Gujarat Technological University
Master of Pharmacy
Semester – II
Paper code -2920108
Subject of Specialization paper –III
Industrial Pharmacy Paper-III
Theory
(Six hours per week, 7 Credits)

1) **Legislative requirements** as per drug & cosmetic act for obtaining manufacturing licenses for different categories of pharmaceutical products. Approval formalities as per factory act, excise and WHO GMP certification scheme, etc. **10 Hrs.**
2) Aims, objects and salient features of following legislations governing Pharmaceutical Industry-Pollution control act, Prevention of Food Adulteration Act 1954, Industrial Development & Regulation Act 1951, Consumer Protection Act **12 Hrs.**
3) **Packaging components and its evaluation**: **10 Hrs.**
   Factors affecting selection, Types and classification, Primary and secondary and regulatory aspects, Contribution in stability of the dosage forms
   Films for Flexible Packages: Types of films, materials used for film production, production and evaluation of *Oriented and Non-oriented, Stretchable films and Laminates.*
   Strip Packaging: Significance of Strip Packing, advantages, economics and limitation of Strip Packing, Strip Packing machinery, films employed in Strip Packing (including composites and laminates) and evaluation of films and strips packs.
   Blister Packaging: Blister packing materials, significance of Blister packing, advantages, economics and limitation of blister packing, blister packing machinery, various types of blister packages, and evaluation of blister package.
   Sterile Product Packaging: General principles of packaging of sterile products. Various types of containers used for sterile products including small volume and large volume parenterals. Types of closures used for the sterile products. Sterile product filling and sealing machinery i.e. ampoule filling and sealing machine. Limitations and merits of various packages. Evaluation of the sterile product packages.
   In-process quality control tests for various dosage forms including packaging and labeling operations.
4) **Disperse systems:** General consideration and recent advances in disperse system technology with main emphasis on pharmaceutical suspensions and emulsions, Quality control of disperse systems
   Aerosols: General considerations, recent developments, study of various components of aerosol system, formulation, aerosol filling processes and machinery, Quality control of aerosols.
   Parenterals: General considerations, recent developments, formulation, stabilization and manufacturing of small and large volume parenterals, production of injectable grade water, environmental controls and design consideration for parenteral production facility, freeze drying. In process quality control.
   Semisolid dosage forms: General considerations, recent developments, formulation and large scale production of various types of semi solid dosage forms, factors affecting release of drugs from semisolid dosage forms. Quality control of semisolid dosage forms. **08 Hrs.**
5) **Stability Study as per** I.P., ICH, other regulatory requirements **12 Hrs.**

6) **SUPAC guidelines** for different dosage forms like; Immediate release, Modified release, semisolid, etc. including equipments amendment. BACPAC guidelines for active pharmaceutical ingredients. **08 Hrs.**

Reference Books:

1. Pharmaceutics "The Science of Dosage Form Design" by Aulton.
2. Encyclopedia of Pharmaceutical Technology Volumes: 1 to 19.
3. Remington's Pharmaceutical Sciences 19th edition.
4. Modern Pharmaceutics by G.S.Banker
5. Yie W. Chien, Novel Drug Delivery Systems, Drugs and Pharm. Sci. Series, Vol.14, Marcel Dekker Inc .N.Y.
6. The Theory and Practice of Industrial Pharmacy by Leon Lachman.
7. Pharmaceutical Production Facilities, Design and applications by Graham C. Cole.
8. International Pharmaceutical Product Registration by Anthony C. Cartwright.
9. Encyclopedia of Controlled Drug Delivery Volumes 1 and 2 by Banker Gilbert
10. Pharmaceutical dosage forms, Parenterals medications: Vol. 1 & 2 by Avis Kenneth
11. Drug stability (Principles and Practices) **by Jens. T. Carstensen.**
12. Stability of drug and dosage forms by Yoskioka.
13. Pharmaceutical dosage forms, Aerosol systems by Lachman L., Liberman H.
14. Pharmaceutical dosage forms, Disperse systems by Lachman L., Liberman H.

Practicals
(Six hours per week, 8 Credits)

Practical exercises formulated bases on the topics mentioned in the theory such as Accelerated stability analysis, Packaging testing and evaluation, Case studies of different acts, Disperse system, parentrals, semisolids etc.