

Pharmaceutical Jurisprudence (Theory)

Course code BP606T

A Textbook for B. Pharm. (Semester VI)

As per the new PCI syllabus 2026 (NEP 2020)

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Preface

A medicine can heal or harm depending on its identity, quality, dose and the hands through which it passes, and the public cannot test any of that at the counter. They rely instead on a chain of legal duties running from the factory to the dispensing label. This book is about that chain. It sets out the law that governs the import, manufacture, distribution, sale, labelling, pricing and advertisement of drugs and cosmetics in India, together with the law governing the pharmacy profession itself, as prescribed in the PCI syllabus for Pharmaceutical Jurisprudence (BP606T).

The aim throughout is to make statutory detail orderly and usable. Pharmacy law can seem a fog of Acts, Schedules and section numbers; the purpose here is that a student should leave able to state exactly what a provision requires, which authority enforces it, and what happens when it is broken. Every provision is therefore taught along a single spine: the problem the law answers, the provision that addresses it, what a regulated person must do to comply, the penalty for failing, and the authority that enforces it. Brief “in practice” signposts connect each rule to what a future pharmacist, manufacturer or regulator will have to do.

Accuracy has been treated as paramount. The law in this field is amended often, and several items in the syllabus have moved in recent years: cosmetics are now under the Cosmetics Rules, 2020; clinical trials under the New Drugs and Clinical Trials Rules, 2019; medical devices under the Medical Devices Rules, 2017; the gestational limits of the Medical Termination of Pregnancy Act were revised in 2021; and the excise duty on medicinal preparations has been subsumed into the Goods and Services Tax. Provisions and figures have been checked against the bare Acts and Rules and the publications of CDSCO, the Pharmacy Council of India, the NPPA and the FSSAI. Where a time-sensitive specific could not be confirmed, the established principle is stated and the point flagged rather than a possibly outdated figure asserted.

Every figure in this book is original, drawn for greyscale print, and every chapter closes with five university-style short-answer questions and model answers written to show where the marks lie. It is hoped that the book will leave the reader not merely able to pass an examination, but able to practice lawfully and to understand why the law is as it is.

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COURSE OBJECTIVES

The objectives of this course are to:

1. Understand the fundamental principles and scope of pharmaceutical legislations governing drug development, manufacture, distribution, and marketing.
2. Gain comprehensive knowledge of Indian pharmaceutical Acts and Rules, including Drugs and Cosmetics Act, Pharmacy Act, NDPS Act, and related regulations.
3. Learn the roles, responsibilities, and functions of regulatory authorities involved in regulation and control of pharmaceuticals in India.
4. Learn the code of pharmaceutical ethics and legal responsibilities in professional pharmacy practice.
5. Develop the ability to analyse regulatory frameworks, pricing controls, and emerging regulations, and assess their impact on public health, industry compliance, and patient safety.

COURSE OUTCOMES (CO):

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

1. Demonstrate understanding of major pharmaceutical legislations and explain their relevance in pharmaceutical product development and marketing.
2. Interpret and apply the provisions of various Indian pharmaceutical Acts and laws in real-world scenarios.
3. Identify regulatory bodies such as CDSCO, IPC, and state regulatory authorities, and explain their roles in drug approval, manufacturing, and distribution.
4. Exhibit ethical awareness by applying the code of ethics in professional pharmaceutical practices.
5. Critically analyze regulatory frameworks and assess their impact on public health, industry operations, and compliance requirements.

SYLLABUS

Unit no.	Topics	No. of lectures
I	Drugs and Cosmetics Act, 1940 and its rules 1945: Objectives, Definitions, Legal definitions of schedules to the Act and Rules, CDSCO guidelines for Import & export of Pharmaceuticals 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.	10 hours
II	Drugs and Cosmetics Act, 1940 and its rules 1945. • Detailed study of Schedule G, H, H1, M, N, P, T, U, V, X, Y, Sch F, Part XII B. • Sale of Drugs – Wholesale, Retail sale and Restricted license. Offences and penalties • Labeling & packing of drugs- General labeling requirements and specimen labels for drugs and cosmetics, List of permitted colors. Offences and penalties. • Administration of the Act and Rules – Drugs Technical Advisory Board, Central drugs Laboratory, Drugs Consultative Committee, Government drug analysts, Licensing authorities, controlling authorities, Drugs Inspectors	10 hours
III	• Pharmacy Act –1948: Objectives, Definitions, Pharmacy Council of India; its constitution and functions, Education Regulations including ER20, State and Joint state pharmacy councils; constitution and functions, Registration of Pharmacists, Offences and Penalties • Medicinal and Toilet Preparation Act –1955: Objectives, Definitions, Licensing, Manufacture In bond and Outside bond, Export of alcoholic preparations, Offences and Penalties. • Narcotic Drugs and Psychotropic substances Act-1985 and Rules: Objectives, Definitions, Authorities and Officers, Constitution and Functions of narcotic & Psychotropic Consultative Committee, National Fund for Controlling the Drug Abuse, Prohibition, Control and Regulation, opium poppy cultivation and production of poppy straw, manufacture, sale and export of opium, Offences and Penalties	8 hours
IV	• Study of Salient Features of Drugs and Magic Remedies Act and its rules: Objectives, Definitions, Prohibition of certain advertisements, Classes of Exempted advertisements, Offences and Penalties • Prevention of Cruelty to animals Act-1960: Objectives, Definitions, Institutional Animal Ethics Committee, CCSEA guidelines for 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 • 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, National List of Essential Medicines (NLEM).	8 hours

V	• Pharmaceutical Legislations – A brief review, Introduction, Study of drugs enquiry committee, Health survey and development committee, Hathi committee and Mudaliar committee • Code of Pharmaceutical ethics: Definition, Pharmacist in relation to his job, trade, medical profession and his profession, • Medical Termination of Pregnancy Act • Brief Introduction to Right to Information Act • Introduction New Drugs and Clinical Trials Rules, 2019 and amendments. • Cosmetic rules 2020 • Regulatory guidelines on similar biologics. • Overview of Medical Device Regulations, Guidelines on Probiotics, Food Safety and Standards (Health Supplements, Nutraceuticals, Food for Special Dietary Use, Food for Special Medical Purpose, Functional Food and Novel Food) Regulations, 2016	9 hours
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