

St. James College of Pharmaceutical Sciences St. James medical Academy River Bank, Chalakudy			
Programme:	B. PHARM	Sem.:	VI semester
Name of Course: (Subject)	PHARMACEUTICAL QUALITY ASSURANCE	Course Code:	BP606 T
Teaching faculty of the course			

Summary of the Lecture Plan

Topic	Lectures	Hours
Quality Assurance and Quality Management concepts	Definition and concept of Quality control,	2
	Quality assurance and GMP	2
Total Quality Management (TQM)	Definition, elements, philosophies	3
ICH Guidelines, Quality by design (QbD), ISO 9000 & ISO 14000, NABL accreditation	purpose, participants, process of harmonization	3
	Brief overview of QSEM, with special emphasis on Q-series guidelines, ICH stability testing guidelines	3
	Definition, overview, elements of QbD program, tools	2
	Overview, Benefits, Elements, steps for registration Principles and procedures for NABL	3
Organization and personnel, Premises,	Personnel responsibilities, training, hygiene and personal records. Design, construction and plant layout, maintenance, sanitation, environmental control, utilities and maintenance of sterile areas, control of contamination.	6
Quality Control, Good Laboratory Practices	Quality control test for containers, rubber closures and secondary packing materials.	3
	General Provisions, Organization and Personnel, Facilities, Equipment, Testing Facilities Operation, Test and Control Articles, Protocol for Conduct of a Nonclinical Laboratory Study, Records and Reports, Disqualification of Testing Facilities	6
Complaints, Document maintenance in pharmaceutical industry	Complaints and evaluation of complaints	1
	Handling of return good, recalling and waste disposal.	2
Calibration and Validation	Introduction, definition and general principles of calibration, qualification and validation, importance and scope of validation	3
Equipment's and raw materials,	Equipment's selection, purchase specifications, maintenance, purchase specifications and maintenance of stores for raw materials.	4
Warehousing	Good warehousing practice, materials management	2

Major Issues or Core Aspects to Be Addressed/ Covered:

Total Quality Management (TQM)
Principle of TQM
Elements, philosophies
Applications of TQM
TQM plan and procedure
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
Complaints
Complaints and evaluation of complaints
Handling of return good
Recalling and waste disposal.