

(B. Pharm.)
(Semester - V)

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Course Code	BP505T
Course Title	Pharmaceutical Jurisprudence - Theory

Scope:

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

Objectives:

Upon completion of this course the student should be able to understand:

1. The Pharmaceutical legislations and their implications in the development and marketing of pharmaceuticals.
2. Various Indian pharmaceutical Acts and Laws
3. The regulatory authorities and agencies governing the manufacture and sale of pharmaceuticals
4. The code of ethics during the pharmaceutical practice

Course Learning Outcomes (CLO):

At the end of the course, students will be able to -

1. Explain importance of Pharmaceutical laws in India
2. Describe regulations related to import and manufacturing of drugs as per Drug & Cosmetic Act.
3. Discuss schedules, sale, labeling & packing of drugs and related regulations as per Drug & Cosmetic Act.
4. Identify functions of state and central pharmacy council
5. Discuss laws related to manufacturing of Narcotic and Alcoholic preparation
6. Understand Indian pharmaceutical Acts and Intellectual Property Rights.

Syllabus:

Teaching hours: 45 Hours

UNIT I

10 Hours

Drugs and Cosmetics Act, 1940 and its rules 1945:

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. Offences and penalties.

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.

UNIT II

10 Hours

Drugs and Cosmetics Act, 1940 and its rules 1945.

Detailed study of Schedule G, H, M, N, P, T, U, V, X, Y, Part XII B, Sch F & DMR (OA)

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

UNIT – III

10 Hours

Pharmacy Act –1948: Objectives, Definitions, Pharmacy Council of India; its constitution and functions, Education Regulations, 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, Manufacture of Ayurvedic, Homeopathic, Patent & Proprietary 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

UNIT – IV

08 Hours

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, CPCSEA 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).

UNIV – V

07 Hours

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, Pharmacist's oath.

Medical Termination of Pregnancy Act

Right to Information Act

Introduction to Intellectual Property Rights (IPR)

Tutorials

Tutorials will be based on above syllabus

Teaching hours: 15 Hours

Suggested Readings[^]: (Latest Edition)

1. Suresh, B. *Forensic Pharmacy: Pharmaceutical Jurisprudence*. Delhi, Birla Publications.
2. Mithal, B.M. *A Text book of Forensic Pharmacy*. Delhi, Vallabh Prakashan.
3. Mehra, M.L. *The Handbook of Drug Laws*. Allahbad, The University Book Agency.
4. Jain N.K. *A text book of Forensic Pharmacy*. Delhi, Vallabh Prakashan.
5. *Drugs and Cosmetics Act/Rules*. Govt. of India publications.
6. *Medicinal and Toilet preparations act 1955*. Govt. of India publications.
7. *Narcotic drugs and psychotropic substances act*. Govt. of India publications.
8. *Drugs and Magic Remedies act*. Govt. of India publications.
9. *Bare Acts of the said laws*. Government of India publications.

L= Lecture, T= Tutorial, P= Practical, C= Credit

[^] this is not an exhaustive list
