TEACHING PLAN: PHARMACY LAW AND ETHICS (ER20-26T)

SCHOOL: (SOP) SCHOOL OF PHARMACY		**ACADEMIC SESSION: 2023 – 2024**	**FOR STUDENTS': D. PHARMACY II**
1	**Course No.**	DP-II	
2	**Course Title**	**Pharmacy law and ethics.**	
3	**Credits**	**4**	
4	**Learning Hours**	Contact Hours 75	
5	**Course Objective**	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	
6	**Course Outcomes**	After completing the 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	
7	**Outline syllabus:**		

7.01	**Paper Code**	**Unit**	**Introduction**	**Page Numbers[1]**	**Lectures**
7.02	**ER20-26T Unit I**	(a)	General Principles of Law, History and various Acts related to Drugs and Pharmacy profession Pharmacy Act-1948 and Rules: Objectives, Definitions, Pharmacy Council of India; its constitution and functions, Education Regulations, State and Joint state pharmacy councils		4
		(b)	Registration of Pharmacists, Offences and Penalties. Pharmacy Practice Regulations 2015		2
		(c)	Drugs and Cosmetics Act 1940 and Rules 1945 and New Amendments 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		4
7.03	**ER20-26T Unit II**	(a)	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		4

			and analysis, manufacture of new drug, loan license and repacking license. Study of schedule C and C1, G, H, H1, K, P, M, N, and X		
		(b)	Narcotic Drugs and Psychotropic Substances Act 1985 and Rules Objectives, Definitions, Authorities and Officers, Prohibition, Control and Regulation, Offences and Penalties.		6
		(c)	Drugs and Magic Remedies (Objectionable Advertisements) Act 1954 Objectives, Definitions, Prohibition of certain advertisements, Classes of Exempted advertisements, Offences and Penalties		3
		(d)	Prevention of Cruelty to Animals Act-1960: Objectives, Definitions, CPCSEA - brief overview, Institutional Animal Ethics Committee, 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. Poisons Act-1919: Introduction, objective, definition, possession, possession for sales and sale of any poison, import of poisons		4
7.04	**ER20-26T Unit III**	(a)	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		4
		(b)	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, Pharmaceutical Policy 2002, National List of Essential Medicines (NLEM)		3
7.05	**ER20-26T Unit IV**	(a)	Code of Pharmaceutical Ethics: Definition, ethical principles, ethical problem solving, registration, code of ethics for Pharmacist in relation to his job, trade, medical profession and his profession, Pharmacist's oath. Medical Termination of Pregnancy Act and Rules – basic understanding, salient features, and Amendments		3
		(b)	Role of all the government pharma regulator bodies – Central Drugs Standards Control Organization (CDSCO), Indian Pharmacopoeia Commission (IPC)		3
		(c)	Good Regulatory practices (documentation, licenses, renewals, e-governance) in Community Pharmacy, Hospital pharmacy, Pharma Manufacturing, Wholesale business, inspections, import, export of drugs and		3

			medical devices		
		(d)	Introduction to BCS system of classification, Basic concepts of Clinical Trials, ANDA, NDA, New Drug development, New Drugs and Clinical Trials Rules, 2019. Brand v/s Generic, Trade name concept, Introduction to Patent Law and Intellectual Property Rights, Emergency Use Authorization		4
		(e)	Blood bank – basic requirements and functions 2 16 Clinical Establishment Act and Rules – Aspects related to Pharmacy		4
		(f)	Biomedical Waste Management Rules 2016 – Basic aspects, and aspects related to pharma manufacture to disposal of pharma / medical waste at homes, pharmacies, and hospitals		4
7.06	**ER20-26T Unit V**	(a)	Bioethics - Basic concepts, history and principles.		4
		(b)	Brief overview of ICMR's National Ethical Guidelines for Biomedical and Health Research involving human participants		4
		(c)	Introduction to the Consumer Protection Act		4
		(a)	Introduction to the Disaster Management Act		4
7.7	**ER20-26T Unit VI**	(b)	Medical Devices – Categorization, basic aspects related to manufacture and sale		4
8	**Course Evaluation**				
8.1	**Internal Assessment: Continuous Mode**				
8.2	**Attendance**	75 Marks			
9	**Text Books & References**				
9.1	**Text book**	A.K Gupta \ S.S Bajaj\pee vee			
9.2	**References**	1. Indian pharmacopoeia. 2. British pharmacopoeia.			
9.3	**Video References**	1. https://www.youtube.com/watch?v=hgtydgMNr3E 2. https://www.youtube.com/watch?v=qGKW_RJzOes 3. https://www.youtube.com/watch?v=4umc9-hIAjI 4. https://www.youtube.com/watch?v=WHYTwG8C69Q 5. https://www.youtube.com/watch?v=6r86n1r-LRQ 6. https://www.youtube.com/watch?v=hnCrQyL0vHc 7. https://www.youtube.com/watch?v=jFH10HJWYPI 8. https://www.youtube.com/watch?v=9r2uWw7gmS8 9. https://www.youtube.com/watch?v=eshYFf-nSGI 10. https://www.youtube.com/watch?v=FMrdRJb1Mr0		

QUESTION BANK

Unit I

11. Write a note on introduction to pharmaceutical jurisprudence.
2. Define the code of ethics
3. Scope of forensic pharmacy
4. Pharmacist role in drug treatment and drug usage
5. Role of pharmacist in drug interaction
6. Role of pharmacist in therapeutic drug monitoring
7. Enumerate the profession of pharmacy
8. Role of pharmacist in relation to his job
9. Pharmacist in relation to medical profession.

UNIT II

1. Write a note on pharmacy council of india (PCI)

2. Constitution and composition of the pharmacy council of india.
3. Note on education regulation
4. Difference between state pharmacy council joint and state pharmacy
5. Describe about the registration of pharmacists
6. Procedure for removal from register.

UNIT III

1. Aims and objective of drugs and cosmetics act 1940.
2. Describe schedules to drug rules.
3. Brief notes on schedule M.
4. Describe the list of diseases of schedule J.
5. Write the classes of drug totally prohibited to be imported.
6. Drugs which can be imported under licence or permit.
7. Shorts notes on imports of schedule C &C1.
8. Notes over control import of drugs and cosmetics.
9. Brief notes on manufacture of biological and other special product.
10. Write about the loan licences.
11. Write down the supply of schedule C drugs.
12. Write down the supply of schedule H drugs.
13. Describe about labelling and packing of drugs.
14. Write the procedure of inspectors.
15. Describe about schedule X drugs.

UNIT IV

1. Definition of drug and magic remedies and notes on exempted advertisement
2. Describe the drugs come under narcotic and psychotropic substance act
3. List of narcotic drugs.
4. List of psychotropic substance
5. Operation controlled by the central government
6. Operation controlled by the state government.
7. Write the offences and penalties of narcotic drugs.
8. Cultivation of poppy for poppy heads only.
9. Production and supply of the opium.
10. Describe import of the narcotic and psychotopic substance.

UNIT V

1. Define the bonded laboratory
2. Describe manufacture of alcoholic preparation
3. Write notes on non –bonded laboratory.
4. Write Brief note on Warehouse of alcoholic preparation.

5. Describe the power to fix retail price.
6. Describe the power to fix ceiling prices.
7. Notes on registration committee.
8. Define the following terms.

a. Bulk drug.
b. Formulation.
c. Ceiling price.
d. Manufacture.