Gujarat Technological University
Master of Pharmacy
Semester – II
Paper code -2920204
Specialization paper - IV
Regulatory Affairs and New Drug Application

Theory
(Six hours per week, 8 credits)

A) REGULATORY AFFAIRS

1. Legislation to regulate the profession of pharmacy – The Pharmacy Act 1948.
2. Legislation to regulate, import, manufacture distribution and sales of drugs, cosmetics- The Drugs & Cosmetic Act 1940 & rules 1945 with amendments.
3. Regulatory aspects of pharmaceutical and bulk drug manufacture and biotechnology derived product.
4. Quality safety and legislation for cosmetic and herbal products.
5. Aims, objects and salient features of following legislations governing Pharmaceutical Industry-
6. Pollution Control Act
7. Prevention of Food Adulteration Act 1954
8. Industrial Development & Regulation Act 1951
9. Consumer Protection Act
10. Standard institutes & certification agencies like ISI, BSS, ASTM, SO, WHO, US-FDA, UK-MCA, TGA
11. Drug Master File (Case Study-3 examples)
12. Material Safety Data Sheet (MSDS) preparation
13. Industrial Safety & Health Guide lines for filing in countries like US & EU
14. Drug Regulatory Agencies-Historical perspectives, organization structure activities & responsibilities: India, US, EU, Japan, ICH
15. Study of compendia – Evolution, Study of parts of compendia like: Policies, General notices, Monographs, Comparative picture of IP, USP, BP, EP&GP

B) Approval of New drugs:

Investigational New Drug (IND) submission, format & content of IND, content of Investigator Brochure, general consideration of New Drug Approval (NDA), specific requirements, content & format of NDA, manufacturing control requirement of NDA.

References Books:

1. Drugs and Cosmetics Laws by Krishnan Arora, Professional Book Publishers, New Delhi
2. Mittal B.M., A Textbook of Forensic Pharmacy, 9th Ed., Vallabh Prakashan
3. Deshpande S.W., Drugs and Cosmetic Act.1940.
4. Gnarino Richard A, New Drug Approval Process, 3rd Ed., Marcel Dekker Inc.
5. P. Warayan, Intellectual Property Laws, Eastern Law House.
6. Drug and Cosmetic Act 1940, Eastern Book company by Vijay Malic, 11th Ed. Patents for Medicine, by N. B. Zareri, Indian Drug Manufacturers Association (IDMA)
7. Ira R. Bery, "Introduction to the Pharmaceutical Regulatory Process", Drugs and Pharm Sci. Series, Vol. 144, Marcel Dekker Inc., N.Y.
8. The Drugs and Cosmetic Act 1940 – Vijay Malik

9. Indian Pharmacopoeia, Vol. 1-3, 2007.The Indian Pharmacopoeia commission, Gahaziabad, Govt. of India.
10. The International Pharmacopoeia Vol 1, 2,3,4,5 3rd Editions
11. Pollution Control Act, 1974
12. Prevention of Food Adulteration Act 1954
13. Industrial Development & Regulation Act 1951
14. Consumer Protection Act 1986
15."WHO Expert Committee on specification on Pharmaceutical Preparation"34th report, Geneva, World Health Organisation, 1996 (WHO Technical Report Series, No. 863
16. Quality Assurance of Pharmaceuticals – A compendium of guidelines and related materials Vol.1 and Vol.2, WHO, (1999)
17. A.C. Cartwright and Brian Mathews,"International Pharmaceutical Registration" Taylor and Francis Ltd. UK, 2002
18. United State Pharmacopoeia (USP) 32,NF27, 2009
19. Industrial Health and Safety, Dr. A.M. Sarma, Himalaya Publication.