

Gujarat Technological University

M. Pharm. Syllabus

Semester I

Paper code-910102

Subject: - Specialization Paper-I

Pharmaceutical Formulation, Development & Bio pharmaceuticals

Theory

(Four hours per week, 6 Credits)

- 1. Preformulation studies** **08**
 - (a) Physical, Chemical and Pharmaceutical factors influencing formulation
 - (b) Solid-state characterization: Crystallinity, hygroscopicity, Particle size and particle size distribution, compaction properties
 - (c) Crystalline and polymorphism and its evaluation. Rationale for selecting the preferred polymorph/crystalline form
 - (d) General principles and applications of various characterization techniques viz: Differential thermal analysis Differential scanning calorimetry, X-Ray diffraction, FTIR in Preformulation study.
 - (e) Drug-excipient compatibility study
 - (f) Traces of organic volatile impurities (OVIs) and their regulatory limits (residual solvents).
 - (g) Preformulation studies of Biotechnological derived products and reference guidelines.

- 2. Solubilization and solubilized system** **08**
 - (a) Theoretical aspects and applications.
 - (b) Techniques for improvement in drug solubilization for development of various dosage forms.

- 3. Dissolution study** **08**
 - (a) Importance, objectives, equipments,
 - (b) Biological classification system (BCS); its significance on dissolution study and application in dosage form development.
 - (c) Selection of dissolution media and conditions.
 - (d) Comparison of dissolution profile by model independent (similarity and dissimilarity factor) and dependent methods.

- 4. Stability Study** **08**
 - (a) Basic concept and objectives of stability study,
 - (b) Order of reaction and their applications in predicting shelf life and half life of pharmaceutical formulations,
 - (c) Importance of accelerated stability study,
 - (d) Effect of various environmental/ processing factors like light, pH, temperature, etc. on stability of the formulation and techniques for stabilization of product against the same.
 - (e) Regulatory requirements related to stability testing with emphasis on matrixing / bracketting techniques, climates zone, impurities in stability study, photostability testing etc.,
 - (f) Applications of microcalorimetry in stability study.

- 5. Drug Absorption** **08**
 - (a) Factors affecting drug absorption; i.e. Physicochemical, Physicality and Pharmaceutical.

- (b) Method of studying bioavailability and bioequivalence.
- (c) Transport across CACO 2 monolayers, Other Cell-lines to predict- Biological, Pharmaceutical and Analytical considerations
- 6. Pharmacokinetic parameters 08**
- (a) Basic concept and importance of biological half-life, volume of distribution, renal clearance, total body clearance, plasma protein binding, and absorption rate constant, elimination rate constant.
- (b) Analysis of blood and urine data, compartment models, kinetics of one and two compartment model.
- 7. In-vitro In-vivo Correlation (IVIVC) 06**
- (a) Methods of establishing IVIVC
- (b) Factors affecting IVIVC
- 8. Cosmetic, Dental and Herbal products 06**
- (a) Formulation and evaluation of various cosmetic and dental products
- (b) Formulation and evaluation of products containing herbal ingredients.

Reference Books:

1. **Remingtons** "Pharmaceutical Sciences" 19th edition.
2. **Lachman** "The theory and Practice of Industrial Pharmacy" 3rd edition.
3. **Pharmaceutics "The Science of Dosage form design" by Aulton**
4. **Pharmaceutical dispensing by Husa.**
5. **Modern pharmaceutics by G. S. Banker.**
6. **Encyclopedia of pharmaceutical technology Volumes: 1 to 19.**
7. **Pharmaceutical dissolution testing by Banaker.**
8. **United States Pharmacopeia.**
9. **Techniques of Solubilization of Drugs by Yalkowsky.**
10. **Drug stability (Principles and Practices) by Jens. T. Carstensen.**
11. **Stability of drug and dosage forms by Yoskioka.**
12. **Applied Biopharmaceutics and pharmacokinetics by Leon Shargel, 4th edition.**
13. **Pharmacokinetics by Welling and Tse.**
14. **Pharmacokinetics by Gibaldi and Perrier**
15. **Biopharmaceutics and pharmacokinetics: An introduction by Notari.**
16. **Pharmacokinetics for pharmaceutical scientist by John Wagner.**
17. **Dissolution, Bioavailability and Bioequivalence by Abdul.**
18. **Clinical Pharmacokinetics, Concepts and applications by Rowland and Tozer.**
19. **Novel Cosmetic Drug Delivery Systems, by Magdassi and Touitou.**
20. **Cosmetics by Sagerin.**
21. **Perfumes, Cosmetics and Soaps by Poucher.**

Pharmaceutical Formulation, Development & Bio pharmaceuticals Practical

(Four hours per week, 6 Credits)

1. To prepare, evaluate and supply microspheres.
2. To prepare, evaluate and supply Aspirin microspheres.
3. To prepare, evaluate and supply microcapsules.
4. To prepare, evaluate and supply Aspirin Effervescent Tablets.
5. To prepare, evaluate and supply Chewable Antacid Tablets.
6. To prepare, evaluate and supply Floating Tablets.
7. Direct Warm Spheronization.
8. To prepare and evaluate Suppositories.
9. To prepare, evaluate and supply Cold Cream.

10. To optimize the formula for vanishing cream and to evaluate it.
11. To prepare Toothpaste.
12. To optimize the formula for gel and to evaluate it.
13. To optimize the formula for Lather Shaving Cream and to evaluate it.
14. Tablet Coating (Dip Coating)
15. Preparation and evaluation of multiple emulsion.
16. To carry out pan coating of tablets.
17. Preparation and evaluation of Fast Dispersible Tablets.