RK UNIVERSITY

SYLLABUS

Course Title	**DOSAGE FORM DESIGN**
Course Code	PH702
Course Credit	Lecture : 3
	Practical : 3
	Tutorial : 0
	Total : 6

Course Objectives

On the completion of the course, students will be able to:

- Apply knowledge of excipients, preformulation studies, stability evaluation in the formulation of pharmaceutical products and drug delivery systems.
- To integrate aspects of preformulation, stability requirements, dissolution study, and validation for the development of Pharmaceutical Dosage Forms.

Detailed Syllabus

Sr. No.	Name of Chapter & Details	Hours Allotted
	Section-I	
1	**Physico-chemical Characterization:** Study of physical properties of drug like physical form, particle size, shape, density, crystallinity, hygroscopicity, wetting, dielectric constant,	14

	solubility, dissolution and organoleptic property and their effect on formulation, stability and bioavailability. Rationale for selecting the preferred polymorph/crystalline form. **Degradation Pathways:** Study of chemical properties of drugs like hydrolysis, oxidation, reduction, polymorphisms, racemization, polymerization etc., and their influence on formulation and stability of products. Study of prodrugs in solving problems related to stability, bioavailability and elegance of formulations. Drug-excipient compatibility studies and its importance in pharmaceutical development. Traces of organic volatile impurities (OVIs) and their regulatory limits (residual solvents).	
2	**Introduction to BCS and dissolution study:** Definition, Importance and objectives of dissolution, Dissolution mechanisms, Factors affecting dissolution, Intrinsic dissolution rate measurement, Dissolution apparatus for various dosage forms, Selection of dissolution media and conditions, Dissolution profile comparison methods, biowaiver. Biological classification system (BCS); its significance on dissolution study and application in dosage form development.	**09**
	Section-II	
3	**Basics of IVIVR and IVIVC:** Methods of establishing IVIVC, Factors affecting IVIVC, Biorelevant Dissolution Medium.	**04**

4	**Stability of pharmaceuticals:** Kinetic principles and stability testing: Reaction rate and order, acid base catalysis, decomposition reactions and stabilization of pharmaceuticals, Effect of various environmental/ processing factors like light, pH, temperature, etc. on stability of the formulation and techniques for stabilization of product against the same, Stability of formulation, MKT, climatic zones, matrixing and bracketing in stability study, accelerated stability testing, real time stability. Current WHO, USFDA and stability testing as per ICH guidelines for pharmaceutical drug substances and drug products. Shelf-life, Overages, Overage calculations.	**12**
5	Efffect of following adjavunts on formulation of different pharmaceutical products: Antioxidants, preservatives, colours, flavours, diluents, binders, disintigrants, antifictional agents, emulsifiers, suspending agents, solvents etc. and other formulation additives.	**06**

Dosage Form Design (Practical)

1. Determination of the angle of repose, Carr's index, Hausner's ratio of given powder/ granules.
2. Determination of solubility of given drug at different pH.
3. To study the compression characteristic of different diluents.
4. To study the effect of various binders on performance of tablet.
5. To study the effect of various disintigrants on performance of tablet.
6. To study the Influence of temperature on the stability of aspirin/ ascorbic acid solution.
7. Compendial dissolution testing and data evaluation for given tablets and capsules.
8. In-vitro dissolution profile comparison of given tablet with reference product using similarity and dissimilarity factor.
9. Enhancement of solubility of poorly water soluble drug by solid dispersion.
10. Enhancement of solubility of poorly water soluble drug by -Cyclodextrin complexation.

11. Preformulation studies including drug-excipient compatibility studies.
12. Calculation of bioavailability parameters from the given pattern of drug absorption from oral & IV formulations.
13. Other practicals covering syllabus aspects.

Instructional Method and Pedagogy:

- Lectures will be conducted with the aid of multi-media projector, black board, OHP etc.
- Assignments based on course content will be given to the students at the end of each unit/topic and will be evaluated at regular interval.
- Surprise tests/Quizzes/Seminar/Tutorials will be conducted.
- The course includes a laboratory, where students have an opportunity to build an appreciation for the concepts being taught in lectures.

Students Learning Outcomes:

- By the end of this course, the student should have a good understanding of basic process which are used in different stage during preparation of pharmaceutical formulation.
- Students should be able to know calculation of formulas, labeling, and packing of different types of pharmaceutical products.

Text Books:

1. Pharmaceutical Dosage Forms and Drug Delivery Systems by Ansel & others.
2. Pharmaceutical Technology by Sambamurthy, New Age publication.

Reference Books:

1. The Science & Practice of Pharmacy: A. G. Remington; Lippincott, Philadelphia.
2. Pharmaceutical Dosage Forms: Tablets: Vol.1, Vol. 2 and Vol.3, Ed. by Lieberman, Leon Lachman and Joseph B. Schwartz, Marcel Dekker Inc., New York.
3. Modern Pharmaceutics by Gilbert S. Banker and Christopher T. Rhodes, Marcel Dekker, Inc., New York.
4. Stability of drug and dosage forms by Yoskioka, BSP publication.
5. Drug stability (Principles and Practices) by Jens. T. Carstensen, Marcel Dekker.
6. Pharmaceutical Preformulation by carstensen, CRC publication.
7. Pharmaceutical Dissolution Testing by Dressman and Jennifer, Informa publication.
8. Pharmaceutical dissolution testing by Umesh V. Banker, Marcel Dekker Inc.

Additional Resources

- Soft copies of dosage form design books are available on http://www.pharmatext.org, www.pharmacyebooks.com, and in www.pharmamirror.com.
- Latest information regarding dosage form design are available on http://www.pharmainfo.net
- Study material of dosage form design are available on mypharmaguide.com, pharmatutor.com, authorstream.com, slideworld.com and in scribd.com .
- Review articles published in international journal covering syllabus aspect.