Gujarat Technological University
M. Pharm. Syllabus
Semester I
Paper Code:910104
QUALITY ASSURANCE SPECIALISATION
Biological Evaluations and Clinical Research

Theory
(Four hours per week, 6 Credits)

Course Content: **Hours**

1. **Biological Standardization:** General Principles, Scope & limitations of Bioassays. Bio-assays of some Official Drugs. **04**
2. **Sterility Tests:** Methodology & Interpretation. **04**
3. **Pyrogen -** chemistry and properties of bacterial pyrogens and endotoxins. Mechanisms of action of pyrogens. Pharmaceutical aspects, pyrogen test of IP compared to that of BP & USP. Interpretation of data, Comparison of LAL and other pyrogen tests. **05**
4. Analysis of drugs from biological samples including, selection of biological sample, extraction of drugs by various methods as LLE, SPE and Membrane filtration. **05**
5. **Microbiological Limit Tests,** Tests for effectiveness of antimicrobial preservatives. **06**
6. **Radio immunoassay:** General principles, scope and limitations, radio immunoassay of some drugs like insulin, digitalis etc. **04**
7. Preclinical Drug Evaluation, acute, sub acute and chronic toxicity studies, LD50 & ED50 determination, evaluation of compound for its biological activity, study of special toxicities like teratogenicity and mutagenicity. **07**
8. **Clinical Research—**
   a. Clinical Research Protocols, objective and protocol design.
   b. Helsinki declaration, US-FDA & ICH guideline for Clinical trials for drugs and dosage forms, reviews and approval of Clinical Study.
   c. Good Clinical Practices. **10**
9. **Bioavailability:-** Objectives and consideration in bio-availability studies, Concept of equivalents, Measurements of bio-availability, Determination of the rate of absorption, Bioequivalence and its importance, Regulatory aspects of bio-availability and bioequivalence studies for conventional dosage forms and controlled drug delivery systems. **07**
10. **Pharmacokinetics:-** Basic consideration, Pharmacokinetic models, Application of Pharmacokinetics in new drug development and designing of dosage forms and Novel drug delivery systems. **08**

BIOLOGICAL EVALUATION AND CLINICAL RESEARCH
Practical

(Four hours per week, 6 Credits)

1. Bio-analytical method development and its validation.
2. Analysis of biological fluids.

3. Analysis of drug in biological fluids.
4. Dissolution study of simple and modified release solid oral dosage forms.
5. Any other relevant exercises based on theory.

Reference Books:

1. Indian Pharmacopoeia
2. British Pharmacopoeia
3. U.S. Pharmacopoeia
4. Bengt Ljunggvist and Berit Davis “Microbiological Risk Assessment in Pharm. Clean rooms”. Harwood International Publishing.
5. Richard Prince, “Microbiology in Pharmaceutical Manufacturing”. Davis Harwood International Publishing.
6. Akers, “Parenteral Quality Control: Sterility, Pyrogen, and Package Integrity Testing,” 2nd Edition (Marcel Dekker).
7. D. C. Garratt, The Quantitative Analysis of Drugs, CBS Publishers, 2001, New Delhi..
8. Mark C. Rogge and David R Taft, “Prclinical Drug Development”, Drugs and Pharm. Sci. Series, Vol. 152, Marcel D
9. ekker Inc., N.Y.
11. Donald Monkhouse, Charles Carney and JimClark, “Drug Products For Clinical Trials”. 2nd Ed. v Drugs and Pharm. Sci. Series, Vol. 147, 2nd Ed., Marcel Dekker Inc., N.Y.
12. Leon Shargel, “Applied Biopharmaceutics and Pharmacokinetics”.
13. Welling and Tse.-Pharmacokinetic
14. Gibaldi and Perrier-Pharmacokinetics
15. G. S, Banker & C.T. Rhodes, "Modern Pharmaceutics", Drugs and Pharm. Sci. Series, Vol. 121, 4th Ed., Maracel Dekker Inc., N.Y.
16. Rowland and Tozer-Clinical Pharmacokinetics, concepts and application.
17. Notari.-Biopharmaceutics and Pharmacokinetics-An introduction.
18. John Wagner- Pharmacokinetics for Pharmaceutical scientist.
19. R V Smith, J T Stewart, Textbook of Bio Pharmaceutical Analysis.