QUALITY ASSURANCE & GMP

THEORY 3 hours/week

UNIT -I

1. **Good Manufacturing Practices (GMPs):** GMP and cGMP, Salient features of Drugs & Cosmetics Act & rules with reference to design of plants for manufacture of drugs in India as under schedule M.

UNIT -II

1. **Pharmaceutical Validation:** Need and scope of validation, validation of water systems for sterile & non-sterile products, cleaning validation, process validation, equipment validation, analytical method validation.

UNIT -III

1. **Quality Assurance (QA):** Basic concept, organization, personnel, building & facility equipment, product control, ware housing, returned goods & reprocessing, documentation.

UNIT -IV

1. **Good Laboratory Practices (GLP):** Need and scope, organization and management, practice of GLP in different laboratories, quality assurance in GLP.
2. **Standard Operating Procedure (SOP):** Need, preparation of SOP, benefits of using SOP, SOP for equipments and analytical instruments (Tablet compression unit, freeze drier, dissolution apparatus, pH meter, UV spectrophotometer, Flame Photometer, HPLC etc.)

UNIT-V

Quality Audit: Definition and objectives, type of Audit-Principles of Auditing, Audit life cycle, Audit methods and techniques, Audit programme record and overview of audit activities.

RECOMMENDED BOOKS:

1. Pharmaceutical Process Validations – Ira R.Berry, Robert A.Nash
2. GMP – P.P.Sharma
3. Quality Assurance Manual – D.H.Shah– Business Hortzons
4. Quality Assurance for Pharmaceuticals – Vol-I&II-Pharma Book Syndicate
5. SOP Guidelines – D.H.Shah – Business Horizons
6. Quality Assurance and Quality Management in Pharmaceutical Industry- Y.Anjaneyulu& R. Marayya- Pharma Book Syndicate
7. ICH Guidelines