DIPLOMA IN PHARMACY – 2nd YEAR
LESSON PLAN
PHARMACY LAW & ETHICS – THEORY

Course Code: ER20-26T 75 Hours (3 Hours/week) + 25 Hour Tutorial (1 Hour/ week)

Name of Tutor/Teacher: Dr. Shiv Kumar, Lecturer in Pharmacy

Schedule of Classes: Theory: Tuesday: 12.00 – 01.00 PM, Friday: 09.00-10.00 PM, Friday: 03.00 to 4.00 PM, Friday: 12.00 – 01.00 PM (Tutorial, Renu)

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 beable to

CO.2.6T.1: Describe the history and evolution of Pharmacy law in India

CO.2.6T.2: Interpret the act and rules regulating the profession and practice of Pharmacy in India

CO.2.6T.3: Discuss the various codes of ethics related to practice standards in Pharmacy

CO.2.6T.4: Interpret the fundamentals of patent laws from the perspectives of Pharmacy

Chapter	Topic	Date	Hour	CO	PO	Coverage	Reason for discrepancy	Plans for compensation in backlog	Taught by	Verified by
1	General Principles of Law, History and various Acts related to Drugs and Pharmacy profession-1		**1**							
	General Principles of Law, History and various Acts related to Drugs and Pharmacy profession-2		**2**							
2 Pharmacy Act-1948 and Rules:	Objectives, Definitions, Pharmacy Council of India;		**1**							
	Pharmacy Council of India; its constitution and functions,		**2**							
	Education Regulations, State and Joint state pharmacy councils,		**3**							
	Registration of Pharmacists, Offences and Penalties.		**4**							
	Pharmacy Practice Regulations 2015		**5**							
3 Drugs and Cosmetics Act 1940 and Rules 1945 and New Amendments	Objectives, Definitions, Legal definitions of schedules to the Act and Rules		**1**							
	Import of drugs – Classes of drugs and cosmetics prohibited from import, Import under license or permit.		**2**							
	Manufacture of drugs – Prohibition of manufacture and sale of certain drugs,		**3**							
	Conditions for grant of license and conditions of license for manufacture of drugs,		**4**							
	Manufacture of drugs for test, examination and analysis, manufacture of new drug,		**5**							
	Loan license and repacking license.		**6**							
	Study of schedule C and C1		**7**							

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3 Drugs and Cosmetics Act 1940 and Rules 1945 and New Amendments	Study of schedule G		**8**							
	Study of schedule H		**9**							
	Study of schedule H1		**10**							
	Study of schedule K		**11**							
	Study of schedule P		**12**							
	Study of schedule M		**13**							
	Study of schedule N		**14**							
	Study of schedule X		**15**							
	Sale of Drugs – Wholesale, Retail sale and Restricted license		**16**							
	Records to be kept in a Pharmacy		**17**							
	Drugs Prohibited for manufacture and sale in India		**18**							
	Administration of the Act and Rules – Drugs TechnicalAdvisory Board		**19**							
	Central Drugs Laboratory		**20**							
	Drugs Consultative Committee		**21**							
	Government analysts		**22**							
	Licensing authorities, controlling authorities, Drug Inspectors		**23**							
4 Narcotic Drugs and Psychotropic Substances Act 1985and Rules	Objectives, Definitions, Authorities and Officers,Prohibition,		**1**							
	Control and Regulation, Offences and Penalties.		**2**							

Chapter	Topic	Date	Hour	CO	PO	Coverage	Reason for discrepancy	Plans for compensation in backlog	Taught by	Verified by
5 Drugs and Magic Remedies (Objectionable Advertisements) Act 1954	Objectives, Definitions, Prohibition of certain advertisements		**1**							
	Classes of Exempted advertisements, Offences and Penalties.		**2**							
6 Prevention of Cruelty to Animals Act-1960:	Objectives, Definitions, CPCSEA - brief overview, Institutional Animal Ethics Committee, Breeding and Stocking of Animals, Performance of Experiments,		**1**							
	Transfer and Acquisition of animals for experiment, Records, Power to suspend or revoke registration, Offences and Penalties.		**2**							
7 Poisons Act-1919:	Introduction, objective, definition, possession		**1**							
	Possession for sales and sale of any poison,import of poisons		**2**							
8 FSSAI (Food Safety and Standards Authority of India) Act and Rules	Brief overview and aspects related to manufacture,									
	Storage, sale, and labelling of Food Supplements									
9 National Pharmaceutical Pricing Authority (NPPA)	Drugs Price Control Order (DPCO) - 2013. Objectives, Definitions,		**1**							
	Sale prices of bulk drugs, Retail price of formulations,		**2**							
	Retail price and ceiling price of scheduled formulations		**3**							
	Pharmaceutical Policy 2002,		**4**							
	National List of Essential Medicines (NLEM)		**5**							

Chapter	Topic	Date	Hour	CO	PO	Coverage	Reason for discrepancy	Plans for compensation in backlog	Taught by	Verified by
10 Code of Pharmaceutical Ethics	Definition, ethical principles,		**1**							
	Ethical problem solving, registration,		**2**							
	Code of ethics for Pharmacist in relation to his job & trade.		**3**							
	Code of ethics for Pharmacist in relation to medical profession and his profession,		**4**							
	Pharmacist's oath.		**5**							
11 Medical Termination of Pregnancy Act and Rules	Basic understanding, salient features,		**1**							
	Amendments		**2**							
12 Role of all the government pharma regulator bodies	Central Drugs Standards Control Organization (CDSCO), Indian Pharmacopoeia Commission (IPC)		**1**							
13 Good Regulatory Practices	Good Regulatory practices (documentation, licenses, renewals, e-governance) in Community Pharmacy		**1**							
	Hospital pharmacy, Pharma Manufacturing		**2**							
	Wholesale business, inspections, import, export of drugs and medical devices		**3**							
14 Intellectual Property Rights	Introduction to BCS system of classification,		**1**							
	Basic conceptsof Clinical Trials,		**2**							
	ANDA, NDA,		**3**							

Chapter	Topic	Date	Hour	CO	PO	Coverage	Reason for discrepancy	Plans for compensation in backlog	Taught by	Verified by
14 Intellectual Property Rights	New Drug development, New Drugs and Clinical Trials Rules, 2019		**4**							
	Brand v/s Generic, Trade name concept		**5**							
	Introduction to Patent Law and Intellectual Property Rights,		**6**							
	Emergency Use Authorization		**7**							
15 Blood Bank	Blood bank – basic requirements		**1**							
	Blood bank –functions		**2**							
16 Clinical Establishment Act and Rules	Aspects related to Pharmacy		**1**							
	Aspects related to Pharmacy		**2**							
17 Biomedical Waste Management Rules 2016	Basic aspects, and aspects related to pharma manufacture to disposal of pharma		**1**							
	Basic aspects, and aspects related to pharma manufacture to disposal of medical waste at homes, pharmacies, and hospitals		**2**							
18 Bioethics	Basic concepts, history and principles.		**1**							
	Brief overview of ICMR's National Ethical Guidelines for Biomedical and Health Research involving human participants		**2**							
19	Introduction to the Consumer Protection Act		**1**							
20	Introduction to the Disaster Management Act		**1**							
21 Medical Devices	Medical Devices – Categorization		**1**							
	Medical Devices –Basic aspects related to manufacture and sale		**2**							

Assignment

The students shall be asked to submit written assignments on the following topics (One assignment per student per sessional period. i.e., a minimum of THREE assignments per student)

1. Requirements for Ayurvedic, Homeopathic manufacturing, sale, and licensing requirements.
2. Layout and contents of official websites of various agencies regulating the profession of pharmacy in India: e.g., CDSCO, SUGAM portal, PCI, etc.
3. Licenses required, application processes (online/offline), drug regulatory officewebsite of the respective state
4. Case studies – actions taken on violation of any act/rule related to Pharmacy
5. Schedule H1 drugs and its implementation in India
6. Counterfeit / Spurious medicines
7. Drug Testing Labs in India
8. Overview of Pharma marketing practices
9. Generic Medicines

Recommended Books

1. Text book of Forensic Pharmacy by B.M. Mithal
2. Forensic Pharmacy by B. Suresh
3. Hand book of drug law-by M.L. Mehra
4. A text book of Forensic Pharmacy by N.K. Jain
5. Drugs and Cosmetics Act/Rules by Govt. of India publications.
6. Medicinal and Toilet preparations Act 1955 by Govt. of India Publications.
7. Narcotic Drugs and Psychotropic Substances Act by Govt. of India Publications
8. Drugs and Magic Remedies Act by Govt. of India Publications.
9. CDSCO Website, NPPA Website
10. Books on Drugs and Cosmetic Act by Nilesh Gandhi and Sudhir Deshpande
11. Text Book of Forensic Pharmacy by Dr Guruprasad Mohanta