

11. Donald Monkhouse, Charles Carney and Jim Clark, "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

Gujarat Technological University

M. Pharm.

Quality Assurance and Regulatory Affairs

Subject Code: 1911502

Subject Name: Basic Concept of Regulatory Affairs Theory
(Four hours per week, 6 Credits)

Sr_No	Content
1.	Basic concepts of Quality control & Quality Assurance, Total Quality Management, Philosophy of GMP, cGMP, GLP, ISO. Introduction of ICH guidelines.
2.	Organization & functions of the Federal Food & Drug Administration of USA. Federal trade commission Act. The Environmental Pollution Control Act, Other laws related to pharmacy including Tort law, Contract law etc.
3.	III. A detailed study of Food & Drug Laws affecting drug products design, manufacture and distribution in USA. <ul style="list-style-type: none"> • The Federal Food. Drugs & Cosmetics Act 1938. • Druham – Humphrey Amendment 1951. • Kefauver – Harris Amendment 1962. • The Drug Listing Act 1972 • Prescription Drug Marketing Act 1987
4.	Concept and historical development of pharmaceutical product registration. Effect of GATT and WTO on commerce of pharmaceuticals. Introduction to Intellectual Property Rights.
5.	Globalization of drug industries, Export Import Policy of drugs, WHO – certification, Trademarks and copyrights.

6.	Regulation & licensing of drugs & cosmetics – recent amendments and other relevant rules. Consumer protection, Factory Act, Loan license.
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Recommended Books

- 1) Medical Product Regulatory Affairs: Pharmaceuticals, Diagnostics, Medical Devices by John J. Tobin and Gary Walsh
- 2) FDA Regulatory Affairs: A Guide for Prescription Drugs, Medical Devices, and Biologics, Second Edition by Douglas J. Pisano and David S. Mantus
- 3) Good Drug Regulatory Practices: A Regulatory Affairs Quality Manual (Good Drug Development Series, Vol 1) by Helene I. Dumitriu
- 4) Pharmaceutical Patent Law by John R. Thomas