugs and polymers for the development of delivering system
- The formulation and evaluation of Novel drug delivery systems.

Course Outcomes (COs): At completion of this course it is expected that the students will be able to

CO 1: Explain the principles and technology used in the design of sustained release and controlled release drug delivery systems

CO 2: Learn the criteria for selection of a drugs and polymers for the development of Novel drug delivery systems

CO 3: Explain development of ocular formulations and intra uterine devices (IUDs) and it's applications

CO 4: Explain the formulation and characterization of transdermal drug Delivery systems

CO5: Learn the various approaches for development of novel drug delivery systems

LECTURE PLAN – Abstract

Sessional	No. of Hours of Didactic Lecture	No of Hours of other Activities	Total No. of Lecture Hours
I	30	3	33
II	30	3	33
Total No. of Hours	60	6	66

I SESSIONAL
LECTURE PLAN 30 Lectures+ 3 Activities

Lecture No.	Lecture Details	
UNIT-1	Sustained Release (SR) and Controlled Release (CR) formulations: Introduction (10)	**Hours**
1.	Introduction & basic concepts	10
2.	advantages/ disadvantages, factors influencing, Physicochemical & biological approaches for SR/CR formulation	
3.	Mechanism of Drug Delivery from SR/CR formulation.	
4.	Polymers: introduction, definition, classification, properties and application	
5.	Dosage Forms for Personalized Medicine: Introduction, Definition	
6.	Pharmacogenetics, Categories of Patients for Personalized Medicines	
7.	Customized drug delivery systems, Bioelectronic Medicines,	
8.	3D printing of pharmaceuticals, Tele pharmacy.	
UNIT-2	Rate Controlled Drug Delivery Systems (10)	10
9.	Principles & Fundamentals,	
10.	Activation; Modulated Drug Delivery Systems	
11.	Mechanically activated System	
12.	pH activated, Enzyme activated System	
13.	Osmotic activated Drug Delivery Systems	
14.	Feedback regulated Drug Delivery Systems;	
Activity1	Test	
Activity2	Test	
UNIT-3	Gastro-Retentive Drug Delivery Systems (10)	
15.	Principle, concepts advantages and disadvantages	
16.	Modulation of GI transit time approaches to extend GI transit	
17.	Buccal Drug Delivery Systems and principle	
18.	Principle of mucoadhesion, advantages and disadvantages	
19.	Mechanism of drug permeation, Methods of formulation and its evaluations	
Activity 3	Test	

II SESSIONAL : 30 Lectures + 3 Activities

UNIT-4	Occular Drug Delivery Systems (06)	
20.	Introduction	

21.	Barriers of drug permeation, Methods to overcome barriers.	06
22.	Types of Occular Drug Delivery Systems	
UNIT-5	Transdermal Drug Delivery Systems (10)	10
23.	Introduction, Structure of skin	
24.	skin and barriers	
25.	Penetration enhancers	
26.	Transdermal Drug Delivery Systems	
27.	Formulation and evaluation	
UNIT-6	Protein and Peptide Delivery (08)	08
28.	Barriers for protein delivery.	
29.	Formulation and Evaluation of delivery systems of proteins	
30.	Formulation and Evaluation of delivery systems of other macromolecules	
UNIT-7	Vaccine delivery systems (06)	06
31.	Vaccines, uptake of antigens	
32.	Single shot vaccines,	
33.	mucosal and transdermal delivery of vaccines	
Activity1	Test	
Activity1	Test	
Activity1	Test	

Recommended Books: (Latest Editions)

1. Y W. Chien, Novel Drug Delivery Systems, 2nd edition, revised and expanded, Marcel Dekker, Inc., New York, 1992.
2. Robinson, J. R., Lee V. H. L, Controlled Drug Delivery Systems, Marcel Dekker,Inc., New York, 1992.
3. Encyclopedia of controlled delivery, Editor- Edith Mathiowitz, Published by WileyInterscience Publication, John Wiley and Sons, Inc, New York! Chichester/Weinheim
4. N.K. Jain, Controlled and Novel Drug Delivery, CBS Publishers & Distributors, New Delhi, First edition 1997 (reprint in 2001).
5. S.P.Vyas and R.K.Khar, Controlled Drug Delivery - concepts and advances, Vallabh Prakashan, New Delhi, First edition 20022

Name of the Subject	**Modern Pharmaceutics-(Theory)**
Name of the Faculty	Dr. R.Sureshkumar M.Pharm., Ph.D
Designation, Department	Assistant Professor, Department of Pharmaceutics
Mobile Number	9865064872
e-Mail i.d.	sureshcoonoor@jssuni.edu.in

Scope, Course Objectives and Course Outcomes

SCOPE

This course is designed to impart knowledge and skills necessary to impart advanced knowledge and skills required to learn various aspects and concepts in pharmaceutical industries

OBJECTIVES

The primary objectives of this course are to

To gain knowledge on the aspects of management of industry

1. Acquire knowledge on the aspects prior to formulation
2. Gain knowledge on the kinetics of drug release
3. Design appropriate statistical approaches for formulation development

COURSE OUTCOMES (COS)

At completion of this course it is expected that the students will be able to

The elements of preformulation studies.

CO1: The Active Pharmaceutical Ingredients and Generic drug Product development

CO2: Industrial Management and GMP Considerations.

CO3: Optimization Techniques & Pilot Plant Scale Up Techniques

CO4: Stability Testing, sterilization process & packaging of dosage forms

LECTURE PLAN – Abstract

Sessional	No. of Hours of Didactic Lecture Modern Pharmaceutics-(MPH 103T)	No of Hours of other Activities	Total No. of Lecture Hours
I	30	6	36
II	20	4	24
Total No. of Hours	50	10	60

I SESSIONAL : 22 Lectures + 6Activities

Lecture No.	Lecture Details	Hours
Modern Pharmaceutics		
Unit-1: Targeted Drug Delivery system		**10**
a. Preformulation Concepts		
1.a.1	Drug Excipient Interactions	
1.a.2	Methods to determine	
1.a.3	kinetics of stability and Stability testing	
1.a.4	Theories of Pharmaceutical dispersion	
1.a.5.1	preparation and stability Large and small Volume parenterals	
1.a.5.2	Formulation consideration-Manufacturing	
1.a.5.3	Evaluation	
b. Optimization techniques inPharmaceutical Formulation		**10**
1.b.1	Concept and parameters of optimization	
1.b.2	Optimization techniques in formulation and processing	
1.b.3	Statistical design	
1.b.4	Response surface method	
1.b.5	Contour designs	
1.b.6	Factorial designs and application	
Unit-2: Validation		**10**
2.1	Introduction to Pharmaceutical Validation	
2.2	Scope & merits of Validation	
2.3	Validation and calibration of Master plan	
2.4.1	ICH & WHO guidelines for calibration	
2.4.2	Validation of equipments	
2.5	Validation of specific dosage form	
2.6	Types of validation	
2.7	Government regulations	
2.8	Manufacturing Process Model URS, DQ, IQ, OQ & P.Q.	
Activity1	Mind Mapping on Selected Topic	
Activity2	MCQ Test	
Activity3	MCQ Test	
Activity4	Revision-1	
Activity5	Revision-2	
Activity6	Revision-3	

II SESSIONAL : 15 Lectures + 4 Activities

Lecture No.	Lecture Details	Hours
Unit-3: cGMP & Industrial Management		
3.1	Objectives and policies of cGMP	
3.2.1	layout of buildings & services,	
3.2.2	Equipments and their maintenance	
3.3	Production management:	
3.3.1	Production organization	
3.3.2	Materials management	**10**
3.3.3	Handling and transportation	
3.3.4	Inventory management and control	
3.3.5	production and planning control	
3.3.6	Sales forecasting, budget and cost control	
3.3.7	Industrial and personal relationship	
3.4	Concept of Total Quality Management	
Unit-4: Compression and compaction		
4.1	Physics of tablet compression	
4.2	Compression, consolidation,	
4.3	effect of friction	**10**
4.4	Distribution of forces	
4.5	compaction profiles	
4.6	Solubility	
Unit-5: Study of consolidation parameters		
5.1	Diffusion parameters	**10**
5.2	Dissolution parameters	
5.3	Pharmacokinetic parameters	
5.5	Heckel plots	
5.6	Similarity factors – f2 and f1	
5.7	Higuchi and Peppas plot	
5.8	Linearity Concept of significance	
5.9	Standard deviation , Chi square test, students T-test , ANOVA test	
Activity-1	MCQ Test	
Activity-2	MCQ Test	
Activity-3	Revision Test 1	
Activity-4	Revision Test 2	

Text Books

1. Theory and Practice of Industrial Pharmacy By Lachmann and Libermann
2. Pharmaceutical dosage forms: Tablets Vol. 1-3 by Leon Lachmann.
3. Pharmaceutical Dosage forms: Disperse systems, Vol, 1-2; By Leon Lachmann.
4. Pharmaceutical Dosage forms: Parenteral medications Vol. 1-2; By Leon Lachmann.

Reference Books

1. Modern Pharmaceutics; By Gillbert and S. Banker. 6. Remington's Pharmaceutical Sciences.
2. Advances in Pharmaceutical Sciences Vol. 1-5; By H.S. Bean & A.H. Beckett.

3. Physical Pharmacy; By Alfred martin
4. Bentley's Textbook of Pharmaceutics – by Rawlins.
5. Good manufacturing practices for Pharmaceuticals: A plan for total quality control, Second edition; By Sidney H. Willig.
6. Quality Assurance Guide; By Organization of Pharmaceutical producers of India.
7. Drug formulation manual; By D.P.S. Kohli and D.H.Shah. Eastern publishers, New
8. Delhi.
9. How to practice GMPs; By P.P.Sharma. Vandhana Publications, Agra.
10. Pharmaceutical Process Validation; By Fra. R. Berry and Robert A. Nash.
11. Pharmaceutical Preformulations; By J.J. Wells.
12. Applied production and operations management; By Evans, Anderson, Sweeney and Williams.
13. Encyclopaedia of Pharmaceutical technology, Vol I – III.

Name of the Subject	**Regulatory Affairs (Theory)**
Name of the Faculty	Dr. K Gowthamarajan M.Pharm., Ph.D
Designation, Department	Professore & Head, Department of Pharmaceutics
Mobile Number	9443089812
e-Mail i.d.	gowthamsang@jssuni.edu.in

Scope, Course Objectives and Course Outcomes

SCOPE

Course designed to impart advanced knowledge and skills required to learn the concept of generic drug and their development, various regulatory filings in different countries, different phases of clinical trials and submitting regulatory documents and filing process of IND, NDAandANDA.

OBJECTIVES

The primary objectives of this course are to

1. Understand the concepts of innovatore and generic drugs
2. Prepare of dossiers and their submission to regulatory agencies in different countries
3. Excute Postapproval regulatory requirements for actives and drug products
4. Submit of global documents in CTD/eCTD formats
5. Implement Preclinical requirements for sumitting requlatory applications
6. Prepare the Clinical trials requirements for approvals and to participate in clinical trials phases

Course Outcomes (COs):

At completion of this course it is expected that the students will be able to

CO 1: Define the basic concepts involved in drug development process
CO 2: Assist and guide the IND,NDA &ANDA applications
CO 3: File the various requlatory submissions for new products and for changes to approved products
CO 4: Prepare dossiers for regulatory agencies in different countries
CO 5: Prepare the precilical and clinical protocols for clinical trials.
Participate the pharmacovigilence programme.

LECTURE PLAN – Abstract

Sessional	Number of Hours of Didactic Lecture	No. of Hours of other activities	Total Number of Lecture Hours
I	**32**	**03**	**35**
II	**30**	**04**	**34**
Total Number of Lecture Hours	**61**	**-**	**69**

I SESSIONAL: 31 lectures +3 Activities

Lecture No.	Lecture Details	Hours
1.	Introduction to Regulatory Affairs (RA)	(01)
Unit-1: Documentation in Pharmaceutical industry		(12)
1.	Master formula record, DMF (Drug Master File), distribution records	**12**
2.	Generic drugs product development : Introduction , HatchWaxman act and amendments	
3.	CFR (Code Of Federal Regulation)	
4.	Drug product performance-in vitro	
5.	Drug product performance-in vitro (cont…)	
6.	ANDA regulatory approval process, NDAapproval process	
7.	BE and drug product assessment-in vivo	
8.	BE and drug product assessment-in vivo (cont…)	
9.	Scale up process approval changes	
10.	Scale up process approval changes (cont…)	
11.	Post marketing surveillance	
12.	Outsourcing BA and BE to CRO	
Unit-2: Regulatory requirement for product approval		(12)
1.	Regulatory requirement for product approval: API obtaining NDA, ANDA for generic drugs ways and means of US registration for foreign drugs	**12**
2.	Regulatory requirement for product approval: API obtaining NDA, ANDA for generic drugs ways and means of US registration for foreign drugs (cont…)	
3.	Regulatory requirement for product approval: API obtaining NDA, ANDA for generic drugs ways and means of US registration for foreign drugs (cont…)	
4.	Regulatory requirement for product approval: API obtaining NDA, ANDA for generic drugs ways and means of US registration for foreign drugs (cont…)	
5.	Regulatory requirement for product approval: Biologics obtaining NDA ,ANDA for generic drugs ways and means of US registration for foreign drugs	
6.	Regulatory requirement for product approval: biologics obtaining NDA ,ANDA for generic drugs ways and means of US registration for foreign drugs (cont…)	
7.	Regulatory requirement for product approval: Biologics obtaining NDA, ANDA for generic drugs ways and means of US	

	registration for foreign drugs (cont…)	
8.	Regulatory requirement for product approval: Biologics obtaining NDA, ANDA for generic drugs ways and means of US registration for foreign drugs (cont…)	
9.	Regulatory requirement for product approval: Novel therapies obtaining NDA, ANDA for generic drugs ways and means of US registration for foreign drugs	
10.	Regulatory requirement for product approval: Novel therapies obtaining NDA, ANDA for generic drugs ways and means of US registration for foreign drugs (cont…)	
11.	Regulatory requirement for product approval: Novel therapies obtaining NDA ,ANDA for generic drugs ways and means of US registration for foreign drugs (cont…)	
12.	Regulatory requirement for product approval: Novel therapies obtaining NDA ,ANDA for generic drugs ways and means of US registration for foreign drugs (cont…)	
Unit-3: Chemistry, Manufacturing, and Controls (CMC)		(06)
1.	Chemistry, Manufacturing, and Controls	**06**
2.	Post approval regulatory affairs	
3.	Regulation for medical devices	
4.	Regulation for combination products	
5.	CTD and ECTD format	
6.	Industry and FDA liaison	
Activity 1	Unit test- 1	
Activity 2	Unit test-2	
Activity 3	Unit test-3	

II SESSIONAL : 30 Lectures +4 Activities

Lecture No.	**Lecture Details**	**Hours**
Unit-3: Chemistry, Manufacturing, and Controls (CMC)		(06)
1.	ICH - Guidelines	**06**
2.	Guidelines of ICH -Q, S	
3.	Guidelines of ICH -E, M.	
4.	Regulatory requirements of EU	
5.	Regulatory requirements of EU (cont…)	
6.	Regulatory requirements of TGA and ROW countries	
Unit-4: Non clinical drug development		(12)
1.	Non clinical drug development: Global submission of IND	**12**
2.	Non clinical drug development: Global submission of IND (cont…)	
3.	Non clinical drug development: Global submission of IND	
4.	Non clinical drug development: Global submission of NDA (cont…)	
5.	Non clinical drug development: Global submission of NDA (cont…)	
6.	Non clinical drug development: Global submission of ANDA	
7.	Non clinical drug development: Global submission of ANDA	

	(cont…)	
8.	Non clinical drug development: Global submission of ANDA (cont…)	
9.	Investigation of medicinal products dossier, dossier (IMPD)	
10.	Investigation of medicinal products dossier, dossier (IMPD) (cont…)	
11.	Investigator brochure (IB)	
12.	Investigator brochure (IB) (cont…)	
Unit-5: Clinical trials		(12)
1.	Clinical trials: Developing clinical trial protocols	**12**
2.	Clinical trials: Developing clinical trial protocols (cont…)	
3.	Clinical trials: Developing clinical trial protocols (cont…)	
4.	Institutional review board/ independent ethics committee- Formulation and working procedures	
5.	Institutional review board/ independent ethics committee- Formulation and working procedures (cont…)	
6.	Informed Consent process and procedures	
7.	informed Consent process and procedures (cont…)	
8.	HIPAA- new, requirement to clinical study process	
9.	HIPAA- new, requirement to clinical study process (cont…)	
10.	Pharmacovigilance safetymonitoringinclinical trials	
11.	Pharmacovigilance safetymonitoringinclinical trials (cont…)	
12.	Pharmacovigilance safetymonitoringinclinical trials (cont…)	
Activity 1	Unit test -3	
Activity 2	Unit test -4	
Activity 3	Unit test -5	
Activity 4	Revision test- 1	

REFERENCES

1. Generic Drug Product Development, Solid Oral Dosage forms,Leon Shargel and Isader K aufer,Marcel Dekker series,Vol.143
2. The Pharmaceutical Regulatory Process, Second Edition Edited by Ira R. Berry and Robert P.Martin,Drugs and the Pharmaceutical Sciences,Vol.185, Informa Healthcare Publishers.
3. New Drug Approval Process: Accelerating Global Registrations By Richard A Guarino, MD,5th edition,Drugs and the Pharmaceutical Sciences,Vol.190.
4. Guidebook for drug regulatory submissions /SandyWeinberg. By JohnWiley &Sons.Inc.
5. FDA regulatory affairs: a guide for prescription drugs, medical devices, and biologics/edited By Douglas J.Pisano,David Mantus. 6. Clinical Trials and Human Research: A Practical Guide to Regulatory Compliance By Fay A.Rozovsky andRodney K.Adams
7. www.ich.org/
8. www.fda.gov/
9. www.europa.eu/index_en.htm
6. www.tga.gov.au/tga-basics

Name of the Subject	**Pharmaceutics practical-I**
Name of the Faculty	Dr. R.Sureshkumar , Dr Krishnaveni , Dr.V Senthil, Dr. K . Gowthamarajan,

LECTURE PLAN – Abstract

Sessional	**No. of Hours of Didactic Practicals**	**Total No. of Practical Hours**
	Pharmaceutical Practicals-I	
I	3×09	27
II	3×09	27
Total No. of Hours	-	54

I SEMESTER

Experiment No:	**Experiment**	**Hours**
1.	Analysis of pharmacopoeial compounds and their formulations by UV Vis spectrophotometer	3 Hours
2.	Simultaneous estimation of multi component containing formulations by UV spectrophotometry	3 Hours
3.	Experiments based on HPLC	3 Hours
4.	Experiments based on Gas Chromatography	3 Hours
5.	Estimation of riboflavin/quinine sulphate by fluorimetry	3 Hours
6.	Estimation of sodium/potassium by flame photometry	3 Hours
7.	To perform In-vitro dissolution profile of CR/ SR marketed formulation	3 Hours
8.	Formulation and evaluation of sustained release matrix tablets	3 Hours
9.	Formulation and evaluation osmotically controlled DDS	3 Hours
10.	Preparation and evaluation of Floating DDS- hydro dynamically balanced DDS	3 Hours
11.	Formulation and evaluation of Muco adhesive tablets.	3 Hours
12.	Formulation and evaluation of trans dermal patches.	3 Hours
13.	To carry out preformulation studies of tablets.	3 Hours
14.	To study the effect of compressional force on tablets disintegration time.	3 Hours
15.	To study Micromeritic properties of powders and granulation.	3 Hours
16.	To study the effect of particle size on dissolution of a tablet.	3 Hours
17.	To study the effect of binders on dissolution of a tablet.	3 Hours
18.	To plot Heckal plot, Higuchi and peppas plot and determine similarity factors.	3 Hours

SEMESTER II

Name of the Subject	**Molecular Pharmaceutics (NanoTechnology and Targeted DDS)**
Name of the Faculty	Dr. R.Sureshkumar M.Pharm., Ph.D
Designation, Department	Assistant Professor, Department of Pharmaceutics
Mobile Number	9865064872
e-Mail i.d.	sureshcoonoor@jssuni.edu.in

Scope, Course Objectives and Course Outcomes

SCOPE

This course is designed to impart knowledge and skills necessary to impart knowledge on the area of advances in novel drug delivery systems

OBJECTIVES

The primary objectives of this course are to

1. To gain knowledge on various novel drug delivery systems
2. Acquire knowledge on various targeting strategies for efficient delivery of drugs
3. Demonstrate the technology for gene therapy
4. To find solution for different barriers for drug entry

COURSE OUTCOMES (COS)

At completion of this course it is expected that the students will be able to
The various approaches for development of novel drug delivery systems.
CO1: The criteria for selection of drugs and polymers for the development of NTDS
CO2: The formulation and evaluation of novel drug delivery systems

LECTURE PLAN – Abstract

Sessional	No. of Hours of Didactic Lecture	No of Hours of other Activities	Total No. of Lecture Hours
I	24	6	30
II	36	4	40
Total No. of Hours	60	10	70

I SESSIONAL : 22 Lectures + 6Activities

Lecture No.	Lecture Details	Hours
Molecular Pharmaceutics (NanoTechnology and Targeted DDS)		
Unit-1: Targeted Drug Delivery system		12
1.1	Concepts and Events of TDDS	
1.2	biological process involved in drug targeting	
1.3	Tumor targeting	
1.4	Brain specific delivery	
Unit-2: Targeting Methods		12
2.1	Introduction	
2.2	preparation and evaluation of Nano Particles	
2.3	Liposomes-preparation and evaluation	
Unit-3: Micro Capsules / Micro Spheres		12
3.1	Types, preparation and evaluation	
3.2	Monoclonal Antibodies	
3.3	preparation and application	
3.4	Preparation and application - Niosomes	
3.5	Aquasomes	
3.6	Phytosomes	
3.7	Electrosomes	
Activity1	Mind Mapping on Selected Topic	
Activity2	MCQ Test	
Activity3	MCQ Test	
Activity4	Revision-1	
Activity5	Revision-2	
Activity6	Revision-3	

II SESSIONAL : 15 Lectures + 4 Activities

Lecture No.	Lecture Details	Hours
Unit-4: Pulmonary Drug Delivery Systems		12
4.1	Aerosols, propellents, ContainersTypes	
4.2	preparation and evaluation	
4.3	Intra Nasal Route Delivery systems	
4.4	Types, preparation and evaluation	
Unit-5: Nucleic acid based therapeutic delivery system		

5.1	Gene therapy	12
5.2	(ex-vivo & in-vivo gene therapy)	
5.3	Potential target diseases for gene therapy	
5.4	Gene expression systems	
5.5	viral and nonviral gene transfer.	
5.6	Liposomal gene delivery systems	
5.7	Biodistribution and Pharmacokinetics	
5.8	knowledge of therapeutic antisense molecules	
5.9	aptamers as drugs of future	
Activity-1	MCQ Test	
Activity-2	MCQ Test	
Activity-3	Revision Test 1	
Activity-4	Revision Test 2	

Text Books

1. Targeted and Controlled Drug Delivery Novel Carrier Systems by Vyas Khar, CBS publishers
2. Ansels Pharmaceutical Dosage Forms And Drug Delivery Systems 11th Edition by ALLEN L V , Wolters Kluwer | Lippincott Williams and Wilkins
3. Controlled and Novel Drug Delivery by Jain N K , CBS PUBLICATION
4. Handbook of Non-Invasive Drug Delivery Systms (Hard Back) by Kulkarni, Elsevier Science

Reference Books

1. Y W. Chien, Novel Drug Delivery Systems, 2nd edition, revised and expanded,Marcel Dekker, Inc., New York, 1992.
2. S.P.Vyas and R.K.Khar, Controlled Drug Delivery - concepts and advances, VallabhPrakashan, New Delhi, First edition 2002. 3. N.K. Jain, Controlled and Novel Drug Delivery, CBS Publishers & Distributors, NewDelhi, First edition 1997 (reprint in 2001).

Name of the Subject	**Advanced Biopharmaceutics and Pharmacokinetics (Theory)**
Name of the Faculty	Dr. N.Jawahar M.Pharm., Ph.D
Designation, Department	Assistant Professore&Industrial Pharmacy Course Coordinator
Mobile Number	9486946314
e-Mail i.d.	jawahar.n@jssuni.edu.in

Scope, Course Objectives and Course Outcomes

SCOPE:
This course is designed to impart knowledge and skills necessary for dose calculations, dose adjustments and to apply biopharmaceutics theories in practical problem solving.

OBJECTIVES:
On completion of this course it is expected that students will be able to

1. Understand the basic concepts of Biopharmaceutics and Pharmacokinetics.
2. Undestand the process of drug absorption, distribution,metabolism and elimination.
3. Calcute using raw data and derive the pharmacokinetic models and parameters the best describe
4. Evaluate biopharmaceutics studies involving drug product equivalency
5. Evaluate dosage regimens of the drugs using pharmacokinetic and biopharmaceutic parameters
6. Formulate the best relese profile drug delivery systems including biopharmaceuticals

COURSE OUTCOMES (COS):
At completion of this course it is expected that the students will be able to

CO 1: Design the absorption model to predict the new molecule's permeability

CO 2: Assist invitro performance studies

CO 3: Establish the pharmacokinetic models

CO 4: Involve bioavalability and bioequivalence studies

CO 5: Construct PKPD model for designing the controlled relese dosgse forms

LECTURE PLAN – Abstract

Sessional	Number of Hours of Didactic Lecture	No. of Hours of other activities	Total Number of Lecture Hours
I	**31**	**03**	**34**
II	**30**	**04**	**34**
Total Number of Lecture Hours	**61**	**-**	**68**

I SESSIONAL: 31 Lectures +03 Activites

Lecture No.	Lecture Details	Hours
1.	**Advanced biopharmaceutics and pharmacokinetics: Introduction**	(01)
Unit-1: Drug Absorption from the Gastrointestinal Tract		(12)
1.	Gastrointestinal tract, Properties of the Gastrointestinal Tract (GIT)	**12**
2.	Mechanism of drug absorption	
3.	Factors affecting, pH–partition theory	
4.	Formulation and physicochemical factors: Dissolution rate, Dissolution process	
5.	Noyes–Whitney equation and drug dissolution, Factors affecting the dissolution rate	
6.	Gastrointestinal absorption: role of the dosage form: Solution (elixir, syrup and solution) as a dosage form ,Suspension as a dosage form	
7.	Capsule as a dosage form, Tablet as a dosage form	
8.	Dissolution methods ,Formulation and processing factors	
9.	Correlation of in vivo data with in vitro dissolution data	
10.	Transport model: Permeability-Solubility-Charge State and the pH Partition Hypothesis	
11.	pH Microclimate Intracellular pH Environment, Tight-Junction Complex	
12.	Solubility: Experimental methods. Permeability: In-vitro, in-situ and In-vivo methods	
Unit-2: Biopharmaceutic Considerations in Drug Product Design and In Vitro Drug Product Performance		(12)
1.	Introduction, biopharmaceutic factors affecting drug bioavailability,	**12**
2.	Rate limiting steps in drug absorption	
3.	Physicochemical nature of the drug formulation factors affecting drug product performance	
4.	In vitro: dissolution and drug release testing	
5.	Compendial methods of dissolution	
6.	Alternative methods of dissolution testing	
7.	Meeting dissolution requirements	
8.	Problems of variable control in dissolution testing performance of drug products	

9.	In vitro–in vivo correlation	
10.	Dissolution profile comparisons	
11.	Drug product stability	
12.	Considerations in the design of a drug product	
Unit-3:Pharmacokinetics		(06)
1.	Basic considerations	**06**
2.	Pharmacokinetic models	
3.	Compartment modeling: One compartment model- IV bolus	
4.	IV infusion	
5.	Extra-vascular	
6.	Multi Compartment model: Two compartment - model in brief	
Activity 1	**Unit test- 1**	
Activity 2	Unit test-2	
Activity 3	Unit test-3	

II SESSIONAL : 30 Lectures+04 Activites

Lecture No.	**Lecture Details**	**Hours**
Unit-3 : Pharmacokinetics		(06)
1.	Non-Linear Pharmacokinetics: Cause of non-linearity, Michaelis – Menten equation, Estimation Kmax and Vmax	**06**
2.	Drug interactions: Introduction	
3.	The effect of protein-binding interactions	
4.	The effect of tissue-binding interactions	
5.	Cytochrome P450-based drug interactions	
6.	Drug interactions linked to transporters	
Unit-4 : Drug Product Performance-In Vivo		(12)
1.	Bioavailability and bioequivalence:	**12**
2.	Drug product performance, purpose of bioavailability studies,	
3.	Relative and absolute availability, ,	
4.	Methods for assessing bioavailability,	
5.	Bioequivalence studies, design and evaluation of bioequivalence studies,	
6.	Study designs, crossover study designs, evaluation of the data, bioequivalence example,	
7.	Study submission and drug review process,	
8.	The biopharmaceutics classification system,	
9.	Generic biologics (biosimilar drug products),	
10.	Clinical significance of bioequivalence studies,	
11.	Special concerns in bioavailability and bioequivalence studies,	
12.	Generic substitution.	
Unit-5 : Application of Pharmacokinetics		(12)
1.	Modified-release drug products	**12**
2.	Targeted drug delivery systems	
3.	Biotechnological products	
4.	Relationship between Pharmacokinetics including Pharmacodynamics:	

5.	Generation of a Pharmacokinetic– Pharmacodynamic (PKPD) equation	
6.	Pharmacokinetic and pharmacodynamic, interactions	
7.	Pharmacokinetics and pharmacodynamics of biotechnology drugs: introduction	
8.	Proteins and peptides	
9.	Monoclonal antibodies	
10.	Oligonucleotides	
11.	Vaccines (immunotherapy)	
12.	Gene therapies	
Activity 1	**Unit test- 3**	
Activity 2	Unit test-4	
Activity 3	Unit test-5	
Activity 4	**Revision test- 1**	

References

1. Biopharmaceutics and Clinical Pharmacokinetics by Milo Gibaldi, 4th edition,Philadelphia,LeaandFebiger,1991
2. Biopharmaceutics and Pharmacokinetics, A. Treatise, D .M. Brahmankar and Sunil B.Jaiswal.,Vallab Prakashan, Pitampura, Delhi
3. Applied Biopharmaceutics and Pharmacokinetics by Shargel. Land YuABC ,2nd edition, Connecticut Appleton Century Crofts,1985
4. Textbook of Biopharmaceutics andPharmacokinetics, Dr. Shobha Rani R. Hiremath,Prism Book
5. Pharmacokinetics by Milo Gibaldi and D. Perrier, 2nd edition, Marcel Dekker Inc.,New York, 1982
6. Current Concepts in Pharmaceutical Sciences: Biopharmaceutics, Swarbrick.J,LeaandFebiger,Philadelphia,1970
7. Clinical Pharmacokinetics, Concepts and Applications 3rd edition by Malcolm Rowland and Thom~ N. Tozer, Lea and Febiger, Philadelphia, 1995
8. Dissolution, Bioavailability and Bioequivalence, Abdou. H.M, Mack Publishing Company, Pennsylvania1989
9. Biopharmaceutics and Clinical Pharmacokinetics, An Introduction, 4th edition, revisedand expande by Robert.E. Notari, Marcel Dekker Inc, New Yorkand Basel,1987.
10. 10.Biopharmaceutics and Relevant Pharmacokinetics by John.G Wagnerand M.Pemarowski, 1st edition, Drug Intelligence Publications, Hamilton, Illinois, 1971.
11. Encyclopedia of Pharmaceutical Technology, Vol 13, James Swarbrick, James. G.Boylan,Marcel Dekker Inc,New York,1996.
12. Basic Pharmacokinetics,1 st edition, Sunil S Jambhekar and Philip J Breen,pharmaceuticalpress,RPS Publishing,2009.
13. Absorption and Drug Development- Solubility, Permeability, and Charge State,AlexAvdeef,JohnWiley&Sons,Inc,2003.

Name of the Subject	**Computer Aided Drug Development (Theory)**
Name of the Faculty	Dr. Karri V V S Narayana Reddy M.Pharm., Ph.D
Designation, Department	Lecturer, Department of Pharmaceutics
Mobile Number	9952478866
e-Mail i.d.	narayana.reddy@jssuni.edu.in

Scope, Course Objectives and Course Outcomes

SCOPE

This course is designed to impart knowledge and skills necessary for computer Applications in pharmaceutical research and development who want to understand the application of computers across the entire drug research and development process. Basic theoretical discussions of the principles of more integrated and coherent use of computerized information (informatics) in the drug development process are provided to help the students to clarify the concepts.

OBJECTIVES

The primary objectives of this course are to

1. History of Computers in Pharmaceutical Research and Development
2. Computational Modeling of Drug Disposition
3. Computers in Preclinical Development
4. Optimization Techniques in Pharmaceutical Formulation
5. Computers in Market Analysis
6. Computers in Clinical Development
7. Artificial Intelligence (AI) and Robotics
8. Computational fluid dynamics(CFD)

COURSE OUTCOMES (COS):

At completion of this course it is expected that the students will be able to

CO 1: Use computers in the pharmaceutical product development

CO 2: Develop a Quality by Design (QbD) product as per the regulatory requirements

CO 3: Effectively intrepret and optimize various drug delivery systems by various computational tools

CO 4: Collect and manage clinical data through computational methods

CO 5: Design and interpret various pharmaceutical equipements and devices through computational fluid dynamics

LECTURE PLAN – Abstract

Sessional	Number of Hours of Didactic Lecture	No. of Hours of other activities	Total Number of Lecture Hours
I	**31**	**-**	**31**
II	**30**	**-**	**30**
Total Number of Lecture Hours	**61**	**-**	**61**

I SESSIONAL: 31 lectures

Lecture No.	Lecture Details	Hours
1.	Introduction to CADD	01
Unit-1: Computers in Pharmaceutical Research and Development		(12)
1.	History of Computers in Pharmaceutical Research and Development	12
2.	Statistical modeling in Pharmaceutical research and development	
3.	Descriptive versus Mechanistic Modeling	
4.	Statistical Parameters, Estimation, Confidence Regions	
5.	Nonlinearity at the Optimum	
6.	Sensitivity Analysis, Optimal Design	
7.	Population Modelling	
8.	ICH Q8 guideline	
9.	Regulatory and industry views on QbD	
10.	Scientific examples	
11.	Acetriptan QbD	
12.	Acetriptan QbD	
Unit-2: Computational Modeling Of Drug Disposition		(12)
13.	Introduction	12
14.	Drug absorption	
15.	Solubility	
16.	Intestinal permeation	
17.	Drug distribution	
18.	Drug excretion	
19.	Active transport	
20.	P-gp & BCRP	
21.	Nucleoside Transporters	
22.	hPEPT1 & ASBT	
23.	OCT & OATP	
24.	BBB-Choline Transporter	
Unit-3: Computer-aided formulation development		(06)
25.	Concept of optimization, Optimization parameters	06
26.	Optimization technology & Screening design	
27.	Design of experiments	
28.	Factorial design	
29.	Response surface designs	
30.	Computers in Pharmaceutical Formulation	

II SESSIONAL : 30 Lectures

Lecture No.	Lecture Details	Hours
Unit-3:		(06)
1.	Development of pharmaceutical emulsions	06
2.	Development of microemulsion	
3.	Development of pharmaceutical emulsion drug carriers	
4.	Legal Protection of Innovative Uses of Computers in R&D	
5.	The Ethics of Computing in Pharmaceutical Research	
6.	Computers in Market analysis	
Unit-4: Computer-aided biopharmaceutical characterization		(12)
1.	Gastrointestinal absorption simulation.	12
2.	Introduction, Theoretical background,	
3.	Model construction,	
4.	Parameter sensitivity analysis,	
5.	Virtual trial, Fed vs. fasted state,	
6.	In vitro dissolution and in vitro in vivo correlation,	
7.	Biowaiver considerations	
8.	Introduction,	
9.	Computer Simulation: Whole Organism, Isolated Tissues	
10.	Organs, Cell, Proteins and Genes.	
11.	Clinical Data Collection and Management	
12.	Regulation of Computer Systems	
Unit-5: Artificial Intelligence (AI), Robotics and Computational fluid dynamics		(12)
1.	Introduction, Merits, Demerits and Feature directions	12
2.	Theoretical background	
3.	CFD in pharmaceutical manufacturing process: Solid handling, size separation, mixing, fluidized bed drier, freeze drying and packaging	
4.	CFD in drug delivery and devices: CFD in pulmonary drug delivery and energy generation & transfer devices	
5.	CFD in Hydrodynamics of Dissolution apparatus	
6.	Artificial Intelligence And Its Applications In Pharmaceutical Sector	
7.	Pharmaceutical Automation: Merits, demerits, current challenges & future directions	
8.	Automation and compliance	
9.	Automation in Pharmaceutical Profiling & drug discovery	
10.	Automation in laboratories	
11.	Automation in Pharmaceutical manufacturing	
12.	Robotics: Introduction and applications in pharmaceutical industry	

REFERENCES:

1. Computer Applications in Pharmaceutical Research and Development, Sean Ekins, 2006, John Wiley & Sons.
2. Computer-Aided Applications in Pharmaceutical Technology, 1st Edition, Jelena Djuris, Woodhead Publishing
3. Encyclopedia of Pharmaceutical Technology, Vol 13, James Swarbrick, James. G.Boylan, Marcel Dekker Inc, New York, 1996.

Name of the Subject	**COSMETICS AND COSMECEUTICALS (MPH 204T)**
Course/ Semester	M.Pharm,, 2nd Semester
Name of the Faculty	Dr V.Senthil, M.Pharm, Ph.D,
Designation, Department	Professor, Pharmaceutics
Mobile Number	9842650602
e-Mail i.d.	senthil.v@jssuni.edu.in

Scope, Course Objectives and Course Outcomes

SCOPE

This course is designed to impart knowledge and skills necessary for the fundamental need for cosmetic and cosmeceutical products.

OBJECTIVES

Upon completion of the course, the students shall be able to understand

- Key ingredients used in cosmetics and cosmeceuticals.
- Key building blocks for various formulations.
- Current technologies in the market
- Various key ingredients and basic science to develop cosmetics and cosmeceuticals
- Scientific knowledge to develop cosmetics and cosmeceuticals with desired Safety, stability, and efficacy.

COURSE OUTCOMES (COS)

At completion of this course it is expected that the students will be able to

CO1: Select key ingredients suitable in the formulation of various cosmetics

CO2: To understand the various problems related to the skin and hair

CO3: Design cosmetics that take care of cleansing needs of the face, eye lids, lips, hands, feet, nail, scalp, neck, body and under-arm

CO4: Design cosmetics with various methods and technologies involved in their manufacture

CO5: Design cosmeceuticals for sun protection, dry skin, acne, sun-protection, pigmentation, prickly heat, wrinkles, body odor.

CO5: Describe the guidelines for the regulation of herbal cosmetics by private bodies.

LECTURE PLAN – Abstract

Sessional	No. of Hours of Didactic Lecture	No of Hours of other Activities	Total No. of Lecture Hours
I	30	3	33
II	30	3	33
Total No. of Hours	60	6	66

I SESSIONAL
LECTURE PLAN 30 Lectures+ 3 Activities

Lecture No.	Lecture Details	
UNIT-1	Cosmetics – Regulatory (12)	**Hours**
1.	Definition of cosmetic products as per Indian regulation.	12
2.	Indian regulatory requirements for labeling of cosmetics Regulatory provisions relating to import of cosmetics	
3.	Misbranded and spurious cosmetics.	
4.	Regulatory provisions relating to manufacture of cosmetics – Conditions for obtaining license	
5.	Prohibition of manufacture and sale of certain cosmetics	
6.	loan license	
7.	offences and penalties	
UNIT-2	Cosmetics - Biological aspects (12)	12
8.	Introduction	
9.	Structure of skin, Skin relating to problems like dry skin, acne	
10.	pigmentation, prickly heat, wrinkles and body odor.	
11.	Structure of hair and hair growth cycle	
12.	Common problems associated with oral cavity.	
13.	Cleansing and care needs for face, eye lids, lips, hands, feet, nail, scalp, neck, body and under-arm.	
Activity1	Test	
Activity2	Test	
UNIT-3	Cosmetics -Formulation Building blocks (12)	06
14.	Building blocks for different product formulations of cosmetics/cosmeceuticals	
15.	Surfactants – Classification and application.	
16.	Emollients, rheological additives: classification and application.	
17.	Antimicrobial used as preservatives, their merits and demerits.	
18.	Factors affecting microbial preservative efficacy.	
Activity 3	Test	

II SESSIONAL : 30 Lectures + 3 Activities

UNIT-3	Cosmetics -Formulation Building blocks *Cont.*	06
19.	Building blocks for formulation of a moisturizing cream, vanishing cream, cold cream, shampoo and toothpaste.	

20.	Soaps and syndetbars.	
21.	Perfumes; Classification of perfumes. Perfume ingredients listed as allergens in EU regulation.	
22.	Controversial ingredients: Parabens, formaldehyde liberators, dioxane.	
UNIT-4 Design of cosmeceutical products (12)		12
23.	Sun protection, sunscreens classification and regulatory aspects.	
24.	Addressing dry skin, acne, sun-protection, pigmentation,	
25.	Addressing prickly heat, wrinkles, body odor	
26.	Dandruff, dental cavities, bleeding gums, mouth odor	
27.	sensitive teeth through cosmeceutical formulations	
UNIT-5 Herbal Cosmetics (12)		12
28.	Introduction,	
29.	Herbal ingredients used in Hair care, skin care and oral care.	
30.	Review of guidelines for herbal cosmetics by private bodies like cosmos	
31.	Challenges in formulating herbal cosmetics	
Activity1	Test	
Activity1	Test	
Activity1	Test	

Recommended Books: (Latest Editions)

1. Harry's Cosmeticology.
2. Poucher's perfume cosmetics and Soaps,
3. Cosmetics - Formulation, Manufacture and quality control, PP.Sharma,
4. Handbook of cosmetic science and Technology A.O.Barel, M.Paye and H.I. Maibach.
5. Cosmetic and Toiletries recent suppliers' catalogue.
6. CTFA directory.

Name of the Subject	Pharmaceutics practical-II
Name of the Faculty	Dr. R.Sureshkumar , Dr.N.Jawahar , Dr.V Senthil, Dr Karri VVS Narayana Reddy

LECTURE PLAN – Abstract

Sessional	**No. of Hours of Didactic Practicals**	**Total No. of Practical Hours**
	Pharmaceutics Practical-II	
I	3×12	36
II	3×12	36
Total No. of Hours	-	72

II SEMESTER

Experiment No:	**Experiment**	**Hours**
1.	To study the effect of temperature change , non solvent addition, incompatible polymer addition in microcapsules preparation	3 Hours
2.	Preparation and evaluation of Alginate beads	3 Hours
3.	Formulation and evaluation of gelatin /albumin microspheres	3 Hours
4.	Formulation and evaluation of liposomes/niosomes	3 Hours
5.	Formulation and evaluation of spherules	3 Hours
6.	Improvement of dissolution characteristics of slightly soluble drug by Solid dispersion technique.	3 Hours
7.	Comparison of dissolution of two different marketed products /brands	3 Hours
8.	Protein binding studies of a highly protein bound drug & poorly protein bound drug	3 Hours
9.	Bioavailability studies of Paracetamol in animals.	3 Hours
10.	Pharmacokinetic and IVIVC data analysis by WinnolineR software	3 Hours
11.	In vitro cell studies for permeability and metabolism	3 Hours
12.	DoE Using Design Expert® Software	3 Hours
13.	Formulation data analysis Using Design Expert® Software	3 Hours
14.	Quality-by-Design in Pharmaceutical Development	3 Hours
15.	Computer Simulations in Pharmacokinetics and Pharmacodynamics	3 Hours
16.	Computational Modeling Of Drug Disposition	3 Hours
17.	To develop Clinical Data Collection manual	3 Hours
18.	To carry out Sensitivity Analysis, and Population Modeling.	3 Hours
19.	Development and evaluation of Creams	3 Hours
20.	Development and evaluation of Shampoo and Toothpaste base	3 Hours
21.	To incorporate herbal and chemical actives to develop	3 Hours

	products	
22.	To address Dry skin, acne, blemish, Wrinkles, bleeding gums and dandruff	3 Hours

JSS Academy of Higher Education & Research, Mysuru
JSS College of Pharmacy, Rocklands, Ooty

I M. PHARMACY TIME TABLE FOR E-LEARN CLASSES : I Semester (AY : 2020 - 2021)

DEPARTMENT : PHARMACEUTICS
COURSE : PHARMACEUTICS

ZOOM / GOOGLE MEET LICENSE - cpoceutics1@jssuni.edu.in

Days	9 - 10 am	10 - 11 am	11 - 12 am	12 - 1 pm	1 - 2 pm	2 - 3 pm	3 - 4 pm	4 - 5 pm
Mon	*Assingment*	**MPAT** ***(NKV)***	**PRA** ***(KG)***	**PRA** ***(KG)***	**LUNCH BREAK**	-	-	-
Tue	*Assingment*	**MPAT** ***(NKV)***	**PRA** ***(KG)***	**PRA** ***(KG)***		**DDS** ***(VS)***	**DDS** ***(VS)***	-
Wed	*Assingment*	**MPAT** ***(NKV)***	**MPT** ***(RSK)***	**MPT** ***(RSK)***		**DDS** ***(VS)***	**DDS** ***(VS)***	-
Thu	Library	**MPAT** ***(NKV)***	**MPT** ***(RSK)***	**MPT** ***(RSK)***		-	-	-
Fri	Library	Seminar	Seminar	Seminar		-	-	-
Sat	Seminar	-	-	-		-	-	-

Subjects : I M.Pharm (Pharmaceutics)

1. Pharmaceutical Regulatory Affairs (PRA-T & P) – Dr. K. Gowthamarajan ***(KG)***
2. Drug Delivery System (DDS-T & P) – Dr. V. Senthil ***(VS)***
3. Modern Pharmaceutics (M.P-T & P) – Dr. R. Suresh Kumar ***(RSK)***
4. Modern Pharmaceutical Analytical Techniques (MPAT-T & P)-Dr. N. Krishnaveni ***(NKV)***

JSS Academy of higher Education & Research, Mysuru

(Deemed to be University, Accredited 'A' Grade by NAAC)

JSS College of Pharmacy, Ooty – 643 001

(An ISO 9001-2015 certified Institution)

I M.Pharm, Pharmaceutics (II.Semester) Time Table (AY: 2020-21)

Days	**09-10**	**10-11**	**11-12**	**12-01**		**2-3**	**3-4**	**4-5**	
Mon		CADD-KVVSNR	ABP-NJ	ABP-NJ	L U N C H	Advanced Bio-pharmaceutics and Pharmacokinetics -NJ			
Tue		ABP-NJ	ABP-NJ	Library		Computer Aided Drug Development - Dr. Karri VVS Narayana Reddy			
Wed		CADD-KVVSNR	CADD-KVVSNR	CADD-KVVSNR		Molecular Pharmaceutics(Nano Tech and Targeted DDS) –RS			
Thu			CC-VS	CC-VS		Cosmetic and Cosmeceuticals-VS			
Fri		MP-RS	CC-VS	CC-VS		MP-RS	MP-RS	MP-RS	Seminar
Sat	Journal club/ Research audit								

Subject-in-Charges:

Advanced Bio-pharmaceutics and Pharmacokinetics- ABP – Dr. N. Jawahar
Cosmetic and Cosmeceuticals -CC- Dr.V Senthil(VS)
Molecular Pharmaceutics(Nano Tech and Targeted DDS-MP – Dr. R. Suresh Kumar(RS)
Computer Aided Drug Development –CADD- Dr. Karri VVS Narayana Reddy (KVVSNR)/Dr,K, Gowthamarajan

M. PHARM
INDUSTRIAL PHARMACY

SYLLABUS
SEMESTER I
MPA101T-MODERN PHARMACEUTICAL ANALYSIS (Theory)

SCOPE

This subject deals with various advanced analytical instrumental techniques for identification, characterization and quantification of drugs. Instruments dealt are NMR, Mass spectrometer, IR, HPLC, GC etc.

OBJECTIVES

After completion of course student is able to know,

- The analysis of various drugs in single and combination dosage forms
- Theoretical and practical skills of the instruments

THEORY		**60 Hrs.**
1.	**UV-Visible spectroscopy**: Introduction, Theory, Laws, Instrumentation associated with UV-Visible spectroscopy, Choice of solvents and solvent effect and Applications of UV-Visible spectroscopy. **IR spectroscopy**: Theory, Modes of Molecular vibrations, Sample handling, Instrumentation of Dispersive and Fourier - Transform IR Spectrometer, Factors affecting vibrational frequencies and Applications of IR spectroscopy **Spectroflourimetry:** Theory of Fluorescence, Factors affecting fluorescence, Quenchers, Instrumentation and Applications of fluorescence spectrophotometer. **Flame emission spectroscopy and Atomic absorption spectroscopy**: Principle, Instrumentation, Interferences and Applications.	**12 Hrs**
2.	**NMR spectroscopy**: Quantum numbers and their role in NMR, Principle, Instrumentation, Solvent requirement in NMR, Relaxation process, NMR signals in various compounds, Chemical shift, Factors influencing chemical shift, Spin-Spin coupling, Coupling constant, Nuclear magnetic double resonance, Brief outline of principles of FT-NMR and 13C NMR. Applications of NMR spectroscopy.	**12 Hrs**
3.	**Mass Spectroscopy**: Principle, Theory, Instrumentation of Mass Spectroscopy, Different types of ionization like electron impact, chemical, field, FAB and MALDI, APCI, ESI, APPI Analyzers of Quadrupole and Time of Flight, Mass fragmentation and its rules, Meta stable ions, Isotopic peaks and Applications of Mass spectroscopy	**12 Hrs**
4.	**Chromatography**: Principle, apparatus, instrumentation, chromatographic parameters, factors affecting resolution and applications of the following: a) Paper chromatography b) Thin Layer chromatography c) Ion exchange chromatography d) Column chromatography e) Gas chromatography f) High Performance Liquid chromatography	**12 Hrs**

	g) Affinity chromatography	
5.	**Electrophoresis**: Principle, Instrumentation, Working conditions, factors affecting separation and applications of the following: a) Paper electrophoresis b) Gel electrophoresis c) Capillary electrophoresis d) Zone electrophoresis e) Moving boundary electrophoresis f) Iso electric focusing **X ray Crystallography**: Production of X rays, Different X ray methods, Bragg's law, Rotating crystal technique, X ray powder technique, Types of crystals and applications of X-ray diffraction.	**12 Hrs**

REFERENCES

1. Spectrometric Identification of Organic compounds - Robert M Silverstein, Sixth edition, John Wiley & Sons, 2004.
2. Principles of Instrumental Analysis - Doglas A Skoog, F. James Holler, Timothy A. Nieman, 5th edition, Eastern press, Bangalore, 1998.
3. Instrumental methods of analysis – Willards, 7th edition, CBS publishers.
4. Practical Pharmaceutical Chemistry – Beckett and Stenlake, Vol II, 4th edition, CBS Publishers, New Delhi, 1997.
5. Organic Spectroscopy - William Kemp, 3rd edition, ELBS, 1991.
6. Quantitative Analysis of Drugs in Pharmaceutical formulation - P D Sethi, 3rd Edition, CBS Publishers, New Delhi, 1997.
7. Pharmaceutical Analysis- Modern methods – Part B - J W Munson, Volume 11, Marcel Dekker Series.

MIP102T-PHARMACEUTICAL FORMULATION DEVELOPMENT (Theory)

SCOPE

This course is designed to impart knowledge and skills necessary to train the students on par with the routine of Industrial activities in R&D and F&D

OBJECTIVES

At completion of this course it is expected that students will be able to understand-

- The scheduled activities in a Pharmaceutical firm.
- The pre formulation studies of pilot batches of pharmaceutical industry.
- The significance of dissolution and product stability

THEORY **60 Hrs**

1.	**Preformulation Studies:** Molecular optimization of APIs (drug substances), crystal morphology and variations, powder flow, structure modification, drug-excipient compatibility studies, methods of determination.	**12 Hrs**
2.	**Formulation Additives**: Study of different formulation additivies, factors influencing their incorporation, role of formulation development and processing, new developments in excipient science, determination methods, drug excipient interactions. Design of experiments – factorial design for product and process development.	**12 Hrs**
3.	**Solubility:** Importance, experimental determination, phase-solubility analysis, pH-solubility profile, solubility techniques to improve solubility and utilization of analytical methods – cosolvency, salt formation, complexation, solid dispersion, micellar solubilization and hydrotropy.	**12 Hrs**
4.	**Dissolution:** Theories, mechanisms of dissolution, *in-vitro* dissolution testing models – sink and non-sink. Factors influencing dissolution and intrinsic dissolution studies. Dissolution test apparatus – designs, dissolution testing for conventional and controlled release products. Data handling and correction factor. Biorelevent media, *in-vitro* and *in-vivo* correlations, levels of correlations.	**12 Hrs**
5.	**Product Stability:** Degradation kinetics, mechanisms, stability testing of drugs and pharmaceuticals, factors influencing-media effects and pH effects, accelerated stability studies, interpretation of kinetic data (API & tablets). Solid state stability and shelf life assignment. Stability protocols, reports and ICH guidelines.	**12 Hrs**

REFERENCES

1. Lachman L, Lieberman HA, Kanig JL. The theory and practice of industrial pharmacy, 3rd ed., Varghese Publishers, Mumbai 1991.
2. Sinko PJ. Martin's physical pharmacy and pharmaceutical sciences, 5th ed., B.I. Publications Pvt. Ltd, Noida, 2006.
3. Lieberman HA, Lachman L, Schwartz JB. Pharmaceutical dosage forms: tablets Vol. I-III, 2nd ed., CBS Publishers & distributors, New Delhi, 2005.
4. Conners KA. A Text book of pharmaceutical analysi Wells JI. Pharmaceutical preformulation: The physicochemical properties of drug substances. Ellis Horwood Ltd., England, 1998.
5. Yalkowsky SH. Techniques of solubilization of drugs. Vol-12. Marcel Dekker Inc., New York, 1981
6. Dressman J, Kramer J. Pharmaceutical dissolution testing. Saurah printer pvt. Ltd., New Delhi,2005.
7. Sethi PD. Quantitative analysis of drugs in pharmaceutical formulations, 3rd ed., CBS publications, New Delhi, 2008.
8. Carstensen JT, Rhodes CT. Drug stability principles and practices, 3rd ed., CBS Publishers & distributors, New Delhi, 2005.
9. Yoshioka S, Stella VJ. Stability of drugs and dosage forms, Springer (India) Pvt. Ltd., New Delhi, 2006.
10. Banker GS, Rhodes CT. Modern Pharmaceutics, 4th ed., Marcel Dekker Inc, New York, 2005.
11. W. Grimm - Stability testing of drug products.
12. Mazzo DJ. International stability testing. Eastern Press Pvt. Ltd., Bangalore, 1999.
13. Beckett AH, Stenlake JB. Practical pharmaceutical chemistry, Part I & II., 4th ed., CBS Publishers & distributors, New Delhi, 2004.
14. Indian Pharmacopoeia. Controller of Publication. Delhi, 1996.
15. British Pharmacopoeia. British Pharmacopoeia Commission Office, London, 2008.
16. United States Pharmacopoeia. United States Pharmacopeial Convention, Inc, USA, 2003.

MIP103T-NOVEL DRUG DELIVERY SYSTEMS (Theory)

SCOPE

This course is designed to impart knowledge and skills necessary to train the students in the area of customized drug delivery systems.

OBJECTIVE

At completion of this course it is expected that students will be able to understand-

- The need, concept, design and evaluation of various customized, sustained and controlled release dosage forms.
- To formulate and evaluate various customized/novel drug delivery systems**.**

THEORY **60Hrs**

1.	**Concept & Models for NDDS:** Classification of rate controlled drug delivery systems (DDS), rate programmed release, activation modulated & feedback regulated DDS, effect of system parameters in controlled drug delivery, computation of desired release rate and dose for controlled release DDS, pharmacokinetic design for DDS – intermittent, zero order & first order release. **Carriers for Drug Delivery:** Polymers / co-polymers-introduction, classification, characterization, polymerization techniques, application in CDDS / NDDS, biodegradable & natural polymers.	**12 Hrs**
2.	**Study of Various DDS:** Concepts, design, formulation & evaluation of controlled release oral DDS, Mucoadhesive DDS (buccal, nasal, pulmonary) Pulsatile, colon specific, liquid sustained release systems.	**12 Hrs**
3.	**Transdermal Drug Delivery Systems:** Theory, design, formulation & evaluation including iontophoresis and other latest developments in skin delivery systems. **Sub Micron Cosmeceuticals:** Biology, formulation science and evaluation of various cosmetics for skin, hair, nail, oral cavity, eye etc and it's regulatory aspects.	**12 Hrs**
4.	**Targeted Drug Delivery Systems:** Importance, concept, biological process and events involved in drug targeting, design, formulation & evaluation, methods in drug targeting – nanoparticles, liposomes, niosomes, pharmacosomes, resealed erythorocytes, microspheres, magnetic microspheres. Specialized pharmaceutical emulsions – multiple emulsions, micro-emulsions. **Protein / Peptide Drug Delivery Systems:** Concepts, delivery techniques, formulation, stability testing, causes of protein destabilization, stability and destabilization. **Biotechnology in Drug Delivery Systems:**	**12 Hrs**

	Brief review of major areas-recombinant DNA technology, monoclonal antibodies, gene therapy.	
5.	**Dosage Forms for Personalized Medicine**: Introduction, Definition, Pharmacogenetics, Categories of Patients for Personalized Medicines: Customized drug delivery systems, Bioelectronic Medicines, 3D printing of pharmaceuticals, Telepharmacy.	**12 Hrs**

REFERENCES

1. Novel Drug Delivery System, Y.W. Chein, Vol 50, Marcel Dekker, NY.
2. Controlled Drug Delivery Systems, Robinson, Vol 29, Marcel Dekker, NY.
3. Transdermal Controlled Systemic Medications, YW Chein, Vol 31, Marcel Dekker, NY.
4. Bioadhesive DDS, E. Mathiowitz, Vol 98, Marcel Dekker, NY.
5. Nasal System Drug Delivery, K.S.E. Su, Vol 39, Marcel Dekker, NY.
6. Drug Delivery Devices, Vol 32, P Tyle Marcel Dekker, NY.
7. Polymers for Controlled Drug Delivery, P.J. Tarcha, CRC Press.
8. Pharmaceutical Biotechnology, Vyas, CBS, Delhi.
9. Biotechnology of Industrial Antibiotics, E.J. Vandamme, Marcel Dekker, NY.
10. Protein Formulation & Delivery, E.J. McNally, Vol 99, Marcel Dekker, NY.
11. Drug Targeting, M.H. Rubinstein, John Wiley, NY.

MIP104T-DRUG REGULATIONS AND INTELECTUAL PROPRTY RIGHTS
(Theory)

SCOPE

This course is designed to impart knowledge and skills necessary to train the students to be on par with the routine of Industrial activities in drug regulatory affairs

OBJECTIVES

At completion of this course it is expected that students will be able to understand-

- Assist in Regulatory Audit process.
- Establish regulatory guidelines for drug and drug products
- The Regulatory requirements for contract research organization

THEORY **60 Hrs.**

1.	Definition, Need for patenting, Types of Patents, Conditions to be satisfied by an invention to be patentable, Introduction to patent search. Parts of patents. Filling of patents. The essential elements of patent; Guidelines for preparation of laboratory note book, Non-obviousness in Patent.	**12 Hrs**
2.	Role of GATT, TRIPS, and WIPO.	**12 Hrs**
3.	Brief introduction to Trademark protection and WHO Patents. IPR's and its types, Major bodies regulating Indian Pharmaceutical sector.	**12 Hrs**
4.	Brief introduction to CDSCO. WHO, USFDA, EMEA, TGA, MHRA, MCC, ANVISA	**12 Hrs**
5.	Regulatory requirements for contract research organization. Regulations for Biosimilars.	**12 Hrs**

REFERENCE

1. Pharmaceutical Process Validation: By Fra R. Berry and Robert A. Nash, Vol 57, 2nd edition.

2. Applied Production and Operation Management By Evans, Anderson and Williams.

3. GMP for pharmaceuticals Material Management by K.K. Ahuja Published by CBS publishers.

4. ISO 9000-Norms and explanations.

5. GMP for pharmaceuticals- Willing S.H. Marcel and Dekke

MIP105P-INDUSTRIAL PHARMACY PRACTICALS I (Practicals)

1. Analysis of pharmacopoeial compounds and their formulations by UV Vis spectrophotometer
2. Simultaneous estimation of multi component containing formulations by UV spectrophotometry
3. Experiments based on HPLC
4. Experiments based on Gas Chromatography
5. Estimation of riboflavin/quinine sulphate by fluorimetry
6. Estimation of sodium/potassium by flame photometry
7. Effect of surfactants on the solubility of drugs.
8. Effect of pH on the solubility of drugs.
9. Dissolution methods of transdermal drug delivery systems.
10. Stability testing of solution and solid dosage forms for photo degradation..
11. Stability studies of drugs in dosage forms at 25 ^{o}C, 60% RH and 40 ^{o}C, 75% RH.
12. Compatibility evaluation of drugs and excipients.
13. Preparation and evaluation of different polymeric membranes.
14. Formulation and evaluation of sustained release oral matrix tablet.
15. Formulation and evaluation of sustained release oral reservoir system.
16. Formulation and evaluation of microspheres / microcapsules.
17. Formulation and evaluation of transdermal films.
18. Design and evaluation of face wash, body- wash, creams, lotions, shampoo, toothpaste, lipstick.

SEMESTER II

MIP201T-ADVANCED BIOPHARMACEUTICS & PHARMACOKINETICS (Theory)

SCOPE

This course is designed to impart knowledge and skills necessary for dose calculations, dose adjustments and to apply Biopharmaceutics theories in practical problem solving.

OBJECTIVES

At completion of this course it is expected that students will be able to understand–

- The basic concepts in Biopharmaceutics and pharmacokinetics.
- The use of raw data and derive the pharmacokinetic models and parameters the best describe the process of drug absorption, distribution, metabolism and elimination.
- To critically evaluate Biopharmaceutics studies involving drug product equivalency.
- To design and evaluate dosage regimens of the drugs using pharmacokinetic and biopharmaceutic parameters.

THEORY **60 Hrs.**

1.	**Drug Absorption From The Gastrointestinal Tract** Gastrointestinal tract, Mechanism of drug absorption, Factors affecting passive drug absorption, pH–partition theory of drug absorption. Factors affecting drug absorption: physicochemical factors: Dissolution rate, Dissolution process, Noyes–Whitney equation and drug dissolution, Factors affecting the dissolution rate. Gastrointestinal absorption: role of the dosage form: Solution (elixir, syrup and solution) as a dosage form ,Suspension as a dosage form, Capsule as a dosage form, Tablet as a dosage form ,Dissolution methods ,Formulation and processing factors, Correlation of in vivo data with in vitro dissolution data. Transport model: Permeability-Solubility-Charge State and the pH Partition Hypothesis, Properties of the Gastrointestinal Tract (GIT), pH Microclimate Intracellular pH Environment, Tight-Junction Complex, Structure of Octanol, Biopharmaceutics Classification System. Solubility: Experimental methods. Permeability: In-vitro, in-situ and In-vivo methods.	**12 Hrs**
2.	**Biopharmaceutic Considerations in Drug Product Design and In Vitro Drug Product Performance** Introduction, Biopharmaceutic Factors Affecting Drug Bioavailability, Rate-Limiting Steps in Drug Absorption, Physicochemical Nature of the Drug Formulation Factors Affecting Drug Product Performance, Drug Product Performance, *In Vitro*: Dissolution and Drug Release Testing, Compendial Methods of Dissolution, Alternative Methods of Dissolution Testing, Meeting Dissolution Requirements, Problems of Variable Control in Dissolution Testing Performance of Drug Products: *In Vitro–In Vivo* Correlation, Dissolution Profile Comparisons, Drug Product Stability, Considerations in the Design of a Drug Product, Drug Product Considerations.	**12 Hrs**

3.	**Pharmacokinetics** Basic considerations, Pharmacokinetic models, Compartment modeling: One compartment model- IV bolus, IV infusion, Extra-vascular; Multi Compartment model: Two compartment - model in brief, Non-Linear Pharmacokinetics: Cause of non-linearity, Michaelis – Menten equation, Estimation Kmax and Vmax. Drug interactions: Introduction, The effect of protein-binding interactions, The effect of tissue-binding interactions, Cytochrome P450-based drug interactions, Drug interactions linked to transporters.	**12 Hrs**
4.	**Drug Product Performance, In Vivo: Bioavailability and Bioequivalence** Drug Product Performance, Purpose of Bioavailability Studies, Relative and Absolute Availability, , Methods for Assessing Bioavailability, Bioequivalence Studies, Design and Evaluation of Bioequivalence Studies, Study Designs, Crossover Study Designs, Evaluation of the Data, Bioequivalence Example, Study Submission and Drug Review Process, The Biopharmaceutics Classification System, Generic Biologics (Biosimilar Drug Products),Clinical Significance of Bioequivalence Studies, Special Concerns in Bioavailability and Bioequivalence Studies, Generic Substitution	**12 Hrs**
5.	**Application of Pharmacokinetics** Modified-Release Drug Products, Targeted Drug Delivery Systems and Biotechnological Products. Relationship between Pharmacokinetics and Pharmacodynamics: Generation of a pharmacokinetic–pharmacodynamic (PKPD) equation, Pharmacokinetic and pharmacodynamic, drug interactions. Pharmacokinetics and pharmacodynamics of biotechnology drugs: Introduction, Proteins and peptides ,Monoclonal antibodies, Oligonucleotides, Vaccines (immunotherapy),Gene therapies.	**12 Hrs**

REFERENCES

1. Biopharmaceutics and Clinical Pharmacokinetics by Milo Gibaldi, 4th edition,Philadelphia, Lea and Febiger, 1991
2. Biopharmaceutics and Pharmacokinetics, A. Treatise, D .M. Brahmankar and Sunil B.J aiswal., Vallab Prakashan, Pitampura, Delhi
3. Applied Biopharmaceutics and Pharmacokinetics by Shargel. Land YuABC, 2nd edition, Connecticut Appleton Century Crofts, 1985
4. Textbook of Biopharmaceutics and Pharmacokinetics, Dr. Shobha Rani R. Hiremath,Prism Book
5. Pharmacokinetics by Milo Gibaldi and D. Perrier, 2nd edition, Marcel Dekker Inc.,New York, 1982
6. Current Concepts in Pharmaceutical Sciences: Biopharmaceutics, Swarbrick. J, Lea and Febiger, Philadelphia, 1970
7. Clinical Pharmacokinetics, Concepts and Applications 3rd edition by Malcolm Rowland and Thom~ N. Tozer, Lea and Febiger, Philadelphia, 1995
8. Dissolution, Bioavailability and Bioequivalence, Abdou. H.M, Mack Publishing Company, Pennsylvania 1989

9. Biopharmaceutics and Clinical Pharmacokinetics, An Introduction, 4th edition, revised and expande by Robert. E. Notari, Marcel Dekker Inc, New York and Basel,1987.
10. Biopharmaceutics and Relevant Pharmacokinetics by John. G Wagner and M.Pemarowski, 1st edition, Drug Intelligence Publications, Hamilton, Illinois, 1971.
11. Encyclopedia of Pharmaceutical Technology, Vol 13, James Swarbrick, James. G.Boylan, Marcel Dekker Inc, New York, 1996.
12. Basic Pharmacokinetics,1 st edition, Sunil S Jambhekar and Philip J Breen,pharmaceutical press, RPS Publishing,2009.
13. Absorption and Drug Development- Solubility, Permeability, and Charge State, Alex Avdeef, John Wiley & Sons, Inc,2003.

MIP202T-SCALE UP AND TECHNOLOGY TRANSFER (Theory)

SCOPE

This course is designed to impart knowledge and skills necessary to train the students to be on scale up, technology transfer process and industrial safety issues.

OBJECTIVES

At completion of this course it is expected that students will be able to understand-

- Manage the scale up process in pharmaceutical industry.
- Assist in technology transfer.
- To establish safety guidelines, which prevent industrial hazards.

THEORY **60 Hrs.**

1. **Pilot plant design** **12 Hrs**
   Basic requirements for design, facility, equipment selection, for tablets, capsules, liquid orals, parentrals and semisolid preparations.
   Scale up
   Importance, Technology transfer from R & D to pilot plant to plant scale, process scale up for tablets, capsules, liquid orals, semisolids, parentrals, NDDS products – stress on formula, equipments, product uniformity, stability, raw materials, physical layout, input, in-process and finished product specifications, problems encountered during transfer of technology.
2. **Validation** **12 Hrs**
   General concepts, types, procedures & protocols, documentation, VMF. Analytical method validation, cleaning validation and vender qualification.
3. **Equipment Qualification** **12 Hrs**
   Importance, IQ, OQ, PQ for equipments – autoclave, DHS, membrane filter, rapid mixer granulator, cone blender, FBD, tablet compression machine, liquid filling and sealing machine.
4. **Process validation** **12 Hrs**
   Importance, validation of mixing, granulation, drying, compression, tablet coating, liquid filling and sealing, sterilization, water process systems, environmental control.
5. **Industrial Saftey** **12 Hrs**
   Hazards – fire, mechanical, electrical, chemical and pharmaceutical, Monitoring & prevention systems, industrial effluent testing & treatment. Control of environmental pollution.

REFERENCES:

1. Pharmaceutical process validation, JR Berry, Nash, Vol 57, Marcel Dekker, NY.
2. Pharmaceutical Production facilities, design and applications, by GC Cole, Taylor and Francis.
3. Pharmaceutical project management, T.Kennedy, Vol 86, Marcel Dekker, NY.

4. The theory & Practice of Industrial Pharmacy, L.Lachman, H.A.Lieberman, Varghese Publ. Bombay.
5. Tablet machine instruments in pharmaceuticals, PR Watt, John Wiloy.
6. Pharmaceutical dosage forms, Tablets, Vol 1, 2, 3 by Lachman, Lieberman, Marcel Dekker, NY.
7. Pharmaceutical dosage forms, Parentral medications, Vol 1, 2 by K.E. Avis, Marcel Dekker, NY.
8. Dispersed system Vol 1, 2, 3 by Lachman, Lieberman, Marcel Dekker, NY.
9. Subrahmanyam, CVS, Pharmaceutical production and Management,2007,Vallabh
10. Prakashan,Dehli.

MIP203T-PHARMACEUTICAL PRODUCTION TECHNOLOGY (Theory)

SCOPE

This course is designed to impart knowledge and skills necessary to train the students to be on par with the routine of Industrial activities in Production

OBJECTIVES

At completion of this course it is expected that students will be able to understand–

- Handle the scheduled activities in a Pharmaceutical firm.
- Manage the production of large batches of pharmaceutical formulations.

THEORY **60 Hrs.**

1. **Improved Tablet Production** **12 Hrs**
   Tablet production process, unit operation improvements, granulation and pelletization equipments, continuous and batch mixing, rapid mixing granulators, rota granulators, speronizers and marumerisers, and other specialized granulation and drying equipments. Problems encountered.
   Coating Technology
   Process, equipments, particle coating, fluidized bed coating, application techniques. Problems encountered
2. **Parenteral Production** **12 Hrs**
   Area planning & environmental control, wall and floor treatment, fixtures and machineries, change rooms, personnel flow, utilities & utilities equipment location, engineering and maintenance.
3. **Lyophilization Technology**
   Principles, process, freeze-drying equipments.
4. **Capsule Production** **12 Hrs**
   Production process, improved capsule manufacturing and filling machines for hard and soft gelatin capsules. Layout and problems encountered.
   Disperse Systems Production
   Production processes, applications of mixers, mills, disperse equipments including fine solids dispersion, problems encountered.
   Packaging Technology
   Types of packaging materials, machinery, labeling, package printin for different dosage forms.
5. **Air Handling Systems** **12 Hrs**
   Study of AHUs, humidity & temperature control, air filtration systems, dust collectors.
   Water Treatment Process
   Techniques and maintenance – RO, DM, ultra – filtration, WFI.

REFERENCES

1. The theory & Practice of Industrial Pharmacy, L. Lachman, Varghese Publ, Bombay.
2. Modern Pharmaceutics by Banker, Vol 72, Marcel Dekker, NY.

3. Pharmaceutical Dosage Forms, Vol 1, 2, 3 by Lachman, Lieberman, Marcel Dekker, NY.
4. Pharmaceutical Dosage Forms, Parentral medications, Vol 1, 2 by K.E. Avis, Marcel Dekker, NY.
5. Pharmaceutical Production Facilities, design and applications, by G.C. Cole, Taylor and Francis.
6. Dispersed System Vol 1, 2, 3 by Lachman, Lieberman, Marcel Dekker, NY.
7. Product design and testing of polymeric materials by N.P. Chezerisionoff.
8. Pharmaceutical Project Management, T.Kennedy, Vol 86, Marcel Dekker, NY.
9. Packaging Pharmaceutical and Health Care, H.Lockhard.
10. Quality Control of Packaging Materials in Pharmaceutical Industy, .Kharburn, Marcel Dekker, NY.
11. Freeze drying / Lyophilization of Pharmaceuticals & Biological Products, L. Ray, Vol 96, Marcel Dekker, NY.
12. Tablet Machine instrumentation in pharmaceuticals, PR Watt, Ellis Horwoods, UK.

MIP204T-ENTREPRENEURSHIP MANAGEMENT (Theory)

SCOPE

This course is designed to impart knowledge and skills necessary to train the students on entrepreneurship management.

OBJECTIVES

At completion of this course it is expected that students will be able to understand-

- The Role of enterprise in national and global economy
- Dynamics of motivation and concepts of entrepreneurship
- Demands and challenges of Growth Strategies And Networking

THEORY **60 Hrs.**

1.	**Conceptual Frame Work** Concept need and process in entrepreneurship development. Role of enterprise in national and global economy.Types of enterprise – Merits and Demerits. Government policies and schemes for enterprise development. Institutional support in enterprise development and management	**12 Hrs**
2.	**Entrepreneur** Entrepreneurial motivation – dynamics of motivation. Entrepreneurial competency – Concepts. Developing Entrepreneurial competencies - requirements and understanding the process of entrepreneurship development, self awareness, interpersonal skills, creativity, assertiveness, achievement, factors affecting entrepreneur role.	**12 Hrs**
3.	**Lyophilization Technology** Principles, process, freeze-drying equipments.	
4.	**Launching And Organising An Enterprise** Environment scanning – Information, sources, schemes of assistance, problems. Enterprise selection, market assessment, enterprise feasibility study, SWOT Analysis. Resource mobilisation - finance, technology, raw material, site and manpower. Costing and marketing management and quality control. Feedback, monitoring and evaluation.	**12 Hrs**
5.	**Preparing Project Proposal To Start On New Enterprise** Project work – Feasibility report; Planning, resource mobilisation and implementation.	**12 Hrs**

REFERENCES

1. Akhauri, M.M.P.(1990): Entrepreneurship for Women in India, NIESBUD, New Delhi.
2. Hisrich, R.D & Brush, C.G.(1996) The Women Entrepreneurs, D.C. Health & Co., Toranto.
3. Hisrich, R.D. and Peters, M.P. (1995): Entrepreneurship – Starting, Developing and Managing a New Enterprise, Richard D., Inwin, INC, USA.
4. Meredith, G.G. etal (1982): Practice of Entrepreneurship, ILO, Geneva.

5. Patel, V.C.(1987): Women Entrepreneurship – Developing New Entrepreneurs, Ahmedabad EDII.

MIP205P-INDUSTRIAL PHARMACY PRACTICALS – II (Practicals)

1. Improvement of dissolution characteristics of slightly soluble drug by Solid dispersion technique.
2. Comparison of dissolution of two different marketed products /brands
3. Protein binding studies of a highly protein bound drug & poorly protein bound drug
4. Bioavailability studies of Paracetamol.
5. Pharmacokinetic and IVIVC data analysis by Winnoline^{R} software
6. *In vitro* cell studies for permeability and metabolism
7. Formulation and evaluation of tablets
8. Formulation and evaluation of capsules
9. Formulation and evaluation of injections
10. Formulation and evaluation of emulsion
11. Formulation and evaluation of suspension.
12. Formulation and evaluation of enteric coating tablets.

DETAILS OF SUBJECT TEACHERS – semester I

S.No	Name of the Subject	Name of the Teachers	Designation and Department	Mobile No.	e-mail
1.	Modern Pharmaceutical Analytical Techniques	Dr. N. Krishnaveni	Professor	9442083447	krisath@jssuni.edu.in
2.	Pharmaceutical Formulation Development	Dr. N.Jawahar	Asst. Professor	9486946314	jawahar.n@jssuni.edu.in
3.	Novel drug delivery systems	Dr.D.Nagasamy Venkatesh	Asst. Professor	8903123467	nagasamyvenkatesh@jssuni.edu.in
4.	Intellectual Property Rights	Dr.K.Gowthamarajan	Professor	9443089812	gowthamsang@jssuni.edu.in

DETAILS OF SUBJECT TEACHERS – semester II

S.No	Name of the Subject	Name of the Teachers	Designation and Department	Mobile No.	e-mail
5.	Advanced Biopharmaceutics and Pharmacokinetics	Dr.K.Gowthamarajan	Professor	9443089812	gowthamsang@jssuni.edu.in
6.	Scale up and Technology Transfer	Dr.D.Nagasamy Venkatesh	Asst. Professor	8903123467	nagasamyvenkatesh@jssuni.edu.in
7.	Pharmaceutical Production Technology	Dr.K.Gowthamarajan	Professor	9443089812	gowthamsang@jssuni.edu.in
8.	Entrepreneurship Management	Dr. GNK. Ganesh	Asst. Professor	9442191918	gnk@jssuni.edu.in

Academic Plan
2020-21

SEMESTER 1

Name of the Subject	**Modern Pharmaceutical Analytical Techniques (Theory)**
Name of the Faculty	Dr. Krishna Veni N M.Pharm., Ph.D
Designation, Department	Professor & Head, Department of Pharmaceutical Analysis
Mobile Number	9442083447
e-Mail i.d.	krisath@jssuni.edu.in

Scope, Course Objectives and Course Outcomes

SCOPE

This subject deals with various advanced analytical instrumental techniques for identification, characterization and quantification of drugs. Instruments dealt are NMR, Mass spectrometer, IR, HPLC, GC etc.

OBJECTIVES

After completion of course student is able to know about

- Chemicals and excipients
- The analysis of various drugs in single and combination dosage forms
- Theoretical and practical skills of the instruments

COURSE OUTCOMES (COs):

At completion of this course it is expected that the students will be able to

CO 1: Explain the general principles and techniques of spectroscopy & Chromatography

CO 2: Perform the assay of single and multiple component pharmaceuticals using various analytical techniques

CO 3: Develop skills in selecting suitable techniques for the analysis of drugs and pharamceutials

CO 4: Apply the knowledge learnt in developing newer analytical methods and procedures of their own design

CO 5: Explore and learn the various instrumental techniques available for the analysis of organic substances

LECTURE PLAN – Abstract

Sessional	No. of Hours of Didactic Lecture	No of Hours of other Activities	Total No. of Lecture Hours
	Advanced Instrumentation Techniques		
I	30	1	31
II	30	--	30
Total No. of Hours	60	--	61

I SESSIONAL : 30 Lectures + 1 Activity

Lecture No.	Lecture Details	Hours
	Orientation of the subject	**01**
Unit-1:		**10**
UV Visible Spectroscopy		
1.	UV Visible Spectroscopy - Introduction, Theory, Laws	
2.	Instrumentation associated with UV Visible Spectroscopy, Choice of Solvents & Solvent Effects	
3.	Applications of UV visible spectroscopy, Difference/ Derivative Spectroscopy	
IR Spectroscopy		
4.	IR Spectroscopy - Theory, Modes of Molecular Vibrations, Samples handling	
5.	Instrumentation of Dispersive and Fourier Transform IR spectrometere	
6.	Factors affecting vibrational frequencies and applications of IR spectroscopy, Data Interpretation	
Spectroflourimetry		
7.	Spectroflourimetry - Theory of fluorescence, Factors affecting fluorescence	
8.	Quenchers, Instrumentation, Applications of Fluorescence Spectrophotometer	
Flame emission spectroscopy & Atomic abosrption spectroscopy		
9.	Principle, Instrumentation	
10.	Interferences and Applications	
Unit-2:		**10**
NMR Spectroscopy		
1.	NMR spectroscopy - Quantum numbers and their role in NMR, Principle	
2.	Instrumentation - Continous wave NMR instrument	
3.	Principle and Instrumentation of FT NMR	
4.	solvent requirements, Relaxation process	
5.	NMR signals in various compounds	
6.	chemical shift, factors influencing chemical shift	
7.	spin spin coupling, coupling constant	
8.	Nuclear magnetic double resonance	
9.	Applications of NMR Spectroscopy	

10.	Principles of 13C NMR	
Unit-3:		**10**
MassSpectrometry		
1.	Principle, theory	
2.	Instrumentation of Mass Spectroscopy - sample introduction techniques	
3.	Different types of ionization - electron impact, chemical	
4.	Different types of ionization - Field, FAB and MALDI	
5.	Different types of ionization - APCI, ESI, APPI	
6.	Analyzers of Quadrupole and Time of Flight	
7.	Mass fragmentation and its rules	
8.	Mass fragmentation and its rules	
9.	Meta stable ions, Isotopic peaks	
10.	Applications of Mass spectroscopy	

II SESSIONAL : 30 Lectures

Lecture No.	Lecture Details	Hours
Unit-4:		**10**
Chromatography - Principle, Apparatus, Instrumentation, Chromatographic Parameters, Factors influencing resolution, Isolation of drugs from excipients, data interpretation and applications of		
1.	Thin Layer Chromatography	
2.	High Performance Thin Layer Chromatography	
3.	Ion Exchange Chromatography	
4.	column Chromatography	
5.	Gas Chromatography	
6.	Gas Chromatography	
7.	HPLC	
8.	HPLC	
9.	Ultra high Performance Liquid Chromatography	
10.	Affinity Chromatography, Gel Chromatography	
Unit-5:		**10**
Electrophoresis - Principle, Instrumentation, Working, Factors affecting separation and applications		
1.	Paper Electrophoresis	
2.	Gel Electrophoresis, Zone Electrophoresis	
3.	Capillary Electrophoresis	
4.	Capillary Electrophoresis	
5.	Moving Boundray Electrophoresis	
6.	Iso Electric Focussing	
X Ray Crystallography		
7.	Production of X Rays, Braggs Law	
8.	Different X Ray diffraction methods - Rotating Crystal Technique	
9.	X Ray Powder technique, Types of Crystals	
10.	Applications of X Ray Diffractions	

Unit-6:		**10**
Immunological Assays		
1.	Potentiometry - Principle, working	
2.	Ion selective Electrodes and other electrodes used in potentiometry	
3.	Applications of potentiometry	
Thermal Techniques		
4.	Differential Scanning Colorimetry - Principle, Thermal transitions	
5.	DSC - Instrumentation (Power compensated, heat flux designs),	
6.	Modulated DSC, Hyper DSC	
7.	Experimental Parameters - sample preparation, experimental conditions, calibration, heating and cooling rates, resolution, source of errors), Their influence, advantages, disadvantages and applications	
8.	Differential Thermal Analysis (DTA) - Principle instrumentation, Advantages & Disadvantages, Pharmaceutical Applications	
9.	Derivative Differential Thermal Analysis	
10.	Thermogravimetric Analysis (TGA) - Principle, instrumentation, factors affecting results, advantages & disadvantages, Pharmaceutical Applications	

TEXT BOOKS

1. Spectrometric Identification of Organic compounds - Robert M Silverstein, Sixth edition, John Wiley & Sons, 2004.
2. Principles of Instrumental Analysis - Doglas A Skoog, F. James Holler, Timothy A. Nieman, 5th edition, Eastern press, Bangalore, 1998.
3. Instrumental methods of analysis – Willards, 7th edition, CBS publishers.
4. Practical Pharmaceutical Chemistry – Beckett and Stenlake, Vol II, 4th edition, CBS Publishers, New Delhi, 1997.
5. Organic Spectroscopy - William Kemp, 3rd edition, ELBS, 1991.
6. Quantitative Analysis of Drugs in Pharmaceutical formulation - P D Sethi, 3rd Edition, CBS Publishers, New Delhi, 1997.
7. Pharmaceutical Analysis - Modern Methods – Part B - J W Munson, Vol 11, Marcel. Dekker Series
8. Spectroscopy of Organic Compounds, 2nd edn., P.S/Kalsi, Wiley estern Ltd., Delhi.
9. Textbook of Pharmaceutical Analysis, KA.Connors, 3rd Edition, John Wiley & Sons, 1982.

REFERENCE BOOKS

1. Introduction to Spectroscopy; by Donald L Pavia

Name of the Subject	**Pharmaceutical Formulation Development (Theory)**
Name of the Faculty	Dr. N.Jawahar M.Pharm., Ph.D
Designation, Department	Assistant Professor & Industrial Pharmacy Course Coordinator
Mobile Number	9486946314
e-Mail i.d.	Jawahar.n@jssuni.edu.in

Scope, Course Objectives and Course Outcomes

SCOPE

This course is designed to impart knowledge and skills necessary to train the students on par with the routine of Industrial activities in R&D and F&D.

OBJECTIVES

On completion of this course it is expected that students will be able to

- The scheduled activities in a Pharmaceutical firm.
- The pre formulation studies of pilot batches of pharmaceutical industry.
- The significance of dissolution and product stability

COURSE OUTCOMES (COs)

At completion of this course it is expected that the students will be able to

CO 1: Design the preformulation study

CO 2: Establish the soloubility, dissolution and stability protocol

LECTURE PLAN – Abstract

Sessional	Number of Hours of Didactic Lecture	No. of Hours of other activities	Total Number of Lecture Hours
I	31	03	34
II	30	04	34
Total Number of Lecture Hours	61	-	68

I SESSIONAL: 31 Lectures +03 Activites

Lecture No.	Lecture Details	Hours
1.	Pharmaceutical Formulation Development: Introduction	**(01)**
Unit-1: Preformulation Study		**(12)**
1.	Molecular optimization of APIs- Introduction	12
2.	Molecular optimization of APIs- Introduction	
3.	Crystal morphology and variations	
4.	Crystal morphology and variations	
5.	Powder flow	
6.	Powder flow	
7.	Structure modification	
8.	Structure modification	
9.	Drug-excipient compatibility studies	
10.	Drug-excipient compatibility studies	
11.	Methods of determination.	
12.	Methods of determination.	
Unit-2: Formulation Additives		**(12)**
1.	Study of different formulation additives	12
2.	Study of different formulation additives	
3.	Study of different formulation additives	
4.	Role of formulation	
5.	Role of formulation	
6.	Development and processing	
7.	New developments in excipient science	
8.	New developments in excipient science	
9.	Design of experiments	
10.	factorial design for product and process development	
11.	factorial design for product and process development	
12.	factorial design for product and process development	
Unit-3: Solubility		**(06)**
1.	Importance	06
2.	Experimental determination	
3.	Phase- solubility analysis	
4.	Continuation	
5.	pH-solubility profile	
6.	Solubility techniqyes to improve solubility and utilization of analytical method	
Activity 1	Unit test- 1	

Activity 2	Unit test-2	
Activity 3	Unit test-3	

II SESSIONAL: 30 Lectures+ 04 Activities

Lecture No.	Lecture Details	Hours
Unit-3 : Pharmacokinetics		**(06)**
1.	Cosolvancy	06
2.	Salt formation	
3.	Complexation	
4.	Solid dispersion	
5.	Micellar solubilization	
6.	Hydrotropy	
Unit-4 : Dissolution		**(12)**
1.	Theories	12
2.	Mechanism of dissolution	
3.	In-vitro dissolution testing models – sink and non-sink	
4.	Factors influencing dissolution and intrinsic dissolution studies	
5.	Dissolution test apparatus – designs	
6.	Dissolution test apparatus – designs	
7.	Dissolution testing for conventional and controlled release products	
8.	Data handling and correction factor	
9.	Biorelevent media	
10.	In-vitro and in-vivo correlations	
11.	In-vitro and in-vivo correlations	
12.	Level of correlation	
Unit-5 : Product Stability		**(12)**
1.	Degradation kinetics	12
2.	Mechanisms	
3.	Stability testing of drug and pharmaceuticals	
4.	Factors influencing-media effects and pH effects	
5.	Factors influencing-media effects and pH effects	
6.	Accelerated stability studies	
7.	Accelerated stability studies	
8.	Interpretation of kinetic data (API & tablets).	
9.	Solid state stability and shelf life assignment	
10.	Stability protocols	
11.	Stability protocols	
12.	Reports and ICH guidelines	
Activity 1	Unit test- 3	
Activity 2	Unit test-4	
Activity 3	Unit test-5	
Activity 4	Revision test- 1	

REFERENCES

1. Lachman L, Lieberman HA, Kanig JL. The theory and practice of industrial pharmacy, 3rd ed., Varghese Publishers, Mumbai 1991.
2. Sinko PJ. Martin's physical pharmacy and pharmaceutical sciences, 5th ed., B.I. Publications Pvt. Ltd, Noida, 2006.
3. Lieberman HA, Lachman L, Schwartz JB. Pharmaceutical dosage forms: tablets Vol. I-III, 2nd ed., CBS Publishers & distributors, New Delhi, 2005.
4. Conners KA. A Text book of pharmaceutical analysi Wells JI. Pharmaceutical preformulation: The physicochemical properties of drug substances. Ellis Horwood Ltd., England, 1998.
5. 5. Yalkowsky SH. Techniques of solubilization of drugs. Vol-12. Marcel Dekker Inc., New York, 1981
6. Dressman J, Kramer J. Pharmaceutical dissolution testing. Saurah printer pvt. Ltd., New Delhi,2005.
7. Sethi PD. Quantitative analysis of drugs in pharmaceutical formulations, 3rd ed., CBS publications, New Delhi, 2008.
8. Carstensen JT, Rhodes CT. Drug stability principles and practices, 3rd ed., CBS Publishers & distributors, New Delhi, 2005.
9. Yoshioka S, Stella VJ. Stability of drugs and dosage forms, Springer (India) Pvt. Ltd., New Delhi, 2006.
10. Banker GS, Rhodes CT. Modern Pharmaceutics, 4th ed., Marcel Dekker Inc, New York, 2005.
11. W. Grimm - Stability testing of drug products.
12. Mazzo DJ. International stability testing. Eastern Press Pvt. Ltd., Bangalore, 1999.
13. Beckett AH, Stenlake JB. Practical pharmaceutical chemistry, Part I & II., 4th ed., CBS Publishers & distributors, New Delhi, 2004.
14. Indian Pharmacopoeia. Controller of Publication. Delhi, 1996.
15. British Pharmacopoeia. British Pharmacopoeia Commission Office, London, 2008.

Name of the Subject	**Novel Drug Delivery System (Theory)**
Name of the Faculty	Dr. D.Nagasamy Venkatesh M.Pharm., Ph.D
Designation, Department	Assistant Professor, Department of Pharmaceutics
Mobile Number	8903123467
e-Mail i.d.	nagasamyvenkatesh@jssuni.edu.in

Scope, Course Objectives and Course Outcomes

SCOPE

This course is designed to impart basic knowledge in the areas of various drug delivery systems. This course will also outline the methods of preparation of different drug delivery systems and their evaluation parameters.The course also included the different approaches involved in the criteria for selection of suitable polymers and drug candidates for the developing the novel drug delivery system.

OBJECTIVES

The primary objectives of this course are to

- Discuss the basic knowledge on the drug delivery systems
- Help the students to understand the different approaches involved in developing different drug delivery systems.
- Equip the students to well verse in the different selecting the suitable polymer and drug moiety for developing the drug delivery systems.
- Facilitating the students to apply knowledge in evaluating the drug delivery systems.

COURSE OUTCOMES (COs)

At completion of this course it is expected that the students will be able to

CO 1: Understand the basic knowledge in development of drug delivery systems.

CO 2: Acquainted with the different approaches involved in developing drug delivery systems.

CO 3: Equip the students to identify suitable polymer and drug candidate for a drug delivery system.

CO 4: Familiar with the evaluation of various drug delivery systems.

LECTURE PLAN – Abstract

Sessional	No. of Hours of Didactic Lecture	No of Hours of other Activities	Total No. of Lecture Hours
	Novel drug delivery systems		
I	36	3	36
II	24	2	26
Total No. of Hours	60	5	62

I SESSIONAL: 36 Lectures + 3 Activities

Lecture No.	Lecture Details	Hours
Unit-1: Concept & Models for NDDS:		**12**
1.	Classification of rate controlled drug delivery systems (DDS),	
2.	Rate programmed release,	
3.	Activation modulated & feedback regulated DDS,	
4.	Effect of system parameters in controlled drug delivery,	
5.	Computation of desired release rate and dose for controlled release DDS,	
6.	Pharmacokinetic design for DDS – intermittent	
7.	Pharmacokinetic design for DDS – Zero order & first order release.	
8.	**Carriers for Drug Delivery:** Polymers / co-polymers-introduction	
9.	Classification, characterization	
10.	Polymerization techniques	
11.	Application in CDDS / NDDS	
12.	Biodegradable & natural polymers.	
Activity 1	**Class Test**	
Unit II - Study of Various DDS:		**12**
1.	Concepts	
2.	Design	
3.	Formulation & evaluation of controlled release oral DDS	
4.	Formulation & evaluation of controlled release oral DDS	
5.	Mucoadhesive DDS (Buccal)	
6.	Mucoadhesive DDS (Nasal)	
7.	Mucoadhesive DDS (Pulmonary)	
8.	Pulsatile DDS	
9.	Pulsatile DDS Contd..	
10.	Colon specific DDS	
11.	Colon specific DDS	
12.	Liquid sustained release systems	
Activity 2	**Revision/Discussion**	

Unit 3: Transdermal Drug Delivery Systems:		**08**
1.	Theory and design	
2.	Theory and design	
3.	Formulation & evaluation including iontophoresis	
4.	Formulation & evaluation including iontophoresis Contd	
5.	Formulation & evaluation including iontophoresis Contd	
6.	Latest developments in skin delivery systems.	
7.	Lther latest developments in skin delivery systems Contd.	
8.	Latest developments in skin delivery systems Contd.	
Unit-4. : Sub Micron Cosmeceuticals		
1.	Biology, formulation science	
2.	Evaluation of various cosmetics for skin,	
3.	Evaluation of various cosmetics for hair, nail, eye	
4.	Regulatory aspects of cosmeceuticals	**04**
Activity 3	**Discussion**	
Unit-5: Targeted Drug Delivery Systems		
1.	Importance and concept,	
2.	Biological process and events involved in drug targeting	
3.	Design, formulation	
4.	Evaluation	
5.	Methods in drug targeting	**12**
6.	Nanoparticles	
7.	Pharmacosomes	
8.	Liposomes, niosomes	
9.	Resealed erythrocytes, microspheres	
10.	Magnetic microspheres	
11.	Specialized pharmaceutical emulsions – multiple emulsions	
12.	Specialized pharmaceutical emulsions –micro-emulsions.	

II SESSIONAL : 24 Lectures + 2 Activities

Lecture No.	Lecture Details	Hours
Unit 6: Protein / Peptide Drug Delivery Systems:		**03**
1.	Concepts, delivery techniques	
2.	Formulation, stability testing,	
3.	Causes of protein destabilization, stabilization methods.	
Unit 7: Biotechnology in Drug Delivery Systems		**03**
1.	Brief review of major areas-recombinant DNA technology	
2.	Monoclonal antibodies	
3.	Gene therapy.	
Unit 8: New trends for Personalized Medicine:		**06**
1.	Introduction, Definition	
2.	Pharmacogenetics	
3.	Categories of Patients for Personalized Medicines	

4.	Customized drug delivery systems	
5.	Bioelectronic Medicines	
6.	3D printing of pharmaceuticals, Telepharmacy.	
Activity 1	Revision	
Activity 2	Discussion	

REFERENCES

1. Novel Drug Delivery System, Y.W. Chein, Vol 50, Marcel Dekker, NY.
2. Controlled Drug Delivery Systems, Robinson, Vol 29, Marcel Dekker, NY.
3. Transdermal Controlled Systemic Medications, YW Chein, Vol 31, Marcel Dekker, NY.
4. Bioadhesive DDS, E. Mathiowitz, Vol 98, Marcel Dekker, NY.
5. Nasal System Drug Delivery, K.S.E. Su, Vol 39, Marcel Dekker, NY.
6. Drug Delivery Devices, Vol 32, P Tyle Marcel Dekker, NY.
7. Polymers for Controlled Drug Delivery, P.J. Tarcha, CRC Press.
8. Pharmaceutical Biotechnology, Vyas, CBS, Delhi.
9. Biotechnology of Industrial Antibiotics, E.J. Vandamme, Marcel Dekker, NY.
10. Protein Formulation & Delivery, E.J. McNally, Vol 99, Marcel Dekker, NY.
11. Drug Targeting, M.H. Rubinstein, John Wiley, NY.

Name of the Subject	**Intellectual Property Rights (Theory)**
Name of the Faculty	Dr. K Gowthamarajan M.Pharm., Ph.D
Designation, Department	Professore&Head, Department of Pharmaceutics
Mobile Number	9443089812
e-Mail i.d.	gowthamsang@jssuni.edu.in

Scope, Course Objectives and Course Outcomes

SCOPE

This course is designed to impart knowledge and skills necessary to train the students to be onpar with the routine of industrial activities in Intellectual Property Rights and Drug Regulatory Affairs.

OBJECTIVES

The primary objectives of this course are to

- Understand the concepts of IPR and RA
- Realize the roles and responsibilities of GATT, TRIPS, and WIPO
- Prepare and Submit regulatory requirement application for Biosimilars
- Aware the functions of national and international regulatory agencies
- Participate in contract research organization

COURSE OUTCOMES (COs)

At completion of this course it is expected that the students will be able to

CO 1: Prepare the patent application and understanding the gobal commercialization
CO 2: Assist in Regulatory Audit process
CO 3: Establish regulatory guidelines for drug and drug products
CO 4: Involve contract research organization
CO 5: Guide to prepare requlatory applications for biosimilar

LECTURE PLAN – Abstract

Sessional	Number of Hours of Didactic Lecture	No. of Hours of other activities	Total Number of Lecture Hours
I	31	03	34
II	30	04	34
Total Number of Lecture Hours	61	-	68

I SESSIONAL: 31 lectures +03 activites

Lecture No.	Lecture Details	Hours
1.	Intellectual Property Rights (IPR)	**01**
Unit-1:		**(12)**
1.	Definition, Need for patenting	12
2.	Types of Patents	
3.	Conditions to be satisfied by an invention to be patentable	
4.	Conditions to be satisfied by an invention to be patentable (cont…)	
5.	Introduction to patent search	
6.	Part sof patents	
7.	The essential elements of patent	
8.	Filling of patents	
9.	Filling of patents (cont…)	
10.	Non-obviousness in Patent	
11.	Guidelines for preparation of laboratory note book	
12.	Guidelines for preparation of laboratory note book (cont…)	
Unit-2		**(12)**
1.	Role of GATT	12
2.	Role of GATT(cont…)	
3.	Role of GATT (cont…)	
4.	Role of GATT (cont…)	
5.	Role of TRIPS	
6.	Role of TRIPS (cont…)	
7.	Role of TRIPS (cont…)	
8.	Role of TRIPS (cont…)	
9.	Role of WIPO	
10.	Role of WIPO (cont…)	
11.	Role of WIPO (cont…)	
12.	Role of WIPO (cont…)	
Unit-3:. IPR'sand itstypes,.		**(06)**
1.	Brief introduction toTrademark protection	06
2.	Brief introduction toTrademark protection (cont…)	
3.	Brief introduction toTrademark protection (cont…)	
4.	WHO Patents	
5.	WHO Patents (cont…)	

6.	WHO Patents (cont…)	
Activity 1	Unit test- 1	
Activity 2	Unit test-2	
Activity 3	Unit test-3	

II SESSIONAL: 30 Lectures +04 Activites

Lecture No.	Lecture Details	Hours
Unit-3		**(06)**
1.	IPR's and its types	06
2.	IPR's and its types (cont…)	
3.	IPR's and its types (cont…)	
4.	Major bodies regulating Indian Pharmaceutical sector	
5.	Major bodies regulating Indian Pharmaceutical sector (cont…)	
6.	Major bodies regulating Indian Pharmaceutical sector (cont…)	
Unit-4		**(12)**
1.	Brief introduction to CDSCO	12
2.	Brief introduction to CDSCO (cont…)	
3.	Brief introduction to WHO	
4.	Brief introduction toWHO (cont…)	
5.	Brief introduction to USFDA	
6.	Brief introduction to USFDA (cont…)	
7.	Brief introduction to EMEA	
8.	Brief introduction to EMEA (cont…)	
9.	TGA	
10.	MHRA	
11.	MCC	
12.	ANVISA	
Unit-5		**(12)**
1.	Regulatory requirements for contract research organization	12
2.	Regulatory requirements for contract research organization (cont…)	
3.	Regulatory requirements for contract research organization (cont…)	
4.	Regulatory requirements for contract research organization (cont…)	
5.	Regulatory requirements for contract research organization (cont…)	
6.	Regulatory requirements for contract research organization (cont…)	
7.	Regulations for Biosimilars	
8.	Regulations for Biosimilars (cont…)	
9.	Regulations for Biosimilars (cont…)	
10.	Regulations for Biosimilars (cont…)	
11.	Regulations for Biosimilars (cont…)	
12.	Regulations for Biosimilars (cont…)	
Activity 1	Unit test- 3	

Activity 2	Unit test-4	
Activity 3	Unit test-5	
Activity 4	Revision test- 1	

REFERENCES

1. Pharmaceutical Process Validation: By Fra R. Berry and Robert A.Nash, Vol 57,2nd Edition
2. Applied Production and Operation Management By Evans, Anderson and Williams
3. GMP for pharmaceuticals Material Management by K.K.Ahuja Published by CBS publishers
4. ISO 9000-Norms and explanations
5. GMP for pharmaceuticals-Willing S.H.Marceland Dekker
6. www.wipo.int
7. www.wto.org

LECTURE PLAN – Industrial Pharmacy-I (Practical)

I SESSIONAL

Practical No.	Name of the Experiment
1.	Analysis of pharmacopoeial compounds and their formulations by UV Vis spectrophotometer
2.	Simultaneous estimation of multi component containing formulations by UV spectrophotometry
3.	Experiments based on HPLC
4.	Experiments based on Gas Chromatography
5.	Estimation of riboflavin/quinine sulphate by fluorimetry
6.	Estimation of sodium/potassium by flame photometry
7.	Effect of surfactants on the solubility of drugs.
8.	Effect of pH on the solubility of drugs.
9.	Dissolution methods of transdermal drug delivery systems.

II SESSIONAL

Practical No.	Name of the Experiment
1.	Stability testing of solution and solid dosage forms for photo degradation.
2.	Stability studies of drugs in dosage forms at 25 oC, 60% RH and 40 oC, 75% RH.
3.	Compatibility evaluation of drugs and excipients.
4.	Preparation and evaluation of different polymeric membranes.
5.	Formulation and evaluation of sustained release oral matrix tablet.
6.	Formulation and evaluation of sustained release oral reservoir system.
7.	Formulation and evaluation of microspheres / microcapsules.
8.	Formulation and evaluation of transdermal films.
9.	Design and evaluation of face wash, body- wash, creams, lotions, shampoo, toothpaste, lipstick.

SEMESTER II

Name of the Subject	**Advanced Biopharmaceutics and Pharmacokinetics (Theory)**
Name of the Faculty	Dr. K Gowthamarajan M.Pharm., Ph.D
Designation, Department	Professore&Head, Department of Pharmaceutics
Mobile Number	9443089812
e-Mail i.d.	gowthamsang@jssuni.edu.in

Scope, Course Objectives and Course Outcomes

SCOPE

This course is designed to impart knowledge and skills necessary for dose calculations, dose adjustments and to apply biopharmaceutics theories in practical problem solving.

OBJECTIVES

On completion of this course it is expected that students will be able to

- Understand the basic concepts of Biopharmaceutics and Pharmacokinetics.
- Understand the process of drug absorption, distribution, metabolism and elimination.
- Calculate using raw data and derive the pharmacokinetic models and parameters the best describe
- Evaluate biopharmaceutics studies involving drug product equivalency
- Evaluate dosage regimens of the drugs using pharmacokinetic and biopharmaceutic parameters
- Formulate the best release profile drug delivery systems including biopharmaceuticals

COURSE OUTCOMES (COs):

CO 1: Design the absorption model to predict the new molecule's permeability

CO 2: Assist invitro performance studies

CO 3: Establish the pharmacokinetic models

CO 4: Involve bioavailability and bioequivalence studies

At completion of this course it is expected that the students will be able to

LECTURE PLAN – Abstract

Sessional	Number of Hours of Didactic Lecture	No. of Hours of other activities	Total Number of Lecture Hours
I	31	03	34
II	30	04	34
Total Number of Lecture Hours	61	-	68

I SESSIONAL: 31 Lectures +03 Activites

Lecture No.	Lecture Details	Hours
1.	Advanced biopharmaceutics and pharmacokinetics: Introduction	**(01)**
Unit-1: Drug Absorption from the Gastrointestinal Tract		**(12)**
1.	Gastrointestinal tract, Properties of the Gastrointestinal Tract (GIT)	12
2.	Mechanism of drug absorption	
3.	Factors affecting, pH–partition theory	
4.	Formulation and physicochemical factors: Dissolution rate, Dissolution process	
5.	Noyes–Whitney equation and drug dissolution, Factors affecting the dissolution rate	
6.	Gastrointestinal absorption: role of the dosage form: Solution (elixir, syrup and solution) as a dosage form ,Suspension as a dosage form	
7.	Capsule as a dosage form, Tablet as a dosage form	
8.	Dissolution methods ,Formulation and processing factors	
9.	Correlation of in vivo data with in vitro dissolution data	
10.	Transport model: Permeability-Solubility-Charge State and the pH Partition Hypothesis	
11.	pH Microclimate Intracellular pH Environment, Tight-Junction Complex	
12.	Solubility: Experimental methods. Permeability: In-vitro, in-situ and In-vivo methods	
Unit-2: Biopharmaceutic Considerations in Drug Product Design and In Vitro Drug Product Performance		**(12)**
1.	Introduction, biopharmaceutic factors affecting drug bioavailability,	12
2.	Rate limiting steps in drug absorption	
3.	Physicochemical nature of the drug formulation factors affecting drug product performance	
4.	In vitro: dissolution and drug release testing	
5.	Compendial methods of dissolution	
6.	Alternative methods of dissolution testing	
7.	Meeting dissolution requirements	
8.	Problems of variable control in dissolution testing performance of drug products	
9.	In vitro–in vivo correlation	
10.	Dissolution profile comparisons	

11.	Drug product stability	
12.	Considerations in the design of a drug product	
Unit-3:Pharmacokinetics		**(06)**
1.	Basic considerations	06
2.	Pharmacokinetic models	
3.	Compartment modeling: One compartment model- IV bolus	
4.	IV infusion	
5.	Extra-vascular	
6.	Multi Compartment model: Two compartment - model in brief	
Activity 1	Unit test- 1	
Activity 2	Unit test-2	
Activity 3	Unit test-3	

II SESSIONAL: 30 Lectures+04 Activites

Lecture No.	Lecture Details	Hours
Unit-3 : Pharmacokinetics		**(06)**
1.	Non-Linear Pharmacokinetics: Cause of non-linearity, Michaelis – Menten equation, Estimation Kmax and Vmax	06
2.	Drug interactions: Introduction	
3.	The effect of protein-binding interactions	
4.	The effect of tissue-binding interactions	
5.	Cytochrome P450-based drug interactions	
6.	Drug interactions linked to transporters	
Unit-4 : Drug Product Performance-In Vivo		**(12)**
1.	Bioavailability and bioequivalence:	12
2.	Drug product performance, purpose of bioavailability studies,	
3.	Relative and absolute availability, ,	
4.	Methods for assessing bioavailability,	
5.	Bioequivalence studies, design and evaluation of bioequivalence studies,	
6.	Study designs, crossover study designs, evaluation of the data, bioequivalence example,	
7.	Study submission and drug review process,	
8.	The biopharmaceutics classification system,	
9.	Generic biologics (biosimilar drug products),	
10.	Clinical significance of bioequivalence studies,	
11.	Special concerns in bioavailability and bioequivalence studies,	
12.	Generic substitution.	
Unit-5 : Application of Pharmacokinetics		**(12)**
1.	Modified-release drug products	12
2.	Targeted drug delivery systems	
3.	Biotechnological products	
4.	Relationship between Pharmacokinetics including Pharmacodynamics:	
5.	Generation of a Pharmacokinetic– Pharmacodynamic (PKPD) equation	

6.	Pharmacokinetic and pharmacodynamic, interactions	
7.	Pharmacokinetics and pharmacodynamics of biotechnology drugs: introduction	
8.	Proteins and peptides	
9.	Monoclonal antibodies	
10.	Oligonucleotides	
11.	Vaccines (immunotherapy)	
12.	Gene therapies	
Activity 1	Unit test- 3	
Activity 2	Unit test-4	
Activity 3	Unit test-5	
Activity 4	Revision test- 1	

REFERENCES

1. Biopharmaceutics and Clinical Pharmacokinetics by Milo Gibaldi, 4th edition,Philadelphia,LeaandFebiger,1991
2. Biopharmaceutics and Pharmacokinetics, A. Treatise, D .M. Brahmankar and Sunil B.Jaiswal.,Vallab Prakashan, Pitampura, Delhi
3. Applied Biopharmaceutics and Pharmacokinetics by Shargel. Land YuABC ,2nd edition, Connecticut Appleton Century Crofts,1985
4. Textbook of Biopharmaceutics andPharmacokinetics, Dr. Shobha Rani R. Hiremath,Prism Book
5. Pharmacokinetics by Milo Gibaldi and D. Perrier, 2nd edition, Marcel Dekker Inc.,New York, 1982
6. Current Concepts in Pharmaceutical Sciences: Biopharmaceutics, Swarbrick.J,LeaandFebiger,Philadelphia,1970
7. Clinical Pharmacokinetics, Concepts and Applications 3rd edition by Malcolm Rowland and Thom~ N. Tozer, Lea and Febiger, Philadelphia, 1995
8. Dissolution, Bioavailability and Bioequivalence, Abdou. H.M, Mack Publishing Company, Pennsylvania1989
9. Biopharmaceutics and Clinical Pharmacokinetics, An Introduction, 4th edition, revisedand expande by Robert.E. Notari, Marcel Dekker Inc, New Yorkand Basel,1987.
10. 10.Biopharmaceutics and Relevant Pharmacokinetics by John.G Wagnerand M.Pemarowski, 1st edition, Drug Intelligence Publications, Hamilton, Illinois, 1971.
11. Encyclopedia of Pharmaceutical Technology, Vol 13, James Swarbrick, James. G.Boylan,Marcel Dekker Inc,New York,1996.
12. Basic Pharmacokinetics,1 st edition, Sunil S Jambhekar and Philip J Breen,pharmaceutical press,RPS Publishing,2009.
13. Absorption and Drug Development- Solubility, Permeability, and Charge State,Alex Avdeef,JohnWiley&Sons,Inc,2003.

Name of the Subject	**Scale up and Technology Transfer (Theory)**
Name of the Faculty	Dr. D. Nagasamy Venkatesh M.Pharm., Ph.D
Designation, Department	Assistant Professor, Department of Pharmaceutics
Mobile Number	8903123467
e-Mail i.d.	nagasamyvenkatesh@jssuni.edu.in

Scope, Course Objectives and Course Outcomes

SCOPE

This course is designed to impart advanced knowledge and skills required to learn various aspects and concepts at pharmaceutical industries. This course will also help the students to update with latest developments in the various validation processes in the industries. The course will also cover the industrial management systems with with cGMP. This course includes the sterilization techniques, stability testing and packaging of dosage forms.

OBJECTIVES

The primary objectives of this course are to

- The elements of preformulation studies.
- The Active Pharmaceutical Ingredients and Generic drug Product development
- Industrial Management and GMP Considerations.
- Optimization Techniques & Pilot Plant Scale Up Techniques
- Stability Testing, sterilization process & packaging of dosage forms.

COURSE OUTCOMES (COs)

At completion of this course it is expected that the students will be able to

CO 1 : Understand the basic knowledge in preformulation studies.

CO 2 : Acquainted the knowledge with the generic drug product development.

CO 3 : Gain knowledge on the industrial management systems with GMP.

CO 4 : Familiar with the pilot plant considerations and evaluation of various drug delivery systems.

LECTURE PLAN – Abstract

Sessional	No. of Hours of Didactic Lecture	No of Hours of other Activities	Total No. of Lecture Hours
	Scale up		
I	36	3	39
II	24	2	26
Total No. of Hours	60	5	65

I SESSIONAL: 36 Lectures + 3 Activities

Lecture No.	Lecture Details	Hours
Unit-1: Pilot plant design:		**12**
1.	Basic requirements for design	
2.	Basic requirements for design	
3.	Basic requirements for facility tablets, capsules	
4.	Basic requirements for equipment selection for liquid orals	
5.	Basic requirements for equipment selection for parental	
6.	Basic requirements for equipment selection for semisolid preparation	
7.	**Scale up:** Importance, Technology transfer from R & D to pilot plant to plant scale,	
8.	Process scale up for tablets, capsules, liquid orals, semisolids,	
9.	Parentral, NDDS products – stress on formula, equipments,	
10.	Product uniformity, stability, raw materials,	
11.	Physical layout, input, in-process and finished product specifications,	
12.	Problems encountered during transfer of technology	
Activity 1	**Class Test**	
Unit 2. Validation:		**12**
1.	General concepts	
2.	Types, procedures	
3.	protocols,	
4.	documentation,	
5.	VMF	
6.	Analytical method validation	
7.	Analytical method validation-Contd	
8.	Analytical method validation-Contd	
9.	Analytical method validation-Contd	
10.	Cleaning validation	
11.	Cleaning validation – Contd	
12.	Vender qualification	
Activity 2	**Revision/Discussion**	
Unit 3: Equipment Qualification:		**08**
1.	Importance,	
2.	IQ, OQ, PQ for autoclave	
3.	IQ, OQ, PQ for DHS	

4.	IQ, OQ, PQ for membrane filter	
5.	IQ, OQ, PQ for rapid mixer granulator	
6.	IQ, OQ, PQ for cone blender	
7.	IQ, OQ, PQ for FBD	
8.	IQ, OQ, PQ for tablet compression machine	
9.	IQ, OQ, PQ for liquid filling machine	
10.	IQ, OQ, PQ for liquid sealing machine	
11.	Aseptic room validation	
12.	Aseptic room validation – Contd	
Activity 3	**Revision/Discussion**	

II SESSIONAL: 24 Lectures + 2 Activities

Lecture No.	**Lecture Details**	**Hours**
Unit-4: Process validation:		**12**
1.	Importance	
2.	Validation of mixing	
3.	Validation of granulation	
4.	Validation of drying	
5.	Validation of compression	
6.	Tablet coating	
7.	Liquid filling and sealing	
8.	Sterilization	
9.	Sterilization – Contd.	
10.	Water process system	
11.	Water process system – Contd	
12.	Environmental Control	
Activity 3	**Revision**	
Unit 5. Industrial safety:		**12**
1.	Hazards – fire	
2.	Hazards – fire Contd	
3.	Hazards – Mechanical	
4.	Hazards – Mechanical Contd	
5.	Hazards – Electrical	
6.	Hazards – Electrical Contd	
7.	Hazards – Chemical	
8.	Hazards – Chemical Contd	
9.	Hazards – Pharmaceutical	
10.	Monitoring & prevention systems	
11.	industrial effluent testing & treatment	
12.	Control of environmental pollution	
Activity 2	Discussion	

REFERENCES

1. Pharmaceutical process validation, JR Berry, Nash, Vol 57, Marcel Dekker, NY.
2. Pharmaceutical Production facilities, design and applications, by GC Cole, Taylor and Francis.

3. Pharmaceutical project management, T.Kennedy, Vol 86, Marcel Dekker, NY.
4. The theory & Practice of Industrial Pharmacy, L.Lachman, H.A.Lieberman, Varghese Publ. Bombay.
5. Tablet machine instruments in pharmaceuticals, PR Watt, John Wiloy.
6. Pharmaceutical dosage forms, Tablets, Vol 1, 2, 3 by Lachman, Lieberman, Marcel Dekker, NY.
7. Pharmaceutical dosage forms, Parentral medications, Vol 1, 2 by K.E. Avis, Marcel Dekker, NY.
8. Dispersed system Vol 1, 2, 3 by Lachman, Lieberman, Marcel Dekker, NY.
9. Subrahmanyam, CVS, Pharmaceutical production and Management, 2007, Vallabh Prakashan,Dehli.

Name of the Subject	**Pharmaceutical Production Technology (Theory)**
Name of the Faculty	Dr. K Gowthamarajan M.Pharm., Ph.D
Designation, Department	Professore&Head, Department of Pharmaceutics
Mobile Number	9443089812
e-Mail i.d.	gowthamsang@jssuni.edu.in

Scope, Course Objectives and Course Outcomes

SCOPE

This course is designed to impart knowledge and skills necessary to train the students to be on par with the routine of Industrial activities in Production

OBJECTIVES

On completion of this course it is expected that students will be able to

- Understand handle the scheduled activities in a Pharmaceutical firm
- Manage the production of large batches of pharmaceutical formulations

COURSE OUTCOMES (COs)

At completion of this course it is expected that the students will be able to

CO 1: Involve the large scale up productions
CO 2: Assist in process and manufacturing troble shootings
CO 3: Establish water and air handing sytems in pharma industries
CO 4: Construct the pharmaceutical machinery layout
CO 5: Design and printing the pharmaceutical packaging sytems

LECTURE PLAN – Abstract

Sessional	Number of Hours of Didactic Lecture	No. of Hours of other activities	Total Number of Lecture Hours
I	31	03	34
II	30	04	34
Total Number of Lecture Hours	61	-	68

I SESSIONAL: 31 lectures +03 Activities

Lecture No.	Lecture Details	Hours
1.	Pharmaceutical Production Technology : Introduction	**(01)**
Unit-1: Improved Tablet Production		**(12)**
1.	Tablet production process	12
2.	Unit operation improvements	
3.	Granulation and pelletization equipments	
4.	Continuous and batch mixing	
5.	Rapid mixing granulators	
6.	Rota granulators	
7.	Spheronizers and marumerisers	
8.	Other specialized granulation and drying equipments	
9.	Problems encountered	
10.	Coating Technology: Process, equipments,	
11.	Particle coating, fluidized bed coating,	
12.	Application techniques. Problems encountered.	
Unit-2: Parenteral Production		**(12)**
1.	Area planning & environmental control	12
2.	Area planning & environmental control (cont…)	
3.	Wall and floor treatment	
4.	Wall and floor treatment (cont…)	
5.	Fixtures and machineries	
6.	Fixtures and machineries (cont…)	
7.	Change rooms	
8.	Personnel flow	
9.	Utilities & utilities equipment location	
10.	Utilities & utilities equipment location (cont…)	
11.	Engineering and maintenance	
12.	Engineering and maintenance (cont…)	
Unit-3: Lyophilization & Spray drying Technology		**(06)**
1.	Lyophilization & Spray drying Technology	06
2.	Principles and process	
3.	Principles and process (cont…)	
4.	Principles and process	
5.	Freeze-drying equipments.	
6.	Freeze-drying equipments (cont…)	

II SESSIONAL : 30 Lectures +04 Activites

Lecture No.	Lecture Details	Hours
Unit-3 : Lyophilization & Spray drying Technology		**(06)**
1.	Freeze-drying equipments (cont…)	06
2.	Freeze-drying equipments (cont…)	
3.	Spray drying equipments	
4.	Spray drying equipments (cont…)	
5.	Spray drying equipments (cont…)	
6.	Spray drying equipments (cont…)	
Unit-4 : Capsule Production,Disperse Systems, Production and Packaging Technology		**(12)**
1.	Production process,	12
2.	Improved capsule manufacturing and filling machines for hard gelatin capsules.	
3.	Improved capsule manufacturing and filling machines for soft gelatin capsules.	
4.	Layout and problems encountered.	
5.	Disperse Systems Production: Production processes,	
6.	Applications of mixers, mills,	
7.	Disperse equipments including fine solids dispersion,	
8.	Problems encountered.	
9.	Packaging Technology:	
10.	Types of packaging materials,	
11.	Machinery, labeling,	
12.	Package printing for different dosage forms.	
Unit-5 : Air Handling Systems and Water Treatment Process		**(12)**
1.	Air Handling Systems	12
2.	Study of AHUs	
3.	Humidity & temperature control	
4.	Air filtration systems	
5.	Air filtration systems	
6.	Dust collectors	
7.	Water Treatment Process:	
8.	Techniques and maintenance – RO,	
9.	Techniques and maintenance – RO	
10.	DM	
11.	Ultra – filtration	
12.	WFI	

REFERENCES

1. The Theory & Practice of Industrial Pharmacy, L. Lachman,Varghese Publ,Bombay.
2. Modern Pharmaceutics by Banker, Vol 72,MarcelDekker,NY.
3. Pharmaceutical Dosage Forms, Vol 1, 2, 3 by Lachman, Lieberman, MarcelDekker,NY.

4. Pharmaceutical DosageForms, Parentral medications, Vol 1, 2 by K.E. Avis,MarcelDekker,NY.
5. Pharmaceutical Production Facilities, design and applications, by G.C. Cole, Taylor and Francis.
6. DispersedSystemVol1,2,3by Lachman, Lieberman,MarcelDekker,NY.
7. Productdesign and testing ofpolymeric materialsbyN.P.Chezerisionoff.
8. Pharmaceutical Project Management, T.Kennedy, Vol 86, Marcel Dekker, NY.
9. PackagingPharmaceuticalandHealthCare,H.Lockhard.
10. Quality Control of Packaging Materials in Pharmaceutical Industy, .Kharburn,MarcelDekker,NY.
11. Freeze drying/Lyophilization ofPharmaceuticals &Biological Products,L. Ray,Vol96,MarcelDekker,NY.
12. Tablet Machine Instrumentation In Pharmaceuticals, PR Watt, Ellis Horwoods,UK.

Name of the Subject	**Entrepreneurship Management (Theory)**
Name of the Faculty	Dr. GNK. Ganesh M.Pharm., Ph.D
Designation, Department	Assistant Professor, Department of Pharmaceutics
Mobile Number	9442191918
e-Mail i.d.	gnk@jssuni.edu.in

Scope, Course Objectives and Course Outcomes

SCOPE

This course is designed to impart knowledge and skills necessary to train the students on entrepreneurship management.

OBJECTIVES

On completion of this course it is expected that students will be able to understand,

- The Role of enterprise in national and global economy
- Dynamics of motivation and concepts of entrepreneurship
- Demands and challenges of Growth Strategies And Networking

COURSE OUTCOMES (COs)

At completion of this course it is expected that the students will be able to

CO1: Understand the Role of enterprise in national and global economy

CO2: Understand the competencies of entrepreneur

CO3: Understand the Dynamics of motivation and concepts of entrepreneurship

CO4: Understand the Demands and challenges of Growth Strategies and Networking in business

CO5: Understand the monitoring and evaluation of business

CO6: Can able to prepare project proposal to start new enterprise

LECTURE PLAN – Abstract

Sessional	Number of Hours of Didactic Lecture	No. of Hours of other activities	Total Number of Lecture Hours
I	30	4	30
II	30	3	30
Total Number of Lecture Hours	60	7	60

I SESSIONAL: 30 lectures

Lecture No.	Lecture Details	Hours
Unit-1: Conceptual Frame Work		**(06)**
1.	Concept need and process in entrepreneurship development	06
2.	Role of enterprise in national and global economy.	
3.	Types of enterprise Merits and Demerits.	
4.	Merits and Demerits	
5.	Government policies and schemes for enterprise development	
6.	Institutional support in enterprise development and management.	
Unit-2: Entrepreneur		**(12)**
1.	Entrepreneurial motivation	12
2.	Dynamics of motivation.	
3.	Entrepreneurial competency –Concepts.	
4.	Developing Entrepreneurial competencies	
5.	Requirements and understanding the process of entrepreneurship development	
6.	Self-awareness	
7.	Interpersonal skills	
8.	Creativity	
9.	Assertiveness	
10.	Achievement	
11.	Factors affecting entrepreneur role.	
Unit-3: Launching And Organising An Enterprise		**(12)**
1.	Environment scanning	12
2.	Information, sources	
3.	Schemes of assistance, problems	
4.	Enterprise selection	
5.	Market assessment	
6.	Enterprise feasibility study	

II SESSIONAL: 30 Lectures

Lecture No.	Lecture Details	Hours
Unit-3: Launching And Organising An Enterprise		**(12)**
1.	SWOT Analysis	12
2.	Resource mobilization	
3.	Finance, technology	
4.	Raw material, site and manpower	
5.	Costing and marketing management and quality control	
6.	Feedback, monitoring and evaluation.	
Unit-4: Growth Strategies And Networking		**(12)**
1.	Performance appraisal and assessment.	12
2.	Profitability and control measures	
3.	Demands and challenges.	
4.	Need for diversification	
5.	Future Growth – Techniques of expansion and diversification	
6.	Vision strategies	
7.	Concept and dynamics.	
8.	Methods, Joint venture	
9.	Co-ordination and feasibility study.	
Unit-5: Preparing Project Proposal To Start On New Enterprise		**(06)**
1.	Project work	06
2.	Feasibility report	
3.	Planning	
4.	Resource mobilization	
5.	Implementation.	
Activity 1	Unit test 1	
Activity 2	Unit test 2	
Activity 3	Unit test 3	
Activity 4	Unit test 4	
Activity 5	Unit test 5	
Activity 6	Revision test 1	
Activity 7	Revision test 2	

REFERENCES

1. Akhauri, M.M.P.(1990): Entrepreneurship for Women in India, NIESBUD, New Delhi.
2. Hisrich, R.D & Brush, C.G.(1996) The Women Entrepreneurs, D.C. Health & Co., Toranto.
3. Hisrich, R.D. and Peters, M.P. (1995): Entrepreneurship – Starting, Developing and Managing a New Enterprise, Richard D., Inwin, INC, USA.
4. Meredith, G.G. etal (1982): Practice of Entrepreneurship, ILO, Geneva.

LECTURE PLAN - Industrial Pharmacy-II Practicals

I SESSIONAL

Practical No.	Name of the Experiment
1.	Improvement of dissolution characteristics of slightly soluble drug by Solid dispersion technique.
2.	Comparison of dissolution of two different marketed products /brands
3.	Protein binding studies of a highly protein bound drug & poorly protein bound drug
4.	Bioavailability studies of Paracetamol.
5.	Pharmacokinetic and IVIVC data analysis by WinnolineR software
6.	In vitro cell studies for permeability and metabolism

II SESSIONAL

Practical No.	Name of the Experiment
1.	Formulation and evaluation of tablets
2.	Formulation and evaluation of capsules
3.	Formulation and evaluation of injections
4.	Formulation and evaluation of emulsion
5.	Formulation and evaluation of suspension.
6.	Formulation and evaluation of enteric coating tablets.

JSS Academy of Higher Education & Research, Mysuru
JSS College of Pharmacy, Rocklands, Ooty

I M. PHARMACY TIME TABLE FOR E-LEARN CLASSES : I Semester (AY : 2020 - 2021)

DEPARTMENT : PHARMACEUTICS
COURSE : INDUSTRIAL PHARMACY
ZOOM / GOOGLE MEET LICENSE - cpoip1@jssuni.edu.in

Days	9 - 10 am	10 - 11 am	11 - 12 am	12 - 1 pm	1 - 2 pm	2 - 3 pm	3 - 4 pm	4 - 5 pm
Mon	*Assingment*	**MPAT** ***(NKV)***	**PFD** ***(NJ)***	**PFD** ***(NJ)***	**LUNCH BREAK**	-	**NDDS** ***(DNV)***	-
Tue	*Assingment*	**MPAT** ***(NKV)***	**PFD** ***(NJ)***	**PFD** ***(NJ)***		-	**NDDS** ***(DNV)***	-
Wed	*Assingment*	**MPAT** ***(NKV)***	**IPR** ***(KG)***	**IPR** ***(KG)***		-	**NDDS** ***(DNV)***	-
Thu	-	**MPAT** ***(NKV)***	**IPR** ***(KG)***	**IPR** ***(KG)***		-	**NDDS** ***(DNV)***	-
Fri	-	Library	Library	-		-	-	-
Sat	Seminar	Seminar	Seminar	Seminar		-	-	-

Subjects : I M.Pharm (Industrail Pharmacy)

1. Intellectual Property Rights(IPR-T & P)-Dr. K. Gowthamrajan ***(KG)***
2. Novel drug Delivery Systems (NDDS-T & P) –Dr. D. Nagasamy Venkatesh ***(DNV)***
3. Pharmaceutical Formulation Development (PFD-T & P) – Dr. N. Jawahar ***(NJ)***
4. Modern Pharmaceutical Analytical Techniques(MPAT-T & P)-Dr. N. Krishnaveni ***(NKV)***

JSS Academy of higher Education & Research, Mysuru
(Deemed to be University, Accredited 'A' Grade by NAAC)
JSS College of Pharmacy, Ooty – 643 001
(An ISO 9001-2015 certified Institution)

I M.Pharm, Industrial Pharmacy (II.Semester) Time Table (AY : 2020-21)

Days	09-10	10-11	11-12	12-01		2pm - 5pm		
Mon		PPT-KG	PPT-KG	Library	L U N C H	Pharmaceutical Production Technology-NJ		
Tue		SST-NV	PPT-KG	PPT-KG		Advanced Bio-pharmaceutics & Pharmacokinetics - KG		
Wed		ABP-KG	ABP-KG	ABP-KG		Scale up and Technology Transfer-NV		
Thu		ABP-KG	SST-NV	SST-NV		EM-GNK	EM-GNK	
Fri		EM-GNK	EM-GNK	SST-NV		Entrepreneurship Management-GNK		
Sat	Journal club/ Research audit							

Subject-in-Charges:
Advanced Bio-pharmaceutics & Pharmacokinetics-ABP (T&P)- Dr. K. Gowthamarajan(KG)
Pharmaceutical Production Technology –PPT- Dr. K. Gowthamarajan(KG)
Scale up and Technology Transfer –SST-Dr. Nagasamy Venkatesh(NV)
Entrepreneurship Management-EM-Dr. GNK Ganesh(GNK)
Course Coordinator: Dr. N.Jawahar

M. PHARM
PHARMACEUTICAL CHEMISTRY

SYLLABUS
SEMESTER I
MPH 101T- MODERN PHARMACEUTICAL ANALYTICAL TECHNIQUES (Theory)

SCOPE
This subject deals with various advanced analytical instrumental techniques for identification, characterization and quantification of drugs. Instruments dealt are NMR, Mass spectrometer, IR, HPLC, GC etc.

OBJECTIVES
After completion of course student is able to know about chemicals and excipients
- The analysis of various drugs in single and combination dosage forms
- Theoretical and practical skills of the instruments

THEORY	**60 Hrs**
1. a. UV-Visible spectroscopy: Introduction, Theory, Laws, Instrumentation associated with UV-Visible spectroscopy, Choice of solvents and solvent effect and Applications of UV-Visible spectroscopy, Difference/ Derivative spectroscopy. b. IR spectroscopy: Theory, Modes of Molecular vibrations, Sample handling, Instrumentation of Dispersive and Fourier - Transform IR Spectrometer, Factors affecting vibrational frequencies and Applications of IR spectroscopy, Data Interpretation. c. Spectroflourimetry: Theory of Fluorescence, Factors affecting fluorescence (Characterestics of drugs that can be analysed by flourimetry), Quenchers, Instrumentation and Applications of fluorescence spectrophotometer. d. Flame emission spectroscopy and Atomic absorption spectroscopy: Principle, Instrumentation, Interferences and Applications.	10 Hrs
2 NMR spectroscopy: Quantum numbers and their role in NMR, Principle, Instrumentation, Solvent requirement in NMR, Relaxation process, NMR signals in various compounds, Chemical shift, Factors influencing chemical shift, Spin-Spin coupling, Coupling constant, Nuclear magnetic double resonance, Brief outline of principles of FT-NMR and 13C NMR. Applications of NMR spectroscopy.	10 Hrs
3 Mass Spectroscopy: Principle, Theory, Instrumentation of Mass Spectroscopy, Different types of ionization like electron impact, chemical, field, FAB and MALDI, APCI, ESI, APPI Analyzers of Quadrupole and Time of Flight, Mass fragmentation and its rules, Meta stable ions, Isotopic peaks and Applications of Mass spectroscopy.	10 Hrs
4 Chromatography: Principle, apparatus, instrumentation, chromatographic parameters, factors affecting resolution, isolation of drug from excipients, data interpretation and applications of the following:	10 Hrs

a) Thin Layer chromatography, b) High Performance Thin Layer Chromatography c) Ion exchange chromatography, d) Column chromatography, e) Gas chromatography f) High Performance Liquid chromatography, g) Ultra High Performance Liquid chromatography, h) Affinity chromatography, i) Gel Chromatography	
5 a.Electrophoresis: Principle, Instrumentation, Working conditions, factors affecting separation and applications of the following: a) Paper electrophoresis b) Gel electrophoresis c) Capillary electrophoresis d) Zone electrophoresis e) Moving boundary electrophoresis f) Iso electric focusing b.X ray Crystallography: Production of X rays, Different X ray methods, Bragg's law, Rotating crystal technique, X ray powder technique, Types of crystals and applications of X-ray diffraction.	10 Hrs
6 a. Potentiometry: Principle, working, Ion selective Electrodes and Application of potentiometry. b. Thermal Techniques: Principle, thermal transitions and Instrumentation (Heat flux and power-compensation and designs), Modulated DSC, Hyper DSC, experimental parameters (sample preparation, experimental conditions, calibration, heating and cooling rates, resolution, source of errors) and their influence, advantage and disadvantages, pharmaceutical applications. Differential Thermal Analysis (DTA): Principle, instrumentation and advantage and disadvantages, pharmaceutical applications, derivative differential thermal analysis (DDTA). TGA: Principle, instrumentation, factors affecting results, advantage and disadvantages, pharmaceutical applications.	10 Hrs

REFERENCES

1. Spectrometric Identification of Organic compounds - Robert M Silverstein, Sixth edition, John Wiley & Sons, 2004.
2. Principles of Instrumental Analysis - Doglas A Skoog, F. James Holler, Timothy A. Nieman, 5th edition, Eastern press, Bangalore, 1998.
3. Instrumental methods of analysis – Willards, 7th edition, CBS publishers.
4. Practical Pharmaceutical Chemistry – Beckett and Stenlake, Vol II, 4th edition, CBS Publishers, New Delhi, 1997.
5. Organic Spectroscopy - William Kemp, 3rd edition, ELBS, 1991. 6. Quantitative Analysis of Drugs in Pharmaceutical formulation - P D Sethi, 3rd Edition, CBS Publishers, New Delhi, 1997.
6. Pharmaceutical Analysis - Modern Methods – Part B - J W Munson, Vol 11, Marcel. Dekker Series
7. Spectroscopy of Organic Compounds, 2nd edn., P.S/Kalsi, Wiley estern Ltd., Delhi.
8. Textbook of Pharmaceutical Analysis, KA.Connors, 3rd Edition, John Wiley & Sons, 1982.

MPC 102T - ADVANCED ORGANIC CHEMISTRY – I (Theory)

SCOPE

The subject is designed to provide in-depth knowledge about advances in organic chemistry, different techniques of organic synthesis and their applications to process chemistry as well as drug discovery.

OBJECTIVES

- Upon completion of course, the student shall be to understand
- The principles and applications of reterosynthesis
- The mechanism & applications of various named reactions
- The concept of disconnection to develop synthetic routes for small target molecule.
- The various catalysts used in organic reactions
- The chemistry of heterocyclic compounds

THEORY **60 Hrs**

1. Basic Aspects of Organic Chemistry: **1. Organic intermediates:** Carbocations, carbanions, free radicals, carbenes and nitrenes. Their method of formation, stability and synthetic applications. 2. Types of reaction mechanisms and methods of determining them, 3. Detailed knowledge regarding the reactions, mechanisms and their relative reactivity and orientations. **Addition reactions** a) Nucleophilic uni- and bimolecular reactions (SN1 and SN2) b) Elimination reactions (E1 & E2; Hoffman & Saytzeff's rule) c) Rearrangement reaction	12 Hrs
2 Study of mechanism and synthetic applications of following named Reactions: Ugi reaction, Brook rearrangement, Ullmann coupling reactions, Dieckmann Reaction, Doebner-Miller Reaction, Sandmeyer Reaction, Mitsunobu reaction, Mannich reaction, Vilsmeyer-Haack Reaction, Sharpless asymmetric epoxidation, Baeyer-Villiger oxidation, Shapiro & Suzuki reaction, Ozonolysis and Michael addition reaction	12 Hrs
3 Synthetic Reagents & Applications: Aluminiumisopropoxide, N-bromosuccinamide, diazomethane, dicyclohexylcarbodimide, Wilkinson reagent, Witting reagent. Osmium tetroxide, titanium chloride, diazopropane, diethyl azodicarboxylate, Triphenylphosphine, Benzotriazol-1-yloxy) tris (dimethylamino) phosphonium hexafluoro-phosphate (BOP). **Protecting groups** a. Role of protection in organic synthesis b. Protection for the hydroxyl group, including 1,2-and1,3-diols: ethers, esters, carbonates, cyclic acetals & ketals	12 Hrs

c. Protection for the Carbonyl Group: Acetals and Ketals d. Protection for the Carboxyl Group: amides and hydrazides, esters e. Protection for the Amino Group and Amino acids: carbamates and amides	
4 Heterocyclic Chemistry: Organic Name reactions with their respective mechanism and application involved in synthesis of drugs containing five, six membered and fused hetrocyclics such as Debus-Radziszewski imidazole synthesis, Knorr Pyrazole Synthesis Pinner Pyrimidine Synthesis, Combes Quinoline Synthesis, Bernthsen Acridine Synthesis, Smiles rearrangement and Traube purine synthesis. Synthesis of few representative drugs containing these hetrocyclic nucleus such as Ketoconazole, Metronidazole, Miconazole, celecoxib, antipyrin, Metamizole sodium, Terconazole, Alprazolam, Triamterene, Sulfamerazine, Trimethoprim, Hydroxychloroquine, Quinine, Chloroquine, Quinacrine, Amsacrine, Prochlorpherazine, Promazine, Chlorpromazine,Theophylline , Mercaptopurine and Thioguanine	12 Hrs
5 Synthon approach and retrosynthesis applications i. Basic principles, terminologies and advantages of retrosynthesis; guidelines for dissection of molecules. Functional group interconvertion and addition (FGI and FGA) ii. C-X disconnections; C-C disconnections – alcohols and carbonyl compounds; 1,2-, 1,3-,1,4-, 1,5-, 1,6-difunctionalized compounds iii. Strategies for synthesis of three, four, five and six-membered ring.	12 Hrs

REFERENCES

1. "Advanced Organic chemistry, Reaction, Mechanisms and Structure", J March, John Wiley and Sons, New York.
2. "Mechanism and Structure in Organic Chemistry", ES Gould, Hold Rinchart and Winston, New York.
3. "Organic Chemistry" Clayden, Greeves, Warren and Woihers., Oxford University Press 2001.
4. "Organic Chemistry" Vol I and II. I.L. Finar. ELBS, Pearson Education Lts, Dorling Kindersley 9India) Pvt. Ltd.,.
5. A guide to mechanisms in Organic Chemistry, Peter Skyes (Orient Longman, New Delhi).
6. Reactive Intermediates in Organic Chemistry, Tandom and Gowel, Oxford & IBH Publishers.
7. Combinational Chemistry – Synthesis and applications – Stephen R Wilson & Anthony W Czarnik, Wiley – Blackwell.
8. Carey, Organic Chemistry, 5th Edition (Viva Books Pvt. Ltd.)
9. Organic Synthesis - The Disconnection Approach, S. Warren, Wily India
10. Principles of Organic Synthesis, ROC Norman and JM Coxan, Nelson Thorns.
11. Organic Synthesis - Special Techniques. VK Ahluwalia and R Agarwal, Narosa Publishers.
12. Organic Reaction Mechanisms IVth Edtn, VK Ahluwalia and RK Parashar, Narosa Publishers.

MPC 103T-ADVANCED MEDICINAL CHEMISTRY (Theory)

SCOPE

The subject is designed to impart knowledge about recent advances in the field of medicinal chemistry at the molecular level including different techniques for the rational drug design.

OBJECTIVES

- At completion of this course it is expected that students will be able to understand
- Different stages of drug discovery
- Role of medicinal chemistry in drug research
- Different techniques for drug discovery
- Various strategies to design and develop new drug like molecules for biological targets
- Peptidomimetics

THEORY **60 Hrs**

1. Drug discovery: Stages of drug discovery, lead discovery; identification, validation and diversity of drug targets. Biological drug targets: Receptors, types, binding and activation, theories of drug receptor interaction, drug receptor interactions, agonists vs antagonists, artificial enzymes.	12 Hrs
2 Prodrug Design and Analog design: a) Prodrug design: Basic concept, Carrier linked prodrugs/Bioprecursors, Prodrugs of functional group, Prodrugs to improve patient acceptability, Drug solubility, Drug absorption and distribution, site specific drug delivery and sustained drug action. Rationale of prodrug design and practical consideration of prodrug design. b) Combating drug resistance: Causes for drug resistance, strategies to combat drug resistance in antibiotics and anticancer therapy, Genetic principles of drug resistance. c) Analog Design: Introduction, Classical & Non classical, Bioisosteric replacement strategies, rigid analogs, alteration of chain branching, changes in ring size, ring position isomers, design of stereo isomers and geometric isomers, fragments of a lead molecule, variation in inter atomic distance.	12 Hrs
3 a) Medicinal chemistry aspects of the following class of drugs Systematic study, SAR, Mechanism of action and synthesis of new generation molecules of following class of drugs: a) Anti-hypertensive drugs, Psychoactive drugs, Anticonvulsant drugs, H1 & H2 receptor antagonist, COX1 & COX2 inhibitors, Adrenergic & Cholinergic agents, Antineoplastic and Antiviral agents. **b) Stereochemistry and Drug action:** Realization that stereo selectivity is a pre-requisite for evolution. Role of chirality in selective and specific therapeutic agents. Case studies, Enantio selectivity in drug adsorption, metabolism, distribution and elimination.	12 Hrs
4 Rational Design of Enzyme Inhibitors Enzyme kinetics & Principles of Enzyme inhibitors, Enzyme inhibitors in medicine, Enzyme inhibitors in basic research, rational design of non-covalently and covalently binding enzyme inhibitors.	12 Hrs

5 Peptidomimetics Therapeutic values of Peptidomimetics, design of peptidomimetics by manipulation of the amino acids, modification of the peptide backbone, incorporating conformational constraints locally or globally. Chemistry of prostaglandins, leukotrienes and thromboxones.	12 Hrs

REFERENCES

1. Medicinal Chemistry by Burger, Vol I –VI.
2. Wilson and Gisvold's Text book of Organic Medicinal and Pharmaceutical Chemistry, 12th Edition, Lppincott Williams & Wilkins, Woltess Kluwer (India) Pvt.Ltd, New Delhi.
3. Comprehensive Medicinal Chemistry – Corwin and Hansch.
4. Computational and structural approaches to drug design edited by Robert M Stroud and Janet. F Moore
5. Introduction to Quantitative Drug Design by Y.C. Martin.
6. Principles of Medicinal Chemistry by William Foye, 7th Edition, Ippincott Williams & Wilkins, Woltess Kluwer (India) Pvt.Ltd, New Delhi.
7. Drug Design Volumes by Arienes, Academic Press, Elsevier Publishers, Noida, Uttar Pradesh..
8. Principles of Drug Design by Smith.
9. The Organic Chemistry of the Drug Design and Drug action by Richard B.Silverman, II Edition, Elsevier Publishers, New Delhi.
10. An Introduction to Medicinal Chemistry, Graham L.Patrick, III Edition, Oxford University Press, USA.
11. Biopharmaceutics and pharmacokinetics, DM.Brahmankar, Sunil B. Jaiswal II Edition, 2014, Vallabh Prakashan, New Delhi.
12. Peptidomimetics in Organic and Medicinal Chemistry by Antonio Guarna and Andrea Trabocchi, First edition, Wiley publishers.

MPC 104T-CHEMISTRY OF NATURAL PRODUCTS (Theory)

SCOPE

The subject is designed to provide detail knowledge about chemistry of medicinal compounds from natural origin and general methods of structural elucidation of such compounds. It also emphasizes on isolation, purification and characterization of medicinal compounds from natural origin.

OBJECTIVES

At completion of this course it is expected that students will be able to understand-

- Different types of natural compounds and their chemistry and medicinal importance
- The importance of natural compounds as lead molecules for new drug discovery
- The concept of rDNA technology tool for new drug discovery
- General methods of structural elucidation of compounds of natural origin
- Isolation, purification and characterization of simple chemical constituents from natural source

THEORY **60 Hrs**

1. Study of Natural products as leads for new pharmaceuticals for the following class of drugs a) Drugs Affecting the Central Nervous System: Morphine Alkaloids b) Anticancer Drugs: Paclitaxel and Docetaxel, Etoposide, and Teniposide c) Cardiovascular Drugs: Lovastatin, Teprotide and Dicoumarol d) Neuromuscular Blocking Drugs: Curare alkaloids e) Anti-malarial drugs and Analogues f) Chemistry of macrolid antibiotics (Erythromycin, Azithromycin, Roxithromycin, and Clarithromycin) and β - Lactam antibiotics (Cephalosporins and Carbapenem)	12 Hrs
2 a) Alkaloids General introduction, classification, isolation, purification, molecular modification and biological activity of alkaloids, general methods of structural determination of alkaloids, structural elucidation and stereochemistry of ephedrine, morphine, ergot, emetine and reserpine. **b) Flavonoids** Introduction, isolation and purification of flavonoids, General methods of structural determination of flavonoids; Structuralelucidation of quercetin. **c) Steroids** General introduction, chemistry of sterols, sapogenin and cardiac glycosides. Stereochemistry and nomenclature of steroids, chemistry of contraceptive agents male & female sex hormones (Testosterone, Estradiol, Progesterone), adrenocorticoids (Cortisone), contraceptive agents and steroids (Vit – D).	12 Hrs
3 a) Terpenoids Classification, isolation, isoprene rule and general methods of structural elucidation of Terpenoids; Structural elucidation of drugs belonging to mono	12 Hrs

(citral, menthol, camphor), di(retinol, Phytol, taxol) and tri terpenoids (Squalene,Ginsenoside), carotinoids (β carotene). **b) Vitamins** Chemistry and Physiological significance of Vitamin A, B1, B2, B12, C, E, Folic acid and Niacin.	
4 a). Recombinant DNA technology and drug discovery rDNA technology, hybridoma technology, New pharmaceuticals derived from biotechnology; Oligonucleotide therapy. Gene therapy: Introduction, Clinical application and recent advances in gene therapy, principles of RNA & DNA estimation b). Active constituent of certain crude drugs used in Indigenous system Diabetic therapy – Gymnema sylvestre, Salacia reticulate, Pterocarpus marsupiam, Swertia chirata, Trigonella foenum graccum; Liver dysfunction – Phyllanthus niruri; Antitumor – Curcuma longa Linn.	12 Hrs
5 Structural Characterization of natural compounds Structural characterization of natural compounds using IR, 1HNMR, 13CNMR and MS Spectroscopy of specific drugs e.g., Penicillin, Morphine, Camphor, Vit-D, Quercetin and Digitalis glycosides.	12 Hrs

REFERENCES

1. Modern Methods of Plant Analysis, Peech and M.V.Tracey, Springer – Verlag, Berlin, Heidelberg.
2. Phytochemistry Vol. I and II by Miller, Jan Nostrant Rein Hld.
3. Recent advances in Phytochemistry Vol. I to IV – Scikel Runeckles, Springer Science & Business Media.
4. Chemistry of natural products Vol I onwards IWPAC.
5. Natural Product Chemistry Nakanishi Gggolo, University Science Books, California.
6. Natural Product Chemistry "A laboratory guide" – Rapheal Khan.
7. The Alkaloid Chemistry and Physiology by RHF Manske, Academic Press.
8. Introduction to molecular Phytochemistry – CHJ Wells, Chapmannstall.
9. Organic Chemistry of Natural Products Vol I and II by Gurdeep and Chatwall, Himalaya Publishing House.
10. Organic Chemistry of Natural Products Vol I and II by O.P. Agarwal, Krishan Prakashan.
11. Organic Chemistry Vol I and II by I.L. Finar, Pearson education.
12. Elements of Biotechnology by P.K. Gupta, Rastogi Publishers.
13. Pharmaceutical Biotechnology by S.P.Vyas and V.K.Dixit, CBS Publishers.
14. Biotechnology by Purohit and Mathur, Agro-Bios, 13th edition.
15. Phytochemical methods of Harborne, Springer, Netherlands.
16. Burger's Medicinal Chemistry.

MPC 105P-PHARMACEUTICAL CHEMISTRY PRACTICAL – I (Practicals)

1. Analysis of Pharmacopoeial compounds and their formulations by UV Vis spectrophotometer, RNA & DNA estimation
2. Simultaneous estimation of multi component containing formulations by UV spectrophotometry
3. Experiments based on Column chromatography
4. Experiments based on HPLC
5. Experiments based on Gas Chromatography
6. Estimation of riboflavin/quinine sulphate by fluorimetry
7. Estimation of sodium/potassium by flame photometry

To perform the following reactions of synthetic importance

1. Purification of organic solvents, column chromatography
2. Claisen-schimidt reaction.
3. Benzyllic acid rearrangement.
4. Beckmann rearrangement.
5. Hoffmann rearrangement
6. Mannich reaction
7. Synthesis of medicinally important compounds involving more than one step along with purification and Characterization using TLC, melting point and IR spectroscopy (4 experiments)
8. Estimation of elements and functional groups in organic natural compounds
9. Isolation, characterization like melting point, mixed melting point, molecular weight determination, functional group analysis, co-chromatographic technique for identification of isolated compounds and interpretation of UV and IR data.
10. Some typical degradation reactions to be carried on selected plant constituents

II SEMESTER
MPC 201T-ADVANCED SPECTRAL ANALYSIS (Theory)

SCOPE

This subject deals with various hyphenated analytical instrumental techniques for identification, characterization and quantification of drugs. Instruments dealt are LC-MS, GC-MS, ATR-IR, DSC etc.

OBJECTIVES

At completion of this course it is expected that students will be able to understand-

- Interpretation of the NMR, Mass and IR spectra of various organic compounds
- Theoretical and practical skills of the hyphenated instruments
- Identification of organic compounds

THEORY	**60 Hrs**
1. UV and IR spectroscopy: Wood ward – Fieser rule for 1,3- butadienes, cyclic dienes and α, β-carbonyl compounds and interpretation compounds of enones. ATR-IR, IR Interpretation of organic compounds.	12 Hrs
2 NMR spectroscopy: 1-D and 2-D NMR, NOESY and COSY, HECTOR, INADEQUATE techniques, Interpretation of organic compounds.	12 Hrs
3 Mass Spectroscopy Mass fragmentation and its rules, Fragmentation of important functional groups like alcohols, amines, carbonyl groups and alkanes, Meta stable ions, Mc Lafferty rearrangement, Ring rule, Isotopic peaks, Interpretation of organic compounds.	12 Hrs
4 Chromatography: Principle, Instrumentation and Applications of the following : a) GC-MS b) GC-AAS c) LC-MS d) LC-FTIR e) LC-NMR f) CEMS g) High Performance Thin Layer chromatography h) Super critical fluid chromatography i) Ion Chromatography j) I-EC (Ion- Exclusion Chromatography) k) Flash chromatography	12 Hrs
5 a). Thermalmethods of analysis Introduction, principle, instrumentation and application of DSC, DTA and TGA. **b). Raman Spectroscopy** Introduction, Principle, Instrumentation and Applications. **c). Radio immuno assay** Biological standardization , bioassay, ELISA, Radioimmuno assay of digitalis and insulin.	12 Hrs

REFERENCES

1. Spectrometric Identification of Organic compounds - Robert M Silverstein, Sixth edition, John Wiley & Sons, 2004.
2. Principles of Instrumental Analysis - Doglas A Skoog, F. James Holler, Timothy A. Nieman, 5th edition, Eastern press, Bangalore, 1998.

3. Instrumental methods of analysis – Willards, 7th edition, CBS publishers.
4. Organic Spectroscopy - William Kemp, 3rd edition, ELBS, 1991.
5. Quantitative analysis of Pharmaceutical formulations by HPTLC - P D Sethi, CBS Publishers, New Delhi.
6. Quantitative Analysis of Drugs in Pharmaceutical formulation - P D Sethi, 3rd Edition, CBS Publishers, New Delhi, 1997.
7. Pharmaceutical Analysis- Modern methods – Part B - J W Munson, Volume 11, Marcel Dekker Series

MPC 202T-ADVANCED ORGANIC CHEMISTRY – II (Theory)

SCOPE

The subject is designed to provide in-depth knowledge about advances in organic chemistry, different techniques of organic synthesis and their applications to process chemistry as well as drug discovery.

OBJECTIVES

- Upon completion of course, the student shall able to understand
- The principles and applications of Green chemistry
- The concept of peptide chemistry.
- The various catalysts used in organic reactions
- The concept of stereochemistry and asymmetric synthesis.

THEORY	**60 Hrs**
1. Green Chemistry: a. Introduction, principles of green chemistry **b. Microwave assisted reactions:** Merit and demerits of its use, increased reaction rates, mechanism, superheating effects of microwave, effects of solvents in microwave assisted synthesis, microwave technology in process optimization, its applications in various organic reactions and heterocycles synthesis **c. Ultrasound assisted reactions:** Types of sonochemical reactions, homogenous, heterogeneous liquid-liquid and liquid-solid reactions, synthetic applications **d. Continuous flow reactors:** Working principle, advantages and synthetic applications	12 Hrs
2 Chemistry of peptides a. Coupling reactions in peptide synthesis b. Principles of solid phase peptide synthesis, t-BOC and FMOC protocols, various solid supports and linkers: Activation procedures, peptide bond formation, deprotection and cleavage from resin, low and high HF cleavage protocols, formation of free peptides and peptide amides, purification and case studies, site-specific chemical modifications of peptides c. Segment and sequential strategies for solution phase peptide synthesis with any two case studies d. Side reactions in peptide synthesis: Deletion peptides, side reactions initiated by proton abstraction, protonation, overactivation and side reactions of individual amino acids.	12 Hrs
3 Photochemical Reactions Basic principles of photochemical reactions. Photo-oxidation, photo-addition and photo-fragmentation. **Pericyclic reactions** Mechanism, Types of pericyclic reactions such as cyclo addition, electrocyclic reaction and sigmatrophic rearrangement reactions with examples	12 Hrs

4 Catalysis: a. Types of catalysis, heterogeneous and homogenous catalysis, advantages and disadvantages **b. Heterogeneous catalysis** – preparation, characterization, kinetics, supported catalysts, catalyst deactivation and regeneration, some examples of heterogeneous catalysis used in synthesis of drugs. **c. Homogenous catalysis,** hydrogenation, hydroformylation, hydrocyanation, Wilkinson catalysts, chiral ligands and chiral induction, Ziegler-Natta catalysts, some examples of homogenous catalysis used in synthesis of drugs **d. Transition-metal and Organo-catalysis in organic synthesis**: Metal-catalyzed reactions **e. Biocatalysis**: Use of enzymes in organic synthesis, immobilized enzymes/cells in organic reaction. **f. Phase transfer catalysis** - theory and applications	12 Hrs
5. Stereochemistry & Asymmetric Synthesis **a. Basic concepts in stereochemistry** optical activity, specific rotation, racemates and resolution of racemates, the Cahn, Ingold, Prelog (CIP) sequence rule, meso compounds, pseudo asymmetric centres, axes of symmetry, Fischers D and L notation, cis-trans isomerism, E and Z notation. **b. Methods of asymmetric synthesis** using chiral pool, chiral auxiliaries and catalytic asymmetric synthesis, enantiopure separation and Stereo selective synthesis with examples.	12 Hrs

.

REFERENCES

1. "Advanced Organic chemistry, Reaction, mechanisms and structure", J March, John Wiley and sons, New York.
2. "Mechanism and structure in organic chemistry", ES Gould, Hold Rinchart and Winston,NewYork.
3. "Organic Chemistry" Clayden, Greeves, Warren and Woihers., Oxford University Press 2001.
4. "Organic Chemistry" Vol I and II. I.L. Finar. ELBS, Sixth ed., 1995.
5. Carey, Organic chemistry, 5th edition (Viva Books Pvt. Ltd.)
6. Organic synthesis-the disconnection approach, S. Warren, Wily India
7. Principles of organic synthesis, ROCNorman and JMCoxan, Nelson thorns
8. Organic synthesis- Special techniques VK Ahluwalia and R Aggarwal, Narosa Publishers.
9. Organic reaction mechanisms IV edtn, VK Ahluwalia and RK Parashar, Narosa Publishers.

MPC 203T-COMPUTER AIDED DRUG DESIGN (Theory)

SCOPE

The subject is designed to impart knowledge on the current state of the art techniques involved in computer assisted drug design.

OBJECTIVES

At completion of this course it is expected that students will be able to understand

- Role of CADD in drug discovery
- Different CADD techniques and their applications
- Various strategies to design and develop new drug like molecules.
- Working with molecular modeling softwares to design new drug molecules
- The in silico virtual screening protocols

THEORY	**60 Hrs**
1. Introduction to Computer Aided Drug Design (CADD) History, different techniques and applications. **Quantitative Structure Activity Relationships:** Basics History and development of QSAR: Physicochemical parameters and methods to calculate physicochemical parameters: Hammett equation and electronic parameters (sigma), lipophilicity effects and parameters (log P, pi-substituent constant), steric effects (Taft steric and MR parameters) Experimental and theoretical approaches for the determination of these physicochemical parameters.	12 hrs
2 Quantitative Structure Activity Relationships: Applications Hansch analysis, Free Wilson analysis and relationship between them, Advantages and disadvantages; Deriving 2D-QSAR equations. 3D-QSAR approaches and contour map analysis. Statistical methods used in QSAR analysis and importance of statistical parameters.	12 hrs
3 Molecular Modeling and Docking a) Molecular and Quantum Mechanics in drug design. b) Energy Minimization Methods: comparison between global minimum conformation and bioactive conformation c) Molecular docking and drug receptor interactions: Rigid docking, flexible docking and extra-precision docking. Agents acting on enzymes such as DHFR, HMG-CoA reductase and HIV protease, choline esterase (AchE & BchE)	12 hrs
4 Molecular Properties and Drug Design a) Prediction and analysis of ADMET properties of new molecules and its importance in drug design. b) De novo drug design: Receptor/enzyme-interaction and its analysis, Receptor/enzyme cavity size prediction, predicting the functional components of cavities, Fragment based drug design. c) Homology modeling and generation of 3D-structure of protein.	12 hrs
5 Pharmacophore Mapping and Virtual Screening Concept of pharmacophore, pharmacophore mapping, identification of	12 hrs

Pharmacophore features and Pharmacophore modeling; Conformational search used in pharmacophore mapping. In Silico Drug Design and Virtual Screening Techniques Similarity based methods and Pharmacophore based screening, structure based In-silico virtual screening protocols.	

REFERENCES

1. Computational and structural approaches to drug discovery, Robert M Stroud and Janet. F Moore, RCS Publishers.
2. Introduction to Quantitative Drug Design by Y.C. Martin, CRC Press, Taylor & Francis group..
3. Drug Design by Ariens Volume 1 to 10, Academic Press, 1975, Elsevier Publishers.
4. Principles of Drug Design by Smith and Williams, CRC Press, Taylor & Francis.
5. The Organic Chemistry of the Drug Design and Drug action by Richard B. Silverman, Elsevier Publishers.
6. Medicinal Chemistry by Burger, Wiley Publishing Co.
7. An Introduction to Medicinal Chemistry –Graham L. Patrick, Oxford University Press.
8. Wilson and Gisvold's Text book of Organic Medicinal and Pharmaceutical Chemistry, Ippincott Williams & Wilkins.
9. Comprehensive Medicinal Chemistry – Corwin and Hansch, Pergamon Publishers.
10. Computational and structural approaches to drug design edited by Robert M Stroud and Janet. F Moore

MPC 204T-PHARMACEUTICAL PROCESS CHEMISTRY (Theory)

SCOPE

Process chemistry is often described as scale up reactions, taking them from small quantities created in the research lab to the larger quantities that are needed for further testing and then to even larger quantities required for commercial production. The goal of a process chemist is to develop synthetic routes that are safe, cost-effective, environmentally friendly, and efficient. The subject is designed to impart knowledge on the development and optimization of a synthetic route/s and the pilot plant procedure for the manufacture of Active Pharmaceutical Ingredients (APIs) and new chemical entities (NCEs) for the drug development phase.

OBJECTIVES

At completion of this course it is expected that students will be able to understand

- The strategies of scale up process of apis and intermediates
- The various unit operations and various reactions in process chemistry

THEORY	**60 Hrs**
1. Process chemistry Introduction, Synthetic strategy Stages of scale up process: Bench, pilot and large scale process. In-process control and validation of large scale process. Case studies of some scale up process of APIs. Impurities in API, types and their sources including genotoxic impurities	12 Hrs
2 Unit operations a) Extraction: Liquid equilibria, extraction with reflux, extraction with agitation, counter current extraction. b) Filtration: Theory of filtration, pressure and vacuum filtration, centrifugal filtration, c) Distillation: azeotropic and steam distillation d) Evaporation: Types of evaporators, factors affecting evaporation. e) Crystallization: Crystallization from aqueous, nonaqueous solutions factors affecting crystallization, nucleation. Principle and general methods of Preparation of polymorphs, hydrates, solvates and amorphous APIs.	12 Hrs
3 Unit Processes - I a) Nitration: Nitrating agents, Aromatic nitration, kinetics and mechanism of aromatic nitration, process equipment for technical nitration, mixed acid for nitration, b) Halogenation: Kinetics of halogenations, types of halogenations, catalytic halogenations. Case study on industrial halogenation process. c) Oxidation: Introduction, types of oxidative reactions, Liquid phase oxidation with oxidizing agents. Nonmetallic Oxidizing agents such as H2O2, sodium hypochlorite, Oxygen gas, ozonolysis.	12 Hrs
4 Unit Processes - II	12 Hrs

a) Reduction: Catalytic hydrogenation, Heterogeneous and homogeneous catalyst; Hydrogen transfer reactions, Metal hydrides. Case study on industrial reduction process. b) Fermentation: Aerobic and anaerobic fermentation. Production of i. Antibiotics; Penicillin and Streptomycin, ii. Vitamins: B2 and B12 iii. Statins: Lovastatin, Simvastatin c) Reaction progress kinetic analysis i. Streamlining reaction steps, route selection, ii. Characteristics of expedient routes, characteristics of cost-effective routes, reagent selection, families of reagents useful for scale-up.	
5 Industrial Safety a) MSDS (Material Safety Data Sheet), hazard labels of chemicals and Personal Protection Equipment (PPE) b) Fire hazards, types of fire & fire extinguishers c) Occupational Health & Safety Assessment Series 1800 (OHSAS-1800) and ISO-14001(Environmental Management System), Effluents and its management	12 Hrs

REFERENCES

1. Process Chemistry in the Pharmaceutical Industry: Challenges in an Ever- Changing Climate-An Overview; K. Gadamasetti, CRC Press.
2. Pharmaceutical Manufacturing Encyclopedia, 3rd edition, Volume 2.
3. Medicinal Chemistry by Burger, 6th edition, Volume 1-8.
4. W.L. McCabe, J.C Smith, Peter Harriott. Unit operations of chemical engineering, 7th edition, McGraw Hill
5. Polymorphism in Pharmaceutical Solids .Dekker Series Volume 95 Ed: H G Brittain (1999)
6. Regina M. Murphy: Introduction to Chemical Processes: Principles, Analysis, Synthesis
7. Peter J. Harrington: Pharmaceutical Process Chemistry for Synthesis: Rethinking the Routes to Scale-Up
8. P.H.Groggins: Unit processes in organic synthesis (MGH)
9. F.A.Henglein: Chemical Technology (Pergamon)
10. M.Gopal: Dryden's Outlines of Chemical Technology, WEP East-West Press
11. Clausen,Mattson: Principle of Industrial Chemistry, Wiley Publishing Co.,
12. Lowenheim & M.K. Moran: Industrial Chemicals
13. S.D. Shukla & G.N. Pandey: A text book of Chemical Technology Vol. II, Vikas Publishing House
14. J.K. Stille: Industrial Organic Chemistry (PH)
15. Shreve: Chemical Process, Mc Grawhill.
16. B.K.Sharma: Industrial Chemistry, Goel Publishing House
17. ICH Guidelines
18. United States Food and Drug Administration official website www.fda.gov.

MPC 205P-PHARMACEUTICAL CHEMISTRY PRACTICALS – II (Practicals)

1. Synthesis of organic compounds by adapting different approaches involving (3 experiments)
   a) Oxidation
   b) Reduction/hydrogenation
   c) Nitration
2. Comparative study of synthesis of APIs/intermediates by different synthetic routes (2 experiments)
3. Assignments on regulatory requirements in API (2 experiments)
4. Comparison of absorption spectra by UV and Wood ward – Fieser rule
5. Interpretation of organic compounds by FT-IR
6. Interpretation of organic compounds by NMR
7. Interpretation of organic compounds by MS
8. Determination of purity by DSC in pharmaceuticals
9. Identification of organic compounds using FT-IR, NMR, CNMR and Mass spectra
10. To carry out the preparation of following organic compounds
11. Preparation of 4-chlorobenzhydrylpiperazine. (an intermediate for cetirizine HCl).
12. Preparation of 4-iodotolene from p-toluidine.
13. NaBH4 reduction of vanillin to vanillyl alcohol
14. Preparation of umbelliferone by Pechhman reaction
15. Preparation of triphenyl imidazole
16. To perform the Microwave irradiated reactions of synthetic importance (Any two)
17. Determination of log P, MR, hydrogen bond donors and acceptors of selected drugs using softwares
18. Calculation of ADMET properties of drug molecules and its analysis using Softwares Pharmacophore modeling
19. 2D-QSAR based experiments
20. 3D-QSAR based experiments
21. Docking study based experiment
22. Virtual screening based experiment

DETAILS OF SUBJECT TEACHERS – semester I

S.No	Name of the Subject	Name of the Teachers	Designation and Department	Mobile No.	e-mail
1.	Modern Pharmaceutical Analytical Techniques	Dr. N. Krishnaveni	Prof & Head Pharm. Analysis	9442083447	krisath@jssuni.edu.in
2.	Advanced Organic Chemistry -I	Dr. S. Jubie	Asst. Prof. Pharm. Chem	9894618588	jubie@jssuni.edu.in
3.	Advanced Medicinal chemistry	Dr. Md. Afzal Azam	Prof & Head Pharm. Chem	9486687029	afzal@jssuni.edu.in
4.	Chemistry of Natural Products	Dr. Md. Afzal Azam	Prof & Head Pharm. Chem	9486687029	afzal@jssuni.edu.in
5.	Pharmaceutical Chemistry Practical I	Dr. Md. Afzal Azam Dr. R. Kalirajan Dr. S. Gomathy	Prof & Head Asst. Prof. Pharm. Chem Asst. Prof. Pharm. Chem	9486687029 9994098087 9486433876	afzal@jssuni.edu.in rkalirajan@jssuni.edu.in gomathys@jssuni.edu.in

DETAILS OF SUBJECT TEACHERS – semester II

S.No	Name of the Subject	Name of the Teachers	Designation and Department	Mobile No.	e-mail
1.	Advanced Spectral Analysis	Dr. Md. Afzal Azam	Prof & Head Pharm. Chem	9486687029	afzal@jssuni.edu.in
2.	Advanced Organic Chemistry -II	Dr. R. Kalirajan	Asst. Prof. Pharm. Chem	9994098087	rkalirajan@jssuni.edu.in
3.	Computer Aided Drug Design	Dr. S. Jubie	Asst. Prof. Pharm. Chem	9894618588	jubie@jssuni.edu.in
4.	Pharmaceutical Process Chemistry	Dr. Md. Afzal Azam	Prof & Head Pharm. Chem	9486687029	afzal@jssuni.edu.in
5.	Pharmaceutical Chemistry Practical II	Dr. Md. Afzal Azam Dr. R. Kalirajan Dr. B,Gowramma	Prof & Head Asst. Prof. Asst. Prof. Pharm. Chem	9994098087 9442111172	rkalirajan@jssuni.edu.in gowrammab@jssuni.edu.in

Academic Plan
2020-21

SEMESTER 1

Name of the Subject	**Modern Pharmaceutical Analytical Techniques (Theory)**
Name of the Faculty	Dr. Krishna Veni N M.Pharm., Ph.D
Designation, Department	Professor & Head, Department of Pharmaceutical Analysis
Mobile Number	9442083447
e-Mail i.d.	krisath@jssuni.edu.in

Scope, Course Objectives and Course Outcomes

SCOPE

This subject deals with various advanced analytical instrumental techniques for identification, characterization and quantification of drugs. Instruments dealt are NMR, Mass spectrometer, IR, HPLC, GC etc.

OBJECTIVES

After completion of course student is able to know about

- Chemicals and excipients
- The analysis of various drugs in single and combination dosage forms
- Theoretical and practical skills of the instruments

COURSE OUTCOMES

At completion of this course it is expected that the students will be able to

CO 1 : Explain the general principles and techniques of spectroscopy & Chromatography

CO 2 : Perform the assay of single and multiple component pharmaceuticals using various analytical techniques

CO 3 : Develop skills in selecting suitable techniques for the analysis of drugs and pharamceutials

CO 4 : Apply the knowledge learnt in developing newer analytical methods and procedures of their own design

CO 5 : Explore and learn the various instrumental techniques available for the analysis of organic substances

LECTURE PLAN – Abstract

Sessional	No. of Hours of Didactic Lecture Advanced Instrumentation Techniques	No of Hours of other Activities	Total No. of Lecture Hours
I	30	1	31
II	30	--	30
Total No. of Hours	60	--	61

I SESSIONAL : 30 Lectures + 1 Activity

Lecture No.	Lecture Details	Hours
	Orientation of the subject	**01**
Unit-1:		**10**
UV Visible Spectroscopy		
1.	UV Visible Spectroscopy - Introduction, Theory, Laws	
2.	Instrumentation associated with UV Visible Spectroscopy, Choice of Solvents & Solvent Effects	
3.	Applications of UV visible spectroscopy, Difference/ Derivative Spectroscopy	
IR Spectroscopy		
4.	IR Spectroscopy - Theory, Modes of Molecular Vibrations, Samples handling	
5.	Instrumentation of Dispersive and Fourier Transform IR spectrometere	
6.	Factors affecting vibrational frequencies and applications of IR spectroscopy, Data Interpretation	
Spectroflourimetry		
7.	Spectroflourimetry - Theory of fluorescence, Factors affecting fluorescence	
8.	Quenchers, Instrumentation, Applications of Fluorescence Spectrophotometer	
Flame emission spectroscopy & Atomic abosrption spectroscopy		
9.	Principle, Instrumentation	
10.	Interferences and Applications	
Unit-2:		**10**
NMR Spectroscopy		
1.	NMR spectroscopy - Quantum numbers and their role in NMR, Principle	
2.	Instrumentation - Continous wave NMR instrument	
3.	Principle and Instrumentation of FT NMR	
4.	solvent requirements, Relaxation process	
5.	NMR signals in various compounds	
6.	chemical shift, factors influencing chemical shift	
7.	spin spin coupling, coupling constant	
8.	Nuclear magnetic double resonance	

9.	Applications of NMR Spectroscopy	
10.	Principles of 13C NMR	
Unit-3:		
MassSpectrometry		
1.	Principle, theory	
2.	Instrumentation of Mass Spectroscopy - sample introduction techniques	**10**
3.	Different types of ionization - electron impact, chemical	
4.	Different types of ionization - Field, FAB and MALDI	
5.	Different types of ionization - APCI, ESI, APPI	
6.	Analyzers of Quadrupole and Time of Flight	
7.	Mass fragmentation and its rules	
8.	Mass fragmentation and its rules	
9.	Meta stable ions, Isotopic peaks	
10.	Applications of Mass spectroscopy	

II SESSIONAL : 30 Lectures

Lecture No.	Lecture Details	Hours
Unit-4:		
Chromatography - Principle, Apparatus, Instrumentation, Chromatographic Parameters, Factors influencing resolution, Isolation of drugs from excipients, data interpretation and applications of		**10**
1.	Thin Layer Chromatography	
2.	High Performance Thin Layer Chromatography	
3.	Ion Exchange Chromatography	
4.	column Chromatography	
5.	Gas Chromatography	
6.	Gas Chromatography	
7.	HPLC	
8.	HPLC	
9.	Ultra high Performance Liquid Chromatography	
10.	Affinity Chromatography, Gel Chromatography	
Unit-5:		
Electrophoresis - Principle, Instrumentation, Working, Factors affecting separation and applications		
1.	Paper Electrophoresis	**10**
2.	Gel Electrophoresis, Zone Electrophoresis	
3.	Capillary Electrophoresis	
4.	Capillary Electrophoresis	
5.	Moving Boundray Electrophoresis	
6.	Iso Electric Focussing	
X Ray Crystallography		
7.	Production of X Rays, Braggs Law	
8.	Different X Ray diffraction methods - Rotating Crystal Technique	

9.	X Ray Powder technique, Types of Crystals	
10.	Applications of X Ray Diffractions	
Unit-6:		**10**
Potentiometric Titrations		
1.	Potentiometry - Principle, working	
2.	Ion selective Electrodes and other electrodes used in potentiometry	
3.	Applications of potentiometry	
Thermal Techniques		
4.	Differential Scanning Colorimetry - Principle, Thermal transitions	
5.	DSC - Instrumentation (Power compensated, heat flux designs),	
6.	Modulated DSC, Hyper DSC	
7.	Experimental Parameters - sample preparation, experimental conditions, calibration, heating and cooling rates, resolution, source of errors), Their influence, advantages, disadvantages and applications	
8.	Differential Thermal Analysis (DTA) - Principle instrumentation, Advantages & Disadvantages, Pharmaceutical Applications	
9.	Derivative Differential Thermal Analysis	
10.	Thermogravimetric Analysis (TGA) - Principle, instrumentation, factors affecting results, advantages & disadvantages, Pharmaceutical Applications	

TEXT BOOKS

1. Spectrometric Identification of Organic compounds - Robert M Silverstein, Sixth edition, John Wiley & Sons, 2004.
2. Principles of Instrumental Analysis - Doglas A Skoog, F. James Holler, Timothy A. Nieman, 5th edition, Eastern press, Bangalore, 1998.
3. Instrumental methods of analysis – Willards, 7th edition, CBS publishers.
4. Practical Pharmaceutical Chemistry – Beckett and Stenlake, Vol II, 4th edition, CBS Publishers, New Delhi, 1997.
5. Organic Spectroscopy - William Kemp, 3rd edition, ELBS, 1991.
6. Quantitative Analysis of Drugs in Pharmaceutical formulation - P D Sethi, 3rd Edition, CBS Publishers, New Delhi, 1997.
7. Pharmaceutical Analysis - Modern Methods – Part B - J W Munson, Vol 11, Marcel. Dekker Series
8. Spectroscopy of Organic Compounds, 2nd edn., P.S/Kalsi, Wiley estern Ltd., Delhi.
9. Textbook of Pharmaceutical Analysis, KA.Connors, 3rd Edition, John Wiley & Sons, 1982.

REFERENCE BOOKS

Introduction to Spectroscopy; by Donald L Pavia

Name of the Subject	**Advanced Organic Chemistry I (Theory)**
Name of the Faculty	Dr.Jubie S M.Pharm., Ph.D
Designation, Department	Assistant Professor, Department of Pharmaceutical Chemistry
Mobile Number	9894618588
e-Mail i.d.	jubie@jssuni.edu.in

Scope, Course Objectives and Course Outcomes

SCOPE

The subject is designed to provide in-depth knowledge about advances in organic chemistry, different techniques of organic synthesis and their applications to process chemistry as well as drug discovery.

OBJECTIVES

The primary objectives of this course are to

- Study the organic reaction intermediates
- Learn the important naming reactions
- Study the important naming synthesis of heterocyclic compounds
- Learn the concepts of protective and deprotective agents
- Study the objectives and types of various reterosynthetic techniques

COURSE OUTCOMES

Upon completion of course, the student shall be to understand

1. The various organic reactions
2. Applications of reaction intermediates
3. The mechanism & applications of various named reactions used for the synthesis of drug intermedistes
4. The application of protective and deprotective groups in organic synthesis.
5. The various catalysts used in organic reactions
6. The chemistryof heterocyclic compounds
7. The principles and applications of reterosynthesis

LECTURE PLAN – Abstract

Sessional	No. of Hours of Didactic Lecture	No of Hours of other Activities	Total No. of Lecture Hours
I	30	-	30
II	30	-	30
Total No. of Hours	60	-	60

I SESSIONAL : 24 Lectures + 3 Activities

Lecture No.	Lecture Details	Hours (30)
Unit-1: Basic aspects of organic Chemistry		**12**
11.	Carbocations-Reaction mechanisms	
12.	Carbocations-Reactivity &orientation	
13.	Carbanions-Reaction mechanisms	
14.	Carbanions -Reactivity &orientation	
15.	Free radicals	
16.	Carbenes & Nitenes	
17.	Types of reaction mechanisms	
18.	Reactivity and orientations of reaction mechanisms	
19.	SN1 and SN2 reactions	
20.	E1 and E2 reactions	
21.	Hoffmann rearrangement reaction	
22.	Beckmann rearrangement reaction	
Unit-2: Naming reactions		**12**
11.	Ugi reaction	
12.	Brook rearrangement	
13.	Ullmann coupling reaction	
14.	Dieckmann reaction	
15.	Doebner-Miller reaction	
16.	Sandmeyer reaction	
17.	Mitsunobu reaction	
18.	Mannich reaction	
19.	Vilsmeyer-Haack reaction	
10.	Sharpless asymmetric oxidation	
11.	Baeyer Villiger Oxidation,Shapiro-Suzuki reaction	
12.	Ozonolysis &Michael addition	
Unit-3: Synthetic reagents and applications		**06**
1.	Aluminium isopropoxide,N-bromyl succinimide	
2.	DCC,Wilkinson reagent	
3.	Wittig reagent,Osmium tetroxide	
4.	Titanium chloride,diazo propane	

5.	Diethylazodicarboxylate,triphenyl phosphine	
6.	BOP	

II SESSIONAL : 30 Lectures

Lecture No.	Lecture Details	Hours (30)
Unit-3: Synthetic reagents and applications (cont…)		**06**
1.	Role of protection in organic synthesis	
2.	Protection of OH group	
3.	Protection of OH group (cont…)	
4.	Protection of carbonyl group	
5.	Protection of carboxyl group	
6.	Protection of amino groups	
Unit-4: Heterocyclic chemistry		**12**
1.	Debus-Radziszewski imidazole synthesis	
2.	Knoor pyrazole synthesis	
3.	Pinner pyrimidine synthesis	
4.	Combes Quinoline synthesis	
5.	Bernthsen acridien synthesis	
6.	Smiles rearrangement	
7.	Traubes purine synthesis	
8.	Synthesis of drugs -Part 1	
9.	Synthesis of drugs--Part 2	
10.	Synthesis of drugs-Part 3	
11.	Synthesis of drugs-Part 4	
12.	Synthesis of drugs-Part 5	
Unit-5: Synthetic approach and reterosynthetic applications		**12**
1.	Basic principles of reterosynthesis	
2.	Advantages of reterosynthesis	
3.	Guidelines for dissection of molecules	
4.	Functional group interconversion	
5.	Functional group adddition	
6.	C-X disconnection	
7.	C-C disconnection	
8.	1,2-1,3 difunctionalized compounds	
9.	1,4-1,5-1,6 difuntionalized compounds	
10.	Strageties for three membered ring synthesis	
11.	Strageties for four membered ring synthesis	
12.	Strageties for five membered ring synthesis	

TEXT BOOKS

1. "Advanced Organic chemistry, Reaction, Mechanisms and Structure", J March, John Wiley and Sons, New York.

2. "Mechanism and Structure in Organic Chemistry", ES Gould, Hold Rinchart and Winston, New York.
3. "Organic Chemistry" Vol I and II. I.L. Finar. ELBS, Pearson Education Lts, Dorling Kindersley 9India) Pvt. Ltd.,.
4. A guide to mechanisms in Organic Chemistry, Peter Skyes (Orient Longman, New Delhi).
5. Reactive Intermediates in Organic Chemistry, Tandom and Gowel, Oxford & IBH Publishers.
6. Organic Reaction Mechanisms IVth Edtn, VK Ahluwalia and RK Parashar, Narosa Publishers.
7. Organic Synthesis - The Disconnection Approach, S. Warren, Wily India

REFERENCE BOOKS

1. "Organic Chemistry" Clayden, Greeves, Warren and Woihers., Oxford University Press 2001.
2. Combinational Chemistry – Synthesis and applications – Stephen R Wilson & Anthony W Czarnik, Wiley – Blackwell.
3. Carey, Organic Chemistry, 5th Edition (Viva Books Pvt. Ltd.)
4. Principles of Organic Synthesis, ROC Norman and JM Coxan, Nelson Thorns.
5. Organic Synthesis - Special Techniques. VK Ahluwalia and R Agarwal, Narosa Publishers.

Name of the Subject	**Advance Medicinal Chemistry (Theory) MPC 103T**
Name of the Faculty	Dr. Md. Afzal Azam M.Pharm., Ph.D
Designation, Department	Professor and Head, Department of Pharmaceutical chemistry
Mobile Number	9486687029
e-Mail i.d.	afzal@jssuni.edu.in

Scope, Course Objectives and Course Outcomes

SCOPE

The course is designed to provide detail knowledge about the chemistry of natural compounds including medicinal compounds from natural origin. The course will impart knowledge about the chemistry and general methods of structural elucidation of such compounds. It also emphasizes on the therapeutic uses of chemical constituents from the medicinal plants.

OBJECTIVES

The primary objectives of this course are to

- Discuss the different types of receptors and their interactions
- Helps to know the different approaches of prodrug design
- Helps to understand different modifications od peptides for lead optimization
- Helps to understand recent advances in the field of medicinal chemistry at the molecular level
- Help to understand different techniques for the rational drug design.

COURSE OUTCOMES

At completion of this course it is expected that the students will be able to

CO 1 : Know the recent advaces in medicinal chemistry
CO 2 : Different stages of drug discovery
CO 3 : Use of Peptidomimetics in drug design
CO 4 : Various strategies to design and develop new drug like molecules for biological targets
CO 5 : Role of medicinal chemistry in drug research
CO 6 : Different techniques for drug discovery

LECTURE PLAN – Abstract

Sessional	No. of Hours of Didactic Lecture	No of Hours of other Activities	Total No. of Lecture Hours
I	30	2	32
II	30	2	32
Total No. of Hours	60	4	64

I SESSIONAL : 30 Lectures + 2 Activities

Lecture No.	Lecture Details	Hours
Unit-1: Drug discovery		*12*
1.	Drug discovery: Stages of drug discovery	
2.	Stages of drug discovery	
3.	Lead identification	
4.	identification, validation and diversity of drug targets.	
5.	identification, validation and diversity of drug targets	
6.	validation and diversity of drug targets.	
7.	Receptors types	
8.	Receptors binding and activation	
9.	theories of drug receptor interaction	
10.	theories of drug receptor interaction	
11.	drug receptor interactions, agonists vs antagonists	
12.	artificial enzymes	
Unit-2: Prodrug Design and Analog design:		12
1.	Prodrug design: Basic concept	
2.	Carrier linked prodrugs Bioprecursors, Prodrugs of functional group,	
3.	Prodrugs to improve patient acceptability, Drug solubility, Drug absorption and distribution,	
4.	Prodrugs to improve patient acceptability, Drug solubility, Drug absorption and distribution,	
5.	Prodrugs to improve patient acceptability, Drug solubility, Drug absorption and distribution,	
6.	site specific drug delivery and sustained drug action	
7.	Rationale of prodrug design and practical consideration of prodrug design.	
8.	Combating drug resistance: Causes for drug resistance, strategies to combat drug resistance in antibiotics and anticancer therapy	
9.	Genetic principles of drug resistance.	
10.	Analog Design: Introduction, Classical & Non classical, Bioisosteric	

	replacement strategies, rigid analogs	
11.	Alteration of chain branching, changes in ring size, ring position isomers,	
12.	Design of stereo isomers and geometric isomers, fragments of a lead molecule, variation in inter atomic distance.	
Unit 3 Medicinal chemistry aspects of drugs		
1.	Medicinal chemistry aspects of Anti-hypertensive drugs, Psychoactive drugs	
2.	Medicinal chemistry aspects of H1 & H2 receptor antagonist,	
3.	Medicinal chemistry aspects of COX1 & COX2 inhibitors	
4.	Medicinal chemistry aspects of Adrenergic and Cholinergic agents	
5.	Medicinal chemistry aspects of Antineoplastic agents.	14
6.	Medicinal chemistry aspects of Antiviral agents.	
7.	Test	
8.	Test	
Second sessional II SESSIONAL : 30 Lectures + 2 Activities		
9.	Stereochemistry and Drug action	
10.	Realization that stereo selectivity is a pre-requisite for evolution	
11.	Role of chirality in selective and specific therapeutic agents	
12.	Case studies	
13.	Enantio selectivity in drug adsorption, metabolism, distribution and elimination.	
14.	Enantio selectivity in drug adsorption, metabolism, distribution and elimination.	

II Sessional

Lecture No.	**Lecture Details**	**Hours**
Unit-4: Rational Design of Enzyme Inhibitors		
1.	Enzyme kinetics	
2.	Enzyme inhibitors in medicine	
3.	Principles of Enzyme inhibitors	**12**
4.	Principles of Enzyme inhibitors	
5.	Enzyme inhibitors in basic research	
6.	Enzyme inhibitors in basic research	
7.	Enzyme inhibitors in basic research	
8.	Rational design of non-covalently	
9.	Rational design of non-covalently binding enzyme inhibitors.	
10.	Rational design of non-covalently inhibitors.	
11.	Rational design of covalently binding enzyme inhibitors.	
12.	Rational design of covalently binding enzyme inhibitors.	
Unit V– Peptidomimetics		
1.	Therapeutic values of Peptidomimetics	
2.	design of peptidomimetics by manipulation of the amino acids	
3.	Design of peptidomimetics by manipulation of the amino acids	**12**

4.	Design of peptidomimetics by manipulation of the amino acids	
5.	Design of peptidomimetics by Modification of the peptide backbone	
6.	Design of peptidomimetics by Modification of the peptide backbone	
7.	Design of peptidomimetics by incorporating conformational constraints locally or globally.	
8.	Design of peptidomimetics by incorporating conformational constraints locally or globally.	
9.	Chemistry of prostaglandins, and thromboxones.	
10.	Chemistry of leukotrienes	
11.	Chemistry of thromboxones.	
12.	Chemistry of thromboxones.	
13.	Test	2
14.	Test	

TEXT BOOKS

1. Organic Chemistry Vol I and II by I.L. Finar, Pearson education
2. Natural Product Chemistry "A laboratory guide" – Rapheal Khan.
3. The Alkaloid Chemistry and Physiology by RHF Manske, Academic Press.
4. Introduction to molecular Phytochemistry – CHJ Wells, Chapmannstall.
5. Organic Chemistry of Natural Products Vol I and II by Gurdeep and Chatwall, Himalaya Publishing House.
6. Organic Chemistry of Natural Products Vol I and II by O.P. Agarwal,
7. Burger's Medicinal Chemistry.

REFERENCE BOOKS

1. Modern Methods of Plant Analysis, Peech and M.V.Tracey, Springer –Verlag, Berlin, Heidelberg.
2. Phytochemistry Vol. I and II by Miller, Jan Nostrant Rein Hld.
3. Recent advances in Phytochemistry Vol. I to IV – Scikel Runeckles,
4. Springer Science & Business Media.
5. Chemistry of natural products Vol I onwards IWPAC.
6. Natural Product Chemistry Nakanishi Gggolo, University Science Books, California

Name of the Subject	**Chemistry of Natural Products (Theory)**
Name of the Faculty	Dr. Md. Afzal Azam M.Pharm., Ph.D
Designation, Department	Professor and Head, Department of Pharmaceutical chemistry
Mobile Number	9486687029
e-Mail i.d.	afzal@jssuni.edu.in

Scope, Course Objectives and Course Outcomes

SCOPE

The course is designed to provide detail knowledge about the chemistry of natural compounds including medicinal compounds from natural origin. The course will impart knowledge about the chemistry and general methods of structural elucidation of such compounds. It also emphasizes on the therapeutic uses of chemical constituents from the medicinal plants.

OBJECTIVES

The primary objectives of this course are to

- Discuss the natural compounds used as leads for the development of new pharmaceuticals
- Helps to know different types of natural compounds and their chemistry and medicinal importance
- Help the students to understand the methods used for the structural elucidation of various natural compounds
- Enable the students to understand the concept of rDNA technology tool for new drug discovery and about gene therapy
- Enable the students to understand the structural characterization of natural compounds using different spectroscopy methods

COURSE OUTCOMES

At completion of this course it is expected that the students will be able to

CO 1 : Know the chemistry of natural products
CO 2 : Identification of lead molecules for new pharmaceuticals
CO 3 : Use of spectroscopy methods for chemical characterization of natural and other compounds.
CO 4 : Know the rDNA technology, hybridoma technology and the pharmaceutical products derived from that.
CO 5 Know the different clssses of natural products and their chemistry
CO 6 : Know the structural elucidation techniques used for the natural compounds

LECTURE PLAN – Abstract

Sessional	No. of Hours of Didactic Lecture	No of Hours of other Activities	Total No. of Lecture Hours
I	30	2	32
II	30	2	32
Total No. of Hours	60	4	64

I SESSIONAL : 31 Lectures + 3 Activities

Lecture No.	Lecture Details	Hours
Unit-1: Natural products as leads for new pharmaceuticals		**12**
1.	Drugs Affecting the Central Nervous System: Morphine Alkaloids	
2.	Anticancer Drugs: Paclitaxel and Docetaxel, Etoposide, and Teniposide	
3.	Cardiovascular Drugs: Lovastatin, Teprotide and Dicoumarol	
4.	Neuromuscular Blocking Drugs: Curare alkaloids	
5.	Anti-malarial drugs and Analogues	
6.	Chemistry of macrolid antibiotics -Erythromycin, Azithromycin	
7.	Chemistry of macrolid antibiotics Roxithromycin, and Clarithromycin	
8.	Chemistry of β-Lactam antibiotics Cephalosporins	
9.	Chemistry of β-Lactam antibiotics Cephalosporins	
10.	Chemistry of β-Lactam antibiotics Cephalosporins	
11.	Chemistry of Carbapenem	
12.	Chemistry of Carbapenem	
Unit-2: Alkaloids		**12**
1.	General introduction, classification, isolation, purification	
2.	molecular modification and biological activity of alkaloids	
3.	General methods of structural determination of alkaloids	
4.	Structural elucidation and stereochemistry of ephedrine	
5.	Structural elucidation of morphine	
6.	Structural elucidation of ergot, reserpine	
7.	Structure elucidation of emetin and ergot	
8.	Introduction, isolation and purification of flavonoids	
9.	General methods of structural determination of flavonoids	
10.	Structural elucidation of quercetin	
11.	Steroids General introduction, chemistry of sterols, sapogenin and cardiac glycosides	
12.	Stereochemistry and nomenclature of steroids, chemistry of contraceptive agents male & female sex hormones	
Unit 3 Terpenoids and vitamins		
1.	Classification, isolation, isoprene rule and general methods of structural	

	elucidation of Terpenoids	**14**
2.	Structural elucidation of citral	
3.	Structural elucidation of menthol	
4.	Structural elucidation of camphor	
5.	di terpenoids - retinol, Phytol, taxol	
6.	tri terpenoids (Squalene,Ginsenoside)	
7.	Test	
8.	Test	
Second sessional II SESSIONAL : 30 Lectures + 2 Activities		
9.	carotinoids (β carotene)	
10.	Chemistry and Physiological significance of Vitamin A	
11.	Chemistry and Physiological significance of Vitamin B12	
12.	Chemistry and Physiological significance of Vitamin B1	
13.	Chemistry and Physiological significance of Vitamin B2	
14.	Chemistry and Physiological significance of Folic acid and Niacin	

Lecture No.	**Lecture Details**	**Hours**
Unit-4: rDNA technology and Active constituent of certain crude drugs indigenous system		**12**
1.	rDNA technology	
2.	hybridoma technology	
3.	New pharmaceuticals derived from biotechnology; Oligonucleotide therapy.	
4.	Gene therapy: Introduction, Clinical application and recent advances in gene therapy	
5.	principles of RNA & DNA estimation	
6.	Active constituent of crude drugs used in Diabetic therapy - Gymnema sylvestre	
7.	Active constituent of crude drugs used in Diabetic therapy - Salacia reticulate	
8.	Pterocarpus marsupiam	
9.	Swertia chirata	
10.	Trigonella foenum graccum	
11.	Liver dysfunction – Phyllanthus niruri	
12.	Antitumor – Curcuma longa Linn	
13.	Test	
Unit V– Structural Characterization of natural compounds		**12**
1.	Structural characterization of natural compounds using IR	
2.	Structural characterization of natural compounds using ^{1}HNMR	
3.	Structural characterization of natural compounds using ^{1}HNMR	
4.	Structural characterization of natural compounds using ^{13}CNMR	
5.	Structural characterization of natural compounds using ^{13}C-NMR	

6.	Structural characterization of natural compounds using IR	
7.	Structural characterization of Penicillin	
8.	Structural characterization of Morphine	
9.	Structural characterization of Camphor	
10.	Structural characterization of Vit-D	
11.	Structural characterization of Quercetin	
12.	Structural characterization of Digitalis glycosides.	
13.	Test	2
14.	Test	

TEXT BOOKS

1. Organic Chemistry Vol I and II by I.L. Finar, Pearson education
2. Natural Product Chemistry "A laboratory guide" – Rapheal Khan.
3. The Alkaloid Chemistry and Physiology by RHF Manske, Academic Press.
4. Introduction to molecular Phytochemistry – CHJ Wells, Chapmannstall.
5. Organic Chemistry of Natural Products Vol I and II by Gurdeep and Chatwall, Himalaya Publishing House.
6. Organic Chemistry of Natural Products Vol I and II by O.P. Agarwal,
7. Burger's Medicinal Chemistry.

REFERENCE BOOKS

1. Modern Methods of Plant Analysis, Peech and M.V.Tracey, Springer –Verlag, Berlin, Heidelberg.
2. Phytochemistry Vol. I and II by Miller, Jan Nostrant Rein Hld.
3. Recent advances in Phytochemistry Vol. I to IV – Scikel Runeckles,
4. Springer Science & Business Media.
5. Chemistry of natural products Vol I onwards IWPAC.
6. Natural Product Chemistry Nakanishi Gggolo, University Science Books, California

II SEMESTER

Name of the Subject	**ADVANCED SPECTRAL ANALYSIS (Theory)**
Name of the Faculty	Dr. Md. Afzal Azam M.Pharm., Ph.D
Designation, Department	Professor and Head, Department of Pharm chemistry
Mobile Number	9486687029
e-Mail i.d.	afzal@jssuni.edu.in

Scope, Course Objectives and Course Outcomes

SCOPE

This subject deals with characterization of organic compounds by UV-Vis, IR, 1HNMR, 13CNMR spectroscopy, various hyphenated analytical techniques LC-MS, GC-MS, ATR-IR, DSC etc. and their applications. Use of spectroscopic techniques for the characterization of natural compounds with complex structures.

OBJECTIVES

The primary objectives of this course are to

- The use of UV-vis and IR for characterization of organic compounds
- The use of 1HNMR, 13CNMR for characterization of organic compounds
- 2D-spectroscopy
- Helps to understand different hyphenated analytical techniques LC-MS, GC-MS, ATR-IR,
- Helps to understand spectroscopic techniques for the characterization of natural compounds

COURSE OUTCOMES

At completion of this course it is expected that the students will be able to

CO 1 : Know the use of UV-Vis and IR
CO 2 : Use of 1HNMR, 13CNMR for characterization
CO 3 : Use of 2D-spectroscopy for characterization
CO 4 : Hyphenated analytical techniques
CO 5 : Understand optimization of reaction route
CO 6 : Learn characterization of natural compounds

LECTURE PLAN – Abstract

Sessional	No. of Hours Lecture ADVANCED SPECTRAL ANALYSIS	No of Hours of other Activities	Total No. of Lecture Hours
I	30	-	30
II	30	-	30
Total No. of Hours	60	-	60

I SESSIONAL: 30 Lectures

Lecture No.	Lecture Details	Hours
PROCESS CHEMISTRY		(60)
Unit-1: UV and IR spectroscopy		12
1.	UV spectroscopy	
2.	Wood ward – Fieser rule for 1,3- butadienes	
3.	Wood ward – Fieser rule for cyclic dienes	
4.	Wood ward – Fieser rule for α,β-carbonyl compounds and interpretation compounds of enones.	
5.	ATR-IR	
6.	IR Interpretation of organic compounds	
7.	IR Interpretation of organic compounds	
8.	IR Interpretation of organic compounds	
9.	IR Interpretation of organic compounds	
10.	IR Interpretation of organic compounds	
11.	IR Interpretation of organic compounds	
12.	IR Interpretation of organic compounds	
Unit-2: NMR spectroscopy		12
1.	1-D NMR	
2.	1-D NMR	
3.	2-D NMR NOESY technique	
4.	2-D NMR COSY technique	
5.	2-D NMR HECTOR technique	
6.	2-D NMR INADEQUATE technique	
7.	Interpretation of organic compounds	
8.	Interpretation of organic compounds	
9.	Interpretation of organic compounds	
10.	Interpretation of organic compounds	
11.	Interpretation of organic compounds	
12.	Interpretation of organic compounds	
Unit-3: Mass Spectroscopy		06
1.	Mass fragmentation and its rules	
2.	Fragmentation pattern of alcohol	

3.	Fragmentation pattern of amines	
4.	Fragmentation pattern of carbonyls	
5.	Fragmentation pattern of alkanes	
6.	Meta stable ions, Mc Lafferty rearrangement	

II SESSIONAL: 30 Lectures

Lecture No.	Lecture Details	Hours
Unit-3: Mass Spectroscopy		
1.	Interpretation of organic compounds by MS	06
2.	Interpretation of organic compounds by MS	
3.	Interpretation of organic compounds by MS	
4.	Interpretation of organic compounds by MS	
5.	Interpretation of organic compounds by MS	
6.	Interpretation of organic compounds by MS	
Unit-4: Chromatography		
1.	GC-MS	12
2.	GC-AAS	
3.	LC-MS	
4.	LC-FTIR	
5.	LC-NMR	
6.	CE-MS	
7.	High Performance Thin Layer chromatography	
8.	Super critical fluid chromatography	
9.	Ion Chromatography	
10.	Ion-Exclusion Chromatography	
11.	Flash chromatography	
12.	Flash chromatography	
Unit-5: Analysis		
1.	Thermalmethods of analysis	12
2.	Introduction, principle, instrumentation and application of DSC,	
3.	Thermal methods of analysis DTA	
4.	Thermalmethods of analysis TGA.	
5.	Introduction, principle, instrumentation and application of DSC,	
6.	Raman Spectroscopy	
7.	Introduction, Principle,	
8.	Instrumentation and Applications	
9.	Raman Spectroscopy Applications	
10.	Radio immuno assay	
11.	Biological standardization , bioassay, ELISA, Radioimmuno	

12.	Assay of digitalis and insulin.	

REFERENCE BOOKS

1. Spectrometric Identification of Organic compounds - Robert M Silverstein, Sixth edition, John Wiley & Sons, 2004.
2. Principles of Instrumental Analysis - Doglas A Skoog, F. James Holler,Timothy A. Nieman, 5th edition, Eastern press, Bangalore, 1998.
3. Instrumental methods of analysis – Willards, 7th edition, CBS publishers.
4. Organic Spectroscopy - William Kemp, 3rd edition, ELBS, 1991.
5. Quantitative analysis of Pharmaceutical formulations by HPTLC - P D Sethi, CBS Publishers, New Delhi.

1. Quantitative Analysis of Drugs in Pharmaceutical formulation - P D Sethi, 3rd Edition, CBS Publishers, New Delhi, 1997.
2. Pharmaceutical Analysis- Modern methods – Part B - J W Munson, Volume 11, Marcel Dekker Series

Name of the Subject	**Advanced Organic Chemistry-II (Theory)**
Name of the Faculty	Dr. R. Kalirajan., B.sc., M.Pharm., Ph.D
Designation, Department	Asst. Professor, Department of Pharm Chemistry
Mobile Number	9994098087
e-Mail i.d.	rkalirajan@jssuni.edu.in

Scope, Course Objectives and Course Outcomes

SCOPE

The subject is designed to provide in-depth knowledge about advances in organic chemistry, different techniques of organic synthesis and their applications to process chemistry as well as drug discovery.

OBJECTIVES

After completion of course student is able to understand

- The principles and applications of Green chemistry
- The concept of peptide chemistry.
- The various catalysts used in organic reactions
- The principles of Photochemical and Pericyclic reactions
- The concept of stereochemistry and asymmetric synthesis.

COURSE OUTCOMES

At completion of this course it is expected that the students will be able to

CO 1: Explain about the principles and applications of Green chemistry
CO 2: Explain about the concept of peptide chemistry
CO 3: Know about the principles of Photochemical and Pericyclic reactions
CO 4: Know about the various catalysts used in organic reactions
CO 5: Explain about the concept of stereochemistry and asymmetric synthesis

LECTURE PLAN – Abstract

Sessional	No. of Hours of Didactic Lecture	No of Hours of other Activities	Total No. of Lecture Hours
	Advanced Instrumentation Techniques		
I	30	1	31
II	30	--	30
Total No. of Hours	60	--	61

I SESSIONAL : 30 Lectures + 1 Activity

Lecture No.	Lecture Details	Hours
Activity-1	**Orientation of the subject**	**01**
Unit-1: Green Chemistry		**12**
1.	Introduction green chemistry	
2.	principles of green chemistry	
Microwave assisted reactions		
3.	Introduction, Principle of MW reactions	
4.	Merit and demerits of its use, increased reaction rate	
5.	mechanism, superheating effects of microwave, effects of solvents in microwave assisted synthesis	
6.	microwave technology in process optimization,	
7.	its applications in various organic reactions and heterocycles synthesis	
Ultrasound assisted reactions		
8.	Introduction, Principle Types of sono chemical reactions	
9.	homogenous, heterogeneous liquid-liquid and liquid-solid reactions,	
10.	synthetic applications	
Continuous flow reactors		
11.	Introduction,Working principle	
12.	advantages and synthetic applications	
Unit-2:		**12**
Chemistry of peptides		
1.	Introduction, Coupling reactions in peptide synthesis	
2.	Principles of solid phase peptide synthesis, t-BOC and FMOC protocols	
3.	various solid supports and linkers: Activation procedures, peptide bond formation	
4.	deprotection and cleavage from resin, low and high HF cleavage protocols	
5.	formation of free peptides and peptide amides purification and case studies	

6.	site-specific chemical modifications of peptides	
7.	Segment and sequential strategies for solution phase peptide synthesis	
8.	any two case studies	
9.	Side reactions in peptide synthesis	
10.	Deletion peptides, side reactions initiated by proton abstraction	
11.	protonation, over activation	
12.	side reactions of individual amino acids.	
Unit-3:		**06**
Photochemical Reactions		
1.	Introduction of photochemical reactions	
2.	Basic principles of photochemical reactions	
3.	Photo-oxidation	
4.	photo-addition	
5.	photo-fragmentation	
6.	Synthetic Applications	

II SESSIONAL : 30 Lectures

Lecture No.	Lecture Details	Hours
Unit-3:		
Pericyclic reactions		**06**
7.	Introduction, Pericyclic reactions Mechanism	
8.	Types of pericyclic reactions	
9.	cyclo addition	
10	electrocyclic reaction	
11	sigmatrophic rearrangement reactions	
12	Synthetic Applications	
Unit-4:		
Catalysis		**12**
1.	Types of catalysis, heterogeneous and homogenous catalysis, advantages and disadvantages	
2.	**Heterogeneous catalysis** – preparation, characterization, kinetics	
3.	supported catalysts, catalyst deactivation and regeneration	
4.	some examples of heterogeneous catalysis used in synthesis of drugs	
5.	**Homogenous catalysis**, hydrogenation, hydro formylation	
6.	hydro cyanation, Wilkinson catalysts	
7.	chiral ligands and chiral induction	
8.	Ziegler-Natta catalysts, some examples of homogenous catalysis used in synthesis of drugs	
9.	Transition-metal and Organo-catalysis in organic synthesis: Metal-catalyzed reactions	
10.	**Biocatalysis:** Use of enzymes in organic synthesis, immobilized enzymes/cells inorganic reaction	

11.	immobilized enzymes/cells inorganic reaction	
12.	Phase transfer catalysis-theory and applications	
Unit-5:		**10**
Stereochemistry & Asymmetric Synthesis		
1.	Basic concepts in stereochemistry- Introduction	
2.	optical activity, specific rotation, racemates	
3.	resolution of racemates	
4.	In gold, Prelog(CIP) sequence rule	
5.	meso compounds, pseudo asymmetric centres	
6.	axes of symmetry	
7.	Fischers D and L notation	
8.	cis-trans isomerism, E and Z notation	
9.	Methods of asymmetric synthesis using chiral pool	
10.	chiral auxiliaries and catalytic asymmetric synthesis	
11.	enantio pure separation	
12.	Stereoselective synthesis with examples	

REFERENCE BOOKS

1. "Advanced Organic chemistry, Reaction, mechanisms and structure", J March, John Wiley and sons, NewYork.
2. "Mechanism and structure in organic chemistry", ES Gould, Hold Rinchart and Winston, NewYork.
3. "Organic Chemistry" Clayden, Greeves, Warren and Woihers., Oxford UniversityPress2001. 4. "OrganicChemistry" Vol I and II. I.L.Finar. ELBS, Sixthed.,1995.
4. Carey, Organic chemistry,5th edition (Viva Books Pvt. Ltd.)
5. Organic synthesis- the disconnection approach, S. Warren, WilyIndia
6. Principles of organic synthesis, ROC Norman and JMCoxan, Nelsonthorns
7. Organic synthesis- Special techniques VK Ahluwalia and R Aggarwal, Narosa Publishers.
8. Organic reaction mechanisms IV edtn, VK Ahluwalia and RK Parashar, Narosa Publishers

Name of the Subject	**Computer Aided Drug design (Theory)**
Name of the Faculty	Dr.Jubie S M.Pharm., Ph.D
Designation, Department	Assistant Professor, Department of Pharm Chemistry
Mobile Number	9894618588
e-Mail i.d.	jubie@jssuni.edu.in

Scope, Course Objectives and Course Outcomes

SCOPE

The subject is designed to impart knowledge on the current state of the art techniques involved in computer assisted drug design.

OBJECTIVES

The primary objectives of this course are to

- Study the 2D &3D QSAR models.
- Learn the molecular mechanics and quantum mechanics.
- Study the molecular docking techniques ad their applications.
- Learn the concepts of denovo drug design.
- Study the objectives and types of various virtual screening and pharmocophore screening techniques.

Course Outcomes

At completion of this course it is expected that students will be able to understand

1. Role of CADD in drug discovery
2. Different CADD techniques and their applications
3. Various strategies to design and develop new drug like molecules.
4. Working with molecular modeling softwares to design new drug molecules
5. The *in silico* virtual screening protocols

LECTURE PLAN – Abstract

Sessional	No. of Hours of Didactic Lecture	No of Hours of other Activities	Total No. of Lecture Hours
I	30	-	30
II	30	-	30
Total No. of Hours	60	-	60

I SESSIONAL : 24 Lectures + 3 Activities

Lecture No.	Lecture Details	Hours (30)
Unit-1: Introduction to computer aided drug design (CADD)		**12**
1.	Basics,history and development of QSAR	
2.	Physicochemical parameters and types	
3.	Hammett Equation	
4.	Electronic parapeters others	
5.	Lipophilicity parameters-Partition co-efficient	
6.	Pi substituent constant	
7.	Taft's steric constant	
8.	Moalr refractivity	
9.	Experimental approach for Partition co-efficient	
10.	Experimental approach for Hammett substituent constant	
11.	Experimental approach for acid dissociation constant	
12.	Experimental approach for molar refractivity	
Unit-2: Quantitative structure activity relationships (Applications)		**12**
1.	Hansch analysis	
2.	Hansch analysis (cont..)	
3.	Free wilson analysis	
4.	Free wilson analysis (cont…)	
5.	Relationship between both analysis	
6.	Advantages &Disadvantages of Hansch analysis	
7.	Advantages &Disadvantages of Freewilson analysis	
8.	3D QSAR Techniques	
9.	COMFA analysis	
10.	Contour maps	
11.	Statistical methods used in QSAR analysis	
12.	Importance of Statistical parameters	
Unit-3: Molecular modelling and docking		**06**
1.	Molecular mechanics	
2.	Quantum mechanics	
3.	Energy minimization methods	
4.	Global energy minimization	

5.	Bioactive conformation	
6.	Molecular docking	

II SESSIONAL : 30 Lectures

Lecture No.	Lecture Details	Hours (30)
Unit-3: Molecular modelling and docking (cont…)		
1.	Rigid docking	**06**
2.	Flexible docking	
3.	Agents acting on DHFR	
4.	Agents acting on HMGCOA Reductase	
5.	Agents acting on HIV protease	
6.	Agents acting on choline esterase	
Unit-4: Molecular properties and drug design		
1.	Prediction and analysis of ADMET properties in drug design	**12**
2.	Importance of ADMET prediction in drug design	
3.	Denovo drug design Receptor/enzyme interaction	
4.	Denovo drug design Receptor/enzyme interaction-ANALYSIS	
5.	Receptor/enzyme cavity size prediction	
6.	Predicting the functional components of cavities	
7.	Fragment based drug design	
8.	Fragment based drug design (cont....)	
9.	Homology modelling	
10.	Homology modelling (Cont.....)	
11.	Generation of 3-D structure of protein	
12.	Generation of 3D structure of protein	
Unit-5: Pharmacophore mapping and virtual screening		
1.	Concept of pharmacophore	**12**
2.	Concept of pharmacophore (cont...)	
3.	Pharmacophore mapping	
4.	Pharmacophore mapping (cont...)	
5.	Identification of pharmacophore features	
6.	Identification of pharmacophore features (cont..)	
7.	Pharmacophore modelling	
8.	Pharmacophore modelling (cont....)	
9.	Pharmacophore modelling (cont....)	
10.	Conformational search used in pharmacophore modelling	
11.	Conformational search used in pharmacophore modelling	
12.	Conformational search used in pharmacophore modelling	

TEXT BOOKS

1. TheOrganic Chemistry of the Drug Design andDrug action byRichard B. Silverman,

Elsevier Publishers.
2. Medicinal Chemistry by Burger, Wiley Publishing Co.
3. An Introduction to Medicinal Chemistry –Graham L. Patrick, Oxford University Press.
4. Wilson and Gisvold's Text book of Organic Medicinal and Pharmaceutical Chemistry, Ippincott Williams & Wilkins.
5. Comprehensive Medicinal Chemistry – Corwin and Hansch, Pergamon Publishers.
6. Computational and structural approaches to drug design edited by Robert M Stroud and Janet. F Moore

REFERENCE BOOKS

1. Computational and structural approaches to drug discovery, Robert M Stroud and Janet. F Moore, RCS Publishers.
2. Introduction to Quantitative Drug Design by Y.C. Martin, CRC Press, Taylor & Francis group.
3. Drug Design by Ariens Volume 1 to 10, Academic Press, 1975, Elsevier Publishers.
4. Principles of Drug Design by Smith and Williams, CRC Press, Taylor & Francis.

Name of the Subject	**Process Chemistry (Theory)**
Name of the Faculty	Dr. Md. Afzal Azam M.Pharm., Ph.D
Designation, Department	Professor and Head, Department of Pharmaceutical chemistry
Mobile Number	9486687029
e-Mail i.d.	afzal@jssuni.edu.in

Scope, Course Objectives and Course Outcomes

SCOPE

Process chemistry is often described as scale up reactions, taking them from small quantities created in the research lab to the larger quantities that are needed for further testing and then to even larger quantities required for commercial production. The goal of a process chemist is to develop synthetic routes that are safe, cost-effective, environmentally friendly, and efficient. The subject is designed to impart knowledge on the development and optimization of a synthetic route/s and the pilot plant procedure for the manufacture of Active Pharmaceutical Ingredients (APIs) and new chemical entities (NCEs) for the drug development phase.

OBJECTIVES

The primary objectives of this course are to

- The strategies of scale up process of apis and intermediates
- Discuss the different type of unit operations
- Helps to know the different reactions and kinetics at industrial scale
- Helps to understand different bioprocess for industrial production.
- Helps to understand Reaction progress kinetic analysis
- Help to understand Characteristics of expedient routes and industrial safety

COURSE OUTCOMES

At completion of this course it is expected that the students will be able to

CO 1 : Know the strategies of scale up process
CO 2 : Know different unit operations
CO 3 : Reaction and kinetics in industrial production
CO 4 : Various bioprocesses for industrial production
CO 5 : Understand optimization of reaction route
CO 6 : Industrial hazards and safety

LECTURE PLAN – Abstract

Sessional	No. of Hours Lecture Process chemistry	No of Hours of other Activities	Total No. of Lecture Hours
I	30	-	30
II	30	-	30
Total No. of Hours	60	-	60

I SESSIONAL: 30 Lectures

Lecture No.	Lecture Details	Hours
PROCESS CHEMISTRY		(60)
Unit-1: Process chemistry		**12**
1.	Introduction, Synthetic strategy	
2.	Stages of scale up process	
3.	Stages of scale up process	
4.	Stages of scale up process	
5.	In-process control validation of large scale process	
6.	In-process control validation of large scale process.	
7.	Case studies of some scale up process of APIs.	
8.	Case studies of some scale up process of APIs.	
9.	Case studies of some scale up process of APIs.	
10.	Impurities in API	
11.	Impurity types and their sources	
12.	genotoxic impurities	
Unit-2: Unit operations		**12**
1.	Extraction	
2.	Filtration	
3.	Distillation	
4.	Distillation	
5.	Evaporation	
6.	Evaporation	
7.	Crystallization from aqueous, nonaqueous solutions	
8.	Factors affecting crystallization, nucleation.	
9.	Principle and general methods of Preparation of polymorphs APIs	
10.	Principle and general methods of Preparation of hydrates APIs	
11.	Principle and general methods of Preparation of solvates APIs	
12.	Principle and general methods of Preparation of amorphous APIs.	
Unit-3: Unit Processes - I		**06**
1.	Nitrating agents, Aromatic nitration	
2.	Kinetics and mechanism of aromatic nitration	
3.	process equipment for technical nitration	

4.	mixed acid for nitration	
5.	Kinetics of halogenations, types of halogenations,	
6.	Nitrating agents, Aromatic nitration	

II SESSIONAL: 30 Lectures

Lecture No.	Lecture Details	Hours
Unit-3: Auditing of vendors and production department		
1.	catalytic halogenations.	**06**
2.	Case study on industrial halogenation process	
3.	Oxidation Introduction	
4.	types of oxidative reactions	
5.	Liquid phase oxidation with oxidizing agents	
6.	Nonmetallic Oxidizing agents such as H2O2	
Unit-4: Unit Processes - II		
1.	Catalytic hydrogenation, Heterogeneous and homogeneous catalyst	**12**
2.	Hydrogen transfer reactions, Metal hydrides.	
3.	Case study on industrial reduction process.	
4.	Aerobic and anaerobic fermentation	
5.	Production of Antibiotics: Penicillin and Streptomycin	
6.	Production of B2 and B12	
7.	Production of Lovastatin, Simvastatin	
8.	Reaction progress kinetic analysis	
9.	Streamlining reaction steps, route selection	
10.	Characteristics of expedient routes, characteristics of cost-effective routes,	
11.	reagent selection, families of reagents useful for scale-up	
12.	Catalytic hydrogenation, Heterogeneous and homogeneous catalyst	
Unit-5: Industrial Safety		
1.	MSDS (Material Safety Data Sheet)	**12**
2.	hazard labels of chemicals	
3.	Personal Protection Equipment	
4.	Fire hazards,	
5.	types of fire	
6.	fire extinguishers	
7.	Occupational Health & Safety Assessment Series 1800 (OHSAS-1800)	
8.	Occupational Health & Safety Assessment Series 1800 (OHSAS-1800)	
9.	Occupational Health & Safety Assessment Series 1800 (OHSAS-1800)	
10.	ISO-14001 (Environmental Management System)	
11.	Effluents and its management	
12.	Effluents and its management	

REFERENCE BOOKS

1. Process Chemistry in the Pharmaceutical Industry: Challenges in an Ever-
1. Changing Climate-An Overview; K. Gadamasetti, CRC Press.
2. Pharmaceutical Manufacturing Encyclopedia, 3rd edition, Volume 2.
3. Medicinal Chemistry by Burger, 6th edition, Volume 1-8.
4. W.L. McCabe, J.C Smith, Peter Harriott. Unit operations of chemical engineering, 7th edition, McGraw Hill
5. Polymorphism in Pharmaceutical Solids .Dekker Series Volume 95 Ed: H G Brittain (1999)
7. Regina M. Murphy: Introduction to Chemical Processes: Principles, Analysis, Synthesis
8. Peter J. Harrington: Pharmaceutical Process Chemistry for Synthesis: Rethinking the Routes to Scale-Up
9. P.H.Groggins: Unit processes in organic synthesis (MGH)
10. F.A.Henglein: Chemical Technology (Pergamon)
11. M.Gopal: Dryden's Outlines of Chemical Technology, WEP East-West Press
6. Clausen,Mattson: Principle of Industrial Chemistry, Wiley Publishing Co.,
7. Lowenheim & M.K. Moran: Industrial Chemicals
8. S.D. Shukla & G.N. Pandey: A text book of Chemical Technology Vol. II, Vikas Publishing House.

JSS Academy of Higher Education & Research, Mysuru
JSS College of Pharmacy, Rocklands, Ooty

I M. PHARMACY TIME TABLE FOR E-LEARN CLASSES : I Semester (AY : 2020 - 2021)

DEPARTMENT : PHARMACEUTICAL CHEMISTRY
COURSE : PHARMACEUTICAL CHEMISTRY

Days	9 - 10 am	10 - 11 am	11 - 12 am	12 - 1 pm	1 - 2 pm	2 - 3 pm	3 - 4 pm	4 - 5 pm
Mon		MPAT ***(NKV)***	Seminar	Seminar	**LUNCH BREAK**	Assignment	CNP ***(MAA)***	CNP ***(MAA)***
Tue		MPAT ***(NKV)***	Seminar	Seminar		Assignment	CNP ***(MAA)***	CNP ***(MAA)***
Wed		MPAT ***(NKV)***	--	--		AOC ***(SJ)***	AMC ***(MAA)***	AMC ***(MAA)***
Thu		MPAT ***(NKV)***	--	--		AMC ***(MAA)***	AMC ***(MAA)***	AOC ***(SJ)***
Fri		--	--	--		Assignment	AOC ***(SJ)***	AOC ***(SJ)***
Sat								

Subjects: I M.Pharm (Pharmaceutical Chemistry)

1. Modern Pharmaceutical Analytical Techniques (MPAT) : Dr. N. Krishna veni ***(NKV)***
2. Chemistry of Natural Products (CNP): Dr. Md. Afzal Azam (***MAA***)
3. Advanced Medicinal Chemistry (AMC): Dr. Md. Afzal Azam (***MAA***)
4. Advance Organic Chemistry (AOC): Dr. S. Jubie (**SJ**)

JSS Academy of higher Education & Research, Mysuru
(Deemed to be University, Accredited 'A$^+$' Grade by NAAC)
JSS College of Pharmacy, Ooty – 643 001
(An ISO 9001-2015 certified Institution)

Department of Pharmaceutical Chemistry
M. Pharmacy, II Semester (AY 2020-2021) (June – Dec 2020)

Day	9-10 AM	10-11 AM	11-12 AM	12-1 PM	1 – 2 PM	2-3 PM	3 -4 PM	4 – 5 PM
Monday		CADD	AOC-II	Assignment		PC	PC	Assignment
Tuesday		CADD	PC	PC		Pharmaceutical Chemistry II practical		
Wednesday		CADD	CADD	Assignment		Pharmaceutical Chemistry iI practical		
Thursday		APC	APC	AOC-II		Pharmaceutical Chemistry II practical		
Friday		Seminar	AOC-II	AOC-II		Assignment	APC	APC
Saturday		Pharmaceutical Chemistry II practical				-	-	-

Subject- In-charge

Advanced Spectral Analysis (APC) - (T)	Dr. Md. Afzal Azam
Advanced organic chemistry-II(AOC-II) (T)	Dr. R. Kalirajan
Computer Aided Drug Design(CADD) (T)	Dr. S. Jubie
Process Chemistry (PC) (T & P)	Dr. Md. Afzal Azam
Pharmaceutical Chemistry-II (P)	Dr. S. Md. Afzal Azam(Wednesday & Thursday) Dr. R. Kalirajan (Tuesday), Dr. B.Gowramma (Saturday)

M. PHARM
PHARMACEUTICAL ANALYSIS

SYLLABUS
SEMESTER I
MPH 101T-MODERN PHARMACEUTICAL ANALYTICAL TECHNIQUES (Theory)

SCOPE
This subject deals with various advanced analytical instrumental techniques for identification, characterization and quantification of drugs. Instruments dealt are NMR, Mass spectrometer, IR, HPLC, GC etc.

OBJECTIVES
After completion of course student is able to know about chemicals and excipients
- The analysis of various drugs in single and combination dosage forms
- Theoretical and practical skills of the instruments

Course Content

THEORY **60 Hrs**

1. a.**UV-Visible spectroscopy**: Introduction, Theory, Laws, Instrumentation associated with UV-Visible spectroscopy, Choice of solvents and solvent effect and Applications of UV-Visible spectroscopy, Difference/ Derivative spectroscopy.
   b.**IR spectroscopy**: Theory, Modes of Molecular vibrations, Sample handling, Instrumentation of Dispersive and Fourier - Transform IR Spectrometer, Factors affecting vibrational frequencies and Applications of IR spectroscopy, Data Interpretation.
   c. **Spectroflourimetry**: Theory of Fluorescence, Factors affecting fluorescence (Characteristics of drugs that can be analyzed by fluorimetry), Quenchers, Instrumentation and Applications of fluorescence spectrophotometer.
   d. **Flame emission spectroscopy** and Atomic absorption spectroscopy: Principle, Instrumentation, Interferences and Applications.
2. **NMR spectroscopy**: Quantum numbers and their role in NMR, Principle, Instrumentation, Solvent requirement in NMR, Relaxation process, NMR signals in various compounds, Chemical shift, Factors influencing chemical shift, Spin-Spin coupling, Coupling constant, Nuclear magnetic double resonance, Brief outline of principles of FT-NMR and 13C NMR. Applications of NMR spectroscopy.
3 **Mass Spectroscopy**: Principle, Theory, Instrumentation of Mass Spectroscopy, Different types of ionization like electron impact, chemical, field, FAB and MALDI, APCI, ESI, APPI Analyzers of Quadrupole and Time of Flight, Mass fragmentation and its rules, Meta stable ions, Isotopic peaks and Applications of Mass spectroscopy.
4 **Chromatography:** Principle, apparatus, instrumentation, chromatographic parameters, factors affecting resolution, isolation of drug from excipients, data interpretation and applications of the following:
   a. Thin Layer chromatography
   b. High Performance Thin Layer Chromatography
   c. Ion exchange chromatography
   d. Column chromatography
   e. Gas chromatography

f. High Performance Liquid chromatography
g. Ultra High Performance Liquid chromatography
h. Affinity chromatography
i. Gel Chromatography

5 a. **Electrophoresis**: Principle, Instrumentation, Working conditions, factors affecting separation and applications of the following:

a) Paper electrophoresis b) Gel electrophoresis c) Capillary electrophoresis d) Zone electrophoresis e) Moving boundary electrophoresis f) Iso electric focusing

b. **X ray Crystallography**: Production of X rays, Different X ray methods, Bragg's law, Rotating crystal technique, X ray powder technique, Types of crystals and applications of X- ray diffraction

6 **Potentiometry**: Principle, working, Ion selective Electrodes and Application of potentiometry.

Thermal Techniques: Principle, thermal transitions and Instrumentation (Heat flux and power-compensation and designs), Modulated DSC, Hyper DSC, experimental parameters (sample preparation, experimental conditions, calibration, heating and cooling rates, resolution, source of errors) and their influence, advantage and disadvantages, pharmaceutical applications.

Differential Thermal Analysis (DTA): Principle, instrumentation and advantage and disadvantages, pharmaceutical applications, derivative differential thermal analysis (DDTA). TGA: Principle, instrumentation, factors affecting results, advantage and disadvantages, pharmaceutical applications.

REFERENCES

1. Spectrometric Identification of Organic compounds - Robert M Silverstein, Sixth edition,
2. John Wiley & Sons, 2004.
3. 2.Principles of Instrumental Analysis - Doglas A Skoog, F. James Holler, Timothy A. Nieman, 5th edition, Eastern press, Bangalore, 1998.
4. Instrumental methods of analysis – Willards, 7th edition, CBS publishers.
5. 4.Practical Pharmaceutical Chemistry – Beckett and Stenlake, Vol II, 4th edition, CBS
6. Publishers, New Delhi, 1997.
7. 5.Organic Spectroscopy - William Kemp, 3rd edition, ELBS, 1991.
8. 6.Quantitative Analysis of Drugs in Pharmaceutical formulation - P D Sethi,3rd Edition, CBS Publishers, New Delhi, 1997.
9. 7.Pharmaceutical Analysis - Modern Methods – Part B - J W Munson, Vol 11, Marcel. Dekker Series
10. 8.Spectroscopy of Organic Compounds, 2nd edn., P.S/Kalsi, Wiley estern Ltd., Delhi.
11. 9.Textbook of Pharmaceutical Analysis, KA.Connors, 3rd Edition, John Wiley & Sons, 1982.

MPA 102T-ADVANCED PHARMACEUTICAL ANALYSIS (Theory)

SCOPE

This subject deals with the various aspects of Impurity, Impurities in new drug products, in residual solvents, Elemental impurities, Impurity profiling and characterization of degradents, Stability testing of phytopharmaceuticals and their protocol preparation. It also covers the biological testing of various vaccines and their principle and procedure.

OBJECTIVE

After completion of the course students shall able to know,

- Appropriate analytical skills required for the analytical method development.
- Principles of various reagents used in functional group analysis that renders necessary support in research methodology and demonstrates its application in the practical related problems.
- Analysis of impurities in drugs, residual solvents and stability studies of drugs and biological products

THEORY **60 Hrs**

1. Impurity and stability studies: Definition, classification of impurities in drug Substance or Active Pharmaceutical Ingredients and quantification of impurities as per ICH guidelines Impurities in new drug products: Rationale for the reporting and control of degradation products, reporting degradation products content of batches, listing of degradation products in specifications, qualification of degradation products. Impurities in residual solvents: General principles, classification of residual solvents, Analytical procedures, limits of residual solvents, reporting levels of residual solvents.

2 Elemental impurities: Element classification, control of elemental impurities, Potential Sources of elemental Impurities, Identification of Potential Elemental Impurities, analytical procedures, instrumentation & C, H, N and S analysis Stability testing protocols: Selection of batches, container orientation, test parameters, sampling frequency, specification, storage conditions, recording of results, concept of stability, commitment etc. Important mechanistic and stability related information provided by results of study of factors like temperature, pH, buffering species ionic strength and dielectric constant etc. on the reaction rates. With practical considerations.

3 **Impurity profiling and degradent characterization**: Method development, Stability studies and concepts of validation accelerated stability testing & shelf life calculation, WHO and ICH stability testing guidelines, Stability zones, steps in development, practical considerations. Basics of impurity profiling and degradent characterization with special emphasis. Photostability testing.

4 **Stability testing of phytopharmaceuticals**: Regulatory requirements, protocols, HPTLC/HPLC finger printing, interactions and complexity.

5 **Biological tests and assays of the following**:

a. Adsorbed Tetanus vaccine b. Adsorbed Diphtheria vaccine c. Human anti haemophilic vaccine d. Rabies vaccine e. Tetanus Anti toxin f. Tetanus Anti serum g. Oxytocin h.Heparin sodium IP, i. Antivenom. PCR, PCR studies for gene regulation, instrumentation (Principle and Procedures)

6 **Immunoassays (IA)**

Basic principles, Production of antibodies, Separation of bound and unbound drug, Radioimmunoassay, Optical IA, Enzyme IA, Fluoro IA, Luminiscence IA, Quantification and applications of IA.

REFERENCES

1. Vogel's textbook of quantitative chemical analysis - Jeffery J Bassett, J. Mendham, R. C. Denney, 5th edition, ELBS, 1991.
2. Practical Pharmaceutical Chemistry - Beckett and Stenlake, Vol II, 4th Edition, CBS publishers, New Delhi, 1997.
3. Textbook of Pharmaceutical Analysis - K A Connors, 3rd Edition, John Wiley & Sons, 1982.
4. Pharmaceutical Analysis - Higuchi, Brochmman and Hassen, 2nd Edition, Wiley – Inter science Publication, 1961.
5. Quantitative Analysis of Drugs in Pharmaceutical formulation – P D Sethi, 3rd Edition, CBS Publishers New Delhi, 1997.
6. Pharmaceutical Analysis- Modern methods - J W Munson – Part B, Volume 11, Marcel Dekker Series.
7. The Quantitative analysis of Drugs - D C Carratt, 3rd edition, CBS Publishers, NewDelhi, 1964.
8. Indian Pharmacopoeia Vol I , II & III 2007, 2010, 2014.
9. Methods of sampling and microbiological examination of water, first revision, BIS
10. Practical HPLC method development – Snyder, Kirkland, Glajch, 2nd edition, John Wiley & Sons.
11. Analytical Profiles of drug substances – Klaus Florey, Volume 1 – 20, Elsevier, 2005
12. Analytical Profiles of drug substances and Excipients – Harry G Brittan, Volume 21 – 30, Elsevier, 2005.
13. The analysis of drugs in biological fluids - Joseph Chamberlain, 2nd edition, CRC press, London.
14. ICH Guidelines for impurity profiles and stability studies.

MPA 103T-PHARMACEUTICAL VALIDATION (Theory)

SCOPE

The main purpose of the subject is to understand about validation and how it can be applied to industry and thus to improve the quality of the products. The subject covers the complete information about validation, types, methodology and application.

OBJECTIVES

Upon completion of the subject student shall be able to

- Explain the aspect of validation
- Carryout validation of manufacturing processes
- Apply the knowledge of validation to instruments and equipment's
- Validate the manufacturing facilities

THEORY **60 Hrs**

1. **Introduction**: Definition of Qualification and Validation, Advantage of Validation, Streamlining of Qualification & Validation process and Validation Master Plan.
   Qualification: User Requirement Specification, Design Qualification, Factory Acceptance Test (FAT)/ Site Acceptance Test (SAT), Installation Qualification, Operational Qualification, Performance Qualification, Re- Qualification (Maintaining status-Calibration Preventive Maintenance, Change management), Qualification of Manufacturing Equipments, Qualification of Analytical Instruments and Laboratory equipments.
2. **Qualification of analytical instruments:** Electronic balance, pH meter, UV-Visible spectrophotometer, FTIR, GC, HPLC, HPTLC Qualification of Glassware: Volumetric flask, pipette, Measuring cylinder, beakers and burette.
3. **Validation of Utility systems:** Pharmaceutical Water System & pure steam, HVAC system, Compressed air and nitrogen**.**
   Cleaning Validation: Cleaning Validation - Cleaning Method development, Validation and validation of analytical method used in cleaning. Cleaning of Equipment, Cleaning of Facilities. Cleaning in place (CIP).
4. **Analytical method validation:** General principles, Validation of analytical method as per ICH guidelines and USP.
   Computerized system validation: Electronic records and digital significance-21 CFR part 11and GAMP 5.
5. **General Principles of Intellectual Property:** Concepts of Intellectual Property (IP), Intellectual Property Protection (IPP), Intellectual Property Rights (IPR); Economic importance, mechanism for protection of Intellectual Property –patents, Copyright, Trademark; Factors affecting choice of IP protection; Penalties for violation; Role of IP in pharmaceutical industry; Global ramification and financial implications. Filing a patent applications; patent application forms and guidelines. Types patent applications-provisional and non-provisional, PCT and convention patent applications; International patenting requirement procedures and costs; Rights and responsibilities of a patentee; Practical aspects regarding maintaining of a Patent file; Patent infringement meaning and scope. Significance of transfer technology (TOT), IP and ethics-positive and negative aspects of IPP; Societal responsibility, avoiding unethical practices.

REFERECES:

1. B. T. Loftus & R. A. Nash, "Pharmaceutical Process Validation", Drugs and Pharm Sci. Series, Vol. 129, 3rd Ed., Marcel Dekker Inc., N.Y.
2. The Theory & Practice of Industrial Pharmacy, 3rd edition, Leon Lachman, Herbert A. Lieberman, Joseph. L. Karig, Varghese Publishing House, Bombay.
3. Validation Master plan by Terveeks or Deeks, Davis Harwood International publishing.
4. Validation of Aseptic Pharmaceutical Processes, 2nd Edition, by Carleton & Agalloco, (Marcel Dekker).
5. Michael Levin, Pharmaceutical Process Scale-Up‖, Drugs and Pharm. Sci. Series, Vol. 157,2nd Ed., Marcel Dekker Inc., N.Y.
6. Validation Standard Operating Procedures: A Step by Step Guide for Achieving Compliance in the Pharmaceutical, Medical Device, and Biotech Industries, Syed Imtiaz Haider
7. Pharmaceutical Equipment Validation: The Ultimate Qualification Handbook, Phillip A. Cloud, Interpharm Press
8. Validation of Pharmaceutical Processes: Sterile Products, Frederick J. Carlton (Ed.) and James Agalloco (Ed.), Marcel Dekker, 2nd Ed.
9. Analytical Method validation and Instrument Performance Verification by Churg Chan, Heiman Lam, Y.C. Lee, Yue. Zhang, Wiley Inter Science.

MPA 104T-FOOD ANALYSIS (Theory)

SCOPE

This course is designed to impart knowledge on analysis of food constituents and finished food products. The course includes application of instrumental analysis in the determination of pesticides in variety of food products.

OBJECTIVES

At completion of this course student shall be able to understand various analytical techniques in the determination of

- Food constituents
- Food additives
- Finished food products
- Pesticides in food
- And also student shall have the knowledge on food regulations and legislations

THEORY **60 Hrs**

1. **1 Carbohydrates:** classification and properties of food carbohydrates, General methods of analysis of food carbohydrates, Changes in food carbohydrates during processing, Digestion, absorption and metabolism of carbohydrates, Dietary fibre, Crude fibre and application of food carbohydrates

   Proteins: Chemistry and classification of amino acids and proteins, Physico-Chemical properties of protein and their structure, general methods of analysis of proteins and amino acids, Digestion, absorption and metabolism of proteins.
2. **Lipids:** Classification, general methods of analysis, refining of fats and oils; hydrogenation of vegetable oils, Determination of adulteration in fats and oils, Various methods used for measurement of spoilage of fats and fatty foods. Vitamins: classification of vitamins, methods of analysis of vitamins, Principles of microbial assay of vitamins of B-series.
3. **Food additives:** Introduction, analysis of Preservatives, antioxidants, artificial sweeteners, flavors, flavor enhancers, stabilizers, thickening and jelling agents. Pigments and synthetic dyes: Natural pigments, their dyes, Non-permitted synthetic dyes used by industries, Method of detection of natural, permitted and non-permitted dyes.
4. General Analytical methods for milk, milk constituents and milk products like ice cream, milk powder, butter, margarine, cheese including adulterants and contaminants of milk. Analysis of fermentation products like wine, spirits, beer and vinegar**.**
5. **Pesticide analysis:** Effects of pest and insects on various food, use of pesticides in agriculture, pesticide cycle, organophosphorus and organochlorine pesticides analysis, determination of pesticide residues in grain, fruits, vegetables, milk and milk products. Legislation regulations of food products with special emphasis on BIS, Agmark, FDA and US-FDA.

REFERENCES

1. The chemical analysis of foods – David Pearson, Seventh edition, Churchill Livingstone, Edinburgh London, 1976
2. Introduction to the Chemical analysis of foods – S. Nielsen, Jones & Bartlett publishers, Boston London, 1994.

3. Official methods of analysis of AOAC International, sixth edition, Volume I & II, 1997.
4. Analysis of Food constituents – Multon, Wiley VCH.
5. Dr. William Horwitz, Official methods of analysis of AOAC International, 18th edition, 2005.

MPA 105P PHARMACEUTICAL ANALYSIS PRACTICALS – I (Practicals)

1. Analysis of Pharmacopoeial compounds and their formulations by UV Vis spectrophotometer
2. Simultaneous estimation of multi component containing formulations by UV spectrophotometry
3. Experiments based on HPLC
4. Experiments based on Gas Chromatography
5. Estimation of riboflavin/quinine sulphate by fluorimetry
6. Estimation of sodium/potassium by flame photometry
7. Assay of official compounds by different titrations
8. Assay of official compounds by instrumental techniques.
9. Quantitative determination of hydroxyl group.
10. Quantitative determination of amino group
11. Colorimetric determination of drugs by using different reagents
12. Imupurity profiling of drugs
13. Calibration of glasswares
14. Calibration of pH meter
15. Calibration of UV-Visible spectrophotometer
16. Calibration of FTIR spectrophotometer
17. Calibration of GC instrument
18. Calibration of HPLC instrument
19. Cleaning validation of any one equipment
20. Determination of total reducing sugar
21. Determination of proteins
22. Determination of saponification value, Iodine value, Peroxide value, Acid value in food products
23. Determination of fat content and rancidity in food products
24. Analysis of natural and synthetic colors in food
25. Determination of preservatives in food
26. Determination of pesticide residue in food products
27. Analysis of vitamin content in food products
28. Determination of density and specific gravity of foods
29. Determination of food additives

SEMESTER II

MPA 201T-ADVANCED INSTRUMENTAL ANALYSIS (Theory)

SCOPE

This subject deals with various hyphenated analytical instrumental techniques for identification, characterization and quantification of drugs. Instruments dealt are LC-MS, GC-MS, and hyphenated techniques.

OBJECTIVES

After completion of course student is able to know,

- interpretation of the NMR, Mass and IR spectra of various organic compounds
- theoretical and practical skills of the hyphenated instruments
- identification of organic compounds

THEORY **60 Hrs**

1 HPLC: Principle, instrumentation, pharmaceutical applications, peak shapes, capacity factor, selectivity, plate number, plate height, resolution, band broadening, pumps, injector, detectors, columns, column problems, gradient HPLC, HPLC solvents, trouble shooting, sample preparation, method development, New developments in HPLC-role and principles of ultra, nano liquid chromatography in pharmaceutical analysis. Immobilized polysaccharide CSP's: Advancement in enantiomeric separations, revised phase Chiral method development and HILIC approaches. HPLC in Chiral analysis of pharmaceuticals. Preparative HPLC, practical aspects of preparative HPLC.

2 Biochromatography: Size exclusion chromatography, ion exchange chromatography, ion pair chromatography, affinity chromatography general principles, stationary phases and mobile phases.

Gas chromatography: Principles, instrumentation, derivatization, head space sampling, columns for GC, detectors, quantification**.**

High performance Thin Layer chromatography: Principles, instrumentation, pharmaceutical applications.

3 Super critical fluid chromatography: Principles, instrumentation, pharmaceutical applications.

Capillary electrophoresis: Overview of CE in pharmaceutical analysis, basic configuration, CE characteristics, principles of CE, methods and modes of CE. General considerations and method development in CE, Crown ethers as buffer additives in capillary electrophoresis. CE-MS hyphenation.

4 **Mass spectrometry**: Principle, theory, instrumentation of mass spectrometry, different types of ionization like electron impact, chemical, field, FAB and MALD, APCI, ESI, APPI mass fragmentation and its rules, meta stable ions, isotopic peaks and applications of mass spectrometry. LC-MS hyphenation and DART MS analysis. Mass analysers (Quadrpole, Time of flight, FT-ICR, ion trap and Orbitrap) instruments. MS/MS systems (Tandem: QqQ, TOF-TOF;Q-IT, Q-TOF, LTQ-FT, LTQ-Orbitrap.

5 **NMR spectroscopy**: Quantum numbers and their role in NMR, Principle, Instrumentation, Solvent requirement in NMR, Relaxation process, NMR signals in various compounds, Chemical shift, Factors influencing chemical shift, Spin-Spin coupling, Coupling constant, Nuclear magnetic double resonance, Brief outline of principles of FT-NMR with reference to 13CNMR:

Spin spin and spin lattice relaxation phenomenon. 13C NMR, 1-D and 2-D NMR, NOESY and COSY techniques, Interpretation and Applications of NMR spectroscopy. LC-NMR hyphenations.

REFERENCES

1. Spectrometric Identification of Organic compounds - Robert M Silverstein, Sixth edition, John Wiley & Sons, 2004.
2. Principles of Instrumental Analysis - Doglas A Skoog, F. James Holler, Timothy A. Nieman, 5th edition, Eastern press, Bangalore, 1998.
3. Instrumental methods of analysis – Willards, 7th edition, CBS publishers.
4. Organic Spectroscopy - William Kemp, 3rd edition, ELBS, 1991.
5. Quantitative analysis of Pharmaceutical formulations by HPTLC - P D Sethi, CBS Publishers, New Delhi.
6. Quantitative Analysis of Drugs in Pharmaceutical formulation - P D Sethi, 3rd Edition, CBS Publishers, New Delhi, 1997.
7. Pharmaceutical Analysis- Modern methods – Part B - J W Munson, Volume 11, Marcel Dekker Series.
8. Organic Spectroscopy by Donald L. Paviya, 5th Edition.

MPA 202T-MODERN BIO-ANALYTICAL TECHNIQUES (Theory)

SCOPE

This subject is designed to provide detailed knowledge about the importance of analysis of drugs in biological matrices.

OBJECTIVES

Upon completion of the course, the student shall be able to understand

- Extraction of drugs from biological samples
- Separation of drugs from biological samples using different techniques
- Guidelines for BA/BE studies.

THEORY **60 Hrs**

1. **Extraction of drugs and metabolites from biological matrices**: General need, principle and procedure involved in the Bioanalytical methods such as Protein precipitation, Liquid - Liquid extraction and Solid phase extraction and other novel sample preparation approach.

Bioanalytical method validation: USFDA and EMEA guidelines.

2 **Biopharmaceutical Consideration**: Introduction, Biopharmaceutical Factors Affecting Drug Bioavailability, In Vitro: Dissolution and Drug Release Testing, Alternative Methods of Dissolution Testing Transport models, Biopharmaceutics Classification System. Solubility: Experimental methods. Permeability: In-vitro, in-situ and In-vivo methods.

3 **Pharmacokinetics and Toxicokinetics**:Basic consideration, Drug interaction (PK-PD interactions), The effect of protein-binding interactions, The effect of tissue-binding interactions, Cytochrome P450-based drug interactions, Drug interactions linked to transporters. Microsomal assays Toxicokinetics-Toxicokinetic evaluation in preclinical studies, Importance and applications of toxicokinetic studies. LC-MS in bioactivity screening and proteomics.

4 **Cell culture techniques**

Basic equipments used in cell culture lab. Cell culture media, various types of cell culture, general procedure for cell cultures; isolation of cells, subculture, cryopreservation, characterization of cells and their applications. Principles and applications of cell viability assays (MTT assays), Principles and applications of flow cytometry.

5 **Metabolite identification**:

In-vitro / in-vivo approaches, protocols and sample preparation.

Microsomal approaches (Rat liver microsomes (RLM) and Human liver microsomes (HLM) in Met –ID. Regulatory perspectives. In-vitro assay of drug metabolites & drug metabolizing enzymes.

Drug Product Performance, In Vivo: Bioavailability and Bioequivalence: Drug Product Performance, Purpose of Bioavailability Studies, Relative and Absolute Availability. Methods for Assessing Bioavailability, Bioequivalence Studies, Design and Evaluation of Bioequivalence Studies, Study Designs, Crossover Study Designs, Generic Biologics (Biosimilar Drug Products), Clinical Significance of Bioequivalence Studies.

REFERENCES

1. Analysis of drugs in Biological fluids - Joseph Chamberlain, 2nd Edition. CRC Press, Newyork. 1995.

2. Principles of Instrumental Analysis - Doglas A Skoog, F. James Holler, Timothy A. Nieman, 5th edition, Eastern press, Bangalore, 1998.
3. Pharmaceutical Analysis - Higuchi, Brochmman and Hassen, 2nd Edition, Wiley – Interscience Publications, 1961.
4. Pharmaceutical Analysis- Modern methods – Part B - J W Munson, Volume 11, Marcel Dekker Series
5. Practical HPLC method Development – Snyder, Kirkland, Glaich, 2nd Edition, John Wiley & Sons, New Jercy. USA.
6. Chromatographic Analysis of Pharmaceuticals – John A Adamovics, 2nd Edition, Marcel Dekker, Newyork, USA. 1997.
7. Chromatographic methods in clinical chemistry & Toxicology – Roger L Bertholf, Ruth E Winecker, John Wiley & Sons, New Jercy, USA. 2007.
8. Good Laboratory Practice Regulations, 2nd Edition, Sandy Weinberg Vol. 69, Marcel Dekker Series, 1995.
9. Good laboratory Practice Regulations – Allen F. Hirsch, Volume 38, Marcel Dekker Series, 1989.
10. ICH, USFDA & CDSCO Guidelines.
11. Palmer

MPA 203T-QUALITY CONTROL AND QUALITY ASSURANCE (Theory)

SCOPE

This course deals with the various aspects of quality control and quality assurance aspects of pharmaceutical industries. It covers the important aspects like cGMP, QC tests, documentation, quality certifications, GLP and regulatory affairs.

OBJECTIVES

At the completion of this subject it is expected that the student shall be able to know

- the cGMP aspects in a pharmaceutical industry
- to appreciate the importance of documentation
- to understand the scope of quality certifications applicable to Pharmaceutical industries
- to understand the responsibilities of QA & QC departments

THEORY **60 hrs**

1. Concept and Evolution of Quality Control and Quality Assurance , Good Laboratory Practice, GMP, Overview of ICH Guidelines - QSEM, with special emphasis on Q-series guidelines. Good Laboratory Practices: Scope of GLP, Definitions, Quality assurance unit, protocol for conduct of non clinical testing, control on animal house, report preparation and documentation.
2. cGMP guidelines according to schedule M, USFDA (inclusive of CDER and CBER) Pharmaceutical Inspection Convention (PIC), WHO and EMEA covering: Organization and personnel responsibilities, training, hygiene and personal records, drug industry location, design, construction and plant lay out, maintenance, sanitation, environmental control, utilities and maintenance of sterile areas, control of contamination and Good Warehousing Practice. CPCSEA guidelines.
3. Analysis of raw materials, finished products, packaging materials, in process quality control (IPQC), Developing specification (ICH Q6 and Q3)
   Purchase specifications and maintenance of stores for raw materials. In process quality control and finished products quality control for following formulation in Pharma industry according to Indian, US and British pharmacopoeias: tablets, capsules, ointments, suppositories, creams, parenterals, ophthalmic and surgical products (How to refer pharmacopoeias), Quality control test for containers, closures and secondary packing materials.
4. Documentation in pharmaceutical industry: Three tier documentation, Policy, Procedures and Work instructions, and records (Formats), Basic principles- How to maintain, retention and retrieval etc. Standard operating procedures (How to write), Master Formula Record, Batch Formula Record, Quality audit plan and reports. Specification and test procedures, Protocols and reports. Distribution records. Electronic data.
5. Manufacturing operations and controls: Sanitation of manufacturing premises, mix-ups and cross contamination, processing of intermediates and bulk products, packaging operations, IPQC, release of finished product, process deviations, charge-in of components, time limitations on production, drug product inspection, expiry date calculation, calculation of

yields, production record review, change control, sterile products, aseptic process control, packaging.

REFERENCES

1. Quality Assurance Guide by organization of Pharmaceutical Procedures of India, 3rd revised edition, Volume I & II, Mumbai, 1996.
2. Good Laboratory Practice Regulations, 2nd Edition, Sandy Weinberg Vol. 69, Marcel Dekker Series, 1995.
3. Quality Assurance of Pharmaceuticals- A compedium of Guide lines and Related materials Vol I & II, 2nd edition, WHO Publications, 1999.
4. How to Practice GMP's – P P Sharma, Vandana Publications, Agra, 1991.
5. The International Pharmacopoeia – vol I, II, III, IV & V - General Methods of Analysis and Quality specification for Pharmaceutical Substances, Excepients and Dosage forms, 3rd edition, WHO, Geneva, 2005.
6. Good laboratory Practice Regulations – Allen F. Hirsch, Volume 38, Marcel Dekker Series, 1989.
7. ICH guidelines
8. ISO 9000 and total quality management
9. The drugs and cosmetics act 1940 – Deshpande, Nilesh Gandhi, 4th edition, Susmit Publishers, 2006.
10. QA Manual – D.H. Shah, 1st edition, Business Horizons, 2000.
11. Good Manufacturing Practices for Pharmaceuticals a plan for total quality control – Sidney H. Willig, Vol. 52, 3rd edition, Marcel Dekker Series.
12. Steinborn L. GMP/ISO Quality Audit Manual for Healthcare Manufacturers and Their Suppliers, Sixth Edition, (Volume 1 - With Checklists and Software Package). Taylor & Francis; 2003.
13. Sarker DK. Quality Systems and Controls for Pharmaceuticals. John Wiley & Sons; 2008.

MPA 204T-HERBAL AND COSMETIC ANALYSIS (Theory)

SCOPE

This course is designed to impart knowledge on analysis of herbal products.
Regulatory requirements, herbal drug interaction with monographs.
Performance evaluation of cosmetic products is included for the better understanding of the equipments used in cosmetic industries for the purpose.

OBJECTIVES

At completion of this course student shall be able to understand

- Determination of herbal remedies and regulations
- Analysis of natural products and monographs
- Determination of Herbal drug-drug interaction
- Principles of performance evaluation of cosmetic products.

THEORY **60 Hrs**

1 **Herbal remedies-** Toxicity and Regulations: Herbals vs Conventional drugs, Efficacy of herbal medicine products, Validation of Herbal Therapies, Pharmacodynamic and Pharmacokinetic issues. Herbal drug standardization: WHO and AYUSH guidelines.

2 **Adulteration and Deterioration:** Introduction, types of adulteration/substitution of herbal drugs, Causes and Measure of adulteration, Sampling Procedures, Determination of Foreign Matter, DNA Finger printing techniques in identification of drugs of natural origin, heavy metals, pesticide residues, phototoxin and microbial contamination in herbal formulations.
Regulatory requirements for setting herbal drug industry: Global marketing management, Indian and international patent law as applicable herbal drugs and natural products and its protocol.

3 **Testing of natural products and drugs**: Effect of herbal medicine on clinical laboratory testing, Adulterant Screening using modern analytical instruments, Regulation and dispensing of herbal drugs, Stability testing of natural products, protocol.
Monographs of Herbal drugs: Study of monographs of herbal drugs and comparative study in IP, USP, Ayurvedic Pharmacopoeia, American herbal Pharmacopoeia, British herbal Pharmacopoeia, Siddha and Unani Pharmacopoeia, WHO guidelines in quality assessment of herbal drugs.

4 **Herbal drug-drug interaction**: WHO and AYUSH guidelines for safety monitoring of natural medicine, Spontaneous reporting schemes for bio drug adverse reactions, bio drug-drug and bio drug-food interactions with suitable examples. Challenges in monitoring the safety of herbal medicines.

5 **Evaluation of cosmetic products**: Determination of acid value, ester value, saponification value, iodine value, peroxide value, rancidity, moisture, ash, volatile matter, heavy metals, fineness of powder, density, viscosity of cosmetic raw materials and finished products. Study of quality of raw materials and general methods of analysis of raw material used in cosmetic manufacture as per BIS.
Indian Standard specification laid down for sampling and testing of various cosmetics in finished forms such as baby care products, skin care products, dental products, personal hygiene preparations, lips sticks. Hair products and skin creams by the Bureau Indian Standards.

REFERENCES

1. Pharmacognosy by Trease and Evans
2. Pharmacognosy by Kokate, Purohit and Gokhale
3. Quality Control Methods for Medicinal Plant, WHO, Geneva
4. Pharmacognosy & Pharmacobiotechnology by Ashutosh Kar
5. Essential of Pharmacognosy by Dr.S.H.Ansari
6. Cosmetics – Formulation, Manufacturing and Quality Control, P.P. Sharma, 4th edition, Vandana Publications Pvt. Ltd., Delhi
7. Indian Standard specification, for raw materials, BIS, New Delhi.
8. Indian Standard specification for 28 finished cosmetics BIS, New Delhi
9. Harry's Cosmeticology 8th edition
10. Suppliers catalogue on specialized cosmetic excipients
11. Wilkinson, Moore, seventh edition, George Godwin. Poucher's Perfumes, Cosmetics and Soaps
12. Hilda Butler, 10th Edition, Kluwer Academic Publishers. Handbook of Cosmetic Science and Technology, 3rd Edition.

MPA 205P-PHARMACEUTICAL ANALYSIS PRACTICALS –II (Practicals)

1. Comparison of absorption spectra by UV and Wood ward – Fiesure rule
2. Interpretation of organic compounds by FT-IR
3. Interpretation of organic compounds by NMR
4. Interpretation of organic compounds by MS
5. Determination of purity by DSC in pharmaceuticals
6. Identification of organic compounds using FT-IR, NMR, CNMR and Mass spectra
7. Bio molecules separation utilizing various sample preparation techniques and Quantitative analysis of components by gel electrophoresis.
8. Bio molecules separation utilizing various sample preparation techniques and Quantitative analysis of components by HPLC techniques.
9. Isolation of analgesics from biological fluids (Blood serum and urine).
10. Protocol preparation and performance of analytical/Bioanalytical method validation.
11. Protocol preparation for the conduct of BA/BE studies according to guidelines.
12. In process and finished product quality control tests for tablets, capsules, parenterals and creams
13. Quality control tests for Primary and secondary packing materials
14. Assay of raw materials as per official monographs
15. Testing of related and foreign substances in drugs and raw materials
16. Preparation of Master Formula Record.
17. Preparation of Batch Manufacturing Record.
18. Quantitative analysis of rancidity in lipsticks and hair oil
19. Determination of aryl amine content and Developer in hair dye
20. Determination of foam height and SLS content of Shampoo.
21. Determination of total fatty matter in creams (Soap, skin and hair creams)
22. Determination of acid value and saponification value.
23. Determination of calcium thioglycolate in depilatories

DETAILS OF SUBJECT TEACHERS – semester I

S.No	Name of the Subject	Name of the Teachers	Designation and Department	Mobile No.	e-mail
1.	Modern Pharmaceutical Analytical Techniques (MPAT) - (T)	Dr. N. Krishnaveni (NKV)	Professor & Head	9442083447	krisath@jssuni.edu..in
2.	Food Analysis FA – (T)	Dr. S. N. Meyyanathan (SNM)	Professor	7010551923	snmeyyanathan@jssuni.edu..in
3.	Pharmaceutical Validation (PV) – (T)	Dr.M.R.Jeyaprakash (JP)	Asst. Professor	9952335392	Jpvis7@jssuni.edu.in
4.	Advanced Pharmaceutical Analysis (APA) – (T)	Mr. J. S. K. Nagarajan (JSK)	Asst. Professor	9443149945 8122131227(W)	Jsk.nagarajan@jssuni.edu..in

DETAILS OF SUBJECT TEACHERS – semester II

S.No	Name of the Subject	Name of the Teachers	Designation and Department	Mobile No.	e-mail
1	Advanced Instrumental Analysis (AIA) - (T)	Dr. N. Krishnaveni (NKV)	Professor & Head	9442083447	krisath@jssuni.edu..in
2	Herbal & Cosmetic Analysis (HCA) – (T)	Dr. S. N. Meyyanathan(SNM)	Professor	7010551923	snmeyyanathan@jssuni.edu..in
3	Quality Control & Quality Assurance (QCQA) – (T)	Dr. B. Babu (BB)	Lecturer	9840142319	babu@jssuni.edu.in
4	Modern Bioanalytical Techniques (MBT) – (T)	Mr. B. Babu(BB)	Lecturer	9840142319	babu@jssuni.edu.in

Academic Plan
2020-21

Name of the Subject	**Modern Pharmaceutical Analytical Techniques (Theory)**
Name of the Faculty	Dr. Krishna Veni N M.Pharm., Ph.D
Designation, Department	Professor & Head, Department of Pharmaceutical Analysis
Mobile Number	9442083447
e-Mail i.d.	krisath@jssuni.edu.in

Scope, Course Objectives and Course Outcomes

SCOPE

This subject deals with various advanced analytical instrumental techniques for identification, characterization and quantification of drugs. Instruments dealt are NMR, Mass spectrometer, IR, HPLC, GC etc

OBJECTIVES

After completion of course student is able to know about

1. Chemicals and excipients
2. The analysis of various drugs in single and combination dosage forms
3. Theoretical and practical skills of the instruments

COURSE OUTCOMES

At completion of this course it is expected that the students will be able to

CO 1 : Explain the general principles and techniques of spectroscopy & Chromatography

CO 2 : Perform the assay of single and multiple component pharmaceuticals using various analytical techniques

CO 3 : Develop skills in selecting suitable techniques for the analysis of drugs and pharamceutials

CO 4 : Apply the knowledge learnt in developing newer analytical methods and procedures of their own design

CO.5 : Explore and learn the various instrumental techniques available for the analysis of organic substances

LECTURE PLAN – Abstract

Sessional	No. of Hours of Didactic Lecture	No of Hours of other Activities	Total No. of Lecture Hours
	Advanced Instrumentation Techniques		
I	30	1	31
II	30	--	30
Total No. of Hours	60	--	61

I SESSIONAL : 30 Lectures + 1 Activity

Lecture No.	Lecture Details	Hours
	Orientation of the subject	**01**
Unit-1:		**10**
UV Visible Spectroscopy		
1.	UV Visible Spectroscopy - Introduction, Theory, Laws	
2.	Instrumentation associated with UV Visible Spectroscopy, Choice of Solvents & Solvent Effects	
3.	Applications of UV visible spectroscopy, Difference/ Derivative Spectroscopy	
IR Spectroscopy		
4.	IR Spectroscopy - Theory, Modes of Molecular Vibrations, Samples handling	
5.	Instrumentation of Dispersive and Fourier Transform IR spectrometere	
6.	Factors affecting vibrational frequencies and applications of IR spectroscopy, Data Interpretation	
Spectroflourimetry		
7.	Spectroflourimetry - Theory of fluorescence, Factors affecting fluorescence	
8.	Quenchers, Instrumentation, Applications of Fluorescence Spectrophotometer	
Flame emission spectroscopy & Atomic abosrption spectroscopy		
9.	Principle, Instrumentation	
10.	Interferences and Applications	
Unit-2:		**10**
NMR Spectroscopy		
11.	NMR spectroscopy - Quantum numbers and their role in NMR, Principle	
12.	Instrumentation - Continous wave NMR instrument	
13.	Principle and Instrumentation of FT NMR	
14.	solvent requirements, Relaxation process	
15.	NMR signals in various compounds	
16.	chemical shift, factors influencing chemical shift	
17.	spin spin coupling, coupling constant	

18.	Nuclear magnetic double resonance	
19.	Applications of NMR Spectroscopy	
20.	Principles of 13C NMR	
Unit-3:		
Mass Spectrometry		
21.	Principle, theory	
22.	Instrumentation of Mass Spectroscopy - sample introduction techniques	**10**
23.	Different types of ionization - electron impact, chemical	
24.	Different types of ionization - Field, FAB and MALDI	
25.	Different types of ionization - APCI, ESI, APPI	
26.	Analyzers of Quadrupole and Time of Flight	
27.	Mass fragmentation and its rules	
28.	Mass fragmentation and its rules	
29.	Meta stable ions, Isotopic peaks	
30.	Applications of Mass spectroscopy	

II SESSIONAL : 30 Lectures

Lecture No.	Lecture Details	Hours
Unit-4:		
Chromatography - Principle, Apparatus, Instrumentation, Chromatographic Parameters, Factors influencing resolution, Isolation of drugs from excipients, data interpretation and applications of		**10**
1.	Thin Layer Chromatography	
2.	High Performance Thin Layer Chromatography	
3.	Ion Exchange Chromatography	
4.	column Chromatography	
5.	Gas Chromatography	
6.	Gas Chromatography	
7.	HPLC	
8.	HPLC	
9.	Ultra high Performance Liquid Chromatography	
10.	Affinity Chromatography, Gel Chromatography	
Unit-5:		
Electrophoresis - Principle, Instrumentation, Working, Factors affecting separation and applications		
11.	Paper Electrophoresis	**10**
12.	Gel Electrophoresis, Zone Electrophoresis	
13.	Capillary Electrophoresis	
14.	Capillary Electrophoresis	
15.	Moving Boundray Electrophoresis	
16.	Iso Electric Focussing	
X Ray Crystallography		
17.	Production of X Rays, Braggs Law	
18.	Different X Ray diffraction methods - Rotating Crystal Technique	
19.	X Ray Powder technique, Types of Crystals	
20.	Applications of X Ray Diffractions	

Unit-6:		**10**
Potentiometry		
21.	Potentiometry - Principle, working	
22.	Ion selective Electrodes and other electrodes used in potentiometry	
23.	Applications of potentiometry	
Thermal Techniques		
24.	Differential Scanning Colorimetry - Principle, Thermal transitions	
25.	DSC - Instrumentation (Power compensated, heat flux designs),	
26.	Modulated DSC, Hyper DSC	
27.	Experimental Parameters - sample preparation, experimental conditions, calibration, heating and cooling rates, resolution, source of errors), Their influence, advantages, disadvantages and applications	
28.	Differential Thermal Analysis (DTA) - Principle instrumentation, Advantages & Disadvantages, Pharmaceutical Applications	
29.	Derivative Differential Thermal Analysis	
30.	Thermogravimetric Analysis (TGA) - Principle, instrumentation, factors affecting results, advantages & disadvantages, Pharmaceutical Applications	

TEXT BOOKS

1. Spectrometric Identification of Organic compounds - Robert M Silverstein, Sixth edition, John Wiley & Sons, 2004.
2. Principles of Instrumental Analysis - Doglas A Skoog, F. James Holler, Timothy A. Nieman, 5th edition, Eastern press, Bangalore, 1998.
3. Instrumental methods of analysis – Willards, 7th edition, CBS publishers.
4. Practical Pharmaceutical Chemistry – Beckett and Stenlake, Vol II, 4th edition, CBS Publishers, New Delhi, 1997.
5. Organic Spectroscopy - William Kemp, 3rd edition, ELBS, 1991.
6. Quantitative Analysis of Drugs in Pharmaceutical formulation - P D Sethi, 3rd Edition, CBS Publishers, New Delhi, 1997.
7. Pharmaceutical Analysis - Modern Methods – Part B - J W Munson, Vol 11, Marcel. Dekker Series
8. Spectroscopy of Organic Compounds, 2nd edn., P.S/Kalsi, Wiley estern Ltd., Delhi.
9. Textbook of Pharmaceutical Analysis, KA.Connors, 3rd Edition, John Wiley & Sons, 1982.

REFERENCE BOOKS

1. Introduction to Spectroscopy; by Donald L Pavia

Name of the Subject	**Advanced Pharmaceutical Analysis (Theory)**
Name of the Faculty	Dr. JSK Nagarajan M.Pharm., Ph.D
Designation, Department	Assistant Professor, Department of Pharmaceutical Analysis
Mobile Number	9443149945
e-Mail i.d.	Jsk.nagarajan@jssuni.edu.in

Scope, Course Objectives and Course Outcomes

SCOPE

This subject deals with the various aspects of Impurity, Impurities in new drug products, in residual solvents, Elemental impurities, Impurity profiling and characterization of degradents, Stability testing of phytopharmaceuticals and their protocol preparation. It also covers the biological testing of various vaccines and their principle and procedure.

OBJECTIVES

Upon completion of this course it is expected that students will be able to understand-
Upon completion of the subject student shall be able to

- Appropriate analytical skills required for the analytical method development.
- Principles of various reagents used in functional group analysis that renders necessary support in research methodology and demonstrates its application in the practical related problems.
- Analysis of impurities in drugs, residual solvents and stability studies of drugs and biological products

COURSE OUTCOMES

At completion of this course it is expected that the students will be able to underrstand
CO 1 : Importance of study of impurities and analysis of impurities in DS & DP
CO 2: To understand the stability studies of phytopharmaceuticals
CO 3: To understand the importance of analysis of vaccines
CO 4: To understand immunoassays

LECTURE PLAN – Abstract

Sessional	No. of Hours of Didactic Lecture	No of Hours of other Activities	Total No. of Lecture Hours
I	30	02	32
II	30	02	32
Total No. of Hours	60	04	64

I SESSIONAL : 31 Lectures + 2 Activities

Lecture No.	Lecture Details	Hours
Unit 1: Impurity and stability studies		**10**
1	Definition, classification of impurities in drug Substance or Active Pharmaceutical Ingredients	
2	Quantification of impurities as per ICH guidelines	
3	Impurities in new drug products: Rationale for the reporting and control of degradation products.	
4	Reporting degradation products content of batches,	
5	Reporting degradation products content of batches, Llisting of degradation products in specifications.	
6	Qualification of degradation products	
7	Qualification of degradation products	
8	**Impurities in residual solvents:** General principles, classification of residual solvents,	
9	Analytical procedures, limits of residual solvents.	
10	Reporting levels of residual solvents.	
11	Assignment 1	**01**
Unit 2: Elemental impurities:		**10**
1	Element classification, control of elemental impurities,	
2	Potential Sources of elemental Impurities, Identification of Potential Elemental Impurities.	
3	analytical procedures, instrumentation	
4	C, H, N and S analysis	
5	C, H, N and S analysis	
6	Selection of batches, container orientation, test parameters.	
7	Sampling frequency, specification, storage conditions, recording of results.	
8	Concept of stability, commitment etc.	
9	Important mechanistic and stability related information provided by results of study of factors like temperature, pH, buffering species ionic strength and dielectric constant etc. on the reaction rates.	
10	Important mechanistic and stability related information provided by results of study of factors like temperature, pH, buffering species ionic strength and dielectric constant etc. on the reaction rates.	

11	Assignment 2	
Unit 3: Impurity profiling and degradent characterization:		**10**
1	Method development, Stability studies and concepts of validation accelerated stability testing	
2	Method development, Stability studies and concepts of validation accelerated stability testing	
3	shelf life calculation	
4	WHO and ICH stability testing guidelines	
5	WHO and ICH stability testing guidelines	
6	WHO and ICH stability testing guidelines	
7	Stability zones, steps in development, practical considerations	
8	Basics of impurity profiling and degradent characterization with special emphasis	
9	Basics of impurity profiling and degradent characterization with special emphasis	
10	Photostability testing.	

II SESSIONAL : 30 Lectures + 2 Activities

Lecture No.	**Lecture Details**	**Hours**
Unit 4: Stability testing of phytopharmaceuticals: , /, interactions and complexity		
1	Regulatory requirements	**10**
2	Protocols	
3	Protocols	
4	HPTLC Finger printing	
5	HPTLC Finger printing	
6	HPLC finger printing	
7	HPLC finger printing	
8	HPLC finger printing	
9	Interactions and complexity	
10	Interactions and complexity	
11	Assignment	**01**
Unit 5: Biological tests and assays of the following		**10**
1	Adsorbed Tetanus vaccine	
2	Adsorbed Diphtheria vaccine	
3	Human anti haemophilic vaccine	
4	Rabies vaccine, Antivenom.	
5	Tetanus Anti toxin f. Tetanus Anti serum	
6	Oxytocin	
7	Heparin sodium	
8	PCR, PCR studies for gene regulation	
9	Instrumentation	
10	Iinstrumentation	
11	Assignment	
Unit 6: Immunoassays (IA)		**10**
1	Basic principles, Production of antibodies	
2	Separation of bound and unbound drug	

3	Radioimmunoassay	
4	Radioimmunoassay	
5	Optical IA	
6	Optical IA	
7	Enzyme IA,	
8	Fluoro IA, Luminiscence IA	
9	Quantification and applications of IA	
10	Quantification and applications of IA	

REFERENCES

1. Vogel's textbook of quantitative chemical analysis - Jeffery J Bassett, J. Mendham, R. C. Denney, 5th edition, ELBS, 1991.
2. Practical Pharmaceutical Chemistry - Beckett and Stenlake, Vol II, 4th Edition, CBS publishers, New Delhi, 1997.
3. Textbook of Pharmaceutical Analysis - K A Connors, 3rd Edition, John Wiley & Sons, 1982.
4. Pharmaceutical Analysis - Higuchi, Brochmman and Hassen, 2nd Edition, Wiley – Inter science Publication, 1961.
5. Quantitative Analysis of Drugs in Pharmaceutical formulation – P D Sethi, 3rd Edition, CBS Publishers New Delhi, 1997.
6. Pharmaceutical Analysis- Modern methods - J W Munson – Part B, Volume 11, Marcel Dekker Series.
7. The Quantitative analysis of Drugs - D C Carratt, 3rd edition, CBS Publishers, NewDelhi, 1964.
8. Indian Pharmacopoeia Vol I , II & III 2007, 2010, 2014.
9. Methods of sampling and microbiological examination of water, first revision, BIS
10. Practical HPLC method development – Snyder, Kirkland, Glajch, 2nd edition, John Wiley & Sons.
11. Analytical Profiles of drug substances – Klaus Florey, Volume 1 – 20, Elsevier, 2005
12. Analytical Profiles of drug substances and Excipients – Harry G Brittan, Volume 21 – 30, Elsevier,
    2005.
13. The analysis of drugs in biological fluids - Joseph Chamberlain, 2nd edition, CRC press, London.
14. ICH Guidelines for impurity profiles and stability studies.

Name of the Subject	**Pharmaceutical Validation (Theory)**
Name of the Faculty	Dr. Jeyaprakash MR M.Pharm., Ph.D
Designation, Department	Assistant Professor, Department of Pharm Analysis
Mobile Number	9952335392
e-Mail i.d.	jpvis7@jssuni.edu.in

Scope, Course Objectives and Course Outcomes

SCOPE

The main purpose of the subject is to understand about validation and how it can be applied to industry and thus to improve the quality of the products. The subject covers the complete information about validation, types, methodology and application.

OBJECTIVES

The primary objectives of this course are to

1. Explain the aspect of validation and different types of qualification and its need
2. Carryout validation of manufacturing processes and selection of equipments
3. Apply the knowledge of validation to instruments and equipments
4. Validate the manufacturing facilities

COURSE OUTCOMES

At completion of this course it is expected that the students will be able to

CO 1: Introduction to types of validation and qualifications

CO 2: Types of calibrations and different types of analytical instrument validations

CO 3: To understand the cleaning validation and protocol development.

CO 4: Procedure and protocol for analytical method and computer system

CO 5: Various types of Applications and significance of intellectual Property Rights in the Pharma industry

LECTURE PLAN – Abstract

Sessional	No. of Hours of Didactic Lecture	No of Hours of other Activities	Total No. of Lecture Hours
I	30	04	34
II	30	04	34
Total No. of Hours	60	08	68

I SESSIONAL : 31 Lectures + 2 Activities

Lecture No.	Lecture Details	Hours
Unit 1: Introduction to validation and Qualification		**12**
1	Definition of Qualification and Validation, Advantage of Validation	
2	Streamlining of Qualification & Validation process	
3	Validation Master Plan (VMP)	
4	Validation Master Plan (VMP)	
5	Qualification: User Requirement Specification	
6	Design Qualification URS	
7	Factory Acceptance Test (FAT)/ Site Acceptance Test (SAT)	
8	Installation Qualification, Operational Qualification and Performance Qualification	
9	Re- Qualification (Maintaining status-Calibration Preventive Maintenance	
10	Qualification of Manufacturing Equipments	
11	Qualification of analytical Instruments	
12	Qualification of analytical Instruments	
13	Assignment 1	**02**
Unit 2: Qualification of analytical instruments		**12**
1	Electronic balance	
2	pH Meter	
3	UV-Visible spectrophotometer	
4	UV-Visible spectrophotometer	
5	FTIR,	
6	HPLC	
7	HPLC	
8	GC	
9	GC	
10	HPTLC	
11	Qualification of Glassware: Volumetric flask, pipette, Measuring	
12	cylinder, beakers and burette	
13	Assignment 2	**02**
Unit 3: Validation of Utility systems and Cleaning Validation		**06**
1	Pharmaceutical Water System & pure steam	
2	Pharmaceutical Water System & pure steam	

3	HVAC system-Heat System	
4	HVAC system- Ventilation system	
5	HVAC system-Air Condition system	
6	Compressed air and nitrogen	

II SESSIONAL : 30 Lectures + 2 Activities

Lecture No.	Lecture Details	Hours
Unit 3: Validation of Utility systems and Cleaning Validation Cont..		**06**
1	Cleaning Validation - Cleaning Method development	
2	Validation of cleaning validation	
3	validation of analytical method used in cleaning	
4	Cleaning of Equipment	
5	Cleaning of Facilities	
6	Cleaning in place (CIP).	
	Assignment 3	**02**
Unit 4: Analytical method validation and Computer System Validation		**12**
1	General principles of ICH and USP	
2	Validation of analytical method	
3	Validation of analytical method	
4	Validation of analytical method	
5	Validation of analytical method	
6	Validation of analytical method	
7	Validation of analytical method	
8	Validation of analytical method	
9	Electronic records	
10	Electronic records	
11	digital significance-21 CFR part 11	
12	GAMP 5.	
Unit 5: General Principles of Intellectual Property		**12**
1	Concepts of Intellectual Property (IP), Intellectual Property Protection (IPP),and IPR	
2	Economic importance, mechanism for protection of Intellectual Property	
3	patents, Copyright, Trademark;	
4	Factors affecting choice of IP protection, Penalties for violation;	
5	Role of IP in pharmaceutical industry;Global ramification and financial implications	
6	Filing a patent applications; patent application forms and guidelines.	
7	Types patent applications-provisional and non-provisional, PCT and Convention	
8	International patenting requirement procedures and costs	
9	Rights and responsibilities of a patentee; Practical aspects regarding maintaining of a Patent file	
10	Patent infringement meaning and scope	
11	Significance of transfer of Technology (TOT)	
12	ethics non ethical -positive and negative aspects Societal responsibility,	

13	Assignment 4	**02**

REFERENCE BOOKS

1. B. T. Loftus & R. A. Nash, "Pharmaceutical Process Validation", Drugs and Pharm Sci. Series, Vol. 129, 3rd Ed., Marcel Dekker Inc., N.Y.
2. The Theory & Practice of Industrial Pharmacy, 3rd edition, Leon Lachman, Herbert A. Lieberman, Joseph. L. Karig, Varghese Publishing House, Bombay.
3. Validation Master plan by Terveeks or Deeks, Davis Harwood International publishing.
4. Validation of Aseptic Pharmaceutical Processes, 2nd Edition, by Carleton & Agalloco, (Marcel Dekker).
5. Michael Levin, Pharmaceutical Process Scale-Up‖, Drugs and Pharm. Sci. Series, Vol. 157,2nd Ed., Marcel Dekker Inc., N.Y.
6. Validation Standard Operating Procedures: A Step by Step Guide for Achieving Compliance in the Pharmaceutical, Medical Device, and Biotech Industries, Syed Imtiaz Haider
7. Pharmaceutical Equipment Validation: The Ultimate Qualification Handbook, Phillip A. Cloud, Interpharm Press
8. Validation of Pharmaceutical Processes: Sterile Products, Frederick J. Carlton (Ed.) and James Agalloco (Ed.), Marcel Dekker, 2nd Ed.
9. Analytical Method validation and Instrument Performance Verification by Churg Chan, Heiman Lam, Y.C. Lee, Yue. Zhang, Wiley Inter Science.

Name of the Subject	**Food Analysis (Theory)**
Name of the Faculty	Dr. Meyyanathan SN, M.Pharm., Ph.D
Designation, Department	Professor, Department of Pharmaceutical Analysis
Mobile Number	7010551923
e-Mail i.d.	snmeyyanathan@jssuni.edu.in

Scope, Course Objectives and Course Outcomes

SCOPE

This course is designed to impart knowledge on analysis of food constituents and finished food products. The course includes application of instrumental analysis in the determination of pesticides in variety of food products.

OBJECTIVES

The primary objectives of this course are to

1. understand the food constituents, food additives, pesticides in food and finished food products
2. perform quantitative & qualitative analysis of drugs using various analytical instruments.

COURSE OUTCOMES

At completion of this course it is expected that the students will be able to

CO 1: know the instrumental techniques used in food analysis

CO 2: analyse the raw materials and food products by various analytical instruments

LECTURE PLAN - Theory

Sessional	Total Number of Lecture Hours
I	24
II	36
Total Number of Lecture Hours	60

I SESSIONAL : 24 Lectures

Lecture No.	Lecture Details	Hours
Unit-1:		**12**
1.	Carbohydrates: classification and properties of food carbohydrates	
2.	General methods of analysis of food carbohydrates	
3.	Changes in food carbohydrates during processing	
4.	Digestion, absorption and metabolism of carbohydrates	
5.	Dietary fibre, Crude fibre	
6.	Application of food carbohydrates	
7.	Proteins: Chemistry and classification of amino acids and proteins	
8.	Physico-Chemical properties of protein and their structure	
9.	General methods of analysis of proteins and amino acids	
10.	General methods of analysis of proteins and amino acids	
11.	Digestion, absorption and metabolism of proteins	
12.	Digestion, absorption and metabolism of proteins	
Unit-2:		**12**
13.	Lipids: Classification, general methods of analysis	
14.	Refining of fats and oils	
15.	Determination of adulteration in fats and oils	
16.	Various methods used for measurement of spoilage of fats and fatty foods	
17.	Various methods used for measurement of spoilage of fats and fatty foods	
18.	Various methods used for measurement of spoilage of fats and fatty foods	
19.	Hydrogenation of vegetable oils	
20.	Hydrogenation of vegetable oils	
21.	Vitamins: classification of vitamins	
22.	Methods of analysis of vitamins	
23.	Methods of analysis of vitamins	
24.	Principles of microbial assay of vitamins of B-series	

II SESSIONAL : 36 Lectures

Lecture No.	Lecture Details	Hours
Unit-3:		**12**
25.	Food additives: Introduction	
26.	Analysis of Preservatives	
27.	Antioxidants	
28.	Artificial sweeteners	
29.	Flavors, flavor enhancers	
30.	Stabilizers, thickening and jelling agents	
31.	Pigments and synthetic dyes: Natural pigments	
32.	Their occurrence and characteristic properties	
33.	Permitted synthetic dyes	
34.	Non-permitted synthetic dyes used by industries	
35.	Method of detection of natural, permitted and non-permitted dyes	
36.	Method of detection of natural, permitted and non-permitted dyes	
Unit-4:		**12**
37.	General Analytical methods for milk, milk constituents and, milk powder	
38.	Milk constituents	
39.	Milk products like ice cream	
40.	Butter	
41.	Margarine, Cheese	
42.	Adulterants and contaminants of milk	
43.	Analysis of fermentation products like wine	
44.	Spirits	
45.	Spirits	
46.	Spirits	
47.	Beer	
48.	Vinegar	
Lecture No.	**Lecture Details**	**Hours**
Unit-5:		**12**
49.	Pesticide analysis: Effects of pest and insects on various food, , pesticide cycle	
50.	Use of pesticides in agriculture	
51.	Organophosphorus and organochlorine pesticides analysis	
52.	Organophosphorus and organochlorine pesticides analysis	
53.	Determination of pesticide residues in grain, fruits, vegetables, milk and milk products	
54.	Determination of pesticide residues in grain, fruits, vegetables, milk and milk products	
55.	Legislation regulations of food products with special emphasis on BIS	
56.	Agmark	

57.	Agmark	
58.	Agmark	
59.	FDA and US-FDA	
60.	FDA and US-FDA	

TEXT BOOKS

1. The chemical analysis of foods – David Pearson, Seventh edition, Churchill Livingstone, Edinburgh London, 1976
2. Introduction to the Chemical analysis of foods – S. Nielsen, Jones & Bartlett publishers, Boston London, 1994.

REFERENCE BOOKS

1. Official methods of analysis of AOAC International, sixth edition, Volume I & II, 1997.
2. Analysis of Food constituents – Multon, Wiley VCH
3. Dr. William Horwitz, Official methods of analysis of AOAC International, 18th edition, 2005

II SEMESTER

Name of the Subject	**Advanced Instrumenal Analysis (Theory)**
Name of the Faculty	Dr. Krishna Veni N M.Pharm., Ph.D
Designation, Department	Professor & Head, Department of Pharmaceutical Analysis
Mobile Number	9442083447
e-Mail i.d.	krisath@jssuni.edu.in

Scope, Course Objectives and Course Outcomes

SCOPE

This subject deals with various hyphenated analytical instrumental techniques for identification, characterization and quantification of drugs, Instruments delat are LC-MS, GC-MS and Hyphenated Techniques.

OBJECTIVES

Upon completion of the course the student shall be able to know,

1. Interpretation of the NMR, Mass and IR spectra of various organic compounds
2. Theoretical and Practical skills of the hyphenated instruments.
3. Identification of organic compounds.

COURSE OUTCOMES

At completion of this course it is expected that the students will be able to

CO 1: Critically interpret and solve the problems faced during analytical method development.

CO 2: Learn the practical aspects of trouple shooting during HPLC & GC analytical method development.

CO 3: Select the mode of separation, stationary phase and mobile phase for pharmaceutical compounds.

CO 4: Interpret and determine the structure of organic compounds using IR, NMR and Mass spectras.

CO 5: Apply the knowledge gained on hyphenated analytical techniques in quantitave and qualitative analysis of pharmaceuticals.

LECTURE PLAN – Abstract

Sessional	No. of Hours of Didactic Lecture	No of Hours of other Activities	Total No. of Lecture Hours
	Advanced Instrumentation Techniques		
I	30	1	31
II	30	--	30
Total No. of Hours	60	--	61

I SESSIONAL : 30 Lectures + 1 Activity

Lecture No.	Lecture Details	Hours
	Orientation of the subject	**01**
Unit-1:		**12**
HPLC		
1.	Principle, instrumentation	
2.	pumps, injector, detectors	
3.	pharmaceutical applications,	
4.	peak shapes, capacity factor, selectivity, plate number,	
5.	plate height, resolution, band broadening,	
6.	Column problems, gradient HPLC, HPLC solvents, trouble shooting, sample preparation	
7.	Method development	
8.	HPLC role and principles of ultra, nano liquid chromatography	
9.	Immobilized polysaccharide CSP's: Advancement in enantiomeric separations, RP chiral method development, HPLC in chiral analysis of pharmaceuticals	
10.	HILIC approaches	
11.	Preparative HPLC	
12.	Practical aspects of preparative HPLC	
Unit-2:		**12**
Biochromatography – General Principles, Stationary Phases and Mobile Phases of		
13.	Size Exclusion Chromatography	
14.	Size Exclusion Chromatography (cont…)	
15.	Ion Exchange Chromatography	
16.	Ion Pair Chromatography	
17.	Ion Pair Chromatography (cont…)	
18.	Affinity Chromatography	
Gas Chromatography		
19.	Principles	
20.	Instrumentation – Head space sampling, Columns for GC	
21.	Instrumentation – Detectors	
22.	Derivatization and Quantification	
High Performance Thin Layer Chromatography		

23.	Principles, Instrumentation	
24.	Instrumentation (cont…), Applications	
Unit-3:		
Super Critical Fluid Chromatography		
25.	Principle	**06**
26.	Instrumentation	
27.	Instrumentation (cont…)	
28.	Pharmaceutical Applications	
Capillary Electrophoresis		
29.	Overview of Capillary Electrophoresis in Pharmaceutical Analysis	
30.	Basic Configuration	

II SESSIONAL : 30 Lectures

Lecture No.	Lecture Details	Hours
Unit-3:		
Capillary Electrophoresis		
1.	CE Characteristics, Principles of CE	
2.	Methods and Modes of CE – Iso Electric Focussing, Gel Capillary Electrophoresis, Zone Capillary Electrophoresis	
3.	Methods and Modes of CE – Isotachophoresis, Micellar Electrokinetic Electrophoresis	**06**
4.	General considerations and Method Development in CE	
5.	Crown Ethers as buffer additives in Capillary Electrophoresis	
6.	CE-MS Hyphenation	
Unit-4:		
Mass Spectrometry		
7.	Principle & Theory	
8.	Instrumentation – Ionization Techniques – Electron Impact, Chemical, Field, FAB, MALDI	**12**
9.	Ionization Techniques – APCI, ESI, APPI	
10.	Mass Analyzers – Quadrpole, Time of Flight, FT-ICR	
11.	Mass Analyzers – Ion Trap, Orbitrap	
12.	Mass Fragmentation and Its rules, Metastable ions, Isotopic peaks	
13.	Applications of Mass Spectrometery	
14.	Applications of Mass Spectrometery – Interpretation of Mass Spectra	
15.	DART – MS Analysis	
16.	LC-MS Hyphenation	
17.	MS/MS Systems – Tandem: QqQ, TOF-TOF, Q-IT	
18.	MS/MS Systems – Tandem: LTQ-FT, Q-TOF, LTQ-Orbitrap	
Unit-5:		
NMR Spectroscopy		
19.	Quantum number and their Role in NMR	
20.	Principle, Solvent Requirements in NMR	**12**
21.	Instrumentation – CW instrument, FT NMR	

22.	Relaxation process – Spin spin Relaxation and Spin Lattice Relaxation process	
23.	Chemical Shift, Factors Influencing Chemical Shift	
24.	Spin Spin Coupling, Coupling Constant	
25.	NMR Signal of various compounds, Interpretation of NMR Spectra	
26.	Applications of NMR Spectroscopy	
27.	13 C NMR	
28.	Nuclear Magnetic Double Resonance	
29.	1-D and 2-D NMR, NOESY and COSY Techniques	
30.	LC-NMR Hyphenation	

TEXT BOOKS

1. Spectrometric Identification of Organic compounds - Robert M Silverstein, Sixth edition, John Wiley & Sons, 2004.
2. Principles of Instrumental Analysis - Doglas A Skoog, F. James Holler, Timothy A. Nieman, 5th edition, Eastern press, Bangalore, 1998.
3. Instrumental methods of analysis – Willards, 7th edition, CBS publishers.
4. Organic Spectroscopy - William Kemp, 3rd edition, ELBS, 1991.
5. Quantitative analysis of Pharmaceutical formulations by HPTLC - P D Sethi, CBS Publishers, New Delhi.
6. Quantitative Analysis of Drugs in Pharmaceutical formulation - P D Sethi, 3rd Edition, CBS Publishers, New Delhi, 1997.
7. Pharmaceutical Analysis- Modern methods – Part B - J W Munson, Volume 11, Marcel Dekker Series.
8. Introduction to Spectroscopy by Donald L. Paviya, 5th Edition.

REFERENCE BOOKS

1. Practical HPLC Method Development; by Lloyd R Snyder, Joseph J Kirkland, Joseph L Glajch.

Name of the Subject	**Modern Bio Analytical Techniques (Theory)**
Name of the Faculty	Dr. B. Babu M.Pharm., Ph.D
Designation, Department	Lecturer, Department of Pharmaceutical Analysis
Mobile Number	9840142319
e-Mail i.d.	babu@jssuni.edu.in

Scope, Course Objectives and Course Outcomes

SCOPE

This subject is designed to provide detailed knowledge about the importance of analysis of drugs in biological matrices.

OBJECTIVES

The primary objectives of this course are to

- Extraction of drugs from biological samples
- Separation of drugs from biological samples using different techniques
- Guidelines for BA/BE studies.

COURSE OUTCOMES

At completion of this course it is expected that the students will be able to

CO 1 : Determine the various biological media and its application in biological sample measurement.

CO 2 : Critically analyse ans selection of the biological matrices for determination.

CO 3 : The various methodology adopted for the extraction of druges from the various biological medias.

CO 4 : The guidelines which govern and approve the methodology.

CO 5 : The concept of carring the clinical study and parameters to determine for quantification.

CO 6 : The importance of various sphositicated techniques adopted for mesurment of these various biological samples.

LECTURE PLAN – Abstract

Sessional	No. of Hours Lecture	No of Hours of other Activities	Total No. of Lecture Hours
	Pharmaceutical Analysis		
I	30	-	30
II	30	-	30
Total No. of Hours	60	-	60

I SESSIONAL : 30 Lectures

Lecture No.	Lecture Details	Hours
MODERN BIO ANALYTICAL TECHNIQUES		**(60)**
Unit-1: Extraction of drugs and metabolites from biological matrices:		**12**
	Orientation to the subject	
1.	Introduction to extraction of drugs and metabolites from biological matrices	
2.	Introduction to extraction of drugs and metabolites from biological matrices	
3.	General need, principle and procedure involved in the biological analysis	
4.	General need, principle and procedure involved in the biological analysis	
5.	Bioanalytical methods such as Protein precipitation	
6.	Bioanalytical methods Liquid - Liquid extraction	
7.	Bioanalytical methods Liquid - Liquid extraction	
8.	Solid phase extraction and other novel sample preparation approach.	
9.	Solid phase extraction and other novel sample preparation approach.	
10.	Bioanalytical method validation: USFDA guidelines	
11.	Bioanalytical method validation: USFDA guidelines	
12.	Bioanalytical method validation:EMEA guidelines	
Unit-2: Biopharmaceutical Consideration		**12**
13.	Biopharmaceutical Consideration Introduction	
14.	Biopharmaceutical Consideration Introduction	
15.	Biopharmaceutical Factors Affecting Drug Bioavailability	
16.	Biopharmaceutical Factors Affecting Drug Bioavailability	
17.	In Vitro: Dissolution and Drug Release Testing	
18.	In Vitro: Dissolution and Drug Release Testing	
19.	Alternative Methods of Dissolution Testing Transport models	
20.	Biopharmaceutics Classification System	
21.	Solubility: Experimental methods	
22.	Solubility: Experimental methods	
23.	Permeability: In-vitro, in-situ and In-vivo methods	
24.	Permeability: In-vitro, in-situ and In-vivo methods	

Unit-3: Pharmacokinetics and Toxicokinetics		
25.	Basic consideration, Drug interaction (PK-PD interactions)	
26.	Basic consideration, Drug interaction (PK-PD interactions)	
27.	The effect of protein-binding interactions	**06**
28.	The effect of tissue-binding interactions	
29.	Cytochrome P450-based drug interactions	
30.	Cytochrome P450-based drug interactions	

II SESSIONAL : 30 Lectures

Lecture No.	Lecture Details	Hours
Unit-3: Pharmacokinetics and Toxicokinetics		
1.	Drug interactions linked to transporters	
2.	Microsomal assays toxicokinetics-Toxicokinetic evaluation in preclinical studies	
3.	Microsomal assays toxicokinetics-Toxicokinetic evaluation in preclinical studies	
4.	Importance and applications of toxicokinetic studies	**06**
5.	Importance and applications of toxicokinetic studies	
6.	LC-MS in bioactivity screening and proteomics	
Unit-4: Cell culture techniques		
7.	Introduction to cell culture techniques	
8.	Basic equipments used in cell culture lab	
9.	Cell culture media various types of cell culture	**12**
10.	Cell culture media various types of cell culture	
11.	General procedure for cell cultures	
12.	General procedure for cell cultures	
13.	Isolation of cells, subculture, cryopreservation	
14.	Characterization of cells and their applications	
15.	Principles and applications of cell viability assays (MTT assays)	
16.	Principles and applications of cell viability assays (MTT assays)	
17.	Principles and applications of flow cytometry	
18.	Principles and applications of flow cytometry	
Unit-5: Metabolite identification		
19.	In-vitro / in-vivo approaches	
20.	Protocols and sample preparation	
21.	Microsomal approaches (Rat liver microsomes (RLM)	**12**
22.	Human liver microsomes (HLM) in Met –ID	
23.	Regulatory perspectives, In-vitro assay of drug metabolites & drug metabolizing enzymes	
24.	Drug Product Performance, In Vivo: Bioavailability and Bioequivalence	
25.	Drug Product Performance, Purpose of Bioavailability Studies Relative and Absolute Availability	
26.	Methods for Assessing Bioavailability, Bioequivalence Studies	
27.	Design and Evaluation of Bioequivalence Studies	
28.	Study Designs, Crossover Study Designs	
29.	Generic Biologics (Biosimilar Drug Products)	

30.	Clinical Significance of Bioequivalence Studies	

REFERENCE BOOKS

1. Analysis of drugs in Biological fluids - Joseph Chamberlain, 2nd Edition.CRC Press, Newyork. 1995.
2. Principles of Instrumental Analysis - Doglas A Skoog, F. James Holler,Timothy A. Nieman, 5th edition, Eastern press, Bangalore, 1998.
3. Pharmaceutical Analysis - Higuchi, Brochmman and Hassen, 2nd Edition,Wiley – Interscience Publications, 1961.
4. Pharmaceutical Analysis- Modern methods – Part B - J W Munson,Volume 11, Marcel Dekker Series
5. Practical HPLC method Development – Snyder, Kirkland, Glaich, 2nd Edition, John Wiley & Sons, New Jercy. USA.
6. Chromatographic Analysis of Pharmaceuticals – John A Adamovics, 2nd Edition, Marcel Dekker, Newyork, USA. 1997.
7. Chromatographic methods in clinical chemistry & Toxicology – Roger L Bertholf, Ruth E Winecker, John Wiley & Sons, New Jercy, USA. 2007.
8. Good Laboratory Practice Regulations, 2nd Edition, Sandy Weinberg Vol. 69, Marcel Dekker Series, 1995.
9. Good laboratory Practice Regulations – Allen F. Hirsch, Volume 38, Marcel Dekker Series, 1989.
10. ICH, USFDA & CDSCO Guidelines.
11. Palmer

Name of the Subject	**Quality Control And Quality Assurance (Theory)**
Name of the Faculty	Dr. B. Babu M.Pharm., Ph.D
Designation, Department	Lecturer, Department of Pharmaceutical Analysis
Mobile Number	9840142319
e-Mail i.d.	babu@jssuni.edu.in

Scope, Course Objectives and Course Outcomes

SCOPE

This course deals with the various aspects of quality control and quality assurance aspects of pharmaceutical industries. It covers the important aspects like cGMP, QC tests, documentation, quality certifications, GLP and regulatory affairs.

OBJECTIVES

The primary objectives of this course are to

1. The cGMP aspects in a pharmaceutical industry
2. To appreciate the importance of documentation
3. To understand the scope of quality certifications applicable to Pharmaceutical industries
4. To understand the responsibilities of QA & QC departments

COURSE OUTCOMES

At completion of this course it is expected that the students will be able to

CO 1:Define the basic concepts of good practices in corporated in manufacturing of pharmaceuticals.

CO 2:The various factors which affect the quality of pharmaceuticals.

CO 3:The critical parameters which are govering the quality of the pharmaceuticals.

CO 4:To under stand the various parameters performed for qualifying the drug substances and products.

CO 5: To define the responsibility of the quality assurance and control and various key personals in the drug industry.

LECTURE PLAN – Abstract

Sessional	No. of Hours Lecture	No of Hours of other Activities	Total No. of Lecture Hours
	Pharmaceutical Analysis		
I	30	-	30
II	30	-	30
Total No. of Hours	60	-	60

I SESSIONAL : 30 Lectures

Lecture No.	Lecture Details	Hours
QUALITY CONTROL AND QUALITY ASSURANCE		**(60)**
Unit-1: Concept and Evolution of Quality Control and Quality Assurance		**12**
	Orientation to the subject	
1.	Introduction Quality Control and Quality Assurance	
2.	Good Laboratory Practice	
3.	Good Laboratory Practice	
4.	Good Manufacturing Practice	
5.	Overview of ICH guidelines	
6.	QSEM, with special emphasis on Q-series guidelines	
7.	QSEM, with special emphasis on Q-series guidelines	
8.	Good Laboratory Practices: Scope of GLP, Definitions	
9.	Quality assurance unit	
10.	Protocol for conduct of non clinical testing	
11.	Control on animal house	
12.	Report preparation and documentation	
Unit-2: cGMP guidelines according to schedule M		**12**
13.	Introduction to cGMP guidelines according to schedule M	
14.	cGMP guidelines according to USFDA CDER and CBER	
15.	Pharmaceutical Inspection Convention	
16.	PIC covering WHO and EMEA	
17.	Organization and personnel responsibilities	
18.	Training, hygiene and personal records	
19.	Drug industry location	
20.	Design, construction and plant lay out	
21.	Maintenance, sanitation, environmental control	
22.	Utilities and maintenance of sterile areas	
23.	Control of contamination and Good Warehousing practice	
24.	CPCSEA guidelines	
Unit-3: Analysis of raw materials		**06**
25.	Analysis of raw materials	
26.	Analysis of Finished products , packaging materials	
27.	In process quality control (IPQC), Developing specification (ICH Q6 and Q3)	

28.	Purchase specifications and maintenance of stores for raw materials	
29.	In process quality control and finished products	
30.	Quality control for following formulation in Pharma industry according to Indian, US and British pharmacopoeias	

II SESSIONAL : 30 Lectures

Lecture No.	Lecture Details	Hours
Unit-3: Analysis of raw materials		**06**
1.	Tablets, Capsules, Ointments, suppositories	
2.	Creams, parenterals, ophthalmic and surgical products (How to refer pharmacopoeias)	
3.	Creams, parenterals, ophthalmic and surgical products (How to refer pharmacopoeias)	
4.	Quality control test for containers, closures	
5.	Quality control test for containers, closures	
6.	Quality control test for secondary packing materials	
Unit-4: Documentation in pharmaceutical industry		**12**
7.	Introduction to documentation in pharmaceutical industry	
8.	Three tier documentation	
9.	Three tier documentation	
10.	Policy, Procedures and Work instructions and records (Formats)	
11.	Basic principles- How to maintain, retention and retrieval etc	
12.	Standard operating procedures (How to write)	
13.	Master Formula Record	
14.	Batch Formula Record	
15.	Quality audit plan and reports	
16.	Specification and test procedures, Protocols and reports	
17.	Distribution records.	
18.	Electronic data	
Unit-5: Manufacturing operations and controls		**12**
19.	Sanitation of manufacturing premises	
20.	Mix-ups and cross contamination	
21.	Processing of intermediates and bulk products	
22.	Packaging operations	
23.	IPQC,	
24.	IPQC, release of finished product	
25.	Process deviations, charge-in of components	
26.	Time limitations on production	
27.	Drug product inspection, expiry date calculation of yields	
28.	Production record review, change control	
29.	Sterile products, aseptic process control packaging	
30.	Sterile products, aseptic process control packaging	

REFERENCE BOOKS

1. Quality Assurance Guide by organization of Pharmaceutical Procedures of India, 3rd revised edition, Volume I & II, Mumbai, 1996.

2. Good Laboratory Practice Regulations, 2nd Edition, Sandy Weinberg Vol. 69, Marcel Dekker Series, 1995.
3. Quality Assurance of Pharmaceuticals- A compedium of Guide lines and Related materials Vol I & II, 2nd edition, WHO Publications, 1999.
4. How to Practice GMP's – P P Sharma, Vandana Publications, Agra, 1991.
5. The International Pharmacopoeia – vol I, II, III, IV & V - General Methods of Analysis and Quality specification for Pharmaceutical Substances, Excepients and Dosage forms, 3rd edition, WHO, Geneva, 2005.
6. Good laboratory Practice Regulations – Allen F. Hirsch, Volume 38, Marcel Dekker Series, 1989.
7. ICH guidelines
8. ISO 9000 and total quality management
9. The drugs and cosmetics act 1940 – Deshpande, Nilesh Gandhi, 4th edition, Susmit Publishers, 2006.
10. QA Manual – D.H. Shah, 1st edition, Business Horizons, 2000.
11. Good Manufacturing Practices for Pharmaceuticals a plan for total quality control – Sidney H. Willig, Vol. 52, 3rd edition, Marcel Dekker Series.
12. Steinborn L. GMP/ISO Quality Audit Manual for Healthcare Manufacturers and Their Suppliers, Sixth Edition, (Volume 1 - With Checklists and Software Package). Taylor & Francis; 2003.
13. Sarker DK. Quality Systems and Controls for Pharmaceuticals. John Wiley & Sons; 2008.

Name of the Subject	**Herbal and Cosmetic Analysis (Theory)**
Name of the Faculty	Dr. Meyyanathan SN, M.Pharm., Ph.D
Designation, Department	Professor, Department of Pharmaceutical Analysis
Mobile Number	7010551923
e-Mail i.d.	snmeyyanathan@jssuni.edu.in

Scope, Course Objectives and Course Outcomes

SCOPE

This course is designed to impart knowledge on analysis of herbal products. Regulatory requirements, herbal drug interaction with monographs. Performance evaluation of cosmetic products is included for the better understanding of the equipments used in cosmetic industries for the purpose.

OBJECTIVES

The primary objectives of this course are to

- understand the herbal remedies, herbal drug-drug interaction, monograph and regulations
- perform quantitative & qualitative analysis of cosmetics using various analytical instruments.

COURSE OUTCOMES

At completion of this course it is expected that the students will be able to

CO 1: know the instrumental techniques used in herbal and cosmetic analysis

CO 2: analyse the raw materials, herbal and cosmetic products by various analytical instruments

LECTURE PLAN - Theory

Sessional	Total Number of Lecture Hours
I	24
II	36
Total Number of Lecture Hours	60

I SESSIONAL : 24 Lectures

Lecture No.	Lecture Details	Hours
Unit-1:		**12**
1.	Herbal remedies - Toxicity and Regulations	
2.	Herbals vs Conventional drugs	
3.	Efficacy of herbal medicine products	
4.	Validation of Herbal Therapies	
5.	Validation of Herbal Therapies	
6.	Validation of Herbal Therapies	
7.	Pharmacodynamic and Pharmacokinetic issues	
8.	Pharmacodynamic and Pharmacokinetic issues	
9.	Pharmacodynamic and Pharmacokinetic issues	
10.	Herbal drug standardization: WHO and AYUSH guidelines	
11.	Herbal drug standardization: WHO and AYUSH guidelines	
12.	Herbal drug standardization: WHO and AYUSH guidelines	
Unit-2:		**12**
13.	Adulteration and Deterioration: Introduction, types of adulteration/substitution of herbal drugs	
14.	Causes and Measure of adulteration	
15.	Sampling Procedures, Determination of Foreign Matter	
16.	DNA Finger printing techniques in identification of drugs of natural origin	
17.	Heavy metals, pesticide residues	
18.	Phototoxin and microbial contamination in herbal formulations	
19.	Regulatory requirements for setting herbal drug industry: Global marketing management	
20.	Regulatory requirements for setting herbal drug industry: Global marketing management	
21.	Regulatory requirements for setting herbal drug industry: Global marketing management	
22.	Indian and international patent law as applicable herbal drugs and natural products and its protocol	
23.	Indian and international patent law as applicable herbal drugs and natural products and its protocol	
24.	Indian and international patent law as applicable herbal drugs and natural products and its protocol	

II SESSIONAL : 36 Lectures

Lecture No.	Lecture Details	Hours
Unit-3:		**12**
25.	Food additives: Introduction Testing of natural products and drugs	
26.	Effect of herbal medicine on clinical laboratory testing	
27.	Adulterant Screening using modern analytical instruments	
28.	Regulation and dispensing of herbal drugs	
29.	Stability testing of natural products	
30.	Protocol	
31.	Monographs of Herbal drugs: Study of monographs of herbal drugs and comparative study in IP, USP	
32.	Ayurvedic Pharmacopoeia	
33.	American herbal Pharmacopoeia	
34.	British herbal Pharmacopoeia	
35.	Siddha and Unani Pharmacopoeia	
36.	WHO guidelines in quality assessment of herbal drugs	
Unit-4:		**12**
37.	Herbal drug-drug interaction: WHO and AYUSH guidelines for safety monitoring of natural medicine	
38.	Herbal drug-drug interaction: WHO and AYUSH guidelines for safety monitoring of natural medicine	
39.	Herbal drug-drug interaction: WHO and AYUSH guidelines for safety monitoring of natural medicine	
40.	Herbal drug-drug interaction: WHO and AYUSH guidelines for safety monitoring of natural medicine	
41.	Spontaneous reporting schemes for bio drug adverse reactions	
42.	Spontaneous reporting schemes for bio drug adverse reactions	
43.	Spontaneous reporting schemes for bio drug adverse reactions	
44.	Bio drug-drug and bio drug-food interactions with suitable examples	
45.	Bio drug-drug and bio drug-food interactions with suitable examples	
46.	Bio drug-drug and bio drug-food interactions with suitable examples	
47.	Challenges in monitoring the safety of herbal medicines	
48.	Challenges in monitoring the safety of herbal medicines	

Lecture No.	Lecture Details	Hours
Unit-5:		**12**
49.	Evaluation of cosmetic products: Determination of acid value, ester value, saponification value, iodine value	
50.	Peroxide value, rancidity, moisture, ash, volatile matter	
51.	Heavy metals, fineness of powder, density, viscosity of cosmetic raw materials and finished products	
52.	Heavy metals, fineness of powder, density, viscosity of cosmetic raw materials and finished products	
53.	Study of quality of raw materials and general methods of analysis of raw material used in cosmetic manufacture as per BIS	
54.	Study of quality of raw materials and general methods of analysis of raw material used in cosmetic manufacture as per BIS	
55.	Indian Standard specification laid down for sampling and testing of various cosmetics in finished forms such as baby care products	
56.	Indian Standard specification laid down for sampling and testing of various cosmetics in finished forms such as baby care products	
57.	Indian Standard specification laid down for sampling and testing of various cosmetics in finished forms such as baby care products	
58.	Skin care products, Dental products	
59.	Personal hygiene preparations, lips sticks	
60.	Hair products and skin creams by the Bureau Indian Standards	

TEXT BOOKS

1. Pharmacognosy by Trease and Evans
2. Pharmacognosy by Kokate, Purohit and Gokhale
3. Quality Control Methods for Medicinal Plant, WHO, Geneva
4. Pharmacognosy & Pharmacobiotechnology by Ashutosh Kar
5. Essential of Pharmacognosy by Dr.S.H.Ansari
6. Cosmetics – Formulation, Manufacturing and Quality Control, P.P. Sharma, 4th edition, Vandana Publications Pvt. Ltd., Delhi

REFERENCE BOOKS

1. Indian Standard specification, for raw materials, BIS, New Delhi.
2. Indian Standard specification for 28 finished cosmetics BIS, New Delhi
3. Harry's Cosmeticology 8th edition
4. Suppliers catalogue on specialized cosmetic excipients
5. Wilkinson, Moore, seventh edition, George Godwin. Poucher's Perfumes, Cosmetics and Soaps
6. Hilda Butler, 10th Edition, Kluwer Academic Publishers. Handbook of Cosmetic Science and Technology, 3rd Edition.

JSS Academy of Higher Education & Research, Mysuru
JSS College of Pharmacy, Rocklands, Ooty
I M. PHARMACY TIME TABLE FOR E-LEARN CLASSES : I Semester (AY : 2020 - 2021)
DEPARTMENT : PHARMACEUTICAL ANALYSIS
COURSE : PHARMACEUTICAL ANALYSIS

1.

ZOOM / GOOGLE MEET LICENSE - cpoana2@jssuni.edu.in

Days	9 - 10 am	10 - 11 am	11 - 12 am	12 - 1 pm	1 - 2 pm	2 - 3 pm	3 - 4 pm	4 - 5 pm
Mon	--	MPAT ***(NKV)***	APA **(JSK)**	PV **(JP)**	**LUNCH BREAK**	**SEMINAR**	--	--
Tue	--	MPAT ***(NKV)***	FA **(SNM)**	PV **(JP)**		--	**ASSIGNMENT**	**LIBRARY**
Wed	--	MPAT ***(NKV)***	FA **(SNM)**	**SEMINAR**		APA **(JSK)**	**SEMINAR**	--
Thu	--	MPAT ***(NKV)***	FA **(SNM)**	PV **(JP)**		**ASSIGNMENT**	--	**LIBRARY**
Fri	--	APA **(JSK)**	FA **(SNM)**	PV **(JP)**		**SEMINAR**	**ASSIGNMENT**	--
Sat	--	APA **(JSK)**	--	--		--	--	--

Subjects : I M.Pharm (Pharm. Analysis)

1. Modern Pharmaceutical Analytical Techniques (MPAT) : Dr. N. Krishna veni ***(NKV)***
2. Pharmaceutical Validation (PV) : Dr. M R Jeyaprakash **(JP)**
3. Food Analysis (FA) : Dr. S N Meyyanathan **(SNM)**
4. Advanced Pharmaceutical Analysis (APA) : Dr. JSK Nagarajan **(JSK)**

JSS Academy of Higher Education & Research, Mysuru
(Deemed to be University, Accredited 'A+' Grade by NAAC)
JSS College of Pharmacy, Ooty – 643 001
(An ISO 9001-2015 certified Institution)

I M. Pharmacy (Pharmaceutical Analysis), II Semester (AY 2020-2021)

Day	9-10 AM	10-11 AM	11-12 AM	12-1 PM	1 – 2 PM	2-3 PM	3 -4 PM	4 – 5 PM
Monday	CALIBRATION	Pharmaceutical Analysis II Practical's (PA II) (SNM, BB, NKV, JP)			LUNCH BREAK	MBT (BB)	HCA (SNM)	QCQA (BB)
Tuesday	SEMINAR	Pharmaceutical Analysis II Practical's (PA II) (SNM, BB, NKV, JP)				MBT (BB)	HCA (SNM)	AIA (NKV)
Wednesday	QCQA (BB)	AIA (NKV)	ASSIGNMENT	SEMINAR		RESEARCH AUDIT	JOURNAL CLUB	ASSIGNMENT
Thursday	AIA (NKV)	Pharmaceutical Analysis II Practical's (PA II) (SNM, BB, NKV, JP)				MBT (BB)	HCA (SNM)	QCQA (BB)
Friday	SEMINAR	Pharmaceutical Analysis II Practical's (PA II) (SNM, BB, NKV, JP)				MBT (BB)	HCA (SNM)	QCQA (BB)
Saturday	SEMINAR	CALIBRATION	ASSIGNMENT	AIA (NKV)				

Subject- In-charge	
Advanced Instrumental Analysis (AIA) - (T)	Dr. N. Krishnaveni (NKV)
Herbal & Cosmetic Analysis (HCA) – (T)	Dr. S. N. Meyyanathan(SNM)
Quality Control & Quality Assurance (QCQA) – (T)	Dr. B. Babu (BB)
Modern Bioanalytical Techniques (MBT) – (T)	Mr. B. Babu(BB)
Pharmaceutical Analysis I Practical's (PA I)	Dr. N. Krishnaveni (NKV), Dr. S. N. Meyyanathan (SNM), Dr. M. R. Jeyaprakash (JP), Mr. B. Babu (BB)

M. PHARM
PHARMACEUTICAL QUALITY ASSURANCE

SYLLABUS
SEMESTER I
MQA 101T-MODERN PHARMACEUTICAL ANALYTICAL TECHNIQUES (Theory)

SCOPE
This subject deals with various advanced analytical instrumental techniques for identification, characterization and quantification of drugs. Instruments dealt are NMR, Mass spectrometer, IR, HPLC, GC etc.

OBJECTIVES
After completion of course student is able to know about chemicals and excipients

- The analysis of various drugs in single and combination dosage forms
- Theoretical and practical skills of the instruments

Course Content

THEORY	**60 Hrs**
1. a. UV-Visible spectroscopy: Introduction, Theory, Laws, Instrumentation associated with UV-Visible spectroscopy, Choice of solvents and solvent effect and Applications of UV-Visible spectroscopy, Difference/ Derivative spectroscopy. b. IR spectroscopy: Theory, Modes of Molecular vibrations, Sample handling, Instrumentation of Dispersive and Fourier - Transform IR Spectrometer, Factors affecting vibrational frequencies and Applications of IR spectroscopy, Data Interpretation. c. Spectroflourimetry: Theory of Fluorescence, Factors affecting fluorescence (Characterestics of drugs that can be analysed by flourimetry), Quenchers, Instrumentation and Applications of fluorescence spectrophotometer. d. Flame emission spectroscopy and Atomic absorption spectroscopy: Principle, Instrumentation, Interferences and Applications.	12 Hrs
2 NMR spectroscopy: Quantum numbers and their role in NMR, Principle, Instrumentation, Solvent requirement in NMR, Relaxation process, NMR signals in various compounds, Chemical shift, Factors influencing chemical shift, Spin-Spin coupling, Coupling constant, Nuclear magnetic double resonance, Brief outline of principles of FT-NMR and 13C NMR. Applications of NMR spectroscopy.	12 Hrs
3. Mass Spectroscopy: Principle, Theory, Instrumentation of Mass Spectroscopy, Different types of ionization like electron impact, chemical, field, FAB and MALDI, APCI, ESI, APPI Analyzers of Quadrupole and Time of Flight, Mass fragmentation and its rules, Meta stable ions, Isotopic peaks and Applications of Mass spectroscopy.	12 Hrs
4. Chromatography: Principle, apparatus, instrumentation, chromatographic parameters, factors affecting resolution, isolation of drug from excipients, data interpretation and applications of the following: • Thin Layer chromatography • High Performance Thin Layer Chromatography • Ion exchange chromatography • Column chromatography • Gas chromatography	12 Hrs

• High Performance Liquid chromatography • Ultra High Performance Liquid chromatography • Affinity chromatography • Gel Chromatography	
5. a. Electrophoresis: Principle, Instrumentation, Working conditions, factors affecting separation and applications of the following: a) Paper electrophoresis b) Gel electrophoresis c) Capillary electrophoresis d) Zone electrophoresis e) Moving boundary electrophoresis f) Iso electric focusing b. X ray Crystallography: Production of X rays, Different X ray methods, Bragg's law, Rotating crystal technique, X ray powder technique, Types of crystals and applications of X-ray diffraction.	12 Hrs
a. Potentiometry: Principle, working, Ion selective Electrodes and Application of potentiometry. b. Thermal Techniques: Principle, thermal transitions and Instrumentation (Heat flux and power-compensation and designs), Modulated DSC, Hyper DSC, experimental parameters (sample preparation, experimental conditions, calibration, heating and cooling rates, resolution, source of errors) and their influence, advantage and disadvantages, pharmaceutical applications. Differential Thermal Analysis (DTA): Principle, instrumentation and advantage and disadvantages, pharmaceutical applications, derivative differential thermal analysis (DDTA). TGA: Principle, instrumentation, factors affecting results, advantage and disadvantages, pharmaceutical applications.	12 Hrs

REFERENCES

1. Spectrometric Identification of Organic compounds - Robert M Silverstein, Sixth edition, John Wiley & Sons, 2004.
2. Principles of Instrumental Analysis - Doglas A Skoog, F. James Holler, Timothy A. Nieman, 5th edition, Eastern press, Bangalore, 1998.
3. Instrumental methods of analysis – Willards, 7th edition, CBS publishers.
4. Practical Pharmaceutical Chemistry – Beckett and Stenlake, Vol II, 4th edition, CBS Publishers, New Delhi, 1997.
5. Organic Spectroscopy - William Kemp, 3rd edition, ELBS, 1991.
6. Quantitative Analysis of Drugs in Pharmaceutical formulation - P D Sethi, 3rd Edition, CBS Publishers, New Delhi, 1997.
7. Pharmaceutical Analysis - Modern Methods – Part B - J W Munson, Vol 11, Marcel. Dekker Series
8. Spectroscopy of Organic Compounds, 2nd edn., P.S/Kalsi, Wiley estern Ltd., Delhi.
9. Textbook of Pharmaceutical Analysis, KA.Connors, 3rd Edition, John Wiley & Sons, 1982.
10. Textbook of Pharmaceutical Analysis, KA.Connors, 3rd Edition, John Wiley & Sons, 1982.

MQA 102T-QUALITY MANAGEMENT SYSTEMS (Theory)

SCOPE

This course is designed to impart fundamental knowledge and concepts about various quality management principles and systems utilized in the manufacturing industry. It also aids in understanding the quality evaluation in the pharmaceutical industries.

OBJECTIVES

At completion of this course it is expected that students will be able to understand-

- The importance of quality
- ISO management systems
- Tools for quality improvement
- Analysis of issues in quality
- Quality evaluation of pharmaceuticals
- Stability testing of drug and drug substances
- Statistical approaches for quality

Course Content

THEORY **60 Hrs**

1. Introduction to Quality: Evolution of Quality, Definition of Quality, Dimensions of Quality Quality as a Strategic Decision: Meaning of strategy and strategic quality management, mission and vision statements, quality policy, Quality objectives, strategic planning and implementation, McKinsey 7s model, Competitive analysis, Management commitment to quality Customer Focus: Meaning of customer and customer focus, Classification of customers, Customer focus, Customer perception of quality, Factors affecting customer perception, Customer requirements, Meeting customer needs and expectations, Customer satisfaction and Customer delight, Handling customer complaints, Understanding customer behavior, concept of internal and external customers. Case studies. Cost of Quality: Cost of quality, Categories of cost of Quality, Models of cost of quality, Optimising costs, Preventing cost of quality.	12 Hrs
2. Pharmaceutical quality Management: Basics of Quality Management, Total Quality Management (TQM), Principles of Six sigma, ISO 9001:2008, 9001:2015, ISO 14001:2004, Pharmaceutical Quality Management – ICH Q10, Knowledge management, Quality Metrics, Operational Excellence and Quality Management Review. OSHAS guidelines, NABL certification and accreditation, CFR-21 part 11, WHO-GMP requirements.	12 Hrs
3. Six System Inspection model: Quality Management system, Production system, Facility and Equipment system, Laboratory control system, Materials system, Packaging and labeling system. Concept of self inspection. Quality systems: Change Management/ Change control. Deviations, Out of Specifications (OOS), Out of Trend (OOT), Complaints - evaluation and handling, Investigation and determination of root cause, Corrective & Preventive Actions (CAPA), Returns and Recalls, Vendor Qualification, Annual Product Reviews, Batch Review and Batch Release. Concept of IPQC, area clearance/ Line clearance.	12 Hrs

4. Drug Stability: ICH guidelines for stability testing of drug substances and drug products. Study of ICH Q8, Quality by Design and Process development report Quality risk management: Introduction, risk assessment, risk control, risk review, risk management tools, HACCP, risk ranking and filtering according to ICH Q9 guidelines.	12 Hrs
5. Statistical Process control (SPC): Definition and Importance of SPC, Quality measurement in manufacturing, Statistical control charts - concepts and general aspects, Advantages of statistical control, Process capability, Estimating Inherent or potential capability from a control chart analysis, Measuring process control and quality improvement, Pursuit of decreased process variability.	12 Hrs
6. Regulatory Compliance through Quality Management and development of Quality Culture Benchmarking: Definition of benchmarking, Reasons for benchmarking, Types of Benchmarking, Benchmarking process, Advantages of benchmarking, Limitations of benchmarking.	12 Hrs

REFERENCES

1. Implementing Juran's Road Map for Quality Leadership: Benchmarks and Results, By Al
2. Endres, Wiley, 2000
3. Understanding, Managing and Implementing Quality: Frameworks, Techniques and Cases, By Jiju Antony; David Preece, Routledge, 2002
4. Organizing for High Performance: Employee Involvement, TQM, Reengineering, and
5. Knowledge Management in the Fortune 1000: The CEO Report By Edward E. Lawler; Susan Albers Mohrman; George Benson, Jossey-Bass, 2001
6. Corporate Culture and the Quality Organization By James W. Fairfield- Sonn, Quorum Books, 2001
7. The Quality Management Sourcebook: An International Guide to Materials and Resources By Christine Avery; Diane Zabel, Routledge, 1997
8. The Quality Toolbox, Second Edition, Nancy R. Tague, ASQ Publications
9. Juran's Quality Handbook, Sixth Edition, Joseph M. Juran and Joseph A. De Feo, ASQ
10. Publications
11. Root Cause Analysis, The Core of Problem Solving and Corrective Action, Duke Okes, 2009, ASQ Publications.

MQA 103T-QUALITY CONTROL AND QUALITY ASSURANCE (Theory)

SCOPE

This course deals with the various aspects of quality control and quality assurance aspects of pharmaceutical industries. It covers the important aspects like cGMP, QC tests, documentation, quality certifications, GLP and regulatory affairs.

OBJECTIVES

Upon completion of this course the student should be able to

- Understand the cGMP aspects in a pharmaceutical industry
- To appreciate the importance of documentation
- To understand the scope of quality certifications applicable to Pharmaceutical industries
- To understand the responsibilities of QA & QC departments.

Course Content

THEORY	**60 Hrs**
1. Introduction: Concept and evolution and scopes of Quality Control and Quality Assurance, Good Laboratory Practice, GMP, Overview of ICH Guidelines - QSEM, with special emphasis on Qseries guidelines. Good Laboratory Practices: Scope of GLP, Definitions, Quality assurance unit, protocol for conduct of non clinical testing, control on animal house, report preparation and documentation. CPCSEA guidelines.	12 Hrs
2. cGMP guidelines according to schedule M, USFDA (inclusive of CDER and CBER) Pharmaceutical Inspection Convention(PIC), WHO and EMEA covering: Organization and personnel responsibilities, training, hygiene and personal records, drug industry location, design, construction and plant lay out, maintenance, sanitation, environmental control, utilities and maintenance of sterile areas, control of contamination and Good Warehousing Practice.	12 Hrs
3. Analysis of raw materials, finished products, packaging materials, in process quality control (IPQC), Developing specification (ICH Q6 and Q3), purchase specifications and maintenance of stores for raw materials. In process quality control and finished products quality control for following dosage forms in Pharma industry according to Indian, US and British pharmacopoeias: tablets, capsules, ointments, suppositories, creams, parenterals, ophthalmic and surgical products (How to refer pharmacopoeias).	12 Hrs
4. Documentation in pharmaceutical industry: Three tier documentation, Policy, Procedures and Work instructions, and records (Formats), Basic principles- How to maintain, retention and retrieval etc. Standard operating procedures (How to write), Master Batch Record, Batch Manufacturing Record, Quality audit plan and reports. Specification and test procedures, Protocols and reports. Distribution records. Electronic data handling. Concepts of controlled and uncontrolled documents. Submission documents for regulators DMFs, as Common Technical Document and Electronic Common Technical Documentation (CTD, eCTD). Concept of regulated and non regulated markets.	12 Hrs

5. Manufacturing operations and controls: Sanitation of manufacturing premises, mix-ups and cross contamination, processing of intermediates and bulk products, packaging operations, IPQC, release of finished product, process deviations, charge-in of components, time limitations on production, drug product inspection, expiry date calculation, calculation of yields, production record review, change control, sterile products, aseptic process control, packaging, reprocessing, salvaging, handling of waste and scrap disposal. Introduction, scope and importance of intellectual property rights. Concept of trade mark, copyright and patents.	12 Hrs

REFERENCES

1. Quality Assurance Guide by organization of Pharmaceutical Procedures of India, 3rd revised edition, Volume I & II, Mumbai, 1996.
2. Good Laboratory Practice Regulations, 2nd Edition, Sandy Weinberg Vol. 69, Marcel Dekker Series, 1995.
3. Quality Assurance of Pharmaceuticals- A compedium of Guide lines and Related materials Vol I & II, 2nd edition, WHO Publications, 1999.
4. How to Practice GMP's – P P Sharma, Vandana Publications, Agra, 1991. 126
5. The International Pharmacopoeia – vol I, II, III, IV & V - General Methods of Analysis and Quality specification for Pharmaceutical Substances, Excepients and Dosage forms, 3rd edition, WHO, Geneva, 2005.
6. Good laboratory Practice Regulations – Allen F. Hirsch, Volume 38, Marcel Dekker Series, 1989.
7. ICH guidelines
8. ISO 9000 and total quality management
9. The drugs and cosmetics act 1940 – Deshpande, Nilesh Gandhi, 4th edition, Susmit Publishers, 2006.
10. QA Manual – D.H. Shah, 1st edition, Business Horizons, 2000.
11. Good Manufacturing Practices for Pharmaceuticals a plan for total quality control – Sidney H. Willig, Vol. 52, 3rd edition, Marcel Dekker Series.
12. Steinborn L. GMP/ISO Quality Audit Manual for Healthcare Manufacturers and Their Suppliers, Sixth Edition, (Volume 1 - With Checklists and Software Package). Taylor & Francis; 2003.
13. Sarker DK. Quality Systems and Controls for Pharmaceuticals. John Wiley & Sons; 2008.
14. Packaging of Pharmaceuticals.
15. Schedule M and Schedule N.

MQA 104T-PRODUCT DEVELOPMENT AND TECHNOLOGY TRANSFER (Theory)

SCOPE

This deal with technology transfer covers the activities associated with Drug Substance, Drug Product and analytical tests and methods, required following candidate drug selection to completion of technology transfer from R&D to the first receiving site and technology transfer related to post-marketing changes in manufacturing places.

OBJECTIVES

Upon completion of this course the student should be able to

- To understand the new product development process
- To understand the necessary information to transfer technology from R&D to actual manufacturing by sorting out various information obtained during R&D
- To elucidate necessary information to transfer technology of existing products between various manufacturing places

Course Content

THEORY	**60 Hrs**
1. Principles of Drug discovery and development: Introduction, Clinical research process. Development and informational content for Investigational New Drugs Application (IND), New Drug Application (NDA), Abbreviated New Drug Application (ANDA), Supplemental New Drug Application (SNDA), Scale Up Post Approval Changes (SUPAC) and Bulk active chemical Post approval changes (BACPAC), Post marketing surveillance, Product registration guidelines – CDSCO, USFDA.	12 Hrs
2. Pre-formulation studies: Introduction/concept, organoleptic properties, purity, impurity profiles, particle size, shape and surface area. Solubility, Methods to improve solubility of Drugs: Surfactants & its importance, co-solvency. Techniques for the study of Crystal properties and polymorphism. Pre-formulation protocol, Stability testing during product development.	12 Hrs
3. Pilot plant scale up: Concept, Significance, design, layout of pilot plant scale up study, operations, large scale manufacturing techniques (formula, equipment, process, stability and quality control) of solids, liquids, semisolid and parenteral dosage forms. New era of drug products: opportunities and challenges.	12 Hrs
4. Pharmaceutical packaging: Pharmaceutical dosage form and their packaging requirments, Pharmaceutical packaging materials, Medical device packaging, Enteral Packaging, Aseptic packaging systems, Container closure systems, Issues facing modern drug packaging, Selection and evaluation of Pharmaceutical packaging materials. Quality control test: Containers, closures and secondary packing materials.	12 Hrs
5. Technology transfer: Development of technology by R & D, Technology transfer from R & D to production, Optimization and Production, Qualitative and quantitative technology models. Documentation in technology transfer: Development report, technology transfer plan and Exhibit.	12 Hrs

REFERENCES

1. The process of new drug discovery and development. I and II Edition (2006) by Charles G. Smith, James T and O. Donnell. CRC Press, Group of Taylor and Francis.
2. Leon Lac Lachman, Herbert A. Liberman, Theory and Practice of Industrial Pharmacy. Marcel Dekker Inc. New York.
3. Sidney H Willing, Murray M, Tuckerman. Williams Hitchings IV, Good manufacturing of pharmaceuticals (A Plan for total quality control) 3rd Edition. Bhalani publishing house Mumbai.
4. Tablets Vol. I, II, III by Leon Lachman, Herbert A. Liberman, Joseph B. Schwartz, 2nd Edn. (1989) Marcel Dekker Inc. New York.
5. Text book of Bio- Pharmaceutics and clinical Pharmacokinetics by Milo Gibaldi, 3rd Edn, Lea & Febriger, Philadelphia.
6. Pharmaceutical product development. Vandana V. Patrevale. John I. Disouza. Maharukh T.Rustomji. CRC Press, Group of Taylor and Francis.
7. Dissolution, Bioavailability and Bio-Equivalence by Abdou H.M, Mack Publishing company, Eastern Pennsylvania.
8. Remingtons Pharmaceutical Sciences, by Alfonso & Gennaro, 19th Edn.(1995)OO2C Lippincott; Williams and Wilkins A Wolters Kluwer Company, Philadelphia.
9. The Pharmaceutical Sciences; the Pharma Path way 'Pure and applied Pharmacy' by D. A Sawant, Pragathi Books Pvt. Ltd.
10. Pharmaceutical Packaging technology by D.A. Dean. E.R. Evans, I.H. Hall. 1st Edition(Reprint 2006). Taylor and Francis. London and New York.

MQA 105P-QUALITY ASSURANCE PRACTICAL – I (Practicals)

1. Analysis of Pharmacopoeial compounds in bulk and in their formulations (tablet/ capsules/ semisolids) by UV Vis spectrophotometer
2. Simultaneous estimation of multi-drug component containing formulations by UV spectrophotometry
3. Experiments based on HPLC
4. Experiments based on Gas Chromatography
5. Estimation of riboflavin/quinine sulphate by fluorimetry
6. Estimation of sodium/potassium by flame photometry or AAS
7. Case studies on
   - Total Quality Management
   - Six Sigma
   - Change Management/ Change control. Deviations,
   - Out of Specifications (OOS)
   - Out of Trend (OOT)
   - Corrective & Preventive Actions (CAPA)
   - Deviations
8. Development of Stability study protocol
9. Estimation of process capability
10. In process and finished product quality control tests for tablets, capsules, parenterals and semisolid dosage forms.
11. Assay of raw materials as per official monographs
12. Testing of related and foreign substances in drugs and raw materials
13. To carry out pre formulation study for tablets, parenterals (2 experiment).
14. To study the effect of pH on the solubility of drugs, (1 experiment)
15. Quality control tests for Primary and secondary packaging materials
16. Accelerated stability studies (1 experiment)
17. Improved solubility of drugs using surfactant systems (1 experiment)
18. Improved solubility of drugs using co-solvency method (1 experiment)
19. Determination of Pka and Log p of drugs.

SEMESTER II

MQA 201T-HAZARDS AND SAFETY MANAGEMENT (Theory)

SCOPE

This course is designed to convey the knowledge necessary to understand issues related to different kinds of hazard and their management. Basic theoretical and practical discussions integrate the proficiency to handle the emergency situation in the pharmaceutical product development process and provides the principle based approach to solve the complex tribulations.

OBJECTIVES

At completion of this course it is expected that students will be able to

- Understand about environmental problems among learners.
- Impart basic knowledge about the environment and its allied problems.
- Develop an attitude of concern for the industry environment.
- Ensure safety standards in pharmaceutical industry
- Provide comprehensive knowledge on the safety management
- Empower an ideas to clear mechanism and management in different
- kinds of hazard management system
- Teach the method of Hazard assessment, procedure, methodology for provide safe industrial atmosphere.

Course Content

THEORY **60 Hrs**

1 Multidisciplinary nature of environmental studies: Natural Resources, Renewable and non-renewable resources, Natural resources and associated problems, a) Forest resources; b) Water resources; c) Mineral resources; d) Energy resources; e) Land resources Ecosystems: Concept of an ecosystem and Structure and function of an ecosystem. Environmental hazards: Hazards based on Air, Water, Soil and Radioisotopes.	12 Hrs
2. Air based hazards: Sources, Types of Hazards, Air circulation maintenance industry for sterile area and non sterile area, Preliminary Hazard Analysis (PHA) Fire protection system: Fire prevention, types of fire extinguishers and critical Hazard management system.	12 Hrs
3. Chemical based hazards: Sources of chemical hazards, Hazards of Organic synthesis, sulphonating hazard, Organic solvent hazard, Control measures for chemical hazards, Management of combustible gases, Toxic gases and Oxygen displacing gases management, Regulations for chemical hazard, Management of over-Exposure to chemicals and TLV concept	12 Hrs
4. Fire and Explosion: Introduction, Industrial processes and hazards potential, mechanical electrical, thermal and process hazards. Safety and hazards regulations, Fire protection system: Fire prevention, types of fire extinguishers and critical Hazard management system mechanical and chemical explosion, multiphase reactions, transport effects and global rates. Preventive and protective management from fires and explosionelectricity passivation, ventilation, and sprinkling, proofing, relief systems -relief valves, flares, scrubbers.	12 Hrs

5. Hazard and risk management: Self-protective measures against workplace hazards. Critical training for risk management, Process of hazard management, ICH guidelines on risk assessment and Risk management methods and Tools Factory act and rules, fundamentals of accident prevention, elements of safety programme and safety management, Physicochemical measurements of effluents, BOD, COD, Determination of some contaminants, Effluent treatment procedure, Role of emergency services.	12 Hrs

REFERENCES

1. Y.K. Sing, Environmental Science, New Age International Pvt, Publishers, Bangalore
2. "Quantitative Risk Assessment in Chemical Process Industries" American Institute of Chemical Industries, Centre for Chemical Process safety.
3. Bharucha Erach, The Biodiversity of India, Mapin Pu blishing Pvt. Ltd., Ahmedabad – 380 013, India,
4. Hazardous Chemicals: Safety Management and Global Regulations, T.S.S. Dikshith, CRC press

MQA 202T-PHARMACEUTICAL VALIDATION (Theory)

SCOPE

The main purpose of the subject is to understand about validation and how it can be applied to industry and thus improve the quality of the products. The subject covers the complete information about validation, types, methodology and application.

OBJECTIVES

At completion of this course, it is expected that students will be able to understand

- The concepts of calibration, qualification and validation
- The qualification of various equipments and instruments
- Process validation of different dosage forms
- Validation of analytical method for estimation of drugs
- Cleaning validation of equipments employed in the manufacture of pharmaceuticals

Course Content

THEORY **60 Hrs**

1 Introduction to validation: Definition of Calibration, Qualification and Validation, Scope, frequency and importance. Difference between calibration and validation. Calibration of weights and measures. Advantages of Validation, scope of Validation, Organization for Validation, Validation Master plan, Types of Validation, Streamlining of qualification & Validation process and Validation Master Plan. Qualification: User requirement specification, Design qualification, Factory Acceptance Test (FAT)/Site Acceptance Test (SAT), Installation qualification, Operational qualification, Performance qualification, Re-Qualification (Maintaining status- Calibration Preventive Maintenance, Change management).	10 Hrs
2. Qualification of manufacturing equipment: Dry Powder Mixers, Fluid Bed and Tray dryers, Tablet Compression (Machine), Dry heat sterilization/Tunnels, Autoclaves, Membrane filtration, Capsule filling machine. Qualification of analytical instruments: UV-Visible spectrophotometer, FTIR, DSC, GC, HPLC, HPTLC, LC-MS.	10 Hrs
3. Qualification of laboratory equipments: Hardness tester, Friability test apparatus, tap density tester, Disintegration tester, Dissolution test apparatus Validation of Utility systems: Pharmaceutical water system & pure steam, HVAC system, Compressed air and nitrogen.	10 Hrs
4. Process Validation: Concept, Process and documentation of Process Validation. Prospective, Concurrent & Retrospective Validation, Re validation criteria, Process Validation of various formulations (Coated tablets, Capsules, Ointment/Creams, Liquid Orals and aerosols.), Aseptic filling: Media fill validation, USFDA guidelines on Process Validation- A life cycle approach. Analytical method validation: General principles, Validation of analytical method as per ICH guidelines and USP.	10 Hrs
5. Cleaning Validation: Cleaning Method development, Validation of analytical method used in cleaning, Cleaning of Equipment, Cleaning of Facilities. Cleaning in place (CIP). Validation of facilities in sterile and non-sterile plant.	10 hrs

Computerized system validation: Electronic records and digital signature - 21 CFR Part 11 and GAMP	
6. General Principles of Intellectual Property: Concepts of Intellectual Property (IP), Intellectual Property Protection (IPP), Intellectual Property Rights (IPR); Economic importance, mechanism for protection of Intellectual Property –patents, Copyright, Trademark; Factors affecting choice of IP protection; Penalties for violation; Role of IP in pharmaceutical industry; Global ramification and financial implications. Filing a patent applications; patent application forms and guidelines. Types patent applications-provisional and non provisional, PCT and convention patent applications; International patenting requirement procedures and costs; Rights and responsibilities of a patentee; Practical aspects regarding maintaining of a Patent file; Patent infringement meaning and scope. Significance of transfer technology (TOT), IP and ethics-positive and negative aspects of IPP; Societal responsibility, avoiding unethical practices.	10 Hrs

REFERENCES

1. B. T. Loftus & R. A. Nash, "Pharmaceutical Process Validation", Drugs and Pharm Sci. Series, Vol. 129, 3rd Ed., Marcel Dekker Inc., N.Y.
2. The Theory & Practice of Industrial Pharmacy, 3rd edition, Leon Lachman, Herbert A.
3. Lieberman, Joseph. L. Karig, Varghese Publishing House, Bombay.
4. Validation Master plan by Terveeks or Deeks, Davis Harwood International publishing.
5. Validation of Aseptic Pharmaceutical Processes, 2nd Edition, by Carleton & Agalloco, (Marcel Dekker).
6. Michael Levin, Pharmaceutical Process Scale-Up", Drugs and Pharm. Sci. Series, Vol. 157,2nd Ed., Marcel Dekker Inc., N.Y.
7. Validation Standard Operating Procedures: A Step by Step Guide for Achieving Compliance in the Pharmaceutical, Medical Device, and Biotech Industries, Syed Imtiaz Haider
8. Pharmaceutical Equipment Validation: The Ultimate Qualification Handbook, Phillip A.
9. Cloud, Interpharm Press
10. Validation of Pharmaceutical Processes: Sterile Products, Frederick J. Carlton (Ed.) and James Agalloco (Ed.), Marcel Dekker
11. Analytical Method validation and Instrument Performance Verification by Churg Chan,
12. Heiman Lam, Y.C. Lee, Yue. Zhang, Wiley Interscience.
13. Huber L. Validation and Qualification in Analytical Laboratories. Informa Healthcare
14. Wingate G. Validating Corporate Computer Systems: Good IT Practice for Pharmaceutical
15. Manufacturers. Interpharm Press
16. LeBlanc DA. Validated Cleaning Technologies for Pharmaceutical Manufacturing. InterpharmPress

MPA 203T-AUDITS AND REGULATORY COMPLIANCE (Theory)

SCOPE

This course deals with the understanding and process for auditing in pharmaceutical industries. This subject covers the methodology involved in the auditing process of different in pharmaceutical industries.

OBJECTIVES

Upon completion of this course the student should be able to

- To understand the importance of auditing
- To understand the methodology of auditing
- To carry out the audit process
- To prepare the auditing report
- To prepare the check list for auditing

Course Content

THEORY **60 Hrs**

1 Introduction: Objectives, Management of audit, Responsibilities, Planning process, information gathering, administration, Classifications of deficiencies	12 Hrs
2. Role of quality systems and audits in pharmaceutical manufacturing environment: cGMP Regulations, Quality assurance functions, Quality systems approach, Management responsibilities, Resource, Manufacturing operations, Evaluation activities, Transitioning to quality system approach, Audit checklist for drug industries	12 Hrs
3. Auditing of vendors and production department: Bulk Pharmaceutical Chemicals and packaging material Vendor audit, Warehouse and weighing, Dry Production: Granulation, tableting, coating, capsules, sterile production and packaging	12 Hrs
4. Auditing of Microbiological laboratory: Auditing the manufacturing process, Product and process information, General areas of interest in the building raw materials, Water, Packaging materials.	12 Hrs
5. Auditing of Quality Assurance and engineering department: Quality Assurance Maintenance, Critical systems: HVAC, Water, Water for Injection systems, ETP.	12 Hrs

REFERENCES

1. Compliance auditing for Pharmaceutical Manufacturers. Karen Ginsbury and Gil Bismuth, Interpharm/CRC, Boca Raton, London New York, Washington D.C.
2. Pharmaceutical Manufacturing Handbook, Regulations and Quality by Shayne Cox Gad. Wiley-Interscience, A John Wiley and sons, Inc., Publications.
3. Handbook of microbiological Quality control. Rosamund M. Baird, Norman A. Hodges, Stephen P. Denyar. CRC Press. 2000.
4. Laboratory auditing for quality and regulatory compliance. Donald C. Singer, Raluca-loana Stefan, Jacobus F. Van Staden. Taylor and Francis (2005).

MPA 204T-PHARMACEUTICAL MANUFACTURING TECHNOLOGY (Theory)

SCOPE

This course is designed to impart knowledge and skills necessary to train the students with the industrial activities during Pharmaceutical Manufacturing.

OBJECTIVES

At completion of this course it is expected that students will be able to
understand,

- The common practice in the pharmaceutical industry developments, plant layout and production planning
- Will be familiar with the principles and practices of aseptic processtechnology, non sterile manufacturing technology and packaging technology.
- Have a better understanding of principles and implementation of Quality by design (QbD) and process analytical technology (PAT) in pharmaceutical manufacturing

Course Content

THEORY	**60 Hrs**
1 Pharmaceutical industry developments: Legal requirements and Licenses for API and formulation industry, Plant location- Factors influencing. Plant layout: Factors influencing, Special provisions, Storage, space requirements, sterile and aseptic area layout. Production planning: General principles, production systems, calculation of standard cost, process planning, routing, loading, scheduling, dispatching of records, production control.	12 Hrs
2. Aseptic process technology: Manufacturing, manufacturing flowcharts, in process-quality control tests for following sterile dosage forms: Ointment, Suspension and Emulsion, Dry powder, Solution (Small Volume & large Volume). Advanced sterile product manufacturing technology : Area planning & environmental control, wall and floor treatment, fixtures and machineries, change rooms, personnel flow, utilities & utilities equipment location, engineering and maintenance. Process Automation in Pharmaceutical Industry: With specific reference to manufacturing of sterile semisolids, Small Volume Parenterals & Large Volume Parenterals (SVP & LVP), Monitoring of Parenteral manufacturing facility, Cleaning in Place (CIP), Sterilization in Place (SIP), Prefilled Syringe, Powdered Jet, Needle Free Injections, and Form Fill Seal Technology (FFS). Lyophilization technology: Principles, process, equipment.	12 Hrs
3. Non sterile manufacturing process technology: Manufacturing, manufacturing flowcharts, in process-quality control tests for following Non-Sterile solid dosage forms: Tablets (compressed & coated), Capsules (Hard & Soft). Advance non-sterile solid product manufacturing technology: Process Automation in Pharmaceutical Industry with specific reference to manufacturing of tablets and coated products, Improved Tablet Production: Tablet production process, granulation	12 Hrs

and pelletization equipments, continuous and batch mixing, rapid mixing granulators, rota granulators, spheronizers and marumerisers, and other specialized granulation and drying equipments. Problems encountered. Coating technology: Process, equipments, particle coating, fluidized bed coating, application techniques. Problems encountered.	
4. Containers and closures for pharmaceuticals: Types, performance, assuring quality of glass; types of plastics used, Drug plastic interactions, biological tests, modification of plastics by drugs; different types of closures and closure liners; film wrapper; blister packs; bubble packs; shrink packaging; foil / plastic pouches, bottle seals, tape seals, breakable seals and sealed tubes; quality control of packaging material and filling equipment, flexible packaging, product package compatibility, transit worthiness of package, Stability aspects of packaging. Evaluation of stability of packaging material.	12 Hrs
5. Quality by design (QbD) and process analytical technology (PAT): Current approach and its limitations. Why QbD is required, Advantages, Elements of QbD, Terminology: QTPP. CMA, CQA, CPP, RLD, Design space, Design of Experiments, Risk Assessment and mitigation/minimization. Quality by Design, Formulations by Design, QbD for drug products, QbD for Drug Substances, QbD for Excipients, Analytical QbD. FDA initiative on process analytical technology. PAT as a driver for improving quality and reducing costs: quality by design (QbD), QA, QC and GAMP. PAT guidance, standards and regulatory requirements.	12 Hrs

REFERENCES

1. Lachman L, Lieberman HA, Kanig JL. The theory and practice of industrial pharmacy, 3rd ed., Varghese Publishers, Mumbai 1991.
2. Sinko PJ. Martin's physical pharmacy and pharmaceutical sciences, 5 th ed., B.I. Publications Pvt. Ltd, Noida, 2006.
3. Lieberman HA, Lachman L, Schwartz JB. Pharmaceutical dosage forms: 2nd tablets Vol. I-III, 2 ed., CBS Publishers & distributors, New Delhi, 2005.
4. Banker GS, Rhodes CT. Modern Pharmaceutics, 4th Ed Marcel Dekker Inc, New York, 2005.,
5. Sidney H Willing, Murray M, Tuckerman. Williams Hitchings IV, Good manufacturing of pharmaceuticals (A Plan for total quality control) 3rd Edition. Bhalani publishing house Mumbai.
6. Indian Pharmacopoeia. Controller of Publication. Delhi, 1996.
7. British Pharmacopoeia. British Pharmacopoeia Commission Office, London, 2008.
8. United States Pharmacopoeia. United States Pharmacopeial Convention, Inc, USA, 2003.
9. Dean D A, Evans E R and Hall I H. Pharmaceutical Packaging Technology. London, Taylor & Francis, 1st Edition. UK.
10. Edward J Bauer. Pharmaceutical Packaging Handbook. 2009. Informa Health care USA Inc.
    New York.
11. Shaybe Cox Gad. Pharmaceutical Manufacturing Handbook. John Willeyand Sons, New Jersey, 2008.

MQA 205P0-QUALITY ASSURANCE PRACTICAL – II (Practicals)

1. Organic contaminants residue analysis by HPLC
2. Estimation of Metallic contaminants by Flame photometer
3. Identification of antibiotic residue by TLC
4. Estimation of Hydrogen Sulphide in Air.
5. Estimation of Chlorine in Work Environment.
6. Sampling and analysis of SO2 using Colorimetric method
7. Qualification of following Pharma equipment
   a.Autoclave
   b.Hot air oven
   c.Powder Mixer (Dry)
   d.Tablet Compression Machine
8. Validation of an analytical method for a drug
9. Validation of a processing area
10. Qualification of at least two analytical instruments
11. Cleaning validation of one equipment
12. Qualification of Pharmaceutical Testing Equipment (Dissolution testing apparatus, Friability Apparatus, Disintegration Tester)
13. Check list for Bulk Pharmaceutical Chemicals vendors
14. Check list for tableting production.
15. Check list for sterile production area
16. Check list for Water for injection.
17. Design of plant layout: Sterile and non-sterile
18. Case study on application of QbD
19. Case study on application of PAT

DETAILS OF SUBJECT TEACHERS – semester I

S.No	Name of the Subject	Name of the Teachers	Designation and Department	Mobile No.	e-mail
1.	Modern Pharmaceutical Analytical Techniques	Dr. N. Krishnaveni	Professor	9442083447	krisath@jssuni.edu.in
2.	Quality Management System	Dr. J. S. K. Nagarajan	Asst. Professor	9443149945	jsk.nagarajan@jssuni.edu.in
3.	Quality Control and Quality Assurance	Dr. N. Krishnaveni	Professor	9442083447	krisath@jssuni.edu.in
4.	Product Development and Technology Transfer	Dr. M. R. Jeyaprakash	Asst. Professor	9952335392	jpvis7@jssuni.edu.in

DETAILS OF SUBJECT TEACHERS – semester II

S.No	Name of the Subject	Name of the Teachers	Designation and Department	Mobile No.	e-mail
5.	Hazards and Safety Management	Dr. M. R. Jeyaprakash	Asst. Professor	9952335392	jpvis7@jssuni.edu.in
6.	Pharmaceutical Validation	Dr. J. S. K. Nagarajan	Asst. Professor	9443149945	jsk.nagarajan@jssuni.edu.in
7.	Audits and Regulatory Compliance	Dr B.Babu	Lecturer	9840142319	babu@jssuni.edu.in
8.	Pharmaceutical Manufacturing Technology	Dr. S. N. Meyyanathan	Professor	7010551923	snmeyyanathan@jssuni.edu.in

Academic Plan
2020-21

SEMESTER 1

Name of the Subject	**Modern Pharmaceutical Analytical Techniques (Theory)**
Name of the Faculty	Dr. Krishna Veni N M.Pharm., Ph.D
Designation, Department	Professor & Head, Department of Pharmaceutical Analysis
Mobile Number	9442083447
e-Mail i.d.	krisath@jssuni.edu.in

Scope, Course Objectives and Course Outcomes

SCOPE

This subject deals with various advanced analytical instrumental techniques for identification, characterization and quantification of drugs. Instruments dealt are NMR, Mass spectrometer, IR, HPLC, GC etc.

OBJECTIVES

After completion of course student is able to know about

- Chemicals and excipients
- The analysis of various drugs in single and combination dosage forms
- Theoretical and practical skills of the instruments

COURSE OUTCOMES

At completion of this course it is expected that the students will be able to

CO 1 : Explain the general principles and techniques of spectroscopy & Chromatography

CO 2 : Perform the assay of single and multiple component pharmaceuticals using various analytical techniques

CO 3 : Develop skills in selecting suitable techniques for the analysis of drugs and pharamceutials

CO 4 : Apply the knowledge learnt in developing newer analytical methods and procedures of their own design

CO 5 : Explore and learn the various instrumental techniques available for the analysis of organic substances

LECTURE PLAN – Abstract

Sessional	No. of Hours of Didactic Lecture Advanced Instrumentation Techniques	No of Hours of other Activities	Total No. of Lecture Hours
I	30	1	31
II	30	--	30
Total No. of Hours	60	--	61

I SESSIONAL : 30 Lectures + 1 Activity

Lecture No.	Lecture Details	Hours
	Orientation of the subject	**01**
Unit-1:		**10**
UV Visible Spectroscopy		
1.	UV Visible Spectroscopy - Introduction, Theory, Laws	
2.	Instrumentation associated with UV Visible Spectroscopy, Choice of Solvents & Solvent Effects	
3.	Applications of UV visible spectroscopy, Difference/ Derivative Spectroscopy	
IR Spectroscopy		
4.	IR Spectroscopy - Theory, Modes of Molecular Vibrations, Samples handling	
5.	Instrumentation of Dispersive and Fourier Transform IR spectrometere	
6.	Factors affecting vibrational frequencies and applications of IR spectroscopy, Data Interpretation	
Spectroflourimetry		
7.	Spectroflourimetry - Theory of fluorescence, Factors affecting fluorescence	
8.	Quenchers, Instrumentation, Applications of Fluorescence Spectrophotometer	
Flame emission spectroscopy & Atomic abosrption spectroscopy		
9.	Principle, Instrumentation	
10.	Interferences and Applications	
Unit-2:		**10**
NMR Spectroscopy		
11.	NMR spectroscopy - Quantum numbers and their role in NMR, Principle	
12.	Instrumentation - Continous wave NMR instrument	
13.	Principle and Instrumentation of FT NMR	
14.	solvent requirements, Relaxation process	
15.	NMR signals in various compounds	
16.	chemical shift, factors influencing chemical shift	
17.	spin spin coupling, coupling constant	

18.	Nuclear magnetic double resonance	
19.	Applications of NMR Spectroscopy	
20.	Principles of 13C NMR	
Unit-3:		
MassSpectrometry		
21.	Principle, theory	
22.	Instrumentation of Mass Spectroscopy - sample introduction techniques	**10**
23.	Different types of ionization - electron impact, chemical	
24.	Different types of ionization - Field, FAB and MALDI	
25.	Different types of ionization - APCI, ESI, APPI	
26.	Analyzers of Quadrupole and Time of Flight	
27.	Mass fragmentation and its rules	
28.	Mass fragmentation and its rules	
29.	Meta stable ions, Isotopic peaks	
30.	Applications of Mass spectroscopy	

II SESSIONAL : 30 Lectures

Lecture No.	Lecture Details	Hours
Unit-4:		
Chromatography - Principle, Apparatus, Instrumentation, Chromatographic Parameters, Factors influencing resolution, Isolation of drugs from excipients, data interpretation and applications of		**10**
1.	Thin Layer Chromatography	
2.	High Performance Thin Layer Chromatography	
3.	Ion Exchange Chromatography	
4.	column Chromatography	
5.	Gas Chromatography	
6.	Gas Chromatography	
7.	HPLC	
8.	HPLC	
9.	Ultra high Performance Liquid Chromatography	
10.	Affinity Chromatography, Gel Chromatography	
Unit-5:		
Electrophoresis - Principle, Instrumentation, Working, Factors affecting separation and applications		
11.	Paper Electrophoresis	**10**
12.	Gel Electrophoresis, Zone Electrophoresis	
13.	Capillary Electrophoresis	
14.	Capillary Electrophoresis	
15.	Moving Boundray Electrophoresis	
16.	Iso Electric Focussing	
X Ray Crystallography		
17.	Production of X Rays, Braggs Law	

18.	Different X Ray diffraction methods - Rotating Crystal Technique	
19.	X Ray Powder technique, Types of Crystals	
20.	Applications of X Ray Diffractions	
Unit-6:		**10**
Immunological Assays		
21.	Potentiometry - Principle, working	
22.	Ion selective Electrodes and other electrodes used in potentiometry	
23.	Applications of potentiometry	
Thermal Techniques		
24.	Differential Scanning Colorimetry - Principle, Thermal transitions	
25.	DSC - Instrumentation (Power compensated, heat flux designs),	
26.	Modulated DSC, Hyper DSC	
27.	Experimental Parameters - sample preparation, experimental conditions, calibration, heating and cooling rates, resolution, source of errors), Their influence, advantages, disadvantages and applications	
28.	Differential Thermal Analysis (DTA) - Principle instrumentation, Advantages & Disadvantages, Pharmaceutical Applications	
29.	Derivative Differential Thermal Analysis	
30.	Thermogravimetric Analysis (TGA) - Principle, instrumentation, factors affecting results, advantages & disadvantages, Pharmaceutical Applications	

TEXT BOOKS

1. Spectrometric Identification of Organic compounds - Robert M Silverstein, Sixth edition, John Wiley & Sons, 2004.
2. Principles of Instrumental Analysis - Doglas A Skoog, F. James Holler, Timothy A. Nieman, 5th edition, Eastern press, Bangalore, 1998.
3. Instrumental methods of analysis – Willards, 7th edition, CBS publishers.
4. Practical Pharmaceutical Chemistry – Beckett and Stenlake, Vol II, 4th edition, CBS Publishers, New Delhi, 1997.
5. Organic Spectroscopy - William Kemp, 3rd edition, ELBS, 1991.
6. Quantitative Analysis of Drugs in Pharmaceutical formulation - P D Sethi, 3rd Edition, CBS Publishers, New Delhi, 1997.
7. Pharmaceutical Analysis - Modern Methods – Part B - J W Munson, Vol 11, Marcel. Dekker Series
8. Spectroscopy of Organic Compounds, 2nd edn., P.S/Kalsi, Wiley estern Ltd., Delhi.
9. Textbook of Pharmaceutical Analysis, KA.Connors, 3rd Edition, John Wiley & Sons, 1982.

REFERENCE BOOKS

1. Introduction to Spectroscopy; by Donald L Pavia

Name of the Subject	**Quality Management Systems (Theory)**
Name of the Faculty	Dr. JSK Nagarajan M.Pharm., Ph.D
Designation, Department	Assistant Professor, Department of Pharmaceutical Analysis
Mobile Number	9443149945
e-Mail i.d.	Jsk.nagarajan@jssuni.edu.in

Scope, Course Objectives and Course Outcomes

SCOPE

This course is designed to impart fundamental knowledge and concepts about various quality management principles and systems utilized in the manufacturing industry. It also aids in understanding the quality evaluation in the pharmaceutical industries.

OBJECTIVES

At completion of this course it is expected that students will be able to understand-

1. The importance of quality
2. ISO management systems
3. Tools for quality improvement
4. Analysis of issues in quality
5. Quality evaluation of pharmaceuticals
6. Stability testing of drug and drug substances
7. Statistical approaches for quality

COURSE OUTCOMES

At completion of this course it is expected that the students will be able to underrstand

CO 1 : Explain the different meanings of the quality concept and its influence

CO 2: Importance of Customers and keep the customers happy by maintaining the quality of the product

CO 3: To understand the importance of QMS, TQM and Sig Sigma.

CO4: Explain the regulation and the phases of a quality system certification process

CO5: Describe, distinguish and use the several techniques and quality management tools

LECTURE PLAN –Abstract

Sessional	No. of Hours of Didactic Lecture Hazards and safety Managemnt	No of Hours of other Activities	Total No. of Lecture Hours
I	30	02	32
II	30	02	32
Total No. of Hours	60	04	64

I SESSIONAL:31 Lectures + 2 Activities

Lecture No.	Lecture Details	Hours
Unit 1: Introduction to Quality		**12**
1	Evolution of Quality, Definition of Quality, Dimensions of Quality.	
2	Quality as a Strategic Decision: Meaning of strategy and strategic quality management, mission and vision statements	
3	quality policy, Quality objectives, strategic planning and implementation, McKinsey 7s model,	
4	Competitive analysis, Management commitment to quality	
5	Customer Focus: Meaning of customer and customer focus, Classification of customers, Customer focus,	
6	Customer perception of quality, Factors affecting customer perception, Customer requirements, Meeting customer needs and expectations	
7	Customer satisfaction and Customer delight,	
8	Handling customer complaints, Understanding customer behavior	
9	concept of internal and external customers. Case studies.	
10	Cost of Quality: Cost of quality, Categories of cost of Quality	
11	Models of cost of quality	
12	Optimising costs, Preventing cost of quality.	
13	Assignment 1	**01**
Unit 2: Pharmaceutical quality Management:		**12**
1	Basics of Quality Management, ISO 9001:2008	
2	ISO 9001:2008	
3	ISO 9001:2008, 9001:2015	
4	ISO 14001:2004	
5	Total Quality Management (TQM),	
6	Principles of Six sigma	
7	Pharmaceutical Quality Management – ICH Q10	
8	Knowledge management	
9	Quality Metrics, Operational Excellence and Quality Management Review	
10	OSHAS guidelines	
11	NABL certification and accreditation	
12	CFR-21 part 11, WHO-GMP requirements.	

13	Assignment 2	**01**
Unit 3:Six Inspection System & Quality System		**06**
1	Six System Inspection model: Quality Management system, Production system,	
2	Facility and Equipment system, Laboratory control system	
3	Materials system, Packaging and labeling system.	
4	Concept of self inspection.	
5	Quality systems: Change Management/ Change control.	
6	Deviations, Out of Specifications (OOS), Out of Trend (OOT),	

II SESSIONAL : 30 Lectures + 2 Activities

Lecture No.	Lecture Details	Hours
Unit 3: Six Inspection System & Quality System		
1	Complaints - evaluation and handling, Investigation and determination of root cause, Corrective & Preventive Actions (CAPA),	**06**
2	Returns and Recalls,	
3	Vendor Qualification	
4	Annual Product Reviews, Batch Review and Batch Release	
5	Concept of IPQC	
6	Area clearance/ Line clearance.	
	Assignment	**01**
Unit 4:Drug Stability & Quality risk management		**12**
1	ICH guidelines for stability testing of drug substances and drug products.	
2	ICH guidelines for stability testing of drug substances and drug products.	
3	Study of ICH Q8	
4	Study of ICH Q8	
5	Quality by Design and Process development report	
6	Quality by Design and Process development report	
7	Introduction, risk assessment, risk control,	
8	risk review, risk management tools	
9	HACCP	
10	HACCP.	
11	Risk ranking and filtering according to ICH Q9 guidelines.	
12	Risk ranking and filtering according to ICH Q9 guidelines.	
Unit 5:Statistical Process control:		**08**
1	Definition and Importance of SPC, Quality measurement in manufacturing	
2	Statistical control charts - concepts and general aspects,	
3	Advantages of statistical control, Process capability,	
4	Estimating Inherent or potential capability from a control chart analysis	
5	Estimating Inherent or potential capability from a control chart analysis	

6	Measuring process control and quality improvement	
7	Measuring process control and quality improvement	
8	Pursuit of decreased process variability	
9	Assignment	**01**
Unit 6:Regulatory Compliance through Quality Management and development of Quality Culture		**04**
1	Regulatory Compliance through Quality Management and development of Quality Culture	
2	Regulatory Compliance through Quality Management and development of Quality Culture	
3	Benchmarking: Definition of benchmarking, Reasons for benchmarking, Types of Benchmarking,	
4	Benchmarking process, Advantages of benchmarking, Limitations of benchmarking	

REFERENCES

1. Implementing Juran's Road Map for Quality Leadership: Benchmarks and Results, By Al Endres, Wiley, 2000
2. Understanding, Managing and Implementing Quality: Frameworks, Techniques and Cases, By Jiju Antony; David Preece, Routledge, 2002
3. Organizing for High Performance: Employee Involvement, TQM, Reengineering, and Knowledge
4. Management in the Fortune 1000: The CEO Report By Edward E. Lawler; Susan Albers Mohrman; George Benson, Jossey-Bass, 2001
5. Corporate Culture and the Quality Organization By James W. Fairfield- Sonn, Quorum Books, 2001
6. The Quality Management Sourcebook: An International Guide to Materials and Resources By
7. Christine Avery; Diane Zabel, Routledge, 1997
8. The Quality Toolbox, Second Edition, Nancy R. Tague, ASQ Publications
9. Juran's Quality Handbook, Sixth Edition, Joseph M. Juran and Joseph A. De Feo, ASQ Publications
10. Root Cause Analysis, The Core of Problem Solving and Corrective Action, Duke Okes, 2009, ASQ Publications.

Name of the Subject	**Quality Control and Qualith Assurance (Theory)**
Name of the Faculty	Dr. Krishna Veni N M.Pharm., Ph.D
Designation, Department	Professor & Head, Department of Pharmaceutical Analysis
Mobile Number	9442083447
e-Mail i.d.	krisath@jssuni.edu.in

Scope, Course Objectives and Course Outcomes

SCOPE

This course deals with the various aspects of quality control and quality assurance aspects of pharmaceutical industries. It covers the important aspects like cGMP, QC tests, documentation, quality certifications, GLP and regulatory affairs.

OBJECTIVES

Upon completion of this course the student should be able to

- Understand the cGMP aspects in a pharmaceutical industry
- To appreciate the importance of documentation
- To understand the scope of quality certifications applicable to Pharmaceutical industries
- To understand the responsibilities of QA & QC departments.

COURSE OUTCOMES

At completion of this course it is expected that the students will be able to

CO 1: Realise the importance of quality, Quality Control and Quality Assurnce in a Pharmaceutical Industry.

CO 2: Implement and Document international quality standards such as GMP and ICH Guidelines.

CO 3: Perform the quality control tests during and after manufacture of pharmaceutical formulations.

CO 4: Realise the importance of documentation & learn the documentation techniques for implementation of quality in pharmaceutical formulations.

CO 5: Explain the organizational structure and design of pharmaceutical industry.

LECTURE PLAN – Abstract

Sessional	No. of Hours of Didactic Lecture Advanced Instrumentation Techniques	No of Hours of other Activities	Total No. of Lecture Hours
I	30	1	31
II	30	--	30
Total No. of Hours	60	--	61

I SESSIONAL : 30 Lectures + 1 Activity

Lecture No.	Lecture Details	Hours
	Orientation of the subject	**01**
Unit-1:		**12**
Introduction		
1.	Concept and evolution and scopes of Quality Control and Quality Assurance	
2.	Good Laboratory Practice	
3.	Good Laboratory Practice	
4.	GMP - Good Manufacturing Practice	
5.	Overview of ICH Guidelines	
6.	QSEM of ICH Guidelines	
7.	Special emphasis on Q- series guidelines	
8.	Special emphasis on Q- series guidelines	
Good Laboratory Practice		
9.	Scope of GLP, Defenitions, Quality Assurance Unit	
10.	Protocol for conduct of non clinical testing	
11.	Control on Animal house, Report preparation and documentation	
12.	CPCSEA Guidelines	
Unit-2:		**12**
cGMP Guidelines according to schedule M, USFDA (Inclusive of CDER and CBER), Pharmaceutical inspection convention (PIC), WHO and EMEA covering		
13.	Organization ans personnel responsibilities	
14.	Training	
15.	Hygiene and Personal records	
16.	Drug industry location, Design	
17.	Construction and Plant layout	
18.	Maintenance, Sanitation	
19.	Environmental Control	
20.	Utilities and Maintenance of Sterile areas	
21.	Utilities and Maintenance of Sterile areas	
22.	Control of Contamination	

23.	Good Warehousing Practice	
24.	Good Warehousing Practice	
Unit-3:		
Inprocess quality control & Finished products quality control for following dosage forms in pharma industry according to Indian, US and British Pharmacopoeias		**06**
25.	Analysis of raw materials, finished products, packaging materials	
26.	In process quality control - Brief overview	
27.	Developing specifications (ICH Q3 & ICH Q6)	
28.	Purchase specifications for raw materials	
29.	Maintenance of stores for raw materials	
30.	IPQC & FPQC tests for Tablets	

II SESSIONAL : 30 Lectures

Lecture No.	Lecture Details	Hours
Unit-3:		**06**
Inprocess quality control & Finished products quality control for following dosage forms in pharma industry according to Indian, US and British Pharmacopoeias		
1.	IPQC & FPQC tests for Capsules	
2.	IPQC & FPQC tests for Ointments & Creams	
3.	IPQC & FPQC tests for Suppositories	
4.	IPQC & FPQC tests for Parenterals	
5.	IPQC & FPQC tests for Opthalmic Products	
6.	IPQC & FPQC tests for Surgical products	
Unit-4:		**12**
Documentation in Pharmaceutical Industry		
7.	Three tier documentation	
8.	Policy, Procedures and Work instructions, and records (Formats)	
9.	Basic principles- How to maintain, retention and retrieval etc.	
10.	Standard operating procedures (How to write)	
11.	Master Batch Record	
12.	Batch Manufacturing Record	
13.	Quality audit plan and reports	
14.	Specification and test procedures, Protocols and reports	
15.	Distribution records. Electronic data handling, Concepts of controlled and uncontrolled documents	
16.	Submission documents for regulators DMFs, as Common Technical Document (CTD)	
17.	Submission documents for regulators DMFs, Electronic Common Technical Documentation (eCTD)	
18.	Concept of regulated and non regulated markets	
Unit-5:		

Manufacturing operations and controls		**12**
19.	Sanitation of Manufacturing Premises	
20.	Mix-ups and Cross Contamination	
21.	Processing of Intermediates and Bulk Products	
22.	Packaging Operations, IPQC, Release of finished product	
23.	Process Deviations, Charge-in of Components	
24.	Time Limitations on Production, Drug Product Inspection	
25.	Expiry date calculation, Calculation of yields, Production record review,	
26.	Change control, Sterile products, Aseptic process control	
27.	Packaging, Reprocessing, Salvaging, Handling of Waste and Scrap disposal	
28.	Introduction, scope and importance of intellectual property rights	
29.	Concept of trade mark, copyright and patents	
30.	Concept of trade mark, copyright and patents	

TEXT BOOKS

1. Quality Assurance Guide by organization of Pharmaceutical Procedures of India, 3rd revised edition, Volume I & II, Mumbai, 1996.
2. Good Laboratory Practice Regulations, 2nd Edition, Sandy Weinberg Vol. 69, Marcel Dekker Series, 1995.
3. Quality Assurance of Pharmaceuticals- A compedium of Guide lines and Related materials Vol I & II, 2nd edition, WHO Publications, 1999.
4. How to Practice GMP's – P P Sharma, Vandana Publications, Agra, 1991. 126
5. The International Pharmacopoeia – vol I, II, III, IV & V - General Methods of Analysis and Quality specification for Pharmaceutical Substances, Excepients and Dosage forms, 3rd edition, WHO, Geneva, 2005.
6. Good laboratory Practice Regulations – Allen F. Hirsch, Volume 38, Marcel Dekker Series, 1989.
7. ICH guidelines
8. ISO 9000 and total quality management
9. The drugs and cosmetics act 1940 – Deshpande, Nilesh Gandhi, 4th edition, Susmit Publishers, 2006.
10. QA Manual – D.H. Shah, 1st edition, Business Horizons, 2000.
11. Good Manufacturing Practices for Pharmaceuticals a plan for total quality control – Sidney H. Willig, Vol. 52, 3rd edition, Marcel Dekker Series.
12. Steinborn L. GMP/ISO Quality Audit Manual for Healthcare Manufacturers and Their Suppliers, Sixth Edition, (Volume 1 - With Checklists and Software Package). Taylor & Francis; 2003.
13. Sarker DK. Quality Systems and Controls for Pharmaceuticals. John Wiley & Sons; 2008.
14. Packaging of Pharmaceuticals.
15. Schedule M and Schedule N.

Name of the Subject	**Product and development of technology Transfer (Theory)**
Name of the Faculty	Dr. Jeyaprakash MR M.Pharm., Ph.D
Designation, Department	Assistant Professor, Department of Pharmaceutical Analysis
Mobile Number	9952335392
e-Mail i.d.	jpvis7@jssuni.edu.in

Scope, Course Objectives and Course Outcomes

SCOPE

This deal with technology transfer covers the activities associated with Drug Substance, Drug Product and analytical tests and methods, required following candidate drug selection to completion of technology transfer from R&D to the first receiving site and technology transfer related to post-marketing changes in manufacturing places.

OBJECTIVES

The primary objectives of this course are to

- To understand the new drug and product development process
- To understand the necessary information to transfer technology from R&D to actual manufacturing by sorting out various information obtained during R&D
- To elucidate necessary information to transfer technology of existing products between various manufacturing places

COURSE OUTCOMES

At completion of this course it is expected that the students will be able to

CO 1: Stages and drug development and discovery procedure
CO2: Protocal to develop the preformulations study
CO3: Pilot plant scaleup study and it's significance
CO4: Modern pharmaceutical packaging technology and its challenges
CO5: Procedure for technology transfer and its importance

LECTURE PLAN – Abstract

Sessional	No. of Hours of Didactic Lecture Hazards and safety Managemnt	No of Hours of other Activities	Total No. of Lecture Hours
I	30	04	34
II	30	04	34
Total No. of Hours	60	08	68

I SESSIONAL : 31 Lectures + 2 Activities

Lecture No.	Lecture Details	Hours
Unit 1: Principles of Drug discovery and development		**12**
1	Introduction to clinical research	
2	Stages of Clinical research process.	
3	Development of content IND	
4	New Drug Application (NDA)	
5	Abbreviated New Drug Application (ANDA)	
6	Supplemental New Drug Application (SNDA),	
7	Scale Up Post Approval Changes (SUPAC)	
8	Scale Up Post Approval Changes (SUPAC)	
9	Bulk active chemical Post approval changes (BACPAC)	
10	Post marketing surveillance	
11	Post marketing surveillance -CDSCO	
12	Post marketing surveillance -USFDA	
13	Assignment 1	**02**
Unit 2: Pre-formulation studies		**12**
1	Sources of Air	
2	Types of air based Hazards,	
3	Air circulation system maintance in industry	
4	HVAC	
5	AC system for Sterile area	
6	AC system for Sterile area	
7	AC system for non sterile area	
8	Preliminary Hazard Analysis (PHA)	
9	Source and prevention of Fire	
10	types of fire extinguishers	
11	critical Hazard management System	
12	Fire accident managements	
13	Assignment 2	**02**
Unit 3: Pilot plant scale up (PPSU)		**06**
1	Concept & Significance PPSU	

2	design of PPSU	
3	Plant lay out PPSU	
4	operations of PPSU	
5	large scale manufacturing- Solid Dosage form	
6	large scale manufacturing- Solid Dosage form	

II SESSIONAL : 29 Lectures + 2 Activities

Lecture No.	Lecture Details	Hours
Unit 3: Pilot plant scale up (PPSU) Cont..		
1	large scale manufacturing- Liquid dosage form	**06**
2	large scale manufacturing- Liquid dosage form	
3	large scale manufacturing- Semi Solid Dosage form	
4	large scale manufacturing- parenteral dosage form	
5	large scale manufacturing- parenteral dosage form	
6	New era of drug products: opportunities and challenges	**02**
	Assignment 3	
Unit 4: Pharmaceutical packaging & Quality control test		**12**
1	Different types Pharmaceutical dosage form	
2	packaging requirments	
3	Pharmaceutical packaging materials	
4	Medical device packaging	
5	Enteral Packaging	
6	Aseptic packaging	
7	Container closure systems	
8	Issues facing modern drug packing	
9	Selection and evaluation of Pharmaceutical packaging	
10	Containers -QC test	
11	Closures-QC	
12	Secondary packing materials.	
Unit 5: Technology transfer and Documentation		**12**
1	Development of technology by R & D	
2	Development of technology by R & D	
3	Technology transfer from R & D	
4	Technology transfer from R & D	
5	R& D to production	
6	Optimization and Production	
7	Qualitative and quantitative technology models	
8	Protocal for Technology transfer	
9	Development of Technology	
10	technology transfer plan and Exhibit	
11	technology transfer plan and Exhibit	
12	technology transfer with IPR	
13	Assignment 4	**02**

REFERENCE BOOKS

1. The process of new drug discovery and development. I and II Edition (2006) by Charles G. Smith, James T and O. Donnell. CRC Press, Group of Taylor and Francis.
2. Leon Lac Lachman, Herbert A. Liberman, Theory and Practice of Industrial Pharmacy. Marcel Dekker Inc. New York.
3. Sidney H Willing, Murray M, Tuckerman. Williams Hitchings IV, Good manufacturing of pharmaceuticals (A Plan for total quality control) 3rd Edition. Bhalani publishing house Mumbai.
4. Tablets Vol. I, II, III by Leon Lachman, Herbert A. Liberman, Joseph B. Schwartz, 2nd Edn. (1989) Marcel Dekker Inc. New York.
5. Text book of Bio- Pharmaceutics and clinical Pharmacokinetics by Milo Gibaldi, 3rd Edn, Lea & Febriger, Philadelphia.
6. Pharmaceutical product development. Vandana V. Patrevale. John I. Disouza. Maharukh T.Rustomji. CRC Press, Group of Taylor and Francis.
7. Dissolution, Bioavailability and Bio-Equivalence by Abdou H.M, Mack Publishing company, Eastern Pennsylvania.
8. Remingtons Pharmaceutical Sciences, by Alfonso & Gennaro, 19th Edn.(1995)OO2C Lippincott; Williams and Wilkins A Wolters Kluwer Company, Philadelphia.
9. The Pharmaceutical Sciences; the Pharma Path way 'Pure and applied Pharmacy' by D. A Sawant, Pragathi Books Pvt. Ltd.
10. Pharmaceutical Packaging technology by D.A. Dean. E.R. Evans, I.H. Hall. 1st Edition(Reprint 2006). Taylor and Francis. London and New York.

MQA105P Pharmaceutical Quality Assurance Practical I

Sessional	Pharmaceutical Quality Assurance I	No of Hours of other Activities	Total No. of Lecture Hours
I	12	04	48
II	11	04	44
Total No. of Hours	23	08	92

I Sessional Practicals

S. No.	Name of the Experiment
1.	Pre-formulation Studies for Tablets
2.	Solubility Improvement study by using Surfactant
3.	Solubility Improvement study by using Co-solvent
4.	IPQC Tests for Tablets
5.	Effect of pH on the Solubility of Drug
6.	Dissolution Study of Tablets in Different pH Buffers
7.	Quality Control Test for Tablet
8.	Quality Control Test for Capsule
9.	Assay of Metformin Tablet, I.P.
10.	Assay of Calcium lactate Tablet, I.P.
11.	Monograph Analysis of Paracetamol Tablet, I.P.
12.	Monograph Analysis of Metronidazole Tablet, I.P.

II Sessional Practicals

S. No.	Name of the Experiment
13.	Protocol for Stability Testing of New Drug Substances and Products
14.	Protocol preparation for Stability and Compatibility of Parenteral Diazepam in Different Storage Conditions
15.	Case Study on Six Sigma
16.	Case Study on Corrective Action and Preventive Action (CAPA)
17.	Case Study on Out of Specifications (OOS)
18.	Case Study on Total Quality Management (TQM)
19.	Assay of Paracetamol Tablets (I. P) using UV Spectrophotometry
20.	Determination of Paracetamol and Ibuprofen by Simultaneous Estimation Method
21.	Estimation of Sodium and Potassium Ions by Flame Photometry
22.	Estimation of Quinine sulphate by Fluorimetry
23.	Assay of Paracetamol Tablets by RP HPLC

SEMESTER II

Name of the Subject	**Hazards and Safety Management (Theory)**
Name of the Faculty	Dr. Jeyaprakash MR M.Pharm., Ph.D
Designation, Department	Assistant Professor, Department of Pharmaceutical Analysis
Mobile Number	9952335392
e-Mail i.d.	jpvis7@jssuni.edu.in

Scope, Course Objectives and Course Outcomes

SCOPE

This course is designed to provide knowledge on the workplace related risk manenement , it impart knowledge and skills necessary for hazard identification, management, risk analysis, controlling procedure, corrective action and preventive actions etc., this course also provide the theory and practical skills to the pupil in qualitytive and quantitative aspects of diffent types of hazards and their limits related health issues.

OBJECTIVES

The primary objectives of this course are to

- It reveals the basic aspects of natural resourse management
- Explain the various types of hazards and their impact on the health
- It helps the young community to understand the concept of natural resource conservation
- The subject concent extend the student knowledge in the hazard risk management process
- It feed the idea on Preliminary Hazard Analysis(PHA) and safety data sheet requirements (Material Safety Data Sheet)

COURSE OUTCOMES

At completion of this course it is expected that the students will be able to

CO 1 : Able to understand the natural resourses and its managements

CO 2: Types of air based hazards and its health hazards

CO 3: Different types of Chemcical hazards and its controlling procedure.

CO4: Effect of Fire accident and its preventive procedure

CO5: Risk management and assessment procedure

LECTURE PLAN – Abstract

Sessional	No. of Hours of Didactic Lecture Hazards and safety Managemnt	No of Hours of other Activities	Total No. of Lecture Hours
I	31	04	35
II	29	04	33
Total No. of Hours	60	08	68

I SESSIONAL : 31 Lectures + 2 Activities

Lecture No.	Lecture Details	Hours
Unit 1: Multidisciplinary nature of environmental studies		**12**
1	Introduction to ECO system	
2	Natural Resources	
3	Renewable and non-renewable resources	
4	Natural Resources associated problems	
5	Forest resources	
6	Water resources	
7	Mineral resources	
8	Energy resources	
9	Land resources	
10	Structure and function ecosystem	
11	Environmental hazards: Hazards based on Air, water and soil	
12	Radioisotope based Hazards	
13	Assignment 1	**02**
Unit 2: Air based hazards and Fire protection system		**12**
1	Sources of Air	
2	Types of air based Hazards,	
3	Air circulation system maintance in industry	
4	HVAC	
5	AC system for Sterile area	
6	AC system for Sterile area	
7	AC system for non sterile area	
8	Preliminary Hazard Analysis (PHA)	
9	Source and prevention of Fire	
10	types of fire extinguishers	
11	critical Hazard management System	
12	Fire accident managements	
13	Assignment 2	**02**
Unit 3:Chemical based hazards Cleaning Validation		**07**

1	Sources of chemical hazards(CH)	
2	Types of CH	
3	Effects of CH	
4	Hazards of Organic synthesis	
5	sulphonating hazard	
6	Organic solvent hazard	
7	Control measures for chemical hazards	

II SESSIONAL : 29 Lectures + 2 Activities

Lecture No.	Lecture Details	Hours
1	Management of combustible gases	**05**
2	Toxic gases and Oxygen displacing gases management	
3	Regulations for chemical hazard ACS and OHSA	
4	Management of over-Exposure to CH	
5	TLV concept of CH	
6	Assignment 3	**02**
Unit 4:Fire and Explosion, Fire protection system, Preventive and protective management		**12**
1	Introduction to firw and explosive	
2	Industrial processes and hazard potential	
3	Mechanical & electrical Hazards	
4	Thermal and process Hazards	
5	Safety and hazards regulations	
6	Fire prevention	
7	types of fire extinguishers	
8	CHM for mechanical and chemical explosion	
9	Transport effects and global rates CHM	
10	fires,explosion, electricity	
11	passivation, ventilation, and sprinkling, proofing, relief system	
12	Relief valves, flares, scrubbers management	
Unit 5: Hazard and risk management		**12**
1	Self-protective measures against work place (PPE)	
2	Critical training for risk management	
3	Process of Hazard management	
4	ICH guidelines on risk assessment	
5	Risk management methods and Tools	
6	Factory act and rules,	
7	fundamentals of accident prevention	
8	elements of safety programme and safety management	
9	Physicochemical measurements of effluents,Effluent treatment procedure	
10	BOD, COD	
11	Determination of some contaminants	
12	Role of emergency services	

13	Assignment 4	**02**

REFERENCE BOOKS

1. Y.K. Sing, Environmental Science, New Age International Pvt, Publishers, Bangalore
2. "Quantitative Risk Assessment in Chemical Process Industries" American Institute of Chemical Industries, Centre for Chemical Process safety.
3. Bharucha Erach, The Biodiversity of India, Mapin Pu blishing Pvt. Ltd., Ahmedabad – 380 013, India,
4. Hazardous Chemicals: Safety Management and Global Regulations,

Name of the Subject	**Pharmaceutical Validation (Theory)**
Name of the Faculty	Dr.JSK NagarajanM.Pharm., Ph.D
Designation, Department	Assistant Professor, Department of Pharmaceutical Analysis
Mobile Number	9443149945
e-Maili.d.	jsk.nagarajan@jssuni.edu.in

Scope, Course Objectives and Course Outcomes

SCOPE

The main purpose of the subject is to understand about validation and how it can be applied to industry and thus to improve the quality of the products. The subject covers the complete information about validation, types, methodology and application.

OBJECTIVES

The primary objectives of this course are to

- Explain the aspect of validation and different types of qualification and its need
- Carryout validation of manufacturing processes and selection of equipments
- Apply the knowledge of validation to instruments and equipments
- Validate the manufacturing facilities

COURSE OUTCOMES

At completion of this course it is expected that the students will be able to

CO 1 : Introduction to types of validation and qualifications

CO 2: Types of calibrations and different types of analytical instrument validations

CO 3: To understand the cleaning validation and protocol development.

CO 4: Procedure and protocol for analytical method and computer system

CO 5: Various types of Applications and significance of intellectual Property Rights in the Pharma industry.

LECTURE PLAN –Abstract

Sessional	No. of Hours of Didactic Lecture Hazards and safety Managemnt	No of Hours of other Activities	Total No. of Lecture Hours
I	30	04	34
II	30	04	34
Total No. of Hours	60	08	68

I SESSIONAL:31 Lectures + 2 Activities

Lecture No.	Lecture Details	Hours
Unit 1: Introduction to validation and Qualification		**12**
1	Definition of Qualification and Validation, Advantage of Validation	
2	Streamlining of Qualification & Validation process	
3	Validation Master Plan (VMP)	
4	Validation Master Plan (VMP)	
5	Qualification: User Requirement Specification	
6	Design Qualification URS	
7	Factory Acceptance Test (FAT)/ Site Acceptance Test (SAT)	
8	Installation Qualification, Operational Qualification and Performance Qualification	
9	Re- Qualification (Maintaining status-Calibration Preventive Maintenance	
10	Qualification of Manufacturing Equipments	
11	Qualification of analytical Instruments	
12	Qualification of analytical Instruments	
13	Assignment 1	**02**
Unit 2: Qualification of analytical instruments		**12**
1	Electronic balance	
2	pH Meter	
3	UV-Visible spectrophotometer	
4	UV-Visible spectrophotometer	
5	FTIR,	
6	HPLC	
7	HPLC	
8	GC	
9	GC	
10	HPTLC	
11	Qualification of Glassware: Volumetric flask, pipette, Measuring	
12	cylinder, beakers and burette	
13	Assignment 2	**02**
Unit 3:Validation of Utility systems and Cleaning Validation		**06**

1	Pharmaceutical Water System & pure steam	
2	Pharmaceutical Water System & pure steam	
3	HVAC system-Heat System	
4	HVAC system- Ventilation system	
5	HVAC system-Air Condition system	
6	Compressed air and nitrogen	

II SESSIONAL : 30 Lectures + 2 Activities

Lecture No.	Lecture Details	Hours
Unit 3: Validation of Utility systems and Cleaning ValidationCont..		**06**
1	Cleaning Validation - Cleaning Method development	
2	Validation of cleaning validation	
3	validation of analytical method used in cleaning	
4	Cleaning of Equipment	
5	Cleaning of Facilities	
6	Cleaning in place (CIP).	
	Assignment 3	**02**
Unit 4:Analytical method validation and Computer System Validation		**12**
1	General principles of ICH and USP	
2	Validation of analytical method	
3	Validation of analytical method	
4	Validation of analytical method	
5	Validation of analytical method	
6	Validation of analytical method	
7	Validation of analytical method	
8	Validation of analytical method	
9	Electronic records	
10	Electronic records	
11	digital significance-21 CFR part 11	
12	GAMP 5.	
Unit 5:General Principles of Intellectual Property		**12**
1	Concepts of Intellectual Property (IP), Intellectual Property Protection (IPP),and IPR	
2	Economic importance, mechanism for protection of Intellectual Property	
3	patents, Copyright, Trademark;	
4	Factors affecting choice of IP protection, Penalties for violation;	
5	Role of IP in pharmaceutical industry;Global ramification and financial implications	
6	Filing a patent applications; patent application forms and guidelines.	
7	Types patent applications-provisional and non-provisional, PCT and Convention	
8	International patenting requirement procedures and costs	
9	Rights and responsibilities of a patentee; Practical aspects regarding maintaining of a Patent file	

10	Patent infringement meaning and scope	
11	Significance of transfer of Technology (TOT)	
12	ethics non ethical -positive and negative aspects Societal responsibility,	
13	Assignment 4	**02**

REFERENCE BOOKS

1. B. T. Loftus & R. A. Nash, "Pharmaceutical Process Validation", Drugs and Pharm Sci. Series, Vol. 129, 3rd Ed., Marcel Dekker Inc., N.Y.
2. The Theory & Practice of Industrial Pharmacy, 3rd edition, Leon Lachman,Herbert A. Lieberman, Joseph. L. Karig, Varghese Publishing House,Bombay.
3. Validation Master plan by Terveeks or Deeks, Davis Harwood Internationalpublishing.
4. Validation of Aseptic Pharmaceutical Processes, 2nd Edition, by Carleton&Agalloco, (Marcel
5. Dekker).
6. Michael Levin, Pharmaceutical Process Scale-Up‖, Drugs and Pharm. Sci.Series, Vol. 157,2nd Ed., Marcel Dekker Inc., N.Y.
7. Validation Standard Operating Procedures: A Step by Step Guide forAchieving Compliance in the Pharmaceutical, Medical Device, and Biotech Industries, Syed ImtiazHaider
8. Pharmaceutical Equipment Validation: The Ultimate QualificationHandbook, Phillip A. Cloud,
9. Interpharm Press
10. Validation of Pharmaceutical Processes: Sterile Products, Frederick J.Carlton (Ed.) and James
11. Agalloco (Ed.), Marcel Dekker, 2nd Ed.
12. Analytical Method validation and Instrument Performance Verification byChurg Chan, Heiman Lam, Y.C. Lee, Yue. Zhang, Wiley Inter Science.

Name of the Subject	**Audit and Regulatory Compliance (Theory)**
Name of the Faculty	Dr. B. Babu M.Pharm., Ph.D
Designation, Department	Lecturer, Department of Pharmaceutical Analysis
Mobile Number	9840142319
e-Mail i.d.	babu@jssuni.edu.in

Scope, Course Objectives and Course Outcomes

SCOPE

This course deals with the understanding and process for auditing in pharmaceutical industries. This subject covers the methodology involved in the auditing process of different in pharmaceutical industries.

OBJECTIVES

The primary objectives of this course are to

- To understand the importance of auditing
- To understand the methodology of auditing
- To carry out the audit process
- To prepare the auditing report
- To prepare the check list for auditing

COURSE OUTCOMES:

At completion of this course it is expected that the students will be able to

CO 1 : The concepts of auditing in pharmaceutical industry.
CO 2 : The process and methodology of auditing.
CO 3 : Preparation like checklist for auditing of pharmaceutical industry.
CO 4 : The importance of auditing and the important components of auditing.
CO 5 : How quality of pharmaceuticals can be deteorated if auditing process is not implemented.

LECTURE PLAN – Abstract

Sessional	No. of Hours Lecture	No of Hours of other Activities	Total No. of Lecture Hours
	Pharmaceutical Analysis		
I	30	-	30
II	30	-	30
Total No. of Hours	60	-	60

I SESSIONAL : 30 Lectures

Lecture No.	Lecture Details	Hours
AUDIT AND REGULATORY COMPLIANCE		**(60)**
Unit-1: Quality Audit		**12**
	Orientation to the subject	
1.	Introduction: Objectives of Quality audit	
2.	Introduction: Objectives of Quality audit	
3.	Management of audit	
4.	Management of audit	
5.	Responsibilities of quality audit	
6.	Responsibilities of quality audit	
7.	Planning process	
8.	Planning process	
9.	Information gathering	
10.	Information gathering	
11.	Administration Classifications of deficiencies	
12.	Administration Classifications of deficiencies	
Unit-2: Role of quality systems		**12**
13.	Role of quality systems and audits in pharmaceutical manufacturing environment	
14.	Role of quality systems and audits in pharmaceutical manufacturing environment	
15.	cGMP Regulations	
16.	cGMP Regulations	
17.	Quality assurance functions	
18.	Quality systems approach	
19.	Management responsibilities, Resource	
20.	Manufacturing operations	
21.	Evaluation activities	
22.	Transitioning to quality system approach	
23.	Audit checklist for drug industries	
24.	Audit checklist for drug industries	
Unit-3: Auditing of vendors and production department		**06**

25.	Auditing of vendors and production department	
26.	Vendors evaluation process and vendor development	
27.	Bulk pharmaceutical Chemicals Vendor audit	
28.	Packaging material Vendor audit	
29.	Warehouse and weighing	
30.	Warehouse and weighing	

II SESSIONAL : 30 Lectures

Lecture No.	Lecture Details	Hours
Unit-3: Auditing of vendors and production department		
1.	Dry Production	**06**
2.	Granulation, tableting	
3.	Granulation, tableting	
4.	Coating, capsules	
5.	Sterile production and packaging	
6.	Sterile production and packaging	
Unit-4: Auditing of Microbiological laboratory		
7.	Introduction to microbiological laboratory	**12**
8.	Auditing of Microbiological laboratory	
9.	Auditing the manufacturing process	
10.	Auditing the manufacturing process	
11.	Product and process information	
12.	Product and process information	
13.	General areas of interest in the building raw materials	
14.	General areas of interest in the building raw materials	
15.	Auditing of Water system	
16.	Auditing of Water system	
17.	Auditing of Packaging materials	
18.	Auditing of Packaging materials	
Unit-5: Auditing of Quality Assurance and engineering department		
19.	Auditing of Quality Assurance unit	**12**
20.	Auditing of Quality Assurance unit	
21.	Auditing of engineering department	
22.	Auditing of engineering department	
23.	Quality Assurance Maintenance	
24.	Auditing of Critical systems HVAC	
25.	Auditing of Critical systems HVAC	
26.	Auditing of Critical systems water	
27.	Auditing of Critical systems water for injection systems	
28.	Auditing of Critical systems water for injection systems	
29.	Auditing of Maintance department	
30.	Auditing of Critical systems ETP	

REFERENCE BOOKS

1. Compliance auditing for Pharmaceutical Manufacturers. Karen Ginsbury and Gil Bismuth, Interpharm/CRC, Boca Raton, London New York,Washington D.C.
2. Pharmaceutical Manufacturing Handbook, Regulations and Quality by Shayne Cox Gad. Wiley-Interscience, A John Wiley and sons, Inc.,Publications.
3. Handbook of microbiological Quality control. Rosamund M. Baird, Norman A. Hodges, Stephen P. Denyar. CRC Press. 2000.
4. Laboratory auditing for quality and regulatory compliance. Donald C.Singer, Raluca-loana Stefan, Jacobus F. Van Staden. Taylor and Francis (2005).

Name of the Subject	**Pharmaceutical Manufactuing Technology (Theory)**
Name of the Faculty	Dr. Meyyanathan SN, M.Pharm., Ph.D
Designation, Department	Professor, Department of Pharmaceutical Analysis
Mobile Number	7010551923
e-Mail i.d.	snmeyyanathan@jssuni.edu.in

Scope, Course Objectives and Course Outcomes

SCOPE

This course is designed to impart knowledge and skills necessary to train the students with the industrial activities during Pharmaceutical Manufacturing

OBJECTIVES

The primary objectives of this course are to

- understand the common practice in the pharmaceutical industry developments, plant layout and production planning
- the principles and practices of aseptic process technology, non sterile manufacturing technology and packaging technology.

COURSE OUTCOMES

At completion of this course it is expected that the students will be able to

CO 1: know the principles and implementation of Quality by design (QbD) and process analytical technology (PAT) in pharmaceutical manufacturing

CO 2: know the in process quality control tests for various drug products and their packaging products

LECTURE PLAN – Theory

Sessional	Total Number of Lecture Hours
I	24
II	36
Total Number of Lecture Hours	60

I SESSIONAL : 24 Lectures

Lecture No.	Lecture Details	Hours
Unit-1:		**12**
1.	Pharmaceutical industry developments: Legal requirements	
2.	Licenses for API and formulation industry	
3.	Plant location - Factors influencing	
4.	Plant location - Factors influencing	
5.	Plant layout: Factors influencing	
6.	Special provisions, Storage space requirements	
7.	Sterile and aseptic area layout	
8.	Sterile and aseptic area layout	
9.	Production planning: General principles, process planning	
10.	Production systems, calculation of standard cost	
11.	Routing, loading, scheduling, dispatching of records	
12.	Production control	
Unit-2:		**12**
13.	Aseptic process technology: Manufacturing	
14.	Manufacturing flowcharts	
15.	In process-quality control tests for following sterile dosage forms: Ointment, Suspension and Emulsion, Dry powder	
16.	Solution (Small Volume & large Volume)	
17.	Advanced sterile product manufacturing technology : location	
18.	Environmental control, wall and floor treatment, fixtures and machineries, change rooms	
19.	Area planning, personnel flow, utilities & utilities equipment	
20.	Engineering and maintenance	
21.	Process Automation in Pharmaceutical Industry: With specific reference to manufacturing of sterile semisolids	
22.	Small Volume Parenterals & Large Volume Parenterals (SVP & LVP)	
23.	Monitoring of Parenteral manufacturing facility, Cleaning in Place (CIP), Sterilization in Place (SIP), Prefilled Syringe, Powdered Jet, Needle Free Injections, and Form Fill Seal Technology (FFS)	
24.	Lyophilization technology: Principles, process, equipment	

II SESSIONAL : 36 Lectures

Lecture No.	Lecture Details	Hours
Unit-3:		**12**
25.	Non sterile manufacturing process technology: Manufacturing	
26.	Manufacturing flowcharts	
27.	In process-quality control tests for following Non-Sterile solid dosage forms: Tablets (compressed & coated), Capsules (Hard & Soft)	
28.	In process-quality control tests for following Non-Sterile solid dosage forms: Tablets (compressed & coated), Capsules (Hard & Soft)	
29.	Advance non-sterile solid product manufacturing technology: Process Automation in Pharmaceutical Industry with specific reference to manufacturing of tablets and coated products	
30.	Advance non-sterile solid product manufacturing technology: Process Automation in Pharmaceutical Industry with specific reference to manufacturing of tablets and coated products	
31.	Improved Tablet Production: Tablet production process	
32.	Granulation and pelletization equipments, continuous and batch mixing, rapid mixing granulators	
33.	Rota granulators, spheronizers and marumerisers, and other specialized granulation and drying equipments. Problems encountered	
34.	Coating technology: Process, equipments	
35.	Particle coating, fluidized bed coating	
36.	Application techniques. Problems encountered	
Unit-4:		**12**
37.	Containers and closures for pharmaceuticals: Types, performance	
38.	Containers and closures for pharmaceuticals: Types, performance	
39.	Assuring quality of glass; types of plastics used	
40.	Assuring quality of glass; types of plastics used	
41.	Drug plastic interactions, biological tests, modification of plastics by drugs	
42.	Drug plastic interactions, biological tests, modification of plastics by drugs	
43.	Different types of closures and closure liners; film wrapper; blister packs; bubble packs	
44.	Different types of closures and closure liners; film wrapper; blister packs; bubble packs	
45.	Shrink packaging; foil / plastic pouches, bottle seals, tape seals, breakable seals and sealed tubes	
46.	Quality control of packaging material and filling equipment	
47.	Flexible packaging, product package compatibility, transit worthiness of package	
48.	Stability aspects of packaging. Evaluation of stability of packaging material	

Unit-5:		**12**
49.	Quality by design (QbD) and process analytical technology (PAT): Current approach and its limitations	
50.	Quality by design (QbD) and process analytical technology (PAT): Current approach and its limitations	
51.	Quality by design (QbD) and process analytical technology (PAT): Current approach and its limitations	
52.	Quality by design (QbD) and process analytical technology (PAT): Current approach and its limitations	
53.	Quality by design (QbD) and process analytical technology (PAT): Current approach and its limitations	
54.	Why QbD is required, Advantages	
55.	Elements of QbD, Terminology: QTPP. CMA, CQA, CPP, RLD, Design space	
56.	Design of Experiments, Risk Assessment and mitigation/minimization	
57.	Quality by Design, Formulations by Design, QbD for drug products, QbD for Drug Substances	
58.	QbD for Excipients, Analytical QbD. FDA initiative on process analytical technology	
59.	PAT as a driver for improving quality and reducing costs: quality by design (QbD), QA, QC and GAMP	
60.	PAT guidance, standards and regulatory requirements	

TEXT BOOKS

1. Lachman L, Lieberman HA, Kanig JL. The theory and practice of industrial pharmacy, 3 rd ed., Varghese Publishers, Mumbai 1991.
2. Sinko PJ. Martin's physical pharmacy and pharmaceutical sciences, 5 th ed., B.I. Publications Pvt. Ltd, Noida, 2006.
3. Lieberman HA, Lachman L, Schwartz JB. Pharmaceutical dosage forms: tablets Vol. I-III, 2 nd ed., CBS Publishers & distributors, New Delhi, 2005.
4. Banker GS, Rhodes CT. Modern Pharmaceutics, 4 th ed., Marcel Dekker Inc, New York, 2005.
5. Sidney H Willing, Murray M, Tuckerman. Williams Hitchings IV, Good manufacturing of pharmaceuticals (A Plan for total quality control) 3rd Edition. Bhalani publishing house Mumbai.

REFERENCE BOOKS

1. Indian Pharmacopoeia. Controller of Publication. Delhi, 1996.
2. British Pharmacopoeia. British Pharmacopoeia Commission Office, London, 2008.
3. United States Pharmacopoeia. United States Pharmacopeial Convention, Inc, USA, 2003.
4. Dean D A, Evans E R and Hall I H. Pharmaceutical Packaging Technology. London, Taylor & Francis, 1st Edition. UK.
5. Edward J Bauer. Pharmaceutical Packaging Handbook. 2009. Informa Health care USA Inc. New york.
6. Shaybe Cox Gad. Pharmaceutical Manufacturing Handbook. John Willey and Sons, New Jersey, 2008.

JSS Academy of Higher Education & Research, Mysuru
JSS College of Pharmacy, Rocklands, Ooty

I M. PHARMACY TIME TABLE FOR E-LEARN CLASSES : I Semester (AY : 2020 - 2021)

DEPARTMENT : PHARMACEUTICAL ANALYSIS
COURSE : QUALITY ASSURANCE

ZOOM / GOOGLE MEET LICENSE - cpoana2@jssuni.edu.in

Days	9 - 10 am	10 - 11 am	11 - 12 am	12 - 1 pm	1 - 2 pm	2 - 3 pm	3 - 4 pm	4 - 5 pm
Mon	--	MPAT ***(NKV)***	SEMINAR	--	**LUNCH BREAK**	PT **(JP)**	QCQA **(NKV)**	QMS **(JSK)**
Tue	--	MPAT ***(NKV)***	--	ASSIGNMENT		PT **(JP)**	QCQA **(NKV)**	QMS **(JSK)**
Wed	--	MPAT ***(NKV)***	SEMINAR	--		SEMINAR	QCQ **(NKV)**	LIBRARY
Thu	--	MPAT ***(NKV)***	--	ASSIGNMENT		PT **(JP)**	QCQA **(NKV)**	QMS **(JSK)**
Fri	--	LIBRARY	SEMINAR			PT **(JP)**	ASSIGNMENT	QMS **(JSK)**
Sat	--	--	--	--		--	--	--

Subjects : I M.Pharm (Pharm. Analysis)

1. Modern Pharmaceutical Analytical Techniques (MPAT) – (T) : Dr. N. Krishna veni ***(NKV)***
2. Pharmaceutical Development and Technology Transfer (PT) – (T) : Dr. M R Jeyaprakash **(JP)**
3. Quality Control and Quality Assurance (QCQA) : Dr. N. Krishnaveni **(NKV)**
4. Quality Management System (QMS) : Dr. JSK Nagarajan **(JSK)**

JSS Academy of Higher Education & Research, Mysuru

(Deemed to be University, Accredited 'A⁺' Grade by NAAC)

JSS College of Pharmacy, Ooty – 643 001

(An ISO 9001-2015 certified Institution)

I M. Pharmacy (Pharmaceutical Quality Assurance), II Semester (AY 2020-2021)

Day	9-10 AM	10-11 AM	11-12 AM	12-1 PM	1 – 2 PM	2-3 PM	3 -4 PM	4 – 5 PM
Monday	CALIBRATION	HSM (JP)	ARA (BB)	PV (JSK)	LUNCH BREAK	Pharmaceutical Quality Assurance II Practical's(PQA II) (SNM, JSK, BB, JP)		
Tuesday	PV (JSK)	ARA (BB)	HSM (JP)	PMT (SNM)		Pharmaceutical Quality Assurance II Practical's(PQA II) (SNM, JSK, BB, JP)		
Wednesday	CALIBRATION	ASSIGNMENT	PMT (SNM)	ARA (BB)		RESEARCH AUDIT	JOURNAL CLUB	SEMINAR
Thursday	SEMINAR	ASSIGNMENT	PMT (SNM)	HSM (JP)		Pharmaceutical Quality Assurance II Practical's(PQA II) (SNM, JSK, BB, JP)		
Friday	ASSIGNMENT	PV (JSK)	ARA (BB)	HSM (JP)		Pharmaceutical Quality Assurance II Practical's(PQA II) (SNM, JSK, BB, JP)		
Saturday	SEMINAR	PMT (SNM)	PV (JSK)	SEMINAR				

Subject- In-charge

Hazard and Safety Management (HSM) - (T)	Dr. M. R. Jeyaprakash (JP)
Pharmaceutical Validation (PV) – (T)	Mr. J. S. K. Nagarajan (JSK)
Audit and Regulatory compliance (ARA) – (T)	Mr. B. Babu (BB)
Pharmaceutical Manufacturing Technology (PMT) – (T)	Dr. S. N. Meyyanathan (SNM)
Pharmaceutical Quality Assurance II Practical's (PQA II)	Mr. B. Babu (BB), Dr. M. R. Jeyaprakash (JP), Dr. N. Krishna veni (NKV), Dr. S. N. Meyyanathan (SNM)

M. PHARM
PHARMACEUTICAL REGULATORY AFFAIRS

SYLLABUS
I SEMESTER
MRA 101T-GOOD REGULATORY PRACTICES (Theory)

SCOPE

This course is designed to impart fundamental knowledge on various Good Regulatory Practices viz., cGMP, GLP, GALP and GDP for Pharmaceuticals, Cosmetics, Food & Nutraceuticals, Medical devices, In-vitro Diagnostic Medical Devices (IVDs) and biological products and understand the rationale behind these requirements and will propose ways and means of complying with them.

OBJECTIVES

At completion of this course it is expected that students will be able to understand,

- The key regulatory and compliance elements with respect to Good Manufacturing Practices, Good Laboratory Practices, Good Automated Laboratory Practices and Good Documentation Practices.
- Prepare and implement the check lists and SOPs for various Good Regulatory Practices
- Implement Good Regulatory Practices in the Healthcare and related Industries
- Prepare for the readiness and conduct of audits and inspections.

course content

THEORY **60 Hrs**

1. Current Good Manufacturing Practices: Introduction, US cGMP Part 210 and Part 211.EC Principles of GMP (Directive 91/356/EEC) Article 6 to Article 14 and WHO cGMP guidelines GAMP-5; Medical device and IVDs Global Harmonization Task Force(GHTF) Guidance docs.	12 Hrs
2. Good Laboratory Practices: Introduction, USFDA GLP Regulations (Subpart A to Subpart K), Controlling the GLP inspection process, Documentation, Audit, goals of Laboratory Quality Audit, Audit tools, Future of GLP regulations, relevant ISO and Quality Council of India(QCI) Standards	12 Hrs
3. Good Automated Laboratory Practices: Introduction to GALP, Principles of GALP, GALP Requirements, SOPs of GALP, Training Documentation,21 CFR Part 11, General check list of 21CFR Part 11, Software Evaluation checklist, relevant ISO and QCI Standards.	12 Hrs
4. Good Distribution Practices: Introduction to GDP, Legal GDP requirements put worldwide, Principles, Personnel, Documentation, Premises and Equipment, Deliveries to Customers, Returns, Self-Inspection, Provision of information, Stability testing principles, WHO GDP, USP GDP (Supply chain integrity), relevant CDSCO guidance and ISO standards	12 Hrs
5. Quality management systems: Concept of Quality, Total Quality Management, Quality by design, Six Sigma concept, Out of Specifications (OOS), Change control. Validation: Types of Validation, Types of Qualification, Validation master plan (VMP), Analytical Method Validation. Validation of utilities, [Compressed air, steam, water systems, Heat Ventilation and Air conditioning	12 Hrs

(HVAC)]and Cleaning Validation. The International Conference on Harmonization (ICH) process, ICH guidelines to establish quality, safety and efficacy of drug substances and products, ISO 13485, Sch MIII and other relevant CDSCO regulatory guidance documents.	

REFERENCES

1. Good Laboratory Practice Regulations, by Sandy Weinberg, Fourth Edition Drugs and the Pharmaceutical Sciences, Vol.168
2. Good Pharmaceutical Manufacturing practice, Rational and compliance by John Sharp, CRC Press
3. Establishing a cGMP Laboratory Audit System, A practical Guide by David M.Bleisner, Wiley Publication.
4. How to practice GLP by PP Sharma, Vandana Publications.
5. Laboratory Auditing for Quality and Regulatory compliance bu Donald C.Singer, Drugs and the Pharmaceutical Sciences, Vol.150.
6. Drugs & Cosmetics Act, Rules & Amendments

MRA 102T- DOCUMENTATION AND REGULATORY WRITING (Theory)

SCOPE

This course is designed to impart fundamental knowledge on documentation and general principles involved in regulatory writing and submission to agencies.

OBJECTIVES

Upon completion of the course the student shall be able to,

- Know the various documents pertaining to drugs in pharmaceutical industry
- Understand the basics of regulatory compilation
- Create and assemble the regulation submission as per the requirements of agencies
- Follow up the submissions and post approval document requirements

COURSE CONTENT

THEORY **60 Hrs**

1. Documentation in pharmaceutical industry: Exploratory Product Development Brief (EPDB) for Drug substance and Drug product, Product Development Plan (PDP), Product Development Report (PDR), Master Formula Record, Batch Manufacturing Record and its calculations, Batch Reconciliation, Batch Packaging Records, Print pack specifications, Distribution records, Certificate of Analysis (CoA), Site Master File and Drug Master Files (DMF)	12 Hrs
2. Dossier preparation and submission: Introduction and overview of dossiers, contents and organization of dossier, binders and sections, compilation and review of dossier. Paper submissions, overview and modules of CTD, electronic CTD submissions; Electronic submission: Planning electronic submission, requirements for submission, regulatory bindings and requirements, Tool and Technologies, electronic dossier submission process and validating the submission, Electronic Submission Gateway (ESG). Non eCTD electronic submissions (NeeS), Asian CTD formats (ACTD) submission. Organizing, process and validation of submission. Submission in Sugam system of CDSCO	12 Hrs
3. Audits: Introduction, Definition, Summary, Types of audits, GMP compliance audit, Audit policy, Internal and External Audits, Second Party Audits, External third party audits, Auditing strategies, Preparation and conducting audit, Auditing strategies, audit analysis, audit report, audit follow up. Auditing/inspection of manufacturing facilities by regulatory agencies. Timelines for audits/inspection. GHTF study group 4 guidance document. ISO 13485.	12 Hrs
4. Inspections: Pre-approval inspections, Inspection of pharmaceutical manufacturers, Inspection of drug distribution channels, Quality systems requirements for national good manufacturing practice inspectorates, inspection report, model certificate of good manufacturing practices, Root cause analysis, Corrective and Preventive action (CAPA).	12 Hrs
5. Product life cycle management: Prior Approval Supplement (PAS), Post Approval Changes [SUPAC], Changes Being Effected in 30 Days (CBE-30), Annual Report, Post marketing Reporting Requirements, Post approval Labeling Changes, Lifecycle Management, FDA Inspection and Enforcement, Establishment	12 Hrs

Inspection Report (EIR), Warning Letters, Recalls, Seizure and Injunctions. ISO Risk Management Standard	

REFERENCES

1. Compliance auditing for Pharmaceutical Manufacturers. Karen Ginsbury and Gil Bismuth, Interpharm/CRC, Boca Raton, London New York, Washington D.C.
2. Pharmaceutical Manufacturing Handbook, Regulations and Quality by Shayne Cox Gad. Wiley-Interscience, A John Wiley and sons, Inc., Publications.
3. Handbook of microbiological Quality control. Rosamund M. Baird, Norman A. Hodges, Stephen P. Denyar. CRC Press. 2000.
4. Laboratory auditing for quality and regulatory compliance. Donald C. Singer, Raluca-loana Stefan, Jacobus F. Van Staden. Taylor and Francis (2005).
5. Implementing Juran's Road Map for Quality Leadership: Benchmarks and Results, By Al Endres, Wiley, 2000
6. Understanding, Managing and Implementing Quality: Frameworks, Techniques and Cases, By Jiju Antony; David Preece, Routledge, 2002
7. Organizing for High Performance: Employee Involvement, TQM, Reengineering, and Knowledge Management in the Fortune 1000: The CEO Report By Edward E. Lawler; Susan Albers Mohrman; George Benson, Jossey-Bass, 2001
8. Corporate Culture and the Quality Organization By James W. FairfieldSonn, Quorum Books, 2001
9. The Quality Management Sourcebook: An International Guide to Materials and Resources By Christine Avery; Diane Zabel, Routledge, 1997
10. The Quality Toolbox, Second Edition, Nancy R. Tague, ASQ Publications
11. Juran's Quality Handbook, Sixth Edition, Joseph M. Juran and Joseph A. De Feo, ASQ Publications
12. Root Cause Analysis, The Core of Problem Solving and Corrective Action, Duke Okes, 2009, ASQ Publications
13. International Medical Device Regulators Forum (IMDRF) Medical Device Single Audit Program (MDSAP)

MRA 103T-CLINICAL RESESRCH REGULATIONS (Theory)

SCOPE

This course is designed to impart the fundamental knowledge on the clinical development process of drugs, pharmaceuticals and Medical Devices, phases and conduct of clinical trials and research, regulations and guidance governing the conduct of clinical research in India, USA and EU. It prepares the students to learn in detail on various laws, legislations and guidance related to safety, efficacy, ethical conduct and regulatory approval of clinical research.

OBJECTIVES

Upon completion of the course, the student shall be able to (know, do and appreciate)

- History, origin and ethics of clinical and biomedical research and evaluation
- Clinical drug, medical device development process and different types and phases of clinical trials
- Regulatory requirements and guidance for conduct of clinical trials and research

COURSE CONTENT

THEORY **60 Hrs**

1. Clinical Drug Development Process • Different types of Clinical Studies • Phases of clinical trials, Clinical Trial protocol • Phase 0 studies • Phase I and subtype studies (single ascending, multiple ascending, dose escalation, methods, food effect studies, drug – drug interaction, PK end points • Phase II studies (proof of concept or principle studies to establish efficacy) • Phase III studies (Multi ethnicity, global clinical trial, registration studies) • Phase IV studies (Post Marketing Studies; PSUR) • Clinical Investigation and Evaluation of Medical Devices & IVDs Different Types of Studies Key Concepts of Medical Device Clinical Evaluation Key concepts of Clinical Investigation	12 Hrs
2. Ethics in Clinical Research: • Historical Perspectives: Nuremberg Code, Thalidomide study , Nazis Trials, Tuskegee Syphilis Study, The Belmont Report, The declaration of Helsinki • Origin of International Conference on Harmonization - Good Clinical Practice (ICH-GCP) guidelines. • The ethics of randomized clinical trials • The role of placebo in clinical trials • Ethics of clinical research in special population • Institutional Review Board/Independent Ethics Committee/Ethics Committee – composition, roles, responsibilities, review and approval process and ongoing monitoring of safety data	12 Hrs

• Data safety monitoring boards. • Responsibilities of sponsor, CRO, and investigator in ethical conduct of clinical research • Ethical principles governing informed consent process • Patient Information Sheet and Informed Consent Form • The informed consent process and documentation	
3. Regulations governing Clinical Trials India: Clinical Research regulations in India – Schedule Y & Medical Device Guidance USA: Regulations to conduct drug studies in USA (FDA) NDA 505(b)(1) of the FD&C Act (Application for approval of a new drug) • NDA 505(b)(2) of the FD&C Act (Application for approval of a new drug that relies, at least in part, on data not developed by the applicant) • ANDA 505(j) of the FD&C Act (Application for approval of a generic drug product) • FDA Guidance for Industry - Acceptance of Foreign Clinical Studies • FDA Clinical Trials Guidance Document: Good Clinical Practice EU: Clinical Research regulations in European Union (EMA)	12 Hrs
4. Clinical Research Related Guidelines • Good Clinical Practice Guidelines (ICH GCP E6) • Indian GCP Guidelines • ICMR Ethical Guidelines for Biomedical Research • CDSCO guidelines GHTF study group 5 guidance documents Regulatory Guidance on Efficacy and Safety ICH Guidance's • E4 – Dose Response Information to support Drug Registration • E7 – Studies in support of General Population: Geriatrics • E8 – General Considerations of Clinical Trials • E10 – Choice of Control Groups and Related Issues in Clinical Trials, • E 11 – Clinical Investigation of Medicinal Products in the Pediatric Population • General biostatics principle applied in clinical research	12 Hrs
5. USA & EU Guidance • CFR 21Part 50: Protection of Human Subjects • CFR 21Part 54: Financial Disclosure by Clinical Investigators • CFR 21Part 312: IND Application • CFR 21Part 314: Application for FDA Approval to Market a New Drug • CFR 21Part 320: Bioavailability and bioequivalence requirements • CFR 21Part 812: Investigational Device Exemptions • CFR 21Part 822: Post-market surveillance • FDA Safety Reporting Requirements for INDs and BA/BE Studies • FDA Med Watch • Guidance for Industry: Good Pharmacovigilance Practices and Pharmacoepidemiologic Assessment	12 Hrs

European Union: EMA Guidance • EU Directives 2001 • EudraLex (EMEA) Volume 3 – Scientific guidelines for medicinal products for human use • EU Annual Safety Report (ASR) • Volume 9A – Pharmacovigilance for Medicinal Products for Human Use • EU MDD with respect to clinical research • ISO 14155	

REFERENCES

1. Clinical Trials and Human Research: A Practical Guide to Regulatory Compliance By Fay A. Rozovsky and Rodney K. Adams
2. HIPAA and Human Subjects Research: A Question and Answer Reference Guide By Mark Barnes, JD, LLM and Jennifer Kulynych, JD, PhD
3. Principles and Practices of Clinical Research, Second Edition Edited by John I. Gallin and Frederick P. Ognibene
4. Reviewing Clinical Trials: A Guide for the Ethics Committee; Johan PE Karlberg and Marjorie A Speers; Karlberg, Johan Petter Einar, Hong Kong.
5. International Pharmaceutical Product Registration: Aspects of Quality, Safety and Efficacy; Anthony C. Cartwright; Taylor & Francis Inc., USA.
6. New Drug Approval Process: The Global Challenge; Guarino, Richard A; Marcel Dekker Inc., NY.
7. FDA regulatory affairs: a guide for prescription drugs, medical devices, and biologics; Douglas J. Pisano, David Mantus; CRC Press, USA
8. Country Specific Guidelines from official websites. 9. Drugs & Cosmetics Act & Rules and Amendments

RECOMMENDED WEBSITES

1. EU Clinical Research Directive 2001: http://www.eortc.be/services/doc /clinical-eudirective-04-april-01.pdf
2. Code of Federal Regulations, FDA: http://www.accessdata.fda.gov/scripts /cdrh /cfdocs/cfcfr/cfrsearch.cfm
3. Guidelines of International Conference on Harmonization: http://www. ich.org /products/guidelines.html
4. Eudralex Guidelines: http://www.gmpcompliance.info/euguide.htm
5. FDA New Drug Application: http://www.fda.gov/regulatoryinformation/legislation/FederalFoodDruga ndCosmetic ActFDCAct/FDCActChapterVDrugsandDevices/ucm108125.htm
6. Medicines and Healthcare products Regulatory Agency: http://www .mhra.gov.uk
7. Central Drugs Standard Control Organization Guidance for Industry: http://cdsco.nic.in/CDSCO-GuidanceForIndustry.pdf
8. ICMR Ethical Guidelines for Biomedical Research: http://icmr.nic.in /ethical_guidelines.pdf

MRA 104 T- REGULATIONS AND LEGISLATIONS FOR DRUGS & COSMETICS, MEDICAL DEVICES, BIOLOGICS & HERBALS AND FOOD & NUTRACEUTICALS IN INDIA AND THE INTELLECTUAL PROPERTY RIGHTS (Theory)

SCOPE

This course is designed to impart fundamental knowledge on regulations and legislation in India w.r.t. Drugs & Cosmetics, Medical Devices, Biologicals & Herbals, and Food & Nutraceuticals. It prepares the students for basic regulatory requirements in India of Drugs & Cosmetics, Medical Devices, Biologicals & Herbals, and Food & Nutraceuticals. for manufacture, import & registration, export, sale, marketing authorization, clinical trials and intellectual property rights

OBJECTIVES

Upon the completion of the course the student shall be able to:

- Know different Acts and guidelines that regulate Drugs & Cosmetics, Medical Devices, Biologicals & Herbals, and Food & Nutraceuticals industry in India.
- Understand the approval process and regulatory requirements for Drugs & Cosmetics, Medical Devices, Biologicals & Herbals, and Food & Nutraceuticals

COURSE CONTENT

THEORY **60 Hrs**

1. Biologicals & Herbals, and Food & Nutraceuticals Acts and Rules (with latest amendments): • Drugs and Cosmetics Act 1940 and Rules 1945: DPCO and NPPA • Other relevant provisions (rules schedules and guidelines for approval of Drugs & Cosmetics, Medical Devices, Biologicals & Herbals, and Food & Nutraceuticals in India Other relevant Acts: Narcotics Drugs and Psychotropic Substances Act; Medicinal and Toilet Preparations (Excise Duties) Act, 1955; Pharmacy Act, 1948; Drugs and Magic Remedies (Objectionable Advertisements) Act, 1955; Prevention of Cruelty to Animals Act.	12 Hrs
2. Regulatory requirements and approval procedures for Drugs & Cosmetics Medical Devices, Biologicals & Herbals, and Food & Nutraceuticals CDSCO (Central Drug Standard Control Organization) and State Licensing Authority: Organization, Responsibilities • Rules, regulations, guidelines and standards for regulatory filing of Drugs & Cosmetics, Medical Devices, Biologicals & Herbals, and Food & Nutraceuticals • Format and contents of Regulatory dossier filing Clinical trial/ investigations	12 Hrs
3. Indian Pharmacopoeial Standards, BIS standards and ISO and other relevant standards	12 Hrs
4. Bioavailability and Bioequivalence data (BA &BE), BCS Classification of Drugs, Regulatory Requirements for Bioequivalence study Stability requirements: ICH and	12 Hrs

WHO Guidelines for Drug testing in animals/Preclinical Studies Animal testing: Rationale for conducting studies, CPCSEA Guidelines Ethical guidelines for human participants ICMR-DBT Guidelines for Stem Cell Research	
5. Intellectual Property Rights: Patent, Trademark, Copyright, Industrial Designs and Geographical Indications, Indian Patent Scenario. IPR vs Regulatory Affairs	12 Hrs

REFERENCES

1. Manual of Patent Practice & Procedure, 3rd Edition, by The Patent Office of India
2. Patent Failure How Judges, Bureaucrats, and Lawyers put innovators at risk by James Bessen and Michael J. Meurer
3. Principles and Practice of Clinical Trial Medicine by Richard Chin and Bruce Y. Lee
4. Ethical Guidelines for Biomedical Research on Human Participants by Indian Council of Medical Research New delhi 2006.
5. CPCSEA Guidelines for Laboratory Animal Facility by Committee for the purpose of control and supervision on experiments on animals (CPCSEA) ICH E6 Guideline ― Good Clinical Practice‖ by ICH Harmonised Tripartite
6. Guidance for Industry on Submission of Clinical Trial Application for Evaluating Safety and Efficacy by CDSCO (Central Drug Standard Control Organisation)
7. Guidance for Industry on Requirement of Chemical & Pharmaceutical Information including Stability Study Data before approval of clinical trials / BE studies by CDSCO
8. Guidelines for Import and Manufacture of Medical Devices by CDSCO 10. Guidelines from official website of CDSCO.

MQA 105P-REGULATORY AFFAIRS PRACTICAL – I (Practicals)

1. Case studies (4 Nos.) of each of Good Pharmaceutical Practices.
2. Documentation for in process and finished products Quality control tests for Solid, liquid, Semisolid and Sterile preparations.
3. Preparation of SOPs, Analytical reports (Stability and validation)
4. Protocol preparation for documentation of various types of records (BMR, MFR, DR)
5. Labeling comparison between brand & generics.
6. Preparation of clinical trial protocol for registering trial in India
7. Registration for conducting BA/ BE studies in India
8. Import of drugs for research and developmental activities
9. Preparation of regulatory dossier as per Indian CTD format and submission in SUGAM
10. Registering for different Intellectual Property Rights in India
11. GMP Audit Requirements as per CDSCO
12. Preparation and documentation for Indian Patent application.
13. Preparation of checklist for registration of IND as per ICH CTD format.
14. Preparation of checklist for registration of NDA as per ICH CTD format.
15. Preparation of checklist for registration of ANDA as per ICH CTD format.
16. Case studies on response with scientific rationale to USFDA Warning Letter
17. Preparation of submission checklist of IMPD for EU submission.
18. Comparison study of marketing authorization procedures in EU.
19. Comparative study of DMF system in US, EU and Japan
20. Preparation of regulatory submission using eCTD software
21. Preparation of Clinical Trial Application (CTA) for US submission
22. Preparation of Clinical Trial Application (CTA) for EU submission
23. Comparison of Clinical Trial Application requirements of US, EU and Japan of a dosage form.
24. Regulatory requirements checklist for conducting clinical trials in India.
25. Regulatory requirements checklist for conducting clinical trials in Europe.
26. Regulatory requirements checklist for conducting clinical trials in USA

SEMESTER II
MRA 201T-REGULATORY ASPECTS OF DRUGS & COSMETICS (Theory)

SCOPE

This course is designed to impart the fundamental knowledge on the drug development process, regulatory requirements for approval of new drugs, drug products and cosmetics in regulated and semi-regulated countriesIt prepares the students to learn in detail on the regulatory requirements, documentation requirements, and registration procedures for marketing the drug products and cosmetics in regulated and semi-regulated countries.

OBJECTIVES

Upon completion of the course, the student shall be able to know

- Process of drug discovery and development and generic product development
- Regulatory approval process and registration procedures for API and drug products in US, EU
- Cosmetics regulations in regulated and semi-regulated countries
- A comparative study of India with other global regulated markets

COURSE CONTENT

THEORY **60 Hrs**

1. USA & CANADA: Organization structure and functions of FDA. Federal register and Code of Federal Regulations (CFR), History and evolution of United States Federal, Food, Drug and Cosmetic Act (FFDCA), Hatch Waxman act and Orange book, Purple book, Drug Master Files (DMF) system in US, Regulatory Approval Process for Investigational New Drug (IND), New Drug Application (NDA), Abbreviated New Drug Application (ANDA), Supplemental New Drug Application (SNDA); Regulatory requirements for Orphan drugs and Combination Products, Changes to an approved NDA / ANDA. Regulatory considerations for manufacturing, packaging and labeling of pharmaceuticals in USA. Legislation and regulations for import, manufacture, distribution and sale of cosmetics in USA and Canada.	12 Hrs
2. European Union & Australia: Organization and structure of EMA & EDQM, General guidelines, Active Substance Master Files (ASMF) system in EU, Content and approval process of IMPD, Marketing Authorization procedures in EU (Centralized procedure, Decentralized procedure, Mutual recognition procedure and National Procedure). Regulatory considerations for manufacturing, packaging and labeling of pharmaceuticals in EU, Eudralex directives for human medicines, Variations & extensions, Compliance of European Pharmacopoeia (CEP)/ Certificate of Suitability (CoS), Marketing Authorization (MA) transfers, Qualified Person (QP) in EU. Legislation and regulations for import, manufacture, distribution and sale of cosmetics in European Union & Australia.	12 Hrs
3. Japan: Organization of the PMDA, Pharmaceutical Laws and regulations, types of registration applications, DMF system in Japan, drug regulatory approval	12 Hrs

	process, Regulatory considerations for manufacturing, packaging and labeling of pharmaceuticals in Japan, Post marketing surveillance in Japan. Legislation and regulations for import, manufacture, distribution and sale of cosmetics in Japan	
4.	Emerging Market: Introduction, Countries covered, Study of the world map,study of various committees across the globe (ASEAN, APEC, EAC, GCC, PANDRH, SADC) WHO: WHO, GMP, Regulatory Requirements for registration of drugs and post approval requirements in WHO through prequalification programme, Certificate of Pharmaceutical Product (CoPP) - General and Country Specific (South Africa, Egypt, Algeria and Morocco, Nigeria, Kenya and Botswana)	12 Hrs
5.	Brazil, ASEAN, CIS and GCC Countries: ASIAN Countries: Introduction to ACTD, Regulatory Requirements for registration of drugs and post approval requirements in China and South Korea & Association of Southeast Asian Nations (ASEAN) Region i.e. Vietnam, Malaysia, Philippines, Singapore and Thailand. CIS (Commonwealth Independent States): Regulatory prerequisites related to Marketing authorization requirements for drugs and post approval requirements in CIS countries i.e. Russia, Kazakhstan and Ukraine GCC (Gulf Cooperation Council) for Arab states: Regulatory pre-requisites related to Marketing authorization requirements for drugs and post approval requirements in Saudi Arabia and UAE Legislation and regulations for import, manufacture, distribution and sale of cosmetics in Brazil, ASEAN, CIS and GCC Countries.	12 Hrs

REFERENCES

1. Generic Drug Product Development, Solid Oral Dosage forms, Leon Shargel and Isader Kaufer, Marcel Dekker series, Vol.143
2. The Pharmaceutical Regulatory Process, Edited by Ira R. Berry Marcel Dekker Series, Vol.144
3. The Pharmaceutical Regulatory Process, Second Edition Edited by Ira R. Berry and Robert P. Martin, Drugs and the Pharmaceutical Sciences, Vol.185 Informa Health care Publishers.
4. New Drug Approval Process: Accelerating Global Registrations By Richard A Guarino, MD, 5th edition, Drugs and the Pharmaceutical Sciences, Vol.190.
5. Guidebook for drug regulatory submissions / Sandy Weinberg. By John Wiley & Sons. Inc.
6. Drugs: From Discovery to Approval, Second Edition By Rick Ng
7. New Drug Development: A Regulatory Overview, Eighth Edition By Mark Mathieu
8. Pharmaceutical Risk Management By Jeffrey E. Fetterman, Wayne L. Pines and Gary H. Slatko
9. Preparation and Maintenance of the IND Application in eCTD Format By William K. Sietsema
10. Country Specific Guidelines from official websites.
11. http://www.who.int/medicines/areas/quality_safety/regulation_legislation/ListMRAWebsites.pdf
12. Roadmap to an ASEAN economic community Edited by Denis Hew. ISEAS Publications, Singapore 2005, ISBN981-230-347-2

13. ASEAN, Rodolfo C. Severino, ISEAS Publications, Singapore 2005, ISBN 978-981-230-750-7
14. Building a Future with Brics: The Next Decade for Offshoring, Mark Kobayashi-Hillary, Springer
15. Outsourcing to India: The Offshore Advantage, Mark Kobayashi-Hillary, Springer Trade performance and Regional Integration of the CIS Countries, Lev Freinkman,
16. The world Bank, Washington, DC, ISBN: 0-8212-5896-0
17. Global Pharmaceutical Policy: Ensuring Medicines for Tomorrow's World ByFrederick M. Abbott, Graham Dukes, Maurice Nelson Graham Dukes 139
18. The Gulf Cooperation Council: A Rising Power and Lessons for ASEAN by Linda Low and Lorraine Carlos Salazar (Nov 22, 2010)
19. Doing Business in the Asean Countries, Balbir Bhasin, Business Expert Press ISBN:13:978-1-60649-108-9
20. Realizing the ASEAN Economic Community: A Comprehensive Assessment, Michael G Plummer (Editor), Chia Siow Yue (Editor), Instute of South east asian studies, Singapore

MRA 202T-REGULATORY ASPECTS OF HERBALS AND BIOLOGICS (Theory)

SCOPE

This course is designed to impart fundamental knowledge on Regulatory Requirements, Licensing and Registration, Regulation on Labelling of Biologics in India, USA and Europe. It prepares the students to learn in detail on Regulatory Requirements for biologics, Vaccines and Blood Products

OBJECTIVES

Upon the completion of the course the student shall be able to :

- Know the regulatory Requirements for Biologics and Vaccines
- Understand the regulation for newly developed biologics and biosimilars
- Know the pre-clinical and clinical development considerations of biologics
- Understand the Regulatory Requirements of Blood and/or Its Components Including Blood Products and label requirements

COURSE CONTENT

THEORY **60 Hrs**

1 India : Introduction, Applicable Regulations and Guidelines , Principles for Development of Similar Biologics, Data Requirements for Preclinical Studies, Data Requirements for Clinical Trial Application, Data Requirements for Market Authorization Application, Post-Market Data for Similar Biologics, Pharmacovigilance. GMP and GDP.	10 Hrs
2. USA: Introduction to Biologics; biologics, biological and biosimilars, different biological products, difference between generic drug and biosimilars, laws, regulations and guidance on biologics/ biosimilars, development and approval of biologics and biosimilars (IND, PMA, BLA, NDA, 510(k), pre-clinical and clinical development considerations, advertising, labelling and packing of biologics	10 Hrs
3. European Union: Introduction to Biologics; directives, scientific guidelines and guidance related to biologics in EU, comparability/ biosimilarity assessment, Plasma master file, TSE/ BSE evaluation, development and regulatory approval of biologics (Investigational medicinal products and biosimilars), pre-clinical and clinical development considerations; stability, safety, advertising, labelling and packing of biologics in EU	10 Hrs
4. Vaccine regulations in India, US and European Union: Clinical evaluation, Marketing authorisation, Registration or licensing, Quality assessment, Pharmacovigilance, Additional requirements Blood and Blood Products Regulations in India, US and European Union: Regulatory Requirements of Blood and/or Its Components Including Blood Products, Label Requirements, ISBT (International Society of Blood Transfusion) and IHN (International Haemovigilence Network)	10 Hrs
5. Herbal Products: Quality, safety and legislation for herbal products in India, USA and European Union.	10 hrs

REFERENCES

1. FDA Regulatory Affairs: A Guide for Prescription Drugs, Medical Devices, and Biologics, Douglas J. Pisano , David S. Mantus ; Informa ,2008
2. Biological Drug Products: Development and Strategies; Wei Wang , Manmohan Singh ; wiley ,2013
3. Development of Vaccines: From Discovery to Clinical Testing; Manmohan Singh , Indresh K. Srivastava ;Wiley, 2011
4. www.who.int/biologicals/en
5. www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInfo rmation/
6. www.ihn-org.com
7. www.isbtweb.org
8. Guidelines on Similar Biologics: Regulatory Requirements for Marketing Authorization in India
9. www.cdsco.nic.in
10. www.ema.europa.eu › scientific guidelines › Biologicals
11. www.fda.gov/biologicsbloodVaccines/GuidanceCompliance Regulatory Information (Biologics)

MRA 203T-REGULATORY ASPECTS OF MEDICAL DEVICES (Theory)

SCOPE

This course is designed to impart the fundamental knowledge on the medical devices and in vitro diagnostics, basis of classification and product life cycle of medical devices, regulatory requirements for approval of medical devices in regulated countries like US, EU and Asian countries along with WHO regulations. It prepares the students to learn in detail on the harmonization initiatives, quality and ethical considerations, regulatory and documentation requirements for marketing medical devices and IVDs in regulated countries.

OBJECTIVES

Upon completion of the course, the student shall be able to know

- basics of medical devices and IVDs, process of development, ethical and quality considerations
- harmonization initiatives for approval and marketing of medical devices and IVDs
- regulatory approval process for medical devices and IVDs in India, US, Canada, EU, Japan and ASEAN
- clinical evaluation and investigation of medical devices and IVDs

COURSE CONTENT

THEORY **60 Hrs**

1 Medical Devices: Introduction, Definition, Risk based classification and Essential Principles of Medical Devices and IVDs. Differentiating medical devices IVDs and Combination Products from that of pharmaceuticals, History of Medical Device Regulation, Product Lifecycle of Medical Devices and Classification of Medical Devices. IMDRF/GHTF: Introduction, Organizational Structure, Purpose and Functions, Regulatory Guidelines, Working Groups, Summary Technical Document (STED), Global Medical Device Nomenclature (GMDN).	12 Hrs
2. Ethics: Clinical Investigation of Medical Devices, Clinical Investigation Plan for Medical Devices, Good Clinical Practice for Clinical Investigation of medical devices (ISO 14155:2011) Quality: Quality System Regulations of Medical Devices: ISO 13485, Quality Risk Management of Medical Devices: ISO 14971, Validation and Verification of Medical device, Adverse Event Reporting of Medical device	12 Hrs
3. USA: Introduction, Classification, Regulatory approval process for Medical Devices (510k) Premarket Notification, Pre-Market Approval (PMA), Investigational Device Exemption (IDE) and In vitro Diagnostics, Quality System Requirements 21 CFR Part 820, Labeling requirements 21 CFR Part 801, Post marketing surveillance of MD and Unique Device Identification (UDI). Basics of In vitro diagnostics, classification and approval process.	12 Hrs
4. European Union: Introduction, Classification, Regulatory approval process for Medical Devices (Medical Device Directive, Active Implantable Medical Device Directive) and In vitro Diagnostics (In Vitro Diagnostics Directive), CE certification process. Basics of In vitro diagnostics, classification and approval process.	12 Hrs

5. ASEAN, China & Japan: Medical Devices and IVDs, Regulatory registration procedures, Quality System requirements and clinical evaluation and investigation. IMDRF study groups and guidance documents.	12 Hrs

REFERENCES

1. FDA regulatory affairs: a guide for prescription drugs, medical devices, and biologics by Douglas J. Pisano, David Mantus.
2. Medical Device Development: A Regulatory Overview by Jonathan S. Kahan
3. Medical Product Regulatory Affairs: Pharmaceuticals, Diagnostics, Medical Devices by John J. Tobin and Gary Walsh
4. Compliance Handbook for Pharmaceuticals, Medical Devices and Biologics by Carmen Medina
5. Country Specific Guidelines from official websites.

MRA 204T-REGULATORY ASPECTS OF FOOD & NUTRACEUTICALS (Theory)

SCOPE

This course is designed to impart the fundamental knowledge on Regulatory Requirements, Registration and Labeling Regulations of Nutraceuticals in India, USA and Europe.

It prepares the students to learn in detail on Regulatory Aspects for nutraceuticals and food supplements.

OBJECTIVES

Upon completion of the course, the student shall be able to

- Know the regulatory Requirements for nutraceuticals
- Understand the regulation for registration and labeling of nutraceuticals and food supplements in India, USA and Europe.

COURSE CONTENT

THEORY **60 Hrs**

1 Nutraceuticals: Introduction, History of Food and Nutraceutical Regulations, Meaning of Nutraceuticals, Dietary Supplements, Functional Foods, Medical Foods, Scope and Opportunities in Nutraceutical Market.	12 Hrs
2. Global Aspects: WHO guidelines on nutrition. NSF International: Its Role in the Dietary Supplements and Nutraceuticals Industries, NSF Certification, NSF Standards for Food And Dietary Supplements. Good Manufacturing Practices for Nutraceuticals.	12 Hrs
3. India : Food Safety and Standards Act, Food Safety and Standards Authority of India: Organization and Functions, Regulations for import, manufacture and sale of nutraceutical products in India, Recommended Dietary Allowances (RDA) in India	12 Hrs
4. USA: US FDA Food Safety Modernization Act, Dietary Supplement Health and Education Act. U.S. regulations for manufacture and sale of nutraceuticals and dietary supplements, Labelling Requirements and Label Claims for Dietary Supplements, Recommended Dietary Allowances (RDA) in the U.S	12 Hrs
5. European Union: European Food Safety Authority (EFSA): Organization and Functions. EU Directives and regulations for manufacture and sale of nutraceuticals and dietary supplements. Nutrition labelling. European Regulation on Novel Foods and Novel Food Ingredients. Recommended Dietary Allowances (RDA) in Europe	12 Hrs

REFERENCES

1. Regulation of Functional Foods and Nutraceuticals: A Global Perspective by Clare M. Hasler (Wiley Online Library)
2. Nutraceutical and Functional Food Regulations in the United States and Around the World by Debasis Bagchi (Academic Press, Elsevier)
3. http://www.who.int/publications/guidelines/nutrition/en/
4. http://www.europarl.europa.eu/RegData/etudes/STUD/2015/536324/IPOL_ STU(2015)536324_EN.pdf
5. Handbook of Nutraceuticals by Yashwant Pathak (CRC Press)

6. Food Regulation: Law, Science, Policy and Practice by Neal D. Fortin (Wiley)
7. Country Specific Guidelines from official websites.

MRA 205P-REGULATORY AFFAIRS PRACTICAL – II (Practicals)

1. Case studies on
    a. Change Management/ Change control. Deviations
    b. Corrective & Preventive Actions (CAPA)
2. Documentation of raw materials analysis as per official monographs
3. Preparation of audit checklist for various agencies
4. Preparation of submission to FDA using eCTD software
5. Preparation of submission to EMA using eCTD software
6. Preparation of submission to MHRA using eCTD software
7. Preparation of Biologics License Applications (BLA)
8. Preparation of documents required for Vaccine Product Approval
9. Comparison of clinical trial application requirements of US, EU and India of Biologics
10. Preparation of Checklist for Registration of Blood and Blood Products
11. Registration requirement comparison study in 5 emerging markets (WHO) and preparing check list for market authorization
12. Registration requirement comparison study in emerging markets (BRICS) and preparing check list for market authorization
13. Registration requirement comparison study in emerging markets (China and South Korea) and preparing check list for market authorization
14. Registration requirement comparison study in emerging markets (ASEAN) and preparing check list for market authorization
15. Registration requirement comparison study in emerging markets (GCC) and preparing check list for market authorization
16. Checklists for 510k and PMA for US market
17. Checklist for CE marking for various classes of devices for EU
18. STED Application for Class III Devices
19. Audit Checklist for Medical Device Facility
20. Clinical Investigation Plan for Medical Devices

DETAILS OF SUBJECT TEACHERS – SEMESTER I

S.No	Name of the Subject	Name of the Teachers	Designation and Department	Mobile No.	e-mail
1.	Good Regulatory Practices	Dr. N. Jawahar	Asst. Professor	9791439545	jawahar.n@jssuni.edu.in
2.	Documentation and Regulatory writing	Dr. GNK. Ganesh	Asst. Professor	9442191918	gnk@jssuni.edu.in
3.	Clinical Research Regulations	Dr. Karri V V S Narayana Reddy	Asst. Professor	9952478866	narayana.reddy@jssuni.edu.in
4.	Pharmaceutical Regulations and IPR	Dr. R. Suresh Kumar	Asst. Professor	9865064872	sureshcoonoor@jssuni.edu.in

DETAILS OF SUBJECT TEACHERS – SEMESTER II

S.No	Name of the Subject	Name of the Teachers	Designation and Department	Mobile No.	e-mail
1.	Regulatory Aspects of Drugs & Cosmetics	Dr. N.Jawahar	Asst. Professor	9791439545	jawahar.n@jssuni.edu.in
2.	Regulatory Aspects of Herbals & Biologics	Dr. R.Suresh Kumar	Asst. Professor	9865064872	sureshcoonoor@jssuni.edu.in
3.	Regulatory Aspects of Medical Devices	Dr. V. Senthil	Professor	9842650602	senthil.v@jssuni.edu.in
4.	Regulatory Aspects of Food and Nutraceuticals	Dr. GNK. Ganesh	Asst. Professor	9442191918	gnk@jssuni.edu.in

Academic Plan
2020-21

SEMESTER 1

Name of the Subject	**Good Regulatory Practice (Theory)**
Name of the Faculty	Dr. N.Jawahar M.Pharm., Ph.D
Designation, Department	Assistant Professor & Industrial Pharmacy Course Coordinator
Mobile Number	9486946314
e-Mail i.d.	jawahar.n@jssuni.edu.in

Scope, Course Objectives and Course Outcomes

SCOPE

This course is designed to impart fundamental knowledge on various Good Regulatory Practices viz., cGMP, GLP, GALP and GDP for Pharmaceuticals, Cosmetics, Food & Nutraceuticals, Medical devices, In-vitro Diagnostic Medical Devices (IVDs) and biological products and understand the rationale behind these requirements and will propose ways and means of complying with them.

OBJECTIVES

At completion of this course it is expected that students will be able to understand,

- The key regulatory and compliance elements with respect to Good Manufacturing Practices, Good Laboratory Practices, Good
- Automated Laboratory Practices and Good Documentation Practices.
- Prepare and implement the check lists and SOPs for various Good Regulatory Practices
- Implement Good Regulatory Practices in the Healthcare and related Industries
- Prepare for the readiness and conduct of audits and inspections.

COURSE OUTCOMES (COs):

At completion of this course it is expected that the students will be able to know

CO 1: Current Good Manufacturing Practice
CO 2: Good Laboratory Practices
CO 3: Good Automated Laboratory Practices
CO 4: Good Distribution Practices
CO 5: Quality Management System

LECTURE PLAN – ABSTRACT

Sessional	Number of Hours of Didactic Lecture	No. of Hours of other activities	Total Number of Lecture Hours
I	**31**	**03**	**34**
II	**30**	**04**	**34**
Total Number of Lecture Hours	**61**	**-**	**68**

I SESSIONAL: 31 Lectures +03 Activites

Lecture No.	Lecture Details	Hours
1.	**Good Regulatory Practice Introduction**	(01)
Unit-1: Current Good Manufacturing Practice		(12)
1.	Introduction	**12**
2.	Introduction	
3.	US cGMP Part 210 and Part 211	
4.	US cGMP Part 210 and Part 211	
5.	EC Principles of GMP (Directive 91/356/EEC) Article 6 to Article 14	
6.	EC Principles of GMP (Directive 91/356/EEC) Article 6 to Article 14	
7.	WHO cGMP guidelines	
8.	WHO cGMP guidelines	
9.	Medical device and IVDs Global Harmonization Task Force(GHTF) Guidance docs	
10.	Medical device and IVDs Global Harmonization Task Force(GHTF) Guidance docs	
11.	GAMP-5	
12.	GAMP-5	
Unit-2: Good Laboratory Practices		(12)
1.	Introduction	**12**
2.	Principles of GALP	
3.	SOPs of GALP	
4.	SOPs of GALP	
5.	GALP Requirements	
6.	Training documentation	
7.	21 CFR part 11	
8.	General checklist of 21CFR part 11	
9.	Software evaluation checklist	
10.	Software evaluation checklist	
11.	relevant ISO and Quality Control of India (QCI) standards	
12.	relevant ISO and Quality Control of India (QCI) standards	
Unit-3: Good Automated Laboratory Practices		(06)
1.	Introduction	**06**
2.	Principles of GALP	
3.	SOPs of GALP	
4.	SOPs of GALP	

5.	GALP Requirements	
6.	Training documentation	
Activity 1	**Unit test- 1**	
Activity 2	**Unit test-2**	
Activity 3	**Unit test-3**	

II SESSIONAL : 30 Lectures+04 Activites

Lecture No.	**Lecture Details**	**Hours**
Unit-3 : Good Automated Laboratory Practices		(06)
1.	21 CFR part 11	**06**
2.	General checklist of 21CFR part 11	
3.	Software evaluation checklist	
4.	Software evaluation checklist	
5.	relevant ISO and Quality Control of India (QCI) standards	
6.	relevant ISO and Quality Control of India (QCI) standards	
Unit-4 : Good Distribution Practices		(12)
1.	Legal GDP requirements put worldwide	**12**
2.	Principles	
3.	Personnel	
4.	Documentation	
5.	Premises	
6.	Equipments	
7.	Deliveries to customers ,Returns	
8.	Self inspection	
9.	Provision of Information	
10.	Stability testing principles	
11.	WHO GDP	
12.	USP GDP (Supply Chain Integrity)	
Unit-5 : Quality Management Systems		(12)
1.	Concept of Quality	**12**
2.	Total Quality Management	
3.	Quality by Design	
4.	Six sigma concept	
5.	Out of specification (OOS)	
6.	Change Control	
7.	Validation,Types of Validation	
8.	Types of Qualification	
9.	Analytical Method Validation	
10.	Validation of Utilities (Compressed air ,steam .water systems ,HVAC	
11.	ICH process,ISO 13485,	
12.	ICH quidelines to establish Quality,Safety ,Efficacy of Drug substances and products	
Activity 1	Unit test- 3	
Activity 2	Unit test-4	
Activity 3	Unit test-5	

Activity 4	Revision test- 1	

REFERENCES

1. Good Laboratory Practice Regulations, by Sandy Weinberg, Fourth EditionDrugs and the Pharmaceutical Sciences, Vol.168
2. Good Pharmaceutical Manufacturing practice, Rational and compliance byJohn Sharp, CRC Press
3. Establishing a cGMP Laboratory Audit System, A practical Guide by DavidM.Bleisner, Wiley Publication.
4. How to practice GLP by PP Sharma, Vandana Publications.
5. Laboratory Auditing for Quality and Regulatory compliance bu DonaldC.Singer, Drugs and the Pharmaceutical Sciences, Vol.150.
6. Drugs & Cosmetics Act, Rules & Amendments

Name of the Subject	Documentation and Regulatory Writing (Theory)
Name of the Faculty	Dr. GNK. Ganesh M.Pharm., Ph.D
Designation, Department	Assistant Professor, Department of Pharmaceutics
Mobile Number	9442191918
e-Mail i.d.	gnk@jssuni.edu.in

Scope, Course Objectives and Course Outcomes

SCOPE

This course is designed to impart fundamental knowledge on documentation and general principles involved in regulatory writing and submission to agencies.

OBJECTIVES

Upon completion of the course the student shall be able to:

- Know the various documents pertaining to drugs in pharmaceutical industry
- Understand the basics of regulatory compilation
- Create and assemble the regulation submission as per the requirements of agencies
- Follow up the submissions and post approval document requirements

COURSE OUTCOMES (COs)

At completion of this course it is expected that the students will be able to

CO1: Understand the basic Documentation in pharmaceutical industry
CO2: Student can able to submit the dossier using CTD
CO3: Student can able to submit the dossier using eCTD softwere
CO4: Understand the basics of CTD submission in India through SUGAM system
CO5: Understand the basics of internal and external audits in pharmaceutical industry
CO7: Understand inspection systems in pharmaceutical companies and follow up actions
CO8: Learn the regulatory aspects of product life-cycle management and product recalls

LECTURE PLAN – ABSTRACT

Sessional	Number of Hours of Didactic Lecture	No. of Hours of other activities	Total Number of Lecture Hours
I	31	4	31
II	30	3	30
Total Number of Lecture Hours	61	7	61

I SESSIONAL: 31 lectures

Lecture No.	Lecture Details	Hours
1.	Introduction to Documentation and Regulatory Writing	01
Unit-1: Documentation in Pharmaceutical Industry		**(12)**
1.	Exploratory Product Development Brief (EPDB) for Drug substance and drug product	12
2.	Product development plan (PDP)	
3.	Product development report (PDR)	
4.	Master Formula Record (MFR)	
5.	Batch manufacturing record and its calculations	
6.	Batch Reconciliations	
7.	Batch packaging records	
8.	Print pack specifications	
9.	Distribution records	
10.	Certificate of Analysis (CoA)	
11.	Site master file (SMF)	
12.	Drug Master File (DMF)	
Unit-2: Dossier preparation and submission		**(12)**
1.	Introduction and overview of dossiers	12
2.	Contents and organisations of dossier, Binders and sections	
3.	Compilation and review of dossier, Paper submission	
4.	Overview and modules of CTD, Electronic CTD submissions	
5.	Requirements for submission	
6.	Regulatory bindings and requirements, tools and technologies	
7.	Electronic dossier submission process and validating the submission	
8.	Electronic Submission gateway (ESG)	
9.	Non eCTD electronic submissions (NeeS)	
10.	Asian CTD formats (ACTD) submission	
11.	Organizing, process and validation of submission	
12.	Submission in SUGAM system of CDSCO	
Unit-3: Audits		**(06)**
1.	Introduction, summary, types of audits	06
2.	GMP compliance audit	
3.	Audit policy	
4.	Internal and External audits	
5.	Second party audit and external third party audit	
6.	Auditing strategies	

II SESSIONAL: 30 Lectures

Lecture No.	Lecture Details	Hours
Unit-3: Audits		**(06)**
1.	Preparation and conducting audit	06
2.	Auditing strategies, audit analysis	
3.	Audit report and audit follow up	
4.	Auditing/inspection of manufacturing facilities by regulatory agencies	
5.	Timelines for audits/inspection	
6.	GHTF study group 4 guidance document, ISO 13485	
Unit-4: Inspections		**(12)**
13.	Pre-approval inspections	12
14.	Inspection of pharmaceutical manufacturers	
15.	Inspection of drug distribution channels	
16.	Quality systems requirements for national good manufacturing practice inspectorates	
17.	Inspection report	
18.	Model certificate of good manufacturing practices	
19.	Root cause analysis	
20.	Corrective and Preventive action (CAPA)	
Unit-5: Product life cycle management		**(12)**
13.	Prior Approval Supplement (PAS)	12
14.	Post Approval Changes [SUPAC]	
15.	Changes Being Effected in 30 Days (CBE-30)	
16.	Annual Report	
17.	Post marketing Reporting Requirements	
18.	Post approval Labeling Changes	
19.	Lifecycle Management	
20.	FDA Inspection and Enforcement	
21.	Establishment Inspection Report (EIR)	
22.	Warning Letters	
23.	Recalls, Seizure and Injunctions	
24.	ISO Risk Management Standard	

Activity 1	Unit test 1
Activity 2	Unit test 2
Activity 3	Unit test 3
Activity 4	Unit test 4
Activity 5	Unit test 5
Activity 6	Revision test 1
Activity 7	Revision test 2

REFERENCES

1. Compliance auditing for Pharmaceutical Manufacturers. Karen Ginsbury and Gil Bismuth, Interpharm/CRC, Boca Raton, London New York, Washington D.C.
2. Pharmaceutical Manufacturing Handbook, Regulations and Quality by Shayne Cox Gad. Wiley-Interscience, A John Wiley and sons, Inc., Publications.

3. Handbook of microbiological Quality control. Rosamund M. Baird, Norman A. Hodges, Stephen P. Denyar. CRC Press. 2000.
4. Laboratory auditing for quality and regulatory compliance. Donald C. Singer, Raluca-loana Stefan, Jacobus F. Van Staden. Taylor and Francis (2005).
5. Implementing Juran's Road Map for Quality Leadership: Benchmarks and Results, By Al Endres, Wiley, 2000
6. Understanding, Managing and Implementing Quality: Frameworks, Techniques and Cases, By Jiju Antony; David Preece, Routledge, 2002
7. Organizing for High Performance: Employee Involvement, TQM, Reengineering, and Knowledge Management in the Fortune 1000: The CEO Report By Edward E. Lawler; Susan Albers Mohrman; George Benson, Jossey-Bass, 2001
8. Corporate Culture and the Quality Organization By James W. FairfieldSonn, Quorum Books, 2001
9. The Quality Management Sourcebook: An International Guide to Materials and Resources By Christine Avery; Diane Zabel, Routledge, 1997
10. The Quality Toolbox, Second Edition, Nancy R. Tague, ASQ Publications

Name of the Subject	**Clinical Research Regulations (Theory)**
Name of the Faculty	Dr. Karri V V S Narayana Reddy M.Pharm., Ph.D
Designation, Department	Lecturer, Department of Pharmaceutics
Mobile Number	9952478866
e-Mail i.d.	narayana.reddy@jssuni.edu.in

Scope, Course Objectives and Course Outcomes

SCOPE

This course is designed to impart the fundamental knowledge on the clinical development process of drugs, pharmaceuticals and Medical Devices, phases and conduct of clinical trials and research, regulations and guidance governing the conduct of clinical research in India, USA and EU. It prepares the students to learn in detail on various laws, legislations and guidance related to safety, efficacy, ethical conduct and regulatory approval of clinical research.

OBJECTIVES

The primary objectives of this course are to

- History, origin and ethics of clinical and biomedical research and evaluation
- Clinical drug, medical device development process and different types and phases of clinical trials
- Regulatory requirements and guidance for conduct of clinical trials and research

COURSE OUTCOMES (COs)

At completion of this course it is expected that the students will be able to

CO 1: Define the basic concepts involved in the clinical trials

CO 2: Assist and guide the clinical trials with respect to its regulations

CO 3: Review all documentation of clinical trial from a regulatory perspective, the documentation includes clinical trials applications, as well as regulatory submissions for new products and for changes to approved products

CO 4: Ensure adherence and compliance with all the applicable Good Clinical Practices in conducting clinical trials

CO 5: Submit the registrations and get aprrovals of new drug product and candidates to regulatory agencies of US, Europe and India

LECTURE PLAN – Abstract

Sessional	Number of Hours of Didactic Lecture	No. of Hours of other activities	Total Number of Lecture Hours
I	31	-	31
II	30	-	30
Total Number of Lecture Hours	61	-	61

I SESSIONAL: 31 lectures

Lecture No.	Lecture Details	Hours
1.	Introduction to Clinical Research Regulations	01
Unit-1: Clinical Drug Development Process		**(12)**
1.	Different types of Clinical Studies	12
2.	Phases of clinical trials, Clinical Trial protocol	
3.	Phase 0 studies	
4.	Phase I and subtype studies single ascending, multiple ascending, dose escalation, methods, food effect studies, drug – drug interaction, PK end points	
5.	Phase II studies: proof of concept or principle studies to establish efficacy	
6.	Phase III studies (Multi ethnicity, global clinical trial, registration studies	
7.	Phase IV studies (Post Marketing Studies; PSUR Clinical Investigation and Evaluation of Medical Devices & IVDs	
8.	Different Types of Studies	
9.	Key Concepts of Medical Device Clinical Evaluation	
10.	Key concepts of Clinical Investigation	
11.	Case study 1	
12.	Case study 2	
Unit-2: Ethics in Clinical Research		**(12)**
1.	Historical Perspectives: Nuremberg Code, Thalidomide study, Nazis Trials, Tuskegee Syphilis Study, The Belmont Report,	12
2.	The declaration of Helsinki	
3.	Origin of International Conference on Harmonization – Good Clinical Practice (ICH-GCP) guidelines.	
4.	The ethics of randomized clinical trials	
5.	The role of placebo in clinical trials	
6.	Ethics of clinical research in special population	
7.	Institutional Review Board/Independent Ethics Committee/Ethics Committee – composition, roles, responsibilities, review and approval process and ongoing monitoring of safety data	
8.	Data safety monitoring boards.	
9.	Responsibilities of sponsor, CRO, and investigator in ethical conduct of clinical research	
10.	Ethical principles governing informed consent process	

11.	Patient Information Sheet and Informed Consent Form	
12.	The informed consent process and documentation	
Unit-3: Regulations governing Clinical Trials		**(06)**
1.	India: Clinical Research regulations in India – Schedule Y & Medical Device Guidance	06
2.	USA: Regulations to conduct drug studies in USA (FDA)	
3.	NDA 505(b)(1) of the FD&C Act (Application for approval of a new drug)	
4.	NDA 505(b)(2) of the FD&C Act (Application for approval of a new drug that relies, at least in part, on data not developed by the applicant)	
5.	ANDA 505(j) of the FD&C Act (Application for approval of a generic drug product)	
6.	Comparision of all NDA applications	

II SESSIONAL : 30 Lectures

Lecture No.	**Lecture Details**	**Hours**
Unit-3: Regulations governing Clinical Trials		**(06)**
1.	FDA Guidance for Industry - Acceptance of Foreign Clinical Studies	06
2.	FDA Clinical Trials Guidance Document: Good Clinical Practice	
3.	EU: Clinical Research regulations in European Union (EMA)	
4.	Comparision of registration process between US, Europe and India	
5.	Comparision of Approval process between US, Europe and India	
6.	Over all comparision	
Unit-4: Clinical Research Related Guidelines		**(12)**
1.	Good Clinical Practice Guidelines (ICH GCP E6)	12
2.	Indian GCP Guidelines	
3.	ICMR Ethical Guidelines for Biomedical Research	
4.	CDSCO guidelines	
5.	GHTF study group 5 guidance documents	
6.	Regulatory Guidance on Efficacy and Safety ICH Guidance's	
7.	E4 – Dose Response Information to support Drug Registration	
8.	E7 – Studies in support of General Population: Geriatrics	
9.	E8 – General Considerations of Clinical Trials	
10.	E10 – Choice of Control Groups and Related Issues in Clinical Trials,	
11.	E 11 – Clinical Investigation of Medicinal Products in the Pediatric Population	
12.	General biostatics principle applied in clinical research	
Unit-5: USA & EU Guidance		**(12)**
1.	CFR 21Part 50: Protection of Human Subjects	
2.	CFR 21Part 54: Financial Disclosure by Clinical Investigators	
3.	CFR 21Part 312: IND Application	

4.	CFR 21Part 314: Application for FDA Approval to Market a New Drug	12
5.	CFR 21 Part 320: Bioavailability and bioequivalence requirements	
6.	CFR 21Part 812: Investigational Device Exemptions	
7.	CFR 21Part 822: Post-market surveillance	
8.	FDA Safety Reporting Requirements for INDs and BA/BE Studies	
9.	FDA Med Watch	
10.	Guidance for Industry: Good Pharmacovigilance Practices and Pharmacoepidemiologic Assessment	
11.	EU Directives 2001	
12.	EudraLex (EMEA)Volume 3 – Scientific guidelines for medicinal products for human use. EU Annual Safety Report (ASR), Volume 9A – Pharmacovigilance for Medicinal Products for Human Use EU Medical Device Directives (MDD) with respect to clinical research ISO 14155:2011 64	

REFERENCES

1. Clinical Trials and Human Research: A Practical Guide to Regulatory Compliance By Fay A. Rozovsky and Rodney K. Adams
2. HIPAA and Human Subjects Research: A Question and Answer Reference Guide By Mark Barnes, JD, LLM and Jennifer Kulynych, JD, PhD
3. Principles and Practices of Clinical Research, Second Edition Edited by John I. Gallin and Frederick P. Ognibene
4. Reviewing Clinical Trials: A Guide for the Ethics Committee; Johan PE Karlberg and Marjorie A Speers; Karlberg, Johan Petter Einar, Hong Kong.
5. International Pharmaceutical Product Registration: Aspects of Quality, Safety and Efficacy; Anthony C. Cartwright; Taylor & Francis Inc., USA.
6. New Drug Approval Process: The Global Challenge; Guarino, Richard ; Marcel Dekker Inc., NY.
7. FDA regulatory affairs: a guide for prescription drugs, medical devices, and biologics; Douglas J. Pisano, David Mantus; CRC Press, USA
8. Country Specific Guidelines from official websites.
9. Drugs & Cosmetics Act & Rules and Amendments

Name of the Subject	**Regulations and Legislations for Drugs and Cosmetics,Medical Devices, Herbals & Biologicals,and Food & Neutraceuticals in India and Intellectual property Rights. (Theory)**
Name of the Faculty	Dr. R.Sureshkumar M.Pharm., Ph.D
Designation, Department	Assistant Professor, Department of Pharmaceutics
Mobile Number	9865064872
e-Mail i.d.	sureshcoonoor@jssuni.edu.in

Scope, Course Objectives and Course Outcomes

SCOPE

This course is designed to impart fundamental knowledge on regulations and legislation in India w.r.t. Drugs & Cosmetics, Medical Devices, Biologicals & Herbals, and Food & Nutraceuticals. It prepares the students for basic regulatory requirements in India of Drugs & Cosmetics, Medical Devices, Biologicals & Herbals, and Food & Nutraceuticals. for manufacture, import & registration, export, sale, marketing authorization, clinical trials and intellectual property rights.

OBJECTIVES

The primary objectives of this course are to

- To gain the knowledge on drugs and cosmetics act 1940 and rules 1945
- To acquire knowledge on regulations and bodies which govern
    - Herbals and biological
    - Medical devices
    - Food and neutraceuticals
- Ascertain the basis of intellectual property rights

COURSE OUTCOMES (COs)

At completion of this course it is expected that the students will be able to

CO1: Know different Acts and guidelines that regulate Drugs & Cosmetics, Medical Devices, Biologicals & Herbals, and Food & Nutraceuticals industry in India.

CO2: Understand the approval process and regulatory requirements for Drugs & Cosmetics, Medical Devices, Biologicals & Herbals, and Food & Nutraceuticals

LECTURE PLAN – Abstract

Sessional	No. of Hours of Didactic Lecture	No of Hours of other Activities	Total No. of Lecture Hours
I	36	6	42
II	24	4	28
Total No. of Hours	60	10	70

I SESSIONAL : 36 Lectures + 6Activities

Lecture No.	Lecture Details	Hours
Regulations and Legislations for Drugs and Cosmetics,Medical Devices, Herbals & Biologicals,and Food & Neutraceuticals in India and Intellectual property Rights. (MRA 104T)		
Unit-1: Biologicals & herbals and Food & Neutraceuticals Acts and Rules (With latest amendments)		**12**
a. Preformulation Concepts		
1.	Drugs and Cosmetics Acts 1940 and Rules 1945	
2.	DPCO	
3.	NPPA	
4.	Rules Schedules and guidelines for approval	
5.	of Drugs & Cosmetics	
6.	Medical Devices	
7.	Herbals & Biologicals	
8.	Food & Neutraceuticals	
9.	Narcotics Drugs and Psychotropic Substances act	
10.	Medicinal and Toilet Preparations Act 1995	
11.	Pharmacy Act 1945	
12.	Drugs and Magic Remedies Act 1955	
13.	Prevention of Cruelty to Animals Act.	
Unit 2: Regulatory requirements and Approval Procedures for Drugs & Cosmetics, Medical Devices, Herbals& Biologicals and Food & Neutraceuticls		**12**
1.	CDSCO and State Licensing Authority: Organisation and Responsibilities	
2.	Regulatory filings of Drugs & Cosmetics	
3.	Medical Devices	
4.	Biologicals and Herbals	
5.	Food & Neutraceuticals	
6.	Format and contents of regulatory dosier filing and clinical trials/Investigations	
Unit-3: Indian Pharmacoeial standards		**12**
1.	Introduction to Pharmaceutical Validation	
2.	Scope & merits of Validation	
3.	Validation and calibration of Master plan	
Activity1	Mind Mapping on Selected Topic	

Activity2	MCQ Test
Activity3	MCQ Test
Activity4	Revision-1
Activity5	Revision-2
Activity6	Revision-3

II SESSIONAL : 24 Lectures + 4 Activities

Lecture No.	Lecture Details	Hours
Unit-4: Bioavailability and Bio- Equivalence Data(BA/BE)		**10**
1.	BCS Classification	
2.	Regulatory requirements for BE studies	
3.	Stability Requirements-ICH	
4.	WHO	
5.	Guielines for testing in animals/Pre-clinical	
6.	Animal testing:Rationale for conducting studies	
7.	CPCSEA-guidelines	
8.	Ethical guidelines for human participants	
9.	ICMR-DBT guidelines for stem cell research	
Unit-5: Intellectual property Rights		**12**
1.	Patent	
2.	Trade Mark	
3.	Copy Right	
4.	Indiustrial designs	
5.	Geographical Indications	
6.	Indian patent Scenario	
7.	IPR vs Regulatory Affairs	
Activity-1	MCQ Test	
Activity-2	MCQ Test	
Activity-3	Revision Test 1	
Activity-4	Revision Test 2	

TEXT BOOKS

1. Generic Drug Product Development, Solid Oral Dosage forms, Leon Shargel and Isader Kaufer, Marcel Dekker series, Vol.143

2. The Pharmaceutical Regulatory Process, Edited by Ira R. Berry Marcel Dekker Series, Vol.144

3. The Pharmaceutical Regulatory Process, Second Edition Edited by Ira R. Berry and Robert P. Martin, Drugs and the Pharmaceutical Sciences, Vol.185 Informa Health care Publishers.

4. New Drug Approval Process: Accelerating Global Registrations By Richard A Guarino, MD, 5th edition, Drugs and the Pharmaceutical Sciences, Vol.190.

5. Guidebook for drug regulatory submissions / Sandy Weinberg. By John Wiley & Sons. Inc.
6. Drugs: From Discovery to Approval, Second Edition By Rick Ng
7. New Drug Development: A Regulatory Overview, Eighth Edition By Mark Mathieu
8. Pharmaceutical Risk Management By Jeffrey E. Fetterman, Wayne L. Pines and Gary H. Slatko
9. Preparation and Maintenance of the IND Application in eCTD Format By William K. Sietsema
10. Country Specific Guidelines from official websites.
11. http://www.who.int/medicines/areas/quality_safety/regulation_legislation/listMRAWebsites.pdf
12. Roadmap to an ASEAN economic community Edited by Denis Hew. ISEAS Publications, Singapore 2005, ISBN981-230-347-2
13. ASEAN, Rodolfo C. Severino, ISEAS Publications, Singapore 2005, ISBN 978-981-230- 750-7
14. Building a Future with Brics: The Next Decade for Offshoring, Mark Kobayashi-Hillary, Springer

REFERENCE BOOKS

1. Manual of Patent Practice & Procedure, 3rd Edition, by The Patent Office of India
2. Patent Failure How Judges, Bureaucrats, and Lawyers put innovators at risk by James Bessen and Michael J. Meurer
3. Principles and Practice of Clinical Trial Medicine by Richard Chin and Bruce Y. Lee
4. Ethical Guidelines for Biomedical Research on Human Participants by Indian Council of Medical Research New delhi 2006.
5. CPCSEA Guidelines for Laboratory Animal Facility by Committee for the purpose of control and supervision on experiments on animals (CPCSEA)
6. ICH E6 Guideline ― Good Clinical Practice‖ by ICH Harmonised Tripartite
7. Guidance for Industry on Submission of Clinical Trial Application for Evaluating Safety and Efficacy by CDSCO (Central Drug Standard Control Organisation)
8. Guidance for Industry on Requirement of Chemical & Pharmaceutical Information including Stability Study Data before approval of clinical trials / BE studies by CDSCO
9. Guidelines for Import and Manufacture of Medical Devices by CDSCO
10. Guidelines from official website of CDSCO

SEMESTER – I : PRACTICALS

Sessional	Total Number of Lecture Hours
I	6
II	6
Total Number of Lecture Hours	12

SESSIONAL – I		
S.No	**Experiment**	**Staff Incharge**
1	Case studies (4 Nos.) of each of Good Pharmaceutical Practices.	Dr.N.Jawahar
2	Documentation for in process and finished products Quality control tests for Solid, liquid, Semisolid and Sterile preparations.	Dr.N.Jawahar
3	Preparation of SOPs, Analytical reports (Stability and validation)	Dr.N.Jawahar
4	Protocol preparation for documentation of various types of records (BMR, MFR, DR)	Dr. GNK.Ganesh
5	Labeling comparison between brand & generics.	Dr.N.Jawahar
6	Preparation of clinical trial protocol for registering trial in India	Dr. R. Suresh kumar
7	Registration for conducting BA/ BE studies in India	Dr. R. Suresh kumar
8	Import of drugs for research and developmental activities	Dr. R. Suresh kumar
9	Preparation of regulatory dossier as per Indian CTD format and submission in SUGAM	Dr. R. Suresh kumar
10	Registering for different Intellectual Property Rights in India	Dr. R. Suresh kumar
11	GMP Audit Requirements as per CDSCO	Dr.N.Jawahar
12	Preparation and documentation for Indian Patent application.	Dr. R. Suresh kumar
13	Preparation of checklist for registration of IND as per ICH CTD format	Dr. GNK.Ganesh
SESSIONAL – II		
14	Preparation of checklist for registration of NDA as per ICH CTD format.	Dr. GNK.Ganesh
15	Preparation of checklist for registration of ANDA as per ICH CTD format.	Dr. GNK.Ganesh
16	Case studies on response with scientific rationale to USFDA Warning Letter	Dr. GNK.Ganesh
17	Preparation of submission checklist of IMPD for EU submission.	Dr. Karri V V S Narayana Reddy
18	Comparison study of marketing authorization procedures in EU.	Dr. Karri V V S Narayana Reddy

19	Comparative study of DMF system in US, EU and Japan	Dr. GNK.Ganesh
20	Preparation of regulatory submission using eCTD software	Dr. GNK.Ganesh
21	Preparation of Clinical Trial Application (CTA) for US submission	Dr. Karri V V S Narayana Reddy
22	Preparation of Clinical Trial Application (CTA) for EU submission	Dr. Karri V V S Narayana Reddy
23	Comparison of Clinical Trial Application requirements of US, EU and Japan of a dosage form.	Dr. Karri V V S Narayana Reddy
24	Regulatory requirements checklist for conducting clinical trials in India.	Dr. R. Suresh kumar
25	Regulatory requirements checklist for conducting clinical trials in Europe.	Dr. Karri V V S Narayana Reddy
26	Regulatory requirements checklist for conducting clinical trials in USA	Dr. Karri V V S Narayana Reddy

SEMESTER II

Name of the Subject	**Regulatory Aspects of Drug and Cosmetics (Theory)**
Name of the Faculty	Dr. N.Jawahar M.Pharm., Ph.D
Designation, Department	Assistant Professor & Industrial Pharmacy Course Coordinator
Mobile Number	9486946314
e-Mail i.d.	Jawahar.n@jssuni.edu.in

Scope, Course Objectives and Course Outcomes

SCOPE

This course is designed to impart the fundamental knowledge on the drug development process, regulatory requirements for approval of new drugs, drug products and cosmetics in regulated and semi-regulated countriesIt prepares the students to learn in detail on the regulatory requirements, documentation requirements, and registration procedures for marketing the drug products and cosmetics in regulated and semi-regulated countries.

OBJECTIVES

On completion of this course it is expected that students will be able to understand

- Process of drug discovery and development and generic product development
- Regulatory approval process and registration procedures for API and drug products in US, EU
- Cosmetics regulations in regulated and semi-regulated countries
- A comparative study of India with other global regulated markets

COURSE OUTCOMES (COs):

At completion of this course it is expected that the students will be able to know the

CO 1: Regulatory approval process and registration procedures for API and drug products in US, EU

CO 2: Cosmetics regulations in regulated and semi-regulated countries

CO 3: study of Regulatory approval process and registration procedures India with other emerging markets

LECTURE PLAN – Abstract

Sessional	Number of Hours of Didactic Lecture	No. of Hours of other activities	Total Number of Lecture Hours
I	**31**	**03**	**34**
II	**30**	**04**	**34**
Total Number of Lecture Hours	**61**	**-**	**68**

I SESSIONAL: 31 Lectures +03 Activites

Lecture No.	Lecture Details	Hours
1.	**Regulatory Aspects of Drug and Cosmetics: Introduction**	(01)
Unit-1: USA and Canada		(12)
1.	Organization structure and functions of FDA	**12**
2.	Federal register and Code of Federal Regulations (CFR)	
3.	History and evolution of United States Federal, Food, Drug and Cosmetic Act (FFDCA)	
4.	Hatch Waxman act	
5.	Orange book & Purple book	
6.	Drug Master Files (DMF) system in US	
7.	Regulatory Approval Process for Investigational New Drug (IND), New Drug Application (NDA), Abbreviated New Drug Application (ANDA)	
8.	Supplemental New Drug Application (SNDA)	
9.	Regulatory requirements for Orphan drugs and Combination Products	
10.	Changes to an approved NDA / ANDA	
11.	Regulatory considerations for manufacturing, packaging and labeling of pharmaceuticals in USA	
12.	Legislation and regulations for import, manufacture, distribution and sale of cosmetics in USA and Canada	
Unit-2: Europian Union and Australia		(12)
1.	Organization and structure of EMA & EDQM	**12**
2.	General guidelines	
3.	Active Substance Master Files (ASMF) system in EU,	
4.	Content and approval process of IMPD	
5.	Marketing Authorization procedures in EU (Centralized procedure,Decentralized procedure, Mutual recognition procedure and National Procedure)	
6.	Regulatory considerations for manufacturing, packaging and labeling of pharmaceuticals in EU	
7.	Eudralex directives for human medicines	
8.	Variations & extensions,	
9.	Compliance of European Pharmacopoeia (CEP)/ Certificate of Suitability (CoS)	
10.	Marketing Authorization (MA) transfers,	
11.	Qualified Person (QP) in EU	

12.	Legislation and regulations for import, manufacture, distribution and sale of cosmetics in European Union & Australia	
Unit-3: Japan		(06)
1.	Organization of the PMDA,	**06**
2.	Pharmaceutical Laws and regulations	
3.	types of registration applications	
4.	DMF system in Japan	
5.	drug regulatory approval process	
6.	Regulatory considerations for manufacturing, packaging and labeling of pharmaceuticals in Japan	
Activity 1	**Unit test- 1**	
Activity 2	Unit test-2	
Activity 3	Unit test-3	

II SESSIONAL : 30 Lectures+04 Activites

Lecture No.	Lecture Details	Hours
Unit-3 : Japan		(06)
1.	Post marketing surveillance in Japang	**06**
2.	Legislation and regulations for import, manufacture, distribution and sale of cosmetics in Japan	
3.	Legislation and regulations for import, manufacture, distribution and sale of cosmetics in Japan	
4.	Continuation	
5.	Continuation	
6.	Continuation	
Unit-4 : Emerging Market		
1.	Introduction	**12**
2.	Countries covered	
3.	Study of world map	
4.	study of various committees across the globe (ASEAN, APEC, EAC, GCC, PANDRH, SADC)	
5.	WHO: GMP	
6.	Regulatory Requirements for registration of drugs and post approval requirements in WHO through prequalification programme	
7.	Certificate of Pharmaceutical Product (CoPP) - General and Country Specific (South Africa, Egypt, Algeria and Morocco, Nigeria, Kenya and Botswana)	
8.	Continuation	
9.	Continuation	
10.	Continuation	
11.	Continuation	
12.	Continuation	
Unit-5 : Application of Pharmacokinetics		(12)
1.	ASIAN Countries: Introduction to ACTD	

2.	Regulatory Requirements for registration of drugs and post approval requirements in China and South Korea	**12**
3.	(ASEAN) Region i.e. Vietnam, Malaysia	
4.	Philippines, Singapore and Thailand	
5.	CIS (Commonwealth Independent States)	
6.	Regulatory prerequisites related to Marketing authorization for CIS countries	
7.	i.e. Russia, Kazakhstan and Ukraine	
8.	GCC (Gulf Cooperation Council) drug regulations	
9.	Regulations for import, manufacture, distribution and sale of cosmetics	
10.	Brazil, ASEAN	
11.	GCC (Gulf Cooperation Council)	
12.	Continuation	
Activity 1	Unit test- 3	
Activity 2	Unit test-4	
Activity 3	Unit test-5	
Activity 4	Revision test- 1	

REFERENCES

1. Generic Drug Product Development, Solid Oral Dosage forms, Leon Shargel and Isader Kaufer, Marcel Dekker series, Vol.143.
2. The Pharmaceutical Regulatory Process, Edited by Ira R. Berry Marcel Dekker Series, Vol.144
3. The Pharmaceutical Regulatory Process, Second Edition Edited by Ira R. Berry and Robert P. Martin, Drugs and the Pharmaceutical Sciences, Vol.185 Informa Health care Publishers.
4. New Drug Approval Process: Accelerating Global Registrations By Richard A Guarino, MD, 5th edition, Drugs and the Pharmaceutical Sciences, Vol.190.
5. Guidebook for drug regulatory submissions / Sandy Weinberg. By John Wiley & Sons. Inc.
6. Drugs: From Discovery to Approval, Second Edition By Rick Ng
7. New Drug Development: A Regulatory Overview, Eighth Edition By Mark Mathieu
8. Pharmaceutical Risk Management By Jeffrey E. Fetterman, Wayne L. Pines and Gary H. Slatko
9. Preparation and Maintenance of the IND Application in eCTD Format By William K. Sietsema
10. Country Specific Guidelines from official websites.
11. http://www.who.int/medicines/areas/quality_safety/regulation_legislation/ListMRAWebsites.pdf
12. Roadmap to an ASEAN economic community Edited by Denis Hew. ISEAS Publications, Singapore 2005, ISBN981-230-347-2
13. ASEAN, Rodolfo C. Severino, ISEAS Publications, Singapore 2005, ISBN 978-981-230-750-7
14. Building a Future with Brics: The Next Decade for Offshoring, Mark Kobayashi-Hillary, Springer

15. Outsourcing to India: The Offshore Advantage, Mark Kobayashi-Hillary, Springer Trade performance and Regiona Integration of the CIS Countries, Lev Freinkman,
16. The world Bank, Washington, DC, ISBN: 0-8212-5896-0
17. Global Pharmaceutical Policy: Ensuring Medicines for Tomorrow's World By Frederick M. Abbott, Graham Dukes, Maurice Nelson Graham Dukes139
18. The Gulf Cooperation Council: A Rising Power and Lessons for ASEAN by Linda Low and Lorraine Carlos Salazar (Nov 22, 2010)
19. Doing Business in the Asean Countries, Balbir Bhasin, Business Expert Press ISBN:13:978-1-60649-108-9
20. Realizing the ASEAN Economic Community: A Comprehensive Assessment, Michael G Plummer (Editor), Chia Siow Yue (Editor), Instute of South east asian studies, Singapore

Name of the Subject	**Regulatory aspects of Herbals and Biologicals**
Name of the Faculty	Dr. R.Sureshkumar M.Pharm., Ph.D
Designation, Department	Assistant Professor, Department of Pharmaceutics
Mobile Number	9865064872
e-Mail i.d.	sureshcoonoor@jssuni.edu.in

Scope, Course Objectives and Course Outcomes

SCOPE

This course is designed to impart fundamental knowledge on Regulatory Requirements, Licensing and Registration, Regulation on Labelling of Biologics in India, USA and Europe It prepares the students to learn in detail on Regulatory Requirements for biologics, Vaccines and Blood Products

OBJECTIVES

The primary objectives of this course are to

- To gain knowledge on various biologicals and biosimilars
- To know the pathways for development of biologicals/Biosimilars
- To know the regulatory bodies which governs the biological/Biosimilars (India,Europe and USA)
- To gain knowledge on various bodies responsible for governing herbals in India,Europe and USA

COURSE OUTCOMES (COs): At completion of this course it is expected that the students will be able to

CO1: Know the regulatory Requirements for Biologics and Vaccines
CO2: Understand the regulation for newly developed biologics and biosimilars
CO3: Know the pre-clinical and clinical development considerations of biologics
CO4: Understand the Regulatory Requirements of Blood and/or Its Components Including Blood Products and label requirements

LECTURE PLAN – Abstract

Sessional	No. of Hours of Didactic Lecture	No of Hours of other Activities	Total No. of Lecture Hours
I	36	6	42
II	24	4	28
Total No. of Hours	60	10	70

I SESSIONAL : 36 Lectures + 6Activities

Lecture No.	Lecture Details	Hours
Regulatory aspects of Herbals and Biologicals		
Unit-1: India		**12**
1.	Introduction	
2.	Applicable Regulations and Guidelines	
3.	Principles for development similar biologics	
4.	Data requirements for pre clinincal studies	
5.	Data requirements for clinincal studies	
6.	Data requirements for Market authorization	
7.	Post Market data for similar biologics	
8.	Pharmacovigilance , GMP and GDP	
Unit 2: USA		**12**
1.	Introduction to Biologics-Rlated Products	
2.	Difference between generic drugs and Biosimilars	
3.	Laws, Regulations and guidence on Biologics	
4.	Development and Approval of Biologics (IND, PMA, BLA, NDA, 510(k)	
5.	Pre-clinical and Clinical consideration	
6.	Advertising, labelling and packaging Considerations	
Unit-3: European Union		**12**
1.	Introduction to Biologics	
2.	scientific guidelines related to Biologics	
3.	Comparability and Biosimilarity Assessment	
4.	Plasma Master File	
5.	TSE/BSE Evaluation	
6.	development and regulatory approval	
7.	Pre-clinical and Clinical consideration	
8.	stability, safety, advertising	
9.	labelling and packing of biologics	
Activity1	Mind Mapping on Selected Topic	
Activity2	MCQ Test	
Activity3	MCQ Test	
Activity4	Revision-1	
Activity5	Revision-2	
Activity6	Revision-3	

II SESSIONAL : 24 Lectures + 4 Activities

Lecture No.	Lecture Details	Hours
Unit-4.1: Vaccine regulations in India USA and European Union		12
1.	Clinical evaluation,	
2.	Marketing authorization	
3.	Registration or licensing	
4.	Quality assessment,	
5.	Pharmacovigilance	
Unit-4.1: Blood and Related products Regulations in India, USA and European Union		
1.	Regulatory Requirements of Blood	
2.	Its Components Including Blood Products	
3.	Label Requirements	
4.	ISBT and IHN	
Unit-5: Herbal Products- India, USA and European Union		12
1.	Quality, safety Herbal Products	
2.	Regulations and Legislations	
Activity-1	MCQ Test	
Activity-2	MCQ Test	
Activity-3	Revision Test 1	
Activity-4	Revision Test 2	

TEXT BOOKS

1. Regulation of Functional Foods and Nutraceuticals: A Global Perspective by Clare M. Hasler (Wiley Online Library)
2. Nutraceutical and Functional Food Regulations in the United States and Around the World by Debasis Bagchi (Academic Press, Elsevier)
3. http://www.who.int/publications/guidelines/nutrition/en/
4. http://www.europarl.europa.eu/RegData/etudes/STUD/2015/536324/IPOL_STU(2015)536324_EN.pdf
5. Handbook of Nutraceuticals by Yashwant Pathak (CRC Press)
6. Food Regulation: Law, Science, Policy and Practice by Neal D. Fortin (Wiley) 7. Country Specific Guidelines from official websites.

REFERENCE BOOKS

1. FDA Regulatory Affairs: A Guide for Prescription Drugs, Medical Devices, and Biologics, Douglas J. Pisano , David S. Mantus ; Informa ,2008
2. Biological Drug Products: Development and Strategies; Wei Wang , Manmohan Singh ; wiley ,2013
3. Development of Vaccines: From Discovery to Clinical Testing; Manmohan Singh , Indresh K. Srivastava ;Wiley, 2011
4. www.who.int/biologicals/en

5. www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInfo rmation/
6. www.ihn-org.com
7. www.isbtweb.org
8. Guidelines on Similar Biologics: Regulatory Requirements for Marketing Authorization in India
9. www.cdsco.nic.in
10. www.ema.europa.eu › scientific guidelines › Biologicals
11. www.fda.gov/biologicsbloodVaccines/GuidanceCompliance Regulatory Information (Biologics)

Name of the Subject	**Regulatory Aspects of Medical Devices**
Course/ Semester	M.Pharm,, IInd Semester
Name of the Faculty	Dr V.Senthil, M.Pharm, Ph.D,
Designation, Department	Professor, Pharmaceutics
Mobile Number	9842650602
e-Mail i.d.	senthil.v@jssuni.edu.in

Scope, Course Objectives and Course Outcomes

SCOPE

This course is designed to impart the fundamental knowledge on the medical devices and in vitro diagnostics, basis of classification and product life cycle of medical devices, regulatory requirements for approval of medical devices in regulated countries like US, EU and Asian countries along with WHO regulations. It prepares the students to learn in detail on the harmonization initiatives, quality and ethical considerations, regulatory and documentation requirements for marketing medical devices and IVDs in regulated countries.

OBJECTIVES

Upon completion of the course, the student shall be able to know

- basics of medical devices and IVDs, process of development, ethical and quality considerations
- harmonization initiatives for approval and marketing of medical devices and IVDs
- regulatory approval process for medical devices and IVDs in India, US, Canada, EU, Japan and ASEAN
- clinical evaluation and investigation of medical devices and IVDs

COURSE OUTCOMES (COs)

Upon completion of the course, the student shall be able to know

CO 1: To know the basics of medical devices and IVDs, process of development, ethical and quality considerations

CO 2: For approval and marketing of medical devices and IVDs

CO3: Approval process for medical devices and IVDs in India, US, Canada, EU, Japan and ASEAN

CO4: How to perform clinical evaluation and investigation of medical devices and IVDs in various countries

LECTURE PLAN – Abstract

Sessional	No. of Hours of Didactic Lecture	No of Hours of other Activities	Total No. of Lecture Hours
I	30	3	33
II	30	3	33
Total No. of Hours	60	6	66

LECTURE PLAN
I SESSIONAL 30 Lectures+ 3 Activities

Lecture No.	Lecture Details	Hours
UNIT-1 : Medical Devices		(12)
1.	Introduction, Definition	12
2.	Risk based classification and Essential Principles of Medical Devices and IVDs.	
3.	Differentiating medical devices IVDs and Combination Products from that of pharmaceuticals	
4.	History of Medical Device Regulation,	
5.	Classification of Medical Devices.	
6.	Product Lifecycle of Medical Devices	
7.	Introduction: IMDRF/GHTF, Organizational Structure, Function	
8.	Summary Technical Document (STED), Global Medical Device Nomenclature (GMDN).	
UNIT-2 Medical Device - Ethics		(12)
1.	Introduction, Clinical Investigation of Medical Devices	12
2.	Good Clinical Practice for Clinical Investigation of medical devices (ISO 14155:2011)	
3.	Quality System Regulations of Medical Devices: ISO 13485	
4.	Quality Risk Management of Medical Devices: ISO 14971	
5.	Validation and Verification of Medical device	
6.	Adverse Event Reporting of Medical device 12	
Activity1	Test	
Activity2	Test	
UNIT-3 Medical Device - USA		(12)
1.	Introduction, Classification, Regulatory approval process for Medical Devices	06
2.	(510k) Premarket Notification, Pre-Market Approval (PMA)	
3.	Investigational Device Exemption (IDE) and *in vitro* Diagnostics	
4.	Quality System Requirements 21 CFR Part 820, Labeling requirements 21 CFR Part 801	
Activity 3	Test	

II SESSIONAL : 30 Lectures + 3 Activities

UNIT-3	**Medical Device - USA *Cont.***	
1.	Post marketing surveillance of MD	06
2.	Unique Device Identification (UDI).	
3.	Basics of *in vitro* diagnostics	
UNIT-4	**Medical Device - European Union**	(12)
1.	Introduction, Classification Medical Device in European Union	12
2.	Regulatory approval process for Medical Devices European Union	
3.	Regulatory approval process for *in vitro* Diagnostics & IVD Directive	
4.	CE certification process	
5.	Basics of In vitro diagnostics, classification and approval process	
UNIT-5	**ASEAN, China & Japan: Medical Devices**	(12)
1.	Introduction, Medical Devices and IVDs	12
2.	Regulatory registration procedures Asia	
3.	Regulatory registration procedures China & Japan	
4.	Quality System requirements and clinical evaluation and investigation	
5.	IMDRF study groups and guidance documents	
Activity 1	Test	
Activity 2	Test	
Activity 3	Test	

REFERENCES (Latest Editions)

1. FDA regulatory affairs: a guide for prescription drugs, medical devices, and biologics by Douglas J. Pisano, David Mantus.
2. Medical Device Development: A Regulatory Overview by Jonathan S.Kahan
3. Medical Product Regulatory Affairs: Pharmaceuticals, Diagnostics, Medical Devices by John J. Tobin and Gary Walsh
4. Compliance Handbook for Pharmaceuticals, Medical Devices and Biologics by Carmen Medina
5. Country Specific Guidelines from official websites.

Name of the Subject	**Regulatory Aspects of Food and Nutraceuticals (Theory)**
Name of the Faculty	Dr. GNK Ganesh M.Pharm., Ph.D
Designation, Department	Lecturer, Department of Pharmaceutics
Mobile Number	9442191918
e-Mail i.d.	gnk@jssuni.edu.in

Scope, Course Objectives and Course Outcomes

SCOPE

This course is designed to impart the fundamental knowledge on Regulatory Requirements, Registration and Labeling Regulations of Nutraceuticals in India, USA and Europe. It prepares the students to learn in detail on Regulatory Aspects for nutraceuticals and food supplements.

OBJECTIVES

Upon completion of the course, the student shall be able to

1. Know the regulatory Requirements for nutraceuticals
2. Understand the regulation for registration and labeling of nutraceuticals and food supplements in India, USA and Europe.

Course Outcomes (COs)

At completion of this course it is expected that the students will be able to

CO1: Define and differentiate nutraceuticals, functional foods, dietary supplements, and medical foods

CO2: understand the scope and opportunities in nutraceutical market

CO3: Understand the NSF certification process

CO4: Understand the Nutraceutical regulations in India

CO5: Understand the Nutraceutical regulations in USA

CO6: Understand the Nutraceutical regulations in European Union

CO7: Understand and compare the Recommended Dietary Allowance in various regulated country

LECTURE PLAN – Abstract

Sessional	Number of Hours of Didactic Lecture	No. of Hours of other activities	Total Number of Lecture Hours
I	36	4	36
II	24	3	24
Total Number of Lecture Hours	60	7	60

I SESSIONAL: 36 lectures

Lecture No.	Lecture Details	Hours
1.	Introduction to Regulatory Aspects of Food and Nutraceuticals	01
Unit-1: Nutraceuticals		(12)
1.	Introduction	12
2.	History of Food and Nutraceutical Regulations	
3.	Meaning of Nutraceuticals	
4.	Dietary Supplements	
5.	Functional Foods	
6.	Medical Foods	
7.	Scope in Nutraceutical Market	
8.	Opportunities in Nutraceutical Market	
Unit-2: Global Aspects		**(12)**
1.	WHO guidelines on nutrition	12
2.	NSF International	
3.	Organization of NSF	
4.	Its Role in the Dietary Supplements and Nutraceuticals Industries	
5.	NSF Certification	
6.	NSF Standards for Food And Dietary Supplements	
7.	Good Manufacturing Practices for Nutraceuticals.	
Unit-3: India		**(12)**
1.	Food Safety and Standards Act	12
2.	Food Safety and Standards Authority of India	
3.	Organization and Functions	
4.	Regulations for import	
5.	Manufacture and sale of nutraceutical products in India	
6.	Recommended Dietary Allowances (RDA) in India.	

II SESSIONAL: 24 Lectures

Lecture No.	Lecture Details	Hours
Unit-4: USA		(12)
1.	US FDA Food Safety Modernization Act	12
2.	Dietary Supplement Health and Education Act	
3.	U.S. regulations for manufacture and sale of nutraceuticals and dietary supplements	
4.	Labelling Requirements for Dietary Supplements	

5.	Label Claims for Dietary Supplements	
6.	Recommended Dietary Allowances (RDA) in the U.S	
Unit-5: European Union		**(12)**
1.	European Food Safety Authority (EFSA)	12
2.	Organization and Functions	
3.	EU Directives and regulations for manufacture and sale of nutraceuticals and dietary supplements.	
4.	Nutrition labeling	
5.	European Regulation on Novel Foods and Novel food ingredients	
6.	Recommended Dietary Allowances (RDA) in Europe.	

Activity 1	Unit test 1
Activity 2	Unit test 2
Activity 3	Unit test 3
Activity 4	Unit test 4
Activity 5	Unit test 5
Activity 6	Revision test 1
Activity 7	Revision test 2

REFERENCES

1. Regulation of Functional Foods and Nutraceuticals: A Global Perspective by Clare M. Hasler (Wiley Online Library)
2. Nutraceutical and Functional Food Regulations in the United States and Around the World by Debasis Bagchi (Academic Press, Elsevier)
3. http://www.who.int/publications/guidelines/nutrition/en/
4. http://www.europarl.europa.eu/RegData/etudes/STUD/2015/536324/IPOL_ STU(2015)536324_EN.pdf
5. Handbook of Nutraceuticals by Yashwant Pathak (CRC Press)
6. Food Regulation: Law, Science, Policy and Practice by Neal D. Fortin (Wiley)
7. Country Specific Guidelines from official websites.

SEMESTER – II : PRACTICALS

Sessional	Total Number of Lecture Hours
I	6
II	6
Total Number of Lecture Hours	12

SESSIONAL – I		
S.No	**Experiment**	
1	Case studies on	Dr. GNK. Ganesh
2	Change Management/ Change control. Deviations	Dr. GNK. Ganesh
3	Corrective & Preventive Actions (CAPA)	Dr. GNK. Ganesh
4	Documentation of raw materials analysis as per official monographs	Dr. GNK. Ganesh
5	Preparation of audit checklist for various agencies	Dr. GNK. Ganesh
6	Preparation of submission to FDA using eCTD software	Dr. GNK. Ganesh
7	Preparation of submission to EMA using eCTD software	Dr. GNK. Ganesh
8	Preparation of submission to MHRA using eCTD software	Dr. GNK. Ganesh
9	Preparation of Biologics License Applications (BLA)	Dr. R. Suresh Kumar
10	Preparation of documents required for Vaccine Product Approval	Dr. R. Suresh Kumar
11	Comparison of clinical trial application requirements of US, EU and India of Biologics	Dr. R. Suresh Kumar
SESSIONAL – II		
12	Preparation of Checklist for Registration of Blood and Blood Products	Dr. R. Suresh Kumar
13	Registration requirement comparison study in 5 emerging markets (WHO) and preparing check list for market authorization	Dr. N. Jawahar
14	Registration requirement comparison study in emerging markets (BRICS) and preparing check list for market authorization	Dr. N. Jawahar
15	Registration requirement comparison study in emerging markets (China and South Korea) and preparing check list for market Authorization	Dr. N. Jawahar
16	Registration requirement comparison study in emerging markets (ASEAN) and preparing check list for market authorization	Dr. N. Jawahar
17	Registration requirement comparison study in emerging markets (GCC) and preparing check list for market authorization	Dr. N. Jawahar
18	Checklists for 510k and PMA for US market	Dr. V. Senthil

19	Checklist for CE marking for various classes of devices for EU	Dr. V. Senthil
20	STED Application for Class III Devices	Dr. V. Senthil
21	Audit Checklist for Medical Device Facility	Dr. V. Senthil
22	Clinical Investigation Plan for Medical Devices	Dr. V. Senthil

JSS Academy of Higher Education & Research, Mysuru
JSS College of Pharmacy, Rocklands, Ooty

I M. PHARMACY TIME TABLE FOR E-LEARN CLASSES : I Semester (AY : 2020 - 2021)

DEPARTMENT : PHARMACEUTICS
COURSE : PHARMACEUTICAL REGULATORY AFFAIRS

ZOOM / GOOGLE MEET LICENSE - cpora1@jssuni.edu.in

Days	9 - 10 am	10 - 11 am	11 - 12 am	12 - 1 pm	1 - 2 pm	2 - 3 pm	3 - 4 pm	4 - 5 pm
Mon	Assingment	**DRW (GNK)**	**DRW (GNK)**	Library	**LUNCH BREAK**	-	-	-
Tue	Assingment	**DRW (GNK)**	**DRW (GNK)**	Library		RLDC **(RSK)**	RLDC **(RSK)**	-
Wed	Assingment	**CRR (KVVSNR)**	**CRR (KVVSNR)**	**CRR (KVVSNR)**		**CRR (KVVSNR)**	-	-
Thu	-	**GRP (NJ)**	**GRP (NJ)**	-		-	-	-
Fri	-	RLDC **(RSK)**	RLDC **(RSK)**	-		GRP **(NJ)**	GRP **(NJ)**	--
Sat	Seminar	Seminar	Seminar	Seminar		-	-	-

Subjects : I M.Pharm (Pharmaceutical Regulatory Affairs)

1. Regulations and Legislation for Drugs & Cosmetics-(RLDC-T&P)- Dr. R. Suresh Kumar**(RSK)**
2. Clinical Research Regulations (CRR-T&P)- Dr. Karri VVS Narayana Reddy **(KVVSNR)**
3. Documentation and Regulatory Writing (DRW-T & P)- Dr. G.N.K. Ganesh **(GNK)**
4. Good Regulatory Practice(GRP-T & P)- Dr. N. Jawahar **(NJ)**

JSS Academy of higher Education & Research, Mysuru
(Deemed to be University, Accredited 'A' Grade by NAAC)
JSS College of Pharmacy, Ooty – 643 001
(An ISO 9001-2015 certified Institution)

I M.Pharm, Pharmaceutical Regulatory Affairs (II.Semester) Time Table (AY : 2020-21)

Days	09-10	10-11	11-12	12-01	LUNCH	2pm -5 pm			
Mon	Library	NJ-RAMD	GNK-RADC	GNK- RADC		Regulatory Aspects of Herbal & Biological-NV			
Tue	Library	VS-RAHD	GNK-RADC	GNK- RADC		Regulatory Aspects of Drug & Cosmetics -NJ			
Wed	Library	VS-RAMD	VS-RAMD	VS- RAMD		Regulatory Aspects of Food & Nutraceuticals-GNK			
Thu	Library	NJ-RADC	Seminar	Seminar		RS/KG-RAHB	RS/KG-RAHB	RS/KG-RAHB	Seminar
Fri	Library	NJ- RADC	NJ- RADC	NJ- RADC		Regulatory Aspects of Medical Device -VS			
Sat	Library	RS/KG-RAHB	Journal club	Research audit					

Subject-in-Charges:
Regulatory Aspects of Medical Device -RAMD- Dr. V. Senthil(VS)
Regulatory Aspects of Herbal & Biological –RAHB\- Dr. K. Gowthamarajan/ Dr. R. Suresh Kumar(RS/KG)
Regulatory Aspects of Drug & Cosmetics-RADC- Dr. N. Jawahar(NJ)
Regulatory Aspects of Food & Nutraceuticals-RAFN- Dr. GNK Ganesh(GNK)
Course Coordinator: Dr. GNK Ganesh

M. PHARM
PHARMACEUTICAL BIOTECHNOLOGY

SYLLABUS
SEMESTER I
MQA 101T-MODERN PHARMACEUTICAL ANALYTICAL TECHNIQUES (Theory)

SCOPE
This subject deals with various advanced analytical instrumental techniques for identification, characterization and quantification of drugs. Instruments dealt are NMR, Mass spectrometer, IR, HPLC, GC etc.

OBJECTIVES
After completion of course student is able to know about chemicals and excipients

- The analysis of various drugs in single and combination dosage forms
- Theoretical and practical skills of the instruments

Course Content:

THEORY	**60 Hrs**
1.a. UV-Visible spectroscopy: Introduction, Theory, Laws, Instrumentation associated with UV-Visible spectroscopy, Choice of solvents and solvent effect and Applications of UV-Visible spectroscopy, Difference/ Derivative spectroscopy. b. IR spectroscopy: Theory, Modes of Molecular vibrations, Sample handling, Instrumentation of Dispersive and Fourier - Transform IR Spectrometer, Factors affecting vibrational frequencies and Applications of IR spectroscopy, Data Interpretation. c. Spectroflourimetry: Theory of Fluorescence, Factors affecting fluorescence (Characterestics of drugs that can be analysed by flourimetry), Quenchers, Instrumentation and Applications of fluorescence spectrophotometer. d. Flame emission spectroscopy and Atomic absorption spectroscopy: Principle, Instrumentation, Interferences and Applications.	12 Hrs
2 NMR spectroscopy: Quantum numbers and their role in NMR, Principle, Instrumentation, Solvent requirement in NMR, Relaxation process, NMR signals in various compounds, Chemical shift, Factors influencing chemical shift, Spin-Spin coupling, Coupling constant, Nuclear magnetic double resonance, Brief outline of principles of FT-NMR and 13C NMR. Applications of NMR spectroscopy.	12 Hrs
3. Mass Spectroscopy: Principle, Theory, Instrumentation of Mass Spectroscopy, Different types of ionization like electron impact, chemical, field, FAB and MALDI, APCI, ESI, APPI Analyzers of Quadrupole and Time of Flight, Mass fragmentation and its rules, Meta stable ions, Isotopic peaks and Applications of Mass spectroscopy.	12 Hrs
4. Chromatography: Principle, apparatus, instrumentation, chromatographic parameters, factors affecting resolution, isolation of drug from excipients, data interpretation and applications of the following: ● Thin Layer chromatography ● High Performance Thin Layer Chromatography ● Ion exchange chromatography ● Column chromatography ● Gas chromatography	12 Hrs

• High Performance Liquid chromatography • Ultra-High-Performance Liquid chromatography • Affinity chromatography • Gel Chromatography	
5. a. Electrophoresis: Principle, Instrumentation, working conditions, factors affecting separation and applications of the following: a) Paper electrophoresis b) Gel electrophoresis c) Capillary electrophoresis d) Zone electrophoresis e) Moving boundary electrophoresis f) Iso electric focusing b. X ray Crystallography: Production of X rays, Different X ray methods, Bragg's law, Rotating crystal technique, X ray powder technique, Types of crystals and applications of X-ray diffraction.	12 Hrs
6. a. Potentiometry: Principle, working, Ion selective Electrodes and Application of potentiometry. b. Thermal Techniques: Principle, thermal transitions and Instrumentation (Heat flux and power-compensation and designs), Modulated DSC, Hyper DSC, experimental parameters (sample preparation, experimental conditions, calibration, heating and cooling rates, resolution, source of errors) and their influence, advantage and disadvantages, pharmaceutical applications. Differential Thermal Analysis (DTA): Principle, instrumentation and advantage and disadvantages, pharmaceutical applications, derivative differential thermal analysis (DDTA). TGA: Principle, instrumentation, factors affecting results, advantage and disadvantages, pharmaceutical applications.	12 Hrs

REFERENCES

1. Spectrometric Identification of Organic compounds - Robert M Silverstein, Sixth edition, John Wiley & Sons, 2004.
2. Principles of Instrumental Analysis - Doglas A Skoog, F. James Holler, Timothy A. Nieman, 5th edition, Eastern press, Bangalore, 1998.
3. Instrumental methods of analysis – Willards, 7th edition, CBS publishers.
4. Practical Pharmaceutical Chemistry – Beckett and Stenlake, Vol II, 4th edition, CBS Publishers, New Delhi, 1997.
5. Organic Spectroscopy - William Kemp, 3rd edition, ELBS, 1991.
6. Quantitative Analysis of Drugs in Pharmaceutical formulation - P D Sethi, 3rd Edition, CBS Publishers, New Delhi, 1997.
7. Pharmaceutical Analysis - Modern Methods – Part B - J W Munson, Vol 11, Marcel. Dekker Series
8. Spectroscopy of Organic Compounds, 2nd edn., P.S/Kalsi, Wiley estern Ltd., Delhi.
9. Textbook of Pharmaceutical Analysis, KA.Connors, 3rd Edition, John Wiley & Sons, 1982.

MPB102T-MICROBIAL AND CELLULAR BIOLOGY (Theory)

SCOPE

This subject is designed to provide the advanced knowledge to the biotechnology students in invaluable areas of advanced microbiology which plays a crucial role in determining its future use and applications in medicine, drug discovery and in pharmaceutical industry.

OBJECTIVE

At the completion of this course it is expected that the students will get an understanding about the following aspects;

- Importance of Microorganisms in Industry
- Central dogma of molecular biology
- Structure and function of cell and cell communication
- Cell culture technology and its applications in pharmaceutical industries.
- Microbial pathogenesis and correlating it to rational use of antimicrobial agents.

Course Content:

THEORY	**60 Hrs**
1. Microbiology Introduction – Prokaryotes and Eukaryotes. Bacteria, fungi, actinomycetes and virus - structure, chemistry and morphology, cultural, physiological and reproductive features. Methods of isolation, cultivation and maintenance of pure cultures. Industrially important microorganisms - examples and applications	12 Hrs
2. Molecular Biology: Structure of nucleus and chromosome, Nucleic acids and composition, structure and types of DNA and RNA. Central dogma of molecular biology: Replication, Transcription and translation. Gene regulation Gene copy number, transcriptional control and translational control. RNA processing Modification and Maturation, RNA splicing, RNA editing, RNA amplification. Mutagenesis and repair mechanisms, types of mutants, application of mutagenesis in stain improvement, gene mapping of plasmids- types purification and application. Phage genetics, genetic organization, phage mutation and lysogeny.	12 Hrs
3. Cell structure and function Cell organelles, cytoskeleton & cell movements, basic aspects of cell regulation, bioenergetics and fuelling reactions of aerobics and anaerobics, secondary metabolism & its applications. Cell communication, cell cycle and apoptosis, mechanism of cell division. Cell junctions/adhesion and extra cellular matrix, germ cells and fertilization, histology – the life and death of cells in tissues. Cell Cycle and Cytoskeleton Cell Division and its Regulation, G-Protein Coupled Receptors, Kinases, Nuclear receptors, Cytoskeleton & cell movements, Intermediate Filaments. Apoptosis and Oncogenes Programmed Cell Death, Tumor cells, carcinogens & repair. Differentiation and Developmental Biology Fertilization, Events of Fertilization, In vitro Fertilization, Embryonic Germ Cells, Stem Cells and its Application.	12 Hrs

4. Principles of microbial nutrition Physical and chemical environment for microbial growth, Stability and degeneration of microbial cultures. Growth of animal cells in culture General procedure for cell culture, Nutrient composition, Primary, established and transformed cell cultures, applications of cell cultures in pharmaceutical industry and research. Growth of viruses in cell culture propagation and enumeration. *In-vitro* screening techniques- cytotoxicity, anti-tumor, anti-viral assays.	12 Hrs
5. Microbial pathology Identifying the features of pathogenic bacteria, fungi and viruses. Mechanism of microbial pathogenicity, etiology and pathology of common microbial diseases and currently recommended therapies for common bacterial, fungal & viral infections. Mechanism of action of antimicrobial agents and possible sites of chemotherapy.	12 Hrs

REFERENCES

1. W.B. Hugo and A.D. Russel: Pharmaceutical Microbiology, Blackwell Scientific publications, Oxford London.
2. Prescott and Dunn, Industrial Microbiology, CBS Publishers & Distributors, Delhi.
3. Pelczar, Chan Kreig, Microbiology, Tata McGraw Hill edn.
4. David Freifelder, Molecular Biology, 2nd edition, Narosa Publishing House.
5. R. Ian Freshney, Culture of animal cells – A manual of Basic techniques, 6th edition, Wileys publication house.
6. David Baltimore, Molecular cell biology, W H Freeman & Co publishers.
7. Cell biology vol-I,II,III by Julio E.Cells
8. Bergeys manual of systematic bacteriology, Williams and Wilkins- A Waverly company.

MPB 103T-BIOPROCESS ENGINEERING AND TECHNOLOGY (Theory)

SCOPE

This paper has been designed to provide the knowledge to the biotechnology students in invaluable areas of bioprocess technology to develop skills to modify, design and operate different types of fermenters, to understand and implement various fermentation procedures, to train students in scale up fermentation operations.

OBJECTIVES

At the completion of this subject it is expected that students will be able to,

- Understand basics and design of fermentation technology
- Scale up and scale down processing of fermentation technology
- Bioprocessing of the industrially important microbial metabolites in industries and R & D organizations.
- Regulation governing the manufacturing of biological products
- Understand and conduct fermentation process kinetics.

Course Content:

THEORY	**60 Hrs**
1. Introduction to fermentation technology Basic principles of fermentation Study of the design and operation of bioreactor Ancillary parts and function, impeller design and agitation, power requirements on measurements and control of dissolved oxygen, carbon dioxide, temperature, pH and foam. Types of bioreactor CSTR, tower, airlift, bubble column, packed glass bead, hollow fiber, configuration and application Computer control of fermentation process System configuration and application	12 Hrs
2. Mass transfer Theory, diffusional resistance to oxygen requirements of microorganisms, measurements of mass transfer co- efficient and factor affecting them, effects of aeration and agitation on mass transfer, supply of air, air compressing, cleaning and sterilization of air and plenum ventilation, air sampling and testing standards for air purity. Rheology Rheological properties of fermentation system and their importance in bioprocessing.	12 Hrs
3. Scale up of fermentation process Principles, theoretical considerations, techniques used, media for fermentation, HTST sterilization, advantage and disadvantage, liquid sterilization. Cultivation and immobilized culture system Cultivation system - batch culture, continuous culture, synchronous cultures, fed batch culture. Graphical plot representing the above systems. Introduction to immobilization	12 Hrs

Techniques, immobilization of whole cell, immobilized culture system to prepare fine chemicals. Immobilization of enzymes and their applications in the industry. Reactors for immobilized systems and perspective of enzyme engineering.	
4. Scale down of fermentation process Theory, equipment design and operation, methods of filtration, solvent extraction, chromatographic separation, crystallization turbidity analysis and cell yield determination, metabolic response assay, enzymatic assay, bioautographic techniques and disruption of cells for product recovery. Isolation and screening Primary and secondary, maintenance of stock culture, strain improvement for increased yield.	12 Hrs
5. Bioprocessing of the industrially important microbial metabolites a) Organic solvents – Alcohol and Glycerol b) Organic acids - Citric acids, Lactic acids, c) Amino acids - Glutamic acids, Lysine, Cyclic AMP and GMP d) Antibiotics - Penicillin, Streptomycin, Griseofulvin, e) Vitamins - B12, Riboflavin and Vitamin C Biosynthetic pathways for some secondary metabolites, microbial transformation of steroids and alkaloids Regulation governing the manufacturing of biological products .	12 Hrs

REFERENCES

1. Peter Stanbury, Allan Whitaker, Stephen Hall, Principles of Fermentation technology, Elsevier stores.
2. L.E. Casida, Industrial Microbiology, John Wiley & sons Inc.
3. F.M. Asubel, Current protocols in molecular biology, volume I and II, John Wiley Publishers.
4. Biotol Board, Bioreactor design and product yield, Butterworth and Helhemann Publishers.
5. H. Patel, Industrial microbiology, Macmillan India Limited.

MPB 104T-ADVANCED PHARMACEUTICAL BIOTECHNOLOGY (Theory)

SCOPE

This paper has been designed to provide the knowledge to the students to develop skills of advanced techniques of isolation and purification of enzymes, to enrich students with current status of development of vaccines and economic importance of biotechnology products.

OBJECTIVES

- At the completion of this subject it is expected that students will be able to
- Understand about the latest technology development in biotechnology technique, tools and their uses in drug and vaccine development.
- Identify appropriate sources of enzymes.
- Understand and perform genetic engineering techniques in gene manipulation, r-DNA technology and gene amplification.
- Understand the overview of pharmacogenomics.
- Learn the regulatory approval process and key regulatory agencies for new drugs, biologics, devices, and drug-device combinations.

Course Content

THEORY	**60 Hrs**
1. Enzyme Technology Classification, general properties of enzymes, dynamics of enzymatic activity, sources of enzymes, extraction and purification, pharmaceutical, therapeutic and clinical application. Production of amyloglucosidase, glucose isomerase, amylase and trypsin.	12 Hrs
2. Genetic Engineering Techniques of gene manipulation, cloning strategies, procedures, cloning vectors expression vectors, recombinant selection and screening, expression in E. coli and yeast. Site directed mutagenesis, polymerase chain reaction, and analysis of DNA sequences. Gene library and cDNA Applications of the above technique in the production of, ● Regulatory proteins - Interferon, ● Interleukins Blood products - Erythropoietin ● Vaccines - Hepatitis-B ● Hormones - Insulin	12 Hrs
3. Therapeutic peptides Study on controlled and site specified delivery of therapeutic peptides and proteins through various routes of administration. Transgenic animals Production of useful proteins in transgenic animals and gene therapy. Human Genome The human genome project-a brief study, Human chromosome – Structure and classification, chromosomal abnormalities – Syndromes	12 Hrs
4. Signal transduction	12 Hrs

Introduction, cell signaling pathways, Ion channels, Sensors and effectors, ON and OFF mechanisms, Spatial and temporal aspects of signaling, cellular process, development, cell cycle and proliferation, neuronal signaling, cell stress, inflammatory responses and cell death, signaling defects and diseases. Oncogenes Introduction, definition, various oncogenes and their proteins.	
5. Microbial Biotransformation Biotransformation for the synthesis of chiral drugs and steroids. Microbial Biodegradation Biodegradation of xenobiotics, chemical and industrial wastes, Production of single-cell protein, Applications of microbes in environmental monitoring. Biosensors Definition, characteristics of ideal biosensors, types of biosensors, biological recognition elements, transducers, application of biosensors.	12 Hrs

REFERENCES

1. Biotechnology-The biological principles: MD Trevan, S Boffey, KH Goulding and P.F. Stanbury.
2. Immobilization of cells and enzymes: HosevearKennadycabral& Bicker staff
3. Principles of Gene Manipulating: RW Old and S.B.Primrose.
4. Molecular Cell Biology: Harvey Lodish, David Baltimore, Arnold Berk, S LawenceZipursky, Paul Matsudaira, James Darnell.
5. Modern Biotechnology: S.B Primrose
6. Gene transfer and expression protocols-methods in Molecular Biology, vol. VII, Edit E.T. Murray
7. Current protocols in Molecular Biology, Vo1.I & II:F.M. Asubel, John wiley Publishers
8. Current protocols in cellular biology, Vo1.1 & II John wiley publishers.
9. Principles of human genetics; by Curt Stern, published by W.H. Freeman.

MPB 105P-PHARMACEUTICAL BIOTECHNOLOGY PRACTICAL – I (Practicals)

1. Analysis of Pharmacopoeial compounds and their formulations by UV Vis spectrophotometer
2. Simultaneous estimation of multi component containing formulations by UV spectrophotometry
3. Experiments based on HPLC
4. Experiments based on Gas Chromatography
5. Estimation of riboflavin/quinine sulphate by fluorimetry
6. Estimation of sodium/potassium by flame photometry
7. Isolation and Purification of microorganism from the soil
8. Microbial contamination of Water and biochemical parameters.
9. Determination of Minimum Inhibitory concentration by gradient plate technique and serial dilution method.
10. UV- survival curve and Dark repair
11. Sterility test for pharmaceutical preparations
12. Sub culturing of cells and cytotoxicity assays.
13. Construction of growth curve and determination of specific growth rate and doubling time
14. Fermentation process of alcohol and wine production
15. Fermentation of vitamins and antibiotics
16. Whole cell immobilization engineering
17. Thermal death kinetics of bacteria
18. Replica plating
19. Bio-autography.
20. Isolation and estimation of DNA
21. Isolation and estimation of RNA
22. Isolation of plasmids
23. Agarose gel electrophoresis.
24. Transformation techniques
25. SDS – polyacrylamide gel electrophoresis for proteins
26. Polymerase chain reaction technique.

SEMESTER II

MPB 201T- PROTEINS AND PROTEIN FORMULATIONS (Theory)

SCOPE

This course is designed to impart knowledge and skills necessary for knowing fundamental aspects of proteins and their formulations is a part of drug research and development process. Basic theoretical discussions of the principles of more integrated and coherent use of information for protein formulation and design are provided to help the students to clarify the various biological concepts of protein.

OBJECTIVES

At the completion of this course it is expected that students will be able to understand,

- Various methods of purification of proteins
- Peptides in drug development
- Protein identification and characterization
- Protein based formulations
- Sequencing proteins

Course Content:

THEORY **60 Hrs**

1. Protein engineering Concepts for protein engineering. Isolation and purification of proteins, Stability and activity-based approaches of protein engineering, Chemical and Physical Considerations in Protein and Peptide Stability, Different methods for protein engineering, gene shuffling, and direct evolution.	12 Hrs
2. Peptidomimetics Introduction, classification; Conformationally restricted peptides, design, pseudopeptides, peptidomimetics and transition state analogs; Biologically active template; Amino acid replacements; Peptidomimetics and rational drug design; CADD techniques in peptidomimetics; Development of non-peptide peptidomimetics.	12 Hrs
3. Proteomics Protein identification and characterization: Methods/strategies, protein identification, de novo protein characterization, Isotope labelling, N- and C-terminal tags. 2-Dimensional gel electrophoresis Methods including immobilized pH gradients (IPGs), resolution, reproducibility and image analysis, future developments	12 Hrs
4. Protein formulation Different strategies used in the formulation of DNA and proteins, Analytical and biophysical parameters of proteins and DNA in pre- formulation, Liposomes, Neon-spears, Neon-particulate system, PEGylation, Biological Activity, Biophysical Characterization Techniques, Forced degradation studies of protein.	12 Hrs
5. Methods of protein sequencing Various methods of protein sequencing, characterisation, Edman degradation, Tryptic and/or Chymotryptic Peptide Mapping.	12 Hrs

REFERENCES

1. H. Lodhishet. Al. Molecular Cell Biology, W. H. Freeman and Company
2. Protein Purification – Hand Book, Amersham pharmacia biotech
3. EngelbertBuxbaum, Fundamentals of Protein Structure and Function, Springer Science
4. Sheldon J. Park, Jennifer R. Cochran, Protein Engineering and Design, CRC press.
5. Robert K. Skopes. Protein purification, principle and practice, springer link.
6. David Whitford, Proteins-Structure and Function, John Wiley & Sons Ltd.
7. James Swarbrick, Protein Formulation and Delivery Informa Healthcare USA,Inc.
8. Rodney Pearlman, Y. John Wang Formulation, Characterization, and Stability of Protein Drugs, Kluwer Academic Publishers.

MPB 202T-IMMUNOTECHNOLOGY (Theory)

SCOPE

This course is designed to impart knowledge on production and engineering of antibodies, the application of antigens, the design of (recombinant) vaccines, strategies for immune intervention, etc. The Immunotechnology - based techniques will be used for therapeutics and diagnostics, industries in the production, quality control and quality assurance, and in R&D.

OBJECTIVES

After this course, the students will be able to,

- Understand the techniques like immunodiagnostic tests,
- Characterization of lymphocytes, purification of antigens and antibody, etc.
- Access health problems with immunological background
- Develop approaches for the immune intervention of diseases

Course Content:

THEORY	**60 Hrs**
1. Fundamental aspects of immunology Introduction, cells and organs of the immune system, cellular basis of Immune response, primary and secondary lymphoid organs, antigen antibody and their structure. Types of immune responses, anatomy of immune response. Overview of innate and adaptive Immunity. Humoral Immunity B – Lymphocytes and their activation. Structure and function of immunoglobulins, idiotypes and anti-idiotypic antibodies. Cell mediated Immunity Thymus derived lymphocytes (T cells) – their ontogeny and types, MHC complex, antigen presenting cells (APC), mechanisms of T cell activation, macrophages, dendritic cells, Langerhans cells, mechanism of phagocytosis	12 Hrs
2. Immune Regulation and Tolerance Complement activation and types and their biological functions, cytokines and their role in immune response. Hypersensitivity Hypersensitivity Types I-IV, Hypersensitivity reactions and treatment Autoimmune diseases.	12 Hrs
3. Vaccine technology Vaccine and their types, conventional vaccines, novel methods for vaccine production, antiidiotype vaccine, DNA vaccine, genetically engineered vaccine, iscoms, synthetic peptides, and immunodiagnostics. Stem cell technology Stem cell technology and applications to immunology	12 Hrs
4. Hybridoma Technology Hybridoma techniques – fusion methods for myeloma cells and B- Lymphocytes, selection and screening techniques. Production and purification of monoclonal antibodies and their applications in Pharmaceutical industry.	12 Hrs
5. Immunological Disorder	12 hrs

Autoimmune disorders and types, pathogenic mechanisms, treatment, experimental models of auto immune diseases, primary and secondary immunodeficiency disorders. Immunodiagnosis Antigen antibody interaction – Precipitation reaction, Agglutination reactions, Principles and applications of ELISA, Radio Immuno Assay, Western blot analysis, immune-electrophoresis, immuno fluorescence, chemiluminescence assay, complement fixation reaction.	

REFERENCES

1. J. Kubey, Immunology – an Introduction.
2. S.C. Rastogi, Immunodiagonstics, New Age International.
3. Ashim Chakravarthy, Immunology and Immunotechnology, Oxford University Press.
4. E. Benjamini, Molecular Immunology.

MPB 203T-BIOINFORMATICS AND COMPUTATIONAL BIOTECHNOLOGY (Theory)

SCOPE

This paper has been designed to provide the advanced knowledge to the biotechnology students in invaluable areas of advanced bioinformatics which plays a crucial role in determining its future use and applications in medicine, drug discovery and in pharmaceutical industry.

OBJECTIVES

Upon completion of this course it is expected that the students will be able to understand,

1. Use of computers in developing a new drug
2. Biological concepts for bioinformatics
3. Proteins and their diversity
4. Various gene finding methods
5. Searching the biological databases
6. Target searching
7. Various methods of drug designing

Course Content:

THEORY **60 Hrs**

1. Introduction to Bioinformatics Definition and History of Bioinformatics, Internet and Bioinformatics, Introduction to Data Mining, Applications of Data Mining to Bioinformatics, Biological Database Protein and nucleic acid databases. Structural data bases. Collecting and storing the sequence and Applications of Bioinformatics.	12 Hrs
2. Sequence analysis Sequence alignment, pair wise alignment techniques, multiple sequence analysis, multiple sequence alignment; Flexible sequence similarity searching with the FAST3 program package, the use of CLUSTAL W and CLUSTAL X for the multiple sequence alignment. Tools used for sequence analysis.	12 Hrs
3. Protein informatics Introduction; Force field methods; Energy, buried and exposed residues, side chains and neighbours; Fixed regions, hydrogen bonds, mapping properties onto surfaces; Fitting monomers, R &S fit of conformers, assigning secondary structures; Sequence alignment-methods, evaluation, scoring; Protein completion, backbone construction and side chain addition; Small peptide methodology, software accessibility, building peptides; Protein displays; Substructure manipulations, annealing. **Protein structure prediction** Protein folding and model generation; Secondary structure prediction, analyzing secondary structures; Protein loop searching, loop generating methods, loop analysis; Homology modeling, concepts of homology modeling, potential applications, description, methodology, homologous sequence identification; Align structures, align model sequence; Construction of variable and conserved regions, threading techniques, Topology fingerprint approach for prediction, evaluation of	12 Hrs

alternate models; Structure prediction on a mystery sequence, structure aided sequence techniques of structure prediction, structural profiles, alignment algorithms, mutation tables, prediction, validation, sequence based methods of structure prediction, prediction using inverse folding, fold prediction; Significance analysis, scoring techniques, sequence- sequence scoring. **Docking** Docking problems, methods for protein- ligand docking, validation studies and applications; Screening small molecule databases, docking of combinatorial libraries, input data, analyzing docking results.	
4. Diversity of Genomes Prokaryotic and Eukaryotic Gene Families. Genome Analysis: Introduction, Gene prediction methods, Gene mapping and applications- Genetic and Physical Mapping, Integrated map, Sequence assembly and gene expression. **Completed Genomes** Bacterium, Nematode, Plant and Human **Evolution of Genomes** Lateral or Horizontal Transfer among Genomes, Transcriptome and Proteome- General Account **Phylogenetic analysis** Evolutionary Change in Nucleotide Sequences, Rates and Patterns of Nucleotide Substitution, Models for Nucleotide Substitution, Construction of Phylogenetic Tree, Genome Annotation technique.	12 Hrs
5. Target searching and Drug Designing Target and lead, timeline for drug development, target discovery, target modulators, In-silico gene expression, microarray, and lead discovery, libraries of ligands, active site analysis, and prediction of drug quality.	12 Hrs

REFERENCES

1. David W. Mount, Bioinformatics Sequence and Genome Analysis, CBS Publishers and Distributors
2. S. C. Rastogiet. al. Bioinformatics- Concepts Skill and Applications, CBS Publishers and Distributors
3. T. E. Creighton, Protein Structure and Molecular Properties, W.
1. H.Freeman and Company
4. Andreas D. Baxevanis, B. F. Francis Ouellette, Bioinformatics; A Practical Guide to the Analysis of Genes and Proteins, John Wiley & Sons, Inc.
5. Arthur M. Lesk, Introduction to Bioinformatics, Oxford University Press.
6. Shui Qing Ye. Bioinformatics: A Practical Approach, Chapman & Hall/CRC.
7. David Posada, Bioinformatics for DNA Sequence Analysis, Humana press.
8. Lesk, A.M. Introduction to Bioinformatics. Oxford University Press.
9. Letovsky, S.I. Bioinformatics. Kluwer Academic Publishers.
10. Baldi, P. and Brunak, S. Bioinformatics. The MIT Press.

MPB 204T-BIOLOGICAL EVALUATION OF DRUG THERAPY (Theory0

SCOPE

This paper has been designed to provide the knowledge to the biotechnology students to understand the importance of biological and evaluation of drug therapy of biological medicines.

OBJECTIVES

At the completion of this subject it is expected that students will be able to,

- Understand about the general concept of standardization of biological
- Understand the importance of transgenic animals and knockout animals
- Understand the biological medicines in development of various diseases.
- Learn the biological evaluation of drugs *in vitro* and *in vivo*

Course Content:

THEORY	**60 Hrs**
1. Biological Standardization General principles, Scope and limitation of bio-assay, bioassay of some official drugs. Preclinical drug evaluation Preclinical drug evaluation of its biological activity, potency and toxicity-Toxicity test in animals including acute, sub-acute and chronic toxicity, ED50 and LD50 determination, special toxicity test like teratogenicity and mutagenicity. Guidelines for toxicity studies Various guidelines for toxicity studies. Animal experiments assessing safety of packaging materials.	12 Hrs
2. Pyrogens Pyrogens: Sources, Chemistry and properties of bacterial pyrogens and endotoxins, Official pyrogen tests. Microbiological assay Assay of antibiotics and vitamins. Biological evaluation of drugs Screening and evaluation (including principles of screening, development of models for diseases: *in vivo* models / *in vitro* models / cell line study).	12 Hrs
3. Biologic Medicines in Development for various diseases - By Therapeutic Category, ● Genetic Disorders ● Eye related Disorders ● Digestive Disorders ● Diabetes/Related Conditions ● Cardiovascular Disease ● Cancer/Related Conditions ● Blood Disorders ● Autoimmune Disorders ● Infectious Diseases ● Neurologic Disorders ● Skin Diseases	12 Hrs

● Organ Transplantation Biologic Medicines in Development for various diseases – by Product Category, ● Antisense ● Vaccines ● Recombinant Hormones/Proteins ● Monoclonal Antibodies (mAb) ● Interferons ● Growth Factors ● Gene Therapy ● RNA Interference	
4. Regulatory aspects: drugs, biologics and medical devices An introduction to the regulations and documents necessary for approval of a medical product. Regulatory consideration Regulatory consideration for pre-clinical testing and clinical testing of drugs, biologics and medical devices. New Drug Applications for Global Pharmaceutical Product Approvals	12 Hrs
5. Bioavailability Objectives and consideration in bio-availability studies of Biopharmaceuticals, Concept of equivalents, Measurements of bio-availability. Determination of the rate of absorption, Bioequivalence and its importance, Regulatory aspects of bio-availability and bioequivalence studies for conventional dosage forms and controlled drug delivery systems of Biopharmaceuticals. Pharmacokinetics Pharmacokinetics:- Basic consideration, Pharmacokinetic models, Application of Pharmacokinetics in new drug development of Biopharmaceuticals and designing of dosage forms and Novel drug delivery systems of Biopharmaceuticals.	12 Hrs

REFERENCES

1. Perkins F.T., Hennessen W. Standardization and Control of Biologicals Produced by Recombinant DNA Technology, International Association of
2. Biological Standardization, Oxford University Press
3. Drug Discovery and Evaluation in Pharmacology assay: Vogel
4. Chow, Shein, Ching, Design and analysis of animal studies in pharmaceutical development,
5. Nodine and Siegler, Animal and Clinical pharmacologic Techniques in Drug Evaluation.
6. Screening methods in pharmacology (vol I & II), R.A. Turner.

MPB 205P-PHARMACEUTICAL BIOTECHNOLOGY - PRACTICAL – II (Practicals)

1. Protein identification
2. Protein characterization
3. Protein biochemistry
4. Recombinant DNA Technology
5. Protein expression
6. Protein formulations
7. Database searching
8. Sequence analysis methods
9. Protein structure prediction
10. Gene annotation methods
11. Phylogenetic analysis
12. Protein, DNA binding studies
13. Preparation of DNA for PCR applications – Isolation, Purity and Quantification
14. Introduction to PCR – working of PCR, Programming.
15. Introduction to RT-PCR – working, programming.
16. Primer design using softwares.
17. Gene DNA amplification by random / specific primers.
18. Southern Hybridization
19. Western Blotting
20. Gene transformation

DETAILS OF SUBJECT TEACHERS – SEMESTER I

S.No	Name of the Subject	Name of the Teachers	Designation and Department	Mobile No.	e-mail
1.	Modern Pharmaceutical Analytical Techniques	Dr. N. Krishnaveni	Professor & Head, Pharm Analysis	9442083447	krisath@jssuni.edu.in
2.	Microbial and Cellular Biology	Dr. Ashish D Wadhwani	Asst. Professor & Head, Pharm Biotechnology	8903638815	dradwadhwani@jssuni.edu.in
3.	Bioprocess Engineering and Technology	Dr. Vasanth Raj	Asst. Professor, Pharm Biotechnology	9500793944	vasanth@jssuni.edu.in
4.	Advanced Pharmaceutical Biotechnology	Dr. Rajeshkumar R	Lecturer, Pharm Biotechnology	8220194532	bathmic@jssuni.edu.in

DETAILS OF SUBJECT TEACHERS – SEMESTER II

S.No	Name of the Subject	Name of the Teachers	Designation and Department	Mobile No.	e-mail
1.	Proteins and protein Formulation	Mr Alin Boss	Lecturer	8197088591	bose.alin@gmail.com
2.	Immunotechnology	Dr. Ashish D Wadhwani	Asst. Professor & Head	8903638815	dradwadhwani@jssuni.edu.in
3.	Bioinformatics and Computer Technology	Dr. Rajeshkumar R	Lecturer	8220194532	bathmic@jssuni.edu.in
4.	Biological Evaluation of Drug Therapy	Dr. Vasanth Raj	Asst. Professor	9500793944	vasanth@jssuni.edu.in

Academic Plan
2020-21

SEMESTER 1

Name of the Subject	**Modern Pharmaceutical Analytical Techniques (Theory)**
Name of the Faculty	Dr. Krishna Veni N M.Pharm., Ph.D
Designation, Department	Professor & Head, Department of Pharmaceutical Analysis
Mobile Number	9442083447
e-Mail i.d.	krisath@jssuni.edu.in

Scope, Course Objectives and Course Outcomes

SCOPE

This subject deals with various advanced analytical instrumental techniques for identification, characterization and quantification of drugs. Instruments dealt are NMR, Mass spectrometer, IR, HPLC, GC etc.

OBJECTIVES

After completion of course, student is able to know,

- The analysis of various drugs in single and combination dosage forms
- Theoretical and practical skills of the instruments

COURSE OUTCOMES (COS)

At completion of this course it is expected that the students will be able to

CO 1 : Explain the general principles and techniques of spectroscopy & Chromatography

CO 2 : Perform the assay of single and multiple component pharmaceuticals using various analytical techniques

CO 3 : Develop skills in selecting suitable techniques for the analysis of drugs and pharmaceuticals

CO 4: Apply the knowledge learnt in developing newer analytical methods and procedures of their own design

CO 5 : Explore and learn the various instrumental techniques available for the analysis of organic substances

LECTURE PLAN – Abstract

Sessional	No. of Hours of Didactic Lecture	No of Hours of other Activities	Total No. of Lecture Hours
	Advanced Instrumentation Techniques		
I	30	1	31
II	30	--	30
Total No. of Hours	60	--	61

I SESSIONAL: 30 Lectures + 1 Activity

Lecture No.	Lecture Details	Hours
	Orientation of the subject	**01**
Unit-1:		**11**
UV Visible Spectroscopy		
1.	UV Visible Spectroscopy - Introduction, Theory, Laws	
2.	Instrumentation associated with UV Visible Spectroscopy	
3.	Choice of Solvents, solvent Effects and Applications of UV visible spectroscopy	
IR Spectroscopy		
4.	IR Spectroscopy - Theory, Modes of Molecular Vibrations, Samples handling	
5.	Instrumentation of Dispersive and Fourier Transform IR spectrometer	
6.	Factors affecting vibrational frequencies and applications of IR spectroscopy	
Spectroflourimetry		
7.	Spectroflourimetry - Theory of fluorescence, Factors affecting fluorescence	
8.	Quenchers, Instrumentation	
9.	Applications fo fluorescence spectrometer	
Flame emission spectroscopy & Atomic abosrption spectroscopy		
10.	Flame emission spectroscopy & Atomic abosrption spectroscopy - Principle, Instrumentation	
11.	Interferences	
12.	Applications	
Unit-2		**11**
NMR Spectroscopy		
1.	NMR spectroscopy - Quantum numbers and their role in NMR, Principle	
2.	Instrumentation - Continous wave NMR instrument	
3.	Principle and Instrumentation of FT NMR	
4.	solvent requirements, Relaxation process	
5.	NMR signals in various compounds	

6.	chemical shift, factors influencing chemical shift	
7.	spin spin coupling, coupling constant	
8.	spin spin coupling	
9.	Nuclear magnetic double resonance	
10.	Applications of NMR Spectroscopy	
11.	Principles of 13C NMR	
12.	Principles of 13C NMR	
Unit-3:		
MassSpectrometry		
1.	Principle	**06**
2.	Theory	
3.	Instrumentation of Mass Spectroscopy - sample introduction techniques	
4.	Different types of ionization - electron impact, chemical	
5.	Different types of ionization - Field, FAB and MALDI	
6.	Different types of ionization - APCI, ESI, APPI	

II SESSIONAL : 30 Lectures

Lecture No.	Lecture Details	Hours
Unit-3:		
Mass Spectrometery		
1.	Analyzers of Quadrupole and Time of Flight	
2.	Mass fragmentation and its rules	
3.	Mass fragmentation and its rules	**06**
4.	Meta stable ions, Isotopic peaks	
5.	Applications of Mass spectroscopy	
6.	Applications of Mass spectroscopy	
Unit-4:		
Chromatography - Principle, Apparatus, Instrumentation, Chromatographic Parameters, Factors influencing resolution, and applications of		
1.	Paper Chromatography	**12**
2.	Thin Layer Chromatography	
3.	Ion Exchange Chromatography	
4.	column Chromatography	
5.	GC	
6.	Gas Chromatography	
7.	Gas Chromatography	
8.	Gas Chromatography	
9.	HPLC	
10.	HPLC	
11.	HPLC	
12.	Affinity Chromatography	
Unit-5:		
Electrophoresis - Principle, Instrumentation, Working, Factors affecting separation and applications		

1.	Paper Electrophoresis	**12**
2.	Gel Electrophoresis	
3.	Capillary Electrophoresis	
4.	Capillary Electrophoresis	
5.	Zone Electrophoresis	
6.	Moving Boundray Electrophoresis	
7.	Iso Electric Focussing	
X Ray Crystallography		
8.	Production of X Rays, Braggs Law	
9.	Different X Ray diffraction methods - Rotating Crystal Technique	
10.	X Ray Powder technique	
11.	Tyes of Crystals	
12.	Applications of X Ray Diffractions	

TEXT BOOKS

1. Spectrometric Identification of Organic compounds - Robert M Silverstein, Sixth edition, John Wiley & Sons, 2004.
2. Principles of Instrumental Analysis - Doglas A Skoog, F. James Holler, Timothy A. Nieman, 5th edition, Eastern press, Bangalore, 1998.
3. Instrumental methods of analysis – Willards, 7th edition, CBS publishers.
4. Practical Pharmaceutical Chemistry – Beckett and Stenlake, Vol II, 4th edition, CBS Publishers, New Delhi, 1997.
5. Organic Spectroscopy - William Kemp, 3rd edition, ELBS, 1991.
6. Quantitative Analysis of Drugs in Pharmaceutical formulation - P D Sethi, 3rd Edition, CBS Publishers, New Delhi, 1997.
7. Pharmaceutical Analysis- Modern methods – Part B - J W Munson, Volume 11, Marcel Dekker Series

REFERENCE BOOKS

1. Introduction to Spectroscopy; by Donald L Pavia
2. Spectroscopy of Organic Compounds, 2nd edn., P.S/Kalsi, Wiley estern Ltd., Delhi.
3. Textbook of Pharmaceutical Analysis, KA.Connors, 3rd Edition, John Wiley & Sons, 1982.

Name of the Subject	**Microbial and Cellular Biology (Theory)**
Name of the Faculty	Dr Ashish Wadhwani M.Pharm., Ph.D
Designation, Department	Assistant Professor & Head Department of Pharmaceutical Biotechnology
Mobile Number	8903638815
e-Mail i.d.	dradwadhwani@jssuni.edu.in

Scope, Course Objectives and Course Outcomes

SCOPE

This subject is designed to provide the advanced knowledge to the biotechnology students in invaluable areas of advanced microbiology which plays a crucial role in determining its future use and applications in medicine, drug discovery and in pharmaceutical industry.

OBJECTIVE

The primary objectives of the course is to:

1. Importance of Microorganisms in Industry
2. Central dogma of molecular biology
3. Structure and function of cell and cell communication
4. Cell culture technology and its applications in pharmaceutical industries
5. Microbial pathogenesis and correlating it to rational use of antimicrobial agents

COURSE OUTCOMES (COS)

At completion of this course it is expected that the students will be able to

CO 1: Understand the world of microbiology – chemistry and morphology, cultural, physiological and reproduction of microorganisms

CO 2: Learn central dogma of molecular biology – DNA & RNA

CO 3: Gain in depth knowledge structure of cell, cell cycle analysis and apoptosis process

CO 4: Know importance of growth of animal cell in culture and importance of *in vitro* techniques in research

CO 5: Comprehend microbial pathogenicity and mechanism of action of antimicrobial agents

LECTURE PLAN – Abstract

Sessional	No. of Hours of Didactic Lecture	No of Hours of other Activities	Total No. of Lecture Hours
I	30	1	31
II	30	1	31
Total No. of Hours	60	**2**	62

I SESSIONAL: 30 Lectures + 01 Activity

Lecutre No	Lecture Details	Hours
Unit 1: Microbiology		**(12)**
1.	Inroduction to the world of microbiology - Prokaryotes and Eukaryotes	
2.	Bacteria structure, chemistry and morphology, cultural, physiological and reproductive features	
3.	Cont…	
4.	Cont…	
5.	Fungi structure, chemistry and morphology, cultural, physiological and reproductive features	
6.	Cont…	
7.	Cont…	
8.	Virus structure, chemistry and morphology, cultural, physiological and reproductive features	
9.	Cont…	
10.	Actinomycetes structure, chemistry and morphology, cultural, physiological and reproductive features	
11.	Methods of isolation, cultivation and maintenance of pure cultures	
12.	Industrially important microorganisms - examples and applications	
Unit 2: Molecular Biology		**(12)**
1.	Structure of nucleus and chromosome,	
2.	Nucleic acids and composition	
3.	structure and types of DNA	
4.	structure and types of RNA	
5.	Central dogma of molecular biology - Replication	
6.	Transcription and translation	
Gene regulation		
7.	Gene copy number, transcriptional control and translational control	
RNA processing		
8.	Modification and Maturation RNA splicing, RNA editing, RNA amplification.	
9.	Mutagenesis and repair mechanisms	
10.	types of mutants, application of mutagenesis in stain improvement	
11.	Gene mapping of plasmids- types purification and application	

12.	Phage genetics, genetic organization, phage mutation and lysogeny.	
Unit 3: Cell structure and function		**(06)**
1.	Cell organelles, cytoskeleton & cell movements	
2.	basic aspects of cell regulation	
3.	bioenergetics and fuelling reactions of aerobics and anaerobics,secondary metabolism & its applications.	
4.	Cell communication, cell cycle and apoptosis	
5.	mechanism of cell division	
6.	Cell junctions/adhesion and extra cellular matrix, germ cells and fertilization, histology	
Activity 1	**Discussion on I Sessional Examination**	

II SESSIONAL: 30 Lectures + 01 Activity

1.	The life and death of cells in tissues	**(06)**
Cell Cycle and Cytoskeleton		
2.	Cell Division and its Regulation, G-Protein Coupled Receptors	
3.	Nuclear receptors, Cytoskeleton & cell movements, Intermediate Filaments	
Apoptosis and Oncogenes		
4.	Programmed Cell Death, Tumor cells, carcinogens & repair	
Differentiation and Developmental Biology		
5.	Fertilization, Events of Fertilization, In vitro Fertilization	
6.	Embryonic Germ Cells, Stem Cells and its Application	
Unit 4: Principles of microbial nutrition		**(12)**
1.	Physical and chemical environment for microbial growth	
2.	Stability and degeneration of microbial cultures	
Growth of animal cells in culture		
3.	General procedure for cell culture	
4.	Cont…	
5.	Nutrient composition,	
6.	Primary, established and transformed cell cultures	
7.	Applications of cell cultures in pharmaceutical industry and research	
8.	Growth of viruses in cell culture propagation	
9.	Growth of viruses in cell culture enumeration	
10.	*In-vitro* screening techniques - cytotoxicity	
11.	*In-vitro* screening techniques - anti-tumor	
12.	*In-vitro* screening techniques - anti-viral assays	
Unit 5: Microbial pathology		**(12)**
1.	Identifying the features of pathogenic bacteria	
2.	Identifying the features of pathogenic fungi	
3.	Identifying the features of pathogenic viruses	
4.	Mechanism of microbial pathogenicity	
5.	Cont…	
6.	Etiology and pathology of common microbial diseases	
7.	Cont…	

8.	currently recommended therapies for common bacterial infections	
9.	currently recommended therapies for common fungal infections	
10.	currently recommended therapies for common viral infections	
11.	Mechanism of action of antimicrobial agents	
12.	possible sites of chemotherapy	
Activity 2	**Discussion on II sessional and final examination**	

REFERENCES

1. W.B. Hugo and A.D. Russel: Pharmaceutical Microbiology, Blackwell Scientific publications, Oxford London.
2. Prescott and Dunn, Industrial Microbiology, CBS Publishers & Distributors, Delhi.
3. Pelczar, Chan Kreig, Microbiology, Tata McGraw Hill edn.
4. David Freifelder, Molecular Biology, 2nd edition, Narosa Publishing House.
5. R. Ian Freshney, Culture of animal cells – A manual of Basic techniques, 6th edition, Wileys publication house.
6. David Baltimore,Molecular cell biology, W H Freeman & Co publishers.
7. Cell biology vol-I,II,III by Julio E.Cells
8. Bergeys manual of systematic bacteriology, Williams and Wilkins- A Waverly company.

Name of the Subject	**Bioprocess Engineering and Technology (Theory)**
Name of the Faculty	Dr P Vasanth Raj, MPharm.,PhD.,PGCHET.,
Designation, Department	Assistant Professor Department of Pharmaceutical Biotechnology
Mobile Number	9500793944
e-Mail i.d.	vasanth@jssuni.edu.in

Scope, Course Objectives and Course Outcomes

SCOPE

This paper has been designed to provide the knowledge to the biotechnology students in invaluable areas of bioprocess technology to develop skills to modify, design and operate different types of fermenters, to understand and implement various fermentation procedures, to train students in scale up fermentation operations.

OBJECTIVE:

The primary objective of the course is to;

1. Understand basics and design of fermentation technology
2. Scale up and scale down processing of fermentation technology
3. Bioprocessing of the industrially important microbial metabolites in industries and R & D organizations.
4. Regulation governing the manufacturing of biological products
5. Understand and conduct fermentation process kinetics.

COURSE OUTCOMES (COS)

At completion of this course it is expected that the students will be able to;

CO 1: Learn the principles of fermentation and operate different types of bioreactors

CO 2: Understand the importance of mass transfer and rheology in bioprocessing

CO 3: Explore scale up processing involved in development of bioprocessed product and understand the role of immobilization techniques

CO 4: Excel the skills of scale down process, isolation and screening process to ultimately get the final yield

CO 5: Perform bioprocessing of the industrially important microbial metabolites and regulations governing biological products

LECTURE PLAN – Abstract

Sessional	No. of Hours of Didactic Lecture	No of Hours of other Activities	Total No. of Lecture Hours
I	30	1	31
II	30	1	31
Total No. of Hours	60	**2**	62

I SESSIONAL: 30 Lectures + 01 Activity

Lecutre No	Lecture Details	Hours
Unit 1: Introduction to fermentation technology		**(12)**
1.	Basic principles of fermentation	
Study of the design and operation of bioreactor		
2.	Ancillary parts and function, impeller design and agitation	
3.	Power requirements on measurements and control of dissolved oxygen, carbon dioxide,	
4.	temperature, pH and foam.	
Types of bioreactor		
5.	CSTR	
6.	Tower bioreactor	
7.	Airlift bioreactor	
8.	bubble column	
9.	packed glass bead	
10.	Hollow fiber	
11.	configuration and application	
Computer control of fermentation process		
12.	System configuration and application	
Unit 2: Mass transfer		**(12)**
1.	Theory of mass transfer	
2.	Cont…	
3.	diffusional resistance to oxygen requirements of microorganisms	
4.	measurements of mass transfer co- efficient	
5.	factor affecting mass transfer	
6.	Cont…	
7.	effects of aeration and agitation on mass transfer	
8.	supply of air, air compressing	
9.	leaning and sterilization of air and plenum ventilation	
10.	air sampling and testing standards for air purity	
Rheology		
11.	Rheological properties of fermentation system	
12.	importance of rheology in bioprocessing	
Unit 3: Scale up of fermentation process		**(06)**

1.	Principles, theoretical considerations, techniques used, media for fermentation	
2.	HTST sterilization	
3.	advantage and disadvantage, liquid sterilization	
Cultivation and immobilized culture system		
4.	Cultivation system - batch culture, continuous culture	
5.	synchronous cultures, fed batch culture.	
6.	Graphical plot representing the above systems.	
Activity 1	Discussion on I Sessioal Examination	

II SESSIONAL : 30 Lectures + 01 Activity

Introduction to immobilization		**(06)**
7.	Techniques of immobilization	
8.	Cont…	
9.	immobilization of whole cell	
10.	immobilized culture system to prepare fine chemicals	
11.	Immobilization of enzymes and their applications in the industry	
12.	Reactors for immobilized systems and perspective of enzyme engineering	
Unit 4: Scale down of fermentation process		**(12)**
1.	Theory	
2.	equipment design and operation	
3.	methods of filtration, solvent extraction,	
4.	chromatographic separation, crystallization	
5.	turbidity analysis	
6.	cell yield determination	
7.	metabolic response assay	
8.	enzymatic assay	
9.	bioautographic techniques	
10.	disruption of cells for product recovery	
Isolation and screening		
11.	Primary and secondary, maintenance of stockculture	
12.	Strain improvement for increased yield	
Unit 5: Bioprocessing of the industrially important microbial metabolites		**(12)**
1.	Organic solvents – Alcohol and Glycerol	
2.	Organic acids - Citric acids, Lactic acids	
3.	Amino acids - Glutamic acids, Lysine	
4.	Cyclic AMP and GMP	
5.	Antibiotics - Penicillin	
6.	Streptomycin	
7.	Griseofulvin,	
8.	Vitamins - B12, Riboflavin	
9.	Vitamin C	

10.	Biosynthetic pathways for some secondary metabolites	
11.	Microbial transformation of steroids and alkaloids	
12.	Regulation governing the manufacturing of biological products	
Activity 2	Discussion on II Sessional and Final examination	

REFERENCES

1. Peter Stanbury, Allan Whitaker, Stephen Hall, Principles of Fermentation technology, Elsevier stores.
2. L.E. Casida, Industrial Microbiology, John Wiley & sons Inc.
3. F.M. Asubel, Current protocols in molecular biology, volume I and II, John Wiley Publishers.
4. Biotol Board, Bioreactor design and product yield, Butterworth and Helhemann Publishers.
5. H. Patel, Industrial microbiology, Macmillan India Limited.

Name of the Subject	**Advanced Pharmaceutical Biotechnology (Theory)**
Name of the Faculty	Dr. Rajeshkumar R M.Pharm., Ph.D
Designation, Department	Lecturer, Department of Pharmaceutical Biotechnology
Mobile Number	820194532
e-Mail i.d.	bathmic@jssuni.edu.in

Scope, Course Objectives and Course Outcomes

SCOPE

This paper has been designed to provide the knowledge to the students to develop skills of advanced techniques of isolation and purification of enzymes, to enrich students with current status of development of vaccines and economic importance of biotechnology products.

OBJECTIVES

At the completion of this subject it is expected that students will be able to

- Understand about the latest technology development in biotechnology technique, tools and their uses in drug and vaccine development.
- Identify appropriate sources of enzymes.
- Understand and perform genetic engineering techniques in gene manipulation, r-DNA technology and gene amplification.
- Understand the overview of pharmacogenomics.
- Learn the regulatory approval process and key regulatory agencies for new drugs, biologics, devices, and drug-device combinations.

COURSE OUTCOMES (COS)

At completion of this course it is expected that the students will be able to,

CO 1 : Gain insight into the advanced techniques in biotechnology
CO 2 : Understand various strategies used in manipulation of DNA
CO 3 : Get insight into Recombinant DNA techniques for production of desired products
CO 4 : Explain the use of therapeutic peptides in drug discovery
CO 5 : Design various biotransformation techniques to synthesis drugs
CO 6 : Understand various biodegradation techniques.

LECTURE PLAN – Abstract

Sessional	No. of Hours of Didactic Lecture	No of Hours of other Activities	Total No. of Lecture Hours
I	30	01	31
II	30	01	31
Total No. of Hours	60	02	62

I SESSIONAL: 30 Lectures + 1 Activity

Lecture No.	Lecture Details	Hours
Unit-1		**12**
	Orientation to the subject	
1.	Classification of enzymes	
2.	General properties of enzymes	
3.	General properties of enzymes (Cont…)	
4.	Dynamics of enzymatic activity	
5.	Dynamics of enzymatic activity (Cont…)	
6.	Sources of enzymes	
7.	Extraction and purification	
8.	Extraction and purification (Cont…)	
9.	Production of amyloglucosidase	
10.	Production of glucose isomerase	
11.	Production of amylase	
12.	Production of trypsin	
Unit-2		**12**
1.	Techniques of gene manipulation	
2.	Techniques of gene manipulation (Cont…)	
3.	Techniques of gene manipulation (Cont…)	
4.	Cloning strategies – Procedure	
5.	Cloning and Expression vectors	
6.	Recombinant selection and screening	
7.	rDNA expression in E. coli and yeast.	
8.	Construction of Gene library and cDNA	
9.	Site directed mutagenesis	
10.	Technique in the production of Regulatory proteins - Interferon, Interleukins	
11.	Technique in the production of Blood products - Erythropoietin	
12.	Technique in the production of Vaccines - Hepatitis-B and Hormones - Insulin	
Unit-3		**12**
1.	Controlled delivery of therapeutic peptides and proteins	
2.	Controlled delivery of therapeutic peptides and proteins (Cont…)	
3.	Specified delivery of therapeutic peptides and proteins	

4.	Specified delivery of therapeutic peptides and proteins (Cont…)	
5.	Transgenic animals	
6.	Production of useful proteins in transgenic animals and gene therapy	
Activity1	Discussion about First sessional examination	

II SESSIONAL: 30 Lectures + 1 Activity

Lecture No.	Lecture Details	Hours
7.	The human genome project - a brief study	
8.	Human chromosome – Structure	
9.	Human chromosome Classification	
10.	Chromosomal abnormalities – Syndromes	
11.	Chromosomal abnormalities – Syndromes (Cont….)	
12.	Chromosomal abnormalities – Syndromes (Cont….)	
Unit-4		
1.	Cell signaling pathways	
2.	Cell signaling pathways (Cont….)	
3.	Cell signaling pathways (Cont….)	**12**
4.	Cell signaling pathways (Cont….)	
5.	Neuronal signaling	
6.	Cell cycle and proliferation	
7.	Cell stress	
8.	Inflammatory responses	
9.	Cell death	
10.	Signaling defects and diseases	
11.	Signaling defects and diseases (Cont….)	
12.	Various oncogenes and their proteins.	
Unit-5		
1.	Biotransformation for the synthesis of chiral drugs and steroids	
2.	Biotransformation for the synthesis of chiral drugs and steroids (Cont….)	**12**
3.	Microbial Biodegradation	
4.	Biodegradation of xenobiotics	
5.	Biodegradation of chemical and industrial wastes	
6.	Production of single-cell protein	
7.	Applications of microbes in environmental monitoring	
8.	Characteristics of ideal biosensors	
9.	Types of biosensors	
10.	Biological recognition elements	
11.	Transducers	
12.	Application of biosensors	
Activity-1	Discussion about First sessional examination	

Text Books

1. Principles of Enzyme Technology by Khan M. Y, PHI Learning Publisher
2. Fundamentals of Enzymology: The Cell and Molecular Biology of Catalytic Proteins by Price Nicholas C., Lewis Stevens, Edition 3 Rev ed Edition
3. Cellular Signal Processing by Marks, Garland Exclusive publishers, 2017 Edition

Reference Books

1. Biotechnology-The biological principles: MD Trevan, S Boffey, KH Goulding and P.F. Stanbury.
2. Immobilization of cells and enzymes: HosevearKennadycabral& Bicker staff
3. Principles of Gene Manipulating: RW Old and S.B.Primrose.
4. Molecular Cell Biology: Harvey Lodish, David Baltimore, Arnold Berk, S LawenceZipursky, Paul Matsudaira, James Darnell.
5. Modern Biotechnology: S.B Primrose
6. Gene transfer and expression protocols-methods in Molecular Biology, vol. VII, Edit E.T. Murray
7. Current protocols in Molecular Biology, Vo1.I & II:F.M. Asubel, John wiley Publishers
8. Current protocols in cellular biology, Vo1.1 & II John wiley publishers.
9. Principles of human genetics; by Curt Stern, published by W.H. Freeman.

SEMESTER II

Name of the Subject	**Proteins and protein formulations (Theory)**
Name of the Faculty	Mr Alin Boss M.Pharm.,
Designation, Department	Lecturer, Department of Pharmaceutical Biotechnology
Mobile Number	8197088591
e-Mail i.d.	boss.alin@gmail.com

Scope, Course Objectives and Course Outcomes

SCOPE

This course is designed to impart knowledge and skills necessary for knowing fundamental aspects of proteins and their formulations is a part of drug research and development process. Basic theoretical discussions of the principles of more integrated and coherent use of information for protein formulation and design are provided to help the students to clarify the various biological concepts of protein.

OBJECTIVES

At the completion of this course it is expected that students will be able to understand,

- Various methods of purification of proteins
- Peptides in drug development
- Protein identification and characterization
- Protein based formulations
- Sequencing proteins

COURSE OUTCOMES (COS)

At completion of this course it is expected that the students will be able to,

CO 1 : Gain insight into the fundamental aspects of protein formulations

CO 2 : Understand various parameters to be considered for stability of proteins during formulation

CO 3 : Get insight into peptidomimetics as a part of drug discovery

CO 4 : Classify and explain the structural properties of proteins

CO 5 : Design various strategies used in protein formulations

CO 6 : Understand various methods of protein sequencing and characterization.

LECTURE PLAN – Abstract

Sessional	No. of Hours of Didactic Lecture	No of Hours of other Activities	Total No. of Lecture Hours
I	30	01	31
II	30	01	31
Total No. of Hours	60	02	62

I SESSIONAL: 30 Lectures + 1 Activity

Lecture No.	Lecture Details	Hours
Unit-1		**12**
	Orientation to the subject	
1.	Isolation and purification of proteins	
2.	Isolation and purification of proteins (Cont…)	
3.	Stability based approaches of protein engineering	
4.	Stability based approaches of protein engineering (Cont…)	
5.	Activity based approaches of protein engineering	
6.	Activity based approaches of protein engineering (Cont…)	
7.	Chemical and Physical Considerations in Protein and Peptide Stability	
8.	Chemical and Physical Considerations in Protein and Peptide Stability (Cont…)	
9.	Chemical and Physical Considerations in Protein and Peptide Stability (Cont…)	
10.	Different methods for protein engineering	
11.	Different methods for protein engineering (Cont…)	
12.	Different methods for protein engineering (Cont…)	
Unit-2		**12**
1.	Peptidomimetics - introduction	
2.	Strategies in Peptidomimetics	
3.	Strategies in Peptidomimetics (Cont…)	
4.	Strategies in Peptidomimetics (Cont…)	
5.	Strategies in Peptidomimetics (Cont…)	
6.	Strategies in Peptidomimetics (Cont…)	
7.	Peptidomimetics and rational drug design	
8.	CADD techniques in peptidomimetics	
9.	CADD techniques in peptidomimetics (Cont…)	
10.	CADD techniques in peptidomimetics (Cont…)	
11.	Development of non-peptide peptidomimetics	
12.	Application of Peptidomimetics	
Unit-3		**12**
1.	Protein identification	
2.	Protein identification (Cont…)	
3.	Protein identification (Cont…)	

4.	Protein characterization	
5.	Protein characterization (Cont…)	
6.	Protein characterization (Cont…)	
Activity1	Discussion about First sessional examination	

II SESSIONAL: 30 Lectures + 1 Activity

Lecture No.	Lecture Details	Hours
7.	2-Dimensional gel electrophoresis	
8.	Immobilized pH gradients (IPGs)	
9.	Resolution	
10.	Reproducibility	
11.	Image analysis	
12.	Future developments	
Unit-4		
1.	Different strategies used in the formulation of DNA and proteins	
2.	Different strategies used in the formulation of DNA and proteins (Cont…)	**12**
3.	Analytical and biophysical parameters of proteins and DNA in pre-formulation	
4.	Analytical and biophysical parameters of proteins and DNA in pre-formulation (Cont…)	
5.	Liposomes	
6.	Neon-spears, Neon-particulate system	
7.	PEGylation	
8.	Biological Activity	
9.	Biophysical Characterization Techniques	
10.	Biophysical Characterization Techniques (Cont…)	
11.	Biophysical Characterization Techniques (Cont…)	
12.	Forced degradation studies of protein.	
Unit-5		
1.	Various methods of protein sequencing	
2.	Various methods of protein sequencing (Cont…)	
3.	Various methods of protein sequencing (Cont…)	**12**
4.	Various methods of protein sequencing (Cont…)	
5.	Characterization of Protein sequence	
6.	Characterization of Protein sequence (Cont…)	
7.	Characterization of Protein sequence (Cont…)	
8.	Characterization of Protein sequence (Cont…)	
9.	Characterization of Protein sequence (Cont…)	
10.	Edman degradation	
11.	Tryptic and/or Chymotryptic Peptide Mapping	
12.	Tryptic and/or Chymotryptic Peptide Mapping (Cont…)	
Activity-1	Discussion about First sessional examination	

TEXT BOOKS

1. Peptides by Sewald Norbert, Wiley-VCH Verlag GmbH
2. Pseudo-peptides in Drug Discovery by Peter E. Nelson, Wiley-VCH Verlag GmbH
3. Vaccine Development and Manufacturing by Emily wen, John Wiley and Sons Ltd
4. Novel Approaches and Strategies for Biologics, Vaccines and Cancer Therapies by Manmohan Singh Maya Salnikova, 1st Edition, Academic Press

REFERENCE BOOKS

1. H. Lodhishet. Al. Molecular Cell Biology, W. H. Freeman and Company
2. Protein Purification – Hand Book, Amersham pharmacia biotech
3. EngelbertBuxbaum, Fundamentals of Protein Structure and Function, Springer Science
4. Sheldon J. Park, Jennifer R. Cochran, Protein Engineering and Design, CRC press.
5. Robert K. Skopes. Protein purification, principle and practice, springer link.
6. David Whitford, Proteins-Structure and Function, John Wiley & Sons Ltd.
7. James Swarbrick, Protein Formulation and Delivery Informa Healthcare USA,Inc.
8. Rodney Pearlman, Y. John Wang Formulation, Characterization, and Stability of Protein Drugs, Kluwer Academic Publishers.

Name of the Subject	**Immunotechnology (Theory)**
Name of the Faculty	Dr Ashish Wadhwani M.Pharm., Ph.D
Designation, Department	Assistant Professor & Head Department of Pharmaceutical Biotechnology
Mobile Number	8903638815
e-Mail i.d.	dradwadhwani@jssuni.edu.in

Scope, Course Objectives and Course Outcomes

SCOPE

This course is designed to impart knowledge on production and engineering of antibodies, the application of antigens, the design of (recombinant) vaccines, strategies for immune intervention, etc. The Immunotechnology – based techniques will be used for therapeutics and diagnostics, industries in the production, quality control and quality assurance, and in R&D.

OBJECTIVES

The primary objectives of the course are to

1. Understand the techniques like immunodiagnostic tests,
2. Characterization of lymphocytes, purification of antigens and antibody etc.
3. Access health problems with immunological background;
4. Develop approaches for the immune intervention of diseases

COURSE OUTCOMES (COS)

At completion of this course it is expected that the students will be able to

CO 1: Learn the fundamental aspects of Immunology
CO 2: Understand Immune Regulation and Tolerance in the system – Hypersensitivity reactions and autoimmune diseases
CO 3: Gain the knowledge on vaccine and stem cell technology
CO 4: Acquire the knowledge on importance of hybridoma technology in research
CO 5: Comprehend immunological disorder and various immunodiagnostic tests

LECTURE PLAN – Abstract

Sessional	No. of Hours of Didactic Lecture	No of Hours of other Activities	Total No. of Lecture Hours
I	30	1	31
II	30	1	31
Total No. of Hours	60	**2**	62

I SESSIONAL: 30 Lectures + 01 Activity

Lecutre No	Lecture Details	Hours
Unit 1: Fundamental aspects of immunology		**(12)**
1.	Cells and organs of the immune system,	
2.	Cellular basis of Immune response	
3.	Primary and secondary lymphoid organs, antigen antibody and their structure	
4.	Types of immune responses, anatomy of immune response	
5.	Overview of innate and adaptive Immunity	
6.	B – Lymphocytes and their activation	
7.	Structure and function of immunoglobulins	
8.	Thymus derived lymphocytes (T cells)	
9.	MHC complex, antigen presenting cells (APC	
10.	Mechanisms of T cell activation, macrophages	
11.	Dendritic cells, langerhans cells	
12.	Mechanism of phagocytosis	
Unit 2: Immune Regulation and Tolerance		**(12)**
1.	Immune Regulation and Tolerance	
2.	Complement activation	
3.	Types of complements	
4.	Biological functions of complements	
5.	Cytokines and their role in immune response	
6.	Overview of Hypersensitivity reactions	
7.	Hypersensitivity type - 1 reaction and treatment	
8.	Hypersensitivity type - 2 reaction and treatment	
9.	Hypersensitivity type - 3 reaction and treatment	
10.	Hypersensitivity type - 4 reaction and treatment	
11.	Autoimmune diseases	
12.	Autoimmune diseases cont…	
Unit 3: Vaccine technology		**(06)**
1.	Introduction to Vaccine technology	
2.	Vaccine and their types,	
3.	conventional vaccines	
4.	novel methods for vaccine production,	
5.	antiidiotype vaccine	
6.	DNA vaccine	

Activity1	**Discussion on I Sessional Examination**	

II SESSIONAL: 30 Lectures + 01 Activity

Unit 3: Vaccine technology		**(06)**
1.	Genetically engineered vaccine	
2.	Iscoms	
3.	Synthetic peptides	
4.	Immunodiagnostics	
5.	Stem cell technology	
6.	Stem cell technology and applications to immunology	
Unit 4: Hybridoma Technology		**(12)**
1.	Hybridoma Technology	
2.	Hybridoma techniques	
3.	Fusion methods	
4.	Myeloma cells	
5.	B-Lymphocytes	
6.	Selection method	
7.	Screening techniques	
8.	Production of Mabs	
9.	Purification of monoclonal antibodies	
10.	Purification of monoclonal antibodies	
11.	Purification of monoclonal antibodies cont...	
12.	Applications in Pharmaceutical industry	
Unit 5: Immunological Disorder		**(12)**
1.	Immunological Disorder	
2.	Autoimmune disorders and types	
3.	Pathogenic mechanisms and treatment	
4.	Experimental models of auto immune diseases	
5.	Primary immunodeficiency disorders	
6.	Secondary immunodeficiency disorders	
7.	Antigen antibody interaction Precipitation reaction, Agglutination reactions	
8.	Principles and applications of ELISA Radio Immuno Assay	
9.	Western blot analysis, immune-electrophoresis	
10.	Immuno fluorescence	
11.	Chemiluminescence assay,	
12.	Complement fixation reaction.	
Activity 2	**Discussion on II sessional and final examination**	

REFERENCES

1. J. Kubey, Immunology – an Introduction, W. H. Freeman; 6th edition edition (9 October 2006)
2. S.C. Rastogi, Immunodiagnostics: Principles and Practice, New Age International Pvt. Ltd.
3. Ashim Chakravarthy, Immunology and Immunotechnology, Oxford University Press.
4. E. Benjamini, Molecular Immunology, Wiley-Liss; 5 edition (October 21, 2003)

Name of the Subject	**Bioinformatics and Computational Biotechnology (Theory)**
Name of the Faculty	Dr. Rajeshkumar R M.Pharm., Ph.D
Designation, Department	Lecturer, Department of Pharmaceutical Biotechnology
Mobile Number	820194532
e-Mail i.d.	bathmic@jssuni.edu.in

Scope, Course Objectives and Course Outcomes

SCOPE

This paper has been designed to provide the advanced knowledge to the biotechnology students in invaluable areas of advanced bioinformatics which plays a crucial role in determining its future use and applications in medicine, drug discovery and in pharmaceutical industry.

OBJECTIVES

Upon completion of this course it is expected that the students will be able to understand,

- Use of computers in developing a new drug
- Biological concepts for bioinformatics
- Proteins and their diversity
- Various gene finding methods
- Searching the biological databases
- Target searching
- Various methods of drug designing

COURSE OUTCOMES (COS)

At completion of this course it is expected that the students will be able to,

CO 1 : Gain insight into the fundamental aspects of bioinformatics

CO 2 : Understand various *in silico* methods used for solving the biological problems

CO 3 : Get insight into data mining, sequence alignment techniques, phylogenetic tree analysis

CO 4 : Predict computational prediction of protein using various methods

CO 5 : Apply various methodology to identify and predict the functional and structural genes in a given genome

CO 6 : Understand various methods of genome annotation

LECTURE PLAN – Abstract

Sessional	No. of Hours of Didactic Lecture	No of Hours of other Activities	Total No. of Lecture Hours
I	30	01	31
II	30	01	31
Total No. of Hours	60	02	62

I SESSIONAL: 30 Lectures + 1 Activity

Lecture No.	Lecture Details	Hours
Unit-1		**12**
	Orientation to the subject	
13.	Definition and History of Bioinformatics	
14.	Internet and Bioinformatics	
15.	Introduction to Data Mining	
16.	Applications of Data Mining to Bioinformatics,	
17.	Protein databases	
18.	Nucleic acid databases	
19.	Structural databases	
20.	Collecting and storing the sequence	
21.	Collecting and storing the sequence (Cont…)	
22.	Collecting and storing the sequence (Cont…)	
23.	Collecting and storing the sequence (Cont…)	
24.	Applications of Bioinformatics	
Unit-2		**12**
13.	Sequence alignment	
14.	Sequence alignment (Cont…)	
15.	Pair wise alignment techniques	
16.	Pair wise alignment techniques (Cont…)	
17.	Multiple sequence analysis	
18.	Multiple sequence analysis (Cont…)	
19.	Multiple sequence alignment	
20.	FAST3 program package	
21.	CLUSTAL W	
22.	CLUSTAL X	
23.	Tools used for sequence analysis	
24.	Tools used for sequence analysis (Cont…)	
Unit-3		**12**
13.	Strategies in Protein informatics	
14.	Strategies in Protein informatics (Cont…)	
15.	Concepts of Protein structure prediction	
16.	Homology modeling	
17.	Comparative modelling	

18.	*Ab initio* modelling	
Activity1	Discussion about First sessional examination	

II SESSIONAL: 30 Lectures + 1 Activity

Lecture No.	Lecture Details	Hours
19.	Requirements for docking	
20.	Screening small molecule databases and protein database	
21.	Methods for protein- ligand docking	
22.	Validation of results	
23.	Docking problems	
24.	Applications of docking	
Unit-4		
13.	Gene prediction in prokaryotic genome	
14.	Gene prediction in Eukaryotic genome	
15.	Gene mapping and applications	**12**
16.	Completed genome - Bacterium, Nematode, Plant and Human	
17.	Evolution of Genomes	
18.	Evolution of Genomes (Cont…)	
19.	Phylogenetic analysis	
20.	Phylogenetic analysis - Tools	
21.	Construction of Phylogenetic Tree	
22.	Understanding Tree	
23.	Genome Annotation technique	
24.	Genome Annotation technique (Cont…)	
Unit-5		
13.	Timeline for drug development	
14.	Target discovery	
15.	Target modulators	**12**
16.	Libraries of ligands	
17.	Active site analysis	
18.	Active site analysis	
19.	Prediction of drug quality	
20.	Prediction of drug quality (Cont…)	
21.	Microarray technology	
22.	*In-silico* gene expression Study	
23.	*In-silico* gene expression Study (Cont…)	
24.	*In-silico* gene expression Study (Cont…)	
Activity-1	Discussion about First sessional examination	

TEXT BOOKS

1. Bioinformatics by S. C. Rastogi, Namita Mendiratta, Parag Rastogi
2. Foundations of Bioinformatics by Darbari Manuj, Khanna Books
3. Basic Bioinformatics by S. Gladis Helen Hepsyba, MJP Publishers

REFERENCE BOOKS

1. David W. Mount, Bioinformatics Sequence and Genome Analysis, CBS Publishers and Distributors
2. S. C. Rastogiet. al. Bioinformatics- Concepts Skill and Applications, CBS Publishers and Distributors
3. T. E. Creighton, Protein Structure and Molecular Properties, W.H.Freeman and Company
4. Andreas D. Baxevanis, B. F. Francis Ouellette, Bioinformatics; A Practical Guide to the Analysis of Genes and Proteins, John Wiley & Sons, Inc.
5. Arthur M. Lesk, Introduction to Bioinformatics, Oxford University Press.
6. Shui Qing Ye. Bioinformatics: A Practical Approach, Chapman & Hall/CRC.
7. David Posada, Bioinformatics for DNA Sequence Analysis, Humana press.
8. Lesk, A.M. Introduction to Bioinformatics. Oxford University Press.
9. Letovsky, S.I. Bioinformatics. Kluwer Academic Publishers.
10. Baldi, P. and Brunak, S. Bioinformatics. The MIT Press.

Name of the Subject	**Biological Evaluation of Drug Therapy (Theory)**
Name of the Faculty	Dr P Vasanth Raj, MPharm., PhD., PGCHET.,
Designation, Department	Assistant Professor Department of Pharmaceutical Biotechnology
Mobile Number	9500793944
e-Mail i.d.	vasanth@jssuni.edu.in

Scope, Course Objectives and Course Outcomes

SCOPE

This paper has been designed to provide the knowledge to the biotechnology students to understand the importance of biological and evaluation of drug therapy of biological medicines.

Objective

The objective of the course is to;

1. Understand about the general concept of standardization of biological.
2. Understand the importance of transgenic animals and knockout animals.
3. Understand the biological medicines in development of various diseases.
4. Learn the biological evaluation of drugs *in vitro* and *in vivo*

COURSE OUTCOMES (COS)

At completion of this course it is expected that the students will be able to

CO 1: understand general concepts of standardization of biologicals

CO 2: know the importance of pyrogen testing and varous *in vitro* and *in vivo* modles

CO 3: gain the knowledge on biologic medicines in development for various diseases - Therapeutic Category

CO 4: learn on biologic medicines in development for various diseases – Product category

CO 5: explain about bioavailability and pharmacokinetics modles

LECTURE PLAN – Abstract

Sessional	No. of Hours of Didactic Lecture	No of Hours of other Activities	Total No. of Lecture Hours
I	30	1	31
II	30	1	31
Total No. of Hours	60	**2**	62

I SESSIONAL: 30 Lectures + 01 Activity

Lecutre No	Lecture Details	Hours
Unit 1: Biological Standardization		**(12)**
1.	Biological Standardization	
2.	General principles	
3.	Scope and limitation of bio-assay	
4.	bioassay of some official drugs.	
5.	Preclinical drug evaluation of its biological activity	
6.	Potency and toxicity-Toxicity test in animals	
7.	including acute, sub-acute and chronic toxicity	
8.	ED50 and LD50 determination	
9.	teratogenecity and mutagenecity	
10.	Guidelines for toxicity studies	
11.	Various guidelines for toxicity studies	
12.	Animal experiments assessing safety of packaging materials	
Unit 2: Pyrogens		**(12)**
1.	Pyrogens	
2.	Pyrogens: Sources, Chemistry	
3.	properties of bacterial pyrogens	
4.	endotoxins	
5.	Official pyrogen tests	
6.	Microbiological assay	
7.	Assay of antibiotics	
8.	Assay of vitamins.	
9.	Biological evaluation of drugs	
10.	Biological evaluation of drugs	
11.	In vivo models	
12.	In vitro models / cell line study	
Unit 3:	**Biologic Medicines in Development for various diseases By Therapeutic Category**	**(06)**
1.	Genetic Eye related Disorders	
2.	Digestive Disorders & Blood Disorders	
3.	Diabetes/Related Conditions	
4.	Cardiovascular Disease	
5.	Cancer/Related Conditions	
6.	Autoimmune Disorders	

Activity1	Discussion on I Sessional Examination	

II SESSIONAL : 30 Lectures + 01 Activity

Unit 3: Biologic Medicines in Development for various diseases By Product Category		**(06)**
1.	Infectious and Neurologic Diseases	
2.	Skin Diseases & Organe Transplantation	
3.	Antisense & Vaccines	
4.	Recombinant Hormones/Proteins and Growth Factors	
5.	Monoclonal Antibodies (mAb) & Gene Therapy	
6.	Interferons and RNA Interference	
Unit 4: Regulatory aspects : drugs, biologics and medical devices		**(12)**
1.	Regulatory aspects- Drugs	
2.	Regulatory - biologicals	
3.	Regulatory - medical devices	
4.	regulations and documents necessary for approval of a medical product.	
5.	regulations and documents necessary for approval of a medical product cont…	
6.	Regulatory consideration for pre-clinical testing testing of drugs	
7.	Regulatory consideration for pre-clinical testing testing of biologicals	
8.	Regulatory consideration for pre-clinical testing testing of medical devices	
9.	New Drug Applications for Global Pharmaceutical Product Approvals	
10.	New Drug Applications for Global Pharmaceutical Product Approvals	
11.	Regulatory aspects- Drugs	
12.	Regulatory - biologicals	
Unit 5: Bioavailability and Pharmacokinetics		**(12)**
1.	Objectives and consideration in bio-availability studies of Biopharmaceuticals,	
2.	Concept of equivalents, Measurements of bio-availability	
3.	"Determination of the rate of absorption Bioequivalence and its importance,"	
4.	bio-availability and bioequivalence studies for conventional dosage forms	
5.	controlled drug delivery systems of Biopharmaceuticals	
6.	Pharmacokinetics: - Basic consideration	
7.	Pharmacokinetic models	
8.	Pharmacokinetic models cont…	
9.	Application of Pharmacokinetics in new drug development	
10.	designing of dosage forms	

11.	Novel drug delivery systems of Biopharmaceuticals	
12.	Novel drug delivery systems of Biopharmaceuticals cont	
Activity 2	**Discussion on II sessional and final examination**	

REFERENCES

1. Perkins F.T., Hennessen W. Standardization and Control of Biologicals Produced by Recombinant DNA Technology, International Association of Biological Standardization
2. J.H. Burn., Biological Standardization, Oxford University Press
3. Drug Discovery and Evaluation in Pharmacology assay: Vogel
4. Chow, Shein, Ching, Design and analysis of animal studies in pharmaceutical development,
5. Nodine and Siegler, Animal and Clinical pharmacologic Techniques in Drug Evaluation.
6. Screening methods in pharmacology (vol I & II), R.A. Turner.

JSS Academy of Higher Education & Research, Mysuru
JSS College of Pharmacy, Rocklands, Ooty

I M. PHARMACY TIME TABLE FOR E-LEARN CLASSES : I Semester (AY : 2020 - 2021)

DEPARTMENT : PHARMACEUTICAL BIOTECHNOLOGY
COURSE : PHARMACEUTICAL BIOTECHNOLOGY
ZOOM / GOOGLE MEET LICENSE - cpobiotech1@jssuni.edu.in

Days	9 - 10 am	10 - 11 am	11 - 12 am	12 - 1 pm	1 - 2 pm	2 - 3 pm	3 - 4 pm	4 - 5 pm
Mon	-	MPAT ***(NKV)***	APB ***(RRK)***	MCB ***(ADW)***	**LUNCH BREAK**	Assignment	Self Learning/ Llibrary	BET ***(VR)***
Tue	-	MPAT ***(NKV)***	APB ***(RRK***	MCB ***(ADW)***		Assignment	Self Learning/ Llibrary	BET ***(VR)***
Wed	-	MPAT ***(NKV)***	APB ***(RRK***	MCB ***(ADW)***		Assignment	Self Learning/ Llibrary	BET ***(VR)***
Thu	-	MPAT ***(NKV)***	APB ***(RRK***	MCB ***(ADW)***		Seminar	Self Learning/ Llibrary	BET ***(VR)***
Fri	-	Seminar Preparation	Seminar Preparation	Seminar		Self Learning	Self Learning/ Llibrary	Seminar
Sat	-	Seminar Preparation	Seminar Preparation	Seminar		-	-	-

Subjects : I M.Pharm (Pharm. Analysis)

1. Modern Pharmaceutical Analytical Techniques (MPAT) : Dr. N. Krishna veni ***(NKV)***
2. Microbial and Cellular Biology (ADW) : Dr. Ashish D Wadhwani **(ADW)**
3. Advacned Pharmaceutical Biotechnology (APB) : Dr. R Rajeshkumar **(RRK)**
4. Bioprocess Engineering and Technology (BET) : Dr. P Vasanth Raj **(VR)**

JSS ACADEMY OF HIGHER EDUCATION & RESEARCH, MYSURU
(Deemed to be University – Accredited 'A' Grade by NAAC)
JSS COLLEGE OF PHARMACY, OOTY
(An ISO 9001:2015 Certified Institute)
M. Pharmacy (Academic Year 2020-2021) – Time Table- II Semester
DEPARTMENT OF PHARMACEUTICAL BIOTECHNOLOGY

Day/ Time	**09:00 – 10:00 AM**	**10:00 – 11:00 AM**	**11:00 – 12:00 Noon**	**12:00 – 01:00 PM**	**01:00 – 02:00 PM**	**2:00 – 3:00 PM**	**3:00 – 4:00 PM**	**4:00 – 5:00 PM**
Monday	**Tutorial** IT	Practical – Core Subject			**L U N C H B R E A K**	Practical Discussion	IT (T) **(ADW)**	BCT (T) **(RRK)**
Tuesday	--	Practical – Core subject				Practical Discussion	IT (T) **(ADW)**	BEDT (T) **(VR)**
Wednesday	**Tutorial** BEDT	BCT (T) **(RRK)**	Group Discussion	Journal Club		Seminar Preparation	PPF (T) **(AB)**	BEDT (T) **(VR)**
Thursday	-	BEDT (T) **(VR)**	PPF (T) **(AB)**	IT(T) **(ADW)**		Practical – Core Subject		
Friday	**Tutorial** BCT	Practical – Core subject				BCT (T) **(RRK)**	BEDT (T) **(VR)**	PPF (T) **(AB)**
Saturday	**Tutorial** PPF	BCT (T) **(RRK)**	PPF (T) **(AB)**	IT (T) **(ADW)**		**Sports**		

Dr. A. D. Wadhwani (ADW) Asst. Prof. and Head : Immunotechnology (IT) - T & P
Dr P Vasanth Raj (VR) Asst. Prof. : Biological Evaluation of Drug Therapy (BEDT) - T & P
Dr. R. Rajesh Kumar (RRK) Lecturer : Protein and Protein Formulation (PPF) - T & P
Mr. Alin Boss (AB) Lecturer : Bioinformatics and Computer Technology (BCT) - T & P

M. PHARM
PHARMACY PRACTICE

SYLLABUS
SEMESTER I
MPP 101T- CLINICAL PHARMACY PRACTICE (Theory)

SCOPE

This course is designed to impart the basic knowledge and skills that are required to practice pharmacy including the provision of pharmaceutical care services to both healthcare professionals and patients in clinical settings.

OBJECTIVES

- Upon completion of this course it is expected that students shall be able to
- Understand the elements of pharmaceutical care and provide comprehensive patient care services
- Interpret the laboratory results to aid the clinical diagnosis of various disorders
- Provide integrated, critically analyzed medicine and poison information to enable healthcare professionals in the efficient patient management

Course Content

1. Introduction to Clinical Pharmacy: 12Hrs

Definition, evolution and scope of clinical pharmacy, International and national scenario of clinical pharmacy practice, Pharmaceutical care.

Clinical Pharmacy Services: Ward round participation, Drug therapy review (Drug therapy monitoring including medication order review, chart endorsement, clinical review and pharmacist interventions)

2. Clinical Pharmacy Services: 12Hrs

Patient medication history interview, Basic concept of medicine and poison information services, Basic concept of pharmacovigilance, Hemovigilance, Materiovigilance and AEFI, Patient medication counselling, Drug utilization evaluation, Documentation of clinical pharmacy services, Quality assurance of clinical pharmacy services.

3. Patient Data Analysis: 12 Hrs

Patient Data & Practice Skills: Patient's case history – its structure and significances in drug therapy management, Common medical abbreviations and terminologies used in clinical practice, Communication skills: verbal and non-verbal communications, its applications in patient care services.

Lab Data Interpretation: Hematological tests, Renal function tests, Liver function tests Lab Data Interpretation: 12 Hrs

Tests associated with cardiac disorders, Pulmonary function tests, Thyroid function tests, Fluid and electrolyte balance, Microbiological culture sensitivity tests

4. Medicines & Poison Information Services: 12 Hrs

Medicine Information Service: Definition and need for medicine information service, Medicine information resources, Systematic approach in answering medicine information queries, Preparation of verbal and written response, Establishing a drug information centre.

Poison Information Service: Definition, need, organization and functions of poison information centre.

RECOMMENDED BOOKS (Latest Editions)

1. A Textbook of Clinical Pharmacy Practice – Essential concepts and skills – Parthasarathi G, Karin Nyfort-Hansen and Milap Nahata
2. Practice Standards and Definitions - The Society of Hospital Pharmacists of Australia

3. Basic skills in interpreting laboratory data - Scott LT, American Society of Health System Pharmacists Inc
4. Relevant review articles from recent medical and pharmaceutical literature.

MPP 102T-PHARMACOTHERAPEUTICS-I (Theory)

SCOPE

This course aims to enable the students to understand the different treatment approaches in managing various disease conditions. Also, it imparts knowledge and skills in optimizing drug therapy of a patient by individualizing the treatment plan through evidence-based medicines.

OBJECTIVES

Upon completion of this course it is expected that students shall be able to:

- Describe and explain the rationale for drug therapy
- Summarize the therapeutic approach for management of various disease conditions including reference to the latest available evidence
- Discuss the clinical controversies in drug therapy and evidence-based medicine
- Prepare individualized therapeutic plans based on diagnosis
- Identify the patient specific parameters relevant in initiating drug therapy, and monitoring therapy (including alternatives, time- course of clinical and laboratory indices of therapeutic response and adverse effect/s)

Course Content

Etiopathogenesis and pharmacotherapy of diseases associated with following systems:

1. Cardiovascular system: 12 Hrs

Hypertension, Congestive cardiac failure, Acute coronary syndrome, Arrhythmias, Hyperlipidemias.

2. Respiratory system: 12 Hrs

Asthma, Chronic obstructive airways disease, Drug induced pulmonary diseases Endocrine system: Diabetes, Thyroid diseases

3. Gastrointestinal system: 12 Hrs

Peptic ulcer diseases, Reflux esophagitis, Inflammatory bowel diseases, Jaundice & hepatitis

4. Gastrointestinal system: 12Hrs

Cirrhosis, Diarrhea and Constipation, Drug-induced liver disease

Hematological diseases: Anemia, Deep vein thrombosis, Drug induced hematological disorders

5. Bone and joint disorders: 12Hrs

Rheumatoid arthritis, Osteoarthritis, Gout, Osteoporosis

Dermatological Diseases: Psoriasis, Eczema and scabies, impetigo, drug induced skin disorders Ophthalmology: Conjunctivitis, Glaucoma

RECOMMENDED BOOKS (Latest Editions)

1. Roger and Walker. Clinical Pharmacy and Therapeutics – Churchill Livingstone publication
2. Joseph T. Dipiro et al. Pharmacotherapy: A Pathophysiologic Approach- Appleton & Lange
3. Robins SL. Pathologic basis of disease -W.B. Saunders publication
4. Eric T. Herfindal. Clinical Pharmacy and Therapeutics- Williams and Wilkins Publication
5. Lloyd Young and Koda-Kimble MA Applied Therapeutics: The clinical Use of Drugs- Lippincott Williams and Wilkins
6. Chisholm- Burns Wells Schwinghammer Malone and Joseph P Dipiro. Pharmacotherapy Principles and practice-– McGraw Hill Publication

7. Carol Mattson Porth. Principles of Pathophysiology- Lippincott Williams and Wilkins
8. Harrison's. Principles of Internal Medicine - McGraw Hill
9. Relevant review articles from recent medical and pharmaceutical literature

MPP 103T-HOSPITAL & COMMUNITY PHARMACY(Theory)

SCOPE

This course is designed to impart basic knowledge and skills that are required to practice pharmacy in both hospital and community settings.

OBJECTIVES

- Upon completion of this course it is expected that students shall be able to:
- Understand the organizational structure of hospital pharmacy
- Understand drug policy and drug committees
- Know about procurement & drug distribution practices
- Know the admixtures of radiopharmaceuticals
- Understand the community pharmacy management
- Know about value added services in community pharmacies

Course Content:

1. Introduction to Hospitals: 12Hrs

Definition, classification, organizational structure

Hospital Pharmacy: Definition, Relationship of hospital pharmacy department with other departments, Organizational structure, legal requirements, work load statistics, Infrastructural requirements, Hospital Pharmacy Budget and Hospital Pharmacy management

Hospital Drug Policy: Pharmacy & Therapeutics Committee, Infection Control committee, Research & Ethics Committee, Management of Medicines as per NABH

2. Hospital Formulary Guidelines and its development 12Hrs

Developing Therapeutic guidelines, Drug procurement process, and methods of Inventory control, Methods of Drug distribution, Intravenous admixtures, Hospital Waste Management

3. Education and training: 12Hrs

Training of technical staff, training and continuing education for pharmacists, Pharmacy students,

Medical staff and students, Nursing staff and students, Formal and informal meetings and lectures, Drug and therapeutics newsletter.

Community Pharmacy Practice: Definition, roles & responsibilities of community pharmacists, and their relationship with other health care providers

Community Pharmacy management: Legal requirements to start community pharmacy, site selection, lay out & design, drug display, super drug store model, accounts and audits, Good dispensing practices, Different softwares & databases used in community pharmacies. Entrepreneurship in community pharmacy.

4. Prescription:

12 Hrs

5. Legal requirements & interpretation, prescription related problems

Responding to symptoms of minor ailments: Head ache, pyrexia, menstrual pains, food and drug allergy,

OTC medication: Rational use of over the counter medications Medication counseling and use of patient information leaflets

Medication adherence: Definition, factors influencing adherence behavior, strategies to improve medication adherence

Patient referrals to the doctors

ADR monitoring in community pharmacies

6. Health Promotion:

12 Hrs

Definition and health promotion activities, family planning, Health screening services, first aid, prevention of communicable and non-communicable diseases, smoking cessation, Child & mother care

National Health Programs: Role of Community Pharmacist in Malaria and TB control programs Home Medicines review program: Definition, objectives, Guidelines, method and outcomes Research in community pharmacy Practice

RECOMMENDED BOOKS (Latest Editions)

1. Hospital Pharmacy - Hassan WE. Lea and Febiger publication.
2. Textbook of hospital pharmacy - Allwood MC and Blackwell.
3. Avery's Drug Treatment, Adis International Limited.
4. Community Pharmacy Practice – Ramesh Adepu, BSP Publishers, Hyderabad
5. Remington Pharmaceutical Sciences.
6. Relevant review articles from recent medical and pharmaceutical literature

MPP 104T-CLINICAL RESEARCH (Theory)

SCOPE

This course aims to provide the students an opportunity to learn drug development process especially the phases of clinical trials and also the ethical issues involved in the conduct of clinical research. Also, it aims to imparts knowledge and develop skills on conceptualizing, designing, conducting and managing clinical trials.

OBJECTIVES

Upon completion of this course it is expected that students shall be able to:

- Know the new drug development process.
- Understand the regulatory and ethical requirements.
- Appreciate and conduct the clinical trials activities
- Know safety monitoring and reporting in clinical trials
- Manage the trial coordination process

Course Content:

1. Drug development process: 12 Hrs

   Introduction, various approaches to drug discovery, Investigational new drug application submission

   Ethics in Biomedical Research: Ethical Issues in Biomedical Research – Principles of ethics in biomedical research, Ethical committee [institutional review board] - its constitution and functions, Challenges in implementation of ethical guidelines, ICH GCP guidelines and ICMR guidelines in conduct of Clinical trials, Drug Safety Reporting.

2. Types and Designs used in Clinical Research: 12 Hrs

   Planning and execution of clinical trials, Various Phases of clinical trials, Bioavailability and Bioequivalence studies, Randomization techniques (Simple randomization, restricted randomization, blocking method and stratification), Types of research designs based on Controlling Method (Experimental, Quasi experimental, and Observational methods) Time Sequences (Prospective and Retrospective), Sampling methods (Cohort study, case Control study and cross sectional study), Health outcome measures (Clinical & Physiological, Humanistic and economic)

   Clinical Trial Study team: Roles and responsibilities of: Investigator, Study Coordinator, Sponsor, Monitor, Contract Research Organization

   Clinical trial Documents: 12 Hrs

   Guidelines to the preparation of following documents: Protocols, Investigator's Brochure, Informed Consent Form, Case report forms, Contracts and agreements, Dairy Cards

   Clinical Trial Start up activities: Site Feasibility Studies, Site/Investigator selection, Pre-study visit, Investigator meeting, Clinical trial agreement execution, Ethics committee document preparation and submission

3. Investigational Product: 12 Hrs

   Procurement and Storage of investigation product

   Filing procedures: Essential documents for clinical trial, Trial Master File preparation and maintenance, Investigator Site File, Pharmacy File, Site initiation visit, Conduct, Report and Follow up

   Clinical Trial Monitoring and Close out: Preparation and conduct of monitoring visit: Review of source

   documents, CRF, ICF, IPstorage, accountabilityandreconciliation, StudyProcedure, EC co mmunications, Safety reporting, Monitoring visit reporting and follow-up

Close-Out visit: Study related documents collection, Archival requirement, Investigational Product reconciliation and destruction, Close-Out visit report.

4. Quality Assurance and Quality Control in Clinical Trials: 12 Hrs

Types of audits, Audit criteria, Audit process, Responsibilities of stakeholders in audit process, Audit follow-up and documentation, Audit resolution and Preparing for FDA inspections, Fraud and misconduct management

Data Management Infrastructure and System Requirement for Data Management: Electronic data capture systems, Selection and implementation of new systems, System validation and test procedures, Coding dictionaries, Data migration and archival

Clinical Trial Data Management: Standard Operating Procedures, Data management plan, CRF & Data base design considerations, Study set-up, Data entry, CRF tracking and corrections, Data cleaning, Managing laboratory and ADR data, Data transfer and database lock, Quality Control and Quality Assurance in CDM, Data mining and warehousing.

RECOMMENDED BOOKS (Latest Editions)

1. Principles and practice of pharmaceutical medicine, Second edition. Authors: Lionel. D. Edward, Aadrew.J. Flether Anthony W Fos , Peter D Sloaier Publisher: Wiley.
2. Handbook of clinical research. Julia Lloyd and Ann Raven Ed. Churchill Livingstone
3. Principles of Clinical Research edited by Giovanna di Ignazio, Di Giovanna and Haynes.
4. Central Drugs Standard Control Organization. Good Clinical Practices- Guidelines for Clinical Trials on Pharmaceutical Products in India. New Delhi: Ministry of Health.
5. International Conference on Harmonization of Technical requirements for registration of Pharmaceuticals for human use. ICH Harmonized Tripartite Guideline. Guideline for Good Clinical Practice.E6; May 1996.
6. Ethical Guidelines for Biomedical Research on Human Subjects. Indian Council of Medical Research, New Delhi.
7. Textbook of Clinical Trials edited by David Machin, Simon Day and Sylvan Green, John Wiley and Sons.
8. Clinical Data Management edited by R K Rondels, S A Varley, C F Webbs. Second Edition, Jan 2000, Wiley Publications.
9. Goodman & Gilman: JG Hardman, LE Limbard, McGraw Hill Publications.
10. Relevant review articles from recent medical and pharmaceutical literature.

MPP 105T-PHARMACY PRACTICE I PRACTICALS (Practicals)

1. Treatment Chart Review (one)
2. Medication History Interview (one)
3. Patient Medication Counseling (two)
4. Drug Information Query (two)
5. Poison Information Query (one)
6. Lab Data Interpretation (two)
7. Presentation of clinical cases of various disease conditions adopting Pharmaceutical Care Plan Model (eight)
8. ABC Analysis of a given list of medications (one)
9. Preparation of content of a medicine, with proper justification, for the inclusion in the hospital formulary (one)
10. Formulation and dispensing of a given IV admixtures (one)
11. Preparation of a patient information leaflet (two)
12. Preparation of Study Protocol (one)
13. Preparation of Informed Consent Form (one)

SEMESTER II
MPP 201T-PRINCIPLES OF QUALITY USE OF MEDICINES (Theory)

SCOPE

This course is designed to impart basic knowledge and skills that are required to practice quality use of medicines (QUM) in different healthcare settings and also to promote quality use of medicines, in clinical practice, through evidence-based medicine approach.

OBJECTIVES

Upon completion of this course it is expected that students shall be able to:

- Understand the principles of quality use of medicines
- Know the benefits and risks associated with use of medicines
- Understand regulatory aspects of quality use of medicines
- Identify and resolve medication related problems
- Promote quality use of medicines
- Practice evidence-based medicines

Course Content:

1. Introduction to Quality use of medicines (QUM): 12 Hrs

Definition and Principles of QUM, Key partners and responsibilities of the partners, building blocks in QMC, Evaluation process in QMC, Communication in QUM, Cost effective prescribing.

2. Concepts in QUM: 12 Hrs

Evidence based medicine: Definition, concept of evidence-based medicine, Approach and practice of evidence-based medicine in clinical settings

Essential drugs: Definition, need, concept of essential drug, National essential drug policy and list

Rational drug use: Definition, concept and need for rational drug use, Rational drug prescribing, Role of pharmacist in rational drug use.

3. QUM in various settings: 12 Hrs

Hospital settings, Ambulatory care/Residential care, Role of health care professionals in promoting the QUM, Strategies to promote the QUM, Impact of QUM on E-health, integrative medicine and multidisciplinary care.

QUM in special population: Pediatric prescribing, Geriatric prescribing, prescribing in pregnancy and lactation, Prescribing in immune compromised and organ failure patients.

Regulatory aspects of QUM in India: 12 Hrs

Regulation including scheduling, Regulation of complementary medicines, Regulation of OTC medicines, Professional responsibility of pharmacist, Role of industry in QUM in medicine development.

4. Medication errors: 12 Hrs

Definition, categorization and causes of medication errors, Detection and prevention of medication errors, Role of pharmacist in monitoring and management of medication errors

Pharmacovigilance: Definition, aims and need for pharmacovigilance, Types, predisposing factors and mechanism of adverse drug reactions (ADRs), Detection, reporting and monitoring of ADRs, Causality assessment of ADRs, Management of ADRs, Role of pharmacist in pharmacovigilance.

RECOMMENDED BOOKS (Latest Editions)

1. A Textbook of Clinical Pharmacy Practice – Essential concepts and skills –Parthasarathi G, Karin Nyfort-Hansen and Milap Nahata
2. Andrews EB, Moore N. Mann's Pharmacovigilance
3. Dipiro JT, Talbert RL, Yee GC. Pharmacotherapy: A Pathophysiologic Approach

4. Straus SE, Richardson WS, Glasziou P, Haynes RB. Evidence-Based Medicine: How to practice and teach it
5. Cohen MR. Medication Errors
6. Online:
7. http://medicinesaustralia.com.au/files/2012/05/MA_QUM_External_Reduced.pdf
8. http://curriculum.racgp.org.au/statements/quality-use-of-medicines/
9. http://www.rug.nl/research/portal/files/14051541/Chapter_2.pdf
10. Relevant review articles from recent medical and pharmaceutical literature.

MPP 202T-PHARMACOTHERAPEUTICS-II (Theory)

SCOPE

This course aims to enable the students to understand the different treatment approaches in managing various disease conditions. Also, it imparts knowledge and skills in optimizing drug therapy of a patient by individualizing the treatment plan through evidence-based medicines.

OBJECTIVES

Upon completion of this course it is expected that students shall be able to:

- Describe and explain the rationale for drug therapy
- Summarize the therapeutic approach for management of various disease conditions including reference to the latest available evidence
- Discuss the clinical controversies in drug therapy and evidence-based medicine
- Prepare individualized therapeutic plans based on diagnosis
- Identify the patient specific parameters relevant in initiating drug therapy, and monitoring therapy (including alternatives, time- course of clinical and laboratory indices of therapeutic response and adverse effects)

Course Content

1. Nervous system: 12 Hrs

Epilepsy, Parkinson's disease, Stroke, Headache, Alzheimer's disease, Neuralgias and Pain pathways and Pain management.

2. Psychiatric disorders: 12 Hrs

Schizophrenia, Depression, Anxiety disorders, Sleep disorders, Drug induced psychiatric disorders Renal system: Acute renal failure, Chronic renal failure, Renal dialysis, Drug induced renal disease

3. Infectious diseases: 12 Hrs

General guidelines for the rational use of antibiotics and surgical prophylaxis, Urinary tract infections, Respiratory tract infections, Gastroenteritis, Tuberculosis, Malaria, Bacterial endocarditis, Septicemia.

4. Infectious diseases: 12 Hrs

Meningitis, HIV and opportunistic infections, Rheumatic fever, Dengue fever, H1N1, Helminthiasis, Fungal infections,

Gynecological disorders: Dysmenorrhea, Hormone replacement therapy.

5. Oncology: 12 Hrs

General principles of cancer chemotherapy, pharmacotherapy of breast cancer, lung cancer, head & neck cancer, hematological malignancies, Management of nausea and vomiting, Palliative care

RECOMMENDED BOOKS (Latest Editions)

1. Roger and Walker. Clinical Pharmacy and Therapeutics – Churchill Livingstone publication.
2. Joseph T. Dipiro et al. Pharmacotherapy: A Pathophysiologic Approach- Appleton & Lange
3. Robins SL. Pathologic basis of disease -W.B. Saunders publication
4. Eric T. Herfindal. Clinical Pharmacy and Therapeutics- Williams and Wilkins Publication
5. Lloyd Young and Koda-Kimble MA Applied Therapeutics: The clinical Use of Drugs-

Lippincott Williams and Wilkins
6. Chisholm- Burns Wells Schwinghammer Malone and Joseph P Dipiro. Pharmacotherapy Principles and practice-– McGraw Hill Publication
7. Carol Mattson Porth. Principles of Pathophysiology- Lippincott Williams and Wilkins
8. Harrison's. Principles of Internal Medicine - McGraw Hill
9. Relevant review articles from recent medical and pharmaceutical literature

MPP 203T-CLINICAL PHARMACOKINETICS AND THERAPEUTIC DRUG MONITORING (Theory)

SCOPE

This course is designed to enable students to understand the basics principles and applications of pharmacokinetics in designing the individualized dosage regimen, to interpret the plasma drug concentration profile in altered pharmacokinetics, drug interactions and in therapeutic drug monitoring processes to optimize the drug dosage regimen. Also, it enables students to understand the basic concepts of pharmacogenetics, pharmacometrics for modeling and simulation of pharmacokinetic data.

OBJECTIVES

Upon completion of this course it is expected that students shall be able to:

- Design the drug dosage regimen for individual patients
- Interpret and correlate the plasma drug concentrations with patients' therapeutic outcomes
- Recommend dosage adjustment for patients with renal/ hepatic impairment
- Recommend dosage adjustment for pediatrics and geriatrics
- Manage pharmacokinetic drug interactions
- Apply pharmacokinetic parameters in clinical settings
- Interpret the impact of genetic polymorphisms of individuals on pharmacokinetics and or pharmacodynamics of drugs
- Do pharmacokinetic modeling for the given data using the principles of pharmacometrics

Course Content:

1. Introduction to Clinical pharmacokinetics: 12 Hrs

Compartmental and Non compartmental models, Renal and non-renal clearance, Organ extraction and models of hepatic clearance, Estimation and determinants of bioavailability, Multiple dosing, Calculation of loading and maintenance doses

Designing of dosage regimens: Determination of dose and dosing intervals, Conversion from intravenous to oral dosing, Nomograms and Tabulations in designing dosage regimen.

2. Pharmacokinetics of Drug Interaction: 12 Hrs

Pharmacokinetic drug interactions, Inhibition and Induction of Drug metabolism, Inhibition of Biliary Excretion

Pharmacogenetics: Genetic polymorphism in Drug metabolism: Cytochrome P-450 Isoenzymes, Genetic Polymorphism in Drug Transport and Drug Targets, Pharmacogenetics and Pharmacokinetic / Pharmacodynamic considerations

Introduction to Pharmacometrics: Introduction to Bayesian Theory, Adaptive method or Dosing with feedback, Analysis of Population pharmacokinetic Data.

3. Non-Linear Mixed Effects Modelling: 12 Hrs

The Structural or Base Model, Modeling Random Effects, Modeling Covariate Relationships, Mixture Model, Estimation Methods, Model Building Techniques, Covariate Screening Methods, Testing the model assumptions, Precision of the parameter estimates and confidence intervals, Model misspecification and violation of the model assumptions, Model Validation, Simulation of dosing regimens and dosing recommendations, Pharmacometrics software.

4. Altered Pharmacokinetics: 12 Hrs

Drug dosing in the elderly, Drug dosing in the pediatrics, Drug dosing in the obese patients, Drug dosing in the pregnancy and lactation, Drug dosing in the renal failure and extracorporeal removal of drugs, Drug dosing in the hepatic failure.

5. Therapeutic Drug monitoring: 12 Hrs

Introduction, Individualization of drug dosage regimen (Variability – Genetic, age, weight, disease and Interacting drugs), Indications for TDM, Protocol for TDM,

Pharmacokinetic/Pharmacodynamic Correlation in drug therapy,
TDM of drugs used in the following conditions:
Cardiovascular disease: Digoxin, Lidocaine, Amiodarone; Seizure disorders: Phenytoin, Carbamazepine, Sodium Valproate; Psychiatric conditions: Lithium, Fluoxetine, Amitriptyline; Organ transplantations: Cyclosporine; Cytotoxic Agents: Methotrexate, 5-FU, Cisplatin; Antibiotics: Vancomycin, Gentamicin, Meropenem.

RECOMMENDED BOOKS (Latest Editions)

1. Leon Shargel, Susanna Wu-Pong, Andrew Yu. Applied Biopharmaceutics & Pharmacokinetics. New York: Mc Graw Hill.
2. Peter L. Bonate. Pharmacokinetic - Pharmacodynamic Modeling and Simulation. Springer Publications.
3. Michael E. Burton, Leslie M. Shaw, Jerome J. Schentag, William E.Evans. Applied Pharmacokinetics & Pharmacodynamics: Principles of Therapeutic Drug Monitoring. Iippincott Williams & Wilkins.
4. Steven How-Yan Wong, Irving Sunshine. Handbook of Analytical Therapeutic Drug Monitoring and Toxicology. CRC Press, USA.
5. Soraya Dhillon, Andrzej Kostrzewski. Clinical pharmacokinetics. 1st edition. London: Pharmaceutical Press.
6. Joseph T.Dipiro, William J.Spruill, William E.Wade, Robert A.Blouin and Jane M.Pruemer .Concepts in Clinical Pharmacokinetics. American Society of Health-System Pharmacists, USA.
7. Malcolm Rowland, Thomas N. Tozer .Clinical Pharmacokinetics and pharmacodynamics: concepts and applications. Lippincott Williams & Wilkins, USA.
8. Evans, Schentag, Jusko. Applied pharmacokinetics. American Society of Health system Pharmacists, USA.
9. Michael E. Winter. Basic Clinical Pharmacokinetics. Lippincott Williams & Wilkins, USA.
10. Milo Gibaldi. Biopharmaceutics and Clinical Pharmacokinetics. Pharma Book Syndicate, USA.
11. Dhillon and Kostrzewski. Clinical pharmacokinetics. Pharmaceutical Press, London.
12. John E .Murphy. Clinical Pharmacokinetics. 5th edition. US: American Society of Health- System Pharmacist, USA.
13. Relevant review articles from recent medical and pharmaceutical literature

MPP 204T-PHARMACOEPIDEMIOLOGY & PHARMACOECONOMICS (Theory)

SCOPE

This course enables students to understand various pharmacoepidemiologic methods and their clinical applications. Also, it aims to impart knowledge on basic concepts, assumptions, terminology, and methods associated with Pharmacoeconomics and health related outcomes, and when should be appropriate Pharmacoeconomic model should be applied for a health care regimen.

OBJECTIVES

Upon completion of this course it is expected that students shall be able to:

- Understand the various epidemiological methods and their applications.
- Understand the fundamental principles of Pharmacoeconomics.
- Identify and determine relevant cost and consequences associated with pharmacy products and services.
- Perform the key Pharmacoeconomics analysis methods
- Understand the Pharmacoeconomic decision analysis methods and its applications.
- Describe current Pharmacoeconomic methods and issues.
- Understand the applications of Pharmacoeconomics to various pharmacy settings.

Course Content

1. Introduction to Pharmacoepidemiology: 12Hrs

Definition, Scope, Need, Aims & Applications; Outcome measurement: Outcome measures, Drug use measures: Monetary units, Number of prescriptions, units of drug dispensed, defined daily doses, prescribed daily doses, Diagnosis and Therapy surveys, Prevalence, Incidence rate, Monetary units, number of prescriptions, unit of drugs dispensed, defined daily doses and prescribed daily doses, medications adherence measurements.

Concept of risk: Measurement of risk, Attributable risk and relative risk, Time- risk relationship and odds ratio

2. Pharmacoepidemiological Methods: 12Hrs

Qualitative models: Drug Utilization Review

Quantitative models: case reports, case series, Cross sectional studies, Cohort and case control studies, Calculation of Odds' ratio, Meta-analysis models.

Drug effects study in populations: Spontaneous reporting, Prescription event monitoring, Post marketing surveillance, Record linkage systems. Applications of Pharmacoepidemiology

3. Introduction to Pharmacoeconomic 12Hrs

Definition, history of Pharmacoeconomics, Need of Pharmacoeconomic studies in Indian healthcare system.

Cost categorization and resources for cost estimation: Direct costs. Indirect costs. Intangible costs.

Outcomes and Measurements of Pharmacoeconomics: Types of outcomes: Clinical outcome, Economic outcomes, Humanistic outcomes; Quality Adjusted Life Years, Disability Adjusted Life Years Incremental Cost-Effective Ratio, Average Cost-Effective Ratio. Person Time, Willingness to Pay, Time Trade Off and Discounting.

4. Pharmacoeconomic evaluations: 12Hrs

Definition, Steps involved, Applications, Advantages and disadvantages of the following Pharmacoeconomic models: Cost Minimization Analysis (CMA), Cost Benefit Analysis (CBA), Cost Effective Analysis (CEA), Cost Utility Analysis (CUA), Cost of Illness (COI), Cost Consequences Analysis (COA).

5. Definition, Steps involved, Applications, Advantages and disadvantages of the following:

12Hrs

Health related quality of life (HRQOL): Definition, Need for measurement of HRQOL, Common HRQOL measures. Definition, Steps involved, Applications of the following: Decision Analysis and Decision tree, Sensitivity analysis, Markov Modeling, Software used in pharmacoeconomic analysis, Applications of Pharmacoeconomics.

RECOMMENDED BOOKS (Latest Editions)

1. Rascati K L. Essentials of Pharmacoeconomics, Woulters Kluwer Lippincott Williams & Wilkins, Philadelphia.
2. Thomas E Getzen. Health economics. Fundamentals and Flow of Funds. John Wiley & Sons, USA.
3. Andrew Briggs, Karl Claxton, Mark Sculpher. Decision Modelling for Health Economic Evaluation, Oxford University Press, London.
4. Michael Drummond, Mark Sculpher, George Torrence, Bernie O'Brien and Greg Stoddart. Methods for the Economic Evaluation of Health Care Programmes Oxford University Press, London.
5. George E Mackinnon III. Understanding health outcomes and pharmacoeconomics.
6. Graker, Dennis. Pharmacoeconomics and outcomes.
7. Walley, Pharmacoeconomics.
8. Pharmacoeconomic – ed. by Nowakowska – University of Medical Sciences, Poznan.
9. Relevant review articles from recent medical and pharmaceutical literature

MPP 205P-PHARMACY PRACTICE PRACTICALS II

1. Causality assessment of adverse drug reactions (three)
2. Detection and management of medication errors (three)
3. Rational use of medicines in special population (three)
4. Presentation of clinical cases of various disease conditions adopting
5. Pharmaceutical Care Plan Model (eight)
6. Calculation of Bioavailability and Bioequivalence from the given data (two)
7. Interpretation of Therapeutic Drug Monitoring reports of a given patient (three)
8. Calculation of various Pharmacoeconomic outcome analysis for the given data (two)

DETAILS OF SUBJECT TEACHERS – Semester I

S. No	Name of the Subject	Name of the Teacher	Designation and Department	Mobile No.	e-mail
1.	Clinical Pharmacy Practice	Dr. S. Ponnusankar	Professor &Head	9489613428	drsponnusankar@jssuni.edu.in
2.	Pharmacotherapeutics- I	Dr. Swathi Swaroopa B	Lecturer	9629547089	swasasree@jssuni.edu.in
3.	Hospital and Community Pharmacy	Mr. H N Vishwas	Lecturer	8304023133	vishwas@jssuni.edu.in
4.	Clinical Research	Dr. B S Roopa	Lecturer	9047155003	roopabs@jssuni.edu.in

DETAILS OF SUBJECT TEACHERS – Semester II

S.No	Name of the Subject	Name of the Teacher	Designation and Department	Mobile No.	e-mail
1.	Principles of Quality use of medicines	Dr.Aneena Suresh	Lecturer	8304023133	aneena@jssuni.edu.in
2.	Pharmacotherapeutics-II	Mr.Vishwas H N	Lecturer	9885104372	vishwas@jssuni.edu.in
3.	Clinical Pharmacokinetics and Pharmacotherapeutic Drug Monitoring	Dr.K.P.Arun	Assistant Professor	9994934663	kparun@jssuni.edu.in
4.	Pharmacoepidemiology and Pharmacoeconomics	Dr.G.K.Sadagoban	Lecturer	9894876656	sadagoban@jssuni.edu.in

Academic Plan 2020-21

Name of the Subject	**Clinical Pharmacy Practice (Theory)**
Name of the Faculty	Dr. S Ponnusankar M.Pharm., Ph.D
Designation, Department	Professor & Head, Department of Pharmacy Practice
Mobile Number	9489613428
e-Mail i.d.	drsponnusankar@jssuni.edu.in

Scope, Course Objectives and Course Outcomes

SCOPE

This course is designed to impart the basic knowledge and skills that are required to practice pharmacy including the provision of pharmaceutical care services to both healthcare professionals and patients in clinical settings.

OBJECTIVES

The primary objectives of this course are to

- Discuss the basis and fundamentals (scope) of clinical pharmacy practice
- Explain how to monitor the drug therapy of the patient through various methods
- Help the students to understand drug related problems (DRP) and resolve it
- Equip the students to detect, assess and monitor adverse drug reactions (ADR)
- Enable the students to apply the theoretical knowledge into clinical practice to interpret selected laboratory results
- Familiarize the sources of drug information / poison information & provision of services

COURSE OUTCOMES (COS)

At completion of this course it is expected that the students will be able to:

CO 1: Define the role of clinical pharmacist at various healthcare settings
CO 2: Monitor drug therapy of the patient through medication chart review and clinical review
CO 3: Conduct the medication history interview and counsel the patients
CO 4: Understand the elements of pharmaceutical care and provide comprehensive patient care services
CO 5: Detect, assess and monitor adverse drug reactions (ADR)
CO 6: Interpret selected laboratory results (as monitoring parameters) of specific disease states
CO 7: Provide critically analyzed drug / poison information services by retrieving, analyzing, interpreting and formulate drug and medicine information by utilizing various databases and softwares

LECTURE PLAN – Abstract

Sessional	umber of Hours of Didactic Lecture
I	30
II	30
Total No. of Hours	60

I SESSIONAL: 30 Lectures

Lecture No.	Lecture Details	Hours
Unit-1: Introduction to Clinical Pharmacy		**(12)**
1.	Definition, evolution and scope of Clinical Pharmacy	
2.	Definition, evolution and scope of Clinical Pharmacy	
3.	International and national scenario of clinical pharmacy practice	
4.	International and national scenario of Clinical pharmacy practice	
5.	Pharmaceutical Care - Introduction, definition and principles	
6.	How to achieve pharmaceutical care plan?	
7.	Pharmacists role in pharmaceutical care	
8.	Clinical Pharmacy Services: Ward round participation	
9.	Drug therapy review – Medication Chart Review	
10.	Medication Chart Endorsement	
11.	Clinical Review	
12.	Pharmacist Intervention	
Unit – 2: Clinical Pharmacy Services		**(12)**
1.	Patient medication history interview	
2.	Basic concept of medicine and poison information services	
3.	Systematic approach in answering drug information services	
4.	Drug /poison information resources & report writing	
5.	Basic concept of Pharmacovigilance, ADR classification, mechanism and predisposing factors	
6.	Adverse drug reactions – causality assessment (different scales)	
	ADR – reporting, evaluation and monitoring & preventing and management	
7.	Hemovigilance and Materiovigilance	
8.	Adverse events following Immunization (AEFI)	
9.	Patient medication counseling	
10.	Patient medication adherence assessment	
11.	Drug Utilization Evaluation (DUE)	
12.	Documentation and quality assurance of clinical pharmacy services	
Unit – 3: Patient Data analysis		**(06)**
1.	Patient case history – its structure and significance in drug therapy management	

2.	Common medical abbreviations and terminologies	
3.	Communication skills: verbal and non-verbal	
4.	Verbal and non-verbal communications	
5.	Patient counselling – counselling session	
6.	Aplications in patient care services	

II SESSIONAL: 30 Lectures

ecture No.	**Lecture Details**	**Hours**
Unit-3: Lab Data Interpretation		
1.	Clinical Laboratory Test – Hematology	
2.	Clinical Laboratory Test - Hematology	**(06)**
3.	Clinical Laboratory Test – Renal function	
4.	Clinical Laboratory Test – Renal function	
5.	Clinical Laboratory Test – Liver Function	
6.	Clinical Laboratory Test – Liver Function	
Unit -4: Lab Data Interpretation		
1.	Clinical Laboratory Test – Tests associated with Cardiac disorders	
2.	Clinical Laboratory Test – Tests associated with Cardiac disorders	
3.	Clinical Laboratory Test – Pulmonary function test	
4.	Clinical Laboratory Test – Pulmonary function test	**(12)**
5.	Clinical Laboratory Test – Pulmonary function test	
6.	Clinical Laboratory Test – Thyroid function	
7.	Clinical Laboratory Test – Fluid and electrolyte balance	
8.	Clinical Laboratory Test – Fluid and electrolyte balance	
9.	Clinical Laboratory Test – Fluid and electrolyte balance	
10.	Clinical Laboratory Test – Microbial culture sensitivity test	
11.	Clinical Laboratory Test – Microbial culture sensitivity test	
12.	Clinical Laboratory Test – Microbial culture sensitivity test	
Unit – 5: Medicine & Poison information services		
1.	Introduction to drug information service and resources	**(12)**
2.	Drug information - Current practice in India and abroad	
3.	Systematic approach in answering drug information services	
4.	Critical evaluation of drug information and literature	
5.	Critical appraisal of biomedical literature	
6.	Critical appraisal of primary research papers	
7.	Critical appraisal of therapeutic guidelines	
8.	Evaluation of biomedical literature	
9.	Preparation of written and verbal reports	
10.	Establishing a drug information center	
11.	Poison information center – organization and resources	

12.	Poison information center – organization and resources	

TEXT BOOKS

1. A text book of Clinical Pharmacy Practice; Essential concepts and skills, Dr. G. Parthasarathi, Karin Nyfort Hansen, Milap Nahata, Orient Longman Pvt. Ltd. ISSBN8125026
2. Practice standards and definitions: Society of Hospital Pharmacists of Australia (SHPA)
3. Basic skills in interpreting laboratory data - Scott LT, American Society of Health System Pharmacists Inc.
4. Relevant review articles from recent medical and pharmaceutical literature

Name of the Subject	**Pharmacotherapeutics I**
Name of the Faculty	Dr. Swathi Swaroopa B., Pharm D
Designation, Department	Lecturer, Department of Pharmacy Practice
Mobile Number	9629547089
e-Mail i.d.	swasasree@jssuni.edu.in

Scope, Course Objectives and Course Outcomes

SCOPE

This course aims to enable the students to understand the different treatment approaches in managing various disease conditions. Also, it imparts knowledge and skills in optimizing drug therapy of a patient by individualizing the treatment plan through evidence- based medicines.

OBJECTIVES

Upon completion of this course it is expected that students shall be able to

- Describe and explain the rationale for drug therapy
- Summarize the therapeutic approach for management of various disease conditions including reference to the latest available evidence
- Discuss the clinical controversies in drug therapy and evidence-based medicine
- Prepare individualized therapeutic plans based on diagnosis
- Identify the patient specific parameters relevant in initiating drug therapy, and monitoring therapy (including alternatives, time- course of clinical and laboratory indices of therapeutic response and adverse effects.

COURSE OUTCOMES (COS)

At completion of this course it is expected that the students will be able to

CO 1: Demonstrate a basic understanding of the ideas and fundamentals of disease condition

CO 2: Identify the Causes and mechanism of pathological process that result in disease.

CO 3: Discuss clinical manifestations or signs and symptoms of selected disease processes and health problems

CO 4: Determine the consequences of the disease process in chronic and acute conditions

CO 5: Recommend Individualized Management therapies for curing and controlling the disease

CO 6: Establish the disease and drug monitoring parameters and Minimize the Drug related problems

CO 7: Educate the Patient about the disease and drug.

LECTURE PLAN-Abstract

Sessional	No. of Hours of Didactic Lecture
I	30
II	30
Total No. of Hours	60

I SESSIONAL: 30 Lectures

Lecture No.	Lecture Details	Hours
Unit 1: Cardiovascular System		**(12)**
1.	Hypertension	**02**
2.	Congestive cardiac failure	**02**
3.	Acute coronary Syndrome	**04**
4.	Arrhythmias	**02**
5.	Hyperlipidemia	**02**
Unit 2		**(12)**
a) Respiratory system		
1.	Asthma	**03**
2.	Chronic obstructive airways diseases	**02**
3.	Drug Induced Pulmonary Disease	**01**
b) Endocrine system		
1.	Diabetes	**03**
2.	Thyroid diseases	**03**
Unit 3		**(06)**
a) Gastrointestinal system		
1.	Peptic Ulcer Disease	
2.	Reflux Esophagitis	

II SESSIONAL: 30 Lectures

Lecture No.	Lecture Details	Hours
Unit 3		**(06)**
a) Gastrointestinal system		
1.	Inflammatory bowel diseases	**03**
2.	Jaundice, Hepatitis	**03**
Unit 4		**(12)**
a) Gastrointestinal system		
1.	Cirrhosis	**03**
2.	Diarrhea & Constipation	**01**
3.	Drug Induced Liver Disease	**02**
b) Hematological Diseases		
1.	Anemia	**03**

2.	Deep Vein Thrombosis	**02**
3.	Drug Induced Hematological Disorder	**01**
Unit 5		**(12)**
a) Bones and joints Disorder		
1.	Rheumatoid arthritis	**02**
2.	Osteoarthritis	**01**
3.	Gout	**02**
4.	Osteoporosis	**01**
b) Dermatological Diseases		
1.	Psoriasis	**02**
2.	Eczema	**01**
3.	Scabies	**01**
4.	Impetigo	**01**
5.	Drug induced skin disorders	
c) Ophthalmology		**01**
1.	Conjunctivitis	
2.	Glaucoma	

TEXT BOOKS

1. Roger and Walker. Clinical Pharmacy and Therapeutics – Churchill Livingstone publication
2. Joseph T. Dipiro et al. Pharmacotherapy: A Pathophysiologic Approach- Appleton & Lange
3. Robins SL. Pathologic basis of disease -W.B. Saunders publication
4. Eric T. Herfindal. Clinical Pharmacy and Therapeutics- Williams and Wilkins Publication
5. Lloyd Young and Koda-Kimble MA Applied Therapeutics: The clinical Use of Drugs- Lippincott Williams and Wilkins
6. Chisholm- Burns Wells Schwinghammer Malone and Joseph P Dipiro. Pharmacotherapy Principles and practice-– McGraw Hill Publication
7. Carol Mattson Porth. Principles of Pathophysiology- Lippincott Williams and Wilkins
8. Harrison's. Principles of Internal Medicine - McGraw Hill
9. Relevant review articles from recent medical and pharmaceutical literature

Name of the Subject	**Hospital and Community Pharmacy (Theory)**
Name of the Faculty	Mr. H N Vishwas, M Pharm
Designation, Department	Lecturer, Department of Pharmacy Practice
Mobile Number	9885104372
e-Mail i.d.	vishwas@jssuni.edu.in

Scope, Course Objectives and Course Outcomes

SCOPE

This course is designed to impart basic knowledge and skills that are required to practice pharmacy in both hospital and community settings.

OBJECTIVES

Upon completion of this course it is expected that students shall be able to:

- Understand the organizational structure of hospital pharmacy
- Understand drug policy and drug committees
- Know about procurement & drug distribution practices
- Know the admixtures of radiopharmaceuticals
- Understand the community pharmacy management
- Know about value added services in community pharmacies

COURSE OUTCOMES (COS)

At completion of this course it is expected that the students will be able to:

CO 1: Know the organizational structure of hospital pharmacy for efficient management.
CO 2: Apply knowledge of drug distribution methods in hospital pharmacy.
CO 3: Comprehend the drug policy and various committees in the hospital.
CO 4: Apply principles of community pharmacy management and become an entrepreneur.

LECTURE PLAN – Abstract

Sessional	No. of Hours of Didactic Lecture
I	30
II	30
Total No. of Hours	60

I SESSIONAL: 30 Lectures

Lecture No.	Lecture Details	Hours
	Orientation to the subject	
Unit-1		**(12)**
a) Introduction to Hospitals		**02**
1.	Definition, classification, organizational structure	**06**
b) Hospital Pharmacy		
1.	Definition, Relationship of hospital pharmacy department with other departments, Organizational structure	
2.	Legal requirements	
3.	work load statistics and Infrastructural requirements	
4.	Hospital Pharmacy Budget	
5.	Hospital Pharmacy management	
c) Hospital Drug Policy		**04**
1.	Pharmacy & Therapeutics Committee	
2.	Infection Control committee	
3.	Research & Ethics Committee	
4.	Management of Medicines as per NABH	
Unit -2		**(12)**
1.	Hospital Formulary Guidelines and its development	**02**
2.	Developing Therapeutic guidelines	**02**
3.	Drug procurement process	**02**
4.	Methods of Inventory control	**02**
5.	Methods of Drug distribution	**02**
6.	Intravenous admixtures	**01**
7.	Hospital Waste Management	**01**
Unit-3		**(12)**
a) Education and training		**05**
1.	Training of technical staff	
2.	Training and continuing education for pharmacists, Pharmacy students	
3.	Medical staff and students, Nursing staff and students	

4.	Formal and informal meetings and lectures	
5.	Drug and therapeutics newsletter.	
b) Community Pharmacy Practice		**01**
1.	Definition, roles & responsibilities of community pharmacists, and their relationship with other health care providers	

II SESSIONAL: 30 Lectures

ecture No.	**Lecture Details**	**Hours**
c) Community Pharmacy management		**06**
1.	Legal requirements to start community pharmacy	
2.	Site selection, lay out & design	
3.	Drug display, super drug store model, accounts and audits	
4.	Good dispensing practices	
5.	Different softwares & databases used in community pharmacies	
6.	Entrepreneurship in community pharmacy	
UNIT-4		**(12)**
a) Prescription		**02**
1.	Legal requirements & interpretation	
2.	Prescription related problems	
b) Responding to symptoms of minor ailments		**04**
1.	Head ache	
2.	Pyrexia	
3.	Menstrual pains	
4.	Food and drug allergy	
c) OTC medication		**02**
1.	Rational use of over the counter medications	
2.	Medication counseling and use of patient information leaflets	
c) Medication adherence		**04**
1.	Definition, factors influencing adherence behavior	
2.	Strategies to improve medication adherence	
3.	Patient referrals to the doctors	
4.	ADR monitoring in community pharmacies	
Unit -5		**(12)**
a) Health Promotion		**09**
1.	Definition and health promotion activities, smoking cessation, Child & mother care	
2.	Family planning	
3.	Health screening services	
4.	First aid	
5.	Prevention of communicable and non-communicable diseases	
6.	Prevention of communicable and non-communicable diseases	

a) National Health Programs		**01**
1.	Role of Community Pharmacist in Malaria and TB control programs	
b) Home Medicines review program		
1.	Definition, objectives, Guidelines, method and outcomes	**01**
c) Research in community pharmacy Practice		**01**
1.	Research in community pharmacy Practice	

TEXT BOOKS

1. Hospital Pharmacy - Hassan WE. Lea and Febiger publication.
2. Textbook of hospital pharmacy - Allwood MC and Blackwell.
3. Avery's Drug Treatment, Adis International Limited.
4. Community Pharmacy Practice – Ramesh Adepu, BSP Publishers, Hyderabad
5. Remington Pharmaceutical Sciences.
6. Relevant review articles from recent medical and pharmaceutical literature

Name of the Subject	**Clinical Research (Theory)**
Name of the Faculty	Ms. Roopa B S M. Pharm., PhD
Designation, Department	Lecturer, Department of Pharmacy Practice
Mobile Number	9047155003
e-Mail i.d.	roopabs@jssuni.edu.in

Scope, Course Objectives and Course Outcomes

SCOPE

This course aims to provide the students an opportunity to learn drug development process especially the phases of clinical trials and also the ethical issues involved in the conduct of clinical research. Also, it aims to imparts knowledge and develop skills on conceptualizing, designing, conducting and managing clinical trials.

OBJECTIVES

The primary objectives of this course are to:

- Know the new drug development process.
- Understand the regulatory and ethical requirements.
- Appreciate and conduct the clinical trials activities
- Know safety monitoring and reporting in clinical trials
- Manage the trial coordination process

COURSE OUTCOMES (COS)

At completion of this course it is expected that the students will be able to:

CO 1: Understanding of basic concepts of drug development processes what it is, how it differs from standard care and why it is undertaken. Demonstrate the competencies of clinical research designs and the regulatory approval process.

CO 2: Familiarize with the various regulatory documents and the guidelines and to evaluate critical domestic and global regulatory and health care implications on the product development.

CO 3: Effectively assess and manage ethical aspects of conduct of clinical trial.

CO 4: Familiarize with the roles and responsibilities of the personnel involved in conduct of clinical research to ensure the quality research is undertaken

LECTURE PLAN – Abstract

Sessional	Number of Hours of Didactic Lecture
I	30
II	30
otal Number of Hours	60

I SESSIONAL: 30 Lectures

Lecture No.	Lecture Details	Hours
Unit-1		
1.	Drug development process**:** Introduction, various approaches to drug discover	**(12)**
2.	Investigational new drug application submission	
3.	Ethics in Biomedical Research: Ethical Issues in Biomedical Research – Principles of ethics in biomedical research,	
4.	Ethical committee [institutional review board] - its constitution and functions, Challenges in implementation of ethical guidelines	
5.	ICH GCP guidelines and ICMR guidelines in conduct of Clinical trials	
6.	Drug Safety Reporting.	
Unit-2		
1.	Types and Designs used in Clinical Research: Planning and execution of clinical trials	**(12)**
2.	Various Phases of clinical trials	
3.	Bioavailability and Bioequivalence studies	
4.	Randomization techniques (Simple randomization, restricted randomization, blocking method and stratification)	
5.	Types of research designs based on Controlling Method (Experimental, Quasi experimental and Observational methods) Time Sequences (Prospective and Retrospective)	
6.	Sampling methods (Cohort study, case Control study and cross sectional study)	
7.	Health outcome measures (Clinical & Physiological, Humanistic and economic)	
8.	Clinical Trial Study team: Roles and responsibilities of: Investigator, Study Coordinator, Sponsor, Monitor, Contract Research Organization	
Unit-3		
1.	Clinical trial Documents: Protocols, Investigator's Brochure, Informed Consent Form, Case report forms, Contracts and agreements, Dairy Cards	**(06)**

2.	Clinical Trial Start up activities: Site Feasibility Studies	

II SESSIONAL: 30 Lectures

Lecture No.	Lecture Details	Hours
Unit-3		
3.	Clinical Trial Start up activities: Site/Investigator selection, Pre-study visit, Investigator meeting, Clinical trial agreement execution, Ethics committee document preparation and submission	**(06)**
Unit-4		
1.	Investigational Product: Procurement and Storage of investigation product	
2.	Filing procedures: Essential documents for clinical trial, Trial Master File preparation and maintenance, Investigator Site File, Pharmacy File, Site initiation visit, Conduct, Report and Follow up Clinical Trial Monitoring and Close out	**(12)**
3.	Preparation and conduct of monitoring visit: Review of source documents, CRF, ICF, IP storage, accountability and reconciliation, Study Procedure, EC communications, Safety reporting, Monitoring visit reporting and follow-up	
4.	Close-Out visit: Study related documents collection, Archival requirement, Investigational Product reconciliation and destruction, Close-Out visit report.	
Unit-5		
1.	Quality Assurance and Quality Control in Clinical Trials: Types of audits, Audit criteria, Audit process, Responsibilities of stakeholders in audit process, Audit follow-up and documentation, Audit resolution and Preparing for FDA inspections, Fraud and misconduct management	
2.	Data Management Infrastructure and System Requirement for Data Management: Electronic data capture systems, Selection and implementation of new systems, System validation and test procedures, Coding dictionaries, Data migration and archival	**(12)**
3.	Clinical Trial Data Management: Standard Operating Procedures, Data management plan, CRF & Data base design considerations, Study set-	
	up, Data entry, CRF tracking and corrections, Data cleaning, Managing laboratory and ADR data	
4.	Data transfer and database lock, Quality Control and Quality Assurance in CDM, Data mining and warehousing	

TEXT BOOKS

1. Principles and practice of pharmaceutical medicine, Second edition. Authors: Lionel. D. Edward, Aadrew.J. Flether Anthony W Fos , Peter D Sloaier Publisher:Wiley;
2. Handbook of clinical research. Julia Lloyd and Ann Raven Ed. Churchill Livingstone
3. Principles of Clinical Research edited by Giovanna di Ignazio, Di Giovanna and Haynes
4. Central Drugs Standard Control Organization. Good Clinical Practices-Guidelines for Clinical Trials on Pharmaceutical Products in India. New Delhi: Ministry of Health.
5. International Conference on Harmonisation of Technical requirements for registration of Pharmaceuticals for human use. ICH Harmonised Tripartite Guideline. Guideline for Good Clinical Practice.E6; May 1996.
6. Ethical Guidelines for Biomedical Research on Human Subjects. Indian Council of Medical Research, New Delhi.
7. Textbook of Clinical Trials edited by David Machin, Simon Day and Sylvan Green, John Wiley and Sons.
8. Clinical Data Management edited by R K Rondels, S A Varley, C F Webbs. Second Edition, Jan 2000, Wiley Publications.
9. Goodman & Gilman: JG Hardman, LE Limbard, McGraw Hill Publications.
10. Relevant review articles from recent medical and pharmaceutical literature.

Name of the Subject	**Principles of Quality Use of Medicines (Theory)**
Name of the Faculty	Dr. Aneena Suresh Pharm D
Designation, Department	Lecturer, Department of Pharmacy Practice
Mobile Number	8304023133
e-Mail i.d.	aneena@jssuni.edu.in

Scope, Course Objectives and Course Outcomes

SCOPE

This course is designed to impart basic knowledge and skills that are required to practice quality use of medicines (QUM) in different healthcare settings and also to promote quality use of medicines, in clinical practice, through evidence-based medicine approach.

OBJECTIVES

Upon completion of this course it is expected that students shall be able to:

- Understand the principles of quality use of medicines
- Know the benefits and risks associated with use of medicines
- Understand regulatory aspects of quality use of medicines
- Identify and resolve medication related problems
- Promote quality use of medicines
- Practice evidence-based medicines

COURSE OUTCOMES (COS)

At completion of this course it is expected that the students will be able to:

CO 1: Demonstrate knowledge and ability to use principles of hospital, community and clinical pharmacy for health promotion.

CO 2: Apply knowledge of medication related problems to improve patient care.

CO 3 : Promote quality use of medicines.

CO 4 : Apply evidence-based medicine to patient care.

LECTURE PLAN – Abstract

Sessional	No. of Hours of Didactic Lecture
I	30
II	30
Total No. of Hours	60

I SESSIONAL: 30 Lectures

Lecture No.	Lecture Details	Hours
Unit-1: Introduction to quality use of medicines (QUM)		**(12)**
1.	Orientation to the subject	
2.	Definition and Principles of QUM	
3.	Key partners and responsibilities of the partners	
4.	Key partners and responsibilities of the partners	
5.	Key partners and responsibilities of the partners	
6.	Key partners and responsibilities of the partners	
7.	Building blocks in QMC	
8.	Building blocks in QMC	
9.	Evaluation process in QMC	
10.	Evaluation process in QMC	
11.	Communication in QUM	
12.	Communication in QUM	
13.	Cost effective prescribing	
Unit-2: Concepts in QUM		**(12)**
a) Evidence based medicine		
1.	Definition, concept of evidence-based medicine	
2.	Definition, concept of evidence-based medicine	
3.	Approach and practice of evidence-based medicine in clinical settings	
4.	Approach and practice of evidence-based medicine in clinical settings	
b) Essential drugs		
6.	Definition, need, concept of essential drug,	
7.	Definition, need, concept of essential drug,	
8.	National essential drug policy and list	
9.	National essential drug policy and list	
c) Rational drug use		
5.	Definition, concept and need for rational drug use	
6.	Definition, concept and need for rational drug use	
7.	Rational drug prescribing	

8.	Role of pharmacist in rational drug use	
UNIT-3		**(06)**
a) QUM in various settings		
	Hospital settings	
	Ambulatory care/Residential care	
	Role of health care professionals in promoting the QUM	
	Strategies to promote the QUM	
	Impact of QUM on E-health	
	integrative medicine and multidisciplinary care	

II SESSIONAL: 30 Lectures

Lecture No.	**Lecture details**	**Hours**
b) QUM in special population		**(06)**
1.	Pediatric prescribing	
2.	Geriatric prescribing	
3.	Prescribing in pregnancy and lactation	
4.	Prescribing in pregnancy and lactation	
5.	Prescribing in immune compromised and organ failure patients	
6.	Prescribing in immune compromised and organ failure patients	
UNIT-4: Regulatory aspects of QUM in India		**(12)**
1.	Regulation including scheduling	
2.	Regulation including scheduling	
3.	Regulation including scheduling	
4.	Regulation of complementary medicines	
5.	Regulation of complementary medicines	
6.	Regulation of OTC medicines	
7.	Regulation of OTC medicines	
8.	Professional responsibility of pharmacist	
9.	Professional responsibility of pharmacist	
10.	Role of industry in QUM in medicine development	
11.	Role of industry in QUM in medicine development	
12.	Role of industry in QUM in medicine development	
Unit -5		**(12)**
a) Medication errors		
1.	Definition, categorization and causes of medication errors	
2.	Definition, categorization and causes of medication errors	
3.	Detection and prevention of medication errors	
4.	Role of pharmacist in monitoring and management of medication errors	
b) Pharmacovigilance		

1.	Definition, aims and need for pharmacovigilance	
2.	Types, predisposing factors and mechanism of adverse drug reactions (ADRs)	
3.	Types, predisposing factors and mechanism of adverse drug reactions (ADRs)	
4.	Detection, reporting and monitoring of ADRs	
5.	Causality assessment of ADRs	
6.	Causality assessment of ADRs	
7.	Management of ADRs	
8.	Role of pharmacist in pharmacovigilance	

TEXT BOOKS

1. 1.A Textbook of Clinical Pharmacy Practice – Essential concepts and skills – Parthasarathi G, Karin Nyfort-Hansen and Milap Nahata
2. Andrews EB, Moore N. Mann's Pharmacovigilance
3. Dipiro JT, Talbert RL, Yee GC. Pharmacotherapy: A Pathophysiologic Approach
4. Straus SE, Richardson WS, Glasziou P, Haynes RB. Evidence-Based Medicine: How to practice and teach it
5. Cohen MR. Medication Errors
6. Online:
   a. http://medicinesaustralia.com.au/files/2012/05/MA_QUM_External_Reduced.pdf
   b. http://curriculum.racgp.org.au/statements/quality-use-of-medicines/
   c. http://www.rug.nl/research/portal/files/14051541/Chapter_2.pdf
7. Relevant review articles from recent medical and pharmaceutical literature.

Name of the Subject	**Pharmacotherapeutics-II (Theory)**
Name of the Faculty	Mr. Vishwas H N, M.Pharm
Designation, Department	Lecturer, Department of Pharmacy Practice
Mobile Number	9885104372
e-Mail i.d.	vishwas@jssuni.edu.in

Scope, Course Objectives and Course Outcomes

SCOPE

This course is designed to impart the knowledge on pharmacotherapy of few common disorders related to organ systems like Nervous system, Psychiatry, Renal system, Gynecological disorders, Infectious diseases and oncology. The students should be able to understand the pharmacological and non-pharmacological management of these diseases along with evidence-based treatments available. The concept helps to understand the complex nature and the complications of the disease and assists the students to design pharmaceutical care for the chronic disease patients when they are exposed in hospital.

OBJECTIVES

The primary objectives of this course are to:

- Enable the students to apply the theoretical knowledge into real time hospital practice
- Enable the students to understand the different treatment approaches in managing various disease conditions.
- Imparts knowledge and skills in optimizing drug therapy of a patient by individualizing the treatment
- Plan through evidence-based medicines.

COURSE OUTCOMES (COS)

At completion of this course it is expected that the students will be able to:

CO 1: Student should Describe and explain the rationale for antibiotic selection and surgical prophylaxis

CO 2: Summarize the therapeutic approach for management of infectious and gynecological diseases

CO 3: Discuss the clinical controversies in drug therapy and evidence-based medicine along with understanding of drug induced disorders.

CO 4: Prepare individualized therapeutic plans based on diagnosis of psychiatric and neuronal disorders

CO 5: Prepare individualized therapeutic plans based on diagnosis of gynecologic disorders

CO6: Assess the patient for renal failure and understand the importance of dialysis in renal failure patients

LECTURE PLAN – Abstract

Sessional	No. of Hours of Didactic Lecture
I	30
II	30
Total No. of Hours	60

II SESSIONAL: 30 Lectures

Lecture No.	Lecture Details	Hours
Unit-1: Nervous system		**(12)**
1.	Epilepsy	
2.	Parkinson's disease	
3.	Stroke	
4.	Stroke (cont…)	
5.	Headache	
6.	Headache (cont…)	
7.	Alzheimer’s disease	
8.	Alzheimer’s disease (cont…)	
9.	Neuralgias	
10.	Neuralgias (cont…)	
11.	Pain pathways and Pain management.	
12.	Pain pathways and Pain management. (cont…)	
Unit-2: Psychiatric disorders & Renal system		**(12)**
1.	Schizophrenia	
2.	Schizophrenia (cont…)	
3.	Depression	
4.	Anxiety disorders	
5.	Sleep disorders	
6.	Drug induced psychiatric disorders	
7.	Acute renal failure	
8.	Acute renal failure (cont…)	
9.	Chronic renal failure	
10.	Chronic renal failure	
11.	Renal dialysis	
12.	Drug induced renal disease	
Unit-3: Infectious diseases		**(12=06 +06))**
1.	General guidelines for the rational use of antibiotics and surgical prophylaxis	
2.	General guidelines for the rational use of antibiotics and surgical prophylaxis (cont…)	

3.	Urinary tract infections	
4.	Urinary tract infections	
5.	Respiratory tract infections	
6.	Respiratory tract infections (cont…)	

II SESSIONAL: 30 Lectures

Lecture No.	**Lecture Details**	**Hours**
7.	Gastroenteritis	
8.	Tuberculosis	
9.	Tuberculosis (cont…)	
10.	Malaria,	
11.	Bacterial endocarditis	
12.	Septicemia.	
Unit-4: Infectious diseases & Gynecological disorders		
1.	Meningitis	
2.	HIV and opportunistic infections	
3.	HIV and opportunistic infections (cont…)	**(12)**
4.	Rheumatic fever	
5.	Dengue fever	
6.	H1N1	
7.	Helminthiasis	
8.	Fungal infections	
9.	Fungal infections (cont…)	
10.	Dysmenorrhea	
11.	Hormone replacement therapy	
12.	Hormone replacement therapy (cont…)	
Unit-5: Oncology		
1.	General principles of cancer chemotherapy	
2.	Pharmacotherapy of breast cancer	
3.	Pharmacotherapy of breast cancer (cont…)	**(12)**
4.	Lung cancer	
5.	Lung cancer (cont…)	
6.	Head & neck cancer	
7.	Head & neck cancer (cont…)	
8.	Hematological malignancies	
9.	Hematological malignancies (cont…)	
10.	Hematological malignancies (cont…)	
11.	Management of nausea and vomiting	
12.	Palliative care	

TEXT BOOKS

1. Roger and Walker. Clinical Pharmacy and Therapeutics – Churchill Livingstone publication.
2. Joseph T. Dipiro et al. Pharmacotherapy: A Pathophysiologic ApproachAppleton & Lange
3. Robins SL. Pathologic basis of disease -W.B. Saunders publication
4. Eric T. Herfindal. Clinical Pharmacy and Therapeutics- Williams and Wilkins Publication Lloyd Young and Koda-Kimble MA Applied Therapeutics: The clinical Use of Drugs- Lippincott Williams and Wilkins

REFERENCE BOOKS

1. Chisholm- Burns Wells Schwinghammer Malone and Joseph P Dipiro. Pharmacotherapy Principles and practice-–McGraw Hill Publication
2. Carol Mattson Porth. Principles of Pathophysiology- Lippincott Williams and Wilkins
3. Harrison's. Principles of Internal Medicine - McGraw Hill
4. Handbook of pharmacy–Health care. Edt. Robin J Harman. The Pharmaceutical press
5. Relevant review articles from recent medical and pharmaceutical literature

Name of the Subject	**Clinical Pharmacokinetics and Therapeutic Drug Monitoring (Theory)**
Name of the Faculty	Dr. Arun KP M.Pharm., Ph.D
Designation, Department	Assistant Professor, Department of Pharmacy Practice
Mobile Number	9994934663
e-Mail i.d.	kparun@jssuni.edu.in

Scope, Course Objectives and Course Outcomes

SCOPE

This course is designed to enable students to understand the basics principles and applications of pharmacokinetics in designing the individualized dosage regimen, to interpret the plasma drug concentration profile in altered pharmacokinetics, drug interactions and in therapeutic drug monitoring processes to optimize the drug dosage regimen. Also, it enables students to understand the basic concepts of pharmacogenetics, pharmacometrics for modeling and simulation of pharmacokinetic data.

OBJECTIVES

Upon completion of this course it is expected that students shall understand the following concepts:

- Design the drug dosage regimen for individual patients
- Interpretation and correlation of the plasma drug concentrations with patients' therapeutic outcomes
- Recommending dosage adjustment for patients with renal/ hepatic impairment
- Recommending dosage adjustment for pediatrics and geriatrics
- Managing pharmacokinetic drug interactions
- Applying pharmacokinetic parameters in clinical settings
- Interpreting the impact of genetic polymorphisms of individuals on pharmacokinetics and or pharmacodynamics of drugs
- Pharmacokinetic modeling for the given data using the principles of pharmacometrics

COURSE OUTCOMES (COS)

At completion of this course it is expected that the students will be able to:

CO 1: Design the dosage regimen for the given drug based on the pharmacokinetic principles and route of administration

CO 2: Individualize the dosage regimen for the patients with altered pharmacokinetics viz. renal / hepatic impairment, pediatrics, geriatrics, etc.

CO 3: Intervene the potential drug-drug interactions in a given case with appropriate recommendations for dosage adjustments

CO 4: Associate the genetic polymorphisms of the patients, if any with the clinical outcomes of the patients

CO 5: Formulate protocol(s) for the therapeutic drug monitoring of drug(s) and initiate the service in collaboration with other healthcare team members

CO 6: Interpret the results of therapeutic drug monitoring services of various drugs and give required recommendations for the dosage adjustment of those drugs, if required towards optimizing the treatment outcomes

LECTURE PLAN (Theory)

Sessional	No. of Hours of Didactic Lecture		Total No. of Lecture Hours
	Clinical Pharmacokinetics	erapeutic Drug Monitoring	
I	24	06	30
II	24	06	30
Total No. of Hours	48	12	60

I SESSIONAL: 30 Lectures

Lecture No.	Lecture Details	Hours
Clinical Pharmacokinetics		**(24)**
Unit-1: Introduction to Clinical Pharmacokinetics		**12**
	Orientation to the subject	
1.	Compartmental models	
2.	Non compartmental models	
3.	Renal clearance	
4.	Non-renal clearance	
5.	Organ extraction and models of hepatic clearance	
6.	Estimation and determinants of bioavailability	
7.	Multiple dosing	
8.	Calculation of loading dose	
9.	Calculation of maintenance doses	
10.	Designing of dosage regimens: Determination of dose and dosing intervals	
11.	Conversion from intravenous to oral dosing	
12.	Nomograms and Tabulations in designing dosage regimen	
Unit-2: Pharmacokinetics of Drug Interaction		**12**
1.	Pharmacokinetic drug interactions	
2.	Inhibition and Induction of Drug metabolism	
3.	Inhibition of Biliary Excretion	
4.	Pharmacogenetics: Genetic polymorphism in Drug metabolism: Cytochrome P-450 Isoenzymes	
5.	Pharmacogenetics: Genetic polymorphism in Drug metabolism: Cytochrome P-450 Isoenzymes (Cont…)	
6.	Pharmacogenetics: Genetic polymorphism in Drug metabolism: Cytochrome P-450 Isoenzymes (Cont…)	
7.	Genetic Polymorphism in Drug Transport and Drug Targets	
8.	Pharmacogenetics and Pharmacokinetic /Pharmacodynamic considerations	
9.	Introduction to Pharmacometrics: Introduction to Bayesian Theory	
10.	Adaptive method or Dosing with feedback	

11.	Analysis of Population pharmacokinetic Data	
12.	Analysis of Population pharmacokinetic Data (Cont…)	
THERAPEUTIC DRUG MONITORING		**(06)**
Unit-5: Therapeutic Drug monitoring		**06**
10.	Introduction, Individualization of drug dosage regimen (Variability – Genetic, age, weight, disease and Interacting drugs)	
11.	Introduction, Individualization of drug dosage regimen (Variability – Genetic, age, weight, disease and Interacting drugs) (Cont…)	
12.	Indications for TDM	
13.	Protocol for TDM	
14.	Protocol for TDM (Cont…)	
15.	Pharmacokinetic/Pharmacodynamic Correlation in drug therapy	

II SESSIONAL: 30 Lectures

Lecture No.	**Lecture Details**	**Hours**
Clinical Pharmacokinetics		**(24)**
Unit-3: Non-Linear Mixed Effects Modelling		**12**
1.	The Structural or Base Model	
2.	Modeling Random Effects	
3.	Modeling Covariate Relationships	
4.	Mixture Model	
5.	Estimation Methods	
6.	Model Building Techniques	
7.	Covariate Screening Methods	
8.	Testing the model assumptions	
9.	Precision of the parameter estimates and confidence intervals	
10.	Model misspecification and violation of the model assumptions	
11.	Model Validation	
12.	Simulation of dosing regimens and dosing recommendations, Pharmacometrics software	
Unit-4: Altered Pharmacokinetics:		**12**
1.	Drug dosing in the elderly	
2.	Drug dosing in the elderly (Cont…)	
3.	Drug dosing in the paediatrics	
4.	Drug dosing in the paediatrics (Cont…)	
5.	Drug dosing in the obese patients	
6.	Drug dosing in the pregnancy and lactation	
7.	Drug dosing in the renal failure	
8.	Drug dosing in the renal failure (Cont…)	

9.	Drug dosing in the extracorporeal removal of drugs	
10.	Drug dosing in the extracorporeal removal of drugs (Cont…)	
11.	Drug dosing in the in hepatic failure	
12.	Drug dosing in the in hepatic failure (Cont…)	
THERAPEUTIC DRUG MONITORING		**(06)**
Unit-5: Therapeutic Drug monitoring (Cont…)		**06**
1.	TDM of drugs used in Cardiovascular disease: Digoxin, Lidocaine, Amiodarone	
2.	TDM of drugs used in Seizure disorders: Phenytoin, Carbamazepine, Sodium Valproate	
3.	TDM of drugs used in Psychiatric conditions: Lithium, Fluoxetine, Amitriptyline	
4.	TDM of drugs used in Organ transplantations: Cyclosporine	
5.	TDM of drugs used in Cytotoxic Agents: Methotrexate, 5-FU, Cisplatin	
6.	TDM of drugs used in Antibiotics: Vancomycin, Gentamicin, Meropenem.	

REFERENCE BOOKS

1. Leon Shargel, Susanna Wu-Pong, Andrew Yu. Applied Biopharmaceutics & Pharmacokinetics. New York: Mc Graw Hill.

2. Peter L. Bonate. Pharmacokinetic - Pharmacodynamic Modeling and Simulation. Springer Publications.

3. Michael E. Burton, Leslie M. Shaw, Jerome J. Schentag, William E.Evans. Applied Pharmacokinetics& Pharmacodynamics: Principles of Therapeutic Drug Monitoring. Iippincott Williams & Wilkins.

4. Steven How-Yan Wong, Irving Sunshine. Handbook of Analytical Therapeutic Drug Monitoring and Toxicology. CRC Press, USA.

5. Soraya Dhillon, Andrzej Kostrzewski. Clinical pharmacokinetics. 1st edition. London: Pharmaceutical Press.

6. Joseph T.Dipiro, William J.Spruill, William E.Wade, Robert A.Blouin and Jane M.Pruemer .Concepts in Clinical Pharmacokinetics. American Society of Health- System Pharmacists, USA.

7. Malcolm Rowland, Thomas N. Tozer .Clinical Pharmacokinetics and pharmacodynamics: concepts and applications. Iippincott Williams & Wilkins, USA.

8. Evans, Schentag, Jusko. Applied pharmacokinetics. American Society of Health system Pharmacists, USA.

9. Michael E. Winter. Basic Clinical Pharmacokinetics. Lippincott Williams & Wilkins, USA.

10. Milo Gibaldi. Biopharmaceutics and Clinical Pharmacokinetics. Pharma Book Syndicate, USA.

11. Dhillon and Kostrzewski. Clinical pharmacokinetics. Pharmaceutical Press, London.

12. John E. Murphy. Clinical Pharmacokinetics. 5th edition. US: American Society of Health-System Pharmacist, USA.

13. Relevant review articles from recent medical and pharmaceutical literature

Name of the Subject	**Pharmacoepidemiology and Pharmacoeconomics (Theory)**
Name of the Faculty	Dr. G K Sadagoban., Pharm.D
Designation, Department	Lecturer, Department of Pharmacy Practice
Mobile Number	9894876656
e-Mail i.d.	sadagoban@jssuni.edu.in

Scope, Course Objectives and Course Outcomes

SCOPE

This course is designed to impart knowledge regarding various methods and applications of pharmacoepidemiology and Pharmacoeconomics in drug safety monitoring, drug approval & regulations, examine the costs of different therapeutic interventions and therapeutic outcomes.

OBJECTIVES

The primary objectives of this course are to

- Understand the scope and applications of pharmacoepidemiology and Pharmacoeconomics
- Understand Pharmacoepidemiological outcome measures
- Adopt the tools effectively in evaluating risk and benefit of therapy
- Conduct pharmacoepidemiology studies and evaluate the outcomes of measures
- Understand the Pharmacoepidemiological databases
- Understand pharmacoeconomic outcome measures
- Conduct pharmacoeconomic studies and evaluate the outcomes of treatment
- Understand the applications of softwares in Pharmacoepidemiology and Pharmacoeconomic analysis.

COURSE OUTCOMES (COS)

At completion of this course, it is expected that the students will be able to:

CO1: Identify the applications of pharmacoepidemiology and Pharmacoeconomics in clinical settings

CO2: Discuss the various Pharmacoepidemiological outcome measures

CO3: Describe the concept of risk in pharmacoepidemiology and different methods of measuring risk

CO4: Explain the various Pharmacoepidemiological methods

CO5: Explain the sources of data for Pharmacoepidemiological studies

CO6: Discuss the methods to measure outcomes in pharmacoeconomic studies

CO7: Describe the current pharmacoeconomic evaluation methods

CO8: Softwares used in Pharmacoepidemiology and Pharmacoeconomics Analysis

LECTURE PLAN

Sessional	No. of Hours of Didactic Lecture		Total No. of Lecture Hours
	Pharmacoepidemiology	Pharmacoeconomics	
I	30	0	30
II	10	20	30
Total No. of Hours	40	20	60

I SESSIONAL: 30 Lectures

Lecture No.	Lecture Details	Hours
PHARMACOEPIDEMIOLOGY		**(30)**
Unit-1: Definition and scope		**05**
	Orientation to the subject	
14.	Origin and evaluation of Pharmacoepidemiology	
15.	Need for pharmacoepidemiology	
16.	Aims and applications of Pharmacoepidemiology.	
Unit-2: Measurement of outcomes in pharmacoepidemiology		**05**
1.	Outcome measure and drug use measures	
2.	Prevalence, incidence and incidence rate. Monetary units	
3.	Number of prescriptions, units of drugs dispensed, defined daily doses and prescribed daily doses	
4.	Medication adherence measurement	
Unit-3: Concept of risk in pharmacoepidemiology		**05**
13.	Measurement of risk	
1.	Attributable risk, relative risk,	
2.	Time-risk relationship	
3.	Odds Ratio	
Unit-4: Pharmacoepidemiological methods		**05**
1.	Drug utilization review	
2.	Case Reports	
3.	Case Series	
4.	Surveys of Drug Use	
5.	Cross – Sectional Studies	
Unit-4: Pharmacoepidemiological methods		**10**
1.	Meta – Analysis Studies	
2.	Spontaneous Reporting	
3.	Prescription Event Monitoring	

4.	Record Linkage System	

II SESSIONAL: 30 Lectures

Lecture No.	Lecture Details	Hours
PHARMACOEPIDEMIOLOGY		**(10)**
Unit-5: Sources of data for pharmacoepidemiological studies		**03**
1.	Ad Hoc data sources	
Unit-6: Selected special applications of pharmacoepidemiology		**07**
1.	Studies of vaccine safety	
2.	Hospital pharmacoepidemiology	
3.	Pharmacoepidemiology and risk management	
4.	Drug induced birth defects.	
5.	Automated data systems.	
PHARMACOECONOMICS		**(20)**
Unit-7: Pharmacoeconomic methods		
1.	Definition, history, needs of pharmacoeconomic evaluations	
2.	Role in formulary management decisions	
3.	Applications of Pharmacoeconomics	
4.	Outcome assessment and types of evaluation	
5.	Cost Minimization Analysis	
6.	Cost of Illness Analysis	
7.	Cost Effectiveness Analysis	
8.	Cost Utility Analysis	
9.	Cost Benefit Analysis	
10.	Markov Modelling & Decision Analysis	
11.	Software and case studies	

TEXT BOOKS

1. Drug safety and pharmacoepidemiology. [s.l.]: Authors: Avianna Stokes foster academics. 2019.
2. West-Strum, D. and Yang, Y., 2013. Understanding Pharmacoepidemiology. New York: McGraw-Hill Rascati, K., 2014. Essentials Of Pharmacoeconomics. Philadelphia: Wolters Kluwer Health/Lippincott Williams & Wilkins.
3. 1999. Introduction To Health Economics And Pharmacoeconomics CD-ROM Series. Secaucus, NJ: Health Economic Research.
4. Walley, T., Haycox, A., Boland, A. and Breckenridge, A., 2004. Pharmacoeconomics. Edinburgh: Churchill Livingstone.

REFERENCE BOOKS

1. Pharmacoeconomics and outcomes: Applications for patient care, case studies. Authors:

Graer DW,Lee J,OdomTD,et al. American college of clinical pharmacy- 2003.
2. Introduction to Applied Pharmacoeconomics, F. Randy Vogenberg, New York; London: McGraw-Hill,
3. Pharmacoepidemiology Editor Brian L Storm, John Wiley and Sons, Ltd 4th edition,
4. Clinical epidemiology- How to do clinical Practice Research. 3rd edition, Brian Haynes,David L Sachett, Lippinkot

JSS Academy of Higher Education & Research, Mysuru

JSS College of Pharmacy, Rocklands, Ooty

I M. PHARMACY TIME TABLE FOR E-LEARN CLASSES : I Semester (AY : 2020 - 2021)

DEPARTMENT : PHARMACY PRACTICE

ZOOM / GOOGLE MEET LICENSE -

Days	10 - 11 am	11 - 12 am	12 - 1 pm	1 - 2 pm	2 - 3 pm	3 - 4 pm	4 - 5 pm	5-6 pm
Mon	Pharmacy Practice (Hospital visit)			LUNCH BREAK	PT – I **(SSB)**	H & CP **(VHN)**	H& CP **(VHN)**	Seminar / Assignment
Tue	Pharmacy Practice (Hospital visit)				PT – I **(SSB)**	Seminar / Assignment	CPP **(SP)**	Seminar / Assignment
Wed	Pharmacy Practice (Hospital visit)				H& CP **(VHN)**	H & CP **(VHN)**	PT – I **(SSB)**	Seminar / Assignment
Thu	Pharmacy Practice Practical I				CPP **(SP)**	Tutorial	Library	Seminar / Assignment
Fri	CR **(BSR)**	Seminar / Assignment	CR **(BSR)**		PT – I **(SSB)**	Library	CPP **(SP)**	Seminar / Assignment
Sat	CR **(BSR)**	CPP **(SP)**	CR **(BSR)**					

Subjects : I M Pharm(Pharmacy Practice)

Clinical Pharmacy Practice (CPP) : Dr S Ponnusankar (SP)

Hospital and Community Pharmacy (H&CP) : Mr. Vishwas H N (VHN)

Pharmacotherapeutics – I (PT-I) : Dr. Swathi Swaroopa B (SSB)

Clinical Research (CR) : Dr BS Roopa (BSR)

JSS Academy of Higher Education & Research, Mysuru
(Accredited 'A+' Grade by NAAC)
JSS College of Pharmacy, Ooty – 643 001
(An ISO 9001-2015 certified Institution)

I M. PHARM – PHARMACY PRACTICE (II Semester (AY-2020-21)

DAY	10 – 11 AM	11AM-12PM	12 – 01 PM	LUNCH BREAK	02-03PM	03-04PM	04-05PM	05-06PM
Monday	Pharmacy Practice (Hospital visit)				PT – II **(VHN)**	QUM **(AS)**	CP&TDM **(KPA)**	Seminar / Assignment
Tuesday	Pharmacy Practice (Hospital visit)				QUM **(AS)**	PT – II **(VHN)**	PE & PE **(GKS)**	Seminar / Assignment
Wednesday	Pharmacy Practice (Hospital visit)				PE & PE **(GKS)**	PT – II **(VHN)**	PE & PE **(GKS)**	Seminar / Assignment
Thursday	Pharmacy Practice Practical II				QUM **(AS)**	CP&TDM **(KPA)**	CP&TDM **(KPA)**	Seminar / Assignment
Friday	Library	Seminar / Assignment	Seminar / Assignent		PE & PE **(GKS)**	PT – II **(VHN)**	QUM **(AS)**	Seminar / Assignment
Saturday	CP&TDM **(KPA)**	Tutorial	Seminar / Assignment					

Subject In-charges:

Principles of Quality Use of Medicines **(QUM)** : Dr. Aneena Suresh **(AS)**
Pharmacotherapeutics – II **(PT-II)** : Mr. Vishwas H N**(VHN)**
Clinical Pharmacokinetics and Therapeutic Drug Monitoring **(CP&TDM)** : Dr. K P Arun **(KPA)**
Pharmacoepidemiology & Pharmacoeconomics **(PE &PE)** : Dr. G Kadagoban**(GKS)**

M. PHARM
PHARMACOLOGY

SYLLABUS
SEMESTER I
MPH101T-MODERN PHARMACEUTICAL ANALYTICAL TECHNIQUE
(Theory)

SCOPE

This subject deals with various advanced analytical instrumental techniques for identification, characterization and quantification of drugs. Instruments dealt are NMR,Mass spectrometer, IR, HPLC, GC etc.

OBJECTIVES

- After completion of course student is able to know about,
- Chemicals and Excipients
- The analysis of various drugs in single and combination dosage forms
- Theoretical and practical skills of the instruments

THEORY **60 HOURS**

UNIT I 10 Hrs

UV-Visible spectroscopy: Introduction, Theory, Laws, Instrumentation associated with UV-Visible spectroscopy, choice of solvents and solvent effect and applications of UV-Visible spectroscopy, difference/deravitive spectroscopy

IR spectroscopy: Theory, Modes of Molecular vibrations, Sample handling,Instrumentation of Dispersive and Fourier - Transform IR Spectrometer, factors affecting vibrational frequencies and applications of IR spectroscopy, Data interpratation

Spectroflourimetry: Theory of Fluorescence, Factors affecting fluorescence,Quenchers, Instrumentation and Applications of fluorescence spectroscopy.Flame emission spectroscopy and Atomic absorption spectroscopy: Principle,Instrumentation, Interferences and Applications.

UNIT II 10 Hrs

NMR spectroscopy: Quantum numbers and their role in NMR, Principle,Instrumentation, Solvent requirement in NMR, Relaxation process, NMR signals invarious compounds, Chemical shift, Factors influencing chemical shift, Spin-Spincoupling, Coupling constant, Nuclear magnetic double resonance.

Brief outline of principles of FT-NMR and 13C NMR. Applications of NMRspectroscopy.

UNIT III 10 Hrs

Mass Spectroscopy: Principle, Theory, Instrumentation of Mass Spectroscopy,Different types of ionization techniques like electron impact, chemical, fielddesorption, FAB and MALDI, APCI, ESI, APPI Analyzers and detectors. Metastable ions, Isotopic peaks and Applications of Mass spectroscopy

UNIT IV 10 Hrs

Chromatography: Principle, apparatus, instrumentation, chromatographic parameters, factors affecting resolution and applications of the following:

a) Thin Layer chromatography b) High performance Thin Layer chromatography c) Ion exchange chromatography d) Column chromatography e) Gas chromatography f) High Performance Liquid chromatography g) Affinity chromatography h) Ultra High Performance Liquid chromatography i) Gel Chromatography

UNIT V 10 Hrs

Electrophoresis: Principle, Instrumentation, Working conditions, factors affecting separation and applications of the following:

a) Paper electrophoresis b) Gel electrophoresis c) Capillary electrophoresis d) Zone electrophoresis e) Moving boundary electrophoresis f) Iso electric focusing

X ray Crystallography: Production of X rays, Different X ray methods, Bragg,,s law, Rotating crystal technique, X ray powder technique, Types of crystals and applications of X-ray diffraction.

UNIT VI 10 Hrs

Potentiometry: Principle, working, Ion selective Electrodes and Application of potentiometry.

Thermal Techniques: Principle, thermal transitions and Instrumentation (Heat flux and power-compensation and designs), Modulated DSC, Hyper DSC, experimental parameters (sample preparation, experimental conditions, calibration, heating and cooling rates, resolution, source of errors) and their influence, advantage and disadvantages, pharmaceutical applications. Differential Thermal Analysis (DTA): Principle, instrumentation and advantage and disadvantages, pharmaceutical applications, derivative differential thermal analysis (DDTA). TGA: Principle, instrumentation, factors affecting results, advantage and disadvantages, pharmaceutical applications.

REFERENCES

1. Spectrometric Identification of Organic compounds - Robert M Silverstein, Sixth edition, John Wiley & Sons, 2004.
2. Principles of Instrumental Analysis - Doglas A Skoog, F. James Holler, Timothy A. Nieman, 5th edition, Eastern press, Bangalore, 1998.
3. Instrumental methods of analysis – Willards, 7th edition, CBS publishers.
4. Practical Pharmaceutical Chemistry – Beckett and Stenlake, Vol II, 4th edition, CBS Publishers, New Delhi, 1997.
5. Organic Spectroscopy - William Kemp, 3rd edition, ELBS, 1991.
6. Quantitative Analysis of Drugs in Pharmaceutical formulation - P D Sethi, 3rd Edition, CBS Publishers, New Delhi, 1997.
7. Pharmaceutical Analysis- Modern methods – Part B - J W Munson, Volume 11, Marcel Dekker Series
8. Spectroscopy of Organic Compounds, 2nd edn., P.S/Kalsi, Wiley estern Ltd., Delhi.

MPL102T-ADVANCED PHARMACOLOGY-I (Theory)

SCOPE

The subject is designed to strengthen the basic knowledge in the field of pharmacology and to impart recent advances in the drugs used for the treatment of various diseases. In addition, this subject helps the students to understand the concepts of drug action and mechanisms involved

OBJECTIVES

Upon completion of the course the student shall be able to:

- Discuss the pathophysiology and pharmacotherapy of certain diseases
- Explain the mechanism of drug actions at cellular and molecular level
- Understand the adverse effects, contraindications and clinical uses of drugs used in treatment of diseases

THEORY **60 Hrs**

UNIT-I

General Pharmacology **12 Hrs**

a. Pharmacokinetics: The dynamics of drug absorption, distribution, biotransformation and elimination. Concepts of linear and non-linear compartment models. Significance of Protein binding.
b. Pharmacodynamics: Mechanism of drug action and the relationship between drug concentration and effect. Receptors, structural and functional families of receptors, quantitation of drug receptors interaction and elicited effects.

UNIT-II **12 Hrs**

Neurotransmission

a. General aspects and steps involved in neurotransmission.
b. b.Neurohumoral transmission in autonomic nervous system (Detailed study about neurotransmitters- Adrenaline and Acetyl choline).
c. Neurohumoral transmission in central nervous system (Detailed study about neurotransmitters- histamine, serotonin, dopamine, GABA, glutamate and glycine).
d. Non-adrenergic non-cholinergic transmission (NANC). Co-transmission
   Systemic Pharmacology
   (A detailed study on pathophysiology of diseases, mechanism of action, pharmacology and toxicology of existing as well as novel drugs used in the following systems)
e. Autonomic Pharmacology: Parasympathomimetics and lytics, sympathomimetics and lytics, agents affecting neuromuscular junction

UNIT-III **12 Hrs**

Central nervous system Pharmacology

General and local anesthetics,Sedatives and hypnotics, drugs used to treat anxiety.
Depression, psychosis, mania, epilepsy, neurodegenerative diseases.Narcotic and non-narcotic analgesics.

UNIT-IV

Cardiovascular Pharmacology **12 Hrs**

Diuretics, antihypertensives, antiischemics, anti- arrhythmics, drugs for heart failure and hyperlipidemia.Hematinics, coagulants , anticoagulants, fibrinolytics and anti-platelet drugs

UNIT- V

Autocoid Pharmacology **12 Hrs**

The physiological and pathological role of Histamine, Serotonin, Kinins, Prostaglandins Opioid autocoids.Pharmacology of antihistamines, 5HT antagonists.

REFEERENCES

1. The Pharmacological Basis of Therapeutics, Goodman and Gillman‘s Principles of Pharmacology.
2. The Pathophysiologic basis of drug Therapy by David E Golan, Armen H, Tashjian Jr, Ehrin J,Armstrong, April W, Armstrong, Wolters, Kluwer-Lippincott Williams & Wilkins Publishers.
3. Basic and Clinical Pharmacology by B.G Katzung
4. Hand book of Clinical Pharmacokinetics by Gibaldi and Prescott.
5. Applied biopharmaceutics and Pharmacokinetics by Leon Shargel and Andrew B.C.Yu.
6. Graham Smith. Oxford textbook of Clinical Pharmacology.
7. Avery Drug Treatment
8. Dipiro Pharmacology, Pathophysiological approach.
9. Green Pathophysiology for Pharmacists.
10. Robbins & Cortan Pathologic Basis of Disease, 9th Ed. (Robbins Pathology)
11. A Complete Textbook of Medical Pharmacology by Dr. S.K Srivastava published by APC Avichal Publishing Company
12. KD.Tripathi. Essentials of Medical Pharmacology.
13. Modern Pharmacology with Clinical Applications, Craig Charles R. & Stitzel Robert E., Lippincott Publishers.
14. Clinical Pharmacokinetics & Pharmacodynamics : Concepts and Applications – Malcolm
15. Rowland and Thomas N.Tozer, Wolters Kluwer, Lippincott Williams & Wilkins Publishers.
16. Applied biopharmaceutics and Pharmacokinetics, Pharmacodynamics and Drug metabolism for industrial scientists.
17. Modern Pharmacology, Craig CR. & Stitzel RE, Little Brown & Company.

MPL103T-PHARMACOLOGICAL AND TOXICOLOGICAL SCREENING METHODS I (Theory)

SCOPE

This subject is designed to impart the knowledge on preclinical evaluation of drugs and recent experimental techniques in the drug discovery and development. The subject content helps the student to understand the maintenance of laboratory animals as per the guidelines, basic knowledge of various in-vitro and in-vivo preclinical evaluation processes

OBJECTIVES

Upon completion of the course the student shall be able to,

- Appraise the regulations and ethical requirement for the usage of experimental animals.
- Describe the various animals used in the drug discovery process and good laboratory practices in maintenance and handling of experimental animals
- Describe the various screening methods involved in the drug discovery process
- Appreciate and correlate the preclinical data to humans

THEORY **60 Hrs**

Unit-I **12 Hrs**

Laboratory Animals

Common lab animals: Description, handling and applications of different species and strains of animals.Transgenic animals: Production, maintenance and applications Anaesthesia and euthanasia of experimental animals. Maintenance and breeding of laboratory animals.
CPCSEA guidelines to conduct experiments on animals.
Good laboratory practice.

Unit-II **12 Hrs**

Preclinical screening of new substances for the pharmacological activity using in vivo, in vitro, and other possible animal alternative models.
General principles of preclinical screening. CNS Pharmacology: behavioral and muscle co-ordination, CNS stimulants and depressants, anxiolytics, anti-psychotics, antiepileptics and nootropics. Drugs for neurodegenerative diseases like Parkinsonism, Alzheimers and multiple sclerosis. Drugs acting on Autonomic Nervous System.

Unit-III **12 Hrs**

Preclinical screening of new substances for the pharmacological activity using in vivo, in vitro, and other possible animal alternative models.
Respiratory Pharmacology: anti-asthmatics, drugs for COPD and anti allergics.
Reproductive Pharmacology: Aphrodisiacs and antifertility agents Analgesics, antiinflammatory and antipyretic agents. Gastrointestinal drugs: antiulcer, anti -emetic, anti-diarrheal and laxatives.

Unit-IV **12 Hrs**

Preclinical screening of new substances for the pharmacological activity using in vivo, in vitro, and other possible animal alternative models.
Cardiovascular Pharmacology: antihypertensives, antiarrythmics, antianginal, antiatherosclerotic agents and diuretics. Drugs for metabolic disorders like anti-diabetic, antihyperlipidemic, and anticancer agents

Unit V **12 Hrs**

Preclinical screening of new substances for the pharmacological activity using in vivo, in vitro, and other possible animal alternative models.

Immunosuppressants and immunomodulators
General principles of immunoassay: theoretical basis and optimization of immunoassay, heterogeneous and homogenous immunoassay systems. Immunoassay methods evaluation; protocol outline, objectives and preparation. Immunoassay for digoxin and insulin
Limitations of animal experimentation and alternate animal experiments.
Extrapolation of in vitro data to preclinical and preclinical to humans.

REFERENCES

1. Biological standardization by J.H. Burn D.J. Finney and I.G. Goodwin
2. Screening methods in Pharmacology by Robert Turner. A
3. Evaluation of drugs activities by Laurence and Bachrach
4. Methods in Pharmacology by Arnold Schwartz.
5. Fundamentals of experimental Pharmacology by M.N.Ghosh
6. Pharmacological experiment on intact preparations by Churchill Livingstone
7. Drug discovery and Evaluation by Vogel H.G.
8. Experimental Pharmacology by R.K.Goyal.
9. Preclinical evaluation of new drugs by S.K. Guta
10. Handbook of Experimental Pharmacology, SK.Kulkarni
11. Practical Pharmacology and Clinical Pharmacy, SK.Kulkarni, 3rd Edition.
12. David R.Gross. Animal Models in Cardiovascular Research, 2nd Edition, Kluwer Academic Publishers, London, UK.
13. Screening Methods in Pharmacology, Robert A.Turner.
14. Rodents for Pharmacological Experiments, Dr.Tapan Kumar chatterjee.
15. Practical Manual of Experimental and Clinical Pharmacology by Bikash Medhi (Author), Ajay Prakash (Author)

MPL104T -CELLULAR AND MOLECULAR PHARMACOLOGY (Theory)

SCOPE

The subject imparts a fundamental knowledge on the structure and functions of cellular components and help to understand the interaction of these components with drugs. This information will further help the student to apply the knowledge in drug discovery process

OBJECTIVES

Upon completion of the course, the student shall be able to,

- Explain the receptor signal transduction processes.
- Explain the molecular pathways affected by drugs.
- Appreciate the applicability of molecular pharmacology and biomarkers in drug discovery process.
- Demonstrate molecular biology techniques as applicable for pharmacology

Unit I **12 Hrs**

Cell biology

Structure and functions of cell and its organelles

Genome organization. Gene expression and its regulation, Cell cycles and its regulation.

Cell death– events, regulators, intrinsic and extrinsic pathways of apoptosis.

Necrosis and autophagy.

Unit II **12Hrs**

Cell signaling

Intercellular and intracellular signaling pathways.

Classification of receptor family and molecular structure ligand gated ion channels; Gprotein coupled receptors, tyrosine kinase receptors and nuclear receptors.

Secondary messengers: cyclic AMP, cyclic GMP, calcium ion, inositol 1,4,5-trisphosphate, (IP3), NO, and diacylglycerol.

Detailed study of following intracellular signaling pathways: cyclic AMP signaling pathway, mitogen-activated protein kinase (MAPK) signaling, Janus kinase (JAK)/signal transducer and activator of transcription (STAT) signaling pathway.

Unit III **12Hrs**

Principles and applications of genomic and proteomic tools DNA electrophoresis, PCR (reverse transcription and real time), Gene sequencing, microarray technique, SDS page, ELISA and western blotting,Recombinant DNA technology and gene therapy.

Basic principles of recombinant DNA technology-Restriction enzymes, various types of vectors. Applications of recombinant DNA technology.

Gene therapy- Various types of gene transfer techniques, clinical applications and recent advances in gene therapy

Unit IV **12Hrs**

Pharmacogenomics

Gene mapping and cloning of disease gene. Importance of siRNA and micro RNA Genetic variation and its role in health/ pharmacology Polymorphisms affecting drug metabolism Genetic variation in drug transporters Genetic variation in G protein coupled receptors

Applications of proteomics science: Genomics, proteomics, metabolomics, functionomics, nutrigenomics.

Types of immunotherapeutics, humanisation antibody therapy, Immunotherapeutics in clinical practice

Unit V **12Hrs**

a) Cell culture techniques

Basic equipments used in cell culture lab. Cell culture media, various types of cell culture, general procedure for cell cultures; isolation of cells, subculture, cryopreservation, characterization of cells and their application.

Principles and applications of cell viability assays and glucose uptake assay. Principles and applications of flow cytometry

b) Biosimilars

REFERENCES:

1. The Cell, A Molecular Approach. Geoffrey M Cooper.
2. Pharmacogenomics: The Search for Individualized Therapies. Edited by J. Licinio and M -L. Wong
3. Handbook of Cell Signaling (Second Edition) Edited by Ralph A. et.al
4. Molecular Pharmacology: From DNA to Drug Discovery. John Dickenson et.al
5. Basic Cell Culture protocols by Cheril D.Helgason and Cindy L.Miller
6. Basic Cell Culture (Practical Approach) by J. M. Davis (Editor)
7. Animal Cell Culture: A Practical Approach by John R. Masters (Editor)
8. Current porotocols in molecular biology vol I to VI edited by Frederick M.Ausuvel et al.

MPL105P-PHARMACOLOGY PRACTICAL- I (Practicals)

1. Analysis of pharmacopoeial compounds and their formulations by UV Vis spectrophotometer
2. Simultaneous estimation of multi component containing formulations by UV
3. spectrophotometry
4. Experiments based on HPLC
5. Experiments based on Gas Chromatography
6. Estimation of riboflavin/quinine sulphate by fluorimetry
7. Estimation of sodium/potassium by flame photometry

Handling of laboratory animals.

1. Various routes of drug administration.
2. Techniques of blood sampling, anesthesia and euthanasia of experimental animals.
3. Functional observation battery tests (modified Irwin test)
4. Evaluation of CNS stimulant, depressant, anxiogenics and anxiolytic, anticonvulsant activity.
5. Evaluation of analgesic, anti-inflammatory, local anesthetic, mydriatic and miotic activity.
6. Evaluation of diuretic activity.
7. Evaluation of antiulcer activity by pylorus ligation method.
8. Oral glucose tolerance test.
9. Isolation and identification of DNA from various sources (Bacteria, Cauliflower, onion, Goat liver).
10. Isolation of RNA from yeast
11. Estimation of proteins by Braford/Lowry's in biological samples.
12. Estimation of RNA/DNA by UV Spectroscopy
13. Gene amplification by PCR.
14. Protein quantification Western Blotting.
15. Enzyme based in-vitro assays (MPO, AChEs, α amylase, α glucosidase).
16. Cell viability assays (MTT/Trypan blue/SRB).
17. DNA fragmentation assay by agarose gel electrophoresis.
18. DNA damage study by Comet assay.
19. Apoptosis determination by fluorescent imaging studies.
20. Pharmacokinetic studies and data analysis of drugs given by different routes of administration using softwares
21. Enzyme inhibition and induction activity
22. Extraction of drug from various biological samples and estimation of drugs in biological fluids using different analytical techniques (UV)
23. Extraction of drug from various biological samples and estimation of drugs in biological fluids using different analytical techniques (HPLC)

REFERENCES

1. CPCSEA, OECD, ICH, USFDA, Schedule Y, EPA guidelines,
2. Fundamentals of experimental Pharmacology by M.N.Ghosh
3. Handbook of Experimental Pharmacology by S.K. Kulkarni.
4. Drug discovery and Evaluation by Vogel H.G.
5. Spectrometric Identification of Organic compounds - Robert M Silverstein,
6. Principles of Instrumental Analysis - Doglas A Skoog, F. James Holler, Timothy A. Nieman,

7. Vogel‘s Text book of quantitative chemical analysis - Jeffery, Basset, Mendham, Denney,
8. Basic Cell Culture protocols by Cheril D. Helgason and Cindy L.Mille
9. Basic Cell Culture (Practical Approach) by J. M. Davis (Editor)
10. Animal Cell Culture: A Practical Approach by John R. Masters (Editor)
11. Practical Manual of Experimental and Clinical Pharmacology by Bikash Medhi(Author), Ajay Prakash (Author) Jaypee brothers’ medical publishers Pvt. Ltd

SEMESTER II

MPL201T-ADVANCED PHARMACOLOGY-II (Theory)

SCOPE

The subject is designed to strengthen the basic knowledge in the field of pharmacology and to impart recent advances in the drugs used for the treatment of various diseases. In addition, the subject helps the student to understand the concepts of drug action and mechanism involved

OBJECTIVES

Upon completion of the course the student shall be able to:

- Explain the mechanism of drug actions at cellular and molecular level
- Discuss the Pathophysiology and pharmacotherapy of certain diseases
- Understand the adverse effects, contraindications and clinical uses of drugs used in treatment of diseases

UNIT-I

Endocrine Pharmacology **12 Hrs**

Molecular and cellular mechanism of action of hormones such as growth hormone, prolactin, thyroid, insulin and sex hormones, Anti-thyroid drugs, Oral hypoglycemic agents, Oral contraceptives, Corticosteroids.

Drugs affecting calcium regulation

UNIT-II

Chemotherapy **12 Hrs**

Cellular and molecular mechanism of actions and resistance of antimicrobial agents such as ß-lactams, aminoglycosides, quinolones, Macrolide antibiotics. Antifungal, antiviral, and anti-TB drugs.

UNIT-III **12 Hrs**

Chemotherapy

Drugs used in Protozoal Infections

Drugs used in the treatment of Helminthiasis

Chemotherapy of cancer

Immunopharmacology

Cellular and biochemical mediators of inflammation and immune response. Allergic or hypersensitivity reactions. Pharmacotherapy of asthma and COPD.

Immunosuppressants and Immunostimulants

UNIT-IV **12 Hrs**

GIT Pharmacology

Antiulcer drugs, Prokinetics, antiemetics, anti-diarrheals and drugs for constipation and irritable bowel syndrome.

Chronopharmacology

Biological and circadian rhythms, applications of chronotherapy in various diseases like cardiovascular disease, diabetes, asthma and peptic ulcer

UNIT-V

Free radicals Pharmacology

Generation of free radicals, role of free radicals in etiopathology of various diseases such as diabetes, neurodegenerative diseases and cancer.

Protective activity of certain important antioxidant

Recent Advances in Treatment of :

Alzheimer‟s disease, Parkinson‟s disease , Cancer, Diabetes mellitus

REFERENCES

1. The Pharmacological basis of therapeutics- Goodman and Gill man‘s
2. Principles of Pharmacology. The Pathophysiologic basis of drug therapy by David E Golan et al.
3. Basic and Clinical Pharmacology by B.G -Katzung
4. Pharmacology by H.P. Rang and M.M. Dale.
5. Hand book of Clinical Pharmacokinetics by Gibaldi and Prescott.
6. Text book of Therapeutics, drug and disease management by E T. Herfindal and Gourley.
7. Applied biopharmaceutics and Pharmacokinetics by Leon Shargel and Andrew B.C.Yu.
8. Handbook of Essential Pharmacokinetics, Pharmacodynamics and Drug Metabolism for Industrial Scientists
9. Robbins & Cortan Pathologic Basis of Disease, 9th Ed. (Robbins
10. Pathology)
11. A Complete Textbook of Medical Pharmacology by Dr. S.K Srivastava published by APC Avichal Publishing Company.
12. KD.Tripathi. Essentials of Medical Pharmacology
13. Principles of Pharmacology. The Pathophysiologic basis of drug Therapy by David E Golan, Armen H, Tashjian Jr, Ehrin J,Armstrong, April W, Armstrong, Wolters, Kluwer-Lippincott Williams & Wilkins Publishers

MPL 202T-PHARMACOLOGICAL AND TOXICOLOGICAL SCREENING METHODS-II (Theory)

SCOPE

This subject imparts knowledge on the preclinical safety and toxicological evaluation of drug & new chemical entity. This knowledge will make the student competent in regulatory toxicological evaluation.

OBJECTIVES

Upon completion of the course, the student shall be able to,

- Explain the various types of toxicity studies.
- Appreciate the importance of ethical and regulatory requirements for toxicity studies.
- Demonstrate the practical skills required to conduct the preclinical toxicity studies.

THEORY **60 Hrs**

Unit I **12 Hrs**

Basic definition and types of toxicology (general, mechanistic, regulatory and descriptive)
Regulatory guidelines for conducting toxicity studies OECD, ICH, EPA and Schedule Y
OECD principles of Good laboratory practice (GLP)
History, concept and its importance in drug development

Unit II **12 Hrs**

Acute, sub-acute and chronic- oral, dermal and inhalational studies as per OECD guidelines.
Acute eye irritation, skin sensitization, dermal irritation & dermal toxicity studies.
Test item characterization- importance and methods in regulatory toxicology studies

Unit III **12 Hrs**

Reproductive toxicology studies, Male reproductive toxicity studies, female reproductive studies (segment I and segment III), teratogenecity studies (segment II)
Genotoxicity studies (Ames Test, in vitro and in vivo Micronucleus and Chromosomal aberrations studies)
In vivo carcinogenicity studies

Unit IV **12 Hrs**

IND enabling studies (IND studies)- Definition of IND, importance of IND, industry perspective, list of studies needed for IND submission.
Safety pharmacology studies- origin, concepts and importance of safety pharmacology.
Tier1- CVS, CNS and respiratory safety pharmacology, HERG assay. Tier2- GI, renal and other studies

Unit V **12 Hrs**

Toxicokinetics- Toxicokinetic evaluation in preclinical studies, saturation kinetics Importance and applications of toxicokinetic studies.
Alternative methods to animal toxicity testing.

REFERENCES

1. Hand book on GLP, Quality practices for regulated non-clinical research and development (http://www.who.int/tdr/publications/documents/glp- handbook.pdf).
2. Schedule Y Guideline: drugs and cosmetics (second amendment) rules, 2005, ministry of health and family welfare (department of health) New Delhi
3. Drugs from discovery to approval by Rick NG.
4. Animal Models in Toxicology, 3rd Edition, Lower and Bryan

5. OECD test guidelines.
6. Principles of toxicology by Karen E. Stine, Thomas M. Brown.
7. Guidance for Industry M3(R2) Nonclinical Safety Studies for the Conduct of Human Clinical Trials and Marketing Authorization for Pharmaceuticals (http://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm073246.pdf)

MPL203T-PRINCIPLES OF DRUG DISCOVERY (Theory)

SCOPE

The subject imparts basic knowledge of drug discovery process. This information will make the student competent in drug discovery process

OBJECTIVES

Upon completion of the course, the student shall be able to,

- Explain the various stages of drug discovery.
- Appreciate the importance of the role of genomics, proteomics and bioinformatics in drug discovery
- Explain various targets for drug discovery.
- Explain various lead seeking method and lead optimization
- Appreciate the importance of the role of computer aided drug design in drug discovery

THEORY **60 Hrs**

Unit I **12 Hrs.**

An overview of modern drug discovery process: Target identification, target validation, lead identification and lead Optimization. Economics of drug discovery.

Target Discovery and validation-Role of Genomics, Proteomics and Bioinformatics. Role of Nucleic acid microarrays, Protein microarrays, Antisense technologies, siRNAs, antisense oligonucleotides, Zinc finger proteins. Role of transgenic animals in target validation.

Unit II **12 Hrs**

Lead Identification- combinatorial chemistry & high throughput screening, in silico lead discovery techniques, Assay development for hit identification.

Protein structure

Levels of protein structure, Domains, motifs, and folds in protein structure. Computational prediction of protein structure: Threading and homology modeling methods. Application of NMR and X-ray crystallography in protein structure prediction

Unit III **12 Hrs**

Rational Drug Design

Traditional vs rational drug design, Methods followed in traditional drug design, High throughput screening, Concepts of Rational Drug Design, Rational Drug Design Methods: Structure and Pharmacophore based approaches

Virtual Screening techniques: Drug likeness screening, Concept of pharmacophore mapping and pharmacophore based Screening,

Unit IV **12 Hrs**

Molecular docking: Rigid docking, flexible docking, manual docking; Docking based screening. De novo drug design. Quantitative analysis of Structure Activity Relationship

History and development of QSAR, SAR versus QSAR, Physicochemical parameters, Hansch analysis, Fee Wilson analysis and relationship between them.

Unit V **12 Hrs**

QSAR Statistical methods – regression analysis, partial least square analysis (PLS) and other multivariate statistical methods. 3D-QSAR approaches like COMFA and COMSIA

Prodrug design-Basic concept, Prodrugs to improve patient acceptability, Drug solubility, Drug absorption and distribution, site specific drug delivery and sustained drug action. Rationale of prodrug design and practical consideration of prodrug design

REFERENCES

1. MouldySioud. Target Discovery and Validation Reviews and Protocols: Volume 2 Emerging Molecular Targetsand Treatment Options. 2007 Humana Press Inc.
2. Darryl León. Scott MarkelIn. Silico Technologies in Drug Target Identification and Validation. 2006 by Taylor and Francis Group, LLC.
3. Johanna K. DiStefano. Disease Gene Identification. Methods and Protocols. Springer New York Dordrecht Heidelberg London.
4. Hugo Kubiny. QSAR: Hansch Analysis and Related Approaches. Methods and Principles in Medicinal Chemistry. Publisher Wiley-VCH
5. Klaus Gubernator, Hans-Joachim Böhm. Structure-Based Ligand Design. Methods and Principles in Medicinal Chemistry. Publisher Wiley-VCH
6. Abby L . Parrill. M . Rami Reddy. Rational Drug Design. Novel Methodology and Practical Applications. ACS Symposium Series; American Chemical Society: Washington, DC, 1999.
7. J. Rick Turner. New drug development design, methodology and, analysis. John Wiley & Sons, Inc., New Jersey.

MPL 204T-CLINICAL RESEARCH AND PHARMACOVIGILANCE (Theory)

SCOPE

This subject will provide a value addition and current requirement for the students in clinical research and pharmacovigilance. It will teach the students on conceptualizing, designing, conducting, managing and reporting of clinical trials. This subject also focuses on global scenario of Pharmacovigilance in different methods that can be used to generate safety data. It will teach the students in developing drug safety data in Pre-clinical, Clinical phases of Drug development and post market surveillance.

OBJECTIVES

Upon completion of the course, the student shall be able to,

- Explain the regulatory requirements for conducting clinical trial
- Demonstrate the types of clinical trial designs
- Explain the responsibilities of key players involved in clinical trials
- Execute safety monitoring, reporting and close-out activities
- Explain the principles of Pharmacovigilance
- Detect new adverse drug reactions and their assessment
- Perform the adverse drug reaction reporting systems and communication in Pharmacovigilance

THEORY **60 Hrs**

Unit I **12 Hrs**

Regulatory Perspectives of Clinical Trials:

Origin and Principles of International Conference on Harmonization - Good Clinical Practice (ICH-GCP) guidelines Ethical Committee: Institutional Review Board, Ethical Guidelines for Biomedical Research and Human Participant- Schedule Y, ICMR Informed Consent Process: Structure and content of an Informed Consent Process Ethical principles governing informed consent process

Unit II **12 Hrs**

Clinical Trials: Types and Design Experimental Study- RCT and Non RCT,Observation Study: Cohort, Case Control, Cross sectional

Clinical Trial Study Team

Roles and responsibilities of Clinical Trial Personnel: Investigator, Study Coordinator, Sponsor, Contract Research Organization and its management.

Unit III **12 Hrs**

Clinical Trial Documentation- Guidelines to the preparation of documents, Preparation of protocol, Investigator Brochure, Case Report Forms, Clinical Study Report Clinical Trial Monitoring- Safety Monitoring in CT

Adverse Drug Reactions: Definition and types. Detection and reporting methods. Severity and seriousness assessment.Predictability and preventability assessment, Management of adverse drug reactions; Terminologies of ADR.

Unit IV **12 Hrs**

Basic aspects, terminologies and establishment of pharmacovigilance

History and progress of pharmacovigilance, Significance of safety monitoring, Pharmacovigilance in India and international aspects, WHO international drug monitoring programme, WHO and Regulatory terminologies of ADR, evaluation of medication safety,

Establishing pharmacovigilance centres in Hospitals, Industry and National programmes related to pharmacovigilance. Roles and responsibilities in Pharmacovigilance

Unit V **12 Hrs**

Methods, ADR reporting and tools used in Pharmacovigilance

International classification of diseases, International Non- proprietary names for drugs, Passive and Active surveillance, Comparative observational studies, Targeted clinical investigations and Vaccine safety surveillance. Spontaneous reporting system and Reporting to regulatory authorities, Guidelines for ADRs reporting. Argus, Aris G Pharmacovigilance, VigiFlow, Statistical methods for evaluating medication safety data.

Pharmacoepidemiology, pharmacoeconomics, safety pharmacology

REFERENCES

1. Central Drugs Standard Control Organization- Good Clinical Practices, Guidelines for Clinical Trials on Pharmaceutical Products in India. New Delhi: Ministry of Health;2001.
2. International Conference on Harmonization of Technical requirements for registration of Pharmaceuticals for human use. ICH Harmonized Tripartite Guideline. Guideline for Good Clinical Practice.E6; May 1996.
3. Ethical Guidelines for Biomedical Research on Human Subjects 2000. Indian Council of Medical Research, New Delhi.
4. Textbook of Clinical Trials edited by David Machin, Simon Day and Sylvan Green, March 2005, John Wiley and Sons.
5. Clinical Data Management edited by R K Rondels, S A Varley, C F Webbs. Second Edition, Jan 2000, Wiley Publications.
6. Handbook of clinical Research. Julia Lloyd and Ann Raven Ed. Churchill Livingstone.
7. Principles of Clinical Research edited by Giovanna di Ignazio, Di Giovanna and Haynes.

MPL 205P-PHARMACOLOGICAL PRACTICAL - II (Practicals)

1. To record the DRC of agonist using suitable isolated tissues preparation.
2. To study the effects of antagonist/potentiating agents on DRC of agonist using suitable isolated tissue preparation.
3. To determine to the strength of unknown sample by matching bioassay by using suitable tissue preparation.
4. To determine to the strength of unknown sample by interpolation bioassay by using suitable tissue preparation
5. To determine to the strength of unknown sample by bracketing bioassay by using suitable tissue preparation
6. To determine to the strength of unknown sample by multiple point bioassay by using suitable tissue preparation.
7. Estimation of PA2 values of various antagonists using suitable isolated tissue preparations.
8. To study the effects of various drugs on isolated heart preparations
9. Recording of rat BP, heart rate and ECG.
10. Recording of rat ECG
11. Drug absorption studies by averted rat ileum preparation.
12. Acute oral toxicity studies as per OECD guidelines.
13. Acute dermal toxicity studies as per OECD guidelines.
14. Repeated dose toxicity studies- Serum biochemical, haematological, urine analysis, functional observation tests and histological studies.
15. Drug mutagenicity study using mice bone-marrow chromosomal aberration test.
16. Protocol design for clinical trial.(3 Nos.)
17. Design of ADR monitoring protocol.
18. In-silico docking studies. (2 Nos.)
19. In-silico pharmacophore based screening.
20. In-silico QSAR studies.
21. ADR reporting

REFERENCES

1. Fundamentals of experimental Pharmacology-by M.N.Ghosh
2. Hand book of Experimental Pharmacology-S.K.Kulakarni
3. Text book of in-vitro practical Pharmacology by Ian Kitchen
4. Bioassay Techniques for Drug Development by Atta-ur-Rahman, Iqbal choudhary and William Thomsen
5. Applied biopharmaceutics and Pharmacokinetics by Leon Shargel and Andrew B.C.Yu.
6. Handbook of Essential Pharmacokinetics, Pharmacodynamics and Drug Metabolism for Industrial Scientists.

DETAILS OF SUBJECT TEACHERS – Semester I

S.No	Name of the Subject	Name of the Teachers	Designation and Department	Mobile No.	e-mail
1.	Modern Pharmaceutical Analytical Techniques	Dr.N. Krishnaveni	Professor & Head	9442083447	krisath@jssuni.edu.in
2.	Advanced Pharmacology I	Dr.M Suresh Kumar	Professor	8903451179	suresh.jsscpo@jssuni.edu.in
3.	Pharmacological and Toxicological Screening Methods-I (T)	Dr.R.Vadivelan	Professor	9047539532	vadivelanr@jssuni.edu.in
4.	Cellular & Molecular Pharmacology	Dr T K Praveen	Professor & Head	9952593850	praveentk@jssuni.edu.in
5.	Expiremental Pharmacology I Practical	Dr T K Praveen	Professor & Head	9952593850	praveentk@jssuni.edu.in

DETAILS OF SUBJECT TEACHERS – Semester II

S.No	Name of the Subject	Name of the Teachers	Designation and Department	Mobile No.	e-mail
1.	Advanced Pharamacology II (T)	Dr.P R Anand Vijayakumar	Professor	9443181573	pranandvijayakumar@jssuni.edu.in
2.	Pharmacological and Toxicological Screening Methods-II (T)	Dr.R.Vadivelan	Professor	9047539532	vadivelanr@jssuni.edu.in
3.	Principles of Drug Discovery (T)	Dr.T K Praveen	Professor & Head	9952593850	praveentk@jssuni.edu.in
4.	Clinical Research & Pharmacovigilance (T)	Dr. M Suresh Kumar	Professor	8903451179	suresh.jsscpo@jssuni.edu.in
5.	Experimental Pharmacology II (P)	Dr.T K Praveen	Professor & Head	9952593850	praveentk@jssuni.edu.in

Academic Plan

2020-21

Name of the Subject	Modern Pharmaceutical Analytical Techniques (Theory)
Name of the Faculty	Dr. Krishna Veni N M.Pharm., Ph.D
Designation, Department	Professor & Head, Department of Pharmaceutical Analysis
Mobile Number	9442083447
e-Mail i.d.	krisath@jssuni.edu.in

Scope, Course Objectives and Course Outcomes

SCOPE:

This subject deals with various advanced analytical instrumental techniques for identification, characterization and quantification of drugs. Instruments dealt are NMR, Mass spectrometer, IR, HPLC, GC etc.

OBJECTIVES:

After completion of course student is able to know about

1. Chemicals and excipients
2. The analysis of various drugs in single and combination dosage forms
3. Theoretical and practical skills of the instruments

COURSE OUTCOMES (COS):

At completion of this course it is expected that the students will be able to

CO 1 : Explain the general principles and techniques of spectroscopy & Chromatography

CO 2 : Perform the assay of single and multiple component pharmaceuticals using various analytical techniques

CO 3 : Develop skills in selecting suitable techniques for the analysis of drugs and pharamceutials

CO 4 : Apply the knowledge learnt in developing newer analytical methods and procedures of their own design

CO 5 : Explore and learn the various instrumental techniques available for the analysis of organic substances

LECTURE PLAN – Abstract

Sessional	No. of Hours of Didactic Lecture	No of Hours of other Activities	Total No. of Lecture Hours
	Advanced Instrumentation Techniques		
I	30	1	31
II	30	--	30
Total No. of Hours	60	--	61

I SESSIONAL : 30 Lectures + 1 Activity

Lecture No.	Lecture Details	Hours
	Orientation of the subject	**01**
Unit-1:		**10**
UV Visible Spectroscopy		
1.	UV Visible Spectroscopy - Introduction, Theory, Laws	
2.	Instrumentation associated with UV Visible Spectroscopy, Choice of Solvents & Solvent Effects	
3.	Applications of UV visible spectroscopy, Difference/ Derivative Spectroscopy	
IR Spectroscopy		
4.	IR Spectroscopy - Theory, Modes of Molecular Vibrations, Samples handling	
5.	Instrumentation of Dispersive and Fourier Transform IR spectrometere	
6.	Factors affecting vibrational frequencies and applications of IR spectroscopy, Data Interpretation	
Spectroflourimetry		
7.	Spectroflourimetry - Theory of fluorescence, Factors affecting fluorescence	
8.	Quenchers, Instrumentation, Applications of Fluorescence Spectrophotometer	
Flame emission spectroscopy & Atomic abosrption spectroscopy		
9.	Principle, Instrumentation	
10.	Interferences and Applications	
Unit-2:		**10**
NMR Spectroscopy		
1.	NMR spectroscopy - Quantum numbers and their role in NMR, Principle	
2.	Instrumentation - Continous wave NMR instrument	
3.	Principle and Instrumentation of FT NMR	
4.	solvent requirements, Relaxation process	
5.	NMR signals in various compounds	
6.	chemical shift, factors influencing chemical shift	
7.	spin spin coupling, coupling constant	
8.	Nuclear magnetic double resonance	
9.	Applications of NMR Spectroscopy	

10.	Principles of 13C NMR	
Unit-3:		
MassSpectrometry		
1.	Principle, theory	**10**
2.	Instrumentation of Mass Spectroscopy - sample introduction techniques	
3.	Different types of ionization - electron impact, chemical	
4.	Different types of ionization - Field, FAB and MALDI	
5.	Different types of ionization - APCI, ESI, APPI	
6.	Analyzers of Quadrupole and Time of Flight	
7.	Mass fragmentation and its rules	
8.	Mass fragmentation and its rules	
9.	Meta stable ions, Isotopic peaks	
10.	Applications of Mass spectroscopy	

II SESSIONAL : 30 Lectures

Lecture No.	Lecture Details	Hours
Unit-4:		
Chromatography - Principle, Apparatus, Instrumentation, Chromatographic Parameters, Factors influencing resolution, Isolation of drugs from excipients, data interpretation and applications of		**10**
1.	Thin Layer Chromatography	
2.	High Performance Thin Layer Chromatography	
3.	Ion Exchange Chromatography	
4.	column Chromatography	
5.	Gas Chromatography	
6.	Gas Chromatography	
7.	HPLC	
8.	HPLC	
9.	Ultra high Performance Liquid Chromatography	
10.	Affinity Chromatography, Gel Chromatography	
Unit-5:		
Electrophoresis - Principle, Instrumentation, Working, Factors affecting separation and applications		
1.	Paper Electrophoresis	**10**
2.	Gel Electrophoresis, Zone Electrophoresis	
3.	Capillary Electrophoresis	
4.	Capillary Electrophoresis	
5.	Moving Boundray Electrophoresis	
6.	Iso Electric Focussing	
X Ray Crystallography		
7.	Production of X Rays, Braggs Law	
8.	Different X Ray diffraction methods - Rotating Crystal Technique	
9.	X Ray Powder technique, Types of Crystals	
10.	Applications of X Ray Diffractions	
Unit-6:		**10**
Immunological Assays		

1.	Potentiometry - Principle, working	
2.	Ion selective Electrodes and other electrodes used in potentiometry	
3.	Applications of potentiometry	
Thermal Techniques		
4.	Differential Scanning Colorimetry - Principle, Thermal transitions	
5.	DSC - Instrumentation (Power compensated, heat flux designs),	
6.	Modulated DSC, Hyper DSC	
7.	Experimental Parameters - sample preparation, experimental conditions, calibration, heating and cooling rates, resolution, source of errors), Their influence, advantages, disadvantages and applications	
8.	Differential Thermal Analysis (DTA) - Principle instrumentation, Advantages & Disadvantages, Pharmaceutical Applications	
9.	Derivative Differential Thermal Analysis	
10.	Thermogravimetric Analysis (TGA) - Principle, instrumentation, factors affecting results, advantages & disadvantages, Pharmaceutical Applications	

Text Books

1. Spectrometric Identification of Organic compounds - Robert M Silverstein, Sixth edition, John Wiley & Sons, 2004.
2. Principles of Instrumental Analysis - Doglas A Skoog, F. James Holler, Timothy A. Nieman, 5th edition, Eastern press, Bangalore, 1998.
3. Instrumental methods of analysis – Willards, 7th edition, CBS publishers.
4. Practical Pharmaceutical Chemistry – Beckett and Stenlake, Vol II, 4th edition, CBS Publishers, New Delhi, 1997.
5. Organic Spectroscopy - William Kemp, 3rd edition, ELBS, 1991.
6. Quantitative Analysis of Drugs in Pharmaceutical formulation - P D Sethi, 3rd Edition, CBS Publishers, New Delhi, 1997.
7. Pharmaceutical Analysis - Modern Methods – Part B - J W Munson, Vol 11, Marcel. Dekker Series
8. Spectroscopy of Organic Compounds, 2nd edn., P.S/Kalsi, Wiley estern Ltd., Delhi.
9. Textbook of Pharmaceutical Analysis, KA.Connors, 3rd Edition, John Wiley & Sons, 1982.

Reference Books

1. Introduction to Spectroscopy; by Donald L Pavia

Name of the Subject	Advance Pharmacology 1 (Theory)
Name of the Faculty	Dr. Suresh K. Mohankumar M.Pharm., Ph.D
Designation, Department	Professor, Department of Pharmacology
Mobile Number	8903451179
e-Mail i.d.	suresh.jsscpo@jssuni.edu.in

Scope, Course Objectives and Course Outcomes

SCOPE

This subject is designed to strengthen the basic knowledge in the field of pharmacology and to impart recent advances in the drugs used for the treatment of various diseases. In addition, this subject helps the students to understand the concepts of drug action and mechanism involved.

OBJECTIVES

The course intend to deliver the following objectives

1. Teach fundamentals of pharmacology including pharmacokinetics and pharmacodynamics
2. Discuss general aspects of neurotransmission, central nevous system (CNS) and cardiovascular system
3. Explain the physiological, pathophysiological and pharmacological mechanisms in systemic and autonomic systems, including CNS and CVS.
4. Enumerate various class of drugs/autocoids and it pharmacodynamics and kinetics, particularly CNS and CVS.

COURSE OUTCOMES (COS)

At completion of this course it is expected that the students will be able to

CO1 : Describe the fundamentals of pharmacodynamics and pharmacokinetics of drugs

CO2 : Detail the general aspects of neurotransmission and relate it to various pathophysiological processes

CO3 : Demonstrate the physiology of CNS, pathophysiology of CNS diseases and pharmacology of CNS drugs

CO4 : Demonstrate the physiology of CVS, pathophysiology of CVS diseases and pharmacology of CVS drugs

CO 5 : Demonstrate the physiology, pathophysiology and pharmacology of autocoids

LECTURE PLAN – Abstract

Sessional	No. of Hours of Didactic Lecture	No of Hours of other Activities	Total No. of Lecture Hours
I	32	04	36
II	14	10	24
Total No. of Hours	46	14	60

I SESSIONAL: 32 Lectures + 4 Activities

Lecture No.	Lecture Details	Hours
Unit-1 General Pharmacology		**12**
	Welcome and Intro to Course	
1.	Intro- GP	
2.	Agonist	
3.	Antagonist	
4.	Drug Targets- GPCR	
5.	Drug Target- Ion Channel	
6.	Drug Target- Catylytic Receptors	
7.	Drug Target- Enzymes and others	
8.	Pharamcokinetics	
9.	Absorption & Distribution	
10.	Metabolism	
11.	Elimiation	
12.	Coursework/Assignment/Activity/Revision	
Unit-2 Neurotransmission		**12**
1.	General aspects of neurotransmission.	
2.	Neurohumoral transmission ANS-1: Adrenaline	
3.	Neurohumoral transmission ANS-2: Acetylcholine	
4.	Neurohumoral transmission CNS-2: Histamine	
5.	Neurohumoral transmission CNS-2: Serotonin	
6.	Nuerohumoral transmission CNS-3: Dopamine	
7.	Neurohumoral transmission CNS-4: Glutamate and Glycine	
8.	Non-adrenergic and Non-cholinergic transimission	
9.	Systemic Pharamcology-1	
10.	Autonomic pharmacology-1	
11.	Autonomic pharmacology-2	
12.	Coursework/Assignment/Activity/Revision	
Unit-3 General Nervous System Pharmacology		**12**
1.	Anasthetics	
2.	Analgesics	
3.	Sedatives	
4.	Hynotics	
5.	Anti-anxiety	
6.	Depression	
7.	Psychosis	

8.	Mania	
9.	Neurodegenerative Diseases-1	
10.	Neurodegenerative Diseases-2	
11.	Coursework/Assignment/Activity/Revision	
12.	Assessment	

II SESSIONAL: 14 Lectures + 10 Activities

Lecture No.	Lecture Details	Hours
Unit- 4 Cardiovascular Pharmacology		**12**
1.	Diuretics	
2.	Anti-Hypertensive	
3.	Anti-Ischemics	
4.	Anti-Arrythmics	
5.	Heart failure	
6.	Hyperlipidemia	
7.	Anti-coagulants	
8.	Fibrinolytics	
9.	Anti-platelet drugs	
10.	Coursework/Assignment/Activity/Revision	
11.	Coursework/Assignment/Activity/Revision	
12.	Coursework/Assignment/Activity/Revision	
Unit-5 Autocoid Pharmacology.		**12**
1.	Histamine and Anti-Histamine	
2.	Serotonin and 5HT antagonist	
3.	Kinins	
4.	Prostaglandins	
5.	Opioids	
6.	Coursework/Assignment/Activity/Revision	
7.	Coursework/Assignment/Activity/Revision	
8.	Coursework/Assignment/Activity/Revision	
9.	Assessment-1	
10.	Assessment-2	
11.	Assessment-3	
12.	Feedback	

TEXT BOOKS

1. The Pharmacological basis oftherapeutics- Goodman and Gill man‘s
2. KD.Tripathi. Essentials of Medical Pharmacology.
3. Principles of Pharmacology. The Pathophysiologic basis of drug therapy by David E Golan et al.
4. Basic and Clinical Pharmacology by B.G -Katzung.
5. Pharmacology by H.P. Rang and M.M. Dale.
6. Robbins & Cortan Pathologic Basis of Disease, 9th Ed. (Robbins Pathology)

REFERNCE BOOKS

1. Hand book of Clinical Pharmacokinetics by Gibaldi and Prescott.

2. Text book of Therapeutics, drug and disease management by E T.Herfindal and Gourley.
3. Applied biopharmaceutics and Pharmacokinetics by Leon Shargel and Andrew B.C.Yu.
4. Handbook of Essential Pharmacokinetics, Pharmacodynamics and Drug Metabolism for Industrial Scientists
5. A Complete Textbook of Medical Pharmacology by Dr. S.KSrivastava published by APC Avichal PublishingCompany.
6. Principles of Pharmacology. The Pathophysiologic basis of drug Therapy by David E Golan,Armen H, Tashjian Jr, Ehrin J,Armstrong, April W, Armstrong,Wolters,Kluwer-LippincottWilliams&WilkinsPublishers

Name of the Subject	Pharmacological and Toxicological Screening Methods - I
Name of the Faculty	Dr. Vadivelan R M.Pharm., Ph.D
Designation, Department	Professor, Department of Pharmacology
Mobile Number	9047539532
e-Mail i.d.	vadivelanr@jssuni.edu.in

Scope, Course Objectives and Course Outcomes

SCOPE

This subject is designed to impart the knowledge on preclinical evaluation of drugs and recent experimental techniques in the drug discovery and development. The subject content helps the student to understand the maintenance of laboratory animals as per the guidelines, basic knowledge of various in-vitro and in-vivo preclinical evaluation processes

OBJECTIVES

The primary objectives of this course are to

- Appraise the regulations and ethical requirement for the usage of experimental animals.
- Describe the various animals used in the drug discovery process and good laboratory practices in maintenance and handling of experimental animals
- Describe the various newer screening methods involved in the drug discovery process
- Appreciate and correlate the preclinical data to humans

COURSE OUTCOMES (COS)

At completion of this course it is expected that the students will be able to

CO 1 : Biomethodology and appliactions of common laboratory animals
CO 2 : Primary Screening methods in drug discovey process
CO 3 : Different types of screening methods for various disesases
CO 4 : Bioassay,types and its appliactions
CO 5 : General Principles of Immunassay

LECTURE PLAN – Abstract

Sessional	No. of Hours of Didactic Lecture	No of Hours of other Activities	Total No. of Lecture Hours
I	30	03	33
II	30	03	33
Total No. of Hours	60	06	66

Lecture No.	Lecture Details	Hours
Unit-1 Laboratory Animals		**12**
	Orientation to the subject	
1.	Common laboratory animals	
2.	Description of Laboratory animals handling (cont..)	
3.	Description of Laboratory animals handling (cont..)	
4.	Applications of different species and strains of animals	
5.	Transgenic animals: Production, maintenance and applications(cont..)	
6.	Transgenic animals: Production, maintenance and applications	
7.	Anaesthesia of experimental animals.	
8.	Euthanasia of experimental animals.	
9.	Maintenance and breeding of laboratory animals	
10.	CPCSEA guidelines to conduct experiments on animals	
11.	Good laboratory practice.	
12.	Bioassay-Principle, scope and limitations and methods	
Unit-2 Preclinical screening of new substances for the pharmacological activity using in vivo, in vitro, and other possible animal alternative models.		**12**
1.	General principles of preclinical screening.	
2.	Behavioral and muscle co ordination	
3.	CNS stimulants and depressants	
4.	Anxiolytics	
5.	Anti-psychotics	
6.	Anti epileptics	
7.	Nootropics.	
8.	Drugs for neurodegenerative diseases like Parkinsonism, Alzheimers and multiple sclerosis. (cont..)	
9.	Drugs for neurodegenerative diseases like Parkinsonism, Alzheimers and multiple sclerosis. (cont..)	
10.	Drugs for neurodegenerative diseases like Parkinsonism, Alzheimers and multiple sclerosis.	
11.	Drugs acting on Autonomic Nervous System (cont..)	
12.	Drugs acting on Autonomic Nervous System	
Unit-3 Preclinical screening of new substances for the pharmacological activity using in vivo, in vitro, and other possible animal alternative models.		**06**
1.	Anti-asthmatics	
2.	Drugs for COPD	
3.	Anti allergics	

4.	Aphrodisiacs	
5.	Antifertility agents (cont..)	
6.	Antifertility agents	
	Activity-1	
	Activity-2	
	Activity-3	

I SESSIONAL: 30 Lectures + 3 Activities

Lecture No.	Lecture Details	Hours
Unit-3 Preclinical screening of new substances for the pharmacological activity using in vivo, in vitro, and other possible animal alternative models.		**06**
1.	Analgesics, antiinflammatory and antipyretic agents.(cont..)	
2.	Analgesics, antiinflammatory and antipyretic agents.	
3.	Anti ulcer agents	
4.	Anti –emetic agents	
5.	Antidiarrheal agents	
6.	Laxatives	
Unit-4 Preclinical screening of new substances for the pharmacological activity using in vivo, in vitro, and other possible animal alternative models.		**12**
1.	Antihypertensives agents (cont..)	
2.	Antihypertensives agents	
3.	Antiarrythmics agents	
4.	Antianginal agents	
5.	Antiatherosclerotic agents	
6.	Diuretics	
7.	Anti-diabetic agents	
8.	Antidyslipidemic agents	
9.	Anti cancer agents (cont..)	
10.	Anti cancer agents	
11.	Hepatoprotective screening methods (cont..)	
12.	Hepatoprotective screening methods	
Unit-5 Preclinical screening of new substances for the pharmacological activity using in vivo, in vitro, and other possible animal alternative models.		**12**
1.	Immunomodulators	
2.	Immunosuppressants	
3.	Immunostimulants	
4.	General principles of Immunoassay: Theoretical basis and optimization of immunoassay (cont..)	
5.	General principles of Immunoassay: Theoretical basis and optimization of immunoassay (cont..)	
6.	Heterogeneous and homogenous immunoassay systems (cont..)	
7.	Heterogeneous and homogenous immunoassay systems (cont..)	
8.	Immunoassay methods evaluation; protocol outline, objectives and preparation (cont..)	

9.	Immunoassay methods evaluation; protocol outline, objectives and preparation (cont..)	
10.	Immunoassay methods evaluation; protocol outline, objectives and preparation	
11.	Immunoassay for digoxin	
12.	Immunoassay for insulin	
	Activity-1	
	Activity-2	
	Activity-3	

TEXT BOOKS

1. Biological standardization by J.H. Burn D.J. Finney and I.G. Goodwin
2. Screening methods in Pharmacology by Robert Turner. A
3. Evaluation of drugs activities by Laurence and Bachrach
4. Methods in Pharmacology by Arnold Schwartz.
5. Fundamentals of experimental Pharmacology by M.N.Ghosh

REFERNCE BOOKS

1. Pharmacological experiment on intact preparations by Churchill Livingstone
2. Drug discovery and Evaluation by Vogel H.G.
3. Experimental Pharmacology by R.K.Goyal.
4. Preclinical evaluation of new drugs by S.K. Guta

Name of the Subject	**Cellular and Molecular Pharmacology (Theory)**
Name of the Faculty	Dr. Praveen TK M.Pharm., Ph.D
Designation, Department	Professor and Head, Department of Pharmacology
Mobile Number	9952593850
e-Mail i.d.	praveentk@jssuni.edu.in

Scope, Course Objectives, and Course Outcomes

SCOPE

The subject imparts a fundamental knowledge on the structure and functions of cellular components and help to understand the interaction of these components with drugs. This information will further help the student to apply the knowledge in drug discovery process.

OBJECTIVES

Upon completion of the course, the student shall be able to,

1. Understand the receptor signal transduction processes.
2. Understand the molecular pathways affected by drugs.
3. Appreciate the applicability of molecular pharmacology and biomarkers in the drug discovery process.
4. Understand molecular biology techniques as applicable for pharmacology

COURSE OUTCOMES (COS)

After this course, it is expected that the students will be able to;

CO1: Summarize genome organization, gene expression, and regulation. Describe cell cycle and its regulators

CO2: Describe the molecular events of apoptosis, necrosis, and autophagy, and explain the difference between them

CO3: Summarize various cell signaling pathway and explain their importance

CO4: Describe the working principle behind DNA electrophoresis, PCR, gene sequencing, microarray, ELISA, Flow cytometry and Western blotting

CO5: Describe the importance of cell culture techniques and explain the principle behind recombinant DNA technology, gene therapy, immunotherapy, and biosimilars

CO6: Explain the role of genetic variation in drug metabolism, transportation, etc.

LECTURE PLAN – Abstract

Sessional	No. of Hours of Didactic Lecture	No of Hours of other Activities	Total No. of Lecture Hours
I	30	03	33
II	30	03	33
Total No. of Hours	60	06	66

I SESSIONAL: 30 Lectures + 3 Activities

Lecture No.	Lecture Details	Hours
Unit-1 Cell biology		**12**
	Orientation to the subject	
1.	Structure and functions of cell and its organelles (cont..)	
2.	Structure and functions of cell and its organelles	
3.	Genome organization (cont..)	
4.	Genome organization	
5.	Gene expression and its regulation (cont..)	
6.	Gene expression and its regulation	
7.	Importance of siRNA and micro RNA	
8.	Gene mapping and gene sequencing	
9.	Cell cycles and its regulation	
10.	Cell death– events, regulators, intrinsic and extrinsic pathways of apoptosis. (cont..)	
11.	Cell death– events, regulators, intrinsic and extrinsic pathways of apoptosis.	
12.	Necrosis and autophagy.	
Unit-2 Cell signalling		**12**
1.	Intercellular and intracellular signaling pathways.(cont..)	
2.	Intercellular and intracellular signaling pathways	
3.	Classification of receptor family	
4.	Molecular structure ligand gated ion channels	
5.	G-protein coupled receptors	
6.	Tyrosine kinase receptors	
7.	Nuclear receptors	
8.	Secondary messengers: cyclic AMP, cyclic GMP, calcium ion	
9.	Secondary messengers: inositol 1,4,5-trisphosphate, (IP3), NO, and diacylglycerol	
10.	Cyclic AMP signaling pathway	
11.	mitogen-activated protein kinase (MAPK) signaling	
12.	Janus kinase (JAK)/signal transducer and activator of transcription (STAT) signaling pathway.	
Unit-3 Principles and applications of genomic and proteomic tools		**06**
1.	DNA electrophoresis	
2.	PCR (reverse transcription and real time),	
3.	Gene sequencing	
4.	Micro array technique	
5.	SDS page	

6.	ELISA and western blotting	
	Activity-1	
	Activity-2	
	Activity-3	

II SESSIONAL : 30 Lectures + 3 Activities

Lecture No.	Lecture Details	Hours
Unit-3 Recombinant DNA technology and gene therapy		**06**
1.	Basic principles of recombinant DNA technology	
2.	Restriction enzymes	
3.	Various types of vectors	
4.	Applications of recombinant DNA technology	
5.	Gene therapy- Various types of gene transfer techniques	
6.	Clinical applications and recent advances in gene therapy	
Unit-4 Pharmacogenomics & Immunotherapeutics		**12**
1.	Gene mapping and cloning of disease gene.	
2.	Genetic variation in G protein coupled receptors	
3.	Genetic variation and its role in health/ pharmacology	
4.	Polymorphisms affecting drug metabolism	
5.	Genetic variation in drug transporters	
6.	Applications of proteomics science: Genomics	
7.	Applications of proteomics science:, Proteomics	
8.	Applications of proteomics science: Functionomics	
9.	Applications of proteomics science: Nutrigenomics	
10.	Types of immunotherapeutics	
11.	Humanisation antibody therapy	
12.	Immunotherapeutics in clinical practice	
Unit-5 Cell culture techniques & Biosimilars		**12**
1.	Basic equipments used in cell culture lab	
2.	Cell culture media	
3.	Various types of cell culture	
4.	Isolation of cells	
5.	Subculture .	
6.	Cryopreservation, characterization of cells and their application	
7.	Characterization of cells and their application	
8.	Principles and applications of cell viability assays	
9.	Principles and applications of glucose uptake assay, calcium influx assays	
10.	Principles and applications of flow cytometry	
11.	Biosimilars	
12.	Biosimilars	
	Activity-1	
	Activity-2	
	Activity-3	

TEXT BOOKS

1. The Cell, A Molecular Approach. Geoffrey M Cooper.

2. Pharmacogenomics: The Search for Individualized Therapies. Edited by J. Licinio and M -L. Wong
3. Handbook of Cell Signaling (Second Edition) Edited by Ralph A. et.al
4. Molecular Pharmacology: From DNA to Drug Discovery. John Dickenson et.al
5. Basic Cell Culture protocols by Cheril D.Helgason and Cindy L.Miller

REFERNCE BOOKS

1. Basic Cell Culture (Practical Approach) by J. M. Davis (Editor)
2. Animal Cell Culture: A Practical Approach by John R. Masters (Editor)
3. Current porotocols in molecular biology vol I to VI edited by Frederick M.Ausuvel

Name of the Subject	**Pharmacology Practical- I (Practical)**
Name of the Faculty	Dr. Vadivelan R M.Pharm., Ph.D
Designation, Department	Professor, Department of Pharmacology
Mobile Number	9047539532
e-Mail i.d.	vadivelanr@jssuni.edu.in

Scope, Course Objectives and Course Outcomes

SCOPE

This subject is designed to impart the knowledge on preclinical evaluation of drugs and recent experimental techniques in the drug discovery and development. The subject content helps the student to practice the maintenance of laboratory animals as per the guidelines, basic knowledge of various in-vitro and in-vivo preclinical evaluation processes

OBJECTIVES

The primary objectives of this course are to

- Skills in biomethodology of experimental animals.
- Study various in vitro in vivo techniques in preclinical pharmacology
- Appreciate and correlate the preclinical data to humans

COURSE OUTCOMES (COS)

At completion of this course it is expected that the students will be able to

CO 1: Practical skills in handling,route of administration of drugs to lab animals

CO 2 : Primary Screening methods in drug discovey process

CO 3 : Perform different types of screening methods for various disesases

CO 4: Biostatistics in experimental pharmacology

PRACTICAL PLAN – Abstract

Sessional	No. of Practicals	No of Hours of Practicals (Each Practical 04 Hrs)	Total No. of Practical Hours
I	12	48	48
II	13	52	52
Total No. of Hours	100	-	100

I SESSIONAL: 12 Practicals

Practical No.	Practical Details	Hours
	Orientation to the subject	48
1.	Handling of laboratory animals.	
2.	Various routes of drug administration	
3.	Techniques of blood sampling, anesthesia and euthanasia of experimental animals.	
4.	Functional observation battery tests (modified Irwin test)	
5.	Evaluation of CNS stimulant and depressant activity.	
6.	Evaluation of anxiogenics and anxiolytic, anticonvulsant activity	
7.	Evaluation of analgesic, anti-inflammatory, local anesthetic, mydriatic and miotic activity.	
8.	Evaluation of diuretic activity.	
9.	Evaluation of antiulcer activity by pylorus ligation method. Oral glucose tolerance test.	
10.	Isolation and identification of DNA from various sources (Bacteria, Cauliflower, onion, Goat liver).	
11.	Isolation of RNA from yeast	
12.	Estimation of proteins by Braford/Lowry's in biological samples	

II SESSIONAL: 13 Practicals

Practical No.	Practical Details	Hours
1.	Analysis of pharmacopoeial compounds and their formulations by UV spectrophotometer	52
2.	Simultaneous estimation of multi component containing formulations by UVspectrophotometry	
3.	Experiments based on HPLC	
4.	Estimation of riboflavin/quinine sulphate by fluorimetry	
5.	Estimation of sodium/potassium by flame photometry	
6.	Enzyme based in-vitro assays (MPO, AChEs, α amylase, α glucosidase).	
7.	Cell viability assays (MTT/Trypan blue/SRB).	
8.	Gene amplification by PCR.	
9.	DNA fragmentation assay by agarose gel electrophoresis.	
10.	DNA damage study by Comet assay.	
11.	Enzyme inhibition and induction activity	

12.	Pharmacokinetic studies and data analysis of drugs given by different routes of administration using softwares	
13.	Extraction of drug from various biological samples and estimation of drugs in biological fluids using different analytical techniques (UV)	

TEXT BOOKS

1. Fundamentals of experimental Pharmacology by M.N.Ghosh
2. Handbook of Experimental Pharmacology by S.K. Kulkarni.
3. Drug discovery and Evaluation by Vogel H.G.
4. Animal Cell Culture: A Practical Approach by John R. Masters (Editor)
5. Practical Manual of Experimental and Clinical Pharmacology by Bikash Medhi(Author), Ajay Prakash (Author) Jaypee brothers medical publishers Pvt. Ltd

REFERENCE BOOKS

1. CPCSEA, OECD, ICH, USFDA, Schedule Y, EPA guidelines,
2. Spectrometric Identification of Organic compounds - Robert M Silverstein
3. Principles of Instrumental Analysis - Doglas A Skoog, F. James Holler, Timothy A. Nieman,
4. Vogel‘s Text book of quantitative chemical analysis - Jeffery, Basset, Mendham, Denney,
5. Basic Cell Culture protocols by Cheril D. Helgason and Cindy L.Mille
6. Basic Cell Culture (Practical Approach) by J. M. Davis (Editor)

Name of the Subject	**Advanced Pharmacology- II**
Name of the Faculty	Dr. Anand VijayaKumar P R M.Pharm., Ph.D
Designation, Department	Professor, Department of Pharmacology
Mobile Number	9443181573
e-Mail i.d.	pranandvijayakumar@jssuni.edu.in

Scope, Course Objectives and Course Outcomes

SCOPE

The subject is designed to strengthen the basic knowledge in the field of pharmacology and to impart recent advances in the drugs used for the treatment of various diseases. In addition, the subject helps the student to understand the concepts of drug action and mechanism involved

OBJECTIVES

Upon completion of the course the student shall be able to:
Explain the mechanism of drug actions at cellular and molecular level.
Discuss the Pathophysiology and pharmacotherapy of certain diseases.
Understand the adverse effects, contraindications and clinical uses of drugs used in treatment of diseases.

COURSE OUTCOMES (COS)

- The students would gain the basic knowledge in the field of pharmacology pertaining to the drugs and its therapeutic applications.
- To discuss the recent advances in the drugs used for the treatment of various diseases.
- They would have understood the concepts of drug action and mechanisms involved.
- They would have studied the pathophysiology and pharmacotherapy of certain diseases
- They would have understood the underlying mechanism of drug actions at cellular and molecular level.
- They would have learnt the adverse effects, contraindications and clinical uses of drugs used in treatment of diseases

LECTURE PLAN

Sessional	No. of Hours of Didactic Lecture	No of Hours of other Activities	Total No. of Lecture Hours
I	30	03	33
II	30	03	33
Total No. of Hours	60	06	66

I SESSIONAL: 30 Lectures + 3 Activities

Lecture No.	Lecture Details	Hours
Orientation to the subject		
Unit-1 Endocrine Pharmacology Molecular and Cellular Mechanism		**12**
1.	Growth hormone	
2.	Prolactin	
3.	Prolactin	
4.	Thyroid	
5.	Thyroid	
6.	Sex hormone	
7.	Sex hormone	
8.	Antithyroid	
9.	oral contraceptives	
10.	Oral hypoglycemic agents	
11.	Corticosteroids	
12.	calcium regulation effecting drugs	
Unit-2 Chemotherapy Molecular and Cellular Mechanism		**12**
1.	Antimicrobial Mechanism and resistance Beta lactum	
2.	aminoglycoside	
3.	Quinolones	
4.	Quinolones	
5.	Macrolide antibiotics	
6.	Macrolide antibiotics	
7.	antifungal	
8.	antifungal	
9.	antiviral	
10.	antiviral	
11.	TB drugs	
12.	TB drugs	
Unit-3 Chemotherapy of Drug Used & Immuno Pharmacology		**06**
1.	Chemotherapy Protozoal Infections	
2.	Chemotherapy Helminthesias	
3.	Chemotherapy of cancer	
4.	Cellular and biochemical mediators of Inflammation and immune response	
5.	Cellular and biochemical mediators of Inflammation and immune response	
6.	Allergic reactions	
		03

1.	**Activity-1**	
2.	**Activity-2**	
3.	**Activity-3**	

II SESSIONAL: 30 Lectures + 3 Activities

Lecture No.	Lecture Details	Hours
Unit-3 Chemotherapy of Drug Used & Immuno Pharmacology		**06**
1.	Pharmacotherapy of COPD	
2.	Pharmacotherapy of COPD	
3.	Pharmacotherapy of Asthma	
4.	Pharmacotherapy of Asthma	
5.	Immunostimulants	
6.	Immunosuppressants	
Unit-4 GI Pharmacology and recent drug used. ChronoPharmacology Application of Chronopharmacology in diseases		**12**
1.	Antiulcer Drugs	
2.	Antiulcer Drugs	
3.	Prokinetics	
4.	Antiemetics	
5.	Antidiarrheals and drugs for constipation	
6.	Irritable Bowel syndrome	
7.	Irritable Bowel syndrome	
8.	Biological and Circadian rythms	
9.	Diabetes	
10.	Alzmiers disease	
11.	Parkinsons disease	
12.	Cancer	
Unit-5 Free Radical Pharmacology. Free Radicals in etiopathology of diseases		**12**
1.	Generation of Free radicals	
2.	Generation of Free radicals	
3.	Diabetes	
4.	Neurodegenarative Diseases	
5.	Alzmiers	
6.	Parkinsons	
7.	cancer	
8.	Protective activity of certain important antioxidants	
Recent Advances in Treatment of		
9.	Alzheimers	
10.	Parkinsons	
11.	cancer	
12.	Diabetes mellitus	
Activities		**03**
1.	**Activity-1**	
2.	**Activity-2**	
3.	**Activity-3**	

TEXT BOOKS

1. The Pharmacological basis oftherapeutics- Goodman and Gill man‘s
2. KD.Tripathi. Essentials of Medical Pharmacology.
3. Principles of Pharmacology. The Pathophysiologic basis of drug therapy by David E Golan et al.
4. Basic and Clinical Pharmacology by B.G -Katzung.
5. Pharmacology by H.P. Rang and M.M. Dale.
6. Robbins & Cortan Pathologic Basis of Disease, 9th Ed. (Robbins Pathology)

REFERNCE BOOKS

1. Hand book of Clinical Pharmacokinetics by Gibaldi and Prescott.
2. Text book of Therapeutics, drug and disease management by E T.Herfindal and Gourley.
3. Applied biopharmaceutics and Pharmacokinetics by Leon Shargel and Andrew B.C.Yu.
4. Handbook of Essential Pharmacokinetics, Pharmacodynamics and Drug Metabolism for Industrial Scientists
5. A Complete Textbook of Medical Pharmacology by Dr. S.KSrivastava published by APC Avichal PublishingCompany.
6. Principles of Pharmacology. The Pathophysiologic basis of drug Therapy by David E Golan,Armen H, Tashjian Jr, Ehrin J,Armstrong, April W, Armstrong,Wolters,Kluwer-LippincottWilliams&WilkinsPublishers

Name of the Subject	Pharmacological and Toxicological Screening Methods - II
Name of the Faculty	Dr. Vadivelan R M.Pharm., Ph.D
Designation, Department	Professor, Department of Pharmacology
Mobile Number	9047539532
e-Mail i.d.	vadivelanr@jssuni.edu.in

Scope, Course Objectives and Course Outcomes

SCOPE

This subject imparts knowledge on the preclinical safety and toxicological evaluation of drug & new chemical entity. This knowledge will make the student competent in regulatory toxicological evaluation.

OBJECTIVES

The primary objectives of this course are to

- Explain the various types of toxicity studies.
- Appreciate the importance of ethical and regulatory requirements for toxicity studies.
- Demonstrate the practical skills required to conduct the preclinical toxicity studies.

COURSE OUTCOMES (COS)

At completion of this course it is expected that the students will be able to

CO 1 : Importance of toxicity studies in drug discovery process

CO 2 : Ethical and regulatory requirements for toxicity studies

CO 3 : Knowledged of skills to conduct preclinical trials

LECTURE PLAN – Abstract

Sessional	No. of Hours of Didactic Lecture	No of Hours of other Activities	Total No. of Lecture Hours
I	30	03	33
II	30	03	33
Total No. of Hours	60	06	66

I SESSIONAL: 30 Lectures + 3 Activities

Lecture No.	Lecture Details	Hours
Unit-1		**12**
	Orientation to the subject	
1.	Basic definition and types of toxicology (general,mechanistic, regulatory and descriptive) (cont..)	
2.	Basic definition and types of toxicology (general, mechanistic, regulatory and descriptive) (cont..)	
3.	Basic definition and types of toxicology (general, mechanistic, regulatory and descriptive)	
4.	Regulatory guidelines for conducting toxicity studies	
5.	Regulatory guidelines for conducting toxicity studies ICH	
6.	Regulatory guidelines for conducting toxicity studies EPA	
7.	Regulatory guidelines for conducting toxicity studies Schedule Y	
8.	Regulatory guidelines for conducting toxicity studies Schedule Y	
9.	OECD principles of Good laboratory practice (GLP) (cont..)	
10.	OECD principles of Good laboratory practice (GLP)	
11.	History, concept and its importance in drug development(cont..)	
12.	History, concept and its importance in drug development	
Unit-2		**12**
1.	Acute, sub-acute and chronic- oral studies as per OECD guidelines. (cont..)	
2.	Acute, sub-acute and chronic- oral studies as per OECD guidelines. (cont..)	
3.	Acute, sub-acute and chronic- oral studies as per OECD guidelines.	
4.	Acute, sub-acute and chronic- dermal studies as per OECD guidelines. (cont..)	
5.	Acute, sub-acute and chronic- dermal studies as per OECD guidelines.	
6.	Acute, sub-acute and chronic- inhalational studies as per OECD guidelines. (cont..)	
7.	Acute, sub-acute and chronic- inhalationalas per OECD guidelines.	
8.	Acute eye irritation and skin sensitization studies	
9.	Dermal irritation studies	
10.	Dermal toxicity studies	
11.	Test item characterization- importance and methods in regulatory toxicology studies (cont..)	
12.	Test item characterization- importance and methods in regulatory toxicology studies	

Unit-3		**06**
1.	Reproductive toxicology studies	
2.	Male reproductive toxicity studies (cont..)	
3.	Male reproductive toxicity studies	
4.	Female reproductive studies (segment I and segment III) (cont..)	
5.	Female reproductive studies (segment I and segment III)	
6.	Teratogenecity studies (segment II)	
	Activity-1	
	Activity-2	
	Activity-3	

II SESSIONAL: 30 Lectures + 3 Activities

Lecture No.	Lecture Details	Hours
Unit-3		**06**
1.	Genotoxicity studies	
2.	Ames Test	
3.	In vitro and in vivo Micronucleus studies (cont..)	
4.	In vitro and in vivo Micronucleus studies	
5.	In vitro and in Chromosomal aberrations studies (cont..)	
6.	In vitro and in Chromosomal aberrations studies	
Unit-4		**12**
1.	IND enabling studies (IND studies)- Definition of IND, importance of IND	
2.	Industry perspectives of IND	
3.	List of studies needed for IND submission.	
4.	Safety pharmacology studies- origin and concepts	
5.	Safety pharmacology studies- importance of safety pharmacology. (cont..)	
6.	Safety pharmacology studies- importance of safety pharmacology	
7.	Tier1- CVS, CNS and respiratory safety pharmacology (cont..)	
8.	Tier1- CVS, CNS and respiratory safety pharmacology	
9.	HERG assay. (cont..)	
10.	HERG assay.	
11.	Tier2- GI, renal and other studies(cont..)	
12.	Tier2- GI, renal and other studies	
Unit-5.		**12**
1.	Toxicokinetics- Toxicokinetic evaluation in preclinical studies (cont..)	
2.	Toxicokinetics- Toxicokinetic evaluation in preclinical studies (cont..)	
3.	Toxicokinetics- Toxicokinetic evaluation in preclinical studies (cont..)	
4.	Toxicokinetics- Toxicokinetic evaluation in preclinical studies	
5.	Saturation kinetics (cont..)	
6.	Saturation kinetics	
7.	Importance and applications of toxicokinetic studies (cont..)	

8.	Importance and applications of toxicokinetic studies (cont..)	
9.	Importance and applications of toxicokinetic studies	
10.	Alternative methods to animal toxicity testing (cont..)	
11.	Alternative methods to animal toxicity testing (cont..)	
12.	Alternative methods to animal toxicity testing	
	Activity-1	
	Activity-2	
	Activity-3	

TEXBOOKS

1. Hand book on GLP, Quality practices for regulated non-clinical research and development http://www.who.int/tdr/publications/documents/glphandbook. pdf
2. Schedule Y Guideline: drugs and cosmetics (second amendment) rules, 2005, ministry of health and family welfare (department of health) New Delhi
3. Drugs from discovery to approval by Rick NG.
4. Animal Models in Toxicology, 3rd Edition, Lower and Bryan
5. Principles of toxicology by Karen E. Stine, Thomas M. Brown.

REFERENCE BOOKS

1. OECD test guidelines.(http://www.oecd..org)
2. Guidance for Industry M3(R2) Nonclinical Safety Studies for the Conduct of Human Clinical Trials and Marketing Authorization for Pharmaceuticals (http://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinform
3. ation/guidances/ucm073246.pdf)

Name of the Subject	**Principles of Drug Discovery**
Name of the Faculty	Dr. Praveen TK M.Pharm., Ph.D
Designation, Department	Professor and Head, Department of Pharmacology
Mobile Number	9952593850
e-Mail i.d.	praveentk@jssuni.edu.in

Scope, Course Objectives and Course Outcomes

SCOPE

The subject imparts basic knowledge of drug discovery process. This information will make the student competent in drug discovery process

OBJECTIVES

The primary goals of this course are to

1. Understand the various stages of drug discovery.
2. Appreciate the importance of the role of genomics, proteomics and bioinformatics tools in drug discovery
3. Understand various stages of drug discovery.
4. Understand various lead seeking method and lead optimization methods
5. Appreciate the importance of the role of computer-aided drug design in drug discovery

COURSE OUTCOMES (COS)

After this course, it is expected that the students will be able to;

CO 1: Describe the stages of the drug discovery process and appreciate the importance of proteomic, genomic and bioinformatic tools

CO 2: Summarize the levels of protein structure and understand the importance of NMR, X-ray crystallography and homology modeling in protein structure prediction

CO 3: Explain the importance of rational drug design and appreciate the importance of molecular docking, QSAR, De nono drug design, Drug like screening,

CO 4: Explain the concept of prodrug design and its applications

LECTURE PLAN

Sessional	No. of Hours of Didactic Lecture	No of Hours of other Activities	Total No. of Lecture Hours
I	30	03	33
II	30	03	33
Total No. of Hours	60	06	66

I SESSIONAL: 30 Lectures + 3 Activities

Lecture No.	Lecture Details	Hours
Unit-1 An overview of modern drug discovery process and Target Discovery and validation		**12**
	Orientation to the subject	
1.	Target validation	
2.	Target identification	
3.	Lead identification and lead Optimization	
4.	Economics of drug discovery	
5.	Role of Genomics, Proteomics and Bioinformatics (cont..)	
6.	Role of Genomics, Proteomics and Bioinformatics	
7.	Role of Nucleic acid microarrays	
8.	Protein microarrays	
9.	Antisense technologies	
10.	siRNAs, antisense oligonucleotides	
11.	Zinc finger proteins	
12.	Role of transgenic animals in target validation	
Unit-2 Lead Identification and Protein structure		**12**
1.	Combinatorial chemistry	
2.	High throughput screening (cont..)	
3.	High throughput screening	
4.	In silico lead discovery techniques	
5.	Assay development for hit identification	
6.	Protein structure	
7.	Levels of protein structure	
8.	Domains, motifs, folds in protein structure	
9.	Computational prediction of protein structure	
10.	Threading and homology modeling methods	
11.	Application of NMR and X-ray crystallography in protein structure prediction (cont..)	
12.	Application of NMR and X-ray crystallography in protein structure prediction	
Unit-3 Rational Drug Design		**06**
1.	Traditional vs rational drug design,	
2.	Methods followed in traditional drug design	
3.	High throughput screening	
4.	Concepts of Rational Drug Design	
5.	Rational Drug Design Methods: Structure and Pharmacophore based approaches (cont..)	

6.	Rational Drug Design Methods: Structure and Pharmacophore based approaches	
	Activity-1	
	Activity-2	
	Activity-3	

I SESSIONAL: 30 Lectures + 3 Activities

Lecture No.	Lecture Details	Hours
Unit-3 Rational Drug Design		**06**
1.	Virtual Screening techniques	
2.	Drug likeness screening	
3.	Concept of pharmacophore mapping (cont..)	
4.	Concept of pharmacophore mapping	
5.	Pharmacophore based screening (cont..)	
6.	Pharmacophore based screening	
Unit-4 Molecular docking and Quantitative analysis of Structure Activity Relationship		**12**
1.	Rigid docking	
2.	Flexible docking	
3.	Manual docking	
4.	Docking based screening	
5.	De novo drug design.	
6.	History and development of QSAR (cont..)	
7.	History and development of QSAR	
8.	SAR versus QSAR	
9.	Physicochemical parameters (cont..)	
10.	Physicochemical parameters	
11.	Hansch analysis	
12.	Fee Wilson analysis and relationship between them.	
Unit-5 QSAR Statistical methods and Prodrug design		**12**
1.	QSAR Statistical methods	
2.	Regression analysis,	
3.	Partial least square analysis (PLS)	
4.	Other multivariate statistical methods	
5.	3D-QSAR approaches like COMFA and COMSIA (cont..)	
6.	3D-QSAR approaches like COMFA and COMSIA	
7.	Prodrug design-Basic concept	
8.	Prodrugs to improve patient acceptability	
9.	Drug solubility	
10.	Drug absorption and distribution site	
11.	specific drug delivery and sustained drug action	
12.	Rationale of prodrug design and practical consideration of prodrug design	
	Activity-1	
	Activity-2	
	Activity-3	

TEXT BOOKS

1. MouldySioud. Target Discovery and Validation Reviews and Protocols: Volume 2 Emerging Molecular Targetsand Treatment Options. 2007 Humana Press Inc.
2. Darryl León. Scott MarkelIn. Silico Technologies in Drug Target Identification and Validation. 2006 by Taylor and Francis Group, LLC.
3. Johanna K. DiStefano. Disease Gene Identification. Methods and Protocols. Springer New York Dordrecht Heidelberg London.
4. Hugo Kubiny. QSAR: Hansch Analysis and Related Approaches. Methods and Principles in Medicinal Chemistry. Publisher Wiley-VCH

REFERNCE BOOKS

1. Klaus Gubernator, Hans-Joachim Böhm. Structure-Based Ligand Design. Methods and Principles in Medicinal Chemistry. Publisher Wiley-VCH
2. Abby L . Parrill. M . Rami Reddy. Rational Drug Design. Novel Methodology and Practical Applications. ACS Symposium Series; American Chemical Society: Washington, DC, 1999.
3. J. Rick Turner. New drug development design, methodology and, analysis. John Wiley & Sons, Inc., New Jersey.

Name of the Subject	**Clinical Research & Pharmacovigilance (Theory)**
Name of the Faculty	Dr. Suresh K. Mohankumar M.Pharm., Ph.D
Designation, Department	Professor, Department of Pharmacology
Mobile Number	8903451179
e-Mail i.d.	suresh.jsscpo@jssuni.edu.in

Scope, Course Objectives and Course Outcomes

SCOPE

This subject will provide a value addition and current requirement for the students in clinical research and pharmacovigilance. This subject also focuses on global scenario of Pharmacovigilance in different methods that can be used to generate safety data.

OBJECTIVES

The course intend to deliver the following objectives

- Teach the students on conceptualizing, designining, conducting, managing and reporting of clinical trials
- Teach the students in developing safety data in pre-clinical, clinical phases of drug development and post market surveillance.

COURSE OUTCOMES (COS)

At completion of this course it is expected that the students will be able to

CO 1 : Explain the regulatory requirement for conducting clinical trial
CO 2 : Demnostrate the types of clinical trial designs
CO 3 : Explain the responsibilities of key players involved in clinical trials
CO 4: Execute safety monitoring, reporting and close-out activities
CO 5 : Explain the priniciple of pharmacovigilance
CO 6: Detect adverse drug reactions and their assessment
CO7: Perform the adverse drug reaction reporting system and communication in pharmacovigilance

LECTURE PLAN – Abstract

Sessional	No. of Hours of Didactic Lecture	No of Hours of other Activities	Total No. of Lecture Hours
I	30	06	36
II	19	05	24
Total No. of Hours	49	11	60

I SESSIONAL: 32 Lectures + 4 Activities

Lecture No.	Lecture Details	Hours
Unit-1 Regulatory Perspectives of Clinical Trials		**12**
	Welcome and Intro to Course	
1.	Origin and History of ICH	
2.	Ethical Guidelines for Human Participation	
3.	GCP	
4.	ICMR- Human ethics	
5.	Schedule Y	
6.	Informed consent-1	
7.	Informed-consent-2	
8.	Informed Consent 3	
9.	Coursework/Assignment/Activity/Revision	
10.	Coursework/Assignment/Activity/Revision	
11.	Coursework/Assignment/Activity/Revision	
12.	Coursework/Assignment/Activity/Revision	
Unit-2 Clinical Trial Types & Design		**12**
1.	Clinical Trial-Phases	
2.	Types of Clinical Trials	
3.	Experimental-RCT	
4.	Experimental- Non-RCT	
5.	Observational- Cohort	
6.	Observational- Case control	
7.	Observational- Cross sectional	
8.	Clinical Trial Study Team- Sponsor	
9.	Clinical Trial Study Team- Investigator	
10.	Clinical Trial Study Team- Study Coordiantor	
11.	Clinical Trial Study Team- CRO	
12.	Coursework/Assignment/Activity/Revision	
Unit-3 Clinical Trial Documentation		**12**
1.	Guidline to prepare Clinical Trial Documents	
2.	Protocol	
3.	Investigators Brochure	
4.	Case Report Forms	
5.	Clinical Study Report	
6.	Clinical Study Saftey Monitoring	
7.	Adverse Drug Reaction: Types	
8.	ADR Detection and Report methods	

9.	Severity and seriousness assessment	
10.	Predict and Prevent assessment ADR	
11.	Management of ADR	
12.	Coursework/Assignment/Activity/Revision	

II SESSIONAL: 19 Lectures + 5 Activities

Lecture No.	Lecture Details	Hours
Unit- 4 Pharmacovigilance		
1.	History and Progress of Pharmacovigilance	**12**
2.	Significance of Safety Monitoring	
3.	Pharmacovigilance in India and International	
4.	WHO drug monitoring program	
5.	WHO and regulatory terminologies of ADR	
6.	Evaluation of medication safety	
7.	Pharmacovigilance Centres, national and international	
8.	Pharmacovigilance in India	
9.	Governance of PVPI	
10.	Coursework/Assignment/Activity/Revision	
11.	Coursework/Assignment/Activity/Revision	
12.	Coursework/Assignment/Activity/Revision	
Unit-5	**Methods ADR Reporting.**	
1.	ADR Repoting	**12**
2.	Active surveillance	
3.	Passive surveillance	
4.	Tools used in ADR reporting	
5.	Vaccine Surveillance	
6.	ADR analysis and interpration	
7.	Pharmacoepidemiology	
8.	Pharmacoeconomics	
9.	Pharmacogenomics	
10.	Safety Pharmacology	
11.	Coursework/Assignment/Activity/Revision	
12.	Coursework/Assignment/Activity/Revision	

TEXT BOOKS & REFERENCES

1. Central Drugs Standard Control Organization- Good Clinical Practices, Guidelines for Clinical Trials on Pharmaceutical Products in India. New Delhi. Ministry of Health; 2001
2. International Conference on Harmonization of Technical requirement for Technical requirements for registration of pharmaceuticals for human use. ICH Harmonized Tripartite Guideline. Guideline for Good Clinical Practice E6; May 1996
3. Ethical Guidelines for Biomedical Research on Human Subjects 2000. Indian Council of Medical Research, New Delhi
4. Textbook of Clinical Trials edited by David Machin, Simon Day and Sylvan Green, March 2005, John Wiley and Sons.
5. Clinical Data Management edited by R K Rondels, S A Varley, C F Webb. Jan 2000, John Wiley and Sons.

6. Handbook of Clinical Research. Julia Loyd and Ann Raven. Ed Churchill Livingstone
7. Principles of Clinical Research edited by Govanna dl Ignazio, Di Giovanna and Hayenes

Name of the Subject	**Pharmacology Practical - II**
Name of the Faculty	Dr. Praveen TK M.Pharm., Ph.D
Designation, Department	Professor and Head, Department of Pharmacology
Mobile Number	9952593850
e-Mail i.d.	praveentk@jssuni.edu.in

Scope, Course Objectives, and Course Outcomes

SCOPE

This subject is designed to impart the practical training with respect to carrying out *in silico* drug design, bioassays using isolated tissues and simulation experiments, preclinical safety and efficacy studies, protocol design for clinical trials.

OBJECTIVES

The primary objectives of this course are to

- Learn basic practical techniques required to carry out bioassays
- Learn CADD methods for in silico designing and screening of drugs
- Understand the practical aspects of preclinical safety studies
- Understand clinical trial protocol design

COURSE OUTCOMES (COS)

At completion of this course it is expected that the students will be able to

CO 1: Demonstrate practical skills required to identify and isolate tissues from whole animal and to carry out bioassay using them

CO 2: Demonstrate ability to use various CADD software's to carry out in silico drug design and screening

CO 3: Demonstrate skills required to interpret bioassay and in silico results

CO 4: Demonstrate skills required for designing clinical protocols

PRACTICAL PLAN – Abstract

Sessional	No. of Practicals	No of Hours of Practicals (Each Practical 04 Hrs)	Total No. of Practical Hours
I	12	48	48
II	13	52	52
Total No. of Hours	100	-	100

I SESSIONAL: 12 Practicals

Practical No.	Practical Details	Hours
	Orientation to the subject	48
1.	To record the DRC of agonist using suitable isolated tissues preparation.	
2.	To study the effects of antagonist/potentiating agents on DRC of agonist using suitable isolated tissue preparation	
3.	To study the effects of antagonist/potentiating agents on DRC of agonist using suitable isolated tissue preparation (cont..)	
4.	To determine to the strength of unknown sample by matching bioassay by using suitable tissue preparation	
5.	To determine to the strength of unknown sample by interpolation bioassay by using suitable tissue preparation	
6.	To determine to the strength of unknown sample by bracketing bioassay by using suitable tissue preparation	
7.	To determine to the strength of unknown sample by multiple point bioassay by using suitable tissue preparation	
8.	Estimation of PA2 values of various antagonists using suitable isolated tissue preparations.	
9.	To study the effects of various drugs on isolated heart preparations (cont..)	
10.	To study the effects of various drugs on isolated heart preparations	
11.	Recording of rat BP, heart rate and ECG.	
12.	Recording of rat BP, heart rate and ECG	

II SESSIONAL: 13 Practicals

Practical No.	Practical Details	Hours
1.	Drug absorption studies by averted rat ileum preparation	52
2.	Acute oral toxicity studies as per OECD guidelines	
3.	Acute dermal toxicity studies as per OECD guidelines	

4.	Repeated dose toxicity studies (cont..)	
5.	Repeated dose toxicity studies	
6.	Drug mutagenicity study using mice bone-marrow chromosomal aberration test.	
7.	Protocol design for clinical trial(cont..)	
8.	Protocol design for clinical trial	
9.	Design of ADR monitoring protocol.	
10.	In-silico docking studies	
11.	In-silico pharmacophore-based screening	
12.	In-silico QSAR studies.	
13.	ADR reporting	

TEXT BOOKS

1. Fundamentals of experimental Pharmacology-by M.N.Ghosh
2. Hand book of Experimental Pharmacology-S.K.Kulakarni
3. Text book of in-vitro practical Pharmacology by Ian Kitchen
4. Bioassay Techniques for Drug Development by Atta-ur-Rahman, Iqbal choudhary and William Thomsen

REFERENCE BOOKS

1. Applied biopharmaceutics and Pharmacokinetics by Leon Shargel and Andrew B.C.Yu. Handbook of Essential Pharmacokinetics, Pharmacodynamics and Drug Metabolism for Industrial Scientists.

JSS Academy of Higher Education & Research, Mysuru
JSS College of Pharmacy, Rocklands, Ooty

I M. PHARMACY TIME TABLE FOR E-LEARN CLASSES : I Semester (AY : 2020 - 2021)

DEPARTMENT : Department of Pharmacology
COURSE : M. Pharm., Pharmacology

ZOOM / GOOGLE MEET LICENSE -

Days	9 - 10 am	10 - 11 am	11 - 12 am	12 - 1 pm	1 - 2 pm	2 - 3 pm	3 - 4 pm	4 - 5 pm
Mon	*CMP* ***(PTK)***	MPAT ***(NKV)***	AP-I **(SKM)**	PTSM-I **(VR)**	**LUNCH BREAK**	Seminar/Assignment	Library	
Tue	*CMP* ***(PTK)***	MPAT ***(NKV)***	AP-I **(SKM)**	PTSM-I **(VR)**		Seminar/Assignment	Library	
Wed	*CMP* ***(PTK)***	MPAT ***(NKV)***	AP-I **(SKM)**	PTSM-I **(VR)**		Seminar/Assignment	Library	
Thu	*CMP* ***(PTK)***	MPAT ***(NKV)***	AP-I **(SKM)**	PTSM-I **(VR)**		Seminar/Assignment	Library	
Fri		Seminar/Assignment				Seminar/Assignment	Library	
Sat		Seminar/Assignment						

Subjects : I M.Pharm (Pharmacology)
1. Modern Pharmaceutical Analytical Techniques (**MPAT**) : Dr. N. Krishna veni (**NKV**)
2. Cellular and molecular pharmacology (**CMP**): Dr. Praveen TK (**PTK**)
3. Advanced Pharmacology-I (**AP**-I): Dr. Suresh Kumar M (**SKM**)
4. Pharmacological & Toxicological Screening Methods-I (**PTSM**-I) Dr. Vadivelam R (**VR**)

JSS Academy of Higher Education & Research, Mysuru
(Deemed to be University)
Accredited 'A' Grade by NAAC
JSS COLLEGE OF PHARMACY, OOTACAMUND
(***An ISO 9001:2015 Certified Institution***)

M.Pharmacy-II Semester (Academic Year 2019 - 2020)

Days	**09.00-10.am**	**10.00-11 am**	**11.00-12 noon**	**12.00-01.00 pm**	**1.00-2.00 Pm - Lunch break**	**02.00-03.00 pm**	**03.00 – 04.00 pm**	**04.00 – 05.00 pm**
Monday	*Library*	Pharmacology-II (P) ***(PTK)***				CRP ***(SKM)***	AP- II ***(PRA)***	PTSM-II ***(RV)***
Tuesday	*Library*	Pharmacology-II (P) ***(PTK)***				PTSM-II ***(RV)***	CRP ***(SKM)***	AP-II ***(PRA)***
Wednesday	*Library*	Seminar/ Assignment	CRP ***(SKM)***	CRP ***(SKM)***		Seminar/ Assignment	Seminar/ Assignment	PDD ***(TKP)***
Thursday	Seminar/ Assignment	Pharmacology-II (P) ***(TKP)***				PTSM-II ***(RV)***	PDD ***(TKP)***	AP- II ***(PRA)***
Friday	Seminar/ Assignment	Pharmacology-II (P) ***(TKP)***				PDD ***(TKP)***	Seminar/ Assignment	Seminar/ Assignment
Saturday	*Library*	PDD (T) ***(TKP)***	PTSM-II ***(RV)***	AP- II ***(PRA)***		-		

Dr T K Praveen (TKP) Professor : Principles of Drug Discovery : (PDD) - T
Dr.R.Vadivelan (RV) Professor : Pharmacological Toxicological Screening Methods-II : (PTSM-II) - T
Dr.P R Anand Vijayakumar (PRA) Professor : Advanced Pharmacology -II : (AP-II) - T
Dr.M Suresh Kumar (SKM) Professor : Clinical Research & Pharmacovigilance : (CRP) - T
Pharmacology Practical -II (P) - (TKP.)

M. PHARM
PHARMACOGNOSY

SYLLABUS
SEMESTER I
MPG 101T-MODERN PHARMACEUTICAL ANALYTICAL TECHNIQUES (Theory)

SCOPE

This subject deals with various advanced analytical instrumental techniques for identification, characterization and quantification of drugs. Instruments dealt are NMR, Mass spectrometer, IR, HPLC, GC etc.

OBJECTIVES

After completion of course student is able to know about chemicals and excipients

- The analysis of various drugs in single and combination dosage forms
- Theoretical and practical skills of the instruments

Course Content:

THEORY	**60 Hrs**
1. a. UV-Visible spectroscopy: Introduction, Theory, Laws, Instrumentation associated with UV-Visible spectroscopy, Choice of solvents and solvent effect and Applications of UV-Visible spectroscopy, Difference/ Derivative spectroscopy. b. IR spectroscopy: Theory, Modes of Molecular vibrations, Sample handling, Instrumentation of Dispersive and Fourier - Transform IR Spectrometer, Factors affecting vibrational frequencies and Applications of IR spectroscopy, Data Interpretation. c. Spectroflourimetry: Theory of Fluorescence, Factors affecting fluorescence (Characterestics of drugs that can be analysed by flourimetry), Quenchers, Instrumentation and Applications of fluorescence spectrophotometer. d. Flame emission spectroscopy and Atomic absorption spectroscopy: Principle, Instrumentation, Interferences and Applications.	12 Hrs
2 NMR spectroscopy: Quantum numbers and their role in NMR, Principle, Instrumentation, Solvent requirement in NMR, Relaxation process, NMR signals in various compounds, Chemical shift, Factors influencing chemical shift, Spin-Spin coupling, Coupling constant, Nuclear magnetic double resonance, Brief outline of principles of FT-NMR and 13C NMR. Applications of NMR spectroscopy.	12 Hrs
3. Mass Spectroscopy: Principle, Theory, Instrumentation of Mass Spectroscopy, Different types of ionization like electron impact, chemical, field, FAB and MALDI, APCI, ESI, APPI Analyzers of Quadrupole and Time of Flight, Mass fragmentation and its rules, Meta stable ions, Isotopic peaks and Applications of Mass spectroscopy.	12 Hrs
4. Chromatography: Principle, apparatus, instrumentation, chromatographic parameters, factors affecting resolution, isolation of drug from excipients, data interpretation and applications of the following: • Thin Layer chromatography • High Performance Thin Layer Chromatography • Ion exchange chromatography • Column chromatography • Gas chromatography • High Performance Liquid chromatography	12 Hrs

• Ultra High Performance Liquid chromatography • Affinity chromatography • Gel Chromatography	
5. a. Electrophoresis: Principle, Instrumentation, Working conditions, factors affecting separation and applications of the following: a) Paper electrophoresis b) Gel electrophoresis c) Capillary electrophoresis d) Zone electrophoresis e) Moving boundary electrophoresis f) Iso electric focusing b. X ray Crystallography: Production of X rays, Different X ray methods, Bragg's law, Rotating crystal technique, X ray powder technique, Types of crystals and applications of X-ray diffraction.	12 Hrs
a. Potentiometry: Principle, working, Ion selective Electrodes and Application of potentiometry. b. Thermal Techniques: Principle, thermal transitions and Instrumentation (Heat flux and power-compensation and designs), Modulated DSC, Hyper DSC, experimental parameters (sample preparation, experimental conditions, calibration, heating and cooling rates, resolution, source of errors) and their influence, advantage and disadvantages, pharmaceutical applications. Differential Thermal Analysis (DTA): Principle, instrumentation and advantage and disadvantages, pharmaceutical applications, derivative differential thermal analysis (DDTA). TGA: Principle, instrumentation, factors affecting results, advantage and disadvantages, pharmaceutical applications.	12 Hrs

REFERENCES

1. Spectrometric Identification of Organic compounds - Robert M Silverstein, Sixth edition, John Wiley & Sons, 2004.
2. Principles of Instrumental Analysis - Doglas A Skoog, F. James Holler, Timothy A. Nieman, 5th edition, Eastern press, Bangalore, 1998.
3. Instrumental methods of analysis – Willards, 7th edition, CBS publishers.
4. Practical Pharmaceutical Chemistry – Beckett and Stenlake, Vol II, 4th edition, CBS Publishers, New Delhi, 1997.
5. Organic Spectroscopy - William Kemp, 3rd edition, ELBS, 1991.
6. Quantitative Analysis of Drugs in Pharmaceutical formulation - P D Sethi, 3rd Edition, CBS Publishers, New Delhi, 1997.
7. Pharmaceutical Analysis - Modern Methods – Part B - J W Munson, Vol 11, Marcel. Dekker Series
8. Spectroscopy of Organic Compounds, 2nd edn., P.S/Kalsi, Wiley estern Ltd., Delhi.
9. Textbook of Pharmaceutical Analysis, KA.Connors, 3rd Edition, John Wiley & Sons, 1982.
10. Textbook of Pharmaceutical Analysis, KA.Connors, 3rd Edition, John Wiley & Sons, 1982.

MPG 102T-ADVANCED PHARMACOGNOSY I (Theory)

SCOPE

To learn and understand the advances in the field of cultivation and isolation of drugs of natural origin, various phytopharmaceuticals, nutraceuticals and their medicinal use and health benefits.

OBJECTIVES

At completion of this course it is expected that students will be able to understand-

- Advances in the cultivation and production of drugs.
- Various phyto-pharmaceuticals and their source, its utilization and medicinal value.
- Various nutraceuticals/herbs and their health benefits.
- Drugs of marine origin.
- Pharmacovigilance of drugs of natural origin.

Course Content:

THEORY **60 Hrs**

1. Plant drug cultivation: General introduction to the importance of Pharmacognosy in herbal drug industry, Indian Council of Agricultural Research, Current Good Agricultural Practices, Current Good Cultivation Practices, Current Good Collection Practices, Conservation of medicinal plants- Ex-situ and In- situ conservation of medicinal plants.	12 Hrs
2. Marine natural products: General methods of isolation and purification, Study of Marine toxins, Recent advances in research in marine drugs, Problems faced in research on marine drugs such as taxonomical identification, chemical screening and their solution.	12 Hrs
3. Nutraceuticals: Current trends and future scope, Inorganic mineral supplements, Vitamin supplements, Digestive enzymes, Dietary fibres, Cereals and grains, Health drinks of natural origin, Antioxidants, Polyunsaturated fatty acids, Herbs as functional foods, Formulation and standardization of neutraceuticals, Regulatory aspects, FSSAI guidelines, Sources, name of marker compounds and their chemical nature, medicinal uses and health benefits of following i) Spirulina ii) Soya bean iii) Ginseng iv) Garlic v) Broccoli vi) Green and Herbal Tea vii) Flax seeds viii) Black cohosh ix) Turmeric.	12 Hrs
4. Phytopharmaceuticals: Occurrence, isolation and characteristic features (Chemical nature, uses in pharmacy, medicinal and health benefits) of following. a Carotenoids – i) α and β - Carotene ii) Xanthophyll (Lutein) b Limonoids – i) d-Limonene ii) α – Terpineol c Saponins – i) Shatavarins d Flavonoids – i) Resveratrol ii) Rutin iii) Hesperidin iv) **Naringin v) Quercetin** e Phenolic acids- Ellagic acid	12 Hrs

f Vitamins g Tocotrienols and Tocopherols h Andrographolide, Glycolipids, Gugulipids, Withanolides, Vascine, Taxol i Miscellaneous	
5. Pharmacovigilance of drugs of natural origin: WHO and AYUSH guidelines for safety monitoring of natural medicine, Spontaneous reporting schemes for biodrug adverse reactions, bio drug-drug and bio drug-food interactions with suitable examples	12 Hrs
6. Regulatory Compliance through Quality Management and development of Quality Culture Benchmarking: Definition of benchmarking, Reasons for benchmarking, Types of Benchmarking, Benchmarking process, Advantages of benchmarking, Limitations of benchmarking.	12 Hrs

REFERENCES (Latest Editions of)

1. Pharmacognosy - G. E. Trease and W.C. Evans. Saunders Edinburgh, New York.
2. Pharmacognosy-Tyler, Brady, Robbers
3. Modem Methods of Plant Analysis- Peach & M.V. Tracey, Vol. I&II
4. Text Book of Pharmacognosy by T.E. Wallis
5. Marine Natural Products-Vol.I to IV.
6. Natural products: A lab guide by Raphael Ikan , Academic Press 1991.
7. Glimpses of Indian Ethano Pharmacology, P. Pushpangadam. Ulf Nyman. V.George Tropical Botanic Garden & Research Institute, 1995.
8. Medicinal natural products (a biosynthetic approach), Paul M. Dewick, John Wiley & Sons Ltd., England, 1998.
9. Chemistry of Marine Natural Products- Paul J. Schewer 1973.
10. Herbal Drug Industry by RD. Choudhary, Eastern Publisher, New Delhi, 1996.
11. Cultivation of Medicinal Plants by C.K. Atal & B.M. Kapoor.
12. Cultivation and Utilization of Aromatic Plants, C.K. Atal & B.M. Kapoor
13. Cultivation of medicinal and aromatic crops, AA Farooqui and B.S. Sreeramu. University Press, 2001.
14. Natural Products from Plants, 1st edition, by Peter B. Kaufman, CRC Press, New York, 1998
15. Recent Advances in Phytochemistry- Vol. 1&4: Scikel Runeckles- Appleton
16. Century crofts.
17. Text book of Pharmacognosy, C.K.Kokate, Purohit, Ghokhale, Nirali Prakasshan, 1996.
18. Pharmacognosy and Pharmacobiotechnology, Ashutoshkar, New Age Publications, New Delhi.

MPG 103T-PHYTOCHEMISTRY (Theory)

SCOPE

Students shall be equipped with the knowledge of natural product drug discovery and will be able to isolate, identify and extract and the phyto- constituents

OBJECTIVES

- Different classes of phytoconstituents, their biosynthetic pathways, their properties, extraction and general process of natural product drug discovery**.**
- Phytochemical fingerprinting and structure elucidation of phytoconstituents.

Course Content:

THEORY	**60 Hrs**
1 Biosynthetic pathways and Radio tracing techniques: Constituents & their Biosynthesis, Isolation, Characterization and purification with a special reference to their importance in herbal industries offollowingphyto-pharmaceuticals containing drugs: a) Alkaloids: Ephedrine, Quinine, Strychynine, Piperine, Berberine, Taxol, Vinca alkoloids. b) Glycosides: Digitoxin, Glycyrrhizin, Sennosides, Bacosides, Quercitin. c) Steroids: Hecogenin, guggulosterone and withanolides d) Coumarin: Umbelliferone. e) Terpenoids: Cucurbitacins	12 Hrs
2 Drug discovery and development: History of herbs as source of drugs and drug discovery, the lead structure selection process, structure development, product discovery process and drug registration, Selection and optimization of lead compounds with suitable examples from the following source : artemesin, andrographolides. Clinical studies emphasising on phases of clinical trials, protocol design for lead molecules.	12 Hrs
3. Extraction and Phytochemical studies: Recent advances in extractions with emphasis on selection of method and choice of solvent for extraction, successive and exhaustive extraction and other methods of extraction commonly used like microwave assisted extraction, Methods of fractionation. Separation of phytoconstituents by latest CCCET, SCFE techniques including preparative HPLC and Flash column chromatography.	12 Hrs
4. Phytochemical finger printing: HPTLC and LCMS/GCMS applications in the characterization of herbal extracts. Structure elucidation of phytoconstituents.	12 Hrs

5. Structure elucidation of the following compounds by spectroscopic techniques like UV, IR, MS, NMR (1H, 13C) a. Carvone, Citral, Menthol b. Luteolin, Kaempferol c. Nicotine, Caffeine iv) Glycyrrhizin.	12 Hrs

REFERENCES (Latest Editions of)

1. Organic chemistry by I.L. Finar Vol.II
2. Pharmacognosy by Trease and Evans, ELBS.
3. Pharmacognosy by Tylor and Brady.
4. Text book of Pharmacognosy by Wallis.
5. Clark's isolation and Identification of drugs by A.C. Mottal.
6. Plant Drug Analysis by Wagner & Bladt.
7. Wilson and Gisvolds text book of Organic Medicinnal and Pharmaceutical Chemistry by Deorge. R.F.
8. The Chemistry of Natural Products, Edited by R.H. Thomson, Springer International Edn. 1994.
9. Natural Products Chemistry Practical Manual by Anees A Siddiqui and SeemiSiddiqui
10. Organic Chemistry of Natural Products, Vol. 1&2. Gurdeep R Chatwal.
11. Chemistry of Natural Products- Vol. 1 onwards IWPAC.
12. Modem Methods of Plant Analysis- Peach & M.V. Tracey, Vol. I&II
13. Medicinal Natural products – a biosynthetic approach, Dewick PM, John Wiley & Sons, Toronto, 1998.
14. Chemistry of Natural Products, Bhat SV, Nagasampagi BA, Meenakshi S, Narosa Publishing House, New Delhi.
15. Pharmacognosy & Phytochemistry of Medicinal Plants, 2nd edition,
16. Bruneton J, Interceptt Ltd., New York, 1999.

MPG 104T- INDUSTRIAL PHARMACOGNOSTICAL TECHNOLOGY (Theory)

SCOPE

To understand the industrial and commercial potential of drugs of natural origin, integrate traditional Indian systems of medicine with modern medicine and also to know regulatory and quality policy of the trade of herbal and drugs of natural origin.

OBJECTIVES

Upon completion of this course the student should be able to

- Orientate the potentials, challenges and opportunities of Herbal Indutries both national and International
- Teach regulatory and technical requirments of herbal industry
- Teach various monographs used for standardisation of herbals and derived products
- Teach various analytical testing methods for herbal products
- Introduce the concepts of intellectual protection and patents specific to herbal drugs and products.

Course Content:

THEORY	**60 Hrs**
1. Herbal drug industry: Infrastructure of herbal drug industry involved in production of standardized extracts and various dosage forms. Current challenges in upgrading and modernization of herbal formulations. Entrepreneurship Development, Project selection, project report, technical knowledge, Capital venture, plant design, layout and construction. Pilot plant scale –up techniques, case studies of herbal extracts. Formulation and production management of herbals.	12 Hrs
2. Regulatory requirements for setting herbal drug industry: Globamarketing management. Indian and international patent law as applicable herbal drugs and natural products. Export - Import (EXIM) policy, TRIPS. Quality assurance in herbal/natural drug products. Concepts of TQM, GMP, GLP, ISO-9000.	12 Hrs
3. Monographs of herbal drugs: General parameters of monographs of herbal drugs andcomparative study in IP, USP, Ayurvedic Pharmacopoeia, Siddha and Unani Pharmacopoeia, American herbal pharmacopoeia, British herbal pharmacopoeia, WHO guidelines in quality assessment of herbal drugs.	12 Hrs
4. Testing of natural products and drugs: Herbal medicines - clinical laboratory testing. Stability testing of natural products, protocols.	12 Hrs

5. Patents: Indian and international patent laws, proposed amendments as applicable to herbal/natural products and process. Geographical indication, Copyright, Patentable subject maters, novelty, non obviousness, utility, enablement and best mode, procedure for Indian patent filing, patent processing, grant of patents, rights of patents, cases of patents, opposition and revocation of patents, patent search and literature, Controllers of patents.	12 Hrs

REFERENCES (Latest Editions of)

1. Herbal drug industry by R.D. Choudhary (1996), Eastern Publisher, New Delhi.
2. GMP for Botanicals - Regulatory and Quality issues on Phytomedicine by Pulok K Mukharjee (2003), Ist Edition, Business horizons Robert Verpoorte, New Delhi.
3. Quality control of herbal drugs by Pulok K Mukarjee (2002), Business Horizons Pharmaceutical Publisher, New Delhi.
4. PDR for Herbal Medicines (2000), Medicinal Economic Company, New **J**ersey.
5. Indian Herbal Pharmacopoeia (2002), IDMA, Mumbai.
6. Text book of Pharmacognosy by C.K. Kokate, Purohit, Gokhlae (1996), Nirali Prakashan, New Delhi.
7. Text book of Pharmacognosy and Phytochemistry by Vinod D. RangarI (2002), Part I & II, Career Publication, Nasik, India.
8. Plant drug analysis by H.Wagner and S.Bladt, Springer, Berlin.
9. Standardization of Botanicals. Testing and extraction methods of medicinal herbs by V. Rajpal (2004), Vol.I, Eastern Publisher, New Delhi.
10. Phytochemical Dictionary. Handbook of Bioactive Compounds from Plants by **J**.B.Harborne, (1999), IInd **E**dition, Taylor and Francis Ltd, UK.
11. Herbal Medicine. Expanded Commission E Monographs by M.Blumenthal, (2004), IST Edition,
12. Drug Formulation Manual by D.P.S.Kohli and D.H.Shah (1998), Eastern Publisher, New Delhi.

MPG I05P- PHARMACOGNOSY PRACTICAL – I (Practicals)

1. Analysis of Pharmacopoeial compounds of natural origin and their formulations by UV Vis spectrophotometer
2. Analysis of recorded spectra of simple phytoconstituents
3. Experiments based on Gas Chromatography
4. Estimation of sodium/potassium by flame photometry
5. Development of fingerprint of selected medicinal plant extracts commonly used in herbal drug industry viz. Ashwagandha, Tulsi, Bael, Amla, Ginger, Aloe, Vidang, Senna, Lawsonia by TLC/HPTLC method.
6. Methods of extraction
7. Phytochemical screening
8. Demonstration of HPLC- estimation of glycerrhizin
9. Monograph analysis of clove oil
10. Monograph analysis of castor oil.
11. Identification of bioactive constituents from plant extracts
12. Formulation of different dosage forms and their standardisation.

SEMESTER II

MPG 201T- MEDICINAL PLANT BIOTECHNOLOGY (Theory)

SCOPE

To explore the knowledge of Biotechnology and the application in the improvement of quality of medicinal plants

OBJECTIVES

At completion of this course it is expected that students will be able to

- Know the process like genetic engineering in medicinalplants for higher yield of Phytopharmaceuticals
- Use the biotechnological techniques for obtaining and improving the quality of natural Products/medicinal plants.

Course Content:

THEORY	**60 Hrs**
1. Introduction to Plant biotechnology: Historical perspectives, prospects for development of plant biotechnology as a source of medicinal agents. Applications in pharmacy and allied fields. Genetic and molecular biology as applied to pharmacognosy, study of DNA, RNA and protein replication, genetic code, regulation of gene expression, structure and complicity of genome, cell signaling, DNA recombinant technology.	12 Hrs
2. Different tissue culture techniques: Organogenesis and embryogenesis, synthetic seed and monoclonal variation, Protoplast fusion, Hairy root multiple shoot cultures and their applications. Micro propagation of medicinal and aromatic plants. Sterilization methods involved in tissue culture, gene transfer in plants and their applications.	12 Hrs
3. Immobilisation techniques & Secondary Metabolite Production: Immobilization techniques of plant cell and its application on secondary metabolite Production. Cloning of plant cell: Different methods of cloning and its applications. Advantages and disadvantages of plant cell cloning. Secondary metabolism in tissue cultures with emphasis on production of medicinal agents. Precursors and elicitors on production of secondary metabolites.	12 Hrs
4. Biotransformation and Transgenesis: Biotransformation, bioreactors for pilot and large scale cultures of plant cells and retention of biosynthetic potential in cell culture. Transgenic plants, methods used in gene identification, localization and sequencing of genes. Application of PCR in plant genome analysis.	12 Hrs

5. Fermentation technology: Application of Fermentation technology, Production of ergot alkaloids, single cell proteins, enzymes of pharmaceutical interest.	12 Hrs

REFERENCES (Latest Editions of)

1. Plant tissue culture, Bhagwani, vol 5, Elsevier Publishers.
2. Plant cell and Tissue Culture (Lab. Manual), JRMM. Yeoman.
3. Elements in biotechnology by PK. Gupta, Rastogi Publications, New Delhi.
4. Anintroduction to plant tissue culture by MK. Razdan, Science Publishers.
5. Experiments in plant tissue culture by John HD and Lorin WR., Cambridge University Press.
6. Pharmaceutical biotechnology by SP. Vyas and VK. Dixit, CBS Publishers.
7. Plant cell and tissue culture by **J**effrey W. **P**ollard and **J**ohn M Walker, Humana press.
8. Plant tissue culture by Dixon, Oxford Press, Washington DC, 1985
9. Plant tissue culture by Street.
10. Pharmacognosy by G. E. Trease and WC. Evans, Elsevier.
11. Biotechnology by Purohit and Mathur, Agro-Bio, 3rd revised edition.
12. Biotechnological applications to tissue culture by Shargool, Peter D, Shargoal, CKC Press.
13. Pharmacognosy by Varo E. Tyler, Lynn R. Brady and James E. Robberrt, That Tjen, NGO.
14. Plant Biotechnology, Ciddi Veerasham.

MPG 202T- ADVANCED PHARMACOGNOSY – II (Theory)

SCOPE

To know and understand the Adulteration and Deterioration that occurs in herbal/natural drugs and methods of detection of the same. Study of herbal remedies and their validations, including methods of screening

OBJECTIVES

The primary objectives of this subject are,

To be familiar with validation of herbal remedies

- To be well-known with methods of detection of adulteration and evaluation techniques for the herbal Drugs
- To be known with methods of screening of herbals for diverse biological assets.

Course Content:

THEORY	**60 Hrs**
1. Herbal remedies – Toxicity and Regulations: Herbals vs Conventional drugs, Efficacy of Herbal medicine products, Validation of herbal therapies, Pharmacodynamic and Pharmacokinetic issues	12 Hrs
2. Adulteration and Deterioration: Introduction, Types of Adulteration/ Substitution of Herbal drugs, Causes and Measures of Adulteration, Sampling Procedures, Determination of Foreign Matter, DNA Finger printing techniquesin identification ofdrugs of natural origin, detection of heavy metals, pesticide residues, phytotoxin, microbial contamination in herbs and their formulations.	12 Hrs
3. Ethnobotany and Ethnopharmacology: Ethnobotany in herbal drug evaluation, Impact of Ethnobotany in traditional medicine, New development in herbals, Bio-prospecting tools for drug discovery, Role of Ethnopharmacology in drug evaluation, Reverse Pharmacology.	12 Hrs
4. Analytical Profiles of herbal drugs: Andrographis paniculata, Boswellia serata, Coleus forskholii, Curcuma longa, Embelica officinalis, Psoralea corylifolia.	12 Hrs
5. Biological screening of herbal drugs: Introduction and Need for Phyto Pharmacological Screening, New Strategies for evaluating Natural Products, In vitro evaluation techniques for Antioxidants, Antimicrobial and Anticancer drugs. In vivo evaluation techniques for Anti-inflammatory, Antiulcer, Anticancer, Wound healing, Antidiabetic, Hepatoprotective, Cardio protective, Diuretics and Antifertility, Toxicity studies as per OECD guidelines.	12 Hrs

REFERENCES (Latest Editions of)

1. Glimpses of Indian Ethano Pharmacology by P. Pushpangadam. Ulf Nyman. V.George Tropical Botanic Garden & Research Institute.
2. Natural products: A lab guide by Raphael Ikan, Academic Press.
3. Pharmacognosy - G. E. Trease and W.C. Evans. WB. Saunders Edinburgh,

New York.
4. Pharmacognosy-Tyler, Brady, Robbers, Lee & Fetiger.
5. Modem Methods of Plant Analysis- Peach & M.V. Tracey, Vol. I & II, Springer Publishers.
6. Herbal Drug Industry by RD. Choudhary, Eastern Publishers, New Delhi.
7. Text book of Pharmacognosy by C.K.Kokate, Purohit, Ghokhale, Nirali Prakashan.
8. Text Book of Pharmacognosy by T.E. Wallis, J & A Churchill Ltd., London.
9. Quality control of herbal drugs by Pulok K Mukherjee, Business Horizons Pharmaceutical Publishers, New Delhi.
10. Indian Herbal Pharmacopoeia, IDMA, Mumbai.
11. Text book of Pharmacognosy and Phytochemistry by Vinod D. RangarI, Part I & II, Career Publication, Nasik, India.
12. Plant drug analysis by H.Wagner and S.Bladt, 2nd edition, Springer, Berlin.
13. Standardization of Botanicals. Testing and extraction methods of medicinal herbs by V. Rajpal (2004), Vol.I, Eastern PublisherS, New Delhi.
14. Herbal Medicine. Expanded Commission E Monographs, M.Blumenthal.

MPG 203T-INDIAN SYSTEMS OF MEDICINE (Theory)

SCOPE

To make the students understand thoroughly the principles, preparations of medicines of various Indian systems of medicine like Ayurveda, Siddha, Homeopathy and Unani. Also focusing on clinical research of traditional medicines, quality assurance and challenges in monitoring the safety of herbal medicines.

OBJECTIVES

This course intend to deliver the following

- To understand the basic principles of various Indian systems of medicine
- To know the clinical research of traditional medicines, Current Good Manufacturing Practice of Indian systems of medicine and their formulations.

Course Content:

THEORY	**60 Hrs**
1. Fundamental concepts of Ayurveda, Siddha, Unani and Homoeopathy systems of medicine. Different dosage forms of the ISM. Ayurveda: Ayurvedic Pharmacopoeia, Analysis of formulations and biocrude drugs with references to: Identity, purity and quality. Siddha: Gunapadam (Siddha Pharmacology), raw drugs/Dhatu/**J**eevam in Siddha system of medicine, Purification process (Suddhi).	12 Hrs
2. Naturopathy, Yoga and Aromatherapy practices a. Naturopathy - Introduction, basic principles and treatment modalities. b. Yoga - Introduction and Streams of Yoga. Asanas, Pranayama, Meditations and Relaxation techniques. c. Aromatherapy – Introduction, aroma oils for common problems, carrier oils.	12 Hrs
3. Formulation development of various systems of medicine Salient features of the techniques of preparation of some of the important class of Formulations as per Ayurveda, Siddha, Homeopathy and Unani Pharmacopoeia and texts. Standardization, Shelf life and Stability studies of ISM formulations.	12 Hrs
4. Schedule T – Good Manufacturing Practice of Indian systems of medicine Components of GMP (Schedule – T) and its objectives, Infrastructural requirements, working space, storage area, machinery and equipments, standard operating procedures, health and hygiene, documentation and records. Quality assurance in ISM formulation industry - GAP, GMP and GLP. Preparation of documents for new drug application and export registration. Challenges in monitoring the safety of herbal medicines: Regulation, quality assurance and control, National/Regional Pharmacopoeias.	12 Hrs
5.TKDL, Geographical indication Bill, Government bills in AYUSH, ISM,	12 Hrs

CCRAS, CCRS, CCRH, CCRU	

REFERENCES (Latest Editions of)

1. Ayurvedic Pharmacopoeia, The Controller of Publications, Civil Lines, Govt. of India, New Delhi.
2. Hand Book on Ayurvedic Medicines, H. Panda, National Institute of
3. Industrial Research, New Delhi.
4. Ayurvedic System of Medicine, Kaviraj Nagendranath Sengupata, Sri Satguru Publications, New Delhi.
5. Ayurvedic Pharmacopoeia. Formulary of Ayurvedic Medicines, IMCOPS, Chennai.
6. Homeopathic Pharmacopoeia. Formulary of Homeopathic Medicines, IMCOPS, Chennai.
7. Homeopathic Pharmacy : Anintroduction & Handbook, Steven B. Kayne, Churchill Livingstone, New York.
8. Indian Herbal Pharmacopoeia, IDMA, Mumbai.
9. British Herbal Pharmacopoeia, bRITISH Herbal Medicine Association, UK.
10. GMP for Botanicals – Regulatory and Quality issues on Phytomedicine, Pulok K Mukharjee, Business Horizons, New Delhi.
11. Indian System of Medicine and Homeopathy in India, Planning and Evaluation Cell, Govt. of India, New Delhi.
12. Essential of Food and Nutrition, Swaminathan, Bappco, Bangalore.
13. Clinical Dietitics and Nutrition, F.P. Antia, Oxford University Press, Delhi.
14. Yoga – The Science of Holistic Living by V.K.Yoga, Vivekananda Yoga Prakashna Publishing, Bangalore.

MPG 204T-HERBAL COSMETICS (Theory)

SCOPE

This subject deals with the study of preparation and standardization of herbal/natural cosmetics. This subject gives emphasis to various national and international standards prescribed regarding herbal cosmeceuticals.

OBJECTIVES

This course intend to deliver the following

- Basic principles of various herbal/natural cosmetic preparations
- GMP of herbal/natural cosmetics as per the regulations.

Course Content:

THEORY **60 Hrs**

1. Introduction: Herbal/natural cosmetics, Classification & Economic aspects. Regulatory Provisions relation to manufacture of cosmetics: - License, GMP, offences & Penalties, Import & Export of Herbal/natural cosmetics, Industries involved in the production of Herbal/natural cosmetics.	12 Hrs
2. Commonly used herbal cosmetics, raw materials, preservatives, surfactants, humectants, oils, colors, and some functional herbs, preformulation studies, compatibility studies, possible interactions between chemicals and herbs, design of herbal cosmetic formulation	12 Hrs
3. Herbal Cosmetics : Physiology and chemistry of skin and pigmentation, hairs, scalp, lips and nail, Cleansing cream, Lotions, Face powders, Face packs, Lipsticks, Bath products, soaps and baby product, Preparation and standardisation of the following :Tonic, Bleaches, Dentifrices and Mouth washes& Tooth Pastes, Cosmetics for Nails.	12 Hrs
4. Cosmeceuticals of herbal and natural origin: Hair growth formulations, Shampoos, Conditioners, Colorants & hair oils, Fairness formulations, vanishing & foundation creams, anti-sun burn preparations, moisturizing creams, deodorants.	12 Hrs
5. Analysis of Cosmetics, Toxicity screening and test methods: Quality control and toxicity studies as per Drug and Cosmetics Act.	12 Hrs

REFERENCES (Latest Editions of)

1. Panda H. Herbal Cosmetics (Hand book), Asia Pacific Business Press Inc, New Delhi.
2. Thomson EG. Modern Cosmetics, Universal Publishing Corporation, Mumbai.
3. P.P.Sharma. Cosmetics - Formulation, Manufacturing & Quality Control, Vandana Publications, New Delhi.
4. Supriya K B. Handbook of Aromatic Plants, Pointer Publishers, Jaipur.
5. Skaria P. Aromatic Plants (Horticulture Science Series), New India Publishing Agency, New Delhi.
6. Kathi Keville and Mindy Green. Aromatheraphy (A Complete Guide to the Healing Art), Sri Satguru Publications, New Delhi.

7. Chattopadhyay PK. Herbal Cosmetics & Ayurvedic Medicines (EOU), National Institute of Industrial Research, Delhi.
8. Balsam MS & Edward Sagarin. Cosmetics Science and Technology, Wiley Interscience, New York.

MPG 205P-HERBAL COSMETICS PRACTICALS (Practicals)

1. Isolation of nucleic acid from cauliflower heads
2. Isolation of RNA from yeast
3. Quantitative estimation of DNA
4. Immobilization technique
5. Establishment of callus culture
6. Establishment of suspension culture
7. Estimation of aldehyde contents of volatile oils
8. Estimation of total phenolic content in herbal raw materials
9. Estimation of total alkaloid content in herbal raw materials
10. Estimation of total flavonoid content in herbal raw materials
11. Preparation and standardization of various simple dosage forms from Ayurvedic, Siddha, Homoeopathy and Unani formulary
12. Preparation of certain Aromatherapy formulations
13. Preparation of herbal cosmetic formulation such as lip balm, lipstick, facial cream, herbal hair and nail care products
14. Evaluation of herbal tablets andcapsules
15. Preparation of sunscreen, UV protection cream, skin care formulations.
16. Formulation & standardization of herbal cough syrup.

DETAILS OF SUBJECT TEACHERS – semester I

S.No	Name of the Subject	Name of the Teachers	Designation and Department	Mobile No.	e-mail
1.	Modern Pharmaceutical Analytical Techniques	Dr. N.Krishnaveni	Professor	9442083447	krisath@jssuni.edu.in
2.	Advanced Pharmacognosy I	Mr. G Ramu	Lecturer	9972317434	ramupharmu@jssuni.edu.in
3.	Phytochemistry	Dr. B Duraiswamy	Professor	9442083818	bdurais@jssuni.edu.in
4.	Industrial Pharmacognostical Technology	Dr. Suresh Mohan Kumar	Professor	8248813425	suresh.jsscpo@jssuni.edu.in

DETAILS OF SUBJECT TEACHERS – semester II

S.No	Name of the Subject	Name of the Teachers	Designation and Department	Mobile No.	e-mail
1.	Medicinal Plant Biotechnology	Dr. B Duraiswamy	Professor	9442083818	bdurais@jssuni.edu.in
2.	Advanced Pharmacognosy II	Dr. Rajendiran. K	Lecturer	9443149945	rajendirankrish@jssuni.edu.in
3.	Indian Systems of Medicine	Mr. G Ramu	Lecturer	9840142319	ramupharmu@jssuni.edu.in
4.	Herbal Cosmetics	Dr. Suresh Mohan Kumar	Professor	7010551923	suresh.jsscpo@jssuni.edu.in

Academic Plan
2020-21

SEMESTER 1

Name of the Subject	**Modern Pharmaceutical Analytical Techniques (Theory)**
Name of the Faculty	Dr. Krishna Veni N M.Pharm., Ph.D
Designation, Department	Professor & Head, Department of Pharmaceutical Analysis
Mobile Number	9442083447
e-Mail i.d.	krisath@jssuni.edu.in

Scope, Course Objectives and Course Outcomes

SCOPE

This subject deals with various advanced analytical instrumental techniques for identification, characterization and quantification of drugs. Instruments dealt are NMR, Mass spectrometer, IR, HPLC, GC etc.

OBJECTIVES

After completion of course student is able to know about

- Chemicals and excipients
- The analysis of various drugs in single and combination dosage forms
- Theoretical and practical skills of the instruments

COURSE OUTCOMES (COs):

At completion of this course it is expected that the students will be able to

CO 1: Explain the general principles and techniques of spectroscopy & Chromatography

CO 2: Perform the assay of single and multiple component pharmaceuticals using various analytical techniques

CO 3: Develop skills in selecting suitable techniques for the analysis of drugs and pharamceutials

CO 4: Apply the knowledge learnt in developing newer analytical methods and procedures of their own design

CO 5: Explore and learn the various instrumental techniques available for the analysis of organic substances

LECTURE PLAN – Abstract

Sessional	No. of Hours of Didactic Lecture	No of Hours of other Activities	Total No. of Lecture Hours
I	30	1	31
II	30	--	30
Total No. of Hours	60	--	61

I SESSIONAL : 30 Lectures + 1 Activity

Lecture No.	Lecture Details	Hours
	Orientation of the subject	**01**
Unit-1:		**10**
UV Visible Spectroscopy		
1.	UV Visible Spectroscopy - Introduction, Theory, Laws	
2.	Instrumentation associated with UV Visible Spectroscopy, Choice of Solvents & Solvent Effects	
3.	Applications of UV visible spectroscopy, Difference/ Derivative Spectroscopy	
IR Spectroscopy		
4.	IR Spectroscopy - Theory, Modes of Molecular Vibrations, Samples handling	
5.	Instrumentation of Dispersive and Fourier Transform IR spectrometere	
6.	Factors affecting vibrational frequencies and applications of IR spectroscopy, Data Interpretation	
Spectroflourimetry		
7.	Spectroflourimetry - Theory of fluorescence, Factors affecting fluorescence	
8.	Quenchers, Instrumentation, Applications of Fluorescence Spectrophotometer	
Flame emission spectroscopy & Atomic abosrption spectroscopy		
9.	Principle, Instrumentation	
10.	Interferences and Applications	
Unit-2:		**10**
NMR Spectroscopy		
1.	NMR spectroscopy - Quantum numbers and their role in NMR, Principle	
2.	Instrumentation - Continous wave NMR instrument	
3.	Principle and Instrumentation of FT NMR	
4.	solvent requirements, Relaxation process	
5.	NMR signals in various compounds	
6.	chemical shift, factors influencing chemical shift	
7.	spin spin coupling, coupling constant	
8.	Nuclear magnetic double resonance	
9.	Applications of NMR Spectroscopy	
10.	Principles of 13C NMR	

Unit-3:		
MassSpectrometry		
1.	Principle, theory	**10**
2.	Instrumentation of Mass Spectroscopy - sample introduction techniques	
3.	Different types of ionization - electron impact, chemical	
4.	Different types of ionization - Field, FAB and MALDI	
5.	Different types of ionization - APCI, ESI, APPI	
6.	Analyzers of Quadrupole and Time of Flight	
7.	Mass fragmentation and its rules	
8.	Mass fragmentation and its rules	
9.	Meta stable ions, Isotopic peaks	
10.	Applications of Mass spectroscopy	

II SESSIONAL : 30 Lectures

Lecture No.	Lecture Details	Hours
Unit-4:		
Chromatography - Principle, Apparatus, Instrumentation, Chromatographic Parameters, Factors influencing resolution, Isolation of drugs from excipients, data interpretation and applications of		**10**
1.	Thin Layer Chromatography	
2.	High Performance Thin Layer Chromatography	
3.	Ion Exchange Chromatography	
4.	column Chromatography	
5.	Gas Chromatography	
6.	Gas Chromatography	
7.	HPLC	
8.	HPLC	
9.	Ultra high Performance Liquid Chromatography	
10.	Affinity Chromatography, Gel Chromatography	
Unit-5:		
Electrophoresis - Principle, Instrumentation, Working, Factors affecting separation and applications		
1.	Paper Electrophoresis	**10**
2.	Gel Electrophoresis, Zone Electrophoresis	
3.	Capillary Electrophoresis	
4.	Capillary Electrophoresis	
5.	Moving Boundray Electrophoresis	
6.	Iso Electric Focussing	
X Ray Crystallography		
7.	Production of X Rays, Braggs Law	
8.	Different X Ray diffraction methods - Rotating Crystal Technique	
9.	X Ray Powder technique, Types of Crystals	
10.	Applications of X Ray Diffractions	
Unit-6:		**10**
Immunological Assays		
1.	Potentiometry - Principle, working	

2.	Ion selective Electrodes and other electrodes used in potentiometry	
3.	Applications of potentiometry	
Thermal Techniques		
4.	Differential Scanning Colorimetry - Principle, Thermal transitions	
5.	DSC - Instrumentation (Power compensated, heat flux designs),	
6.	Modulated DSC, Hyper DSC	
7.	Experimental Parameters - sample preparation, experimental conditions, calibration, heating and cooling rates, resolution, source of errors), Their influence, advantages, disadvantages and applications	
8.	Differential Thermal Analysis (DTA) - Principle instrumentation, Advantages & Disadvantages, Pharmaceutical Applications	
9.	Derivative Differential Thermal Analysis	
10.	Thermogravimetric Analysis (TGA) - Principle, instrumentation, factors affecting results, advantages & disadvantages, Pharmaceutical Applications	

Text Books

1. Spectrometric Identification of Organic compounds - Robert M Silverstein, Sixth edition, John Wiley & Sons, 2004.
2. Principles of Instrumental Analysis - Doglas A Skoog, F. James Holler, Timothy A. Nieman, 5th edition, Eastern press, Bangalore, 1998.
3. Instrumental methods of analysis – Willards, 7th edition, CBS publishers.
4. Practical Pharmaceutical Chemistry – Beckett and Stenlake, Vol II, 4th edition, CBS Publishers, New Delhi, 1997.
5. Organic Spectroscopy - William Kemp, 3rd edition, ELBS, 1991.
6. Quantitative Analysis of Drugs in Pharmaceutical formulation - P D Sethi, 3rd Edition, CBS Publishers, New Delhi, 1997.
7. Pharmaceutical Analysis - Modern Methods – Part B - J W Munson, Vol 11, Marcel. Dekker Series
8. Spectroscopy of Organic Compounds, 2nd edn., P.S/Kalsi, Wiley estern Ltd., Delhi.
9. Textbook of Pharmaceutical Analysis, KA.Connors, 3rd Edition, John Wiley & Sons, 1982.

Reference Books

1. Introduction to Spectroscopy; by Donald L Pavia

Name of the Subject	**Advanced Pharmacognosy I** (Theory)
Name of the Faculty	Mr. G. Ramu M. Pharm
Designation, Department	Lecturer, Department of Pharmacognosy
Mobile Number	9972317434
e-Mail i.d.	ramupharmu@jssuni.edu.in

Scope, Course Objectives and Course Outcomes

SCOPE

To learn and understand the advances in the field of cultivation and isolation of drugs of natural origin, various phytopharmaceuticals, nutraceuticals and their medicinal use and health benefits.

OBJECTIVES

This course intend to deliver the following

- Advances in the cultivation and production of drugs.
- Various phyto-pharmaceuticals and their source, its utilization and medicinal value.
- Various nutraceuticals/herbs and their health benefits.
- Drugs of marine origin.
- Pharmacovigilance of drugs of natural origin.

COURSE OUTCOMES (COs)

At completion of this course it is expected that the students will be able to

CO 1: Know about the basic concept, history and background of Advanced Pharmacognosy.

CO 2: Familiarize with the Pharmacognosy and some of the cultivation practices

CO 3: Distinguish nutraceuticals and pharmaceuticals

CO 4: Understand markers and their chemical nature.

CO 5: Understand phytopharmaceuticals and their benefits.

LECTURE PLAN – Abstract

Sessional	No. of Hours of Didactic Lecture	No of Hours of other Activities	Total No. of Lecture Hours
I	28	08	36
II	16	08	24
Total No. of Hours	44	16	60

I SESSIONAL : 25 Lectures + 11 Activities

Lecture No.	Lecture Details	Hours
Unit-1 Plant Drug Cultivation:		**12**
	Welcome and Introduction to Course	
1.	Council of Agricultural Research	
2.	Current Good Agricultural Practices	
3.	Current Good Cultivation Practices	
4.	Current Good Collection Practices	
5.	Conservation of medicinal plants	
6.	Ex-situ conservation of medicinal plants I	
7.	Ex-situ conservation of medicinal plants II	
8.	In-situ conservation of medicinal plants I	
9.	In-situ conservation of medicinal plants II	
10.	Other methods of Conservation	
11.	Coursework/Assignment/Activity/Revision	
12.	Coursework/Assignment/Activity/Revision	
Unit-2 Marine Natural Products:		**12**
1.	Introduction to Marine natural products	
2.	General methods of isolation and purification	
3.	Study of Marine toxins	
4.	Research Advances in research in marine drugs	
5.	General problems faced in research in marine drugs	
6.	Taxonomical identification I	
7.	Taxonomical identification II	
8.	Chemical screening of marine natural products	
9.	Coursework/Assignment/Activity/Revision	
10.	Coursework/Assignment/Activity/Revision	
11.	Coursework/Assignment/Activity/Revision	
12.	Coursework/Assignment/Activity/Revision	
Unit-3 Nutraceuticals:		**12**
1.	Nutraceuticals Introduction	
2.	Current trends and future scope	
3.	Inorganic mineral supplements	
4.	Vitamin supplements	
5.	Digestive enzymes, Digestive fibres and Cereals and grains	

6.	Health drinks of natural origin	
7.	Antioxidants and Polyunsaturated fatty acids	
8.	Herbs as functional foods and formulation	
9.	FSSAI guidelines	
10	Marker compounds	
11.	Coursework/Assignment/Activity/Revision	
12	Coursework/Assignment/Activity/Revision	

II SESSIONAL : 16 Lectures + 8 Activities

Lecture No.	Lecture Details	Hours
Unit- 4	**Phytopharmaceuticals:**	**12**
1.	Carotenoids	
2.	Limonoids	
3.	Saponins	
4.	Flavonoids	
5.	Phenolic acids	
6.	Vitamins	
7.	Tocotrienols, Tocopherols, Withanolides, Vascine and Taxol	
8.	Andrographolide, Glycolipids and Gugulipids	
9.	Coursework/Assignment/Activity/Revision	
10.	Coursework/Assignment/Activity/Revision	
11.	Coursework/Assignment/Activity/Revision	
12.	Coursework/Assignment/Activity/Revision	
Unit-5 Pharmacovigilance:		**12**
1.	Introduction and Need	
2.	WHO guidelines for safety monitoring of natural medicine	
3.	AYUSH guidelines for safety monitoring of natural medicine	
4.	Spontaneous reporting schemes for bio-drug adverse reactions	
5.	Bio drug - drug interactions I	
6.	Bio drug - drug interactions II	
7.	Bio drug - food interactions I	
8.	Bio drug - food interactions II	
9.	Coursework/Assignment/Activity/Revision	
10.	Coursework/Assignment/Activity/Revision	
11.	Coursework/Assignment/Activity/Revision	
12.	Coursework/Assignment/Activity/Revision	

Text Books & References

1. Pharmacognosy by G. E. Trease and W. C. Evans. Saunders Edinburgh, New York.
2. Pharmacognosy by Tyler, Brady, Robbers
3. Modern Methods of Plant analysis by Peach & M. V. Tracey, Vol. I & II
4. Text Book of Pharmacognosy by T. E. Wallis
5. Marine Natural Products by Vol. I to IV.
6. Natural products: A lab guide by Raphael Ikan, Academic Press 1991
7. Glimpses of Indian Ethano Pharmacology, P. Pushpagandam. Ulf Nyman. V. George

Tropical Botanic Garden & Research Institute, 1995.
7. Cultivation of Medicinal Plants by C.K. Atal & B.M. Kapoor.
8. Cultivation and Utilization of Aromatic Plants, C.K. Atal & B.M. Kapoor
9. Chemistry of Marine Natural Products –Paul J. Schewer 1973.

Name of the Subject	**Phytochemistry (Theory)**
Name of the Faculty	Dr. B. Duraiswamy, M.Pharm., Ph.D
Designation, Department	Professor & Head, Department of Pharmacognosy
Mobile Number	9442083818
e-Mail i.d.	bdurais@jssuni.edu.in

Scope, Course Objectives and Course Outcomes

SCOPE

Students shall be equipped with the knowledge of natural product drug discovery and will be able to isolate, identify and extract the phytoconstituents

OBJECTIVES

This course intend to deliver the following

- Different classes of phytoconstituents, their biosynthetic pathways, their properties, extraction and general process of natural product drug discovery**.**
- Phytochemical fingerprinting and structure elucidation of phytoconstituents.

COURSE OUTCOMES (COs)

At completion of this course it is expected that the students will be able to

CO 1: Understand the different phytochemical pathways through which the phytoconstituents are synthesized

CO 2: Understand the methods present in the new drug discovery process.

CO 3: Demonstrate the different extraction techniques involved in the extraction of phytochemicals

CO 4: Understand the various techniques involved in the structural elucidation of phytochemicals

CO 5: Understand and demonstrate the various spectroscopic methods involved in the characterization of phytoconstituents

LECTURE PLAN – Abstract

Sessional	No. of Hours of Didactic Lecture	No of Hours of other Activities	Total No. of Lecture Hours
I	28	08	36
II	16	08	24
Total No. of Hours	44	16	60

I SESSIONAL : 25 Lectures + 11 Activities

Lecture No.	Lecture Details	Hours
Unit-1 Biosyhnthetic pathways		**12**
	Welcome and Introduction to Course	
1.	Biosynthetic pathways – Shikimic Acid pathway and its secondary metabolities	
2.	Acetate Mevalonate pathway and its secondary metabolities	
3.	Acetate-Malonate pathway and its secondary metabolities	
4.	Alkaloids: Ephedrine, Quinine, Strychnine	
5.	Alkaloids: Piperine, Berberine, taxol, and vinca alkaloids	
6.	Glycosides: Digitoxin, Glycyrrhizin, Sennosides,	
7.	Bacosides, Quercitin.	
8.	Steroids: Hecogenin, guggulosterone and withanolides	
9.	Coumarin: Umbelliferone.	
10.	Terpenoids: Cucurbitacins	
11.	Coursework/Assignment/Activity/Revision	
12.	Coursework/Assignment/Activity/Revision	
Unit-2 Drug discovery and development:		**12**
1.	History of herbs as source of drugs and drug discovery	
2.	The lead structure selection process	
3.	structure development, product discovery process and drug registration,	
4.	Selection and optimization of lead compounds with suitable examples	
5.	Artemesin and andrographolides	
6.	Clinical studies emphasising on phases of clinical trials	
7.	Clinical studies emphasising on phases of clinical trials	
8.	Protocol design for lead molecules.	
9.	Coursework/Assignment/Activity/Revision	
10.	Coursework/Assignment/Activity/Revision	
11.	Coursework/Assignment/Activity/Revision	
12.	Coursework/Assignment/Activity/Revision	
Unit-3 Extraction and Phytochemical studies		**12**
1.	Recent advances in extractions with emphasis on selection of method and choice of solvent for extraction	
2.	Maceration, Percolation, Decoction, Infusion	
3.	Hot continuous extraction (Soxhlation) & Counter current extraction	
4.	Microwave assisted extraction & Successive extraction	

5.	Super critical Fluid extraction	
6.	Fractionation techniques	
7.	Separation techniques by chromatographic methods	
8.	CCCET	
9.	HPLC	
10.	Flash chromatography	
11.	Coursework/Assignment/Activity/Revision	
12.	Coursework/Assignment/Activity/Revision	

II SESSIONAL : 16 Lectures + 8 Activities

Lecture No.	Lecture Details	Hours
Unit- 4 Phytochemical finger printing:		**12**
1.	HPTLC and its applications	
2.	HPTLC and its applications	
3.	LCMS and its applications	
4.	LCMS and its applications	
5.	GCMS and its applications	
6.	Structure elucidation of phytoconstituents	
7.	Structure elucidation of phytoconstituents	
8.	Structure elucidation of phytoconstituents	
9.	Coursework/Assignment/Activity/Revision	
10.	Coursework/Assignment/Activity/Revision	
11.	Coursework/Assignment/Activity/Revision	
12.	Coursework/Assignment/Activity/Revision	
Unit-5 Structure elucidation of the following compounds by spectroscopic techniques like UV, IR, MS, NMR (1H, 13C)		**12**
1.	UN, IR, MS and NMR analysis of Carvone	
2.	UN, IR, MS and NMR analysis of Citrol	
3.	UN, IR, MS and NMR analysis of Menthol	
4.	UN, IR, MS and NMR analysis of Luteolin	
5.	UN, IR, MS and NMR analysis of Kaempferol	
6.	UN, IR, MS and NMR analysis of Nicotine	
7.	UN, IR, MS and NMR analysis of Caffeine	
8.	UN, IR, MS and NMR analysis of Glycyhrrhizin	
9.	Coursework/Assignment/Activity/Revision	
10.	Coursework/Assignment/Activity/Revision	
11.	Coursework/Assignment/Activity/Revision	
12.	Coursework/Assignment/Activity/Revision	

Text Books & References

1. Organic chemistry by I.L. Finar Vol.II
2. Pharmacognosy by Trease and Evans, ELBS.
3. Pharmacognosy by Tylor and Brady.
4. Text book of Pharmacognosy by Wallis.
5. Clark's isolation and Identification of drugs by A.C. Mottal.
6. Plant Drug Analysis by Wagner & Bladt.

7. Wilson and Gisvolds text book of Organic Medicinnal and Pharmaceutical Chemistry
by Deorge. R.F.
8. The Chemistry of Natural Products, Edited by R.H. Thomson, Springer International
Edn. 1994.
9. Natural Products Chemistry Practical Manual by Anees A Siddiqui and Seemi Siddiqui
10. Organic Chemistry of Natural Products, Vol. 1&2. Gurdeep R Chatwal.
11. Chemistry of Natural Products- Vol. 1 onwards IWPAC.
12. Modem Methods of Plant Analysis- Peach & M.V. Tracey, Vol. I&II
13. Medicinal Natural products – a biosynthetic approach, Dewick PM, John Wiley &
Sons, Toronto, 1998.
14. Chemistry of Natural Products, Bhat SV, Nagasampagi BA, Meenakshi S, Narosa
Publishing House, New Delhi.
15. Pharmacognosy & Phytochemistry of Medicinal Plants, 2nd edition, Bruneton J,
Interceptt Ltd., New York, 1999.

Name of the Subject	**Industrial Pharmacognostical Technology (Theory)**
Name of the Faculty	Dr. Suresh K. Mohankumar M.Pharm., Ph.D
Designation, Department	Professor, Department of Pharmacognosy
Mobile Number	8903451179
e-Mail i.d.	suresh.jsscpo@jssuni.edu.in

Scope, Course Objectives and Course Outcomes

SCOPE

To understand the industrial and commercial potential of drugs of natural origin, integrate traditional Indian systems of medicine with modern medicine and also to know regulatory and quality policy of the trade of herbal and drugs of natural origin.

OBJECTIVES

The course intend to deliver the following objectives

- Orientate the potentials, challenges and opportunities of Herbal Indutries both national and International
- Teach regulatory and technical requirments of herbal industry
- Teach various monographs used for standardisation of herbals and derived products
- Teach various analytical testing methods for herbal products
- Introduce the concepts of intellectual protection and patents specific to herbal drugs and products.

COURSE OUTCOMES (COs):

At completion of this course it is expected that the students will be able to

CO 1 : Demonstrate the understanding of the potentials of herbal drug market

CO 2 : Demonstrate the regulatory and technical requirement of herbal industry set-up

CO 3 : Explain the contents and significance of various monographs to standardize herbals

CO 4: Demonstrate tests used to standardize herbals and to ensure quality

CO 5 : Demonstrage the patenting/IPR of herbals/natural drugs and trade of raw and finished materials.

LECTURE PLAN – Abstract

Sessional	No. of Hours of Didactic Lecture	No of Hours of other Activities	Total No. of Lecture Hours
I	29	07	36
II	17	07	24
Total No. of Hours	46	14	60

I SESSIONAL : 29 Lectures + 7 Activities

Lecture No.	Lecture Details	Hours
Unit-1 Herbal Drug Industry		
	Welcome and Intro to Course	**12**
1.	Infrastructure of herbal drug industry involved in production of standardized extracts	
2.	Infrastructure of herbal drug industry involved in production of standardized various dosage forms	
3.	Infrastructure of herbal drug industry involved in production of standardized extracts various dosage forms	
4.	Current challenges in upgrading and modernization of herbal formulations.	
5.	Entrepreneurship Development and Capital venture	
6.	Project selection, project report, technical knowledge, Capital venture, plant design, layout and construction.	
7.	Project selection, project report, technical knowledge, plant design, layout and construction.	
8.	Pilot plant scale -up techniques	
9.	Case studies of herbal extracts.	
10.	Formulation and production management of herbals	
11.	Coursework/Assignment/Activity/Revision	
12.	Coursework/Assignment/Activity/Revision	
Unit-2 Regulatory requirements for setting herbal drug industry		
1.	Global marketing management.	**12**
2.	Indian patent law as applicable herbal drugs and natural products.	
3.	International patent law as applicable herbal drugs and natural products.	
4.	Export – Import (EXIM) policy	
5.	TRIPS.	
6.	Quality assurance in herbal/natural drug products	
7.	TQM	
8.	GMP	
9.	GLP	
10.	ISO	
11.	Coursework/Assignment/Activity/Revision	
12.	Coursework/Assignment/Activity/Revision	
Unit-3 Monographs of herbal drugs		

1.	General parameters of monographs of herbal drugs and comparative study	**12**
2.	IP	
3.	USP	
4.	Ayurvedic Pharmacopeia	
5.	Sidhha Pharmacopeia	
6.	Unani Pharmacopeia	
7.	American Herbal Pharmacopeia	
8.	Bristish Herbal Pharmacopeia	
9.	WHO guidelines in quality assessment of herbal drugs	
10.	Coursework/Assignment/Activity/Revision	
11.	Coursework/Assignment/Activity/Revision	
12.	Coursework/Assignment/Activity/Revision	

II SESSIONAL : 19 Lectures + 5 Activities

Lecture No.	Lecture Details	Hours
Unit- 4 Testing of natural products and drugs:		
1.	Herbal medicines – clinical laboratory testing-1	**12**
2.	Herbal medicines – clinical laboratory testing-2	
3.	Herbal medicines – clinical laboratory testing-3	
4.	Herbal medicines – clinical laboratory testing-4	
5.	Stability testing of natural products, protocols-1	
6.	Stability testing of natural products, protocols-2	
7.	Stability testing of natural products, protocols-3	
8.	Coursework/Assignment/Activity/Revision	
9.	Coursework/Assignment/Activity/Revision	
10.	Coursework/Assignment/Activity/Revision	
11.	Coursework/Assignment/Activity/Revision	
12.	Coursework/Assignment/Activity/Revision	
Unit-5 Patents		
1.	Indian and international patent laws,. Geographical indication, Copyright, Patentable subject maters, novelty, non obviousness, utility, enablement and best mode, procedure for Indian patent filing,.	**12**
2.	proposed amendments as applicable to herbal/natural products and process	
3.	Geographical indication	
4.	Copyright	
5.	Patentable subject maters	
6.	Novelty and non obviousness	
7.	Utility, enablement and best mode for Indian patent filing	
8.	Patent processing, grant of patents, rights of patents, cases of patents,	
9.	Opposition and revocation of patents,	
10.	Patent search and literature, Controllers of patents	
11.	Coursework/Assignment/Activity/Revision	
12.	Coursework/Assignment/Activity/Revision	

Text Books & References

1. Herbal drug industry by R.D. Choudhary (1996), Eastern Publisher, New Delhi.
2. GMP for Botanicals – Regulatory and Quality issues on Phytomedicine by Pulok K Mukharjee (2003), Ist Edition, Business horizons Robert Verpoorte, New Delhi.
3. Quality control of herbal drugs by Pulok K Mukarjee (2002), Business Horizons Pharmaceutical Publisher, New Delhi.
4. PDR for Herbal Medicines (2000), Medicinal Economic Company, New Jersey.
5. Indian Herbal Pharmacopoeia (2002), IDMA, Mumbai.
6. Text book of Pharmacognosy by C.K. Kokate, Purohit, Gokhlae (1996), Nirali Prakashan, New Delhi.
7. Text book of Pharmacognosy and Phytochemistry by Vinod D. RangarI (2002), Part I & II, Career Publication, Nasik, India.
8. Plant drug analysis by H.Wagner and S.Bladt, Springer, Berlin.
9. Standardization of Botanicals. Testing and extraction methods of medicinal herbs by V. Rajpal (2004), Vol.I, Eastern Publisher, New Delhi.
10. Phytochemical Dictionary. Handbook of Bioactive Compounds from Plants by J.B.Harborne, (1999), IInd Edition, Taylor and Francis Ltd, UK.

MPG 105P Pharmacognosy Practical I

Sessional	Pharmacognosy Practical I	No of Hours of other Activities	Total No. of Lecture Hours
I	09	54	54
II	06	36	36
Total No. of Hours		90	90

I Sessional Practicals

S. No.	Name of the Experiment
1.	Analysis of Pharmacopoeial compounds of natural origin and their formulations by UV Vis spectrophotometer
2.	Analysis of recorded spectra of simple phytoconstituents
3.	Experiments based on Gas Chromatography
4.	Estimation of sodium/potassium by flame photometry
5.	Development of fingerprint of selected medicinal plant extracts commonly used in herbal drug industry viz. Ashwagandha, Tulsi, Bael, Amla, Ginger, Aloe, Vidang, Senna, Lawsonia by TLC/HPTLC method.
6.	Methods of extraction- Soxhlation
7.	Isolation of quinine from cinchona bark
8.	Isolation of Hesperidine from Orange peel
9.	Isolation of curcuminoids from turmeric

II Sessional Practicals

S. No.	Name of the Experiment
10.	Phytochemical screening
11.	Demonstration of HPLC- estimation of glycerrhizin
12.	Monograph analysis of clove oil
13.	Monograph analysis of castor oil.
14.	Identification of bioactive constituents from plant extracts
15.	Formulation of different dosage forms and their standardization

SEMESTER II

Name of the Subject	**Medicinal plant Biotechnology (Theory)**
Name of the Faculty	Dr. B. Duraiswamy, M.Pharm., Ph.D
Designation, Department	Professor & Head, Department of Pharmacognosy
Mobile Number	9442083818
e-Mail i.d.	bdurais@jssuni.edu.in

Scope, Course Objectives and Course Outcomes

SCOPE

To explore the knowledge of Biotechnology and the application in the improvement of quality of medicinal plants

OBJECTIVES

The primary objectives of this course are to

1. Know the process like genetic engineering in medicinalplants for higher yield of Phytopharmaceuticals
2. Use the biotechnological techniques for obtaining and improving the quality of natural products/medicinal plants.

COURSE OUTCOMES (COs)

On successful completion of the subject the student shall be able to

CO 1 : Understand the genetic engineering and the DNA recombinant technology
CO 2 : Different Tissue culture techniques and the production of secondary metabolities.
CO 3: Immobilization techniqies and different methods of cloning
CO 4: Biotransformation techniqies and transgenic plants
CO 5: Fermentation technology and its application in the production of phytopharmaceuticals

LECTURE PLAN – Abstract

Sessional	No. of Hours of Didactic Lecture	No of Hours of other Activities	Total No. of Lecture Hours
I	22	14	36
II	16	08	24
Total No. of Hours	44	16	60

I SESSIONAL : 30 Lectures

Lecture No.	Lecture Details	Hours 36
Unit-1: Introduction to Plant Biotechnology		
1.	Introducion Class	**12**
2.	Historical Perspectives and Prospects for development of Biotechnology as a source of medicinal plants	
3.	Application of Plant biotechnology in Pharmacy and Allied fields	
4.	Genetic and Molecular Biology-Introduction, Study of DNA and RNA	
5.	Protein Replication, Genetic code and regulation of gene expression	
6.	Structure and Complicity of genome; Cell signaling	
7.	DNA recombinant technology	
8.	Coursework/Assignment/Activity/Revision	
9.	Coursework/Assignment/Activity/Revision	
10.	Coursework/Assignment/Activity/Revision	
11	Coursework/Assignment/Activity/Revision	
12	Coursework/Assignment/Activity/Revision	
Unit-2: Different tissue culture techniques		**12**
1.	Introduction to tissue culture techniques	
2.	Organogenesis and Embryogenesis	
3.	Synthetic seed and Monoclonal variation; Applications	
4	Protoplast fusion, Hairy root, multiple shoot cultures and their applications	
5.	Micropropogation of medicinal and aromatic plants	
6	Sterilization in tissue culture and Methods of sterilisation	
7	Gene transfer in plants	
8	Gene transfer in plants and their applications	
9	Coursework/Assignment/Activity/Revision	
10	Coursework/Assignment/Activity/Revision	
11	Coursework/Assignment/Activity/Revision	
12	Coursework/Assignment/Activity/Revision	
Unit-3: Immobilization techniques & Secondary metabolite production		**12**
1.	Immobilization – Introduction	
2.	Applications on secondary metabolites production	
3.	Cloning of Plant Cell - Introduction	

4.	Different methods of Cloning	
5.	Applications of cloning and its advantages	
6.	Secondary metabolism in tissue cultures	
7.	Precursors and elicitors on production of secondary metabolites	
8.	Coursework/Assignment/Activity/Revision	
9	Coursework/Assignment/Activity/Revision	
10.	Coursework/Assignment/Activity/Revision	
11.	Coursework/Assignment/Activity/Revision	
12.	Coursework/Assignment/Activity/Revision	

II SESSIONAL : 30 Lectures

Lecture No.	Lecture Details	Hours 30
Unit-4: Good Manufacturing Practice		**12**
1.	Biotransformation - Introduction	
2.	Transgenesis - Introduction	
3.	Bioreactors for Pilot scale culture of plant cells	
4.	Bioreactors for large scale culture of plant cells	
5.	Retention of Biosynthetic potential in cell culture	
6.	Transgenic plants- Introduction	
7.	Methods used in gene identification - I	
8.	Localization and sequencing of genes - I	
9.	Application of PCR in plant genome analysis - I	
10.	Application of PCR in plant genome analysis - II	
11.	Coursework/Assignment/Activity/Revision	
12.	Coursework/Assignment/Activity/Revision	
Unit-5 Fermentation Technology		**12**
1.	Fermentation - Introduction	
2.	Different techniques	
3.	Applications of Fermentation technology - I	
4.	Applications of Fermentation technology - II	
5.	Production of Ergot alkaloids - I	
6.	Enzymes of Pharmaceutical Interest	
7.	Enzymes of Pharmaceutical Interest	
8.	Coursework/Assignment/Activity/Revision	
9.	Coursework/Assignment/Activity/Revision	
10.	Coursework/Assignment/Activity/Revision	
11.	Coursework/Assignment/Activity/Revision	
12.	Coursework/Assignment/Activity/Revision	

REFERENCES

1. Plant tissue culture, Bhagwani, vol 5, Elsevier Publishers.
2. Plant cell and Tissue Culture (Lab. Manual), JRMM. Yeoman.

3. Elements in biotechnology by PK. Gupta, Rastogi Publications, New Delhi.
4. An introduction to plant tissue culture by MK. Razdan, Science Publishers.
5. Experiments in plant tissue culture by John HD and Lorin WR., Cambridge University Press.
6. Pharmaceutical biotechnology by SP. Vyas and VK. Dixit, CBS Publishers.
7. Plant cell and tissue culture by Jeffrey W. Pollard and John M Walker, Humana press.
8. Plant tissue culture by Dixon, Oxford Press, Washington DC, 1985
9. Plant tissue culture by Street.
10. Pharmacognosy by G. E. Trease and WC. Evans, Elsevier.
11. Biotechnology by Purohit and Mathur, Agro-Bio, 3 revised edition.
12. Biotechnological applications to tissue culture by Shargool, Peter D, Shargoal, CKC Press.
13. Pharmacognosy by Varo E. Tyler, Lynn R. Brady and James E. Robberrt, That Tjen, NGO.
14. Plant Biotechnology, Ciddi Veerasham. Rd

Name of the Subject	Advanced Pharmacognosy - II
Name of the Faculty	Dr. Rajendiran Krish M.Pharm., Ph.D
Designation, Department	Lecturer, Department of Pharmacognosy
Mobile Number	9486604970
e-Mail address	rajendirankrish@jssuni.edu.in

Scope, Course Objectives and Course Outcomes

SCOPE

To know and understand the adulteration and deterioration that occurs in herbal/natural drugs and methods of detection of the same. Study of herbal remedies and their validations, including methods of screening.

OBJECTIVES

The primary objectives of this subject are,

To be familiar with validation of herbal remedies

- To be well-known with methods of detection of adulteration and evaluation techniques for the herbal drugs
- To be known with methods of screening of herbals for diverse biological assets.

COURSE OUTCOMES (COs)

At completion of this subject, it is expected that the students will be able to

CO 1 : Define herbal remedies, regulations facet and toxicity concern of herbal remedies, benefit and value of herbal drugs over conventional drugs, validation of herbal remedies and pharmacodynamic and pharmacokinetic subject of herbal remedies.

CO 2 : Define Adulteration and Deterioration, types, causes and measures of Adulteration, sampling procedure and determination of foreign matter, detection of heavy metals and pestiside residues, microbial contamination and DNA finger printing techniques in identification of drugs of natural origin

CO 3 : Define ethnobotany and ethnopharmacology, nuance and impact of ethnobotany and ethnopharmacology in herbal drug evaluation, bio-prospecting tools and reverse pharmacology for drug discovery

CO 4 : Draw the anaytical profile of Andrographis paniculata , Boswellia serata , Coleus forskholii , Curcuma longa , Embelica officinalis and Psoralea corylifolia

CO 5 : Execute *in - vitro* and *in - vivo* techniques for anti oxidant, antimicrobial and anticancer, anti-inflammatory, antiulcer, anticancer, wound healing, antidiabetic, hepatoprotective, cardio protective, diuretic potential of herbals. To explore toxicity studies as per OECD guidelines

LECTURE PLAN – Abstract

Sessional	No. of Hours of Didactic Lecture	No of Hours of other Activities	Total No. of Lecture Hours
I	36	03	39
II	24	02	26
Total No. of Hours	60	05	65

I SESSIONAL : 36 Lectures + 3 Activities

S No.	Lecture Details	Hours
HERBAL REMEDIES		**(12)**
Unit-1: Herbal remedies		**12**
1.	Introduction to Advanced Pharmacognosy II	
2.	Introduction to Herbal remedies	
3.	Toxicity and Regulations of herbal remedies	
4.	Herbals vs conventiona drugs	
5.	Efficacy of Herbal medicine products	
6.	Validation of herbal therapies	
7.	Pharmacodynamic and Pharmacokinetic issues	
ADULTERATION AND DETERIORATION		**(12)**
Unit-2: Adulteration and Deterioration		**12**
1.	Introduction	
2.	Types of Adulteration/ Substitution of Herbal drugs	
3.	Causes and Measures of Adulteration,	
4.	Sampling Procedures	
5.	Determination of Foreign Matter	
6.	DNA Finger printing techniques in identification of drugs of natural origin	
7.	detection of heavy metals	
8.	pesticide residues	
9.	phytotoxin,	
10.	microbial contamination in herbs and their formulations	
ETHNOBOTANY AND ETHNOPHARMACOLOGY		**(12)**
Unit-3: Ethnobotany and Ethnopharmacology		**12**
1.	Ethnobotany in herbal drug evaluation	
2.	Impact of Ethnobotany in traditional medicine	
3.	New development in herbals	
4.	Bio-prospecting tools for drug discovery	
5.	Role of Ethnopharmacology in drug evaluation	
6.	Reverse Pharmacology	
Activity1	CLASS Test (Herbal remedies)	
Activity2	CLASS Test (Adulteration and Deterioration)	
Activity3	CLASS Test (Ethnobotany and Ethnopharmacology)	

II SESSIONAL : 24 Lectures + 2 Activities

S No.	Lecture Details	Hours
ANALYTICAL PROFILES OF HERBAL DRUGS		**(12)**

Unit-4: Analytical Profiles of herbal drugs:		
1.	Introduction to analytical profiles of herbal drugs	**12**
2.	Analytical Profile of Andrographis paniculata	
3.	Analytical Profile of Boswellia serata	
4.	Analytical Profile of Coleus forskholii	
5.	Analytical Profiles of Curcuma longa	
6.	Analytical Profiles of Embelica officinalis	
7.	Analytical Profiles of Psoralea corylifolia	
BIOLOGICAL SCREENING OF HERBAL DRUGS		**(12)**
Unit-5: Biological screening of herbal drugs		
11.	Introduction and Need for Phyto-Pharmacological Screening	**12**
12.	New Strategies for evaluating Natural Products	
13.	In vitro evaluation techniques for Antioxidants	
14.	In vitro evaluation techniques for Antimicrobial and Anticancer drugs.	
15.	In vivo evaluation techniques for Anti-inflammatory	
16.	In vivo evaluation techniques for Antiulcer	
7.	In vivo evaluation techniques for Anticancer,	
8.	In vivo evaluation techniques for Wound healing,	
9.	In vivo evaluation techniques for Antidiabetic	
10.	In vivo evaluation techniques for Hepatoprotective	
11.	In vivo evaluation techniques for Cardio protective	
12.	In vivo evaluation techniques for Diuretics	
13.	In vivo evaluation techniques for Antifertility	
14.	Toxicity studies as per OECD guidelines	
Activity-1	CLASS Test (Analytical Profiles of herbal drugs)	
Activity-2	CLASS Test (Biological screening of herbal drugs)	

Text Books

1. W.C.Evans, Trease and Evans Pharmacognosy, 16th edition, W.B. Sounders & Co., London, 2009.
2. Mohammad Ali. Pharmacognosy and Phytochemistry, CBS Publishers & Distribution, New Delhi.
3. Text book of Pharmacognosy by C.K. Kokate, Purohit, Gokhlae (2007), 37th Edition, Nirali Prakashan, New Delhi.
4. Essentials of Pharmacognosy, Dr.SH.Ansari, IInd edition, Birla publications, New Delhi, 2007
5. Pharmacognosy-Tyler, Brady, Robbers, Lee & Fetiger.
6. Text Book of Pharmacognosy by T.E. Wallis, J & A Churchill Ltd., London.
7. Text book of Pharmacognosy and Phytochemistry by Vinod D. RangarI, Part I & II, Career Publication, Nasik, India.

Reference Books

1. Herbal drug industry by R.D. Choudhary (1996), Ist Edn, Eastern Publisher, New Delhi.
2. A.N. Kalia, Textbook of Industrial Pharmacognosy, CBS Publishers, New Delhi, 2005.

3. Pharmacognosy & Pharmacobiotechnology. James Bobbers, Marilyn KS, VE Tylor.
4. Glimpses of Indian Ethano Pharmacology by P. Pushpangadam. Ulf Nyman. V.George Tropical Botanic Garden & Research Institute.
5. Natural products: A lab guide by Raphael Ikan, Academic Press.
6. Modem Methods of Plant Analysis- Peach & M.V. Tracey, Vol. I & II, Springer Publishers.
7. Herbal Drug Industry by RD. Choudhary, Eastern Publishers, New Delhi.
8. Quality control of herbal drugs by Pulok K Mukherjee, Business Horizons Pharmaceutical Publishers, New Delhi.
9. Indian Herbal Pharmacopoeia, IDMA, Mumbai.
10. Plant drug analysis by H.Wagner and S.Bladt, 2nd edition, Springer, Berlin.
11. Standardization of Botanicals. Testing and extraction methods of medicinal herbs by V. Rajpal (2004), Vol.I, Eastern PublisherS, New Delhi.
12. Herbal Medicine. Expanded Commission E Monographs, M.Blumenthal

Name of the Subject	**Indian System of Medicine** (Theory)
Name of the Faculty	Mr. G. Ramu M. Pharm
Designation, Department	Lecturer, Department of Pharmacognosy
Mobile Number	9972317434
e-Mail i.d.	ramupharmu@jssuni.edu.in

Scope, Course Objectives and Course Outcomes

SCOPE

To make the students understand thoroughly the principles, preparations of medicines of various Indian systems of medicine like Ayurveda, Siddha, Homeopathy and Unani. Also focusing on clinical research of traditional medicines, quality assurance and challenges in monitoring the safety of herbal medicines.

OBJECTIVES

This course intend to deliver the following

- To understand the basic principles of various Indian systems of medicine
- To know the clinical research of traditional medicines, Current Good Manufacturing Practice of Indian systems of medicine and their formulations.

COURSE OUTCOMES (COs):

At completion of this course it is expected that the students will be able to

CO 1: Understand the therapeutic efficacy of medicinal plants used in this alternative system of medicine-herbal medicine.

CO 2: Know about the Aromatherapy practices

CO 3: Study the formulation and development of practices

CO 4: Understand the good manufacturing practices of Indian Systems of Medicine.

LECTURE PLAN – Abstract

Sessional	No. of Hours of Didactic Lecture	No of Hours of other Activities	Total No. of Lecture Hours
I	28	08	36
II	16	08	24
Total No. of Hours	44	16	60

I SESSIONAL : 25 Lectures + 11 Activities

Lecture No.	Lecture Details	Hours
Unit-1 Fundamental concepts of ISM:		**12**
	Welcome and Introduction to Course	
1.	Different dosage forms of ISM	
2.	Principle Involved in Ayurveda	
3.	Principle Involved in Homeopathy	
4.	Principle Invoved in Siddha	
5.	Principle Involved in Unani	
6.	Ayurvedic Pharmacopoeia	
7.	Analysis of Crude Drugs	
8.	Analysis of Formulations	
9.	Gunapadam and Purification	
10.	Raw drugs and Dhatu in Siddha	
11.	Coursework/Assignment/Activity/Revision	
12.	Coursework/Assignment/Activity/Revision	
Unit-2 Naturopathy, Yoga and Aromatherapy:		**12**
1	Introduction to Naturopathy	
2	Basic Principles I	
3	Basic Principles II	
4	Treatment modalities in Naturopathy	
5	Introduction to Yoga	
6	Various streams of Yoga	
7	Asanas and Pranayama	
8	Meditations and Relaxation Techniques	
9	Coursework/Assignment/Activity/Revision	
10	Coursework/Assignment/Activity/Revision	
11	Coursework/Assignment/Activity/Revision	
12	Coursework/Assignment/Activity/Revision	
Unit-3 Formulation of ISM:		**12**
1	Salient features of Formulations	
2	Methods of preparation	
3	Siddha formulations	
4	Ayurveda formulations	
5	Unani formulations	
6	Standardisation of Unani formulations	

7.	Standardisation of Homeopathy	
8.	Standardisation of Siddha	
9.	Standardisation of Ayurveda	
10	Shelf Life and stability studies	
11.	Coursework/Assignment/Activity/Revision	
12	Coursework/Assignment/Activity/Revision	

II SESSIONAL : 16 Lectures + 8 Activities

Lecture No.	Lecture Details	Hours
Unit- 4 Good Manufacturing Practice		**12**
1	Schedule T	
2	Introduction to GMP	
3	Components of GMP	
4	Infrastructural requirements	
5	Working place, storage area and equipments	
6	Standard operating procedures	
7	Documentation and Records	
8	Quality Assurance	
9	GAP, GMP and GLP and Pharmacopoeias	
10	New Drug application and Export registration	
11	Coursework/Assignment/Activity/Revision	
12	Coursework/Assignment/Activity/Revision	
Unit-5 Pharmacopoeias and Bills:		**12**
1	TKDL	
2	Geographical indication bill I	
3	Geographical indication bill II	
4	Government bills in AYUSH	
5	Bills in ISM	
6	Bills in ISM II	
7	CCRAS, CCRH	
8	CCRS, CCRU	
9	Coursework/Assignment/Activity/Revision	
10	Coursework/Assignment/Activity/Revision	
11	Coursework/Assignment/Activity/Revision	
12	Coursework/Assignment/Activity/Revision	

Text books & References

1. Ayurvedic Pharmacopoeia, The Controller of Publications, Civil Lines, Govt. of India, New Delhi.
2. Hand Book on Ayurvedic Medicines, H. Panda, National Institute of Industrial Research, New Delhi. Ayurvedic System of Medicine, Kaviraj Nagendranath Sengupata, Sri Satguru Publications, New Delhi.
3. Ayurvedic Pharmacopoeia. Formulary of Ayurvedic Medicines, IMCOPS, Chennai.
4. Homeopathic Pharmacopoeia. Formulary of Ayurvedic Medicines, IMCOPS, Chennai.

5. Indian Herbal Pharmacopoeia, IDMA, Mumbai
6. Homeopathic Pharmacy : An introduction and Hand book, Steven B. Kayne, Churchill Livingstone, New York
7. Essential of Food and Nutrition, Swaminathan, Bappco, Bangalore. Tropical Botanic Garden & Research Institute, 1995.

Name of the Subject	**Herbal Cosmetics (Theory)**
Name of the Faculty	Dr. Suresh K. Mohankumar M.Pharm., Ph.D
Designation, Department	Professor, Department of Pharmacognosy
Mobile Number	8903451179
e-Mail i.d.	suresh.jsscpo@jssuni.edu.in

Scope, Course Objectives and Course Outcomes

SCOPE

This subject deals with the study of preparation and standardization of herbal/natural cosmetics. This subject gives emphasis to various national and international standards prescribed regarding herbal cosmeceuticals.

OBJECTIVES

This course intend to deliver the following

- Basic principles of various herbal/natural cosmetic preparations
- GMP of herbal/natural cosmetics as per the regulations.

COURSE OUTCOMES (COs):

At completion of this course it is expected that the students will be able to

CO 1 :Demonstrate the understanding of the regulatory provisions to manufacture of cosmetics

CO 2 : Demonstrate the commonly used herbal cosmetics and the possible interactions between chemicals and herbs

CO 3 : Demonstrate the Preparation and standardization of herbal cosmetics

CO 4: Demonstrate preparation of cosmoceuticals

CO 5 : Demonstrate analysis of cosmetics

LECTURE PLAN – Abstract

Sessional	No. of Hours of Didactic Lecture	No of Hours of other Activities	Total No. of Lecture Hours
I	25	11	36
II	16	08	24
Total No. of Hours	41	19	60

I SESSIONAL : 25 Lectures + 11 Activities

Lecture No.	Lecture Details	Hours
Unit-1 Herbal Cosmetic Industry		**12**
	Welcome and Intro to Course	
1	Introduction: Herbal/natural cosmetics	
2	Classification & Economic aspects	
3	Regulatory Provisions relation to manufacture of cosmetics:	
4	License, GMP, offences & Penalties	
5	Import & Export of Herbal/natural cosmetics	
6	Industries involved in the production of Herbal/natural cosmetics	
7	Coursework/Assignment/Activity/Revision	
8	Coursework/Assignment/Activity/Revision	
9	Coursework/Assignment/Activity/Revision	
10	Coursework/Assignment/Activity/Revision	
11	Coursework/Assignment/Activity/Revision	
12	Coursework/Assignment/Activity/Revision	
Unit-2 Commonly used herbal cosmetics		**12**
1	Commonly used herbal cosmetics	
2	Raw materials	
3	Preservatives	
4	Surfactants	
5	Humectants	
6	Oils	
7	Colours	
8	Preformulation studies and design of herbal cosmetic formulation.	
9	Compatibility studies	
10	Possible interactions between chemicals and herbs	
11	Coursework/Assignment/Activity/Revision	
12	Coursework/Assignment/Activity/Revision	
Unit-3 Herbal Cosmetics		**12**
1.	Physiology and chemistry of skin and pigmentation	
2.	Skin & Skin Care-1	
3.	Skin and Skin Care-2	
4.	Nail & Nail Care	
5.	Hair & Hair Care	
6.	Toileteris	
7.	Baby Products	
8.	Oral and Oral Care	
9.	Beautification products	

10.	Coursework/Assignment/Activity/Revision	
11.	Coursework/Assignment/Activity/Revision	
12.	Coursework/Assignment/Activity/Revision	

II SESSIONAL : 16 Lectures + 8 Activities

Lecture No.	Lecture Details	Hours
Unit- 4 Cosmetic of Natural Origin		**12**
1.	Hair growth formulations	
2.	Shampoo & Conditioners	
3.	Colorants and hair oils	
4.	Fairness Formulation	
5.	Vanishing and Foundation Creams	
6.	Anti-Sun Burn Preparations	
7.	Moisturising Creams	
8.	Deodorants	
9.	Coursework/Assignment/Activity/Revision	
10.	Coursework/Assignment/Activity/Revision	
11.	Coursework/Assignment/Activity/Revision	
12.	Coursework/Assignment/Activity/Revision	
Unit-5 Analysis of cosmetics		**12**
1.	Analysis of Cosmetics	
2.	Analysis of Cosmetics	
3.	Quality control and toxicity studies as per Drug and Cosmetics Act.	
4.	Quality control and toxicity studies as per Drug and Cosmetics Act.	
5.	Quality control and toxicity studies as per Drug and Cosmetics Act.	
6.	Toxicity screening and test methods	
7.	Toxicity screening and test methods	
8.	Toxicity screening and test methods	
9.	Coursework/Assignment/Activity/Revision	
10.	Coursework/Assignment/Activity/Revision	
11.	Coursework/Assignment/Activity/Revision	
12.	Coursework/Assignment/Activity/Revision	

Text Books & References

1. Panda H. Herbal Cosmetics (Hand book), Asia Pacific Business Press Inc, New Delhi.
2. Thomson EG. Modern Cosmetics, Universal Publishing Corporation, Mumbai.
3. P.P.Sharma. Cosmetics – Formulation, Manufacturing & Quality Control, Vandana Publications, New Delhi.
4. SupriyaK B. Handbook of Aromatic Plants, Pointer Publishers, Jaipur.
5. Skaria P.Aromatic Plants (Horticulture Science Series), New India Publishing Agency, New Delhi.
6. Kathi Keville and Mindy Green. Aromatheraphy (A Complete Guide to the Healing Art), Sri Satguru Publications, New Delhi.
7. Chattopadhyay PK. Herbal Cosmetics & Ayurvedic Medicines (EOU), National Institute of Industrial Research, Delhi.

8. Balsam MS & Edward Sagarin. Cosmetics Science and Technology, Wiley Interscience, New York.

MPG 205P Herbal Cosmetics Practicals

Sessional	Herbal Cosmetics Practicals	No of Hours of other Activities	Total No. of Lecture Hours
I	08	48	48
II	07	42	42
Total No. of Hours	15	90	90

I Sessional Practicals

S. No.	Name of the Experiment
1.	Isolation of nucleic acid from Cauliflower heads
2.	Isolation of RNA from yeast
3.	Quantitative estimation of DNA
4.	Immobilization technique
5.	Establishment of Callus culture
6.	Establishment of suspension culture
7.	Estimation of aldehyde contents of volatile oil
8.	Estimation of total phenolic content in herbal raw materials

II Sessional Practicals

S. No.	Name of the Experiment
1.	Estimation of total alkaloid content in herbal raw materials
2.	Estimation of total flavonoid content in herbal raw materials
3	Preparation and standardization of dosage forms from ISM
4.	Preparation of certain Aromatherapy formulations
5	Preparation of some herbal cosmetic formulations
6	Evaluation of herbal tablets and capsules
7	Preparation of sunscreen, UV protection cream, skin care formulations.
8	Formulation and standardization of herbal cough syrup.

JSS Academy of Higher Education & Research, Mysuru
JSS College of Pharmacy, Rocklands, Ooty

I M. PHARMACY TIME TABLE FOR E-LEARN CLASSES : I Semester (AY : 2020 - 2021)

DEPARTMENT : PHARMACOGNOSY

ZOOM / GOOGLE MEET LICENSE - cpocog1@jssuni.edu.in

Days	9 - 10 am	10 - 11 am	11 - 12 am	12 - 1 pm	1 - 2 pm	2 - 3 pm	3 - 4 pm	4 - 5 pm
Mon		MPAT ***(NKV)***	PC ***(BDS)***	Virtual Library	**LUNCH BREAK**	IPT **(SMK)**		Seminar
Tue		MPAT ***(NKV)***	PC ***(BDS)***	Virtual Library		IPT **(SMK)**	AP1 ***(GR)***	Seminar
Wed		MPAT ***(NKV)***	PC ***(BDS)***			IPT **(SMK)**	AP1 ***(GR)***	Seminar
Thu		MPAT ***(NKV)***		PC ***(BDS)***		IPT **(SMK)**	AP1 ***(GR)***	Seminar
Fri		Assignment	Virtual Library				AP1 ***(GR)***	Assignment
Sat		Assignment						

Subjects : I M.Pharm (Pharm. Analysis)

1. Modern Pharmaceutical Analytical Techniques MPAT MPG101T : Dr. N. Krishna veni ***(NKV)***
2. Advanced Pharmacognosy -1 AP1 MPG102T : Mr. G. Ramu ***(GR)***
3. Phytochemistry PC MPG103T : Dr. B. Duraiswamy ***(BDS)***
4. Industrial Pharmacognostical Technology IPT MPG104T : Dr. Suresh Kumar Mohan ***(SMK)***

JSS Academy of Higher Education & Research, Mysuru
(Deemed to be University, Accredited 'A' Grade by NAAC)
JSS College of Pharmacy, Rocklands, Ootacamund
(An ISO 9001-2015 Certified Institution)
Department of Pharmacognosy and Phytopharmacy
I M. Pharmacy, II Semester (AY 2020-21 (Jan – May 2021)

Day	09-10 AM	10-11 AM	11AM -12 Noon	12 Noon- 1PM	LUNCH BREAK	02– 03 PM	03-04 PM	04-05 PM
Monday	Library	MPB (T) *(BDS)*	AP II (T) *(KR)*	Revision		Pharmacognosy Practicals I (ISM) *(GR)*		
Tuesday	AP II (T) *(KR)*	Pharmacognosy Practicals II (PP II) *(KR)*				ISM (T) *(GR)*	ISM (T) *(GR)*	Test
Wednesday	Library	HC (T) *(SKM)*	HC (T) (SKM)	Library		Pharmacognosy Practicals II (MPB) *(BDS)*		
Thursday	HC (T) (SKM)	MPB (T) *(BDS)*	HC (T) (SKM)	Test		Pharmacognosy Practicals II (HC) *(SKM)*		
Friday	HC (T) (SKM)	MPB (T) *(BDS)*	AP II (T) *(KR)*	Seminar		ISM (T) *(GR)*	MPB (T) *(BDS)*	Test
Saturday	Library	ISM (T) *(GR)*	AP II (T) *(KR)*					

Advanced Pharmacognosy II (AP II) - Dr. K. Rajendiran (KR)
Medicinal Plant Biotechnology (MPB) - Dr. B. Duraiswamy *(BDS)*
Indian System of Medicine (ISM) - G. Ramu *(GR)*
Herbal Cosmetics (HC) - Dr. Suresh Mohan Kumar *(SMK)*