Gujarat Technological University
Master of Pharmacy
Semester – II
Paper code -2920208
Subject of Specialization paper –IV
Industrial Pharmacy Paper-IV
Theory
(Six hours per week, 8 Credits)

1. Basic concepts of quality assurance, Requirements of CGMP/GLP, ISO 9000 series, OHSAS 14000, Quality audits etc. **08 Hrs.**
2. Precision, accuracy and biases, sampling and operating characteristic curves, sampling plans, statistical inference in estimation of hypothesis testing, statistical procedure in assay development. **04 Hrs.**
3. Brief introduction to general requirements of health regulatory agencies such as USFDA, MCC, TGA, MHRA, ANVISA, eCTD, WHO, ICH **12 Hrs.**
4. Preparation of documents for new drug application and export registration. Clinical study and basic concepts of Good clinical practice. **03 Hrs.**
5. Concepts in validation, validation of manufacturing and analytical equipments. Process validation in production of pharmaceuticals.
   Electronic records (21CFR11) **10 Hrs.**
6. Introduction to orange book, freedom of information (FOI), inactive ingredient guide (IIG), Drug master file (DMF), open part of DMF, codes of therapeutic equivalency, CDER, CBER. **08 Hrs.**
7. Regulatory aspects of pharmaceutical and bulk drug manufacture and biotechnology derived product. **08 Hrs.**
8. Study of compendia – Evolution, Study of parts of compendia like: Policies, General notices, Monographs, Comparative picture of IP, USP, BP, EP&GP **07 Hrs.**

Reference Books:

1. S. H. Willig, M.M.Tuckeman and W.S.Hitchings, "Good Manufacturing Practices for Pharmaceuticals", Drugs and Pharm. Sci. Series, Vol. 16, Marcel Dekker Inc., N.Y.
2. B. T. Loftus & R. A. Nash, "Pharmaceutical Process Validation", Drugs and Pharm Sci. Series, Vol. 23, Marcel Dekker Inc., N.Y.
3. S. Bolton, "Pharmaceutical Statistics: Practical & Clinical Applications", Drugs and Pharm. Sci. Series, Vol. 25, Marcel Dekker Inc., N.Y.
4. G.S, Banker & C.T. Rhodes, "Modern Pharmaceutics", Drugs and Pharm. Sci. Series, Vol. 7, Marcel Dekker Inc., N.Y.
5. The guidance documents shall be procured from the website of the respective Government.