GUJARAT TECHNOLOGICAL UNIVERSITY
PHARM.D
5th Year

Subject Name: Clinical Pharmacokinetics & Pharmacotherapeutic Drug Monitoring
Subject Code: 858803

Scope: This course is designed to make the students to understand and apply pharmacokinetic principles in designing / individualizing dosage regimen. Also, enable the students to interpret the plasma drug range, and hepatic / renal function in optimizing the drug therapy.

Objectives:
On completion of the course, the student shall be able to
1. Design the drug therapy regimen for individual patient
2. Interpret and correlate the plasma drug concentration with patient's thera- peutic outcome.
3. Recommend dosage adjustment for patients with renal/ hepatic impairment
4. Detect and manage drug –drug interactions

Teaching scheme and examination scheme:

Teaching Scheme				Evaluation Scheme				Total Marks
Theory	Tutorial	Practical	Total	Theory		Practical		
				External	Internal	External	Internal	
2	1	0	3	70	30	0	0	100

Sr.	Topic	Hr	% Weightage
1.	**Introduction to Clinical pharmacokinetics**	02	5
2.	**Design of dosage regimens:** Nomograms and Tabulations in designing dosage regimen, Conversion from intravenous to oral dosing, Determination of dose and dosing intervals, Drug dosing in the elderly and pediatrics and obese patients.	06	14
3.	**Pharmacokinetics of Drug Interaction:** a. Pharmacokinetic drug interactions b. Inhibition and Induction of Drug metabolism c. Inhibition of Biliary Excretion.	03	7
4.	**Therapeutic Drug monitoring:** a. Introduction b. Individualization of drug dosage regimen (Variability – Genetic, Age and Weight , disease, Interacting drugs). c. Indications for TDM. Protocol for TDM. d. Pharmacokinetic/Pharmacodynamic Correlation in drug therapy. e. TDM of drugs used in the following disease conditions: cardiovascular disease, Seizure disorders, Psychiatric conditions, and Organ transplantations	12	25
5.	**Dosage adjustment in Renal and hepatic Disease.** a. Renal impairment b. Pharmacokinetic considerations c. General approach for dosage adjustment in Renal disease. d. Measurement of Glomerular Filtration rate and creatinine clearance. e. Dosage adjustment for uremic patients. f. Extracorporeal removal of drugs. g. Effect of Hepatic disease on pharmacokinetics	12	25

6.	**Population Pharmacokinetics.** a. Introduction to Bayesian Theory. b. Adaptive method or Dosing with feed back. c. Analysis of Population pharmacokinetic Data.	**05**	**12**
7.	**Pharmacogenetics** a. Genetic polymorphism in Drug metabolism: Cytochrome P-450 Isoenzymes. b. Genetic Polymorphism in Drug Transport and Drug Targets. c. Pharmacogenetics and Pharmacokinetics/Pharmacodynamic considerations	**05**	**12**

Text Books:

1. Biopharmaceutics and Applied Pharmacokinetics. Leon Shargel. Publisher- Prentice Hall. Latest edition.
2. Applied Pharmacokinetics& Pharmacodynamics: Principles of Therapeutic Drug Monitoring. Michael E. Burton, Leslie M. Shaw, Jerome J. Schentag, William E. Evans. Publisher- Lippincott Williams & Wilkins. Latest edition.

Reference books:

1. Handbook of Analytical Therapeutic Drug Monitoring and Toxicology. Steven How-Yan Wong, Irving Sunshine. Publisher- CRC Press. Latest edition.
2. Clinical pharmacokinetics. Soraya Dhillon, Andrzej Kostrzewski. Publisher- Pharmaceutical Press. Latest edition.
3. Clinical Pharmacokinetics. Rowland and Tozer. Publisher- Williams and Wilkins. Latest edition.
4. Principles of Clinical Pharmacology. Arthur J Atkinson. Publisher-TNQ books and Journals Pvt Ltd. Latest edition

Other references:

1. Therapeutic Drug monitoring, Clinical guide. Abbott Diagnostics. Published by Abbott. Journals – Clinical Pharmacokinetics, Therapeutic drug monitoring