St. James' College of Pharmaceutical Sciences St.James' medical Academy River Bank, Chalakudy			
Programme:	M.Pharm	Sem/Year:	1st SEM
Name of Course: (*Subject*)	Advanced Pharmaceutical Analysis	Subject Code:	MPA 102T
Teaching faculty of the course	Dr. David Paul		

Summary of the Lecture Plan

Topic	Lectures	Hours
Impurity and stability studies	Definition, classification of impurities in drug Substance or Active Pharmaceutical Ingredients and quantification of impurities as per ICH guidelines	3
Impurities in new drug products	Rationale for the reporting and control of degradation products, reporting degradation products content of batches, listing of degradation products in specifications, qualification of degradation products	4
Impurities in residual solvents	General principles, classification of residual solvents, Analytical procedures, limits of residual solvents, reporting levels of residual solvents	3
Elemental impurities	Element classification, control of elemental impurities, Potential Sources of elemental Impurities, Identification of Potential Elemental Impurities, analytical procedures, instrumentation & C, H, N and S analysis	5
Stability testing protocols	Selection of batches, container orientation, test parameters, sampling frequency, specification, storage conditions, recording of results, concept of stability, commitment etc. Important mechanistic and stability related information provided by results of study of factors like temperature, pH, buffering species ionic strength and dielectric constant etc. on the reaction rates. With practical considerations.	5
Impurity profiling and degradent characterization	Method development, Stability studies and concepts of validation accelerated stability testing & shelf life calculation, WHO and ICH stability testing guidelines, Stability zones, steps in development, practical considerations. Basics of impurity profiling and degradent characterization with special emphasis. Photostability testing	10

	guidelines, ICH stability guidelines for biological products	
Stability testing of phytopharmaceuticals	Regulatory requirements, protocols, HPTLC/HPLC finger printing, interactions and complexity.	10
Biological tests and assays of the following	a. Adsorbed Tetanus vaccine b. Adsorbed Diphtheria vaccine c. Human anti haemophilic vaccine d. Rabies vaccine e. Tetanus Anti toxin f. Tetanus Anti serum g. Oxytocin h. Heparin sodium IP i. Antivenom. PCR, PCR studies for gene regulation, instrumentation (Principle and Procedures)	10
Immunoassays (IA)	Basic principles, Production of antibodies, Separation of bound and unbound drug, Radioimmunoassay, Optical IA, Enzyme IA, Fluoro IA, Luminiscence IA, Quantification and applications of IA.	10

Major issues or Core aspects addressed/ covered:

Advanced Pharmaceutical Analysis (MPA 102T)
Mentioned Detail in Summary

Sample Questions from Lectures

Topic	Lectures	Hours
Impurity and stability studies	Explain in detail classification of impurities in drug Substance or Active Pharmaceutical Ingredients and quantification of impurities as per ICH guidelines	3
Impurities in new drug products	Give a note on the rationale for the reporting and control of degradation products.	4
Impurities in residual solvents	Explain in detail the principles, classification of residual solvents, Analytical procedures, limits of residual solvents, reporting levels of residual solvents	3
Elemental impurities	Explain in detail the classification, control of elemental impurities, Potential Sources of elemental Impurities, Identification of Potential Elemental Impurities, analytical procedures, instrumentation & C, H, N and S analysis	5

Stability testing protocols	Give a note on the Selection of batches, container orientation, test parameters, sampling frequency, specification, storage conditions, recording of results. Important mechanistic and stability related information provided by results of study of factors in volved in stability studies.	5
Impurity profiling and degradent characterization	Explain in detail the method development, Stability studies and concepts of validation accelerated stability testing & shelf life calculation Give a note on the WHO and ICH stability testing guidelines, Briefly explain the Photostability testing guidelines Give anote on the ICH stability guidelines for biological products	10
Stability testing of phytopharmaceuticals	Give the Regulatory requirements, protocols, HPTLC/HPLC finger printing, interactions and complexity.	10
Biological tests and assays of the following	Explain the Principle and Procedures: a. Adsorbed Tetanus vaccine b. Adsorbed Diphtheria vaccine c. Human anti haemophilic vaccine d. Rabies vaccine e. Tetanus Anti toxin f. Tetanus Anti serum g. Oxytocin h. Heparin sodium IP i. Antivenom. PCR, PCR studies for gene regulation, instrumentation	10
Immunoassays (IA)	Briefly explain the basic principles, Production of antibodies, Separation of bound and unbound drug, Radioimmunoassay, Optical IA, Enzyme IA, Fluoro IA, Luminiscence IA, Quantification and applications of IA.	10