

BIRLA INSTITUTE OF TECHNOLOGY AND SCIENCE, PILANI-HYDERABAD CAMPUS

FIRST SEMESTER 2021-22

Course Handout (Part II)

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 : **Mohammed Shareef Khan**

Description : Introduction to pharmacokinetic modeling of drugs; Compartmental modelling including one compartmental and two compartmental models; Non-compartmental analysis (NCA); Bioequivalence and comparative bioavailability studies; Pharmacokinetic Pharmacodynamic modelling techniques, determination of order of absorption and absorption rate constant by WagnerNelson method; non-linear pharmacokinetics; Pharmacokinetic drug interactions; multi-dose pharmacokinetics of drugs following one compartmental model; Design of multi-dose regimen; Dosage regimen adjustment in renal impairment; Application of the pharmacokinetic principles for better therapeutic outcomes

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 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 of Pharmacokinetics | Pharmacokinetics & ADME characters of drugs | R |
| 3 | Concept of compartment model in pharmacokinetics | Compartment model : one, two & multicompartment | 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 | TB and R |
| 12-14 | Multi compartment pharmacokinetics, drugs in plasma for iv injection | Two compartment iv injection | TB and R |
| 15-16 | Multi compartment pharmacokinetics of infusion, 1st order absorption | Two compartment first-order absorption | TB and R |
| 17-20 | Concept of Non compartmental analysis: approach and modeling | Non compartment Analysis | TB and R |
| 21-25 | Study of bioavailability | Bioavailability: Rate and extent of absorption | TB and R |
| 26-29 | Study of non-linear pharmacokinetics | Non-linear | TB and R |

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|-------|---|---|-------------|
| | | pharmacokinetics | |
| 30-31 | Concept and study of apparent volume of distribution | Apparent volume of distribution | TB and R |
| 32-34 | Concepts on Clearance | Clearance | TB and R |
| 35-38 | Various applications of pharmacokinetic studies including in renal impairment | Application of pharmacokinetic studies | Class Notes |
| 39-40 | Experimental techniques & Analysis of Biological samples. | Analysis of drugs in biological samples | Class Notes |

7. Evaluation Scheme:

| EC No. | Evaluation component | Duration | Weightage | Date and Time | Nature of Component |
|--------|----------------------|----------|-----------|----------------------------|---------------------|
| 1 | Assignment | Home | 10 | Will be announced in class | OB |
| 2 | Mid-Term Exam | 90 min. | 30 | | CB |
| 3 | Lab Sessions | - | 20 | Regular lab sessions | OB |
| 4 | Comprehensive | 2 hrs. | 40 | | OB |

*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). 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 given during the online classes and also uploaded in CMS.

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**