

BP606T. PHARMACEUTICAL QUALITY ASSURANCE (Theory)

45 Hours

Course content:

Unit-I

10 Hours

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.

Unit-II

10 Hours

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.

Unit-III

10 Hours

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 of Testing Facilities.

Unit-IV

08 Hours

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.

Unit-V

07 Hours

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.