

INSTITUTE	FACULTY OF PHARMACY
PROGRAM	BACHELOR OF PHARMACY
SEMESTER	4
COURSE TITLE	PHARMACEUTICAL JURISPRUDENCE
COURSE CODE	13PH0405
COURSE CREDITS	4

Objective:

- 1 This course is designed to impart basic knowledge on important legislation related to the profession of pharmacy in India
- 2 The main purpose of the subject is to understand what drugs do to living organisms and how their effects can be applied to therapeutics. The subject covers information about the drugs like mechanism of action, physiological and biochemical effects (pharmacodynamics) as well as absorption, distribution, metabolism, and excretion (pharmacokinetics) along with the adverse effects, clinical uses, interactions, doses, contraindications and routes of administration of different classes of drugs.

Course Outcomes: After completion of this course, student will be able to:

- 1 The Pharmaceutical legislation 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

Pre-requisite of course: This course is designed to impart basic knowledge on important legislations related to the profession of pharmacy in India

Teaching and Examination Scheme

Theory Hours	Tutorial Hours	Practical Hours	ESE	IA	CSE	Viva	Term Work
3	1	0	75	15	10	0	0

Contents : Unit	Topics	Contact Hours
1	<p>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.</p>	
2	<p>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</p>	
3	<p>Pharmacy Act –1948 Pharmacy Act –1948: Objectives, Definitions, Pharmacy Council of India;its constitution and functions, Education Regulations, State and Joint statepharmacy councils; constitution and functions, Registration ofPharmacists, Offences and Penalties Medicinal and Toilet Preparation Act –1955: Objectives, Definitions,Licensing, Manufacture In bond and Outside bond, Export of alcoholicpreparations, 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</p>	
4	<p>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)</p>	

Contents : Unit	Topics	Contact Hours
5	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)	
Total Hours		

Suggested List of Experiments:

Contents : Unit	Topics	Contact Hours
1	Workshop Workshop no.1, Workshop no.2, Workshop no.3, Workshop no.4, Workshop no.5, Workshop no.6, Workshop no.7, Workshop no.8, Workshop no.9, Workshop no.10, Workshop no.11, Workshop no.12, Workshop no.13, Workshop no.14, Workshop no.15	
Total Hours		

Textbook :

- 1 Forensic, Pharmacy , by B. Suresh, 123

References:

- 1 Text book of Forensic Pharmacy by B.M. Mithal
- 2 Hand book of drug law-by M.L. Mehra
- 3 A text book of Forensic Pharmacy by N.K. Jain
- 4 Drugs and Cosmetics Act/Rules by Govt. of India publications.
- 5 Medicinal and Toilet preparations act 1955 by Govt. of India publications.
- 6 Narcotic drugs and psychotropic substances act by Govt. of India publications
- 7 Drugs and Magic Remedies act by Govt. of India publication
- 8 Bare Acts of the said laws published by Government. Reference books (Theory)

Suggested Theory Distribution:

The suggested theory distribution as per Bloom's taxonomy is as follows. This distribution serves as guidelines for teachers and students to achieve effective teaching-learning process

Distribution of Theory for course delivery					
Remember / Knowledge	Understand	Apply	Analyze	Evaluate	Higher order Thinking / Creative
30.00	25.00	20.00	15.00	10.00	0.00

Instructional Method:

- 1 The course delivery method will depend upon the requirement of content and the need of students. The teacher in addition to the conventional teaching method by the blackboard may also use any tools such as demonstration, role play, quiz, brainstorming, MOOCs etc.
- 2 The internal evaluation will be done based on continuous evaluation of students in the laboratory and classroom.
- 3 Students will use supplementary resources such as online videos, NPTEL videos, MOOCs/ e-courses, virtual laboratories.