GUJARAT TECHNOLOGICAL UNIVERSITY

Bachelor of Pharmacy
Subject Code: BP814TT
SEMESTER: VIII
Subject Name: Pharmaceutical Product Development

Scope: To understand the regulations related to preformulation, formulation development, stability assessment, manufacturing and quality control testing of different types of dosage forms. The subject also includes an advanced study of pharmaceutical excipients in pharmaceutical product development. It also covers optimization techniques to be used in pharmaceutical product development.

Objectives: Upon completion of the course the student shall be able to -
1. To know and explain about the basic concepts of product development and right selection of excipients for the conventional and novel formulation.
2. To describe Quality by design, Optimization technique and experimental design pharmaceutical product development for the conventional and novel formulation.
3. To explain the GRAS listing & inactive ingredient guide (IIG) limit for the excipients.
4. To discuss Regulatory requirement for Selection of packaging material and Quality control of various dosage form.

Teaching scheme and examination scheme:

Teaching Scheme				Evaluation Scheme			
Theory	Tutorial	Practical	Total	Theory		Practical	
				External	Internal	External	Internal
3	1	0	4	80	20	0	0

Sr No	Topics	Teaching Hrs
1.	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.	7
2.	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 sorbitol's v. Suspending and emulsifying agents vi. Semi solid excipients	10
3.	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	10
4.	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.	8

5.	Selection and quality control testing of packaging materials for pharmaceutical product development- regulatory considerations.	7

References:

1. Pharmaceutical dosage forms - Tablets, volume 1 -3 by H.A. Liberman, Leon Lachman & J.B.Schwartz.
2. Pharmaceutical dosage form - Parenteral medication vol- 1&2 by Liberman & Lachman.
3. Theory and Practice of Industrial Pharmacy by Liberman & Lachman.
4. Pharmaceutics- The science of dosage form design by M.E. Aulton, Churchill livingstone, Latest edition.
5. Introduction to Pharmaceutical Dosage Forms by H. C. Ansel, Lea & Febiger, Philadelphia, 5th edition, 2005.
6. Drug stability - Principles and practice by Cartensen & C.J. Rhodes, 3rd Edition, Marcel Dekker Series, Vol 107.
7. Gennaro, Alfonso R., Remington: The Science and Practice of Pharmacy, Vol-I & II, Lippincott Williams & Wilkins, New York.
8. Bolton S. Optimization techniques. In: Pharmaceutical Statistics: Practical and Clinical Applications. 3rd ed. New York: Marcel Dekker, 1997