



ROYAL COLLEGE OF PHARMACY
COURSE: DIPLOMA IN PHARMACY
LESSON PLAN

Year	2nd
subject	Pharmacy Law and Ethics(ER20-26T)
Total Lecture	75
Each Lecture	1hr
*Practical	Not applicable

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

Course Objectives: This course will discuss the following

1. General perspectives, history, evolution of pharmacy law in India
2. Act and Rules regulating the profession and practice of pharmacy in India
3. Important code of ethical guidelines pertaining to various practice standards
4. Brief introduction to the patent laws and their applications in pharmacy

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

1. Describe the history and evolution of pharmacy law in India
2. Interpret the act and rules regulating the profession and practice of pharmacy in India
3. Discuss the various codes of ethics related to practice standards in pharmacy
4. Interpret the fundamentals of patent laws from the perspectives of pharmacy

Lecture No.	Topic to be Covered	Date	Remarks
	Unit -1: Introduction(2hr)		
1	General Principles of Law, History and various Acts related to Drugs and Pharmacy profession		
2	History and various Acts related to Drugs and Pharmacy profession		
	Unit -2: Pharmacy Act-1948 and Rules(5hr)		
3	Objectives, Definitions, Pharmacy Council of India; its constitution and functions		
4	Education Regulations		
5	State and Joint state pharmacy councils, Registration of Pharmacists		
6	Offences and Penalties.		

7	Pharmacy Practice Regulations 2015		
	Unit -3 :Drugs and Cosmetics Act 1940 and Rules 1945 and New Amendments(23hr)		
	CLASS TEST		
8	Objectives, Definitions		
9	Legal definitions of schedules to the Act and Rules Import of drugs – Classes of drugs and cosmetics prohibited from import,		
10	Import under license or permit.		
11	Manufacture of drugs		
12	Prohibition of manufacture and sale of certain drugs		
13	Conditions for grant of license and conditions of license for manufacture of drugs		
14	Manufacture of drugs for test		
15	Examination and analysis		
16	Manufacture of new drug, loan license and repacking license		
17	Study of schedule C and C1, G, H, H1, K, P, M, N, and X		
18	Sale of Drugs		
19	Wholesale, Retail sale and Restricted license		
20	Records to be kept in a pharmacy Drug		
21	Prohibited for manufacture and sale in India		
22	Administration of the Act and Rules – Drugs Technical Advisory Board, Committee, Central Drugs Laboratory, Drugs Consultative Government analysts, licensing authorities, controlling authorities, Drug Inspectors.		
23	Drugs Technical Advisory Board,		
24	Drugs Technical Advisory Board,		
25	REVISION		
26	Central Drugs Laboratory, Drugs		
27	Consultative Government analysts		
28	licensing authorities		
29	controlling authorities, Drug Inspectors		
30	Drug Inspectors		
	Unit -4 :Narcotic Drugs and Psychotropic Substances Act 1985 and Rules(2hr)		

31	Objectives, Definitions, Authorities and Officers, Prohibition.		
32	Control and Regulation, Offences and Penalties		
	Unit -5 :Drugs and Magic Remedies (Objectionable Advertisements) Act 1954(2hr)		
33	Objectives, Definitions, Prohibition of certain advertisements		
34	Classes of Exempted advertisements, Offences and Penalties.		
	ASSIGNMENT		
	Unit -6 :Prevention of Cruelty to Animals Act-1960(2hr)		
35	Objectives, Definitions, CPCSEA - brief overview, Institutional Animal Ethics Committee, Breeding and Stocking of Animals, Performance of Experiments		
36	Transfer and Acquisition of animals for experiment, Records, Power to suspend or revoke registration, Offences and Penalties		
	Unit -7:Poisons Act-1919 (2hr)		
37	Introduction, objective, definition, possession		
38	possession for sales and sale of any poison, import of poisons		
	Unit -8:FSSAI (Food Safety and Standards Authority of India) Act and Rules (2hr)		
39	Brief overview and aspects related to manufacture		
40	Storage, sale, and labelling of Food Supplements		
	Unit -9:National Pharmaceutical Pricing Authority: Drugs Price Control Order (DPCO) - 2013(5hr)		
41	Objectives, Definitions		
42	Sale prices of bulk drugs		
43	Retail price of formulations, Retail price and ceiling price of scheduled formulations		
44	Pharmaceutical Policy 2002		
45	National List of Essential Medicines (NLEM)		
	Unit -10: Code of Pharmaceutical Ethics(5hr)		

46	Definition, ethical principles,		
47	Ethical problem solving,		
48	Registration, code of ethics for		
49	Pharmacist in relation to his job, trade		
50	Medical profession and his profession, Pharmacist's oath		
	Unit -11: Medical Termination of Pregnancy Act and Rules (2hr)		
51	Basic understanding, salient features		
52	Amendments		
	Unit -12: Role of all the government pharma regulator bodies (1hr) Central Drugs Standards Control Organization (CDSCO), Indian Pharmacopoeia Commission (IPC)		
	Unit -13: Good Regulatory practices (documentation, licenses, renewals, e-governance) in Community Pharmacy(3hr)		
54	Hospital pharmacy, Pharmacy Manufacturing,		
55	Hospital pharmacy, Pharma Manufacturing,		
56	Import, export of drugs and medical devices		
	Unit -14: (7hr)		
57	Introduction to BCS system of classification		
58	Basic concepts of Clinical Trials		
59	ANDA, NDA, New Drug development		
60	ANDA, NDA, New Drug development		
61	Introduction to Patent Law		
62	Intellectual Property Rights		
63	Emergency Use Authorization		
	Unit -15: Blood bank (2hr)		
64	Basic requirement		
65	functions		
	ASSIGNMENT		
	Unit -16: Clinical Establishment Act and Rules(2hr)		
66	Aspects related to Pharmacy		
67	Aspects related to Pharmacy		

	Unit -17: Biomedical Waste Management Rules 2016(2hr)		
68	Basic aspects, and aspects related to pharma manufacture to disposal of pharma		
69	Medical waste at homes, pharmacies, and hospitals		
	Unit -18: Bioethics (2hr)		
70	Basic concepts, history and principles		
71	Brief overview of ICMR's National Ethical Guidelines for Biomedical and Health Research involving human participant		
	CLASS TEST		
	Unit -19:Introduction to the Consumer Protection Act (1hr)		
72	Introduction to the Consumer Protection Act		
	Unit -20:Introduction to the Disaster Management Act (1hr)		
73	Introduction to the Disaster Management Act		
	CLASS TEST		
	ASSIGNMENT		
	Unit -21: Medical Devices – Categorization, basic aspects related to manufacture and sale(2hr)		
74	Medical Devices – Categorization, basic aspects related to manufacture and sale		
75	Basic aspects related to manufacture and sale		

Sign of Faculty_____

Sign of H.O.D_____