BIRLA INSTITUTE OF TECHNOLOGY AND SCIENCE. PILANI
HYDERABAD CAMPUS
INSTRUCTION DIVISION,
FIRST SEMESTER 2016-2017
Course Handout (Part-II)

Date: 01/08/2016

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 G542**
Course Title : Advanced Physical Pharmaceutics
Instructor-in-charge : **V V Vamsi Krishna**
Instructor : Anup Jose

1. Course Description:
Physico-chemical principles involved in effective formulation development, including various aspects like, crystallinity, particle size, solubility, pKa and stability, development and validation of analytical method, principles and kinetics of dissolution, polymer science, etc.

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 required duration and intensity of effect can be ensured at the intended site of action.

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

4. 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,

5. Course Plan:

Number of sessions	**Learning Objectives**	**Topic to be covered**	Chapter in Text book
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,	Solid state pharmaceutics	Chapter 7, TB

	hydrates and solvates on dosage forms		
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	R1; Chapter 14, R2
23-26	Kinetics of chemical degradation and influence of temperature on degradation	Kinetics of drug stability	R1; 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	Polymer classification, synthesis and characterization. Polymers in dosage forms and drug delivery	Polymers	Chapter 20, R2
37-40	Diffusion and dissolution controlled release process and their mathematical treatment	Principles of diffusion and dissolution	Chapter 10, TB; Chapter 13, R2
41, 42	Modeling of drug release kinetics	Release characterization	Class notes

6. Evaluation Scheme:

Components	Duration	Weightage	Date and Time	Nature of component
Test I	60 minutes	15%	13/09/2016; 8.30 – 9.30 AM	Closed Book
Test II	60 minutes	15%	21/10/2016; 8.30 – 9.30 AM	Closed Book

Lab work/ Seminar/ Assignments	Continuous	Weekly lab work 15% Lab quiz 5% Lab viva 5% Seminar 10% Assignment 5%	continuous	Open book except for lab quiz
Comprehensive Examination	180 minutes	30%	14/12/2016 FN	Closed Book (10%)/ Open Book (20%)

7. **Mid-Semester Evaluation:** Will be announced in the first week of Oct' 2015
8. **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.
9. **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.
10. **Chamber Consultation Hours:** To be announced in the class.
11. **Notices**: Notices concerning the course will be displayed in the Pharmacy Group notice board only.

Instructor-in-charge
PHA G542