# JSS Academy of Higher Education and Research

# **JSS College of Pharmacy**

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> Website: <u>www.jssuni.edu.in</u> An ISO 9001:2015 Certified Institution



V<sup>th</sup> Pharm.D. Course Handout 2020-21



Ranked 4th in India for 2019

# Academic Calendar 2020-21

# (V Pharm.D.)

# **Teacher's Incharge**

Class	Class Teacher	Batch No.	Batch Teacher
V Pharm.D.	Dr. Juny Sebastian (JUS)	Ι	Dr. Juny Sebastian
	DI. Juliy Sebastian (103)	II	Dr. Krishna Undela

# **ACTIVITIES AND COORDINATORS 2020-21**

# **Curricular & Co curricular activities**

SI. No	Activities	Coordinator/s
1.	Induction, learning skills and personality development programs for fresher's	DHP/MPG
2.	Selection of class representative in first week of con	nmencement of each course
3.	Anti ragging cell	HP/BM
4.	Grievance and redressal cell	РКК
5.	Industrial Visits, Training and placements	TS/ABP
6.	Guest lectures & Seminars/ conferences/ training / workshop • organized at college • delivered/attended by staff	Respective department all HODs
7.	Internal Assessment Committee Chairperson Members	GVP RSS/SNM/DAT/BMV
8.	<ul> <li>Academic Council Board</li> <li>Identification of Advanced/ Medium/ Slow learners</li> </ul>	Class Teachers Subject Teachers
9.	Ethics committee Meeting • Animal • Human	KLK MR
10.	Time table	DHP TS/URR/VR/AMM/HYK
11.	Internal Quality Assurance Cell Chairperson Members	PKK/ AMM/AKT/HVG/SP
	Women's cell (Prevention of Sexual Harassment Cell)	SNM
13.	Scholarship Bureau	RSC

14.	Compilation of publications (Research papers/books/chapters)	BMG	
15.	Research Coordination Committee -Compilation of Ph.D details and funded projects - Plagiarism - Review of publications	Chairperson – DVG Members – BRP/SB/JS	
16.	Pharmacy Education Unit (CCLPE)	PKK/KU/RSS	
17.	Annual result analysis List of merit students	UG – Subject Teacher, Class teacher & Program committee PG – Course Coordinator & Abhishek (Office)	
18.	GPAT and other competitive exams (TOEFL, GRE etc.)	BM/ CSH/MPG	
19.	Library orientation	Librarian	
20.	Soft Skills Training	ABP	

# Extracurricular activities

Sl. No.	Activities	Coordinator/s
21.	Selection of Class Representatives,	MSS/ SRD
	Pharmaceutical society members	
	<ul> <li>Annual planning and execution of Student</li> </ul>	
	centered and professional activities including	
	inauguration of IPS	
22.	JASPHARM	BS/SM/CSH
23.	STUMAG	НҮК
24.	Sports coordinators	MPV/HKS
25.	NSS coordinators	MPG / UM/ SND
26.	Cultural & Literary coordinators	KNS/CI

# Other Institutional activities

Sl.	Activities	Coordinator/s	
No.	Activities		
27.	Annual Day celebration / Graduation day	DAT/SM	
28.	Course handouts/ Teachers diary/	HYK/PS	
	Student handbook/Faculty handbook		
29.	National Pharmacy Week (NPW) & Pharmacists	VJ/ UM + IPA team	
	Day		
30.	Alumni association	HVG/AKT/SM/BS	
31.	Herbal and College Garden	JS/ NPK/VR	
32.	ISO	DHP/SNM	
33.	Press and publicity	KLK/BMV/OFFICE	
34.	Foreign students cell	MPV	

35.	Governing council meeting	JUS/ Office
36.	Monthly/Annual report of college	HoDs/JUS/ST/AKT/AM/KU/NPK
	activities to JSS AHER and other agencies	Asha (office)
37.	College website	HKS/KU
38.	Research & Consultancy Co-ordinator	DVG/SB/KM
	<ul> <li>Collaboration with Industries/organizations</li> </ul>	
	<ul> <li>Interdepartment/Interdisciplinary research</li> </ul>	
39.	Coordinator - JSSUonline.com	ABP/TS
40.	JSSU Newsletter	KLK
		SRD/ KNS
41.	Annual group photo session	MSS/ SRD
42.	Lab coat and Blazers	JS / Ningaraju
43.	Notice Board (SNB, LNB and IIPC), Departmental	Nagaraju
	staff list	
44.	Stock verification	Office staff /Librarian
45.	Student Liaison	Divya S
<b>46.</b>	Student ID Cards / Attendance entry	Shivanna / Manjunath
47.	Retreat for Pharmacy Students	AKT/ HKS/BRJ
48.	Feedback	VJ
<b>49.</b>	Institute Innovation Cell	HVG/PKK
50.	Practice School	MPG/VJ

# Program Committee

Sl. No.	Program committees	Chairperson	Member Secretary
51.	D.Pharm	РКК	BMV
52.	B.Pharm	РКК	DAT
53.	Pharm.D	MR	RSS
54.	M.Pharm	РКК	SNM
55.	B.Pharm – Practice	MR	BRJ
56.	PG Diploma	РКК	JS

# M.Pharm Program Coordinators

Sl. No.	M.Pharm Program	Coordinator	
57.	Pharmaceutics	VJ	
58.	Industrial Pharmacy	ABP	
<b>59.</b>	Pharmaceutical Regualatory Affairs	MPV	
60.	Pharmaceutical Quality Assurance	HVG	
61.	Pharmaceutical Chemistry	BRP	

62.	Pharmaceutical Analysis	BMG
63.	Pharmacology	KLK
64.	Pharmacognosy	NPK
65.	Pharmacy Practice	SP

# PG Diploma Program Coordinators

Sl. No.	PG Diploma Program	Coordinator	
66.	Pharmacovigilance	CSH	
67.	Medicine & Poison Information	RSS	
<b>68.</b>	Clinical Research	JUS	
69.	Nanotechnology	VJ	
70.	Pharmaceutical Quality Assurance	HVG	
71.	Pharmaceutical Regulatory Affairs	MPV	
72.	Medical Devices	BMV	
73.	Intellectual Property Rights	BMV	
74.	Computer Aided Drug Design	DAT	
75.	Food and Drug Analysis	RSC	
76.	Regulatory Toxicology	SB	
77.	Phytopharmaceutical and Industrial Applications	JS	

# **Certificate Course Coordinators**

Sl. No.	Certificate Course	Coordinator	
78.	Pharmaceutical Quality Assurance	HVG	
79.	Herbal Drug Standardization	JS	
80.	Medicine Information RSS		

# **TEACHING STAFF LIST**

Sl. No	NAME	QUALIFICATION	DESIGNATION	Department
1	Dr. T.M. Pramod Kumar (TMP)	M.Pharm., Ph.D.	Professor &	Pharmaceutics

			Principal	
2	Dr. P.K. Kulkarni (PKK)	M.Pharm., Ph.D.	Professor & Vice Principal	Pharmaceutics
3	Dr. D. Vishakante Gowda (DVG)	M.Pharm., Ph.D.	Professor & Head	Pharmaceutics
4	Dr. Balamuralidhara V. (BMV)	M.Pharm., Ph.D.	Asst. Professor	Pharmaceutics
5	Dr. Gangadharappa H.V.(HVG)	M.Pharm., Ph.D.	Asst. Professor	Pharmaceutics
6	Dr. M.P. Venkatesh (MPV)	M.Pharm., Ph.D.	Asst. Professor	Pharmaceutics
7	Dr. Vikas Jain (VJ)	M.Pharm., Ph.D.	Asst. Professor	Pharmaceutics
8	Dr. Amit B Patil (ABP)	M.Pharm., Ph.D.	Asst. Professor	Pharmaceutics
9	Dr. Gowrav M P (MPG)	M.Pharm., Ph.D.	Lecturer	Pharmaceutics
10	Mr. Hemanth Kumar S (HKS)	M.Pharm	Lecturer	Pharmaceutics
11	Mrs. Asha Spandana K M (ASP)	M.Pharm	Lecturer	Pharmaceutics
12	Mr B Mahendran (BM)	M.Pharm	Lecturer	Pharmaceutics
13	Dr Shailesh T (TS)	M.Pharm., Ph.D.	Lecturer	Pharmaceutics
14	Smt Preethi S (PS)	M.Pharm	Lecturer	Pharmaceutics
15	Dr. M. Ramesh (MR)	M.Pharm., Ph.D.	Professor & Head	Pharmacy Practice
16	Mr. D.H. P. Gowda (DHP)	M.Sc., PGDCA.	Asst. Professor	Pharmacy Practice
17	Mrs. Shilpa Palaksha (SP)	M.Pharm.	Asst. Professor	Pharmacy Practice
18	Mrs. Savitha R S (RSS)	M.Pharm.	Asst. Professor	Pharmacy Practice
19	Mr. Jaidev Kumar B R (BRJ)	M.Pharm.	Lecturer	Pharmacy Practice
20	Dr. M Umesh (UM)	Pharm D.	Lecturer	Pharmacy Practice
21	Dr. Juny Sebstian (JUS)	M.Pharm., Ph.D.	Lecturer	Pharmacy Practice
22	Dr Sri Harsha Chalasani (CSH)	M.Pharm., Ph.D.	Lecturer	Pharmacy Practice
23	Dr. Krishna Undela (KU)	M.Pharm., Ph.D.	Lecturer	Pharmacy Practice
24	Dr Srikanth M S (MSS)	M.Pharm., Ph.D.	Lecturer	Pharmacy Practice
25	Mr Balaji S (BS)	M.Pharm	Lecturer	Pharmacy Practice
26	Dr U R Rakshith (URR)	Pharm D	Lecturer	Pharmacy Practice
27	Dr. B.M. Gurupadayya (BMG)	M.Pharm., Ph.D.	Professor	Pharma. Chemistry
28	Dr. Gurubasavaraj V Pujar (GVP)	M.Pharm., Ph.D.	Professor & Head	Pharma. Chemistry
29	Dr. Prashantha Kumar B R (BRP)	M.Pharm., Ph.D.	Asst. Professor	Pharma. Chemistry
30	Dr. R. S. Chandan (RSC)	M.Pharm., Ph.D.	Asst. Professor	Pharma. Chemistry
31	Dr. Anand Kumar Tengli (AKT)	M.Pharm., Ph.D.	Asst. Professor	Pharma. Chemistry
32	Dr. Durai Ananda Kumar (DAT)	M.Pharm., Ph.D.	Asst. Professor	Pharma. Chemistry
33	Dr. Jaishree V (JV)	M.Pharm., Ph.D.	Asst. Professor	Pharma. Chemistry
34	Dr. H. Yogish Kumar (HYK)	M.Pharm., Ph.D.	Lecturer	Pharma. Chemistry
35	Dr. Sheshagiri Dixit (SRD)	M.Pharm., Ph.D.	Lecturer	Pharma. Chemistry
36	Mr. Chetan.I.A	M.Pharm	Lecturer	Pharma. Chemistry
37	Dr.K Mruthunjaya (KM)	M.Pharm., Ph.D.	Professor & Head	Pharmacognosy
38	Dr. J. Suresh (JS)	M.Pharm., Ph.D.	Professor	Pharmacognosy

39	Dr. N Paramakrishnan (NPK)	M.Pharm., Ph.D.	Lecturer	Pharmacognosy
40	Mr. Vageesh Revadigar (VR)	M.Pharm	Lecturer	Pharmacognosy
41	Ms. Haripriya G	M Pharm	Lecturer	Pharmacognosy
42	Dr. S. N. Manjula (SNM)	M.Pharm., Ph.D.	Professor &	Pharmacology
			Head	
43	Dr. Saravana Babu C (SB)	M.Pharm., Ph.D.	Asso.Professor	Pharmacology
44	Dr. K L Krishna (KLK)	M.Pharm., Ph.D.	Asst. Professor	Pharmacology
45	Mrs. A M Mahalakshmi	M.Pharm.	Lecturer	Pharmacology
	(AMM)			
46	Mrs. Seema Mehdi (SM)	M.Pharm	Lecturer	Pharmacology
47	Dr. Nagashree K S (KNS)	M.Pharm., Ph.D	Lecturer	Pharmacology

## PHARM.D

## **Expected Competencies and outcomes:**

- 1. Development of knowledge and skills
- 2. Assessment of patient medical condition
- 3. Development of pharmaceutical care plan
- 4. Management of patient medication therapy
- 5. Pharmacotherapeutic decision-making skills
- 6. Hospital pharmacy management
- 7. Promote public health care program
- 8. Ethics and professionalism
- 9. Analytical thinking and interpretational skills
- 10. Communication skills
- 11. Management skills
- 12. Design and conduct of need based research projects
- 13. Life-long learning

# COURSE HAND OUT 2020-21

# Class: V Pharm. D

#### I Course Details

S.No.	Name of Subject	No. of hours of Theory	No. of hours of Practical/ Hospital Posting	No. of hours of Seminar
(1)	(2)	(3)	(4)	(5)
5.1	Clinical Research	3		1
5.2	Pharmacoepidemiology and	3		1
	Pharmacoeconomics			
5.3	Clinical Pharmacokinetics &	2		1
	Pharmacotherapeutic Drug Monitoring			
5.4	Clerkship *			1
5.5	Project work (Six Months)		20	
	Total hours	8	20	4
	Grand Total		32 hrs/ week	

#### \* Attending ward rounds on daily basis.

#### 2. Evaluations:

**Theory**: Internal assessment Marks: 30. Three periodic theory sessional examinations will be conducted in theory for 30 marks (*duration 1.5 Hours*) and average of best two will be considered for evaluation.

Classes will be awarded on the basis of total (sessional and annual examination) marks secured.

Class	Marks
Distinction	75% and above
First class	60% and above and less than 75%
Second class	50% and above and less than 60%
Pass class	Passed examination in more than one attempt.

- **3** Sessional Examination schedule: I, II and III sessional dates will be announced separately.
- **4** Attendance: Minimum of 80% attendance is necessary to appear for both Sessional and Annual examination.
- 5 Chamber consultation hours: Any time during College hours.
- 6 Seminar

Objective of the seminar is to enhance the learning ability and help students in better understanding of the given topic. This provides a best opportunity for the students to clarify their subject doubts. This involves discussions, presentations on specified topics, assignments and evaluation.

# **5.1 CLINICAL RESEARCH**

#### Theory: 3 Hrs / Week

#### **Responsible member/s of the academic staff: Dr. Juny Sebastian (JUS)**

**Scope and Objectives:** This course is designed to make the students to understand the principles and gain adequate knowledge regarding the various approaches to drug discovery including clinical phase of development. Also enables the students to understand and implement all regulatory and ethical requirements that are required during the process of drug development.

#### At completion of this course it is respected that student will be able to:

#### (Student learning outcomes)

#### Theory:

- 1. Discuss process of preclinical and clinical development of a new drug
- 2. Describe the different regulatory requirements to conduct a clinical trial
- 3. List out various clinical trial documents and describe their respective components
- 4. Explain the roles and responsibilities of various clinical trial personnel as per ICH-GCP
- 5. Explain the process of reporting safety information to various stakeholders

#### Teaching/learning methodologies used:

- 1. Lecture
- 2. Discussion

#### 2. Course material

#### **TEXT BOOKS:**

- a. Principles and practice of pharmaceutical medicine, Second edition. Authors:Lionel. D. Edward,Aadrew.J.Flether Anthony W Fos, Peter D Sloaier Publisher:Wiley;
- b. Handbook of clinical research. Julia Lloyd and Ann Raven Ed. Churchill Livingstone
- c. Principles of Clinical Research edited by Giovanna di Ignazio, Di Giovanna and Haynes.

#### **REFERENCES:**

- a. Central Drugs Standard Control Organization. Good Clinical Practices-Guidelines for Clinical Trials on Pharmaceutical Products in India. New Delhi: Ministry of Health; 2001.
- b. 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.

- c. Ethical Guidelines for Biomedical Research on Human Subjects 2000. Indian Council of Medical Research, New Delhi.
- d. Textbook of Clinical Trials edited by David Machin, Simon Day and Sylvan Green, March 2005, John Wiley and Sons.
- e. Principles of Clinical Research edited by Giovanna di Ignazio, Di Giovanna and Haynes.
- f. Clinical Data Management edited by R K Rondels, S A Varley, C F Webbs. Second Edition, Jan 2000, Wiley Publications.
- g. Goodman & Gilman: JG Hardman, LE Limbard, 10th Edn. McGraw Hill Publications, 2001.

#### Lecture wise programme

Topics	Hrs
1. Drug development process:	10
Introduction	
Various Approaches to drug discovery	
1. Pharmacological	
2. Toxicological	
3. IND Application	
4. Drug characterization	
5. Dosage form	
2. Clinical development of drug:	
1. Introduction to Clinical trials.	02
2. Various phases of clinical trial.	08
3. Methods of post marketing surveillance.	04
4. Abbreviated New Drug Application submission.	02
5. Good Clinical Practice – ICH, GCP, Central drug standard control	10
organisation (CDSCO) guidelines.	
6. Challenges in the implementation of guidelines.	02
7. Ethical guidelines in Clinical Research.	02
8. Composition, responsibilities, procedures of IRB / IEC.	02
9. Overview of regulatory environment in USA, Europe and India.	10
10. Role and responsibilities of clinical trial personnel as per ICH GCP	05
a. Sponsor	
b. Investigators	
c. Clinical research associate	
d. Auditors	
e. Contract research coordinators	
f. Regulatory authority	
11. Designing of clinical study documents (protocol, CRF, ICF, PIC with	08
assignment).	

12. Informed consent Process.	02
13. Data management and its components.	05
14. Safety monitoring in clinical trials.	03

## Theory Sessional examination syllabus

Sessional Number	Chapters
Ι	1, 2 (2.1, 2.2, 2.3)
II	2.4,2.5, 2.6, 2.7, 2.8, 2.9
III	2.10, 2.11, 2.12, 2.13, 2.14

# 5.2 PHARMACOEPIDEMIOLOGY & PHARMACOECONOMICS

Theory: 3 Hrs / Week

## Responsible member/s of the academic staff: Mr. Krishna Undela (KU)

**Scope and Objectives:** This course is designed to impart knowledge regarding various methods and applications of Pharmacoepidemiology and Pharmacoeconomics in drug safety monitoring, drug approval and regulations.

## At completion of this course it is respected that student will be able to:

#### (Student learning outcomes)

#### Theory:

- 1. Describe the study designs of Pharmacoepidemiology and types of Pharmacoeconomic evaluations
- 2. Calculate and interpret the various outcome measures used in Pharmacoepidemiology&Pharmacoeconomics
- 3. Apply the concepts of Pharmacoepidemiology&Pharmacoeconomics in performing research.

## Teaching/learning methodologies used:

- 1. Lecture
- 2. Case studies
- 3. Journal Club

## **Course materials:**

## **REFERENCE BOOKS**

- Pharmacoepidemiology. Editors: Brian L Strom, Stephen E Kimmel, Sean Hennessy. Wiley-Black Well (Latest Edition)
- Clinical Epidemiology- How to Do Clinical Practice Research. R. Brian Haynes, David L Sackett, Gordon H. Guyatt, Peter Tugwell, Lippinkot (Latest Edition)
- Essentials of Pharmacoeconomics. Karen L. Rascati. Lippincott, Williams & Wilkins (Latest Edition)
- Pharmacoeconomics and Outcomes: Applications for Patient Care: Case Studies. Editors: Grauer DW, Lee J, Odom TD, et al. American College of Clinical Pharmacy (Latest Edition)

 Introduction to Applied Pharmacoeconomics. F. Randy Vogenberg. New York; London: McGraw-Hill (Latest Edition)

## Lecture wise Programme:

2.       Measurement of outcomes in pharmacoepidemiology       06         Outcome measure and drug use measures       Prevalence, incidence and incidence rate. Monetary units, number of prescriptions, units of drugs dispensed, defined daily doses and prescribed daily doses, medication adherence measurement       06         3.       Concept of risk in Pharmacoepidemiology measurement of risk, attributable risk, relative risk, time-risk relationship and odds ratio       06         4.       Pharmacoepidemiological methods       22         Includes theoretical aspects of various methods and practical study of various methods with the help of case studies for individual methods; Drug utilization review, case reports, case control studies, case – cohort studies, meta – analysis studies, spontaneous reporting, prescription event monitoring and record linkage system.       04         5.       Sources of data for pharmacoepidemiological studies Ad Hoc data sources and automated data systems       04         6.       Selected special applications of pharmacoepidemiology pharmacoepidemiology and risk management and drug induced birth defects.       02         7.       Pharmacoeconomics: Role in formulary management decisions Pharmacoeconomic evaluation Guitom technols with the help of case studies of various methods and practical study of various methods with the help of case studies of various methods and practical study of various methods with the help of advection set of various for harmacoepidemiology       04         6.       Selected special applications of pharmacoepidemiology pharmacoepidemiology and risk management and drug induced birth	1.	<b>Topic</b> <b>Pharmacoepidemiology: Definition and scope:</b> Origin and evaluation of Pharmacoepidemiology, need for pharmacoepidemiology, aims and applications of Pharmacoepidemiology.	Hours 06
Image: Construction of the second state of the sec	2.	Outcome measure and drug use measures Prevalence, incidence and incidence rate. Monetary units, number of prescriptions, units of drugs dispensed, defined daily doses and	06
Includes theoretical aspects of various methods and practical study of various methods with the help of case studies for individual methods; Drug utilization review, case reports, case series, surveys of drug use, cross – sectional studies, cohort studies, case control studies, case – cohort studies, meta – analysis studies, spontaneous reporting, prescription event monitoring and record linkage system.045.Sources of data for pharmacoepidemiological studies Ad Hoc data sources and automated data systems046.Selected special applications of pharmacoepidemiology Studies of vaccine safety, hospital pharmacoepidemiology, pharmacoepidemiology and risk management and drug induced birth defects.027.Pharmacoeconomics: Definition, history, needs of pharmacoeconomic evaluations Pharmacoeconomic evaluation Includes theoretical aspects of various methods and practical study of various methods with the help of case studies for individual methods: Cost – minimization, cost- benefit, cost – effectiveness and cost utility Applications of Pharmacoeconomics03	3.	measurement of risk, attributable risk, relative risk, time-risk	06
Ad Hoc data sources and automated data systems086.Selected special applications of pharmacoepidemiology Studies of vaccine safety, hospital pharmacoepidemiology, pharmacoepidemiology and risk management and drug induced birth defects.087.Pharmacoeconomics: Definition, history, needs of pharmacoeconomic evaluations Role in formulary management decisions Pharmacoeconomic evaluation02Role in formulary management decisions Pharmacoeconomic evaluation02Includes theoretical aspects of various methods and practical study of various methods with the help of case studies for individual methods: Cost – minimization, cost- benefit, cost – effectiveness and cost utility Applications of Pharmacoeconomics03	4.	Includes theoretical aspects of various methods and practical study of various methods with the help of case studies for individual methods; Drug utilization review, case reports, case series, surveys of drug use, cross – sectional studies, cohort studies, case control studies, case – cohort studies, meta – analysis studies, spontaneous reporting,	22
6.Selected special applications of pharmacoepidemiology Studies of vaccine safety, hospital pharmacoepidemiology, pharmacoepidemiology and risk management and drug induced birth defects.087.Pharmacoeconomics: 	5.		04
Definition, history, needs of pharmacoeconomic evaluations02Role in formulary management decisions02Pharmacoeconomic evaluation16Outcome assessment and types of evaluation16Includes theoretical aspects of various methods and practical study of various methods with16the help of case studies for individual methods: Cost – minimization, cost- benefit, cost – effectiveness and cost utility03	6.	Selected special applications of pharmacoepidemiology Studies of vaccine safety, hospital pharmacoepidemiology, pharmacoepidemiology and risk management and drug induced birth	08
Applications of Pharmacoeconomics 03	7.	Definition, history, needs of pharmacoeconomic evaluations Role in formulary management decisions Pharmacoeconomic evaluation Outcome assessment and types of evaluation Includes theoretical aspects of various methods and practical study of various methods with the help of case studies for individual methods: Cost – minimization,	02
NOTIWARE and case studies (assignment discussion)		•	03 02

Sessional No.	Syllabus Chapters No.
Ι	1, 4
II	2, 3, 5, 6
III	7

# Theory Sessional examination syllabus

# 5.3 CLINICAL PHARMACOKINETICS & THERAPEUTIC DRUG MONITORING

## Theory: 2 Hrs/Week

## Responsible member/s of the academic staff: Dr. Sri Harsha Chalasani (CSH)

**Scope and Objectives:** This course is designed to make the students to understand and apply pharmacokinetic principles in designing / individualizing dosage regimen. Also, enable the students to interpret the plasma drug range, and hepatic / renal function in optimizing the drug therapy.

## At completion of this course it is respected that student will be able to:

#### (Student learning outcomes)

Theory:

- 1. List out the factors affecting the designing of dosage regimens and design drug therapy regimen in special populations
- 2. Describe the process of therapeutic drug monitoring of selected drugs and interpret and correlate the plasma drug concentration with therapeutic outcome.
- 3. Describe the various approaches for dosage adjustment in renal and hepatic disease.
- 4. Explain the inter-individual variability in drug metabolism and drug transport due to genetic polymorphism.
- 5. Explain the concepts of population pharmacokinetics

## Teaching/learning methodologies used:

- 1. Lecture
- 2. Discussion

#### **Course materials:**

## **REFERENCE BOOKS**

- a. Applied Pharmacokinetics & Pharmacodynamics: Principles of Therapeutic Drug Monitoring; Author: Michael E. Burton, Leslie M. Shaw, Jerome J. Schentag, William E. Evans Published by: Lippincott Williams & Wilkins, 2005
- b. Handbook of Analytical Therapeutic Drug Monitoring and Toxicology By Steven How-Yan Wong, Irving Sunshine, Published by CRC Press, 1996

c. Clinical pharmacokinetics, Author: Soraya Dhillon, Andrzej Kostrzewski, Publisher: Pharmaceutical Press

d. Clinical Pharmacokinetics - Rowland and Tozer, Williams and Wilkins Publication.

e. Biopharmaceutics and Applied Pharmacokinetics - Leon Shargel, Prentice Hall publication

## Lecture wise Programme:

Topics	Hrs
on to Clinical pharmacokinetics	01
and Tabulations in designing dosage regimen, conversion from intra- nination of dose and dosing intervals, drug dosing in the elderly and	
kinetics of Drug Interaction: macokinetic drug interactions bition and Induction of Drug metabolism	03
<b>c Drug monitoring</b> luction idualization of drug dosage regimen (Variability – Genetic, age, we ase and Interacting drugs). ations for TDM, Protocol for TDM. macokinetic/Pharmacodynamic Correlation in drug therapy.	20 ight,
re disorders, Psychiatric conditions, and Organ transplantations. <b>justment in Renal and hepatic Disease</b> . I impairment macokinetic considerations eral approach for dosage adjustment in Renal disease. surement of Glomerular Filtration rate. age adjustment for uremic patients.	10
ct of Hepatic disease on pharmacokinetics. <b>Pharmacokinetics.</b> oduction to Bayesian Theory. ptive method or Dosing with feed back. lysis of Population pharmacokinetic Data. genetics	05 04 mes.
	Topics ion to Clinical pharmacokinetics dosage regimens and Tabulations in designing dosage regimen, conversion from intra mination of dose and dosing intervals, drug dosing in the elderly and s. binetics of Drug Interaction: macokinetic drug interactions bition and Induction of Drug metabolism bition and Induction of Drug metabolism bition of Biliary Excretion. ic Drug monitoring duction vidualization of drug dosage regimen (Variability – Genetic, age, wei ase and Interacting drugs). ations for TDM, Protocol for TDM. macokinetic/Pharmacodynamic Correlation in drug therapy. I of drugs used in the following conditions: Cardiovascular disease, are disorders, Psychiatric conditions, and Organ transplantations. Jjustment in Renal and hepatic Disease. al impairment macokinetic considerations eral approach for dosage adjustment in Renal disease. surement of Glomerular Filtration rate. age adjustment for uremic patients. acorporeal removal of drugs. ct of Hepatic disease on pharmacokinetics. n Pharmacokinetics. oduction to Bayesian Theory. ptive method or Dosing with feed back. lysis of Population pharmacokinetic Data. genetics etc polymorphism in Drug metabolism: Cytochrome P-450 Isoenzy etc Polymorphism in Drug Transport and Drug Targets.

## Theory Sessional examination Syllabus

Sessional Number	Chapters	
Ι	1,2, 3 and 7	
II	4	
III	5 and 6	

# JSS Academy of Higher Education & Research JSS College of Pharmacy, Mysuru

## Modified Schedule and Link for Online Classes – PharmD

(w.e.f 01-06-2020)

## PharmD – Fifth Year

Day	02:00 PM to 02:50 PM	03:00 PM to 03:50 PM	04:00 PM to 04:50 PM
Mon	Clinical Research	Pharmacoepidemiology and Pharmacoeconomics	Case Presentation / Journal Club
Tue	Clinical Pharmacokinetics & Pharmacotherapeutic Drug Monitoring	Pharmacoepidemiology and Pharmacoeconomics	Case Presentation / Journal Club
Wed	Clinical Research	Clinical Pharmacokinetics & Pharmacotherapeutic Drug Monitoring	Case Presentation / Journal Club
Thu	Clinical Research	Pharmacoepidemiology and Pharmacoeconomics	Case Presentation / Journal Club
Fri	Clinical Pharmacokinetics & Pharmacotherapeutic Drug Monitoring	Pharmacoepidemiology and Pharmacoeconomics	Case Presentation / Journal Club

#### JSS Academy of Higher Education & Research JSS College of Pharmacy Sri Shivarathreeshwara Nagara, Mysore-570015 CLASS TIME TABLE- 2020-21

#### Lunch Break: 1.00 to 2.00 PM Tea Break: 10.40 to 11.10 AM 3.50 PM to 4.05 PM

#### Time 11.10-12.05PM 12.05-1.00PM 5.00-5.55PM 9.50-10.40AM 2.00-2.55PM 9.00-09.50AM 2.55-3.50PM 4.05-5.00PM Day Pharmacoepidemiology & Pharmacoeconomics Pharma coepidemiology & Monday Pharmacoeconomics KU KU Pharma coepidemiology & Pharma coepidemiology Pharmacoeconomics Tuesday & Pharmacoeconomics L (Seminar) T E U N C H KU KU T E Clinical A Pharmacokinetics A & Pharmacotherapeut Clinical Research в Clinical Research Wednesday R \_ B R E JUS JUS ie Drug Monitoring CSH Ε в A K R E A K Clinical **Clinical Pharmacokinetics** A K Pharma cokinetics & Pharma cotherapeutic & Pharmacotherapeutic Pharmacotnesser Drug Monitoring CSH Thursday Drug Monitoring (Seminar)CSH Clinical Research Clinical Research (Seminar) Friday JUS JUS Saturday

\*Effective from: 24th June 2020

Class: PHARM. D -FIFTH YEAR

Note: 1. No tea break for practicals

Time table Coordinator Copy: SNB/LNB/SCF/e.copy – teachers/ Office in charge – time table / Time table coordinator

Principal

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