BIRLA INSTITUTE OF TECHNOLOGY AND SCIENCE, Pilani
Pilani Campus

INSTRUCTION DIVISION
FIRST SEMESTER 2015-2016
Course Handout (Part-II)

Date: 03/08/2015

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 : **Dr. ANUPAMA MITTAL**

1. Course Description:
Physicochemical principles involved in effective formulation development, including various aspects like, pharmaceutical preformulation, development and validation of analytical method, principles of dissolution, IVIVC, pharmacokinetic-pharmacodynamic modeling, 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 1: Carstensen, J. T, Pharmaceutical Preformulation. Technomic Publishing comp. USA.

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: Carstensen, J. T., 1980. Solid Pharmaceuticals: Mechanical properties and Rate Phenomenon, Academic Press, New York.
R3: Carstensen, J. T., 1972. Theory of Pharm. Systems, Vols. 1, Academic Press, New York.
R4: Carstensen, J. T., 1973. Theory of Pharm. Systems, Vols. 2, Academic Press, New York.

5. Course Plan:

Lecture No.	Learning Objectives	Topic to be covered	Reference
1	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	TB: Ch. 1; R1: Ch. 9;
3-4	Study and impact of polymorphism, hydrates, hygroscopicity; vapour pressure, etc	Drug substance considerations	TB: Ch. 7; R1: Ch. 9;
5-6	Techniques of aqueous solubility determination of non-ionized, ionized and unstable drugs	Determination of solubility	TB: Ch. 2; Class-notes
7-8	Impact of pH, ionic strength, surfactants, partition coefficients, dielectric constant, and mixed solvent systems on solubility; Enhancement of solubility	Factors/ parameters affecting solubility	TB: Ch. 2 & R3: Ch. 3
9-10	Compatibility test for solid and liquid dosage forms.	Compatibility testing.	TB: Ch. 14; R1: Ch. 9;
11-12	Important physicochemical/ mechanical aspects to be considered during design and formulation of good quality pharmaceutical preparations	Physicochemical aspects of pharmaceutical preparations	Class-notes
13-14	Stability studies of drug substances and drug products with special reference to ICH guidelines, Various types and sources of stability problems and procedure/ protocol	Drug and formulation stability	ICH guidelines; R3: Ch. 4; R4: Ch. 5
15-17	Specifications for drug substance and drug product. Impurity limits determination as per ICH guidelines.	Specifications and impurity limits	ICH guidelines;
18-19	Highlights on accelerated/ ambient/ controlled physical stability testing of formulations	Physical stability testing of pharmaceutical preparations	R1: Ch.10; R2: Ch. 6;
20-21	Rational approach to development and validation of stability-indicating analytical method	Analytical method development and validation	TB: Ch. 13; R1: Ch. 11; Class-notes
22-23	Principles and applications of adsorption; Factors affecting surface tension and Pharmaceutical applications of surfactants	Surface phenomenon	TB: Ch. 4; R3: Ch. 3; Class-notes
24-28	Diffusion and dissolution process and their mathematical treatment; dissolution test design;	Principles of diffusion and dissolution, Release characterization	TB: Ch. 15; R2: Ch. 6;

	Drug release kinetics		Class-notes
29-31	In vitro - in vivo correlations with respect to BCS classification	IVIVC	R2: Ch. 6; Class-notes
32-33	Establishment of pharmacokinetic-pharmacodynamic relationships	PK/PD modeling	Class-notes
34-37	Various types of polymers employed in dosage forms and approach for choosing the right ones; Mechanism of release with respect to polymers	Polymers	Class-notes
38-40	Class discussions on recently published articles	Recent advances in physical pharmaceutics	Various journals

6. Evaluation Scheme:

Components	Duration	Weightage	Date and Time	Remarks
Mid-semester test	90 minutes	25%	8/10 10:00 - 11:30 AM	CB
Seminar/ Assignments	Continuous	20%	Continuous	-
Lab work	Continuous	20%	Continuous	-
Comprehensive Examination	180 minutes	35%	8/12 AN	CB+OB

7. Mid-Semester Evaluation: Will be announced after Mid sem exam.

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 Department of Pharmacy notice board only.

Instructor-in-charge
PHA G542