BIRLA INSTITUTE OF TECHNOLOGY AND SCIENCE, PILANI-HYDERABAD CAMPUS

FIRST SEMESTER 2020-2021

Course Handout (Part II)

Date: 17/08/2020

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 F314**

Course Title **: Pharmaceutical Formulations and Biopharmaceutics**

Instructor In-charge **: Dr. NIRMAL J**

Instructor : Raghuraman Manimaran; Parameswar Patra; Priyadarshni Sathe

1. **Scope & Objective of the Course:**

This course is intended to give the students an insight into the selection and design of appropriate pharmaceutical dosage forms for drugs. It brings together various sciences that are involved in the development, manufacture pharmaceutical products and their evaluation as per the quality standards set by the regulatory agencies. The laboratory component involves some fundamental exercises in the preparation of pharmaceutical products such as tablets, liquid orals, semi-solids etc. It also imparts knowledge of sustained release dosage forms.

2. Learning Outcomes (course benefits): Students who have undergone the course are expected to

- Explain the importance of pre-formulation studies in the design of pharmaceutical formulations
- Select appropriate excipients used in the preparation of dosage form for a given drug
- Choose a suitable manufacturing method and equipment for preparing a pharmaceutical product for a given drug
- Evaluate the pharmaceutical products like Tablets/Capsules/Liquid Orals/Semi-solids as per the regulatory guidelines
- Describe modified release drug delivery systems

3. Textbooks:

1. Lachman/Lieberman's The Theory and Practice of Industrial Pharmacy, edited by: Roop K Khar, S. P. Vyas, Farhan J. Ahmad and Gaurav K. Jain. Fourth Edition. (CBS Publishers, 2013)
2. Pharmaceutics: The Design and Manufacture of Medicines, edited by: Michael E. Aulton. Third Edition. (Churchill Livingstone [Elsevier], 2007).

4. Reference Books:

1. Raymond C., Sheskey, Paul J.,Owen, Sian C., Handbook of Pharmaceutical Excipients 6th Edition, Pharmaceutical Press.
2. Joseph P. Remington., Remington: The Science and Practice of Pharmacy, volume I and volume II, 22nd Edition

5. Course Plan:

a) Lectures:

Course Plan:

Lec. No.	Learning objectives	Topics to be covered	Chapter in the Text Book/Ref Book
1-3	To know the importance of preformulation studies in the design of dosage forms	Physical, Chemical and biological properties of drug and their importance in the design, manufacture & stability of dosage form.	T2: Ch. 24
4-7	To understand various types of dosage forms and excipients used in the preparation of dosage forms	Different types of dosage form like solids, liquids and semi-solid dosage forms. Various categories of excipients used in the preparation of dosage forms.	T1: Ch.12 T2: Ch.21 R1
8-13	Design, development and evaluation of tablets	Different type of Tablets, categories of excipients used in tablets, different manufacturing methods for preparing tablets, physical characterization and in vitro evaluation of tablets	T1: Ch.13 T2: Ch. 31 R2
14-18	Design, development and evaluation of capsules	Different type of capsules, categories of excipients used in capsules, different manufacturing methods for preparing capsules, physical characterization and in vitro evaluation of capsules	T1: Ch.14 T2: Ch. 34 & 35 R2
19-21	Coating of powders, granules, tablets and capsules	Why coating is needed for solid dosage forms, components used in coating solutions/suspensions, equipment used and important process parameters in coating	T1: Ch.13 T2: Ch.33
22-24	Sterile Product Formulations	Large and small volume parenteral	T1: Ch.23 R2
25-27	Design, development and evaluation of liquid preparations	Solutions/Suspensions/Emulsions: Categories of excipients used in liquid preparations, different manufacturing methods for preparing liquid preparations, physical characterization and in vitro evaluation of liquid formulations	T1: Ch.17 T1: Ch.18 R2
28-31	Modified release drug delivery systems	What are modified release drug delivery systems (ex: Controlled and	T1: Ch.24

		Targeted drug delivery systems) advantages of designing modified release systems.	T2: Ch.32

b) List of Experiments:

S.No	Title of the experiment
1	Formulation of Paracetamol IP conventional uncoated tablets using wet granulation method
2	Formulation of Diclofenac sodium IP super disintegrant tablets
3	Formulation of Diclofenac sodium IP effervescent tablets
4	Characterization of paracetamol uncoated tablets, diclofenac sodium super disintegrant and effervescent tablets
5	Preparation and characterization of chewable antacid tablets
6	Preparation of amoxicillin suspension
7	Preparation of antacid suspension
8	Demonstration and filing of capsule filling machine
9	Preparation of artificial tears/eye drops
10	Preparation of different formulations of Diclofenac sodium gel
11	Preparation of castor oil emulsion
12	Preparation of calcium alginate beads for Diclofenac sodium
13	Formulation of nano/microparticles
14	Formulation of liposomes

4. Evaluation Scheme:

Component	Duration	Weightage (%)	Date & Time	Remarks
Test 1	30 mins	15	September 10 –September 20 (During scheduled class hour)	Open book
Test 2	30 mins	15	October 09 –October 20 (During scheduled class hour)	Open book
Test 3	30 mins	10	November 10 – November 20 (During scheduled class hour)	Open book
Surprise quiz (2-3), Assignment		15	Continuous	Open book
Lab component	Weekly	10	Continuous	Open book
Compre. Exam.	120 min	35	TBA	Open book

5. Mid-Semester Grading: Will be announced after test 2.

6. Make-up: Prior approval or intimation to take a make-up is mandatory. It is solely at the discretion of the instructor-in-charge, depending upon the genuineness of the circumstances, to allow or disallow a student to appear for a make-up evaluation component. No makeup will be granted for Assignments/Quizzes under any circumstances.

7. Grading Procedure:

- Grading will be done by "bunching" procedure. Total marks obtained by the students will be arranged in descending order, 'bunches' will be identified and grades awarded accordingly. Fine grading system (A, A-, B, B-....) will be followed.
- It is not mandatory for the instructor-in-charge to award all the grades (A to E); subjective judgment will be used for awarding the grades.
- As specified in Handout – Part I, appended to the timetable, the instructor in-charge reserves the right to award a NC report in case the student does not make himself/ herself available for any of the evaluation component mentioned above.
- Borderline cases during grading will be judged on the basis of regularity to classes and consistency or progress in the performance in evaluation components.

8. Chamber Consultation Hours: To be announced in class.

9. Notices: All the notices pertaining to this course will be displayed on CMS.

10. 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
PHA F314