

Semester VIII – Elective course on Pharmaceutical Product Development

No of Hours: 3

Tutorial:1

Credit points:4

Unit-I

10 Hours

Introduction to pharmaceutical product development, objectives, regulations related to preformulation, formulation development, stability assessment, manufacturing and quality control testing of different types of dosage forms

Unit-II

10 Hours

An advanced study of Pharmaceutical Excipients in pharmaceutical product development with a special reference to the following categories

- i. Solvents and solubilizers
- ii. Cyclodextrins and their applications
- iii. Non - ionic surfactants and their applications
- iv. Polyethylene glycols and sorbitols
- v. Suspending and emulsifying agents
- vi. Semi solid excipients

Unit-III

10 Hours

An advanced study of Pharmaceutical Excipients in pharmaceutical product development with a special reference to the following categories

- i. Tablet and capsule excipients
- ii. Directly compressible vehicles
- iii. Coat materials
- iv. Excipients in parenteral and aerosols products
- v. Excipients for formulation of NDDS

Selection and application of excipients in pharmaceutical formulations with specific industrial applications

Unit-IV

08 Hours

Optimization techniques in pharmaceutical product development. A study of various optimization techniques for pharmaceutical product development with specific examples. Optimization by factorial designs and their applications. A study of QbD and its application in pharmaceutical product development.

Unit-V

07 Hours

Selection and quality control testing of packaging materials for pharmaceutical product development- regulatory considerations.

Recommended Books (Latest editions)

1. Pharmaceutical Statistics Practical and Clinical Applications by Stanford Bolton, CharlesBon; Marcel Dekker Inc.
2. Encyclopedia of Pharmaceutical Technology, edited by James swarbrick, Third Edition, Informa Healthcare publishers.
3. Pharmaceutical Dosage Forms, Tablets, Volume II, edited by Herbert A. Lieberman and Leon Lachman; Marcel Dekker, Inc.
4. The Theory and Practice of Industrial Pharmacy, Fourth Edition, edited by Roop kKhar, S P Vyas, Farhan J Ahmad, Gaurav K Jain; CBS Publishers and Distributors Pvt.Ltd. 2013.
5. Martin's Physical Pharmacy and Pharmaceutical Sciences, Fifth Edition, edited by Patrick J. Sinko, BI Publications Pvt. Ltd.
6. Targeted and Controlled Drug Delivery, Novel Carrier Systems by S. P. Vyas and R. K.Khar, CBS Publishers and Distributors Pvt. Ltd, First Edition 2012.
7. Pharmaceutical Dosage Forms and Drug Delivery Systems, Loyd V. Allen Jr., Nicholas B.Popovich, Howard C. Ansel, 9th Ed. 40
8. Aulton's Pharmaceutics – The Design and Manufacture of Medicines, Michael E. Aulton, 3rd Ed.
9. Remington – The Science and Practice of Pharmacy, 20th Ed.
10. Pharmaceutical Dosage Forms – Tablets Vol 1 to 3, A. Liberman, Leon Lachman and Joseph B. Schwartz
11. Pharmaceutical Dosage Forms – Disperse Systems Vol 1 to 3, H.A. Liberman, Martin, M.R and Gilbert S. Banker.
12. Pharmaceutical Dosage Forms – Parenteral Medication Vol 1 & 2, Kenneth E. Avis and H.A. Libermann.
13. Advanced Review Articles related to the topics.