

PC702: BIOPHARMACEUTICS AND PHARMACOKINETICS

B. Pharm IV Year I sem

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Course Objectives: This course is designed to impart fundamental knowledge of Biopharmaceutics and Pharmacokinetics. It also helps to know how the absorption distribution, metabolism, excretion takes place and bioavailability and bioequivalence parameters.

Course Outcome: The students shall be able to understand Bioavailability, Bioequivalence, Biopharmaceutical parameters, Pharmacodynamic and Pharmacokinetics of the drug. It also explains the ADME of the drug besides non-linear pharmacokinetics.

UNIT - I

- a) **Introduction:** Definitions of Biopharmaceutics, Pharmacokinetics and Pharmacodynamics.
- b) **Drug Absorption.** Mechanisms of GI absorption, physico-chemical, biological and dosage form factors influencing absorption.

UNIT - II

Drug distribution: Factors of drug distribution, volume of distribution, protein binding – factors affecting and significance and kinetics of protein binding.

UNIT - III

- a) **Drug Metabolism:** Pathways of drug metabolism. Phase-I (oxidative, reductive and hydrolytic reactions). Phase II reactions (conjugation) Enzyme induction and inhibition
- b) **Drug excretion.** Glomerular filtration, tubular secretion and reabsorption, effect of pH and other drugs. Clearance concept, excretion through bile, feces, lungs and skin in brief.

UNIT - IV

Bioavailability and bioequivalence

Definitions, concept of equivalence, Definitions of various types of equivalence, types of Bioavailability studies, measurement of Bioavailability, plasma level and urinary excretion studies. Bioequivalence study design. Bioavailability testing procedure and protocol (CDSCO), Invitro – Invivo correlation of data

UNIT - V

Pharmacokinetics: Basic considerations, compartment modeling, one compartment open model - i.v. bolus and extra vascular administration, urinary excretion studies. Calculation of pharmacokinetic parameters, brief over view of nonlinear kinetics, noncompartmental models

TEXT BOOKS

1. Venkateshwarlu, Fundamentals of Biopharmaceutics and Pharmacokinetics, Pharma Book Syndicate.
2. Milo Gibaldi, Biopharmaceutics and clinical pharmacokinetics 4/Edn. Pharma Book Syndicate. Hyderabad
3. DM Brahmkar and SB Jaiswal, biopharmaceutics and pharmacokinetics- a treatise, vallabh prakasham, Delhi.

REFERENCES

1. Remington's pharmaceutical sciences, Mac Pub. Co., Easton Pennsylvania.
2. Modern pharmaceutics by banker Marcel Dekker Inc., NY