# A training session report on Development and Characterization of Nanoformulations

Under

STUTI program funded by DST



In association with

## Indian Institute of Technology, Gandhinagar

(Project Management Unit)



Coordinated By **Dr. Shailesh A. Shah** 

Maliba Pharmacy College Uka Tarsadia University, Bardoli, Surat, Gujarat 12<sup>th</sup> to 18<sup>th</sup> September 2022

## 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 conducted on 'Development and Characterization of Nanoformulations' on the instruments purchased under the DST-FIST grant (Sanctioned Letter No.: SR/FST/College-2017/231 (C)) coordinated 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.

**Project** Coordinator

Dr. Shailesh A. Shah

## Summary

The goal of this training session is to popularize DST-FIST instruments among students, faculty, scientists and industry professionals through a week-long training workshop. The workshop was conducted at Maliba Pharmacy College from 12<sup>th</sup> to 18<sup>th</sup> September 2022 and 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 was aimed to provide an insight into the basic principles and 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 focus of this workshop was to have a proper *balance between theory and practical training on the equipment. Emphasis is on hands-on use of equipment for demonstration/characterization by each participant and analysis of participant's samples''.* 

## Introduction

Maliba Pharmacy College conducted 7-day long training session on DST- FIST funded instrument on 'Development and Characterization of Nanoformulations' workshop in its premises. Participants from various backgrounds such as Post Graduate, Professors, Scientists, B.E./B.Tech. Ph.D. and Post-Doctoral Fellows and Industry persons were invited (Annex-1). The following workshop's activities took place from 12<sup>th</sup> to 18<sup>th</sup> September 2022 (Annex-2 & 3). This report provides a quick overview of both the lecture and technical sessions.

## • <u>Lecture sessions</u>

The session was inaugurated by Dr Montukumar Patel (The President of Pharmacy Council of India), invited as a chief guest. Participants were welcomed by the invited speaker's **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 participants about the objectives of the training program. 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. Dr. Krutika Sawant, (Professor, MSU, Baroda) presented a lecture on 'Overview of preparation techniques of Nanoformulations'. Key aspects of the lecture session was about the various preparatory techniques of nano-carriers like polymeric nano-particles, solid lipid nano-particles, lipid polymer hybrid nano-particles, etc., along with its advantages and disadvantages. Dr. Hitendra Mahajan (Professor, R. C. Patel Institute of Pharmaceutical Education and Research, Shirpur) delivered his talk on 'Stability of nano-formulation'. Dr. Mahajan focused on the aspects of physical, chemical and biological stability of nano-formulations and strategies to improve stability. Mr. Tejas Kharva (Application Specialist, Aimil Ltd., Vadodara), gave a thorough and engaging presentation on the Malvern Zetasizer's principles, instruments, troubleshooting, and operation. Dr. Pranav J. Shah (Professor, Maliba Pharmacy College) shared his experience on 'Development of nanoformulations: A Quality by design approach' and its importance in development and optimization of drug product with a short case study. **Dr. Furqan Maulvi** (Assistant Professor, Maliba Pharmacy College) gave an overview on 'Rheology' in relation to development of nanoformulations, stability of product during storage and mechanical stress. **Dr. Sujata Sawarkar** (Professor, Dr. Bhanuben Nanavati College of Pharmacy, Mumbai) delivered a lecture on 'Mucoadhesive Drug Delivery Systems' with an emphasis on development of vaginal muco-adhesive system for dual delivery of Fluoxetine and Atazanavir. **Dr. Shailesh Shah (Professor,** Maliba Pharmacy College) discussed the principles of HPLC and various aspects of development of a new method for analysis of drug. **Dr. Ketan Ranch** (Associate Professor, L. M. College of Pharmacy, Ahmedabad) delivered a lecture on 'Lyophilization and its importance'. **Mr. Jayakar Shetty** (Sr. Product Specialist- Traceable & Cole-Parmer) discussed about principle, instrumentation and working of Freeze Dryer through an illustration of different models. **Mr. Suhas Yewale** (Associate Director Techno Commercial at *Sotax* India Pvt. Ltd., Mumbai) conducted a lecture on 'USP Type IV Dissolution Apparatus'.

## • <u>Technical Sessions</u>

**On the day one, Dr. Hetal Patel** (Assistant Professor, Maliba Pharmacy College) gave demonstration on various techniques of preparation of nanoparticles. About six different formulations were prepared and characterized. **Mr. Tejas Kharva** and his colleagues (Mr. Kishore Chavada and Mr. Ghanshyam Nikam) gave demonstration on Zetasizer (Malvern Panalytical, ZS-90) to the participants on handling of instrument, software and loading the samples. **On the day two, Dr. Furqan Maulvi** along with Ms. Kiran Shetty (JRF, GUJCOST), Mrs. Vidya Dhupkar and Mr. Santosh Kori (Service engineer, Komal Scientific Co., Mumbai) demonstrated the Brook field viscometer (DV3TLV) and Brookfield texture analyzer (CT3-4500). The hands-on session on HPLC (Shimadzu), was conducted by **Dr. Pintu Prajapati**, (Assistant professor, Maliba Pharmacy College). **Day three lab sessions** was covered by **Mr. Jayakar Shetty** and their colleagues provided practical session on a freeze dryer. **On the Day four**, participants were taken to industrial visit to **M/s. Gufic Biosciences Ltd., Navsari** accompanied by **Dr. Pranav Shah** and **Dr. Ditixa Desai**. The participants were demonstrated the manufacturing of Lyophilized injections. **On the day five**, lab session was conducted by **Dr**.

Shrikant Joshi (Associate Professor, Maliba Pharmacy College) guided the participants in hands-on session, on how to put small animal on artificial ventilation system by anesthetised rat. On the day six, **Dr. Rutvi Vaidya** (Assistant Professor, Maliba Pharmacy College) showed experimental models on zebrafish and led hands-on session on behavioural and visual studies. **On the day seven including hands-on session, a** Valedictory function was held and was graced by **Dr. Dinesh Shah** (Provost, Uka Tarsadia University).

## • Types of samples tested

During the technical session, all of the participants expressed an interest in learning from the workshop and characterized about 19 no. of samples. Moreover, it was observed that, 10 samples were tested on Zetasizer (Liquid- Micelles, micro-emulsion, polymeric nanoparticles, lipid nano-carriers), Viscometer (Liquid and semisolid- water, cream, gels, ointment), Texture analyzer (semisolid and solid- cream, gels, tablet), Freeze dryer (to convert liquid into solid powder polymeric nanoparticles) instruments.

## Outcome of the workshop

The DST-STUTI workshop enticed with 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 Nano formulations which involved its method of preparation and characterization. The participants learned preparation technique of 6 different formulations i.e. micelles, micro-emulsion, polymeric nanoparticles, gel, metal nanoparticles and solid lipid nanoparticles. The inhouse 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 (Annex-4). 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.





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

Annex 1: Brochure for the program.



- 2. Zeta Sizer
  - 3. Rheometer
  - 4. Texture Analyser
  - 5. Freeze Dryer
  - 6. Diffusion / Dissolution Apparatus
  - 7. Rat Ventilator / Zebra Fish Models



on principle, working, data interpretation and analysis, with a mélange of

lectures, demonstrations and practical sessions, conducted by experts in the

field.







#### **ABOUT THE UNIVERSITY**

Uka Tarsadia University (UTU), a state private university was established in 2011 by Bardoli Pradesh Kelavani Mandal, with an objective of meeting the growing demands for quality education. The university received NAAC accreditation 'B+' grade with CGPA of 2.74. The University offers a comprehensive array of academic programs across the disciplines of Management, Commerce, Engineering and Technology, Architecture, Design, Applied Science (Chemistry, Physics, Mathematics, Microbiology, Biotechnology), Computer Science, Pharmacy, Nursing, Physiotherapy and others that lead students to self-enrichment and productive careers in their respective professions, government, business and industry. Located near the town of Bardoli, Gujarat, on a 100+ acre land, the university provides educational opportunities to over 10.000 students.

#### **ABOUT THE INSTITUTE**

Maliba Pharmacy College, a constituent Institute of UTU, is located in the picturesque campus of Gopal Vidyanagar on Bardoli - Mahuva road. The college is approved by All India Council for Technical Education (AICTE), the Pharmacy Council of India (PCI) and Directorate of Technical Education, Govt. of Gujarat. It has been consistently ranked amongst top 100 pharmacy colleges of India as per NIRF. The college has also secured 3<sup>rd</sup> position in GSIRF in 2020 and 2021. The college has won award for excellence in research from Education Department- Government of Gujarat and Outstanding Institute from South Gujarat Chamber of Commerce & Industries (SGCCI). The college has state-of-the-art infrastructure and instrumental facilities and provides a serene atmosphere for academic excellence. The college houses a voluminous library; classrooms with multimedia facilities, well equipped DST-FIST and GUJCOST laboratories, CPCSEA approved animal house, modern Computer and Language labs. The college has its own sophisticated instruments laboratory for the characterization and analysis of pharmaceuticals. The college offers B. Pharm., M. Pharm, Pharm. D, Post baccalaureate PharmD and Ph.D. degree.

#### WORKSHOP DETAILS

#### Eligibility:

Minimum qualification should be Post Graduate (Science/ Pharmacy), Faculty Members/ Scientists/ Post-Doc Fellows/ Ph.D. Fellows/ Industry Personnel who are actively involved in R&D

Duration: 7 days No. of participants: 30

## REGISTRATION

Interested participants must register and only selected candidates would be invited for the workshop. For selected candidates Registration fees, local travel (3<sup>rd</sup> AC train support only), Boarding and lodging will be covered by STUTI grant.

**Registration Deadline: Aug 20, 2022** 

For registration follow the link or Scan QR code https://forms.gle/EkvAaf3emJwkLgRM9



# CONTENTS OF THE WORKSHOP



## Day 1

- Inauguration
- Introduction of the Participants and the Host
- Lecture session 1: Basic introduction to the preparation techniques of nanoparticles
- Lab visit
- Lab session: Preparation of nanoparticles by different techniques

#### Day 2

- Lecture session 2: Particle size measurement techniques
- Lecture session 3: Principle, instrumentation and working of Malvern Zetasizer
- Lab session: Practical training on Zetasizer

#### Day 3

- Lecture session 4: Rheology in pharmaceutical formulations
- Lecture session 5: Principle, instrumentation and working of Brookfield Rheometer
- Lab session: Practical training on Brookfield Rheometer

#### Day 4

- Lecture session 6: Mucoadhesive drug delivery systems
- Lecture session 7: Principle, instrumentation and working of Brookfield Texture Analyzer
- Lab session: Practical training on Brookfield Texture Analyzer

#### Day 5

- Lecture session 8: Lyophilization and its importance
- Lecture session 9: Principle, instrumentation and working of Freeze Dryer
- Lab session: Practical training on Freeze Dryer and Franz Diffusion cell

#### Day 6

- Lecture session 10: Current perspectives in dissolution testing of conventional and novel dosage forms
- Lecture session 11: Introduction and demonstration of type IV dissolution apparatus
  Industrial visit

#### Day 7

- Lecture session 12: Hands-on training on rat ventilator and zebra fish models
- Students sample analysis
- Q & A session, closing remarks and feedback

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Annex 2: List of participants registered and their attendance for the Development and
Characterization of Nanoformulations workshop.

Sr. No.	Candidate Name	Gender	Educational Qualification	University/Institute	
1	Harshilkumar Sharadchandra Jani	Male	M.Pharm (Pharmaceutics)	L. M. College of Pharmacy, GTU, Gujarat	
2	Dipti Gohil	Female	M.Pharm (Pharmaceutics)	Sumandeep Vidyapeeth, Vadodara, Gujarat	
3	DR. Anindita Behera	Female	M.Pharm (Chemistry)	Siksha O Anusandhan Deemed to be University, Odisha	
4	Anuraag Moturi	Male	M.Sc. (Chemistry)	Illia Tana dia University Dandali Crienat	
5	Shiv Rohitbhai Desai	Male	M.Sc. (Chemistry)	Oka Taisadia Oliiveisity, Bardoli, Gujarat	
6	Dalwadi Saloni Bharatbhai	Female	M.Pharm (Pharmaceutics)	Anand Pharmacy College, Anand, Gujarat	
7	Makrani Shaharukh Ismail	Male	M.Pharm (Pharmaceutics)	Ali Allana College of Pharmacy, Dist.	
8	Khalifa Mahmadasif Yunus	Male	M.Pharm (Pharmaceutics)	Nandurbar, Maharashtra	
9	Ms. Sheetal Baban Gosavi	Female	M.Pharm (Quality Assurance)	METs, Institute of Pharmacy, Bhujbhal	
10	Madhuri D. Deshmukh	Female	M.Pharm (Quality Assurance)	Knowledge City, Nashik, Maharashtra	
11	Solanki Bhaumikkumar Mukeshbhai	Male	B.Pharm	Maharaja Sayajirao University of Baroda,	
12	Krishna Patel	Female	M.Sc. (Microbiology)	Vadodara, Gujarat	
13	Ratjhva Yogeshkumar A	Male	B.Pharm		
14	Devika Unnithan	Female	M.Pharm ((Pharmaceutics)	School of Pharmaceutical Education and Research (SPER), Jamia Hamdard, New	
15	Bushra jabi	Female	M.Pharm (Pharmaceutics)	Delhi, India	
16	Dhrumi Kalpeshbhai Naik	Female	M.Pharm (Quality Assurance)		
17	Kiran Shetty	Female	M.Pharm (Pharmaceutics)	Maliba Pharmacy College, Surat, Gujarat	
18	Prajapati Bhumika Nitinkumar	Female	M.Pharm (Quality Assurance)		
19	Benedict Mathews P	Male	M.Sc.(Botany)	Bharathiar university, Coimbatore,	
20	Gowtham K	Male	M.Sc. (Botany)	Tamilnadu	
21	Benarji Patrudu Tammina	Male	Ph.D (Analytical Chemistry)	GITAM University, Hyderabad Campus	
22	Ashwini P. Dhruv	Female	M.Pharm (Quality assurance)	Marrie I' Hainer its Dailast Cairest	
23	Nikita Kishan solanki	Female	M.Pharm (Herbal drug technology)	Marwadi University, Kajkot, Gujarat	
24	Dr. Bhumikaben Chirag Desai	Female	Ph.D (Pharmaceutics)	C K Pithawala College of Engineering and Technology in Surat	
25	Hetvi Naik	Female	M.Sc (Microbiology)		
26	Zinalkumari Pravinbhai Mistry	Female	M.Sc (Microbiology)	C. G. Bhakta Institute of Biotechnology, Gujarat	
27	Dixita Rajeshbhai Panchal	Female	M.Sc (Microbiology)		
28	Lajja Patel	Female	M.Pharm (Pharmaceutics)		
29	Harshit Pramod Barot	Male	B.Pharm	Nirma University Ahmedahad Guiarat	
30	Dhvani Padhiyar	Female	M.Pharm (Pharmaceutical Technology)	Tunna Oniversity, Tunnedaoad, Oujarat	

## Annex 3: Schedule date and activities during the workshop.

## Day 1

- Inauguration
- Introduction of the Participants and the Host
- Lecture session 1: Basic introduction to preparation techniques of nanoparticles
- Lab visit
- Lab session: Hands-on training of formulation and development of nanoparticles by different techniques.

## Day 2

- Lecture session 2: Particle size measurement techniques
- Lecture session 3: Principle, instrumentation and working of Malvern Zetasizer
- Lab session: Practical training on Zetasizer.
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## Day 3

- Lecture session 4: Rheology in pharmaceutical formulations
- Lecture session 5: Principle, instrumentation and working of Brookfield Rheometer
- Lab session: Practical training on Brookfield Rheometer.

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## Day 4

- Lecture session 6: Mucoadhesive drug delivery systems
- Lecture session 7: Principle, instrumentation and working of Brookfield Texture Analyzer
- Lab session: Practical training on Brookfield Texture Analyzer.

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## Day 5

- Lecture session 8: Nano particulate drug delivery systems
- Lecture session 9: Principle, instrumentation and working of Freeze Dryer
- Lab session: Practical training on Freeze Dryer.
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## Day 6

- Lecture session 10: Current perspectives in dissolution testing of conventional and novel dosage forms
- Lecture session 11: Introduction of type 4 dissolution system
- Lab session: Practical training on Franz diffusion cell apparatus.

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## Day 7

- Industrial visit
- Students sample analysis
- Q&A session, closing remarks and feedback

## Annex-4: Feedback

Sr. No.	Content	% Rating
1	Overall grading of the programme with reference to relevance of cource, module/content etc.	97% rated 8 and above 8 points
2	Overall grading of the facilities provided by the institute, i.e, Hostel, Mess, Classroom, inftrastructure etc.	98% rated 8 and above 8 points
3	Overall grading of the faculty members conducting the training	98% rated 8 and above 8 points
4	How do you rate the overall training methodology	97% rated 8 and above 8 points
5	How far the field visit is relevant and related to your research study	95% rated 8 and above 8 points
6	Usefulness of this training in your current role	96% rated 8 and above 8 points
7	Usefulness of this training in future work/job you may handle	94% rated 8 and above 8 points
8	How far has you benefitted from interaction with the fellow participants of the training	93% rated 8 and above 8 points
9	How far the course material supplied relevant and related to the training curriculum	95% rated 8 and above 8 points
10	Overall grading of the process of training	92% rated 8 and above 8 points
11	Your recommendation to your peers/ collegues for the training programme	97% rated 8 and above 8 points