18BP071 PHARMACEUTICAL QUALITY ASSURANCE

Hours Per Week :

L	T	P	CP	CL
3	1	-	-	4

Total Hours :

L	T	P
45	1	-

WA/RA	SSH/HSH	CS	SA	S	BS

SCOPE:

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.

COURSE OUTCOMES:

Upon completion of the course, the student will be able to achieve the following outcomes:

COs	Course Outcomes	POs	PSOs
1	Understand the CGMP aspects in a pharmaceutical industry.	1	1 ,2
2	Appreciate the importance of documentation.	1	1,2
3	Understand the scope of quality certifications applicable to pharmaceutical industries.	15	1, 2
4	Understand the responsibilities of QA &QC departments.	15	1, 2

UNIT – I **10HOURS**

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, Dis qualification 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 **07HOURS**

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.

RECOMMENDED BOOKS: (LATEST EDITION)

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 Vole I WHO Publications.
4. A guide to Total Quality Management- Koushik Maître and Sedan K Ghosh.
5. How to Practice GMP's – P Sharma.
6. ISO 9000 and Total Quality Management – Sad hank G Ghosh.
7. The International Pharmacopoeia – Vole I, II, III, IV- General Methods of Analysis and Quality .specification for Pharmaceutical Substances, Excipients and Dosage forms.
8. Good laboratory Practices – Marcel Deckker Series.
9. ICH guidelines, ISO 9000 and 14000guidelines.