PE-640

PHARMACEUTICAL PRODUCT DEVELOPMENT-II (2 CREDITS)

1. **Formulation additives**: Study of different types of additives e.g. antioxidants and preservatives, coloring and flavoring agents, emulsifying and suspending agents, basic materials for ointment bases, diluents and pharmaceutical solvents, regulatory perspectives: GRAS, IIG; new developments in excipient science, functional and co-processed excipients, international patented excipients. Implication of quantitative selection of each excipient in product development.

2. **Drug-excipient interaction**: Drug-excipient interaction and incompatibilities, physical, chemical, pharmaceutical and therapeutic, analytical techniques to characterize drug excipient incompatibility.

3. **Solid dosage forms**: Tablets, benefits, improved tablet production, advances in materials, material handling and granulation; process automation. Processing problems in tablet and troubleshooting. Specialized tablets: formulation and evaluation of effervescent, orodispersible and chewable tablets.

4. **Tablet Coating**: Coating pans, sugar coating, film coating, advanced coating technologies, aqueous based film coating, solvent free coating, coating defects.


6. **Sterile products and admixtures**: Formulation development, vehicles and other additives, containers and closures, evaluation of stability and sterility, requirements of facilities for production, recent advances and developments.

7. **Aerosols**: Components of aerosol package, containers, nebulizers, pressured metered dose inhalers, dry powder inhalers, formulation aspects, types of propellants used, stability testing of pharmaceutical aerosols, Quality control and testing evaluation of pharmaceutical aerosols.

8. **Package development**: Package types for different dosage forms, packaging materials like glass and plastic, selection of proper material, labelling, preformulation screening of package components, regulatory perspectives.

9. **Design of materials and product specifications**: Factory design, laying down and optimization of material and product specifications, process and in-process controls.

10. **Documentation**: Protocols, forms and maintenance of records in product development department including clinical batches.

**READING MATERIAL**

   Herbert A. Lieberman, Leon Lachman and Joseph B. Schwartz
   Marcel Dekker
   Herbert A. Lieberman, Gilbert S. Banker and Martin M. Rieger
   Marcel Dekker

   Herbert A. Lieberman, Leon Lachman and Kenneth E. Avis
   Marcel Dekker

4. The Theory and Practice of Industrial Pharmacy, 1991
   Herbert A. Lieberman, Leon Lachman and Joseph L. Kanig
   Varghese Publication House

   M.E. Aulton, Churchill Livingstone