INSTRUCTION DIVISION
FIRST SEMESTER 2016-2017
Course Handout (Part-II)

Date: 02/08/2016

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 : **Dr. Gautam Singhvi**
Instructor : **Dr. Anupama Mittal**

1. Course Description:
Physicochemical principles involved in effective formulation development, including various aspects like, pharmaceutical preformulation including bulk characteristics, polymorphism, solubility analysis, solid and solution state stability, compatibility. This course also cover various ICH guidelines like stability study, specifications, impurities which are required during formulation development. This course also discussed details about mechanical properties of powders, principles of dissolution, in-vitro in-vivo correlation (IVIVC), 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. Learning outcomes of the course:
After thorough study of this course students will able to

- Perform preformulations studies for any drug candidate
- Design a effective and stable pharmaceutical formulation and study its various physicochemical parameters.
- Know the regulatory requirement which are related to pharmaceutical product development

Overall this course will build up a strong foundation for pharmaceutical formulation development to meet the industrial requirements.

4. Text Book (TB):
TB 1: Carstensen, J. T, Pharmaceutical Preformulation. Technomic Publishing comp. USA.

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: 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	Rational approach to development and validation of stability-indicating analytical method	Analytical method development and validation	TB: Ch. 13; R1: Ch. 11
5-6	Impact of powder densities, particle size, particle size distribution on process and product performance	Bulk characteristics, powder cohesion, blending and micromeritics	TB: Ch. 1; R1: Ch. 9;
7-9	Study and impact of polymorphism, hydrates, hygroscopicity; vapour pressure, etc	Drug substance considerations	TB: Ch. 7; R1: Ch. 9;
10-12	Techniques of aqueous solubility determination of non-ionized, ionized and unstable drugs	Determination of solubility	TB: Ch. 2; Class-notes
13-14	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
15-16	Compatibility test for solid and liquid dosage forms.	Compatibility testing.	TB: Ch. 14; R1: Ch. 9;
17-18	Important physicochemical/ mechanical aspects to be considered during design and formulation of good quality pharmaceutical preparations	Physicochemical aspects of pharmaceutical preparations	Class-notes
19-20	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
21-24	Specifications for drug substance and drug product. Impurity limits determination as per ICH guidelines.	Specifications and impurity limits	ICH guidelines;

25-26	Highlights on accelerated/ ambient/ controlled physical stability testing of formulations	Physical stability testing of pharmaceutical preparations	R1: Ch.10; R2: Ch. 6;
27-28	Principles and applications of adsorption; Factors affecting surface tension and Pharmaceutical applications of surfactants	Surface phenomenon	TB: Ch. 4; R3: Ch. 3; Class-notes
29-31	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
32-34	Diffusion and dissolution process and their mathematical treatment; Drug release kinetics	Principles of diffusion and dissolution, Release characterization	TB: Ch. 15; R2: Ch. 6; Class-notes
35-37	Concept behind development of discriminating dissolution media, quality control media, bio relevant media during product development	In-vitro drug release (dissolution) test design	R2: Ch. 6; Class notes
38-40	In vitro - in vivo correlations with respect to BCS classification	IVIVC	R2: Ch. 6; Class-notes
41-43	Newtonian and Non- Newtonian flow characteristics and application	Rheology concepts in drug delivery systems	
44-45	Recent advancement in physical pharmaceutics with respect pharmaceutical product development.	Recent advancement in physical pharmaceutics	Various journals

6. **Evaluation Scheme:**

Components	Duration	Weightage	Date and Time	Remarks
Mid-semester test	90 minutes	30%	6/10 8:00 - 9:30 AM	Closed Book
Seminar/ Assignments/ Research activity	Continuous	15%	Continuous	
Lab work	Continuous	20%	Continuous	
Comprehensive Examination	180 minutes	35%	8/12 AN	Closed Book + Open Book

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