

St. James' College of Pharmaceutical Sciences St.James' medical Academy River Bank, Chalakudy			
Programme:	M.Pharm	Sem/Year:	2 nd SEM
Name of Course: (Subject)	Modern Bio-analytical Techniques	Subject Code:	MPA 202T
Teaching faculty of the course	Dr. David Paul		

Summary of the Lecture Plan

Topic	Lectures	Hours
Sample preparation	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.	7
Bioanalytical method validation	USFDA and EMEA guidelines.	5
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
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
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 and applications of flow cytometry.	12
Metabolite identification	In-vitro / in-vivo approaches, protocols and sample preparation. Microsomal approaches (Rat liver microsomes (RLM) and Human liver microsomes (HLM) in Met -ID. Regulatory perspectives. In-vitro assay of drug metabolites & drug metabolizing	12

	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.	
--	--	--

Major issues or Core aspects addressed/ covered:

Modern Bio-analytical Techniques (MPA 202T)

Mentioned Detail in Summary

Sample Questions from Lectures

Topic	Lectures
Sample preparation	Explain in detail the sample extraction of drugs and metabolites from biological matrices Write a note on LLE, SPE and PPT.
Bioanalytical method validation	Explain the validation parameters of USFDA or EMEA guidelines.
Biopharmaceutical Consideration	Give the Biopharmaceutical Factors Affecting Drug Bioavailability Explain the In Vitro Dissolution and Drug Release Testing, Alternative Methods of Dissolution Testing Transport models Give a note on Biopharmaceutics Classification System. Solubility: Explain various experimental methods for Permeability studies
Pharmacokinetics and Toxicokinetics	Give a note on the drug interaction (PK-PD interactions) Give a note on protein binding studies. Explain Cytochrome P450/Transporter based drug interactions and its experimental procedures. Briefly explain the Toxicokinetic evaluation in preclinical studies. Write briefly on LC-MS in bioactivity screening and proteomics.
Cell culture techniques	Explain in detail the general procedure for cell cultures like isolation of cells, subculture, cryopreservation, characterization of cells and their applications. Give the Principles and applications of cell viability assays (MTT assays). Write briefly on the Principles and applications of flow cytometry.

<p>Metabolite identification</p>	<p>Give the In-vitro / in-vivo approaches, protocols and sample preparation for Met-ID studies.</p> <p>Briefly explain the Microsomal approaches (Rat liver microsomes (RLM) and Human liver microsomes (HLM) in Met-ID.</p> <p>Explain in detail about In Vivo: Bioavailability and Bioequivalence studies.</p> <p>Write a note of various Study Designs for Bioequivalence Studies. And its Clinical Significance.</p>
----------------------------------	--