Gautam College Of Pharmacy, Hamirpur (H.P)

LESSON PLAN

Name of Faculty-Priyanka Sharma
Session – 2024 – 2025
Subject Name: Pharmacy Law and Ethics
Subject Code: ER20-26T
Course: D. Pharmacy
Semester/Year: 2nd Year
Total Number of Lectures: 86
Each Lecture: 1 Hour

Syllabus Coverage Schedule

Unit No.	Topic No.	Title of Topic	Learning outcomes	Scheduled Date	Teaching aids to be used	Remarks
1	1	**General Principles of Law**	Understand the foundational principles that govern legal systems relevant to pharmacy	13/08/24	Handwritten notes & PPT	
Tutorial-1 Discussed and clarified doubts from the previous lectures.				14/08/24		
	2	**History and Various acts related to drugs and the Pharmacy Profession**	Gain insights into the evolution of pharmacy laws and key drug-related legislations in India.	14/08/24	Handwritten notes & PPT	
2	3	**Pharmacy Act 1948 and rules**	Explain the objectives and key definitions under the Pharmacy Act, 1948.	16/08/24	Handwritten notes & PPT	

	4	**The Pharmacy Council of India and its regulation and function**	Describe the structure, regulation, and functions of the Pharmacy Council of India.	20/08/24	Handwritten notes & PPT	
Tutorial-2 Conducted a revision quiz on key concepts covered so far.				21/08/24		
	5	**Education regulations**	Understand the educational standards and regulations for pharmacy education in India.	21/08/24	Handwritten notes & PPT	
	6	**State and joint state pharmacy council**	Identify the composition and duties of the State and Joint State Pharmacy Councils.	23/08/24	Handwritten notes & PPT	
	7	**Registration of pharmacists, offences and penalties, Pharmacy Practice Regulations 2015**	Learn the process of pharmacist registration, offences, penalties, and practice regulations.	27/08/24	Handwritten notes & PPT	
Tutorial-3 Addressed student queries related to last week's topic.				28/8/24		

3	**8**	**Drug and Cosmetics Act, 1940, and rules 1945**	Interpret the objectives and definitions under the Drugs and Cosmetics Act, 1940.	28/8/24	Handwritten notes & PPT	
	9	**Legal definition of schedule**	Define and understand the significance of various drug schedules under Indian law.	30/08/24	Handwritten notes & PPT	
	10	**Schedules**	Differentiate between various schedules of drugs with respect to their regulation	3/09/24	Handwritten notes & PPT	
Tutorial-4 Group discussion held to reinforce understanding of core principles.				4/09/24		
	11	**Classes of drugs and Cosmetics are prohibited from import**	List the classes of drugs and cosmetics prohibited from being imported into India.	4/09/24	Handwritten notes & PPT	
	12	**Import under license or permit**	Understand the licensing requirements for the legal import of drugs	6/09/24	Handwritten notes & PPT	
	13	**Prohibition of the manufacture and sale of certain drugs**	Identify the drugs whose manufacture and sale are prohibited under the law.	10/09/24	Handwritten notes & PPT	
Tutorial-5 Focused on conceptual clarity through interactive Q&A.				11/09/24		
	14	**Manufacture of drugs for testing**	Understand the legal provisions for manufacturing drugs for test and analysis.	11/09/24	Handwritten notes & PPT	

	15	**Examination and analysis of the drug**	Describe the examination and testing procedures for quality control of drugs	13/09/24	Handwritten notes & PPT	
	16	**License and repacking license**	Explain the licensing process, including repacking licenses for drugs.	17/09/24	Handwritten notes & PPT	
Tutorial-6 Recap of important definitions discussed in previous classes.				18/09/24		
	17	**Study of schedule c and c1**	Study and understand the significance of	18/09/24	Handwritten notes & PPT	

	18	**Study of schedule G, H, H1, K**	Identify the regulatory provisions under Schedules G, H, H1, and K.	20/09/24	Handwritten notes & PPT	
	19	**Study of schedule P,M,N and X**	Interpret the use and legal significance of Schedules P, M, N, and X.	24/09/24	Handwritten notes & PPT	
Tutorial-7 Worked through case-based scenarios to apply lecture content.				25/09/24		
	20	**Wholesale, retail sales**	Describe the legal norms governing wholesale and retail sales of drugs.	25/09/24	Handwritten notes & PPT	
	21	**Restricted license**	Understand the requirements for obtaining restricted drug licenses.	27/09/24	Handwritten notes & PPT	
	22	**Records are to be kept in the pharmacy**	List the types of records to be maintained in a pharmacy.	1/10/24	Handwritten notes & PPT	
Tutorial-8 Encouraged students to summarize topics in their own words.				9/10/24		

	23	**Drug Technical Advisory Board**	Describe the role and composition of the Drug Technical Advisory Board.	9/10/24	Handwritten notes & PPT	
	24	**Central Drug Laboratory**	Understand the structure and responsibilities of the Central Drug Laboratory.	4/08/24	Handwritten notes & PPT	
	25	**Drugs Consultative Committee**	Define the functions of the Drugs Consultative Committee	8/10/24	Handwritten notes & PPT	
Tutorial-9 Reviewed practical examples linked to the theoretical content.				16/10/24		
	26	**Government analyst**	Explain the role and authority of a Government Analyst in drug analysis.	16/10/24	Handwritten notes & PPT	
	27	**License authority**	Identify the licensing authorities involved in drug regulation.	18/10/24	Handwritten notes & PPT	
	28	**Controlling authorities**	Describe the powers of the drug, Controlling authorities	22/10/24	Handwritten notes & PPT	
Tutorial-10 Conducted peer-led discussion to promote active learning.				23/10/24		

	29	**CMO**	Understand the role and responsibility of a Chief Medical Officer (CMO).	23/10/24	Handwritten notes & PPT	
	30	**Drug inspector**	Learn the powers and	25/10/24	Handwritten notes & PPT	

			duties of a Drug Inspector			
4	**31**	**Narcotic Drugs Act 1985 and rules**	Explain the objectives and structure of the Narcotic Drugs and Psychotropic Substances Act, 1985.	25/10/24	Handwritten notes & PPT	
Tutorial-11 Identified common misconceptions and corrected them.				30/10/24		
	32	**Objective, definition, authorities, and officer**		30/10/24	Handwritten notes & PPT	
	33	**Prohibition, control, and regulations, offence and penalties**	Understand the legal framework for prohibition, control, and penalties under the NDPS Act.	5/11/24	Handwritten notes & PPT	
5	**34**	**Drugs and magic Remedies act 1954**	Describe the objectives and restrictions under the Drugs and Magic Remedies Act, 1954.	6/11/24	Handwritten notes & PPT	
Tutorial-12 Facilitated in-depth discussion on critical subtopics.				6/11/24		
	35	**Objective, definition, prohibition of certain advertisements**		8/11/24	Handwritten notes & PPT	
	36	**Classes of exempted advertisements, offences, and penalties**	List the exempted advertisements and associated penalties under the act.	12/11/24	Handwritten notes & PPT	
6	**37**	**Prevention of cruelty to animals Act1954**	Understand the Prevention of Cruelty to Animals Act and the role of IAEC	13/11/24	Handwritten notes & PPT	
Tutorial-13 Explored real-world applications of previously taught content.				13/11/24		

	38	**Objective, definition. Brief overview of the institutional Animal Ethics Committee**		15/11/24	Handwritten notes & PPT	
	39	**Breeding and stocking of animals. Transfer and acquisitions of animals for experiments**	Describe regulations related to animal breeding, stock, and transfer for research.	26/11/24	Handwritten notes & PPT	
7	**40**	**PoisonAct_1919**	Explain the objectives and definitions under the Poisons Act, 1919.	27/11/24	Handwritten notes & PPT	
Tutorial-14 Explained tricky concepts using analogies.				27/11/24		
	41	**Possession for sale of poison, import of poison**	Learn about legal provisions for the possession, sale, and import of poisons.	29/11/24	Handwritten notes & PPT	
8	**42**	**FSSAI Act And Rules**	Briefly understand the FSSAI Act and its impact on pharmaceutical manufacturing.	3/12/24	Handwritten notes & PPT	
	43	**Storage, sales, and labelling of food supplements**	Understand rules related to the storage, sale, and labelling of food supplements.	4/12/24	Handwritten notes & PPT	
Tutorial-15 Conducted a rapid-fire quiz round for revision.				11/12/24		
9	**44**	**National Pharmaceutical Pricing Authority**	Explain the functions of the National Pharmaceutical Pricing Authority.	6/12/24	Handwritten notes & PPT	
	45	**Drug price control order**		10/12/24	Handwritten notes & PPT	

	46	**Sales prices of bulk drugs**	Learn how the government regulates the pricing of bulk drugs.	11/12/24	Handwritten notes & PPT	
	47	**Retail price of formulation**	Understand the calculation and control of retail pricing of formulations	13/12/24-17/12/24	Handwritten notes & PPT	
Tutorial-16 Encouraged students to ask "why" behind each concept.				18/12/24		
	48	**Pharmaceutical Policy 2002**	Study the key elements and objectives of the Pharmaceutical Policy, 2002	20/12/24	Handwritten notes & PPT	
	49	**National List of Essential Medicines**	Describe the purpose and scope of the National List of Essential Medicines	24/12/24	Handwritten notes & PPT	
10	**50**	**Code of Pharmaceutical Ethics**	Understand the ethical responsibilities outlined in the Code of Pharmaceutical Ethics.	27/12/24, 31/12/24	Handwritten notes & PPT	
Tutorial-17 Summarized major points from previous lectures using tables and charts.				18/01/25		

	51	**Definition, ethical principles**		16/01/25	Handwritten notes & PPT	
	52	**Ethical problem solving**	Learn approaches to resolving ethical dilemmas in pharmaceutical practice.	17/01/25	Handwritten notes & PPT	
	53	**Code of ethics**	Reinforce the importance of ethics in pharmacy with reference to ethics.	20/01/25	Handwritten notes & PPT	

Tutorial-18 Conducted a revision quiz on key concepts covered so far.				23/01/25		
	54	**A pharmacist's relationship to his job and trade**	Understand the professional expectations of a pharmacist in the workplace.	24/01/25	Handwritten notes & PPT	
	55	**Pharmacist‘s Oath**	Recite and interpret the Pharmacist’s Oath.	27/01/25	Handwritten notes & PPT	
11	**56**	**The Medical termination of pregnancy act**	Learn the basic legal framework of the Medical Termination of Pregnancy Act	30/01/25	Handwritten notes & PPT	
Tutorial-19 Revisited previous concepts through student-led questioning.				25/01/25		
	57	**Basic understanding And rules**	Rules of Medical Termination of Pregnancy Act	31/01/25	Handwritten notes & PPT	
	58	**Salient features and amendments**	Understand key amendments and features of the MTP Act	3/2/25	Handwritten notes & PPT	
12	**59**	**Role of all the government pharma regular bodies**	Identify the role of regulatory bodies like CDSCO and IPC.	6/2/25	Handwritten notes & PPT	
Tutorial-20 Conducted a rapid recap using short oral tests.				1/2/25		
	60	**Central drug standards control organization or the Indian Pharmacopoeia Commission**		7/2/25	Handwritten notes & PPT	
13	**61**	**Good regulatory practice (documentation, renewal, governance)**	Describe the principles of good regulatory practices in pharmacy	10/2/25	Handwritten notes & PPT	

	62	**Hospital pharmacy, manufacture, wholesale business, inspection**	Understand the legal norms of hospital pharmacy.	13/2/25	Handwritten notes & PPT	
Tutorial-21 Held a small group discussion to promote peer learning.				8/2/25		

	63	**Import and export of drugs and medical device**	Learn about the regulations concerning the import and export of drugs/devices.	14/2/25	Handwritten notes & PPT	
14	**64**	**Introduction to BCS system of classification**	Explain the Biopharmaceutical Classification System (BCS) of drug solubility and permeability.	17/2/25	Handwritten notes & PPT	
	65	**Basic concept of clinical trials**	Understand the basic phases and structure of clinical trials.	20/2/25	Handwritten notes & PPT	
Tutorial-22 Conducted a "teach-back" activity where students explained to peers.				15/2/25		
	66	**ANDA and NDA**	Differentiate between ANDA and NDA in drug approvals.	21/2/25	Handwritten notes & PPT	
	67	**New drug development**	Describe the stages of new drug development.	24/2/25	Handwritten notes & PPT	
	68	**New drug and clinical trial rules**	Study the updated rules related to new drug and clinical trials in India.	27/2/25	Handwritten notes & PPT	
Tutorial-23 Addressed student queries related to last week's topic.				22/2/25		
	69	**Brand, Trade, generic name concept, introduction to patent law**	Differentiate between brand, trade, and generic names; introduce patent laws.	28/2/25	Handwritten notes & PPT	
	70	**Emergency Use Authorization**	Understand the process of Emergency Use Authorization (EUA) for drugs.	3/3/25	Handwritten notes & PPT	

15	**71**	**Blood bank**	Learn basic infrastructural and regulatory requirements of a blood bank	17/3/25	Handwritten notes & PPT	
Tutorial-24 Focused on conceptual clarity through interactive Q&A.				1/3/25		
	72	**Functions**	Understand the critical functions and services of a blood bank.	20/3/25	Handwritten notes & PPT	
16	**73**	**Clinical Establishment Act and Rules**	Get introduced to the Clinical Establishment Act and its rules.	21/3/25	Handwritten notes & PPT	
	74	**Introduction**		24/3/25	Handwritten notes & PPT	
Tutorial-25 Discussed frequently asked exam questions on the topic.				15/3/25		
	75	**Aspects related to pharmacy**	Learn aspects of the Act relevant to pharmacy practice.	27/3/25	Handwritten notes & PPT	
17	**76**	**Biomedical Waste Management Act and Rules**	Study the pharma-related guidelines under Biomedical Waste Management Rules.	28/3/25	Handwritten notes & PPT	
	77	**Basic aspects related to the pharma Manufacture for the disposal of pharma/medical waste at home**		3/4/25	Handwritten notes & PPT	
Tutorial-26 Discussed and clarified doubts from the previous lectures.				22/3/25		
	78	**Pharmacy and hospital**	Understand the legal aspects connecting pharmacy and hospital practices.	4/4/25	Handwritten notes & PPT	
18	**79**	**Bioethics**	Learn the basic principles, history, & scope of bioethics.	7/4/25	Handwritten notes & PPT	

	80	**Basic concept, history, and principle**		11/4/25	Handwritten notes & PPT	
Tutorial-27 Discussed and clarified doubts from the previous lectures.				29/3/25		
	81	**A brief overview of ICMR National Ethical Guidelines for Biomedical**	Understand key ethical guidelines from ICMR for biomedical research.	17/4/25	Handwritten notes & PPT	
19	**82**	**Consumer Protection Act**	Get a brief understanding of the Consumer Protection Act related to pharmacy.	21/4/25	Handwritten notes & PPT	
20	**83**	**Disaster Management Act**	Study the basics of the Disaster Management Act from a healthcare perspective.	24/4/25	Handwritten notes & PPT	
Tutorial-28 Discussed frequently asked exam questions on the topic.				5/4/25		
	84	**Brief introduction about Disaster Management Act**		24/4/25	Handwritten notes & PPT	
21	**85**	**Medical devices**	Understand the classification and regulation of medical devices.	25/4/25	Handwritten notes & PPT	
	86	**Basic aspects related to manufacturing and sales**	Learn the basic requirements for manufacturing and selling medical devices.	26/4/25	Handwritten notes & PPT	

1. Total No. of Assignments: 03
2. Model question paper given: Yes/No
3. Number of extra lectures delivered:
4. Feedback from the student taken: Yes/No

Signature of the Subject Teacher **HOD** **Director cum Principal**