

Gujarat Technological University

M. Pharm. Syllabus

Semester I

Paper code-910202

Subject: - Specialization Paper-II

Industrial Pharmacy

Theory

Four hours per week, 6 Credits

Course Content:

1. Pharmaceutical factory location: Selection, layout and planning.
2. Utility services, Service facilities, HVAC and personnel facilities.
3. Preparation of qualitative and quantitative departmental layout with equipments
4. Required for different dosage forms, solids, liquids, semisolids, sterile.
5. Detailed study of the equipments required in the manufacture of different dosage
6. Forms as per Schedule-M.
7. Preparation of documents like batch manufacturing record, batch packing record,
8. Validation protocols.
9. Preparation of standard operative procedure (SOPs) for equipments
10. And manufacturing or processing steps.
11. GMP and its implementation
12. Production planning and materials control.
13. Pilot plant, scale up technique.

Reference Books:

1. **Lachman** "The theory and Practice of Industrial Pharmacy
2. **Remingtons** "Pharmaceutical Sciences"
3. Bentley's **Pharmaceutics**.
4. Pilot plants model and scale-up methods, by **Johnstone and Thring**.
5. GMP practices for pharmaceutical –**James Swarbrick**.
6. How to practice GMPs by **P.P.Sharma**.
7. Chemical Engineering Plant Design by **Vibrant**.
8. Pharmaceutical Process Validation by **Loftus and Nash**.
9. Drug and Cosmetic Act 1940 and rules.