Pharmacy Law and Ethics

Course Code ER20-26T *for* **Second Year Diploma in Pharmacy**

is a comprehensive textbook gives the essential content to impart basic knowledge to pharmacy students on the relevant topics of law and ethics.

Salient Features

- Important legislations related to the profession of pharmacy in India.
- Definitions, the origin, and nature of pharmaceutical legislations in India with their principles and significance of professional ethics.
- Regulatory authorities and agencies governing the manufacture and sale of pharmaceuticals.
- Special attempt has been made to provide case study on various pharmacy laws.

The book also includes chapter-wise multiple choice questions and long and short questions for self-assessment and practice for various competitive examinations.

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As per the latest syllabus prescribed by Pharmacy Council of India

Vishal Suresh Bagul
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Syllabus

(As per PCI)

Pharmacy Law and Ethics

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

COURSE CONTENT

CHAPTER I

General Principles of Law, History and various Acts related to Drugs and Pharmacy profession

CHAPTER II

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

CHAPTER III

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.

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, X and Y

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.

CHAPTER IV

Medicinal and Toilet Preparations Act 1955: Objectives, Definitions, Licensing, Offences and Penalties.

CHAPTER V

Narcotic Drugs and Psychotropic Substances Act 1985 and Rules: Objectives, Definitions, Authorities and Officers, Prohibition, Control and Regulation, Offences and Penalties

CHAPTER VI

Drugs and Magic Remedies (Objectionable Advertisements) Act 1954: Objectives, Definitions, Prohibition of certain advertisements, Classes of Exempted advertisements, Offences and Penalties.

CHAPTER VII

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.

CHAPTER VIII

Poisons Act 1919: Introduction, objective, definition, possession, possession for sales and sale of any poison, import of poisons

CHAPTER IX

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

CHAPTER X

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)

CHAPTER XI

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.

CHAPTER XII

Medical Termination of Pregnancy Act and Rules—basic understanding/salient features

CHAPTER XIII

Role of all the government pharma regulator bodies—Central Drugs Standards Control Organization (CDSCO), Indian Pharmacopoeia Commission (IPC)

CHAPTER XIV

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.

CHAPTER XV

Introduction to BCS system of classification, Basic concepts of Clinical Trials, ANDA, NDA, New Drug development, Schedule Y Brand v/s Generic, Trade name concept, Introduction to Patent Law and Intellectual Property Rights, Emergency Use Authorization

CHAPTER XVI

Blood bank—Basic requirements and functions

CHAPTER XVII

Clinical Establishment Act and Rules—Aspects related to Pharmacy

CHAPTER XVIII

Biomedical Waste Management Rules 2016—Basic aspects, and aspects related to pharma manufacture to disposal of pharma/medical waste at homes, pharmacies, and hospitals

CHAPTER XIX

Bioethics—Basic concepts, history and principles. Brief overview of ICMR's National Ethical Guidelines for Biomedical and Health Research involving human participants

CHAPTER XX

Introduction to the Consumer Protection Act

CHAPTER XXI

Medical Devices—Categorization, basic aspects related to manufacture and sale
Content beyond Syllabus

CHAPTER XXII

Right for Information Act, 2005 (RTI Act)

Case Study XXIII

Content