Gujarat Technological University
M. Pharm. Syllabus
Semester I

Paper code: 910108
Subject of Specialization paper –I
Industrial Pharmacy Paper-I
Theory
(Four hours per week, 6 Credits)

Course Content: **Hours**

1) Pharmaceutical factory location: Selection, layout and planning. Utility services like Humidity, Temperature, Ventilating and air conditioning (HVAC), water system (RO, WFI, hot and cold water), Steam, Electrical services, Compressed air, Vacuum systems, Dust collection, Effluent treatment plant, etc. Service facilities, and personnel facilities **10**
2) Preparation of qualitative and quantitative departmental layout with equipments required for different dosage forms, solids, liquids, semisolids, sterile.
   Plant and Machinery based on various dosage forms: Equipment design, material of plant constructions, selection criteria, factors affecting equipment design, properties and types of material used for plant construction. **10**
3) Detailed study of the equipments required in the manufacture of different dosage forms as per Schedule-M. **10**
4) Preparation of documents like batch manufacturing record (BMR), batch packing record (BPR), and validation protocols **08**
   Preparation of standard operative procedure (SOPs) for equipments and manufacturing or processing steps **08**
5) GMP and its implementation and introduction to PAT **14**
   a. Organization & Personnel, responsibilities, training, hygiene.
   b. Premises: Location, design, Plant Layout, Construction, Maintenance and Sanitation, Environmental control, utilities and services like gas, water, maintenance of sterile areas, and control of contamination.
   c. Equipments: Selection, purchase specifications, maintenance, clean in place, sterilize in place, Methods (TP & STP).
   d. Raw Materials: Purchase specifications, maintenance of Stores, selection of Vendors, control on raw materials and finished dosage forms.
   e. Manufacture of & control on dosage forms: manufacturing documents, master formula, batch formula records, standard operating procedures, quality audits of manufacturing processes and facilities.
   f. In Process quality controls on various dosage forms: Sterile and non sterile, standard operating procedures for various operations like cleaning, filling, drying, compression, coating, disinfections, sterilization, membrane filtration etc.
   g. Packaging and labeling control, Line clearance, reconciliation of labels, cartons and other packaging materials.
   h. Quality control Laboratory: Responsibilities. Routine controls instruments, reagents, sampling plans, standard test Procedures, protocols, data generation and storage, quality control documents, retention samples, records, audits of quality control facilities.
   i. Finished product release, quality review, quality audits and batch release documents.
   j. Warehousing, design, construction, maintenance and sanitation; good warehousing practice, materials and management.
   k. Distribution and distribution records, handling of returned goods, recovered materials and reprocessing.
   l. Complaints and recalls, evaluation of complaints, recall procedures, related records and documents.

m. Waste disposal, scrap disposal procedures and records.

Reference Books:

1. **Lachman** "The theory and Practice of Industrial Pharmacy
2. **Remingtons** "Pharmaceutical Sciences"
3. Bentley's **Pharmaceutics.**
4. Pharmaceutical facilities: Design, layouts and validation by **Manohar A Potdar**
5. GMP practices for pharmaceutical –**James Swarbrick.**
6. How to practice GMP**s by P.P.Sharma.**
7. Chemical Engineering Plant Design **by Vibrant.**
8. Pharmaceutical Process Validation **by Loftus and Nash.**
9. **G.S. Banker & C.T. Rhodes**, "Modern Pharmaceutics", Drugs and Pharm. Sci. Series, Vol. 7, Maracel Dekker Inc., N.Y.
10. SOP guidelines by D. H. Shah
11. Drug and Cosmetic Act 1940 and rules.

Industrial Pharmacy Paper-I
Practicals
(Four hours per week, 6 Credits)

Practical exercises formulated bases on the topics mentioned in the theory such as
Illustrative flow sheets of each dosage form with detailed idea of placement of equipment, men and material movement and service lines, Equipment selection factors, size and maintenance, preparation of BMR & BPR, Validation , Sampling plans (Product wise), preparation of SOP (Equipment, Process and service lines) and other records.