Gujarat Technological University
Master of Pharmacy
Semester – II
Paper code -2920207
Specialization paper – IV
PHARMACEUTICAL ANALYSIS SPECIALISATION
QUALITY CONTROL & QUALITY ASSURANCE
Theory
(Six hours per week, 8 credits)

1) **Drug Regulatory Affairs)-** Harmonization of regulatory requirements including ICH activity. Regulatory requirements of different regions applicable to pharmaceutical developments, manufacturing, quality control on finished products, extended release products, biopharmaceutical and bioequivalence assessment and good clinical practices and Comparison with regulation in India. Filing of INDA, NDA and ANDA for approval and registration.

15 Hrs

2) **Stability Testing-** Role of stability testing, stability test guidelines and Regulatory requirements. Protocol of stability testing including testing under different climatic zones and conditions. Conduct of stability testing. Presentation and recording of stability data, Interpretation of data, determination of shelf life. Stability test equipment and recent developments in this area. **15 Hrs**

3) **Documentation-** Importance of documentation, statutory requirements and procedure for documentation, critical examination of documents. **2 Hrs**

4) **GMP of Pharmaceuticals-** Current GMP in manufacturing, processing, packaging of drugs. GMP for finished products. General provision, organization and personnel, building and facilities, equipment, control of components and drug product, container and closures, production and process, packaging and labeling, laboratory and control of records and reports. **15 Hrs**

5) **Good Laboratoy Practice-** Current GLP in manufacturing, responsibilities. General provision, organization and personnel, building and facilities, equipment, control of components and drug product, laboratory and control of records and reports, Non-clinical testing, Controls on animal house, Application of Computers in Quality control Laboratory. **10 Hrs**

6) Regulatory aspects of Pharmaceuticals and Bulk Manufacturing, WHO Certification Globalization of Drug Industry, Patent regime. **3 Hrs**

Reference Books:

1. Sidney H. Willig, "Good Manufacturing Practices for Pharmaceuticals", Drugs and Pharm. Sci. Series, Vol. 109, Marcel Dekker Inc., N.Y.
2. S. Weinberg, “Good Laboratory Practice Regulation” Drugs and Pharm. Sci. Series, Vol. 124, 2nd Ed., Maracel Dekker Inc., N.Y.
3. WHO’s “Drug” Bulletins
4. GMP practices for pharmaceutical-James Swarbrick.

5. Gnarino Richard A, New Drug Approval Process, 3 rd Ed., Marcel Dekker Inc.
6. Ira R. Bery, “Introduction to the Pharmaceutical Regulatory Process”, Drugs and Pharm Sci. Series, Vol. 144, Marcel Dekker Inc., N.Y.
7. ICH guide lines
8. Drug stability: Principles and practices by Jens T. Carstensen
9. Stability Testing of Drug Products by W.Grimm. .
10. Stability of Drugs and Dosage Forms by Yoshioka and Stella.
11. A.C. Cartwright and Brian Mathews,”International Pharmaceutical Registration” Taylor and Francis Ltd. UK, 2002