BIRLA INSTITUTE OF TECHNOLOGY AND SCIENCE, Pilani
Pilani Campus
AUGS/ AGSR Division

SECOND SEMESTER 2020-21
Course Handout (Part II)

Date: 14.01.2021

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 F414**

Course Title : **BIOPHARMACEUTICS**

Instructor-in-Charge : **Dr. Gautam Singhvi**

1. Course Description:

Biopharmaceutics and Biopoharmaceutical aspects of drug delivery covering absorptions, distribution, metabolism and elimination (ADME) characters of drugs. Compartment model, pharmacokinetics of drugs and their applications, bioavailability, bioequivalence and their studies, drug-drug interactions and other related matters.

2. Scope and Objective of the Course:

The prime objective of this course is to impart knowledge of biopharmaceutical process based on fundamental concepts. The primary focus will be on mechanisms of and factors influencing drug absorption as well as bioavailability. This course also deals with distribution, biotransformation and excretion of drugs. In order to develop a background knowledge in the up-coming field like pharmacokinetics, a brief discussion about basic considerations in pharmacokinetics such as rates and orders of reactions, compartment modeling, bioequivalance and design of dosage regimen is also included. The knowledge of this branch of pharmacy is very essential for a professional pharmaceutical scientist, as concepts regarding plasma drug concentration profile, Bioavailability and Bioequivalance as well as Dosage Regimen is resourceful working tool in every branch of pharmacy, be it pharmaceutics, pharmacology or medicinal chemistry. Therefore, it is essential for every graduate student in pharmacy to be familiar with the outlines of these concepts and that is what this course aims to achieve.

3. Text Books:

1. Brahmankar, D M and Jaiswal, S N Biopharmaceutics and Pharmacokinetcs a treatise 2nd edition Vallabh prakashan 2009.

4. Reference Books:

1. Gibaldi, M and Perrier, D, Pharmacokinetics, 3rd edition Revised and Expanded Marcel Dekker Inc.
2. Hassan, Williams E Hospital Pharmacy 4th edition phil Lea & febiger 1981

5. Course Plan:

Module Number	Lecture Session	Reference	Learning Outcome
1. Introduction to bio-pharmaceutics	L.1.Definition, scope, terms used, L.2.Processes involved in drug therapeutics	TB1- Chapter 1 & Class notes	Orientation to the biopharmaceutics
2. ADME of drugs	L.3-L.4.Gastrointestinal absorption of drugs L.5. Cell membrane- structure and physiology mechanisms L.6-L.7.Factors influencing drug absorption and bioavailability L.8. pH-Partition hypothesis Theories of drug dissolution and dissolution rate L.9. Absorption of drugs from non *per os* extravascular routes	TB1- Chapter 2 & Class notes	Imparting knowledge of different aspects of absorption of drugs
	L.10-L.11.Tissue permeability of drugs, volume of distribution L.12-L.13.Protein binding of drugs, tissue binding, kinetics of protein-drug binding	TB1- Chapters 3 & 4	Understanding of the process of drug distribution
	L.14-L.16.Drug metabolizing organs and enzymes, chemical pathways phase I and phase II reactions L.17.Factors affecting Biotransformation of Drugs	TB1- Chapter 5	Knowledge of the signi-ficance and mechanism of drug metabolism
	L.18. Application of prodrug design L.19. Advantage and limitations of prodrugs	Class notes	Exposure to the applications of prodrugs
	L.20-L.23.Renal excretion: glomerular filtration, active tubular secretion, tubular re-absorption, concept of clearance, factors affecting renal excretion L.24-L.25.Dose adjustment in renal failure, Non-renal routes of drug excretion	TB1- Chapter 6	Understanding of the mechanism and effects of drug excretion
3.Pharmacokinetic drug interactions	L.26-L.28. Mechanisms of drug interactions, interactions affecting absorption, distribution, metabolism and excretion of drugs	TB1- Chapter 7	Imparting concept and significance of drug interactions
4.Pharmacokinetics: Basic consideration: Introduction to comparment modeling and	L.29-L.31.Plasma drug concentration time profile rates, rate constants and orders of reactions L.32-L.33.Pharmacokinetic models: Compartmental & Non-compartmental analysis	TB1- Chapter 8	Concept of basic pharmacokinetics and compartmental

pharmacokinetic softwares	L.34-L.35. One-compartment open model, two-comparment open model, multi comparment models, an introduction to various pharmacokinetic softwares	TB1- Chapter 9 & Class notes	pharmacokinetic modeling
5.Bioavailability and bioequivalence	L.36. Objective and considerations in bioavailability studies, measurement of bioavailability L.37. Methods for enhancement of bioavailability	TB1- Chapter 11	Understanding of bio-availability and bio-equivalence
6.Application of pharmacokinetic principles	L.38. Design of dosage regimen	TB1- Chapter 12	Knowledge of the use of pharmacokinetics in dose determination

6. Evaluation Scheme:

Components	Duration	Weightage	Date and Time	Remarks
Mid-semester test	90 minutes	30%		Closed Book
Continues assessment (Quizzes /case studies /application/ assignments / presentation)	Continuous	30%	Continuous	Closed/Open book
Comprehensive examination	180 minutes	40%		Closed Book

7. Mid-Semester Evaluation: Will be announced in the class.

8. Chamber Consultation Hour: To be announced in the class.

9. Make-up Policy: Make-ups are not given as a routine. It is solely dependent on the "genuineness" of the circumstances under which a student fails to appear in a scheduled evaluation component. Prior permission should be sought from the instructor-in-charge in advance.

10. Note (if any): -

Instructor-in-charge
PHA F414