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DEPARTMENT OF
SCIENCE & TECHNOLOGY

# A REPORT

# On

# Hands-on Training Program on

# **Development and Characterization of Nanoformulations**

Under the scheme of

# Synergistic Training Program Utilizing the Scientific

and Technological Infrastructure (STUTI)

Organized by

Indian Institute of Technology, Gandhinagar (PMU)

An initiative by

Department of Science and Technology, India

Hosted by

Maliba Pharmacy College

Uka Tarsadia University

Bardoli, Surat, Gujarat

#### ACKNOWLEDGEMENT

The success and final outcome of the DST-STUTI training program required a lot of guidance and assistance from many people and we are extremely fortunate to have got this along the completion of the training. First and foremost, I want to express my sincere appreciation to the Department of Science and Technology (DST) for promoting such programs. Also, I am grateful to IIT Gandhinagar for entrusting Maliba Pharmacy College and designate us as a host institute.

The workshop was convened by Dr. Shailesh A. Shah, Principal, Maliba Pharmacy College and jointly co-ordinated by Dr. Pranav Shah, Dr. Furqan Maulvi and Dr. Ditixa Desai. I extend my gratitude to Dr. Dinesh R. Shah, Provost, Uka Tarsadia University who has been a constant inspiration for the upliftment of Maliba Pharmacy College. I would like to thank Dr. Montu Patel, President of PCI and GSPC; Shri Kiritbhai Patel, Vice President, UTU and Shri Arvindbhai Patel, Joint secretary, UTU to grace the inaugural function with their presence. Organizing team acknowledge the contributions of the speakers and trainers from academia and industry in the implementation and the execution of the program to achieve the objectives of the project. I also acknowledge the untiring efforts of proactive and dedicated staff of Maliba Pharmacy College for the smooth conduction of the program. The organisers would also like to thank the student volunteers and non-teaching staff for their involvement. Last but not the least, I thank all the participants who had come from different parts of the India to attend DST-STUTI training program.

> Convenor Dr. Shailesh A. Shah

#### SUMMARY

Maliba Pharmacy College is approved by All India Council for Technical Education (AICTE), Pharmacy Council of India (PCI), New Delhi and Directorate of Technical Education, Govt. of Gujarat; and affiliated to Uka Tarsadia University. It runs B.Pharm program with an intake of 100 students and is also running M.Pharm and Ph. D. programs in subjects Quality Assurance, Pharmaceutics, Pharmacology and Pharmaceutical Chemistry. Maliba Pharmacy College also runs Pharm. D and Pharm.D (PB) program approved by PCI.

Maliba Pharmacy College has received grants from different agencies like Department of Science and Technology [DST-FIST, Sanction letter No: SR/FST/College-2017/231 (C)], AICTE, Gujarat Council on Science and Technology (GUJCOST), and Uka Tarsadia University. The college also has consultancy project from Leo Lens Technology USA and Sahajanand Medical Technologies Pvt. Ltd, Surat on emerging area of healthcare.

A hand-on training program on the **DST-FIST** supported instruments entitled **"Development and Characterization of Nanoformulations"** was organised at Maliba Pharmacy College from 12<sup>th</sup> to 18<sup>th</sup> September. About 30 participants including faculty members, doctoral and post-graduate students from around the country have attended this training program.

The event was funded by the **Department of Science and Technology (DST)**, under **STUTI (Synergistic Training Program Utilizing the Scientific and Technological Infrastructure)** program, in which **IIT Gandhinagar** acted as **a Project Management Unit (PMU)**.

Apart from the theoretical knowledge, the workshop aimed to provide practical handson experience to the participants through a laboratory session where the characterization of samples and operation of instruments was demonstrated to create awareness among the students, research scholars and faculty. The participants were introduced to various instruments like Zeta sizer, viscometer, texture analyser, HPLC, freeze dryer, dissolution apparatus Type IV, rat ventilator and zebra fish model, its working, troubleshooting, sample analysis and interpretation of results. The lectures also focused on the applications of these instruments in diverse fields like pharmacy, biotechnology, chemistry, microbiology, etc. The participant's samples were also analysed during the program.

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# DAY 1 (12-09-2022)

#### 1. Inaugural Ceremony (10:00 to 11:00 am)

Inauguration ceremony began with the UTU anthem and presence of The President of Pharmacy Council of India, Dr Montukumar Patel as chief guest and dignitaries from university. The STUTI Workshop at Maliba Pharmacy College began with traditional lamp lighting done by Dr Montukumar Patel (President, PCI), Dr Dinesh Shah (Provost, Uka Tarsadia University), Shri Kirit Patel (Vice president, Uka Tarsadia University), Shri Arvind Patel (Vice President, BPKM), Dr Shailesh Shah (Principal, Maliba Pharmacy College) and Dr Ashish Mishra (Dean, Faculty of Pharmacy). **Dr. Pranav J. Shah**, Professor, Maliba Pharmacy College addressed the audience about the objectives of the training program. **Dr. Shailesh A. Shah** welcomed the participants and motivated them to conduct research in their respective fields. **Dr. Dinesh R. Shah** narrated entire journey of the inception of Maliba Pharmacy College and University. In addition, **Dr. Montu Patel** presented an encouraging speech about the changes being bought by Pharmacy Council of India. Inaugural vote of thanks was conveyed by Dr Ditixa Desai, Assistant Professor, Maliba Pharmacy College. The technical sessions began thereafter.



Inaugural ceremony



Group photo of participants with chief guest

## 2. Lecture session 1 (11:00 am to 12:30 pm)

**Dr. Krutika Sawant**, Professor, M. S. University, Baroda, presented a lecture on '**Overview of preparation techniques of Nanoformulations'**. During her lecture, she explained about various techniques of preparation of nanocarriers like polymeric Nanoparticles, solid lipid nanoparticles, lipid polymer hybrid nanoparticles, etc along with its advantages and disadvantages.



Lecture session



Speakers/ Trainers of Day 1: Dr. Krutika Sawant and Dr. Hetal Patel

## 3. Lab Session(2:00 pm to 4:00 pm)

**Dr. Hetal Patel**, Assistant Professor in the Department of Pharmaceutics at Maliba Pharmacy College gave demonstration on various techniques of preparation of nanoparticles. During the session the participants were divided into six groups. They prepared six different formulations which will be characterized in upcoming sessions.



Lab session: Participants in Pharmaceutics Lab

# DAY 2 (13-09-2022)

#### 1. Lecture session 2 (10:00 am to 11:30 am)

**Dr. Hitendra Mahajan,** Professor, Department of Pharmaceutics, R. C. Patel Institute of Pharmaceutical Education and Research, Shirpur, delivered his talk on 'Stability of nanoformulation'. Dr. Mahajan focused on the aspects of physical, chemical and biological stability of nanoformulations and strategies to improve stability.



Speakers/ Trainers of Day 2: Dr. Hitendra Mahajan and Mr. Tejas Kharva



Instrument photograph- Malvern Panalytical, ZS-90

## 2. Lecture session 3 (11:30 am to 1:00 pm)

**Mr. Tejas Kharva,** Application Speciality, Aimil Ltd., Vadodara, gave a thorough and engaging presentation on the Malvern Zetasizer's principles, instruments, troubleshooting, and operation. The Zetasizer provides the ability to measure three characteristic of particles or molecules in a liquid medium. These three fundamental parameters are Particle size, Zeta potential and Molecular weight.



Lecture/ Lab session: Participants in DST-FIST Lab

# 3. Lab session (02:00 pm to 04:00 pm)

**Mr. Tejas Kharva** along with his colleagues Mr. Kishore Chavada and Mr. Ghanshyam Nikam trained participants to operate the instrument, software, load the samples and interpret the results obtained from Zetasizer (Malvern Panalytical, ZS-90).

# DAY 3 (14-09-2022)

# 4. Lecture session 4 (10:00 am to 11:30 am)

**Dr. Pranav J. Shah,** Professor in the Department of Pharmaceutics, Maliba Pharmacy College shared his experience on **'Development of nanoformulations: A Quality by design approach'.** He explained about the fundamentals of the Quality by Design, its importance in development and optimization of drug product with a short case study.



Speakers/ Trainers of Day 3: Dr. Pranav Shah and Dr. Furqan Maulvi

# 5. Lecture session 5 (11:30 am to 1:00 pm)

**Dr. Furqan Maulvi, Assistant Professor** in the Department of Pharmaceutics, Maliba Pharmacy College gave an overview on **'Rheology'** which included the types of flow, its importance in development of nanoformulations, stability of product during storage and mechanical stress. He also focussed his talk on mixing and flow of materials, their packaging into containers, and their removal prior to use, whether it is achieved by pouring from a bottle, extrusion from a tube or passage through a syringe needle.



Instrument photograph-Brookfield Viscometer (DV3TLV) and Texture Analyzer (CT3-4500)



Lab session: Participants in DST-FIST Lab

#### 6. Lab session (2:00 pm to 4:00 pm)

Dr. Furqan Maulvi along with Ms. Kiran Shetty (Junior Research Fellow, GUJCOST), Mrs. Vidya Dhupkar and Mr. Santosh Kori (Service engineer, Komal Scientific Co., Mumbai) demonstrated the Brook field viscometer (DV3TLV) and Brookfield texture analyzer (CT34500). During the training, Dr. Maulvi trained the participants regarding the operation, different modes of analysis and different probes available for different types of samples along with its applications.

# DAY 4 (15-09-2022)

## 7. Lecture session 6 (10:00 am to 11:30 am)

**Dr. Sujata Sawarkar,** Professor, Department of Pharmaceutics, Dr. Bhanuben Nanavati College of Pharmacy, Mumbai delivered a lecture on '**Mucoadhesive Drug Delivery Systems'** with emphasis on development vaginal mucoadhesive system for dual delivery of Fluoxetine and Atazanavir.



Speakers/ Trainers of Day 4: Dr. Sujata Sawarkar and Dr. Shailesh Shah

## 8. Lecture session 7 (11:30 am to 01:00 pm)

HPLC is one of the most trusted methods for analyzing drug content within a formulation. **Dr. Shailesh Shah, Professor,** Department of Quality Assurance, Maliba Pharmacy College taught about HPLC method development. He discussed the principles of HPLC and various aspects of development of a new method for analysis of drug.





Lab session: Participants in Quality Assurance Lab



Instrument photograph- HPLC

## 9. Lab session (2:00 pm to 4:00 pm)

The college is equipped with advanced HPLC (Shimadzu). The hands-on training session on HPLC was conducted by **Dr. Pintu Prajapati,** Assistant professor, Department of Quality Assurance, Maliba Pharmacy College.

# DAY 5 (16-09-2022)

# 10. Lecture session 8 (10:00 am to 11:30 am)

**Dr. Ketan Ranch**, Associate Professor, Department of Pharmaceutics, L. M. College of Pharmacy, Ahmedabad, delivered lecture on 'Lyophilization and its importance'. Dr. Ranch explained the principle of freeze drying process, critical steps involved during the process, variables to be optimized and its applications. He also spoke about the various types of freeze-dried products available in the market and advantages of freeze drying.



Speakers/ Trainers of Day 5: Dr. Ketan Ranch and Mr. Jayakar Shetty

# 11. Lecture session 9 (11:30 am to 01:00 pm)

**Mr. Jayakar Shetty,** Sr. Product Specialist- Traceable & Cole-Parmer discussed about principle, instrumentation and working of Freeze Dryer. He also showed different models available and its distinctive features.



Lab session: Participants in DST-FIST Lab (Instrument photograph)

## 12. Lab session (2:00 pm to 4:00 pm)

**Mr. Jayakar Shetty** along with his colleagues Mr. Kamesh Darji, Mr Sanjeev Mishra and Mr Gaurav.Parashar (From Antylia Scientific) provided practical training on a freeze dryer. During the session, they explained about the importance of pre-freezing the samples, choice of glassware, method of pre-freezing and how to attach a sample on the dryer.



Lab session: Participants in DST-FIST Lab

# DAY 6 (17-09-2022)

#### 13. Industrial Visit (9:30 am)

Apart from theoretical and practical knowledge, it is also important to understand the recent trends and practices which are followed in Industry. In order to expand the knowledge, the participants were guided to **Gufic Biosciences Ltd., Navsari** for an industrial visit accompanied by Dr. Pranav Shah and Dr. Ditixa Desai. On reaching, we meet Mr. Ashok Dev, General Manager, Operations and Mr. Gaurang Pancholi, Dy. General Manager, QA. They gave brief introduction about the industry, its various sites in India, products they manufacture and various departments. Since they are one of the largest manufacturers of Lyophilized injections in India and have a fully automated lyophilization plant, they discuss about Lyophilization equipment. They also discussed about new products which are in pipeline to be marketed. Thereafter we were guided for visit to the lyophilization plant, QC and QA department.



Industrial Visit at Gufic Biosciences

## 14. Lecture session 10 (1:30 am to 4:00 pm)

**Mr. Suhas Yewale,** Associate Director Techno Commercial at Sotax India Pvt. Ltd., Mumbai conducted a lecture on **'USP Type IV Dissolution Apparatus'**. Since dissolution testing plays an important role during drug development, it is used as a quality control tool to monitor batch-to-batch consistency of drug release from a dosage form. It is also used as an *in vitro* surrogate for *in vivo* performance that can guide formulation development and ascertain the need for bioequivalence tests. Several apparatus (compendial and noncompendial) are used for the study of dissolution of compounds and dosage forms. Mr. Yewale focused on the advantages, application and case studies of USP Type IV apparatus.



Speakers/ Trainers of Day 6: Mr. Suhas Yewale

# DAY 7 (18-09-2022)

# 15. Lab Session 11 (9 am to 10:30 am)

A lab session was conducted by **Dr Shrikant Joshi**, Associate Professor, Department of Pharmacology, Maliba Pharmacy College on how to put small animal on artificial ventilation system by demonstrating process on anesthetised rat through hands-on training.





Instrument Photograph- Rat ventilator

### 16. Lab Session (10:30 am to 12:00 noon)

To learn about and explore experimental models on zebrafish, a lab session was conducted by **Dr Rutvi Vaidya** Assistant Professor, Department of Pharmacology, Maliba Pharmacy College where behavioural and visual studies related models were explained followed by hands-on training.

# 17. Valedictory Function (12:00 noon to 12:45 pm)

Valedictory function of the seven day DST- STUTI training program was graced by Dr. Dinesh Shah, Provost, Uka Tarsadia University and Dr Shailesh Shah, Principal, Maliba Pharmacy College. The function began with address by Dr Dinesh Shah followed by closing remarks from Dr. Shailesh Shah. The participants shared their valuable feedback and their learning experiences. Invited dignitaries and faculty members of Maliba Pharmacy College presented certificates to participants with a good will to utilise the knowledge they have earned into practice. On behalf of co-ordinators Dr Furqan Maulvi conveyed vote of thanks to everyone who made the event possible. After group photograph and lunch, team parted from programme to their respective bases.



**Valedictory function** 



Group photo on 7<sup>th</sup> Day



Figure 1: Participants registered for the training program from 16 different institutes.

Sr. No.	Content	Average Rating [0-9]
1	Overall grading of the programme with reference to relevance of cource, module/content etc.	9.8
2	Overall grading of the facilities provided by the institute, i.e, Hostel, Mess, Classroom ,inftrastructure etc.	9.8
3	Overall grading of the faculty members conducting the training	9.8
4	How do you rate the overall training methodology	9.7
5	How far the field visit is relevant and related to your research study	9.5
6	Usefulness of this training in your current role	9.4
7	Usefulness of this training in future work/job you may handle	9.7
8	How far I have you benefitted from interaction with the fellow participants of the training	9.3
9	How far the course material supplied relevant and related to the training curriculum	9.5
10	Overall grading of the process of training	9.9
11	Your recommendation to your peers/ collegues for the training programme	9.9

# Table 1: Feedback Summary [rating from 0 to 10 scale]

Table 2: Types of samples tested

Sr. No.	Instrument Name	Type of sample analyzed	No. of samples
1	Zetasizer	Liquid- Micelles, microemulsion, polymeric nanoparticles, lipid nanocarriers	10
2	Viscometer	Liquid and semisolid- water (reference), cream, gels, ointment	5
3	Texture analyzer	Semisolid and solid- cream, gels, tablet	3
4	Freeze dryer	To convert liquid into solid powder - polymeric nanoparticles	1



Figure 3: Analysis of samples brought during the workshop by participants.



Figure 4: Institute faculty group



Figure 5: Hands on training of participants with instruments

#### Outcome of workshop

The DST-STUTI workshop enticed participants from 16 different institutes (Figure 1) and 4 major areas namely pharmacy, chemistry, biotechnology and microbiology. The goal of this training program was to bring together participants from different disciplines and raise awareness of the institute's advanced facilities. The hands-on training program was focused on development of nanoformulations which involved its method of preparation and characterization. The participants learned preparation technique of 6 different formulations i.e. micelles, microemulsion, polymeric nanoparticles, gel, metal nanoparticles and solid lipid nanoparticles. The in-house prepared samples were than analysed using Zetasizer, viscometer and texture analyser. During the session, participants asked major questions on the optimization and interpretation of instrument generated reports. Apart from these, there was demonstration of HPLC, USP dissolution apparatus IV, rat ventilator and zebra fish models. The above sessions were focussed on the application of the instruments for the development of drug product. Industrial visit was also very fruitful in order to understand the industrial scenario of the process and importance of freeze drying. Finally, the feedback from the participants was considered in the evaluation of the training program (Table 1). The majority of the participants were pleased with the training session and suggested that many such programs be held in the future on topics such as development of novel drug delivery systems, troubleshooting techniques of data collection and optimization of drug product.