



SECOND SEMESTER 2023-2024

Course Handout Part II

Date: 08-Jan-2024

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	:	Radhika Mahajan, Girish SH

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 of 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 route.
- 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, 2nd, 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 to Pharmacokinetics	Pharmacokinetics & ADME characters of drugs	R
3	Concept of compartmental models in pharmacokinetics	Compartmental models: one, two & multi-compartments	TB and R
4 - 6	Pharmacokinetic study of drugs and métabolites: in plasma & urine for i.v injection; modeling of data	One compartment (IV Bolus Injection)	TB and R
7-8	Pharmacokinetics of iv infusion	One compartment (IV Infusion)	TB and R
9-14	Pharmacokinetics of drugs administered through extravascular route; modeling of data	First-order absorption	TB and R
15-16	Multi compartmental pharmacokinetic model	Two compartment (IV Bolus injection)	TB and R
17-19	Multi-dose Pharmacokinetics	Multi-dose Pharmacokinetics: IV bolus and first-order absorption	TB and R
20-23	Concept of Non compartmental analysis	Statistical moments, AUC and MRT determination	TB and R
24-27	Study of bioavailability	Bioavailability : Rate and extent of absorption	TB and R
28-29	Non-linear pharmacokinetics	What is non-linear pharmacokinetics? How to determine non-linearity in PK	TB and R
30-32	Concept of apparent volume of distribution	Apparent volume of distribution	TB and R
33-34	Concept on Clearance	Total Body Clearance, Renal Clearance and Hepatic Clearance	TB and R
35-36	Introduction to PBPK	What is PBPK and its application to drug discovery and drug product development	TB and R
37-39	Applications of pharmacokinetics in dose identification in special populations	Dose adjustments in renal impairment	Class Notes

Laboratory Session Plan:



Lab. No.	Learning objectives	Topics to be covered
1-4	Development and Validation of Bio-analytical Method Using HPLC	Various steps involved in the development of bio-analytical method for a drug in plasma including different sample processing methods (like protein precipitation, liquid-liquid extraction etc). Optimization of the method conditions. Validation of the method based on the current ICH guidelines.
5-8	Perform IV pharmacokinetic studies of a drug and determine the pharmacokinetic parameters of the drug	Design of the pharmacokinetic study (including, details of recommended dosing volumes, site of administration, sites for blood sample collection, processing of the blood sample for separation of plasma etc). Analyze the plasma time course data to determine the pharmacokinetic parameter.
9-11	Perform Oral pharmacokinetic studies of a drug and determine the pharmacokinetic parameters of the drug	Design of the pharmacokinetic study (including, details of recommended dosing volumes, devices use for oral dosing, sites for blood sample collection, processing of the blood sample for separation of plasma etc). Analyze the plasma time course data to determine the pharmacokinetic parameter.
12-13	Analysis of pharmacokinetic data using Phoenix WinNonlin Software	How to analyze pharmacokinetic data (from intravenous or extravascular administration) by either compartmental or NCA approaches using Phoenix WinNonlin software. A thorough hands-on training would be provided to the students on how to use compartmental modeling or NCA of data. Interpretation of the results and drawing appropriate inferences on the pharmacokinetic parameters of the drug.

6. Evaluation Scheme:

EC No.	Evaluation component	Duration	Weightage	Date and Time	Nature of Component
1	Pre mid-term assignment	50 min	10	Will be announced in class	CB
2	Mid-Term Exam	90 min.	25	Will be announced in class	CB
3	Post mid-term assignment	60 min	15	Will be announced in class	OB
4	Lab Sessions	-	15	Regular lab sessions	OB
5	Comprehensive	3 hrs.	35	Will be announced in class	CB(10)+OB(25)

Laboratory assignments will be given during the semester including use of computer software in pharmacokinetic study (WinNonLin). CB-closed book, OB-open book.



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

8. Notices: The notices concerning this course will be given during the online classes and also uploaded in CMS.

9. 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**

