

BP813ET. PHARMACEUTICAL PRODUCT DEVELOPMENT (Theory)

45 Hours

Course Content:

Unit-I

10 Hours

Introduction to pharmaceutical product development, objectives, and 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:

Solvents and solubilizers. Cyclodextrins and their applications.

Non - ionic surfactants and their applications. Polyethylene glycols and sorbitols.

Suspending and emulsifying agents. 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:

Tablet and capsule excipients. Directly compressible vehicles. Coat materials.

Excipients in parenteral and aerosols products. Excipients for formulation of NDDS.

Selection and application of excipients for 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.