

**GUJARAT TECHNOLOGICAL UNIVERSITY**  
**PHARM.D**  
**3<sup>rd</sup> Year**

**Subject Name: PHARMACEUTICAL JURISPRUDENCE**  
**Subject Code: 838804**

**Scope:** This course exposes the student to several important legislations related to the profession of pharmacy in India. The Drugs and Cosmetics Act, along with its amendments are the core of this course. Other acts, which are covered, include the Pharmacy Act, dangerous drugs, medicinal and toilet preparation Act etc. Besides this the new drug policy, professional ethics, DPCO, patent and design Act will be discussed.

**Objectives:** Upon completion of the subject student shall be able to (Know, do, and appreciate) –

- a. practice the Professional ethics;
- b. understand the various concepts of the pharmaceutical legislation in India;
- c. know the various parameters in the Drug and Cosmetic Act and rules;
- d. know the Drug policy, DPCO, Patent and design act;
- e. understand the labeling requirements and packaging guidelines for drugs and cosmetics;
- f. be able to understand the concepts of Dangerous Drugs Act, Pharmacy Act and Excise duties Act; and
- g. other laws as prescribed by the Pharmacy Council of India from time to time including International Laws.

**Theory (2 Hours/ Week, Total: 60 Hours)**

Teaching Scheme				Evaluation Scheme				Total Marks
Theory	Tutorial	Practical	Total	Theory		Practical		
				External	Internal	External	Internal	
2	0	0	2	70	30	0	0	100

Sr.	Topic	Hr	% Weig htag e
1.	<b>Pharmaceutical Legislations</b> – A brief review	3	5%
2.	Principle and Significance of professional ethics. Critical study of the code of pharmaceutical ethics drafted by PCI	3	5%
3.	<b>Drugs and Cosmetics Act, 1940, and its rules 1945.</b> Objectives, Legal definition, Study of Schedule's with reference to Schedule B, C&C1, D, E1, F&F1, F2, F3, FF, G, H, J, K, M, N, P, R, V, W, X, Y. Sales, Import, labeling and packaging of Drugs And Cosmetics Provisions Relating to Indigenous Systems. Constitution and Functions of DTAB, DCC, CDL. Qualification and duties –Govt. analyst and Drugs Inspector	16	26.7%
4.	<b>Pharmacy Act –1948.</b> Objectives Legal Definitions, General Study, Constitution and Functions of State & Central Council, Registration & Procedure, ER	6	10%
5.	<b>Medicinal and Toilet Preparation Act –1955.</b> Objectives, Legal Definitions, Licensing, Bonded and Non Bonded Laboratory, Ware Housing, Manufacture of Ayurvedic, Homeopathic, Patent & Proprietary Preparations.	5	8.33%
6.	<b>Narcotic Drugs and Psychotropic substances Act-1985 and Rules.</b> Objectives, Legal Definitions, General Study, Constitution and Functions of narcotic &	7	11.7%

	Psychotropic Consultative Committee, National Fund for Controlling the Drug Abuse, Prohibition, Control and regulations, Schedules to the Act.		
7.	<b>Study of Salient Features of Drugs and magic remedies Act and its rules</b>	4	6.67%
8.	<b>Study of essential Commodities Act Relevant to drugs price control Order</b>	3	5%
9.	<b>Drug Price control Order &amp; National Drug Policy (Current).</b>	3	5%
10.	<b>Prevention Of Cruelty to animals Act-1960</b>	2	3.33%
11.	<b>Patents &amp; design Act-1970</b>	4	6.67%
12.	<b>Brief study of prescription and Non-prescription Products</b>	4	6.67%

### Assignments:

#### Format of the assignment

Minimum & Maximum number of pages 2. It shall be a computer draft copy 3. Reference(s) shall be included at the end. 4. Name and signature of the student 5. Assignment can be a combined presentation at the end of the academic year. 6. Time allocated for presentation may be 8+2 Min

#### Case studies relating to

1. Drugs and Cosmetics Act and rules along with its amendments, Dangerous Drugs Act, Medicinal and Toilet preparation Act, New Drug Policy, Professional Ethics, Drugs (Price control) Order, Patent and Design Act.
2. Various prescription and non-prescription products.
3. Medical and surgical accessories.
4. Diagnostic aids and appliances available in the market

#### Text books (Theory)

Mithal , B M. Textbook of Forensic Pharmacy. Calcutta :National; Latest Edition.

#### Reference books (Theory)

- a. Singh, KK, editor. Beotra's the Laws of Drugs, Medicines & cosmetics. Allahabad: Law Book House; Latest Edition.
- b. Jain, NK. A Textbook of forensic pharmacy. Delhi: Vallabh prakashan ; Latest Edition
- c. Reports of the Pharmaceutical enquiry Committee
- d. I.D.M.A., Mumbai. DPCO Latest Edition
- e. Various reports of Amendments.
- f. Deshpande, S.W. The drugs and magic remedies act 1954 and rules 1955. Mumbai: Susmit Publications; Latest Edition.
- g. Eastern Book Company .The narcotic and psychotropic substances act 1985, Lucknow: Eastern; Latest Edition.