PHARMACY LAW AND ETHICS – THEORY

Course Code: ER20-26T **75 Hours (3 Hours/week)**

Scope: This course is designed to impart basic knowledge on several important legislations related to the profession of pharmacy in India

Course Objectives: This course will discuss the following

1. General perspectives, history, evolution of pharmacy law in India
2. Act and Rules regulating the profession and practice of pharmacy in India
3. Important code of ethical guidelines pertaining to various practice standards
4. Brief introduction to the patent laws and their applications in pharmacy

Course Outcomes: Upon successful completion of this course, the students will be able to

1. Describe the history and evolution of pharmacy law in India
2. Interpret the act and rules regulating the profession and practice of pharmacy in India
3. Discuss the various codes of ethics related to practice standards in pharmacy
4. Interpret the fundamentals of patent laws from the perspectives of pharmacy

Chapter	Topics	Hours
1	General Principles of Law, History and various Acts related to Drugs and Pharmacy profession	2
2	**Pharmacy Act-1948 and Rules:** Objectives, Definitions, Pharmacy Council of India; its constitution and functions, Education Regulations, State and Joint state pharmacy councils, Registration of Pharmacists, Offences and Penalties. **Pharmacy Practice Regulations 2015**	5
3	**Drugs and Cosmetics Act 1940 and Rules 1945 and New Amendments** Objectives, Definitions, Legal definitions of schedules to the Act and Rules **Import of drugs** – Classes of drugs and cosmetics prohibited from import, Import under license or permit.	23

	Manufacture of drugs – Prohibition of manufacture and sale of certain drugs, Conditions for grant of license and conditions of license for manufacture of drugs, Manufacture of drugs for test, examination and analysis, manufacture of new drug, loan license and repacking license. Study of schedule C and C1, G, H, H1, K, P, M, N, and X. ***Sale of Drugs*** – Wholesale, Retail sale and Restricted license, Records to be kept in a pharmacy Drugs Prohibited for manufacture and sale in India ***Administration of the Act and Rules*** – Drugs Technical Advisory Board, Central Drugs Laboratory, Drugs Consultative Committee, Government analysts, licensing authorities, controlling authorities, Drug Inspectors.	
4	**Narcotic Drugs and Psychotropic Substances Act 1985 and Rules** Objectives, Definitions, Authorities and Officers, Prohibition, Control and Regulation, Offences and Penalties.	**2**
5	**Drugs and Magic Remedies (Objectionable Advertisements) Act 1954** Objectives, Definitions, Prohibition of certain advertisements, Classes of Exempted advertisements, Offences and Penalties.	**2**
6	**Prevention of Cruelty to Animals Act-1960**: Objectives, Definitions, CPCSEA - brief overview, Institutional Animal Ethics Committee, Breeding and Stocking of Animals, Performance of Experiments, Transfer and Acquisition of animals for experiment, Records, Power to suspend or revoke registration, Offences and Penalties.	**2**
7	**Poisons Act-1919**: Introduction, objective, definition, possession, possession for sales and sale of any poison, import of poisons	**2**
8	**FSSAI (Food Safety and Standards Authority of India) Act and Rules**: brief overview and aspects related to manufacture, storage, sale, and labelling of Food Supplements	**2**

9	**National Pharmaceutical Pricing Authority**: Drugs Price Control Order (DPCO) - 2013. Objectives, Definitions, Sale prices of bulk drugs, Retail price of formulations, Retail price and ceiling price of scheduled formulations, Pharmaceutical Policy 2002, National List of Essential Medicines (NLEM)	**5**
10	**Code of Pharmaceutical Ethics**: Definition, ethical principles, ethical problem solving, registration, code of ethics for Pharmacist in relation to his job, trade, medical profession and his profession, Pharmacist's oath.	**5**
11	Medical Termination of Pregnancy Act and Rules – basic understanding, salient features, and Amendments	**2**
12	Role of all the government pharma regulator bodies – Central Drugs Standards Control Organization (CDSCO), Indian Pharmacopoeia Commission (IPC)	**1**
13	Good Regulatory practices (documentation, licenses, renewals, e-governance) in Community Pharmacy, Hospital pharmacy, Pharma Manufacturing, Wholesale business**,** inspections, import, export of drugs and medical devices	**3**
14	Introduction to BCS system of classification, Basic concepts of Clinical Trials, ANDA, NDA, New Drug development, New Drugs and Clinical Trials Rules, 2019. Brand v/s Generic, Trade name concept, Introduction to Patent Law and Intellectual Property Rights, Emergency Use Authorization	**7**
15	Blood bank – basic requirements and functions	**2**
16	Clinical Establishment Act and Rules – Aspects related to Pharmacy	**2**
17	Biomedical Waste Management Rules 2016 – Basic aspects, and aspects related to pharma manufacture to disposal of pharma / medical waste at homes, pharmacies, and hospitals	**2**
18	Bioethics - Basic concepts, history and principles. Brief overview of ICMR's National Ethical Guidelines for Biomedical and Health Research involving human participants	**2**
19	Introduction to the Consumer Protection Act	**1**
20	Introduction to the Disaster Management Act	**1**
21	Medical Devices – Categorization, basic aspects related to manufacture and sale	**2**

Assignments

The students shall be asked to submit written assignments on the following topics (One assignment per student per sessional period. i.e., a minimum of THREE assignments per student)

1. Requirements for Ayurvedic, Homeopathic manufacturing, sale, and licensing requirements
2. Layout and contents of official websites of various agencies regulating the profession of pharmacy in India: e.g., CDSCO, SUGAM portal, PCI, etc.
3. Licenses required, application processes (online/offline), drug regulatory office website of the respective state
4. Case studies – actions taken on violation of any act / rule related to pharmacy
5. Schedule H1 drugs and its implementation in India
6. Counterfeit / Spurious medicines
7. Drug Testing Labs in India
8. Overview of Pharma marketing practices
9. Generic Medicines