PE-630

PHARMACEUTICAL PRODUCT DEVELOPMENT-I (2 CREDITS)

1. **Preformulation studies**: Preformulation studies of drug substances, proteins and peptides. Fundamental and derived properties in preformulation profiling, preformulation worksheet.

2. **Role of pre-formulation in drug discovery**: Material properties in lead selection, high throughput preformulation studies, ‘drugability’ of new chemical entities, tools to assist in lead selection.

3. **Role of preformulation in drug development**: Preformulation as a support for formulation development, identification of challenges during formulation development, dosage form specific studies.

4. **Complexation**: Metal and organic molecular complexes, inclusion compounds with reference to cyclodextrins, chemical characteristics of inclusion complexes, applications in solubilization/taste masking/enhancement of permeability/enhancement of oral bioavailability, methods of preparation of cyclodextrin complexes.

5. **Solubilization**: Solubility and solubilization of nonelectrolyte, drug solubilization in surfactant systems, use of co solvents, solid-state manipulations and drug derivitization.


7. **Micromeritics**: Particle size distribution, evaluation methods including advanced techniques like atomic force microscopy, significance of particle size in different dosage forms including aerosols, parenterals and solid dosage forms.

8. Development of dosage forms, four stage development, biological basis and opportunities, dosage form and its implications; Manipulation of physiological processes.

9. Case studies will be discussed after each topic with current literature, case study dealing with use of preformulation data for lead selection and dosage form decision.

**READING MATERIAL**

1. Physicochemical Principles of Pharmacy, 2006
   Alexander T. Florence and David Attwood
   Pharmaceutical Press

2. Martin’s Physical Pharmacy and Pharmaceutical Science, 2006
   Pratrick J. Sinko
   B.I. Publication Pvt. Ltd.

   M. E. Aulton
   Churchill livingstone

   James I. Wells
   Ellis Horwood Limited