



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

Date: 26/07/2016

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 G612
Course Title : Pharmacokinetics & Clinical Pharmacy
Instructor Incharge : SUNIL KUMAR DUBEY
Instructors : Sushil K. Yadav, Sorabh Sharma

1. Course Description:

The study of pharmacokinetics and its clinical applications in the design, development, evaluation and use of drugs; the time course of drug and metabolite levels in different fluids, tissues and excreta of the body, mathematical relationship required to develop models to interpret the data for single and multiple dosing, study of bioavailability, dosage regimen adjustment in renal impairment, application of the pharmacokinetic principles to the therapeutic management of patients, population pharmacokinetics, IVIVC, PK-PD correlation.

2. Scope and Objective of the Course:

The course is designed to impart knowledge of pharmacokinetics, its application, pharmacokinetic studies, mathematical modeling, experimental design. This will help students to gain knowledge in a very important area of pharmacy. Practical's are designed to expose students to pharmacokinetic studies.

3. Text Book : T1. Gibaldi, M & Perrier, O., Pharmacokinetics, Marcel Dekker, N.Y., 2nd ed. 1993.

4. Reference Books :

R1 Lachman, Libermann and Kanig., The Theory and Practice of Industrial Pharmacy, Vergish Publication, 2nd edn.

R2 Rowland., Clinical Pharmacokinetics: Concepts and Applications.

R3 Herfindal and Hirschman., Clinical Pharmacy and Therapeutics.





R4 Remington., Pharmaceutical Sciences.

R5 Curr and Whelpton., Pharmacokinetics Lab. Manual.

R6 Gibaldi M. & Pervier O., Pharmacokinetics, Marcel Dekker, N Y, 1st Edn.

R7 Gibaldi M., Biopharmaceutics and Clinical Pharmacokinetics, 4th Edn.

R8 Journals.

5. Course Plan:

Lecture No.	Learning objective	Topics to be covered	Reference
1-2	Introduction to Pharmacokinetics and its application	Pharmacokinetics & ADME characters of drugs	R 1, R2
3	Concept of compartment in pharmacokinetics	Compartment model : one, two & multi-compartments	R1, R7
4 - 6	Pharmacokinetic study of drugs and métabolites : in plasma & urine for i.v injection	One compartment i.v. bolus	T1-
7-8	Pharmacokinetics of drugs by iv infusion	i.v. infusion	T1-1
9-11	Pharmacokinetics of drugs administered through absorption	Ist order absorption & zero order absorption	T1-1
12-14	Multi-compartment pharmacokinetics, drugs in plasma, urine for iv injection	Two compartment iv injection	T1-2
15	Multi-compartment Pharmacokinetics of infusion, 1st order absorption	Two compartment iv infusion and 1st order absorption	T-2
16-17	Pharmacokinetics of one compartment multiple dosing : drug in plasma, iv injection, 1st order absorption	Multiple dosing : pharmacokinetics of iv injection, 1st order absorption	T1-3
18-19	Pharmacokinetics of two compartment multiple dosing iv injection, 1st order absorption	Two compartment Multiple dosing	T1-3
20-21	Concept of Non compatment analysis :	Non compartment	T1-4





	approach, modeling	Analysis	
22-24	Study of bioavailability and bioequivalence	Bioavailability : Rate and extent of absorption	T1-4
25-26	Study of nonlinear pharmacokinetics	Non-linear pharmacokinetics	T1-7
27	Concept and study of apparent volume of distribution	Apparend volume of distribution	T1-5
28	Concept & Study of Clearance	Clearance concept	T1-8
29	Use and study of physiological model of pharmacokinetics	Physiological model of pharmacokinetics	T1-9
30-31	Various applications of pharmacokinetic studies ; including in renal impairment	Application of pharmacokinetic studies	T1-10
32-33	Q.S.Pk.R : use in drug design	Quantitative structure Pharmacokinetic Relationship studies	Notes & Journals
34-35	Experimental techniques & Analysis of Biological samples.	Analysis of drugs in biological samples	R6
36-37	Population Pharmacokinetics and its applications	Population Pharmacokinetics	Literatures
38-39	PK-PD relationship : Determination and importance	PK-PD relationship	Literatures
40	Generic Biologics (Biosimilar Drug Products)	Bioavailability and Bioequivalence studies of Biologics	Notes & Journals

5. Home Assignments:

Study of relevant topics and research articles from journals for evaluation component 3 and problem solving assignments will be given during the semester.

6. Laboratory component:

Laboratory component will be assigned during the semester including use of computer software in pharmacokinetic study (WinNonlin).





7. Evaluation Scheme :

EC No.	Evaluation Component	Duration	Weightage	Date, Time & Venue	Nature of Component
1	Mid-term test	90 minutes	30	-4/10 4:00 - 5:30 PM	CB
2	Lab assigned	-	20	Throughout the semester	
3	Assignment (in class/take home)/Seminar	-	10	Throughout the semester: To be announced in classes	
4	Comprehensive Exam.	3 hours	40	5/12 AN	CB/OB

8. Chamber Consultation Hour: Tuesday 4th Hr.

9. Grading Procedure (In addition to Part I): The student shall not be considered as exposed to the course, unless he/she demonstrates appreciable skill in both laboratory and theory components of the course. In border line cases subjective judgment, based on attendance in lecture/practical classes, performance in laboratory and involvement in the course, assignment/seminar will be used to award grade. Laboratory attendance is must and no make up will be given.

10. Notices: The Notices concerning this course will be displayed on the **Department of Pharmacy** Notice Board.

**Instructor-In-Charge
PHA G612**

