****

**SECOND SEMESTER 2021-2022**

# Course Handout Part II

Date: 16-Jan-2022

In addition to part-I (General Handout for all courses appended to the time table) this portion gives further specific details regarding the course.

*Course No.* :  *PHA G 632*

## Course Title : Dosage Form Design

## Instructor-in-Charge : PUNNA RAO RAVI

**Description :** Role of physical, chemical and biopharmaceutical factors (preformulation studies) of drug in the design, manufacture and stability of dosage forms; dosage form factors affecting the absorption of drugs; Biopharmaceutical Classification System (BCS); development of in-vitro in-vivo correlation; Controlled release drug delivery systems; Design of delivery systems for various routes/purposes like oral (gastro-retention, colon targeted), parenteral, buccal/ sublingual, nasal, ocular, pulmonary and transdermal

**Scope and Objective of the Course:**

This course deals with the preformulation studies and various physico-chemical and biopharmaceutical properties to be considered in the design of dosage forms of a drug. The mechanisms involved in the absorption and the factors affecting absorption of a drug from a dosage form are discussed. Biopharmaceutical classification system, the concepts of controlled release formulations and drug delivery systems like gastro-retentive, colon targeted, buccal/sublingual, nasal, ocular, transdermal and pulmonary drug delivery systems will also be covered.

The objective of the course is to provide the students the knowledge required to design of drug delivery systems administered through oral, buccal/sublingual, nasal, ocular, transdermal and pulmonary routes.

**Textbooks:**

1. Pharmaceutics: The Design and Manufacture of Medicines, ed: Michael E. Aulton. Third Edition, Churchill Livingstone (Elsevier, 2007).

**Reference books**

1. Physiological pharmaceutics: Barriers to drug absorption, ed: Neena Washington, Clive Washington and Clive G. Wilson. Second Edition. (Taylor and Francis, 2001)

**Course Plan:**

|  |  |  |  |
| --- | --- | --- | --- |
| **Lec.No.** | **Learning objectives** | **Topics to be covered** | **Chapter in the Text Book/Ref Book** |
| 1-4 | Preformulation studies in design of dosage forms | Physical, Chemical and biological properties of drug and their importance in the design, manufacture & stability of dosage form. | T1: Ch. 24 |
| 5-6 | To understand the process of drug absorption | Drug absorption process, mechanisms involved and factors affecting the absorption of drug | T1:Ch. 20, 21, 22 |
| 7-9 | To understand Biopharmaceutical Classification System (BCS). | What is BCS? Different classes of drugs. Experimental studies to classify a drug according to BCS | Lecture Notes |
| 10-14 | To understand In vitro in vivo correlation (IVIVC) | What is IVIVC? Different levels of IVIVC. Experimental studies to determine the level of correlation | Lecture Notes |
| 15-20 | To understand the design of oral drug delivery | Various physiological and anatomical factors affecting the absorption of drug through oral route. The formulation factors and manufacturing factors affecting absorption of oral formulations,  Gastro-retentive drug delivery systems, Colon Targeted drug delivery systems. | R1: Ch 5, 6, 7  and Lecture Notes |
| 21-22 | To understand the design of buccal and sublingual drug delivery | Various physiological and anatomical factors affecting the absorption of drug through buccal and sublingual route. Formulations for buccal and sublingual route | R1: Ch 3 and Lecture Notes |
| 23-25 | To understand the design of nasal drug delivery | Various physiological and anatomical factors affecting the absorption of drug through nasal route. Formulations for nasal route | R1: Ch 9 and Lecture Notes |
| 26-28 | To understand the design of ocular drug delivery | Various physiological and anatomical factors affecting the absorption of drug through ocular route. Formulations for ocular route | R1: Ch 11 and Lecture Notes |
| 29-31 | To understand the design of pulmonary drug delivery | Various physiological and anatomical factors affecting the absorption of drug through pulmonary route. Formulations for pulmonary route | R1: Ch 10 and Lecture Notes |
| 32-35 | To understand the design of transdermal drug delivery | Various physiological and anatomical factors affecting the absorption of drug through transdermal route. Formulations for transdermal route. Permeability enhancement through transdermal route | R1: Ch 8 and Lecture Notes |
| 36-38 | To understand controlled release drug delivery systems (CRDDS) | What are CRDDS, disadvantages and disadvantages, different types/designs of CRDDS, factors affecting drug release from CRDDS and evaluation of CRDDS | T1: Ch 33  Lecture Notes |

**Evaluation Scheme:**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **EC No.** | **Evaluation component** | **Duration** | **Weightage** | **Date and Time** | **Nature of Component** |
| 1 | Mid-Term Exam | 90 min. | 30 | As per Time Table | CB |
| 2 | Lab Sessions | - | 20 | Regular lab sessions | OB |
| 3 | Assignment (2 Nos) | 50 min | 15 | During Class Hour | CB |
| 3 | Comprehensive | 120 min. | 35 | As per Time Table | CB (15) + OB (20) |

CB – Closed Book; OB - Open Book.

**Instructor Consultation Hour:** To be announced in the class.

**Notices:** Notices pertaining to this course will be displayed **only on Pharmacy Department Notice Board.**

**Make-up Policy:** Make-up will be given only for **genuine** reasons. It is expected that students shall avoid misuse of this feature.

**Academic Honesty and Integrity Policy**: Academic honesty and integrity are to be maintained by all the students throughout the semester and no type of academic dishonesty is acceptable.

**INSTRUCTOR-IN-CHARGE**