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 Institution)

JSSAHER, Mysuru and Department of Science & Technology R&D Infrastructure Division "Synergistic Training program Utilizing the Scientific and Technological Infrastructure (STUTI)"

Sponsored 7 days training program on

"Basic techniques in Pharmaceutical Formulations, Analytical and Pre-clinical studies"

Inauguration Program

Seeking the blessings of his holiness Jagadguru Swamiji the Inauguration Program was held on 27/06/2022 at 9:00 Am after the registration of the participants was done by 8:30Am, Dr. A.P.J Abdul Kalam Seminar Hall was selected as the venue of the function. The function started with Thamizhthai Vazhthu and Prayer song. Then the dignitaries and participants were welcomed with the speech of **Dr. S.P. Dhanabal**, Principal, JSS College of Pharmacy, Ooty. The formal opening was performed by Lighting of Kuthuvilaku by the respected guests. **Dr. Prashant V**, Program Coordinator and Research Director JSS AHER, Mysuru addressed the gathering by giving them an insight of genesis training program and its importance. The guests of honor, **Dr. B Manjunatha,** Registrar, JSS AHER **Dr. Surinder Singh,** Vice Chancellor, JSS AHER, Mysuru gave their view about the training program and importance of the institute in the field of pharmaceutical sciences. President of the program, **Dr. C.G. Betsurmath,** Executive Secretary, JSS Mahavidyapeetha, Mysuru delivered his thoughts about the program and future of DST-STUTI sponsored programs in the University. At last Dr. Pramod Kumar T.M, Dean, JSSAHER and Principal, JSS College of Pharmacy, Mysore Conveyed the university message and congratulated the College of Pharmacy, Ooty for the upcoming 7-day training workshop.

Then Every Participant introduced themselves and the scientific sessions started after a brief refreshment gap.

Department of pharmaceutics (DST -FIST Sponsored)

Report for the events that were conducted in the Department of Pharmaceutics, with respect to the DST-STUTI event "Basic techniques in Pharmaceutical Formulations, Analytical and Pre-clinical studies" The total workshop was for 7 days, in which the first 2 days were conducted by the department of pharmaceutics.

The events that took place in the Department of Pharmaceutics were divided into 2 days comprising of both theory and practical sessions in each day keeping in mind the formulation strategies for both traditional and nano dosage forms.

Theory interactions were limited only to the necessary requirements for the practical involvement and focus was kept more towards discussion and sessions that might enhance the knowledge of the participants in the future of formulations and to help them create ideas for novel formulations in the future.

Day 1 (27/06/2022)

After the formal inauguration program, Department of pharmaceutics officially started the technical sessions for the 7-day long workshop. Following is a consolidated report of the events that took place.

10Am- 11.30 Pm

Dr. K. Gowthamarajan, Professor and head, Department of Pharmaceutics started the technical session with a lecture and discussion on the topic "Formulation strategy for designing of dosage form". In the 1.5 hour talk he covered the vast history of development of formulations as we see it today, spoke about different formulations, challenges and ways to reduce the problems in formulation. He spoke in detail about stress reduction of dosage form and thermodynamic stability. His talk also included topics like, Microneedle formulations, electronic formulations, future of drug delivery, theranostics, and 3D printing of medicines.
Later in the talk, he went on to describe the concept of personalized formulations and ways to make it a reality. The Session also included topics about space medicine and future of the formulation.

11:30Am- 11:45 Am
Tea Break.

11:45 Am- 1:00Pm:

Texture Analyzer
By: Dr. V. Senthil
Dr. V Senthil, Produced an Overview of the Instrument Texture Analyzer. He described in detail about the Principle, Theoretical Procedure, Construction, Working and the applications of the instrument in both pharmaceutical and food industry. The talk then included data management from the instrument, different portions of the graph, and interpretation of obtained results. The talk included measurement of properties like viscosity, density, tensile strength, Tablet hardness, brittleness, spread ability. Bloom strength, adhesion and cohesion properties of different dosage forms.

Differential Scanning Calorimeter
By: Dr. Karri VVS Narayana Reddy
Dr. Karri VVS Narayana Reddy conducted a theoretical lecture on the instrument Differential Scanning Calorimeter, this talk included important topics like principle of thermal conduction, thermal properties of matter, different transitions of states of matter, mechanism, Instrumentation, Data management, interpretation of graph to report purity, thermal incompatibility, melting point, transitions of different materials.
He then provided the participants a theoretical overview of parts of the instrument and requirements for handling of the Instrument.

1:00Pm – 2:00Pm

Lunch Break.

2:00 – 6:00 pm

Practical Session:
All the participants were divided into 4 groups, and they were taken for hands on training on Differential scanning calorimeter and texture analyzer simultaneously. Each batch spend 1 hour time with each instrument.

Texture Analyzer:

By Dr. V. Senthil.
The participants were given a hand on training on calibration, fixing of different jigs, manual fixing of the moving head, instruction about the safety features and other requirements were also discussed. Then the participants were individually given training on method development on the TrapeziumX software from shimadzu and then they were trained for testing of Tensile strength of fiber, hardness of tablet, burst test of capsules and spread ability of gel.

Diffrential Scanning Calorimeter:

By Dr. Karri VVS Narayana Reddy

The participants were briefed about the operations and sampling pans and sample preparations of DSC. They were shown on how to operate the cooling system, sampling chamber and nitrogen gas flow. Then hands on training were given by using gaba pentene and PEG 4000 in sealed T-Zero aluminum pans and the purity, Melting point was analyzed from the obtained graph.

They were briefed about interpretation of both endothermic and exothermic graphs and as well as they were versed in a facile manner about compatibility studies using thermograms of physical mixture of excipients and API.

Day 2:

Day 2 was planned to have lectures and demonstrations with hands on training keeping nano formulations in mind. It started with lectures on nano emulsion

9:00 Am – 11:30 Am:
Dr. Suresh Kumar R, Dr. N Jawahar, and Dr. GNK Ganesh Conducted a lecture on the topic of "**Formulation strategy for designing nano tools and Regulatory guidelines for nano tools**" Each of the speakers took equal time in turns to explain the different types of nano formulation preparations like chemical, biological and mechanical methods. Then each of the methods were elaborated along with their principles, methods, and applications. They have put in more efforts in explanation of requirement for green and sustainable synthesis, top down, and bottom-up methods for synthesis of nano particles.
The lecture also included different types of nanoparticle explanations like Solid lipid nano particles, nanocarriers, liposomes, phytosomes, metallic nanoparticles etc.
Then the speakers explained the parameters related to nanoparticles and their stability like particle size, zeta potential, entrapment efficiency, size, and shape etc. and formulation impact on these formulations were also discussed.
The next part of the lecture consisted of various regulatory guidelines for successful marketing of nano formulations in current Indian and International scenario.

11:30 Am – 11:45 Am
Tea Break

11:45 Am – 1:00 Pm

Lecture on Spray Dryer:
By: Dr. N. Jawahar.
In this Lecture Dr. N Jawahar covered topics related to spray drying technology regarding the mechanism, principle, construction and working of spray dryer, function of different nozzles and application of the tech in pharmaceutical products. He also discussed the topic od spray drying related to nano particles using nano nozzle.

Lecture on Particle size analyzer.
By: Dr. Suresh Kumar R.
This lecture delivered by Dr. Suresh Kumar R consisted of application driven theoretical portion of working, construction and applications of size analyzers. Measurement of zeta potential and fundamentals of Dynamic light scattering was also described in this session.

2:00 Pm – 6:00 Pm

Practical Session

Spray Dryer:
By: Dr. N. Jawahar and Dr. Suresh Kumar R

The participants were divided into 4 groups, and they were given hands on demonstration on how to connect, operate and collect sample using spray dryer with nano nozzle.
The demonstration was performed by taking paracetamol as sample. The participants were also given hands on training on how to program the spray dryer and how to attach different components like, Nozzle, cyclone separator, injection pump, air compressor etc.

Particle size Analyzer:
By: Dr. N Venkatesh and dr. GNK. Ganesh

These 4 groups were then involved in the demonstration of Anton Paar litesizer, for particle size analysis and zeta potential. The participants were briefed about the handling, sampling technique and different type of cuvettes that are used in the determination of particle size and zeta potential.
Then they were given hands on training on operation of the software and the data retrieval process along with the interpretation of graph and terms like hydrodynamic diameter, Polydispersity index, etc.

The session ended with an end note about formulations and providing the participants with essential information about other aspects of conventional and nano formulation, giving them slight insight about the vast area that is, Pharmaceutical Formulations.

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Department of Pharmaceutical Analysis (DST – FIST Sponsored Department)

After the completion of the training at Department of Pharmaceutics, the 30 DST STUTI training participants were trained at the department of Pharmaceutical Analysis for two days i.e., 29 – 30 June 2022. The participants had an opportunity to learn about the utilization of various analytical instruments Viz., UV, IR, HPLC and LC-MS/MS for the quality control of the pharmaceuticals.

The two days session started with an introduction to the department, departmental faculty and various research and academic activities carried out in the department by Dr. N. Krishna Veni. Two lecture sessions were organized on the following topics to make them understand the basic theoretical aspects and practical aspects of HPLC and LC-MS/MS as the participants were from various specialization.

In the afternoon session the participants were divided in to two groups of 15 each. A practical session on the utilization of UV visible spectrophotometer for the analysis of samples withdrawn from the dissolution samples/ The use of IR spectrophotometer for the identification of pharmaceuticals as per IP were organized.

On the second day the participants were divided into two groups. On the first half session, group I was trained on HPLC for the quantification of related substances in paracetamol and Group II was demonstrated the use of LC-MS/MS for the quantification of Paracetamol in bulk and tablet formulation. In the afternoon session the groups were swapped and the training was provided.

Day I: 29.06.2022

9.45 – 10.00 AM

The session of Day I started with introduction to the department and department activities. Dr. N. Krishna veni, Professor & Head, presented on the various academic and research activities carried out by the department. She also provided the brief introduction to the faculty including their research background for the benefit of the participants.

10.00 – 11.30 AM – Basic Theoretical aspects of Chromatography

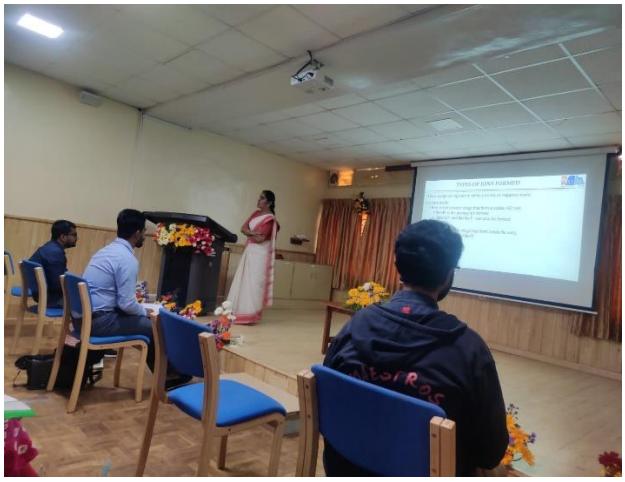
Dr. JSK Nagarajan, Associate Professor, delivered a lecture on the basic theoretical aspects of HPLC to the participants. In his lecture he briefly discussed about the instrumentation of

HPLC, use of various detectors with respect to the nature of the analyte. The practical's aspects of method development including selection of mobile phase, selection of the stationary phase, wavelength selection and other aspects. He had also discussed the application and trouble shooting parameters for the HPLC.

11.30 – 11.45 AM – Tea Break

11.45 – 1.00 PM – Theory, Principle, Instrumentation and Application of LC-MS/MS

Dr. N. Krishna Veni, Professor & Head delivered this lecture to the participants. She discussed in the detail the use of HPLC, the advantages of the hyphenated techniques, various interfaces, detectors used in LC-MS/MS. She also discussed the practical aspects of ionization, enhancement of ionization efficiency, use of LC-MS/ MS for qualitative and quantitative aspects, interpretation of results and the application of the techniques in various fields including pharmaceuticals, herbals and environmental studies.



1.00 – 2.00 PM - Lunch

2.00 – 6.00 PM - Practical Demonstration, performance of Quantification of paracetamol content from dissolution samples by UV /Practical Demonstration, performance of identification test and compatibility studies for paracetamol tablets by IR

On the second half of the day 1, the participants were divided into two batches – Batch I & II.

Between 2.00 – 4.00 PM the batch I was provided with the practical demonstration of UV along with the practical hands-on training on the use of UV visible spectrophotometer for the quantification of paracetamol in dissolution studies. The trainer of the session was Dr. M R Jeyaprakash, Associate professor. He explained the basic aspects of dissolution and the use of analytical instrument for the quantification of dissolution samples utilizing the prepared tablets

of Paracetamol (150 mg). The participants were then trained to carry out the dissolution study, ie., use of dissolution instrument for the study, analysis of the samples using UV visible spectrophotometer.

Whereas the Batch II Was provided hands on training on IR instrument by Dr. S N Meyyanathan, Professor of the department. He explained the participants the practical aspects of IR including the sample preparation techniques. He also demonstrated the preparation of KBr pellets for recording the IR spectra and also the use of IR software to record the spectra. He also demonstrated the interpretation of the spectra for various functional groups present in the drug selected ie., paracetamol.

Between 4.00 – 6.00 PM the batches were swapped, and the training was provided.

Day 2 – 30.06.2022 - Demonstration and practical training on – HPLC for estimation of related substances & Quantification of paracetamol by LC-MS/MS

10.00 AM – 6.00 PM

On Day two of the training program, again the participants were divided into two batches and were provided demonstration and hands on training for the use of HPLC and LC-MS/MS for the quality control of pharmaceuticals.

Dr. MR Jeyaprakash, Associate professor trained the participants on the use of HPLC and Dr. B. Babu, Assistant Professor trained them for the use of LC-MS/MS in the quantitative analysis of paracetamol and related substances.

During the second half of the day the batches were interchanged, and the training was provided.

The participants were trained on the use of HPLC instrument for the analysis of related substances in paracetamol as per Indian Pharmacopoeia. Firstly, they were demonstrated on the various components of HPLC instrument, preparation of mobile phase, standard and sample solutions for analysis and then they were asked to inject the samples and record the chromatograms using the HPLC instruments. The recorded chromatograms were further provided to the participants for reporting the results. They were also trained in calculating the system suitability parameters for the qualification of the analytical method as per the IP.

Whereas Dr. B. Babu, firstly provided a practical demonstration on the use of LC-MS/MS instrument for the quantification of paracetamol in formulations. He demonstrated the various components of LC-MS/MS instrument, the preparation of mobile phase, selection of stationary phase, use of scan, SIM and MRM mode for the quantification of paracetamol. The participants were then trained to interpret the results obtained during the analysis of standard and sample solutions using the TIC chromatograms.

Department of pharmacology (DST -FIST Sponsored)

The last two days i.e., 01 & 02 July 2022 of the DST-STUTI program was hosted in Department of Pharmacology. The participants of this training program had an opportunity to learn various preclinical screening techniques of drugs. First day, the participants were learned about basic principle and history of animal testing, alternative techniques to animal models and ethical guidelines for the animal experimentation. Also, the participants were given with hands-on training on animal handling, routes of drug administration, anesthesia induction and blood collection techniques in laboratory animals.

Second day, the participants were taught about design of animal experiments, randomization, groupings and principle of bioassay techniques. They had a training on dose calculation methods and stereotaxic surgery including intracerebroventricular drug administration methods. The training program was conducted in preclinical laboratory of pharmacology department. The detailed session wise report has been summarized below.

Day 1: 01.07.2022 – Basic Techniques on Animal Experimentation

10.00 – 11.30 am: Animal Testing: History and Alternative Techniques by Dr Praveen TK
Dr Praveen has discussed about scientifically validated alternative methods for animal testing in research and the Principles of Humane Experimental Technique, which introduced the "3Rs" of alternative experimental methods. He also added about the concepts of humane research and the importance of alternatives.

He explained about 3Rs i.e., 1. Refine animal use by lessening or liminating pain or distress in animals, or enhancing animal well-being 2. Reduce animal use by decreasing the number of animals required for testing while still obtaining the testing objectives 3. Replace animal use with either non-animal methods or a less developed animal species (for example, replacing a mouse with a fish). Dr Praveen has detailed about epidemiological studies, in vitro human tissue culture models, clinical studies, autopsies and post-mortem studies, Computerized patient-drug databases and post-marketing surveillance, Mathematical models and computer simulations and finally about Non-invasive imaging techniques, Chromatography and spectroscopy.

11.30 – 11.45 am: Tea Break

11.45– 1.00 pm: CPCSEA Guidelines and Animal Experimentation by Dr Vadivelan R

Dr Vadivelan has discussed about usage of animals in research for development of medicine, He has explained about Cartesian philosophy in the 17th century, i.e., the experiments on animals could be performed without great moral problems. He defined about biological similarities between man and animal, contributed to the increase of animal experimentation. Dr Vadivelan emphasized on increased interest in and concern about animal welfare issues led to legislative regulations in many countries and the establishment of animal ethics committees. He discussed about Committee for the Purpose of Control and Supervision on Experiments on Animals (CPCSEA) guidelines for animal testing and its goal is to promote the humane care of animals used in biomedical and behavioural research and testing. He has described about animal wellbeing, quality in the pursuit of advancement of biological knowledge that is relevant to humans and animals.

1.00 – 2.00 pm: Lunch Break

2.00 – 3.30 pm: Basic Techniques in Laboratory Animals – Handling and Routes of Drug Administration by Dr Divakar S

Dr Divakar has demonstrated about various handling methods of animals like rats and mice. He has elaborated about proper handling methods of animals. Also, he has explained about gender identification methods in animals. He also demonstrated the various routes of drug administration like oral, subcutaneous, intravenous and intramuscular injection techniques.

3.30 – 3.45 pm: Tea Break

3.45 – 6.00 pm: Basic Techniques in Laboratory Animals – Anesthesia and Blood Collection Techniques by Mr Saravanan J

In this session, the participants were demonstrated with various anesthesia methods to experimental animals and basics in blood collection & bleeding techniques in experimental animals. The participants had an opportunity to learn about difference between the local and general anesthetics methods, short duration anesthetic agents, long duration anesthetic agents, pre-anesthetic medications and anesthetic chambers. The participants also learned about various

blood collection techniques like tail vein puncture, orbital sinus puncture in rats and marginal ear vein blood collection in rabbits.

Day 2: 02.07.2022 – Design of Preclinical Experiments and Bioassay

10.00 – 11.30 am: Design of Animal Experiments: Dose calculation by Dr Anand Vijayakumar PR

Dr Anand Vijayakumar has described about various dose calculation methods in animals for preclinical research. He elaborated on dose volume, concentration of dosing mixture, individual animal doses, dose adjustment and human to animal dose conversion methods. He also given examples for rats and mice dose calculations from human dose. The participants had given with some sample dose calculations and answers were validated and corrected.

11.30 – 11.45 am: Tea Break

– 1.00 pm: Design of Animal Experiments: Randomization, groupings and surgical techniques by Dr Justin A

Dr Justin has detailed about the randomization and grouping methods in experimental animals. He has discussed about simple randomization, block randomization and stratified randomization. He elaborated about vehicle control, sham control, negative control, positive control and test control groups. He detailed the various surgical techniques including principle, steps and applications of stereotaxic surgery techniques. He also demonstrated in the lab about intracerebroventricular drug administration in rats using stereotaxic apparatus. He also emphasized about various brain coordinates used in the stereotaxic surgery and its applications.

1.00 – 2.00 pm: Lunch Break

2.00 – 3.30 pm: Bioassay using Chick Ileum by Dr Praveen TK and Mr Shivaramakrishnan

Mr Shivaramakrishnan has discussed about principle of bioassay, types and applications of bioassay. He also elaborated about significance of plotting dose response curve. Dr Praveen TK and his scholar, Ms. Sai Varshini demonstrated the bioassay of acetylcholine using chick ileum in laboratory. The participants were learned about organ bath, mounting of tissues, plotting

graphs and logarithms of doses. They also learned about acetyl choline mechanism of action on chick ileum.

3.30 – 3.45 pm: Tea Break

The valedictory function of the seven days training program was organized on 03.07.2022 at 1.00 PM. Dr. S. P. Dhanabal, Principal. The program coordinators Dr. K. Gowthamarajan, Dr. N. Krishna Veni and Dr. T K Praveen were present for the valedictory function. Dr. K. Gowthamarajan, Professor & Head, Department of Pharmaceutics welcomed the guest and the participants. Dr. T K Praveen, Professor & Head, Department of Pharmacology presented the report on the seven days training program. The feed back was provided by the participants. Dr. S P Dhanabal, Principal Delivered the Chief guest address and presented the certificates to the participants. Dr. N. Krishna Veni, Professor & Head, Department of Pharmaceutical Analysis proposed the vote of thanks.

-- End of Report --