# BIRLA INSTITUTE OF TECHNOLOGY AND SCIENCE, PILANI-HYDERABAD CAMPUS <u>Course Handout (Part II)</u>

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 In-charge : PUNNA RAO RAVI

Instructor : Avantika Dalvi, Chandra Teja Uppuluri

### 1. Course Description:

The study of pharmacokinetics and its clinical applications in the 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 in the therapeutic management of patients.

## 2. Scope and Objective of the Course:

The course is designed to impart fundamental concepts of pharmacokinetics. The students will be introduced to the pharmacokinetic modeling of drugs, both compartmental as well as non-compartmental models. The complete mathematical derivation of one compartmental intravenous bolus administration (blood sample and urine sample analysis), intravenous infusion and extravascular administration and two compartmental intravenous bolus administration will be covered. Bioequivalence or comparative bioavailability studies, determination or order of absorption and absorption rate constant by Wagner-Nelson method will also be discussed. Multi-dose pharmacokinetics of drug following one compartmental model administered through intravenous route will also be discussed.

#### **Learning Outcomes (course benefits):**

- Understand the basic concepts of pharmacokinetics.
- Describe the different pharmacokinetic models.
- Determine the basic pharmacokinetic parameters that describe drug absorption, distribution and elimination.
- Analyze data obtained from any pharmacokinetic study using compartmental and non-compartmental analysis
- Assess the absolute and relative bioavailability of drugs from different dosage forms.
- Design multi-dose regimen for a one compartmental drug administered through IV
- Design of dosage regimen of drugs in renal impaired patients and patients suffering from obesity.

- **3. Text Book:** Milo Gibaldi and Donald Perrier, Pharmacokinetics, Informa Healthcare, 2<sup>nd</sup>, ed., 1982.
- **4. Reference Book:** Sunil S Jambhekar and Philip J Breen, Basic Pharmacokinetics, Pharmaceutical Press, 2009.

## 5. Course Plan:

Lecture No.	Learning objective	Topics to be covered	Reference
1-2	Introduction of Pharmacokinetics	Pharmacokinetics & ADME characters of drugs	R
3	Concept of compartment model in pharmacokinetics	Compartment model : one, two & multicompartments	TB and R
4 - 6	Pharmacokinetic study of drugs and métabolites: in plasma & urine for i.v injection; modeling of data	One compartment i.v. bolus	TB and R
7-8	Pharmacokinetics of iv infusion	One compartment i.v. infusion	TB and R
9-11	Pharmacokinetics of drugs administered through extravascular route; modeling of data	First-order absorption & zero order absorption	TB and R
12-14	Multi compartment pharmacokinetics, drugs in plasma, urine for iv injection	Two compartment iv injection	TB and R
15-16	Multi compartment pharmacokinetics of infusion, 1st order absorption	Two compartment iv infusion and first-order absorption	TB and R
17-19	Pharmacokinetics of one compartment multiple dosing : drug in plasma, iv injection first-order absorption	Multiple dosing: pharmacokinetics of iv injection, first-order absorption	TB and R
20-22	Pharmacokinetics of two compartment multiple dosing iv injection, first-order absorption; modeling of data	Two compartment Multiple dosing	TB and R
23-24	Concept of Non compartmental analysis : approach and modeling	Non compartment Analysis	TB and R
25-27	Study of bioavailability	Bioavailability : Rate and extent of absorption	TB and R
28-29	Study of non-linear pharmacokinetics	Non-linear	TB and R

		pharmacokinetics	
30-32	Concept and study of apparent volume of distribution	Apparent volume of distribution	TB and R
33-34	Concepts on Clearance	Clearance	TB and R
35-36	Use and study of physiological models of pharmacokinetics	Physiological models of pharmacokinetics	TB and R
37-39	Various applications of pharmacokinetic studies including in renal impairment	Application of pharmacokinetic studies	Class Notes
40-42	Expeimental techniques & Analysis of Biological samples.	Analysis of drugs in biological samples	Class Notes

#### 7. Evaluation Scheme:

EC No.	Evaluation component	Duratio n	Weightage	Date and Time	Nature of Component
1	Pre-Mid Term Assignment	60 min.	10	Will be announced in class	СВ
2	Mid-Term Exam	90 min.	25	30/9 , 11:00 – 12:30 PM	СВ
4	Post-Mid Term Assignment	60 min	10	Will be announced in class	СВ
5	Lab Sessions	-	20	Regular lab sessions	ОВ
6	Comprehensive	3 hrs.	35	04/12 AN	CB (15) +OB (20)

<sup>\*</sup>Assignments include study of certain topics and research articles from reference books and/or journals for Evaluation Component. Laboratory assignments will be given during the semester including use of computer software in pharmacokinetic study (WinNonLin). Assignments/seminar will involve 3 contact hours per week for each student. CB-closed book, OB-open book.

- **8. Chamber Consultation Hour:** To be announced in the class.
- **9. Notices:** The Notices concerning this course will be displayed only on the **Pharmacy Department** Notice Board.
- **10. Academic Honesty and Integrity Policy**: Academic honesty and integrity are to be maintained by all the students throughout the semester and no type of academic dishonesty is acceptable.

Instructor-in-charge PHA G612