NIRMA UNIVERSITY
Institute of Pharmacy

B. Pharm.
(Semester - VIII)

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Course Code	**BP813ET**
Course Title	**Pharmaceutical Product Development**

Scope:
Course enables the student to understand the pharmaceutical product development cycle and appreciate the influence of pharmaceutical additives, QbD concepts and packaging technology on the performance of the drug product.

Objectives:
Upon completion of the course the student shall be able to
1. Know the development cycle and optimization of various pharmaceutical dosage forms.
2. Know various excipients and their role in development of pharmaceutical dosage forms
3. Formulate pharmaceutical dosage forms using concepts of QbD

Course Learning Outcomes (CLO):
At the end of the course, students will be able to -
1. Recognize the development cycle of a pharmaceutical product.
2. Describe various types of excipients like solubilizer, suspending agents.
3. Determine quality control testing of packaging materials for product development.
4. Apply quality by design concepts for optimization of pharmaceutical dosage forms.
5. Interpret application of excipients for formulation development.

Syllabus: **Teaching hours: 45 Hours**

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

1. Solvents and solubilizers
2. Cyclodextrins and their applications
3. Non - ionic surfactants and their applications
4. Polyethylene glycols and sorbitols
5. Suspending and emulsifying agents
6. 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

1. Tablet and capsule excipients
2. Directly compressible vehicles
3. Coat materials
4. Excipients in parenteral and aerosols products
5. 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.

Tutorials **Teaching hours: 15 Hours**

Tutorials will be based on above syllabus

Suggested Readings^: (Latest Edition)

1. Bolton, Stanford; Bon, Charles, *Pharmaceutical Statistics Practical and Clinical Applications*, USA: Marcel Dekker Inc.
2. swarbrick, James, *Encyclopedia of Pharmaceutical Technology*, USA: Informa Healthcare publishers.
3. Lieberman, Herbert; Lachman, Leon, *Pharmaceutical Dosage Forms, Tablets*, USA: Marcel Dekker Inc.
4. Khar, Roop; Vyas, S. P.; Ahmad, Farhan; Jain, Gaurav, *The Theory and Practice of Industrial Pharmacy*, India: CBS Publishers and Distributors Pvt.Ltd.
5. Sinko, Patrick, *Martin's Physical Pharmacy and Pharmaceutical Sciences*, USA: Lippincott Williams & Wilkins.

6. Vyas, S. P.; Khar, Roop, *Targeted and Controlled Drug Delivery, Novel Carrier Systems*, India: CBS Publishers and Distributors Pvt.Ltd.
7. Allen, Loyd; Popovich, Nicholas; Ansel, Howard, *Pharmaceutical Dosage Forms and Drug Delivery Systems*, USA: Lippincott Williams & Wilkins.
8. Aulton, Michael, *Aulton's Pharmaceutics – The Design and Manufacture of Medicines*, UK: Churchill Livingstone.
9. Remington, Joseph, *Remington – The Science and Practice of Pharmacy*, USA: Lippincott Williams & Wilkins.
10. Lieberman, Herbert; Martin, M; Banker, Gilbert, *Pharmaceutical Dosage Forms – Disperse Systems*, USA: Marcel Dekker Inc.
11. Avis, Kenneth; Lieberman, Herbert, *Pharmaceutical Dosage Forms – Parenteral Medication*, USA: Marcel Dekker Inc.

L= Lecture, T= Tutorial, P= Practical, C= Credit

^this is not an exhaustive list