

St. James College of Pharmaceutical Sciences St. James medical Academy River Bank, Chalakudy			
Programme:	M.PHARM	Sem.:	II semester
Name of Course: (Subject)	QUALITY CONTROL AND QUALITY ASSURANCE	Course Code:	MPA 203T
Teaching faculty of the course			

Summary of the Lecture Plan

Topic	Lectures	Hours
Concept and Evolution of Quality Control and Quality Assurance	Good Laboratory Practice, GMP, Overview of ICH Guidelines	4
	Quality assurance unit, protocol for conduct of nonclinical testing	4
cGMP guidelines according to schedule M, USFDA	Organization and personnel responsibilities, training, hygiene and personal records, drug industry location, design, construction and plant layout, maintenance	5
Analysis of raw materials, finished products, packaging materials	Purchase specifications and maintenance of stores for raw materials	3
	In process quality control and finished products quality control	3
	Quality control test for containers, closures and secondary packing materials.	2
	In process quality control (IPQC), Developing specification (ICH Q6 and Q3)	3
Documentation in pharmaceutical industry	Three tier documentation, Policy, Procedures and Work instructions Distribution records. Electronic data	6
Manufacturing operations and controls	Sanitation of manufacturing premises, mix-ups and cross contamination, processing of intermediates and bulk products	4

Major Issues or Core Aspects to Be Addressed/ Covered:

Finished products
Good Laboratory Practice
Overview of ICH Guidelines
Purchase specifications
Distribution records. Electronic data
Premises
Design, construction and plant layout
Control of contamination
Maintenance of sterile areas

Maintenance, sanitation, environmental control
Calibration and Validation
Introduction, definition and general principles of calibration
Importance and scope of validation
Qualification and validation
Types of validation, validation master plan.
Calibration of pH meter, Qualification of UV-Visible spectrophotometer
General principles of Analytical method Validation.
Complaints
Complaints and evaluation of complaints
Handling of return good
Recalling and waste disposal.
Equipment's and raw materials
Equipment's selection
Specifications and maintenance of stores for raw materials
Purchase specifications
Good Laboratory Practices
General Provisions, Organization and Personnel
Facilities, Equipment, Testing Facilities Operation
Test and Control Articles, Protocol for Conduct of a Nonclinical Laboratory Study

Sample Questions

Calibration and Validation
Explain Importance and scope of validation?
Discuss on Calibration of PH meter?
Qualification of UV-Visible spectrophotometer?
Types of validation, and validation master plan?
General principles of Analytical method Validation?
General principles of calibration?
Equipment's and raw materials
Explain Equipment's selection?
Write on Specifications and maintenance of stores for raw materials?
Discuss about Purchase specifications?
Premises
Explain Design construction and plant layout?
Discuss Handling of return good
Total Quality Management (TQM)
Explain Principle of TQM?

Write on Applications of TQM
Discuss about TQM plan and procedure
Good Laboratory Practices
General Provisions, Organization and Personnel
Facilities, Equipment, Testing Facilities Operation
Test and Control Articles
Protocol for Conduct of a Nonclinical Laboratory Study
Documentation in pharmaceutical industry
Complaints and evaluation of complaints
Handling of return good
Distribution records. Electronic data