

# FORMULATION DEVELOPMENT SUMMER / WINTER TRAINING (#One Month)

**B.V. Patel Pharmaceutical Education and Research Development (PERD) Centre, Thaltej, Ahmedabad**

	Module 1	Module 2	Module 3	Module 4
<b>Topics</b>	<b>Understanding Quality by Design (QbD)</b>	<b>Molecular Pharmaceutics (Nanotechnology and Targeted DDS )</b>	<b>Dissolution for Solid Oral Dosages</b>	<b>Pharmaceutical Preformulation</b>
<b>Content</b>	<ul style="list-style-type: none"> <li>• The importance of QbD</li> <li>• DoE vs. one-factor-at-a-time</li> <li>• The sequential approach of DoE: screening, modelling and optimization – which design in which context-                             <ul style="list-style-type: none"> <li>➢ Experimental designs</li> <li>➢ Screening designs</li> <li>➢ Factorial designs</li> <li>➢ Composite designs</li> <li>➢ Mixture designs</li> </ul> </li> <li>• Factor screening and modelling: how to identify the Critical Process Parameters (CPP's) and Material Attributes (CMA's) as well as their interactions</li> <li>• Optimization of a response variable with response surface models</li> <li>• Graphical visualization and interpretation of the results</li> <li>• DoE for formulations</li> <li>• Defining the Design Space</li> <li>• Applications of systematic optimization techniques</li> </ul> <p><b>HANDS ON SESSION (Optional) on Design-expert software (Additional 1 week)</b></p>	<ul style="list-style-type: none"> <li>• Targeting strategies in drug delivery                             <ul style="list-style-type: none"> <li>➢ Passive targeting</li> <li>➢ Active targeting</li> </ul> </li> <li>• Challenges in the use of nanoformulations for drug delivery- Barriers, Opportunities, Nanoformulations in current clinical practice</li> <li>• Nanoparticulates and their applications Short Introduction and Basic principles on Nanotechnology</li> <li>• Nanoparticulate systems in therapeutics                             <ul style="list-style-type: none"> <li>➢ Lipidic drug carriers, Liposomes</li> <li>➢ Polymeric nanosystems</li> <li>➢ Mixed nanosystems</li> <li>➢ Thermo-responsive release</li> <li>➢ Enzyme responsive release</li> <li>➢ pH responsive release</li> </ul> </li> <li>• Nanosystems characteristics                             <ul style="list-style-type: none"> <li>➢ Biophysical principles of nanosystems</li> <li>➢ Stability of nano-systems</li> </ul> </li> </ul> <p><b>PRACTICAL (OPTIONAL)</b> Selection of appropriate excipients and preparation and characterization</p> <ul style="list-style-type: none"> <li>• Biphasic nanosystems</li> <li>• Lipidic nanoparticles</li> <li>• Vesicular systems (Liposomes etc)</li> </ul>	<ul style="list-style-type: none"> <li>• The BCS classification</li> <li>• Dissolution method development for solid orals</li> <li>• Dissolution instruments qualification- performance verification vs. physical calibration</li> <li>• Fundamentals and applications of USP-3 reciprocating cylinder</li> <li>• Fundamentals of USP-4, flow through cell</li> <li>• Fundamentals and applications of USP-5 paddle over disc</li> <li>• Fundamentals and application of Franz diffusion cell (permeation analysis for transdermals)</li> <li>• Introduction to IVIVC and dissolution testing</li> </ul> <p><b>Practical Demonstration of</b> USP Dissolution Type I USP Dissolution Type II USP Dissolution Type III USP Dissolution type V</p>	<ul style="list-style-type: none"> <li>• Introduction to Pharmaceutical Preformulation</li> <li>• Importance, role and determination of -                             <ul style="list-style-type: none"> <li>➢ Aqueous solubility</li> <li>➢ Permeability</li> <li>➢ Stability Studies</li> <li>➢ pKa</li> <li>➢ Log P</li> <li>➢ Solid State Properties at molecular level- crystallinity, polymorphism, solvated state, amorphous form and co-crystals etc</li> <li>➢ Compaction Studies</li> <li>➢ Compatibility Studies (especially using DSC and IR- with practicals)</li> </ul> </li> </ul> <p><b>Practical Demonstration of –</b> Compatibility Studies using- 1. Controlled temperature and humidity 2. DSC 3. IR</p>
<b>Time</b>	8 weeks+ 1 week	4 weeks + 1 week	<b>2 weeks</b>	<b>2 weeks</b>
<b>Individual</b>	Rs. 5,000 (Only theory) + 5,000 (hands on)	Rs. 5,000 (Only theory) + Rs 1500 (practical)	Rs. 5000/-	Rs 4000/-
<b>Group of 5 max. upto 10</b>	Rs. 4000 + 4000 per individual	Rs. 5500/- per individual	Rs. 4500/- per individual	Rs. 3500/- per Individual

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# Four hours a day, 5 days in a week