

Report on AICTE-GTU Jointly Sponsored

Online Faculty Development Programme on

“Recent Formulation Approaches for Improving the Dissolution Properties of Poorly Soluble Drugs”

Organized by B. K. Mody Government Pharmacy College, Rajkot

during 7-12 March, 2022

AICTE-GTU Jointly Sponsored Online Faculty Development Programme on “Recent Formulation Approaches for Improving the Dissolution Properties of Poorly Soluble Drugs” was Organized by B. K. Mody Government Pharmacy College, Rajkot during 7-12 March, 2022.

Total 94 participants registered for the course. Out of registered participants 74 participants, who were found eligible to join FDP as per rules laid down by AICTE and GTU, were sent confirmation mail, detailed schedule and link to join the online Faculty Development Programme.

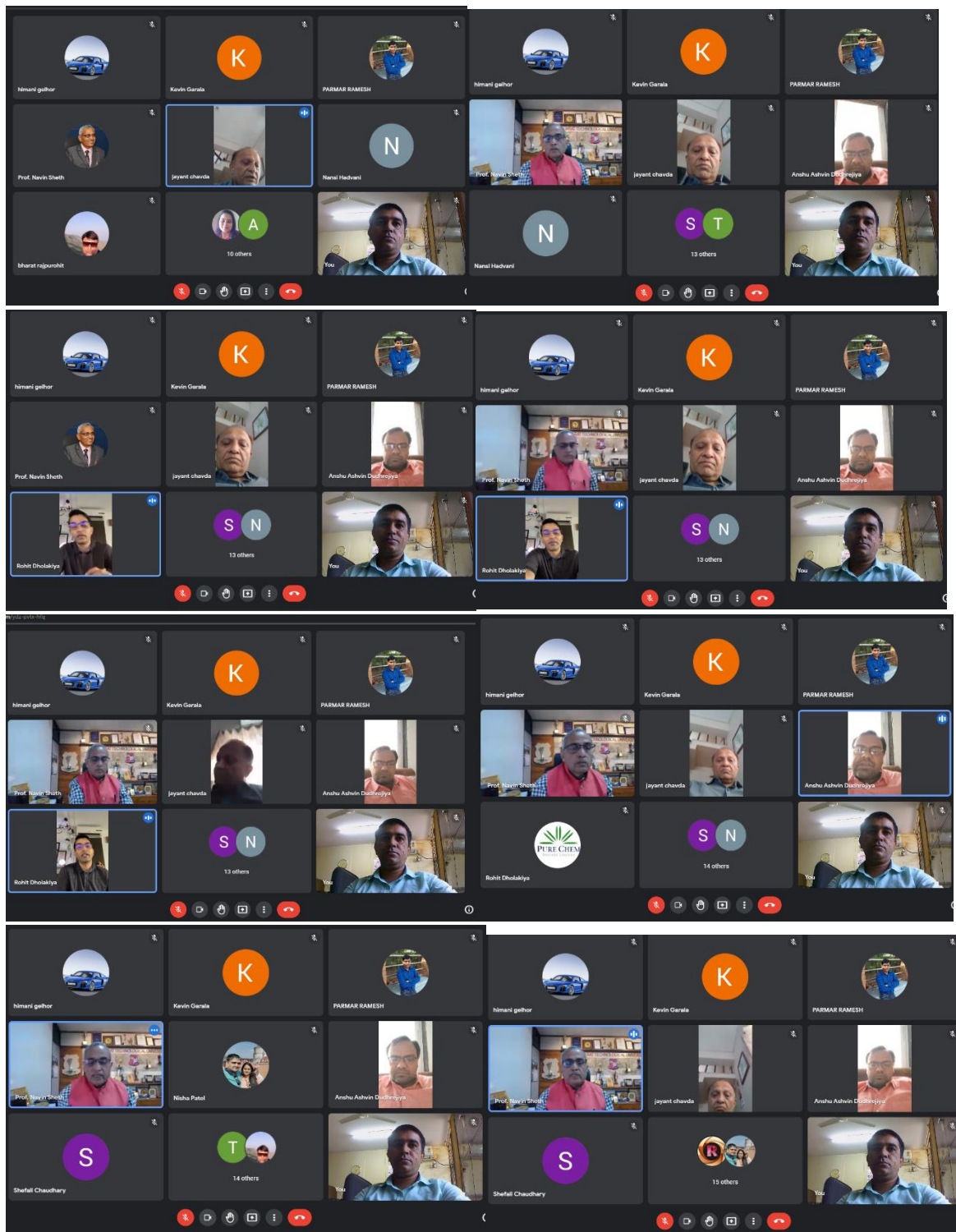
Inaugural session of the program was held on 7th March 2022, at 9:00 am in the august presence of Hon. Vice-chancellor Dr. N. R. Sheth sir as Chief Guest, Mr. Rohit Dholkiya, Director, Pure Chem Pvt. Ltd. as special guest, Dr. J. R. Chavda, Principal, B. K. Mody Government Pharmacy College, Rajkot, Dr. A. V. Dudhrejiya, Head Diploma, Dr. Lalji Baldaniya, Principal, Faculty of Pharmacy, Marwadi University and All participants.

Hon. Vice-Chancellor sir explained the need of the topic giving an outline of conventional dissolution and solubility enhancement techniques. Sir emphasized on the need dissolution enhancement techniques as a solution to biggest challenge of pharmaceutical industry and a great need of innovations in this area.

Mr. Rohit Dholakiya gave outline of API manufacturing and role of Indian Pharma sector as a potential growing market. He also encouraged the participants to contribute to research and putting their ideas to market. He also instructed participants to encourage their students for the same.

Dr. J. R. Chavda gave outline of various activities and novel practices carried out by B. K. Mody Government Pharmacy College.

Dr. A. V. Dudhrejiya gave vote of thanks.



Inaugural Session, 07/03/2022, 9 am onwards

Inaugural session was followed by a session for briefing the participants regarding attending Faculty Development Programme, minimum attendance criteria and passing criteria in the final exam to earn certificate.

After briefing sessions for day 1 started at 10:30 am.

First session was conducted by Dr. D. Mori, Assistant Professor, B. K. Mody Government Pharmacy College, Rajkot. The title of his talk was Salt formation and recent advances in salt formation: Amorphous salt formation. He discussed importance, techniques and recent innovations of salt formation.

The screenshot shows a Zoom meeting interface. The main content is a slide with the following text and flow:

- At the top: **Poor solubility**
- Two arrows point downwards from 'Poor solubility' to:
 - Greece ball**
 - Brick dust**
- From 'Greece ball', an arrow points to: **Poor wettability – High lipophilicity**
- From 'Brick dust', an arrow points to: **High Crystalline energy – High adhesiveness**

The Zoom interface includes a grid of participant avatars on the right, a toolbar at the bottom, and a status bar at the top left indicating 'dhaval mori is presenting'.

Lecture 1: Dr. D. D. Mori

Second session was conducted by Dr. S. R. Shah, Assistant Professor, B. K. Mody Government Pharmacy College, Rajkot on Recent advances in strategies to formulate poorly soluble drugs. He discussed different approaches for dissolution and solubility enhancement.

The screenshot shows a Zoom meeting interface. The main content is a slide with the following text and background:

- Background image: Test tubes containing colored liquids.
- Slide title: **Recent advances in strategies to formulate poorly soluble drugs**
- Slide subtitle: **Dr. Sunny R. Shah | B. K. Mody Government Pharmacy College, Rajkot | 07-03-2022**

The Zoom interface includes a grid of participant avatars on the right, a toolbar at the bottom, and a status bar at the top left indicating 'Sunny Shah is presenting'.

Lecture 2: Dr. S. R. Shah

Third session was conducted by Dr. M.M Soniwala, Professor, B. K. Mody Government Pharmacy College, Rajkot titled Liquisolid compact approach for improving the solubility of poorly soluble drugs. He discussed importance of liquid load factor, carrier to coating ration and selection of oils.

Sunny Shah is presenting

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ANCTE
All India Council of Technical Education

JOINT AICTE – GTU ONLINE FACULTY DEVELOPMENT PROGRAMME
on
Recent formulation approaches for improving the dissolution properties of poorly soluble drugs
7-12 March, 2022

Dissolution Enhancement Through Liqui-Solid Technology
07/03/2022, 4.00 pm – 6.00 pm

Presented by
Dr. M. M. Soniwala
Professor,
B K Mody Government Pharmacy College Rajkot

16:02 | ydz-pvtx-hfq

divya solanki, binal samir patel, Jasmina Surati, patel tejas, Samir Shah, Sunny Shah, payal vaja, 16 others, You

Lecture 3: Dr. M. M. Soniwala

On second day three sessions were conducted. Session started at 10:30 am with first lecture of the day and fourth of the Faculty Development Programme.

First session was conducted by Mr. Vivek Chavda, Assistant Professor, L. M. College of Pharmacy, Ahmedabad on Phytochemicals-loaded liposomes for anticancer therapy. He gave outline of discovery of vesicular DDS and ended with marketed formulation containing vesicular DDS.

Vivek Chavda is presenting

Anticancer Phytochemicals

- The major obstacles observed in current chemotherapy are severe adverse effects, narrow therapeutic indexes and multidrug resistance.
- Anticancer phytochemicals are extracted and purified from natural plants, providing alternative therapeutic approaches with recognized biomedical benefits. However, poor bioavailability, high dose requirements and non-specific targeting have made those molecules less effective.

Original herbals: Standardized extracts, Enzyme conjugation, Lipid conjugation, Nanoparticles

Emerging herbals: Polymeric micelles, Lipid vesicles, Liposomes, Nanosomes

Enabling factors: Targeted delivery, Personalized medicine

Types of Cancer Treatment: Hormonal therapy, Surgery, Bone marrow transplant, Chemotherapy, Immunotherapy, Radiotherapy, Personalized therapy

11:16 | ydz-pvtx-hfq

Vivek Chavda, Ripal Mistry, Dr. Dikshitkumar Mo..., Tanvi Desai, binal samir patel, patel tejas, MALAY RATHOD, 26 others, You

Speakers / Headphones (Realtek(R) Audio)

Lecture 4: Mr. Vivek Chavda

Second session of the day was conducted by Dr. C. H. Borkhataria, Assistant Professor, B. K. Mody Government Pharmacy College, Rajkot. Topic of his talk was Co-crystals for improving the solubility of poorly soluble drugs. He discussed application of cocrystal formation for solubility and dissolution enhancement. He also outlined the techniques used to evaluate cocrystals.

The screenshot shows a Zoom meeting in progress. The main window displays a presentation slide with a table of contents for a lecture. The slide is titled '01 Powder X-ray Diffraction (PXRD)' and '02 Thermal Analysis'. Below these, it lists '03 FTIR, RAMAN, FT-RAMAN' and '04 Solubility study'. The slide also features a network diagram on the right side. The meeting interface on the right shows a grid of participants, including chetan borkhataria, Vishal Chudasama, binal samir patel, sanket vyas, Dr. Shailesh Koradia, Jasmina Surati, Ripal Mistry, and 26 others. The bottom of the screen shows the Zoom control bar with icons for mute, video, chat, and other functions.

Lecture 5: Dr. C. H. Borkhataria

Third session was conducted by Dr. D. M. Patel, Associate Professor, Graduate School of Pharmacy, GTU titled Solid Dispersions: Past, Present and Future. He described generations of solid dispersions, methods of preparation, polymers, salts and other materials used for preparing solid dispersions.

The screenshot shows a Zoom meeting in progress. The main window displays a presentation slide titled 'Solid Dispersions: Past, Present & Future'. The slide includes the following text: 'Delivered at AICTE-GTU jointly sponsored e- Faculty Development Program held at B. K. Mody Govt. Pharmacy College, Rajkot on 8th March 2022'. Below this, it identifies the presenter as 'Dr. D. M. Patel, Associate Professor, Graduate School of Pharmacy, Gujarat Technological University'. The slide also features the Gujarat Technological University logo and 'ESTD - 2001'. The meeting interface on the right shows a grid of participants, including Dr. Shailesh Koradia, Dr. D. M. Patel, PARMAR RAMESH, himani gelhor, Tanvi Desai, Mariyambibi Mandarawala, Suresh sanja, and 6 others. The bottom of the screen shows the Zoom control bar with icons for mute, video, chat, and other functions.

Lecture 6: Dr. D. M. Patel

Day three started with a lecture by Dr. Jaydip Vasoya, Scientist, Formulations-Catalent Pharma Solutions, USA. His topic was Early Drug Development for New Molecules-Delivering Poorly Soluble Drugs

The screenshot shows a Zoom meeting interface. The main content is a slide titled "Drug Development" which illustrates the drug development process. The slide is divided into four main stages: 1. In-vitro and In-vivo Testing (Basic Research, Early Discovery, Pre Clinical), 2. Human Testing (Volunteers 10s -> 100s -> 1000s) (IND Application, Clinical Development, Phase I, Phase II, Phase III), 3. Data Review (FDA Review, NDA/BLA Application), and 4. Surveillance (FDA Approval, Post-Market Monitoring). A bracket under the first three stages is labeled "Early development". The slide also includes a source link: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2731111/>. The Zoom interface shows the presenter's name "Jaydip vasoya" and a grid of participant avatars including binal samir patel, Mariyambibi Mandarawala, Ankur Patel, Farooque S Shah, dhaval mori, reema jaiswal, and 15 others. The meeting ID is ydz-pvtx-hfq and the time is 10:32.

Lecture 7: Dr. Jaydip Vasoya

Second lecture of day three was conducted by Dr. Kevin Garala, Assistant Professor, School of Pharmaceutical Sciences, Atmiya University, Rajkot. He discussed Application of DoE in solubility improvement. He emphasized on application of quality by design approach for dissolution enhancement.

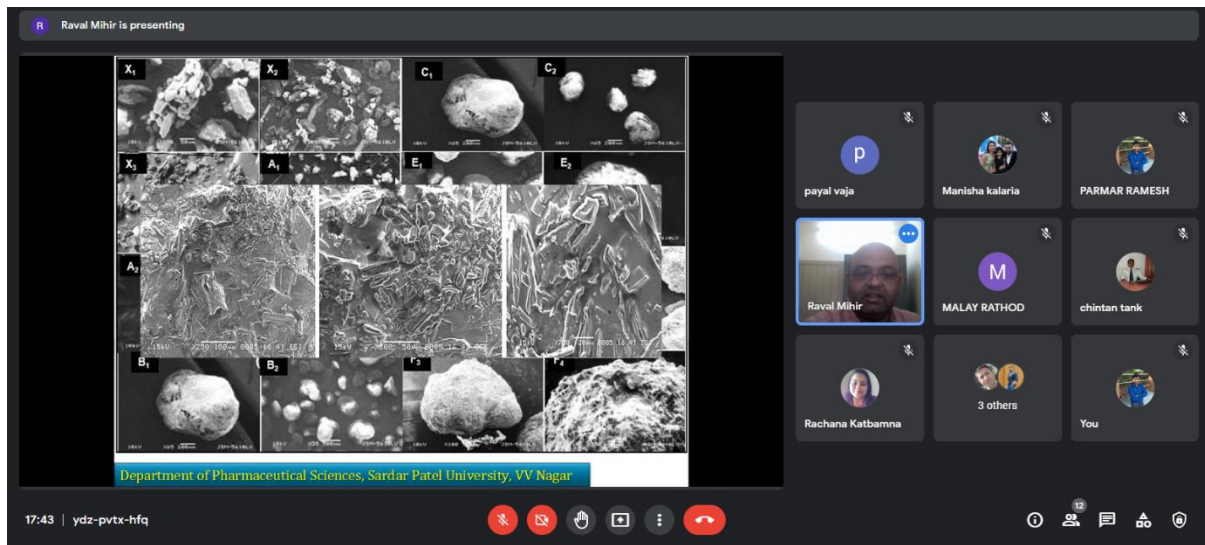
The screenshot shows a Zoom meeting interface. The main content is a slide titled "Elements of QbD" (Quality by Design) with the following bullet points:

- Define the Quality Target Product Profile
- Identify the Quality Attributes
- Perform a Risk (Assessment) Analysis
- Determine the Critical Quality Attributes and Critical Process Parameters
- Determine the Design Space
- Identify a Control Strategy

The slide also includes a slide number "40". The Zoom interface shows the presenter's name "Kevin Garala" and a grid of participant avatars including Megha Patel, binal samir patel, Jasmina Surati, Ankur Patel, patel tejas, 29 others, and bharat rajpurohit. The meeting ID is ydz-pvtx-hfq and the time is 14:22.

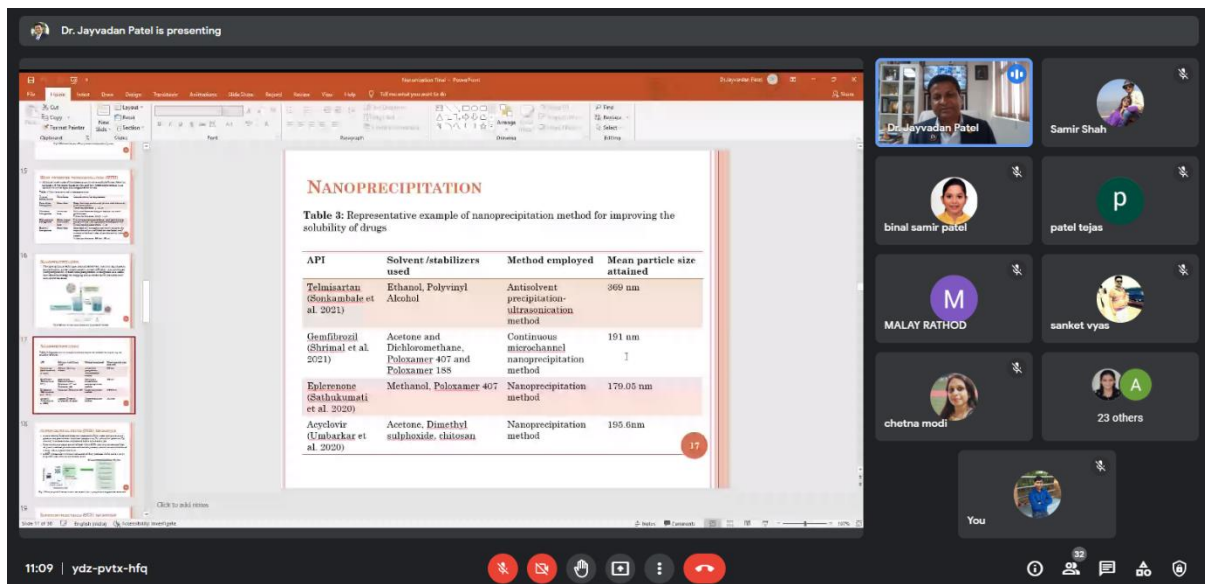
Lecture 8: Dr. Kevin Garala

Third session of the day 3 was on Crystallo-co-agglomeration: a particle engineering approach for manufacturability improvement delivered by Dr. Mihir Raval, PG Department of Pharmaceutical Sciences, Sardar Patel University, Vallabh Vidyanagar, Gujarat, India.



Lecture 9: Dr. Mihir Raval

Day 4 started with a lecture by Dr. J.K Patel, Principal, Nootan Pharmacy college, Gujarat. He discussed Micronization/Nanonization for improving the solubility. He explained supercritical fluid techniques like rapid expansion of supercritical solution for generation of micro and nanoparticles by bottom-up technique. this technique is organic solvent free techniques hence its eco-friendly.



Lecture 10: Dr. J. K. Patel

Second session of the day was titled Critical differences and similarities between various lipid-based drug delivery system by Dr. Mahesh Dabhi, Drug inspector, Food and Drug administration, Government of Gujarat. He outlined critical differences between various lipid-based systems like liposomes, SLNs, Lipospheres, SEDDS etc.

TYPES OF LIPID FORMULATIONS

Lipid nanocapsules [LNC]

- o LNC are lipidic systems in a nanometer-size range.
- o Made of an oily liquid core surrounded by a 2 - 10nm thickness solid or a semisolid surfactant shell.
- o Combine the colloidal stability of solid particles suspensions in biological fluids and the solubilizing properties of liquids.

Lecture 11: Dr. M. R. Dabhi

Third session of the day was conducted by Dr. R. D. Parmar, Lecturer, B. K. Mody Government Pharmacy College, Rajkot. He discussed Recent advances in lipid-based drug delivery system. He emphasized on the ability of lipid based drug delivery systems in delivery of vaccines, targeting brain and 3D printing for lipid based DDS.

Classes of LBDDS

- 1 • Solid lipid particulate dosage forms
- 2 • Emulsion based system
- 3 • Solid lipid tablets/Capsule
- 4 • Vesicular systems

Lecture 12: Dr. R. D. Parmar

First lecture of day 5 was titled Particle size manipulation for improving the dissolution of the poorly soluble drugs by Dr. Lalji Baldaniya Principal, Faculty of Pharmacy, Marwadi University, Rajkot. He discussed the changes in the dissolution media needed for dissolution study of poorly soluble drugs and regulatory guidelines pertaining to it.

Selection of dissolution media

- The selection of an appropriate dissolution medium is a fundamental stage of the dissolution test.
- It is more important that the test closely simulate the environment in the GI tract than necessarily produce sink condition.

Sink condition:

- Suppose we have a product with a label claim 200mg and say solubility is 1 mg/ml then obviously 200 ml is sufficient for its solubility. If you maintain sink conditions with say 220ml or 230 ml I think it is practically difficult to work with or dissolution with these small amounts of the medium. Hence it is better to maintain a 3:1 ratio.
- A flow-through system and reservoir may be used to provide sink conditions by continually removing solvent and replacing it with fresh solvent.

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Lecture 13: Dr. Lalji Baldaniya

Second lecture of day was conducted by Dr. J. S. Paun, Assistant Professor, B. K. Mody Government Pharmacy College, Rajkot. She talked on Self-Emulsifying Drug Delivery Systems. She emphasized on different natural oils, lipids and surfactants as a promising alternative for dissolution and solubility enhancement.

Table 10. Literature Reports on Various Solid SEDDS

Drug	Oils/Lipids	Surfactants/Co-surfactants	Other Vital Excipients	Technique for Solidification
Candesartan cilexetil	Miglyol 812	Labrasol Tween 80	Colloidal silicon dioxide Microcrystalline cellulose	Adsorption on solid carriers
Carvedilol	Capmul MCM	HCO 50 Lutrol F 68	--	--
Diazepam	Cithrol GMS	Solutol HS 15	Avicel PH 101	Extrusion/spherulization
Diclofenac	Goat fat	Tween 85	-	Moulding
Ezetimibe	Capryol 90	Cr-EL	Aerosil 200	Mixing
Loratadine	Captox 200 and Capmul MCM	Cr-EL	Porous polystyrene	Beads formation by evaporation
Lovastatin	Capmul MCM	HCO 50 Lutrol F 68	--	--
Methyl paraben & propyl paraben	Imwitor 742	Tween 80	Avicel PH101	Extrusion/spherulization
Nimesulide	Cithrol GMO	Tween 80	Microcel 101	Spray drying
Nimodipine (SMEODS)	Ethyl oleate	Labrasol Cr RH 40	Dextran 40	Spray drying
Nimodipine (SEF)	Ethyl oleate	Labrasol Cr RH 40	Methocel® K4M Premium CR EP, K15M Premium CR EP, and K100M Premium CR EP	Spray drying

Dr. Jalpa S. Paun, Asst. Professor, B.K. Mody Govt. Pharmacy College, Rajkot, Gujarat, India. 3/11/2022

Lecture 14: Dr. J. S. Paun

Third lecture of fifth day was conducted by Dr. Vijay Parmar, Head, PG Department of Pharmaceutical Sciences, Sardar Patel University, Vallabh Vidyanagar, Gujarat, India. He discussed pharmaceutical co-crystals as a tool to enhance dissolution and solubility. He also described different crystal structures and their impact on dissolution and solubility. He also discussed ways to modify crystal structure.

The screenshot shows a Zoom meeting interface. The main window displays a presentation slide titled "Fundamentals of Crystal Structure". The slide contains the following text:

- Crystals consist of minimal building blocks, termed unit cells, each of which contains all the structural features and symmetry elements and is repeated regularly in three-dimensional space.
- The dimensions of the unit cell are characterized by six quantities; three axial lengths (a , b , c) and three interaxial angles (α , β , γ).
- Each unit cell contains at least one molecule and can be classified by one of the seven three-dimensional coordinate systems, which are the seven primitive crystal systems.

Two diagrams illustrate unit cells: (a) a simple 3D wireframe cube, and (b) a 3D model of a crystal lattice with molecules inside. The Zoom interface shows a grid of participants including Sunny Shah, Khooshbu Patel, Suresh sanja, V K PARAMAR, Mariyambibi Mandarawala, Megha Patel, Manisha kalaria, and 19 others. The bottom status bar shows the time as 17:01 and the meeting ID as ydz-pvtx-hfq.

Lecture 15: Dr. Vijay Parmar

There were two sessions on last day of the Programme. First lecture was delivered by Dr. Punit Parejiya, Associate Professor, Dept. Pharmaceutics, KB Institute of Pharmaceutical Education and research, Gandhinagar. He elaborated Six sigma methodology for formulation approaches. He discussed different ways of minimizing errors and producing products with minimum defects leading to increased customer satisfaction and reduced recalls, leading to reduction in overall production cost.

The screenshot shows a Zoom meeting interface. The main window displays a presentation slide titled "Inference". The slide includes three control charts:

- Outliers:** A chart showing "Isolated points outside control limits".
- Trend:** A chart showing "Long-term trends up or down".
- Shift:** A chart showing "Shifts away from the target".

Below the charts, there is a section for "Ideal" performance:

- Random variation around target (common cause)
- All points within the control limits

The Zoom interface shows a grid of participants including Punit Parejiya, Meeta Jiladia, Saikat Pande, Ankur Patel, Tarvi Desai, himani gelhor, and Principal MNCI, Khambhat, along with 16 others. The bottom status bar shows the time as 11:34 and the meeting ID as ydz-pvtx-hfq.

Lecture 16: Dr. Punit Parejiya

Second session was on national education policy- 2020 by Dr. Upama N. Trivedi, Professor, Sardar Patel College of Pharmacy, Bakrol, Anand, Gujarat. She explained various aspects of new education policy, entry level, education pattern, diploma, certificate, graduation etc. she also explained the flexibility provided by NEP with respect to study and its impact on reducing dropouts.

Lecture 17: Dr. Upama N. Trivedi

Valedictory function of the Faculty Development Programme was conducted after second session. Chief guest of the session was Chief Guest Mr. Hitesh Dholariya, Owner, Erva Healthcare Pvt. Ltd., Rajkot. He discussed problems faced by industries due to improper dissolution characteristics and a strong need of improving dissolution.

Valedictory Function

An Online MCQ based Examination was conducted covering topics discussed during the Faculty Development Programme. 49 participants attended the exam out of which 46 successfully cleared the examination. Attendance was recorded for all sessions through google forms. Considering the attendance and marks secured in the MCQ based examinations, 44 participants were found eligible for certificate and they were awarded e-certificates. The certificates were sent through e-mail to all successful participants.

Verbal and online form-based feedback was collected from all participants covering questions related to quality of sessions, content, schedule, duration etc.

Outcome of the Faculty Development Programme

Participants were sensitized with need of dissolution enhancement using statistical data published by different regulatory agencies and different approaches used for dissolution enhancement. Participants gained in depth knowledge of salt formation, solid dispersions, co-amorphous systems, liposomes, nanoparticles, self-emulsifying drug delivery systems, micronisation, cocrystals, quality by design approaches, 3D printing for soft materials, modifications of dissolution studies needed for poorly soluble drugs etc. The sessions will help the participants to find solutions for dissolution problems faced by pharmaceutical industries and will open new avenues for research in the field of dissolution enhancement. The faculty may encourage their students to work upon dissolution enhancement research projects further widening the knowledge and availability of data on dissolution and solubility.

The session on national education policy helped participants to know about the important provisions of new national education policy viz. entry age, multiple entry points, multiple exit points without loss of the years spent in study due to graded systems and earning of credits that may help if a student changes mind and switches to another course.