GUJARAT TECHNOLOGICAL UNIVERSITY

M.Pharm

PHARMACEUTICAL ANALYSIS

SEMESTER: II

Subject Name: MODERN BIO-ANALYTICAL TECHNIQUES
Subject Code: MPA202T

Scope: This subject is designed toprovide detailed knowledge about the importance of analysisofdrugs in biological matrices.

Objectives: Upon completion of this course the student should be able to

1. Extraction of drugs from biological samples
2. Separation of drugs from biological samples using different techniques
3. Guidelines for BA/BE studies

Sr No	Course Contents	Total Hrs
1	Extraction of drugs and metabolites from biological matrices: General need, principle and procedure involved in the Bioanalytical methods such as Protein precipitation, Liquid Liquid extraction and Solid phase extraction and other novel sample preparation approach. Bioanalytical method validation: USFDA and EMEA guidelines	12
2	Biopharmaceutical Consideration: Introduction, Biopharmaceutical Factors Affecting Drug Bioavailability, In Vitro: Dissolution and Drug Release Testing, Alternative Methods of Dissolution Testing Transport models, Biopharmaceutics Classification System. Solubility: Experimental methods. Permeability: In-vitro, in-situ and In-vivo methods	12
3	Pharmacokinetics and Toxicokinetics: Basic consideration, Drug interaction (PK-PD interactions), The effect of protein-binding interactions, The effect of tissue-binding interactions, Cytochrome P450-based drug interactions, Drug interactions linked to transporters. Microsomal assays Toxicokinetics-Toxicokinetic evaluation in preclinical studies, Importance and applications of toxicokinetic studies. LC-MS in bioactivity screening and proteomics	12
4	Cell culture techniques Basic equipments used in cell culture lab. Cell culture media, various types of cell culture, general procedure for cell cultures; isolation of cells, subculture, cryopreservation, characterization of cells and their applications. Principles and applications of cell viability assays (MTT assays),Principles andapplications of flow cytometry	12
5	Metabolite identification: In-vitro / in-vivo approaches, protocols and sample preparation. Microsomal approaches (Ratlivermicrosomes (RLM) and Human liver microsomes (HLM)inMet–ID.Regulatory perspectives. In-vitro assay of drug metabolites & drug metabolizing enzymes. Drug Product Performance, In Vivo: Bioavailability and Bioequivalence: Drug Product Performance, Purpose of Bioavailability Studies, Relative and Absolute Availability. Methods for Assessing Bioavailability, Bioequivalence Studies, Design and Evaluation of Bioequivalence Studies, Study Designs, Crossover Study Designs, Generic Biologics (Biosimilar Drug Products), Clinical Significance of Bioequivalence Studies	12

REFERENCES:

1. Analysis of drugs in Biological fluids - Joseph Chamberlain, 2ndEdition. CRC Press, New york.1995.
2. Principles of Instrumental Analysis - Doglas A Skoog,F. James Holler, TimothyA.Nieman,5th edition, Easternpress,Bangalore,1998.
3. Pharmaceutical Analysis -Higuchi, Brochmman and Hassen, 2ndEdition, Wiley– Interscience Publications,1961.
4. Pharmaceutical Analysis- Modern methods – Part B - J W Munson, Volume 11, Marcel Dekker Series
5. Practical HPLC method Development – Snyder, Kirkland, Glaich, 2nd Edition, John Wiley & Sons, NewJercy. USA.
6. Chromatographic Analysis of Pharmaceuticals – John A Adamovics, 2nd Edition, Marcel Dekker, Newyork, USA. 1997.
7. Chromatographic methods in clinical chemistry & Toxicology – Roger L Bertholf, RuthE Winecker, John Wiley & Sons, NewJercy, USA. 2007.
8. Good Laboratory Practice Regulations, 2ndEdition, Sandy Weinberg Vol. 69,Marcel Dekker Series,1995.
9. Good laboratory Practice Regulations – Allen F. Hirsch, Volume 38, MarcelDekkerSeries,1989
10. ICH, USFDA & CDSCO Guidelines.
11. Palmer