# A training session report on Pre-Clinical Drug Screening and Characterization of Pharmaceuticals

Under STUTI program funded by DST



In association with

## Indian Institute of Technology, Gandhinagar

(Project Management Unit)



Coordinated by

Dr Ketan Ranch; Dr M. M. Mansuri; Dr. Devang Sheth

L. M. College of Pharmacy Ahmedabad, Gujarat, India 26<sup>th</sup> September to 2<sup>nd</sup> October 2022

#### Acknowledgement

We convey gratitude for the encouragement and support received from multiple sources during the execution of this training since its beginning. First and foremost, we want to express our sincere appreciation to the IIT Gandhinagar (PMU) and Department of Science and Technology (DST) for entrusting us with this project. The workshop was coordinated by **Dr Ketan Ranch**, **Dr M. M. Mansuri** and **Dr. Devang Sheth**. The workshop was conducted on the '*Pre-Clinical Drug Screening and Characterization of Pharmaceuticals*' on the instrument funded by the FIST program (Sanction No.: <u>SR/FST/College-135/2012(C) Date:03/06/2014</u>). Organizing team acknowledge the contributions of the committee, in the implementation and the execution of the program to achieve the objectives of the project, particularly, **Dr M. T. Chhabria** (Convenor and Principal), **Dr. G. B. Shah** (Dept. of Pharmacology), **Prof C. G. Joshi** (Director, GBRC, Gandhinagar) and **Dr. Hiren Patel** (Associate Director, R&D and M.S.T.G, Emcure Pharmaceuticals Pvt Ltd.). We also acknowledge the contributions of LMCP staff and student volunteers without which these sessions could not have been possible.

I also acknowledge all the teaching and non-teaching staff for their contributions, without which these could not have been possible.

Dr Ketan Ranch Dr M. M. Mansuri Dr. Devang Sheth Coordinators

#### **Summary**

The goal of this training session was to provide a general overview on the practical aspects of pre-clinical drug screening and characterization of pharmaceuticals along with the hands on practical knowledge using sophisticated instrumentation techniques among research scholars, faculty, young scientists and industry professionals through a week-long training workshop. The workshop was conducted at L. M. College of Pharmacy from 26<sup>th</sup> September to 2<sup>nd</sup> October 2022 which comprised of lectures and hands on training sessions. This initiative is funded by Department of Science & Technology under the program STUTI (Synergistic Training Program Utilizing the Scientific and Technological Infrastructure). This workshop is aimed to provide an insight into the basic principles and various techniques of animal handling, in vitro drug screening methods, biochemical analysis using ELISA and semi auto analyser, histology and immune-histochemical analysis, preclinical screening of CNS disorders, gel electrophoresis and gel doc, cytotoxicity and cell-viability assays, spirometric analysis using biopac data acquisition system, simulated system for instrumented tablet machines, liposomal formulations, particle size determination, lyophilizer, drug delivery from the hydrogel/ silicone contact lens, challenges in processing of parenteral formulations, innovation trends in pharma & healthcare sector, orally dissolving films and strips, rotary evaporator, etc. The focus of this workshop was to have a balance between theory and practical training on the equipment and schedule was designed in a way that if a theory session for a topic was organized in morning, the hands-on training session for the same topic was organized in afternoon/evening session. 'Emphasis was given on handson use of equipment for demonstration/characterization of sample by each participant for better understanding'.

#### Introduction

L. M. College of Pharmacy conducted 7-day long hands-on training program on 'Pre-Clinical Drug Screening and Characterization of Pharmaceuticals' organized by IIT Gandhinagar, (PMU). The participants from various backgrounds such as Post Graduate, Professors, Scientists, Post-Doc Fellows, Ph.D. Fellows and Industry persons participated in this workshop (Annex-1). The training program was organized during 26<sup>th</sup> September 2022 to 2<sup>nd</sup> October 2022, the activities of which are as mentioned in (Annex-2 and 3). This report provides a quick overview of both the lecture and technical sessions.

#### • <u>Lecture Sessions:</u>

Dr. Satish Patel briefed about the methods of animal handling and care, normal and abnormal behaviors of animals. Mr. Mittal Dalal briefed about the common in-vitro drug screening techniques including in-vitro experiments based on different cellular levels, cell line studies, and their methodology. Dr. Devang Sheth discussed the introduction, application and characteristics of various biochemical analysis techniques such as ELISA and semi-auto analyzer. Dr. Gaurang B. Shah delivered session on general histology and Immuno histochemical analysis, various types of sectioning, staining methods. Dr. Sandip Patel discussed different preclinical screening of CNS disorders, in-vitro and in-vivo evaluation methods, and selection of animal models for psychiatric and neurodegenerative diseases. Mr. Smit Bhavsar explained and demonstrated simulated system for tablet compression machine including various parts of machine & its functioning, tablet press simulator and its operation by using 21CFR Part-11 software. Dr. Praful Bharadia presented and the discussed USFDA and FDA guidelines of parenteral formulations. Mr. Tejas Kharva delivered lecture on the basic preparation and working principal of Dynamic Light Scattering (DLS), stability of nanoparticulate system, formation of agglomerates and prevention of formation of agglomerates in the Nano systems as well as the importance of zeta potential for stability and shelf life of products. Mr. Sarang Shashi delivered the lecture on Lyophilization cycle development and incorporation of PAT as well the instrumentation aspects. Dr. Ketan Ranch delivered a lecture on Drug Delivery from contact lenses which comprised drug delivery aspects, their challenges as well as he presented numerous case studies for an efficient explanation. **Dr. Srinivas Savle** discussed the Innovation trends in Pharma and Healthcare sectors. **Dr. Hiren Patel** explained the need of liposomes in the current market, associated challenges in scale-up and QbD parameters of liposomes. A special focus was levied on the market size and numerous drugs and excipients that can be used for the development of liposomes.

#### • Technical Session

On the first day, Dr. Mustakim Mansuri briefed the participants about the CPCSEA guidelines for animal handling, different forms and annexures required for regulatory filings. Dr. Mehul Chorawala covered the topics such as the basic equipments, cages, housing facilities and food for animals, different strains of mice, handling of mice and rats and animal dosing. All the participants had hands-on experience of handling the animals. On second day, Dr. Devang Sheth provided hands-on training to the participants about the semi-automatic biochemical analyzer. Dr. Avinash khadela explained about the ELISA Plate reader and all the participants had hands-on experience of it. Dr. Sandip Patel introduced and provided hands-on training for the determination of the hematocrit of a blood sample using a hematology analyzer. The third day included hands-on training by Dr. Chirag Patel and Dr. Vishvas Patel for extraction and characterization of human DNA using gel electrophoresis and gel document system with a brief explanation of its clinical significance. Parallel session about cell line study including maintenance of cells, cytotoxicity and cell viability assays i.e., MTT assay, cell counting was conducted by Dr. Sneha Chacko and Mr. Mittal Dalal. On fourth day, Dr. Sandip Patel and Dr. Chirag Patel delivered training to the participants on microtome and microscopy with a brief explanation of sectioning, slicing of parts, fixing and staining. All the participants along with Dr. Ketan Ranch and Dr. Devang Sheth visited GBRC (Gujarat Biotechnology Research Centre), Gandhinagar on fifth day which has state of art instrumental facility in Proteomics & Genomics, Bioinformatics, Next Generation Sequencing and in Analytics. All the participant understood about the instruments and project they have been working on alongside the facility visit. Later, they visited Emcure Pharmaceutical Ltd, Adalaj where Dr. Hiren Patel, Dr. Rushil Shah, Dr. Sanket Shah and Head of HR Department welcomed at their R&D facility and

participants visited different department namely, F&D Oral solid, F&D Injectable and NDDS, Analytical development oral solid and analytical development Injectable. They have excellent facility for Research and development and pilot plant studies. On Sixth Mr. Ghanshaym Nikam (Joint Business Managerday, Industrial. Aimil Instrumentation & Technology, Vadodara) demonstrated the Malvern zeta sizer instrument including basic structure of instrument, sample preparation, how to use software and how to take care of instrument. They also provided hands on experience to all the participants. Mr. M. Esakkiappan (Sr. Service Manager-Process Technology Dept. Spinco Biotech Pvt Ltd.) explained instrumentation part of lyophiliser and briefed about general freeze-drying cycle. The participant learned screen control and preparation of cycle. The seventh day concluded with three technical sessions wherein Mrs. Ishika Shah Modi (Product Manager, Antylia Scientific, Mumbai) and Mr. Manoj Dubey (Antylia Scientific, Mumbai) demonstrated the working of the bead beating homogenizer, Genomax instrument. Dr. Manish Patel discussed about the various aspects of orodispersible films followed by its application and formulation. Hands on training for spreading of film on glass plate using film applicator and use of Vernier caliper was done by each student. Dr. Radhika Pandya and Mrs. Mansi Athalye provided hands-on training of Rotary Evaporator where Ms. Mansi Athalye explained all the basic parts with their significance and application. The participants had hands-on experience of operating the instrument and they were also shown the pre-formulated liposome product and their images prepared by Rotary evaporator.

#### • <u>Types of samples tested</u>

During the technical session, all of the participants expressed an interest in learning from the workshop and characterized samples like microemulsion, micelle, nanosuspension, whole uncoagulated blood, serum, tissue (liver), cell culture, etc.

#### **Outcomes of the Workshop**

The STUTI workshop attracted participants from 13 different institutes (Figure 1). About 30 participants enrolled and attended the "Hands-on Training program on PreClinical Drug Screening and Characterization of Pharmaceuticals". The goal of this training event was to provide a general overview on the practical aspects of preclinical drug screening and characterization of pharmaceuticals along with the hands-on practical knowledge using sophisticated instrumentation techniques. To bring together participants from many disciplines and raise awareness of the institute's advanced facilities. Throughout the workshop, participants actively involved in the session and developed expertise's, asked major questions regarding theoretical and practical aspects of drug screening. This hands-on training program collaborations from many small institutions and national level institutes. Finally, the feedback from the participants was considered in the evaluation of the workshop. The majority of the participants were pleased with the training session and suggested that more workshops should be held in the future. Few participants suggested organizing such a workshop/training session on more regarding full instrumental technique workshop and regulatory needs.





Figure 1. Participants registered workshop from different institutes

### Annexure 1: Brochure for the program



Sr. No.	Candidate Name	Gender	Educational Qualification	Email address	University/Institute
1	Archana Pillai	Female	M.Pharm (Pharmaceutics)	archanapillai1996@gmail.com	Shankersinh Vaghela Bapu Institute of Pharmacy, Gandhinagar, Gujarat
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5	Kapil Kumar	Male	Ph.D (Pharmaceutics)	kapil.py@gmail.com	Apeejay Stya University, Gurgaon, Haryana
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7	Nisha Harendra Khobragade	Female	M.Pharm (Pharmaceutics)	nishakhobragade1994@gmail.com	
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9	J. Subramaniam	Male	Ph.D (Zoology)	jayapalsubramaniam@gmail.com	Bharathiar University, Coimbatore, Tamilnadu
10	Hari Prakash Yadav	Male	M.Sc. (Biochemistry)	hariprakashyadav.rs.chy19@itbhu.ac.in	IIT (BHU), Varanasi, Uttar Pradesh
11	Ingole Kiran Ashok	Female	M.Pharm (Pharmaceutics)	ingolekiran15@gmail.com	Raosaheb Patil Danve College of Pharmacy, Aurangabad, Maharashtra
12	Jigneshkumar Ishwarlal Patel	Male	Ph.D. (Pharmaceutics)	jigneshmpharma@yahoo.com	B.K. Mody Government Pharmacy College, Rajkot, Gujarat
13	Lingaraj Anawal	Male	M.Pharm (Pharmacology)	lingarajanawal@gmail.com	Hanagal Shri Kumareshwar College of Pharmacy, Bagalkot
14	Ms. Hani M. Jani	Female	M.Pharm (Pharmaceutics)	hani.jani@atmiyauni.ac.in	Atmiya University, Rajkot, Gujarat
15	Patel Pratikshkumar	Male	Ph.D. (Polymer Science)	pratiksh.patel@gmail.com	CSIR-National Chemical laboratory, Pune, Maharashtra
16	Rajeshkumar Shantarang Palva	Male	M.Pharm (Pharmaceutics)	rajeshpalva@arghpharmacy.ac.in	A.R.College of Pharmacy and G.H. Patel Institute of Pharmacy, Anand, Gujarat
17	Ruchi Yadav	Female	M.Pharm (Pharmacology)	25ppihu@gmail.com	Nirma University, Ahmedabad, Gujarat
18	Sachin Nashik Sanap	Male	M.Pharm (Pharmaceutics)	sachinsanap505@gmail.com	Pharmaceutics and Pharmacokinetics Division, CSIR-Central Drug Research Institute, Lucknow, Uttara Pradesh
19	Saif Ahmad Khan	Male	M.Pharm (Pharmaceutics)	iamsaif1994@gmail.com	Jamia Hamdard University, New Delhi
20	Smita Jain	Female	M.Pharm (Pharmacology)	smitajain1994@gmail.com	Banasthali Vidyapith, Rajasthan
21	Yashwini Kansara	Female	M.Pharm (Pharmaceutics)	yashwinikansara@gmail.com	Maliba Pharmacy College, Bardoli, Gujarat
22	Sarika Maruti Kamble	Female	Ph.D. (Pharmacology)	sarikakamble999@gmail.com	K K Wagh College of pharmacy Nashik, DBTU University, Maharashtra
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24	Anjali Negi	Female	M.Sc. (Biotechnology)	anjali28negi@gmail.com	CSIR- Indian Institute of Integrative Medicines, Jammu
25	Ms Diksha kumari	Female	M.Sc. (Zoology)	dikshak2012@gmail.com	
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28	Jadav Mukti Anilkumar	Female	M.Pharm (Pharmacology)	jadavmukti@gmail.com	1
29	Shriya Kachroo	Male	M.Sc. (Biochemistry)	shriyakachroo5@gmail.com	Maharaja Sayajirao university of Baroda, Vadodara, Gujarat
30	Dipeksha Hansoti	Female	M.Sc. (Microbiology)	dipeksha- microbiophd@msubaroda.ac.in	

## Annexure 2: List of registered participants for the workshop

	Day 1		Day 5	
26 <sup>th</sup> September, 2022	09:30 Registration 10:30 Inauguration ceremony 12:00 lecture Session-I 01:30 Lunch 02:30 Lab Session-I 04:00 Tea Break	30 <sup>th</sup> September, 2022	Visit to Gujrat Biotechnology Research Centre and Emcure Pharmaceutical LLP	
	Day 2	Day 6		
27 <sup>th</sup> September, 2022	11:00 lecture Session-I 12:00 lecture Session-II 01:30 Lunch 02:30 Lab Session-II 04:00 Tea Break 04:15 Lab Session-III	1 <sup>st</sup> September, 2022	10:30 lecture Session-VIII 12:00 lecture Session-IX 01:30 Lunch 02:30 Lab Session-VIII 04:00 Tea Break 04:15 Lab Session-IX	
	Day 3		Day 7	
28 <sup>th</sup> September, 2022	11:00 lecture Session-IV 12:00 lecture Session-V 01:30 Lunch 02:30 Lab Session-IV 04:00 Tea Break 04:15 Lab Session-V	2 <sup>nd</sup> October, 2022	09:00 lecture Session-X 10:00 lecture Session-XI 11:00 lecture Session-XII 12:00 Lunch 12:30 Lab Session-X 01:15 Lab Session-IX 04:00 Valedictory and Closing Remarks 05:30 Tea Break	
	Day 4			
29 <sup>th</sup> September, 2022	11:00 lecture Session-VI 12:00 lecture Session-VII 01:30 Lunch 02:30 Lab Session-VI 04:00 Tea Break 04:15 Lab Session-VII			

## Annexure 3: Schedule date and activities during the workshop

Sr. No	Content	% Rating
1	Overall grading of the program with reference to relevance of course, module/ content etc.	98% Rated on or above 8 points
2	Overall grading of the facilities provided by the institute, i.e., Hostel, Mess, Classrooms, Transport/infrastructure etc.	99% Rated on or above 8 points
3	Overall grading of the faculty members conducting the training	97% Rated on or above 8 points
4	How do you rate the overall training methodology	98% Rated on or above 8 points
5	How far the field visit is relevant and related to your research study	99% Rated on or above 8 points
6	Usefulness of this training in your current role	98% Rated on or above 8 points
7	Usefulness of this training in future work/job you may handle	98% Rated on or above 8 points
8	How far have you benefitted from interaction with the fellow participants of the training	97% Rated on or above 8 points
9	How far the course material supplied relevant and related to the training curriculum	95% Rated on or above 8 points
10	Overall grading of the process of training	96% Rated on or above 8 points
11	Your recommendation to your peers/ colleagues for the training Program	98% Rated on or above 8 points

## Annexure 4: Feedback summary