

Jss Academy of Higher Education & Research, Mysuru
JSS COLLEGE OF PHARMACY, ROCKLANDS, OOTY

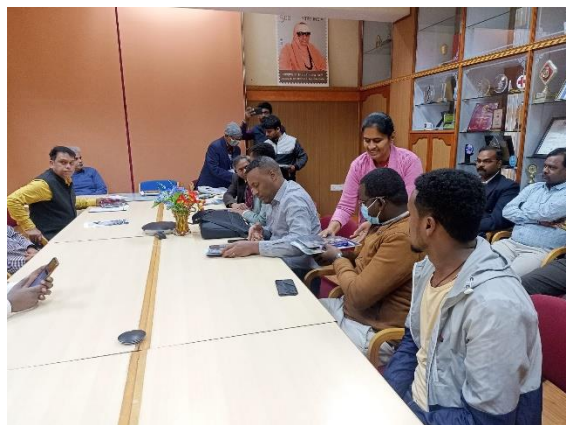
JSSAHER, Mysuru Sponsored

7 Days Training Program for Ethiopian Food and Drug Authority Officials (EFDA)
On
“Analytical Instrumentation, Medicine Microbiology and Audit, Inspection”
19 – 25 January 2023

Report

The 7 days training program for the Ethiopian FDA officials was hosted by JSS AHER, Mysuru at JSS College of Pharmacy, Ooty from 19 – 25 January 2023. About 9 delegates working in the various disciplines of Ethiopian FDA including QC chemist for Pharmaceuticals & Food, Regulatory auditors, Food inspectors and microbiologists participated in the training program. These delegates were trained in the various fields of Advanced analytical techniques – LC-MS/MS, GC-MS/MS, HPTLC, Advanced Medicine Microbiology Techniques for Bacterial Endotoxin, Microbial Limit & Sterility Testing; and Advanced audit Inspection Techniques”.

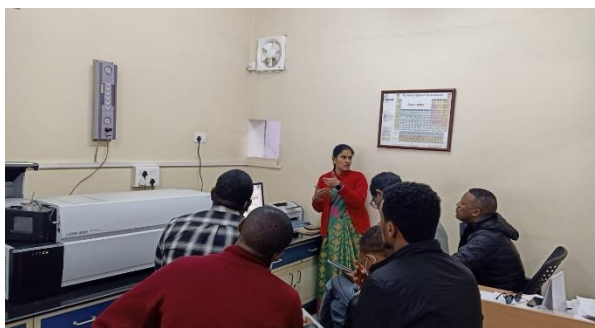
The delegates were formally welcomed at the board room by Dr. S N Meyyanathan, Professor, Department of Pharmaceutical Analysis and the Coordinators of the training program Dr. N. Krishna veni, Professor & Head, Department of Pharmaceutical Analysis, Dr. K. Gowthamarajan, Professor & Head, Department of Pharmaceutics, Dr. R. Rajesh Kumar, Assistant Professor & Head i/c, Department of Pharmaceutical Biotechnology and Dr. G N K Ganesh, Associate Professor on 19.01.2023. The coordinators of the training program briefed about the various components of the training to the delegates. The kit bags along with the abstract books were distributed to the Ethiopian FDA officials.



The officials were then divided into groups based on the training opted and were sent to the departments. The training program was successfully initiated with interaction with the department faculty to understand their needs and further skill development.

Seven Ethiopian FDA officials namely Mr. Tibebu Abuna Worku, Mr. Siyalkalem Endeshaw Zeleke, Mr. Amogne Manaye Wagaw, Mr. Muzeyen Abuna Chiro, Mr. Mesfin Mezemir Abebe, Mr. Mewdedie Shiferaw Tulu and Mr. Wosenyeleh Ambaw Ayele from the QC

laboratory for quality control testing of pharmaceuticals and food were provided training in the theoretical and practical aspects of HPLC, LC-MS/MS, HPTLC for four days by the department faculty Dr. N. Krishna veni and Dr. S N Meyyanathan, Faculty, Department of Pharmaceutical Analysis. All the officials were first provided the demonstration on handling the LC-MS/MS, use of the software and analysis of the pharmacopoeial components. Then on the day two and three they were allowed to handle the instrument including the selection of the interface used, selection of various modes for the quantification and qualification of analytes viz., SCAN, SIM, Product ion scan, Precursor ion scan and MRM mode. They were also provided hands on training on the use of the LC-MS software (LC solutions). Insight was also provided to the participants on the report generation and optimisation of the LC method for quantification using LC-MS/MS technique.



The Officials were trained on gas chromatography and GC-MS/MS for two days. The theoretical concepts were well explained by Dr. N. Krishna Veni, Faculty, Department of Pharmaceutical Analysis. The practical training on the GC-MS/MS & ICP-MS including the utilisation of the software was provided at SACON (Salim Ali Centre for Ornithology and Natural History), Anaikatty, Coimbatore Facility.



The Advanced Medicine Audit and Inspection Techniques training was provided to one Ethiopian FDA official namely, Mr. Eyobed Atakilt Shawel. The day 1 was started with the discussions on understanding the guidelines and types of audits, Auditor skills and competencies, Principles and audit planning. The sessions were handled by Mr. Murugappan.M and Mr. Vivek Reddy, Faculty, Department of Pharmaceutics. The next consecutive days started with discussions on Auditing Operational control, Auditing Product Control, Auditing Laboratory, Auditing other systems, Audit – closer and reporting, Case studies, Global Trend Analysis and Shaping future Pharma Firms. The sessions were handled by Mr. Balaji. K, director, pharmagenie, Chennai. Discussions on Auditing of Quality Management Systems – auditing facility, Material management handling and storage was handled by Dr. G.N.K. Ganesh, Faculty, Department of Pharmaceutics. The training was provided by including case studies and real time happening in the pharmaceutical industries during audits.



Whereas in the Department of Biotechnology, Mr. Betizaz Damew Belete was provided seven days training Advanced Medicine Microbiology Techniques for Bacterial Endotoxin, Microbial Limit & Sterility Testing. Training sessions on bacterial endotoxin tests, antimicrobial assays, growth promotion tests, preservative efficacy tests, and clean room design were provided for EFDA officials.



The Department provided hands-on training, addressed both theoretical and practical components, and thoroughly covered the numerous parameters that must be evaluated during each test. The first day of the training covered the fundamental safety procedures to be followed in the microbiology lab as well as a demonstration of the tools and equipment used in medical microbiology. On the appropriate days, we conducted tests to identify bacterial toxins in sterile preparations, assess antibiotic concentration and potency, measure the effectiveness of a preservative added to pharmaceutical preparations, and finally determine the parameters that must be examined when designing a clean room. The Department faculty Dr. Vasanth Raj. P and Mr. Alin Bose were actively involved in providing the required training to the Ethiopian FDA official.



On the last day, the feed back form was requested, all the Ethiopian FDA officials were highly satisfied with the training provided by the trainers and appreciated the hospitality extended and the efforts put forth by the trainers to teach them at JSS College of Pharmacy, Ooty. The Ethiopian EFDA officials were formally felicitated as per the Indian Tradition on the valedictory session of the program held on 25.01.2023 at 9.30 AM.



The Departments of Pharmaceutical Analysis, Pharmaceutics & Pharmaceutical Biotechnology are thankful to the leadership of JSS Mahavidyapeetha and JSS AHER, Mysuru for providing the opportunity to train the international delegates during the phase II Session.