

Performa : Hindu College of Pharmacy		
Lesson Plan		
Name of the faculty	Ruchi Bansal	
Discipline	Pharmacy	
Year	2nd Year	
Subject	Pharmacy Law & Ethics	
Lesson plan Duration	25 weeks (August 12, 2024 to April 30, 2025)	
Work Load/week(In hour)	Lecture- 03	
Week	Theory	
	Lecture Day	Topic
1st (Aug. 3rd week)	1st	General Principles of Law, History
	2nd	Various Acts related to Drugs and Pharmacy profession
	3rd	Pharmacy Act 1948 and Rules: Objectives, Definitions, Pharmacy Council of India
2nd (Aug. 4th week)	1st	Its constitution and functions
	2nd	Education Regulations
	3rd	Revision
3rd (Aug. 5th week)	1st	State and Joint state pharmacy councils
	2nd	Registration of Pharmacists, Offences and Penalties. Pharmacy Practice Regulations 2015
	3rd	Drugs and Cosmetics Act 1940 and Rules 1945 and New Amendments: Objectives, Definitions
4th (SEP. 1st week)	1st	Legal definitions of schedules to the Act and Rules
	2nd	Import of drugs ,Classes of drugs and cosmetics
	3rd	Manufacture of drugs – Prohibition of manufacture and sale of certain drugs

5th(SEP. 2nd week)	1st	Conditions for grant of license
	2nd	Conditions of license for manufacture of drugs
	3rd	Revision
6th(SEP. 3rd week)	1st	Manufacture of drugs for test
	2nd	Examination and analysis, manufacture of new drug
	3rd	Loan license and repacking license.
7th(SEP. 4th week)	1st	Study of schedule C and C1
	2nd	Schedule H, H1
	3rd	Schedule G, K
8th(OCT. 1st week)	1st	Schedule P, M
	2nd	Schedule N, and X.
	3rd	Revision
9th(OCT. 2nd week)	1st	Sale of Drugs – Wholesale, Retail sale and Restricted license
	2nd	Records to be kept in a pharmacy
	3rd	Drugs Prohibited for manufacture and sale in India
10th(OCT. 3rd week)	1st	Administration of the Act and Rules Drugs Technical Advisory Board, Central Drugs Laboratory
	2nd	Drugs Consultative Committee
	3rd	Government analysts, licensing authorities
11th(OCT. 4th week)	1st	Controlling authorities, Drug Inspectors
	2nd	Narcotic Drugs and Psychotropic Substances Act 1985 and Rules Objectives, Definitions, Authorities and Officers
	3rd	Prohibition, Control and Regulation, Offences and Penalties.
12th(OCT. 5th week)	1st	Drugs and Magic Remedies (Objectionable Advertisements) Act 1954 Objectives, Definitions, Prohibition of certain advertisements,
	2nd	Classes of Exempted advertisements, Offences and Penalties.

	3 rd	Class Test
13 th (NOV. 1 st week)	1 st	Prevention of Cruelty to Animals Act-1960: Objectives, Definitions, CPCSEA - brief overview, Institutional Animal Ethics Committee, Breeding and Stocking of Animals
	2 nd	Performance of Experiments, Transfer and Acquisition of animals for experiment, Records, Power to suspend or revoke registration, Offences and Penalties.
	3 rd	Poisons Act-1919: Introduction, objective, definition, possession,
14 th (NOV. 2 nd week)	1 st	Possession for sales and sale of any poison, import of poisons
	2 nd	FSSAI (Food Safety and Standards Authority of India) Act and Rules: brief overview and aspects related to manufacture,
	3 rd	Storage, sale, and labelling of Food Supplements
15 th (NOV. 3 rd week)	1 st	National Pharmaceutical Pricing Authority: Drugs Price Control Order (DPCO) - 2013. Objectives, Definitions
	2 nd	Sale prices of bulk drugs, Retail price of formulations,
	3 rd	Revision
16 th (NOV. 4 th week)	1 st	Retail price and ceiling price of scheduled formulations,
	2 nd	Pharmaceutical Policy 2002
	3 rd	National List of Essential Medicines (NLEM)
17 th (DEC.1 st week)	1 st	Code of Pharmaceutical Ethics: Definition, ethical principles
	2 nd	Ethical problem solving, registration
	3 rd	Code of ethics for Pharmacist in relation to his job
18 th (DEC.2 nd week)	1 st	Trade, medical profession and his profession
	2 nd	Pharmacist's oath
	3 rd	Class Test
19 th (JAN.2 nd week)	1 st	Medical Termination of Pregnancy Act and Rules basic understanding
	2 nd	MTP salient features, and Amendments
	3 rd	Central Drugs Standards Control Organization (CDSCO)

		Indian Pharmacopoeia Commission (IPC)
20th(JAN.3rd week)	1st	Good Regulatory practices (documentation, licenses, Renewals, e governance) in Community Pharmacy, Wholesale business,
	2nd	Hospital pharmacy, Pharma Manufacturing,
	3rd	Inspections, import, export of drugs and medical devices
21st(JAN 4th week)	1st	Introduction to BCS system of classification, Basic concepts of Clinical Trials
	2nd	ANDA, NDA, New Drug development,
	3rd	New Drugs and Clinical Trials Rules, 2019.
22nd(FEB. 1st week)	1st	Brand v/s Generic, Trade name concept,
	2nd	Introduction to Patent Law and Intellectual Property Rights, Emergency Use Authorization
	3rd	Revision
23rd(FEB. 2nd week)	1st	Blood bank – basic requirements and functions
	2nd	Clinical Establishment Act and Rules – Aspects related to Pharmacy
	3rd	Biomedical Waste Management Rules 2016 Basic Aspects.
24th(FEB. 3rd week)	1st	Aspects related to pharma manufacture to disposal of pharma / medical waste at homes, pharmacies and hospitals
	2nd	Bioethics - Basic concepts, history and principles. Brief overview of ICMR's
	3rd	National Ethical Guidelines for Biomedical and Health Research involving human participants
25th MAR.4th week)	1st	Introduction to the Consumer Protection Act
	2nd	Introduction to the Disaster Management Act
	3rd	Medical Devices – Categorization, basic aspects related to manufacture and sale
26th (APR. 1ST WEEK)	1ST	REVISION

