GUJARAT TECHNOLOGICAL UNIVERSITY

M.Pharm

INDUSTRIAL PHARMACY

SEMESTER: I

SUBJECT NAME: PHARMACEUTICAL FORMULATION DEVELOPMENT
Subject Code: MIP102T

SCOPE: This course is designed to impart knowledge and skills necessary to train the students on par with the routine of Industrial activities in R&D and F&D.

OBJECTIVES: Upon completion of the course, student shall be able to understand

1. The scheduled activities in a Pharmaceutical firm.
2. The pre formulation studies of pilot batches of pharmaceutical industry
3. The significance of dissolution and product stability.

Sr.No	Course content	Total Hrs
1.	Preformulation Studies: Molecular optimization of APIs (drug substances), crystal morphology and variations, powder flow, structure modification, drug-excipient compatibility studies, methods of determination	12
2.	Formulation Additives: Study of different formulation additives, factors influencing their incorporation, role of formulation development and processing, new developments in excipient science. Design of experiments – factorial design for product and process development.	12
3.	Solubility: Importance, experimental determination, phasesolubility analysis, pH-solubility profile, solubility techniques to improve solubility and utilization of analytical methods – cosolvency, salt formation, complexation, solid dispersion, micellar solubilization and hydrotropy	12
4.	Dissolution: Theories, mechanisms of dissolution, in-vitro dissolution testing models – sink and non-sink. Factors influencing dissolution and intrinsic dissolution studies. Dissolution test apparatus – designs, dissolution testing for conventional and controlled release products. Data handling and correction factor. Biorelevent media, in-vitro and in-vivo correlations, levels of correlations	12
5.	Product Stability: Degradation kinetics, mechanisms, stability testing of drugs and pharmaceuticals, factors influencing-media effects and pH effects, accelerated stability studies, interpretation of kinetic data (API & tablets). Solid state stability and shelf life assignment. Stability protocols, reports and ICH guidelines	12

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2. Sinko PJ. Martin's physical pharmacy and pharmaceutical sciences, 5 ed., B.I. Publications Pvt. Ltd, Noida, 2006.
3. Lieberman HA, Lachman L, Schwartz JB. Pharmaceutical dosage forms: tablets Vol. I-III, 2 ed., CBS Publishers & distributors, New Delhi, 2005.

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5. Yalkowsky SH. Techniques of solubilization of drugs. Vol-12. Marcel Dekker Inc., New York, 1981
6. Dressman J, Kramer J. Pharmaceutical dissolution testing. Saurah printer pvt. Ltd., New Delhi,2005.
7. Sethi PD. Quantitative analysis of drugs in pharmaceutical formulations, ed., CBS publications, New Delhi, 2008.
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11. W. Grimm - Stability testing of drug products. ed., Marcel Dekker
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