

Subject Code: BP606T	Subject Title: QUALITY ASSURANCE - Theory
Pre-requisite Subject	- NONE -

Objectives of course:

This course deals with the various aspects of quality control and quality assurance aspects of pharmaceutical industries. It deals with the important aspects like cGMP, QC tests, documentation, quality certifications and regulatory affairs.

Learning outcomes:

On the completion of the course, students will be able to:

- 1 understand the cGMP aspects in a pharmaceutical industry
- 2 appreciate the importance of documentation
- 3 understand the scope of quality certifications applicable to pharmaceutical industries
- 4 understand the responsibilities of QA & QC departments

Teaching Scheme (Hours per week)				Evaluation Scheme (Marks)		
Lecture	Tutorial	Practical	Credit	Theory (T)		Total Marks
				University Assessment	Continuous Assessment	Theory
3	1	NA	4	75	25	100

	Subject Contents		
Sr. No.	Topic	Total Hours	Weight (%)
1	Unit – I Quality Assurance and Quality Management concepts: Definition and concept of Quality control, Quality assurance and GMP Total Quality Management (TQM): Definition, elements, philosophies ICH Guidelines: purpose, participants, process of harmonization, Brief overview of QSEM, with special emphasis on Q-series guidelines, ICH stability testing guidelines Quality by design (QbD): Definition, overview, elements of QbD program, tools ISO 9000 & ISO14000: Overview, Benefits, Elements, steps for registration NABL accreditation : Principles and procedures	10	22
2	Unit – II Organization and personnel: Personnel responsibilities, training, hygiene and personal records. Premises: Design, construction and plant layout, maintenance, sanitation, environmental control, utilities and maintenance of sterile areas, control of contamination. Equipments and raw materials: Equipment selection, purchase specifications, maintenance, purchase specifications and maintenance of stores for raw materials.	10	22
3	Unit – III Quality Control: Quality control test for containers, rubber closures and secondary packing materials. 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, Records and Reports, Disqualification	10	22

	of Testing Facilities		
4	UNIT – IV Complaints: Complaints and evaluation of complaints, Handling of return good, recalling and waste disposal. Document maintenance in pharmaceutical industry: Batch Formula Record, Master Formula Record, SOP, Quality audit, Quality Review and Quality documentation, Reports and documents, distribution records.	8	18
5	UNIT – V Calibration and Validation: Introduction, definition and general principles of calibration, qualification and validation, importance and scope of validation, types of validation, validation master plan. Calibration of pH meter, Qualification of UV-Visible spectrophotometer, General principles of Analytical method Validation. Warehousing: Good warehousing practice, materials management	7	16

List of References:

Reference Books:

1. Quality Assurance Guide by organization of Pharmaceutical Products of India.
2. Good Laboratory Practice Regulations, 2nd Edition, Sandy Weinberg Vol. 69.
3. Quality Assurance of Pharmaceuticals- A compendium of Guide lines and Related materials Vol I WHO Publications.
4. A guide to Total Quality Management- Kushik Maitra and Sedhan K Ghosh
5. How to Practice GMP's – P P Sharma.
6. ISO 9000 and Total Quality Management – Sadhan G Ghosh
7. The International Pharmacopoeia – Vol I, II, III, IV- General Methods of Analysis and Quality specification for Pharmaceutical Substances, Excipients and Dosage forms
8. Good laboratory Practices – Marcel Dekker Series
9. ICH guidelines, ISO 9000 and 14000 guidelines