

# GUJARAT TECHNOLOGICAL UNIVERSITY

B.Pharm (Practice)

2<sup>nd</sup> Year

**Subject Name: Pharmaceutical Jurisprudence**

**Subject Code: PP206TP**

**Scope:** A profession becomes successful when it is guided with suitable laws. This course describes about the Pharmacy Act, Drugs and Cosmetics Act, Dangerous drugs act, Medicinal and Toilet preparation act, DPCO and Professional ethics

**Objectives:** Upon completion of the course student shall be able to

1. Understand various concepts of the pharmaceutical legislation in India
2. Know various rules drafted in Drug and Cosmetic Act, Pharmacy Act, NDPS Acts, relevant to pharmacy practice
3. Know the Consumer Protection Act, PFA Act, DPCO
4. Understand the labeling requirements and packaging guidelines for drugs and cosmetics

**Course duration:**

**Learning:** 40 hours of learning by blended mode of teaching. Blended teaching includes didactic and onsite learning.

**Case Presentations:** During the course each student should present **5 cases** covering the diseases prescribed in the syllabus.

**Assignments:** Each student should complete **two assignments** covering therapeutics and pharmacy practice concepts and will be evaluated at the time Final Examination

Sr No	Course Contents	Total Hrs
1	<b>A brief review of Pharmaceutical legislations.</b> (a) A Study of various pharmaceutical and related legislations with more emphasis on aspects relevant to community & hospital pharmacy practice in India. Study the aspects only from practical angle, with examples, case studies, etc	1
2	<b>Drugs and Cosmetics Act-1940 and Rules 1945</b> <ul style="list-style-type: none"><li>• Duties &amp; Responsibilities of Drug Inspectors, other officers, and obligations of the pharmacy to them</li><li>• Brief about DTAB, DCC, Drug testing laboratories</li><li>• Various drug licences for retail pharmacy, requirements to start a pharmacy/medical store, application forms, issue of licence, display of licences, duration of licences, laws related to stocking, handling and sale of drugs and devices</li><li>• Various schedules under the Act &amp; Rule – study in brief –those relevant to pharmacy practice</li><li>• Labelling requirements of drugs – various aspects</li><li>• Spurious, misbranded, adulterated, counterfeit drugs – various aspects related to this, how to recognize, role of the pharmacist</li><li>• Import of drugs for personal use</li><li>• Various documents to be maintained under the Act &amp; Rules by a pharmacy</li><li>• Storage requirements, handling expired goods</li><li>• Various punishments under the Act</li></ul> Practical study of Prescription and non-prescription drugs, market samples, examine for labeling, etc.	15

	Laws relating to various traditional systems/ medicines approved in India • Banning of drugs	
<b>3</b>	Pharmacy Act – 1948	3
<b>4</b>	Medicinal and Toilet Preparation Act-1955	4
<b>5</b>	Narcotic Drugs and Psychotropic Substances Act – 1985	4
<b>6</b>	Drugs and Magic Remedies (Objectionable Advertisements) Act and Rules, 1954	2
<b>7</b>	Essential Commodities Act	2
<b>8</b>	Drugs Prices Control Order	2
<b>9</b>	Prevention of Cruelty to Animals Act, 1960	2
<b>10</b>	Consumer Protection Act , 1986	2
<b>11</b>	Prevention of Food Adulteration Act & Rules, laws relating to Dietary Supplements, Food supplements, etc	2
<b>12</b>	The Infant Milk Substitutes, Feeding Bottles and Infant Foods (Regulation of Production, Supply and Distribution) Amendment Act, 2003	2