BIRLA INSTITUTE OF TECHNOLOGY AND SCIENCE. PILANI
HYDERABAD CAMPUS
ACADEMIC-GRADUATE STUDIES AND RESEARCH DIVISION
FIRST SEMESTER 2023-2024
Course Handout (Part-II)

Date: 11/08/2023

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

Course No : **PHA G542**
Course Title : Advanced Physical Pharmaceutics
Instructor-in-charge : **Vamsi Venuganti**
Instructor : Shreya Chauhan, Shridula Sankar

1. Course Description:
Preliminary evaluations and molecular optimization, Drug substance considerations including protein, peptide and biological products, Bulk characterization, Solubility analysis, Rheology and dispersed systems, Micrometrics and shape factor analysis, Compression and compaction, Principles of dissolution, Dissolution test design and release kinetics evaluation, Compatibility testing, Stability analysis and test design according to international standard, Rationale basis of formulation recommendation.

2. Scope and objective of the course:
Prior to the development of any dosage form with a new or old drug candidate, it is essential that certain fundamental physical and chemical properties of the drug molecule and other derived properties of the drug are determined. This information dictates possible approaches in formulation development. The aim of this course is to make the students understand those physicochemical principles which must be applied in the formulation and development of an efficacious dosage form, so that the required duration and intensity of effect can be ensured at the intended site of action.

3. Learning outcomes:
- The student should be able to understand the importance of preformulation characterization of pharmaceuticals and its role in formulation development
- The student should be able understand crystallinity and polymorphism and its importance in formulation development
- The student should be able to apply solubility enhancement strategies
- The student should be able to perform stability studies in accordance with ICH guidelines and understand the outcomes
- The student should be able to calculate the drug release parameters and correlate to physico-chemical properties

4. Text Book (TB):
TB: Carstensen, J.T. Pharmaceutical Preformulation CRC Press, 1998

5. Reference Books (R):
R1: Carstensen, J. T., Rhodes, C.T., 2000. Drug Stability: Principles and Practices, Drugs and Pharm. Sci. Series, Vol. 43, 3rd edn, Marcel Dekker Inc., New York.
R2: Martin's Physical Pharmacy and Pharmaceutical Sciences,

6. **Course Plan:**

Number of sessions	**Learning Objectives**	**Topic to be covered**	Chapter in Textbook
1	Stages of drug development, significance of physical pharmaceutics in formulation development	Introduction to physical pharmaceutics	Class notes
2	Overview of preformulation studies carried out during/ prior to formulation development	Pharmaceutical preformulation	Class notes Chapter 1, TB
3-10	Study and impact of crystallinity/ polymorphism, hydrates and solvates on dosage forms	Solid state pharmaceutics	Chapter 7, TB
11, 12	Techniques of aqueous solubility determination of non-ionized, ionized and unstable drugs	Solubility	Chapter 2, TB; Chapter 9, R2
13-16	Impact of pH, ionic strength, surfactants, partition coefficients, dielectric constant, and mixed solvent systems on solubility; Enhancement of solubility	Factors/ parameters affecting solubility	Chapter 2, TB; Chapter 9, R2
17, 18	Characterization of powders, microparticles and nanoparticles	Particle size	Chapter 11, TB; Chapter 18, R2
19-22	Various types and sources of stability problems; procedure/ protocol to perform stability studies of drug substances; compatibility studies; characterization of stability; Stability indicating analytical method development	Drug and formulation stability	ICH Q1
23-26	Kinetics of chemical degradation and influence of temperature on degradation	Kinetics of drug stability	Chapter 14, R2
27-30	Overview of chemical and physical protein degradation and useful analytical methods for detecting the same	Stability of polypeptides and proteins	Class notes
31-33	Principles and applications of adsorption; Factors affecting surface tension and critical micelle concentration; Pharmaceutical applications of surfactants	Surface phenomenon	Chapter 9, TB; Chapter 15, R2
34-36	Deformation and viscoelasticity	Rheology	Notes
37-40	Diffusion and dissolution-controlled release process and their mathematical treatment	Principles of diffusion and dissolution	Chapter 10, TB; Chapter 13, R2
41	Modeling of drug release kinetics	Release characterization	Class notes

List of experiments

No.	Experiment Name	Week
1	Introduction	
2	Recrystallization and identification of polymorphic forms of select drugs Demonstration of microscope, DSC, XRD and FTIR	
3	Enhancement of solubility of poorly water soluble drugs and determination of solubility	
4	Preparation and characterization of micro/nanoparticles	
5	Drug stability and drug-excipient compatibility study (4 weeks)	
6	Stability of proteins, demonstration of gel electrophoresis	
7	Determination of mechanical properties (tensile strength, elastic modulus, deformation) of polymeric films	
8	Characterization of semisolid preparation by rheometric analysis	
9	Preparation of adsorption isotherms	
10	Dissolution studies of tablets and release kinetics	
11	Diffusion kinetics of caffeine solution – skin permeation studies	

7. Evaluation Scheme:

Components	Duration	Weightage	Date and Time	Nature of component
Mid-semester test	90 minutes	25%	12/10 4.00 - 5.30PM	Closed book
Lab work	Continuous	Weekly lab 25% Lab comprehensive exam 5%	Continuous	Open book
Seminar/ Assignments	Continuous	Seminar 5% Assignment 5%	Continuous	Open book
Comprehensive Examination	180 minutes	35%	16/12 FN	Closed book (20%) Open book (15%)

8. **Mid-Semester Evaluation:** Will be announced after mid-semester test

9. **Make-up:** Prior approval or intimation to take a make-up is a must. It is solely the discretion of the instructor-in-charge dependent upon the genuineness of the circumstances to allow a student to appear for a make-up evaluation component.

10. **Grading policy:** 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. Also it is not imperative on part of the instructor in-charge to award all the grades. Borderline cases during grading will be judged on the basis of regularity to classes and consistency or progress in the performance in evaluation components. The maximum pull-up to be exercised by the instructor in-charge will be announced in the class and shall be based on the subjective judgment of the evaluator.

11. **Chamber Consultation Hours:** Wednesday 5-6 PM in A005.

12. **Notices**: Notices concerning the course will be displayed in the CMS course page only.

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 G542