

Gujarat Technological University

M.Pharm

Pharmaceutical Management and Regulatory Affairs (Branch 15)

Proposed Teaching Scheme (W.E.F. January 2013)

Semester – II

Subject Name: Regulatory Affairs-I(Theory)

Subject Code: 2921601

(Four hours per week, 4 Credits) Total: 60 hours

Sr_No	Content
1.	Origin, development, scope, objectives and nature of Pharmaceutical legislation in India. History and ethics of profession of Pharmacy.
2.	A study of regulatory aspects that affect drug product design, manufacture and distribution in India with special emphasis on the detailed study of the following Acts (with latest amendments)
3.	The Narcotics Drugs and Psychotropic Substances Act.
4.	Medicinal and Toilet Preparations (Excise Duties) Act, 1955.
5.	The Pharmacy Act, 1948.
6.	The Drugs and Cosmetics Act, 1940 and Rules there under.
7.	Drugs (Price Control) Order in force.
8.	Introduction to Intellectual Property Rights; Copy Right Act, Trade Mark Act, Patent Act and Biodiversity Act, WTO, TRIPS and TRIMS.
9.	The Drugs and Magic Remedies (Objectionable Advertisements) Act, 1955.
10.	Prevention of Cruelty to Animals Act.
11.	Schedule U requirements- Product development stage documentation, factory procedures - Standard operating procedures and standard test procedures

12.	Legal Environment of Business- Need for government regulations; financial regulations, SEBI, BIFR, FEMA and others, Contract Act and Sale of Goods Act, Company Act, Corporate tax laws - Direct and Indirect.
13.	Indian Patent Law: Critical evaluation of development of Indian Patent law with necessary changes. Comparison with US and EP Patent Law.

Reference Books:

1. Original laws published by Govt. of India.
2. Text Book of Forensic Pharmacy by Mithal B. M.; VallabhPrakashan, New Delhi.
3. Laws of Drugs in India by Hussain.
4. Text Book of Forensic Pharmacy by Jain N. K.; VallabhPrakashan, New Delhi.

Gujarat Technological University

M.Pharm

Pharmaceutical Management and Regulatory Affairs (Branch 15)

Proposed Teaching Scheme (W.E.F. January 2013)

Semester – II

Subject Name: Regulatory Affairs-I(Practical)

Subject Code: 2921501

Laboratory examination including oral and practical examination in general course illustrative of theory section in the syllabus.