DIPLOMA IN PHARMACY (FIRST YEAR)

SUBJECT : **PHARMACY LAW AND ETHICS**
SUBJECT TEACHER : MR. JATIN MOHANTY
TOTAL HOURS ASSIGNED : **Theory: 75 hours or 82 classes**

SL. NO.	TITLE OF UNIT/ CHAPTER	THEORY DAY	TOPICS TO BE COVERED	DATE	ACTUALLY COVERED	REMARK
1.	Introduction	1.	General Principles of Law			
		2.	History and various Acts related to Drugs and Pharmacy profession			
2.	Pharmacy Act-1948 and Rules	3.	Objectives, Definitions, Pharmacy Council of India its constitution			
		4.	Pharmacy Council of India its functions			
		5.	Offences and Penalties			
		6.	Education Regulations, State and Joint state pharmacy councils			
		7.	Registration of Pharmacists			
		8.	Offences and Penalties			
		9.	Pharmacy Practice Regulations 2015			
3.	Drugs and Cosmetics Act 1940 and Rules 1945 and New Amendments	10.	Objectives, Definitions, Legal definitions of schedules to the Act and Rules			
		11.	Import of drugs – Classes of drugs and cosmetics prohibited from import			
		12.	Import under license or permit.			
		13.	Import under license or permit.			
		14.	Manufacture of drugs – Prohibition of manufacture and sale of certain drugs			
		15.	Conditions for grant of license and conditions of license for manufacture of drugs			
		16.	Manufacture of drugs for test, examination and analysis			
		17.	manufacture of new drug, loan license and repacking license.			

		18.	Study of schedule C and C1, G, H, H1, K, P, M, N, and X.			
		19.	Study of schedule C and C1, G, H, H1, K, P, M, N, and X.			
		20.	Study of schedule C and C1, G, H, H1, K, P, M, N, and X.			
		21.	Study of schedule C and C1, G, H, H1, K, P, M, N, and X.			
		22.	Study of schedule C and C1, G, H, H1, K, P, M, N, and X.			
		23.	Study of schedule C and C1, G, H, H1, K, P, M, N, X.			
		24.	Sale of Drugs – Wholesale			
		25.	Sale of Drugs –Retail sale			
		26.	Sale of Drugs –Restricted license			
		27.	Records to be kept in a pharmacy Drugs Prohibited for manufacture and sale in India			
		28.	Records to be kept in a pharmacy Drugs Prohibited for manufacture and sale in India			
		29.	Administration of the Act and Rules – Drugs Technical Advisory Board			
		30.	Central Drugs Laboratory			
		31.	Drugs Consultative Committee			
		32.	Government analysts			
		33.	licensing authorities			
		34.	controlling authorities			
		35.	Drug Inspectors			
4.	Narcotic Drugs and Psychotropic Substances Act 1985 and Rules	36.	Objectives, Definitions, Authorities and Officers, Prohibition			
		37.	Control and Regulation, Offences and Penalties.			
5.	Drugs and Magic Remedies (Objectionab	38.	Objectives, Definitions, Prohibition of certain advertisements			
		39.	Classes of Exempted			

	Ic Advertisements) Act 1954		advertisements, Offences and Penalties.			
6.	Prevention of Cruelty to Animals Act-1960:	40.	Objectives, Definitions, CPCSEA - brief overview, Institutional Animal Ethics Committee, Breeding and Stocking of Animals, Performance of Experiments			
		41.	Transfer and Acquisition of animals for experiment, Records, Power to suspend or revoke registration, Offences and Penalties			
7.	Poisons Act-1919	42.	Introduction, objective, definition, possession			
		43.	possession for sales and sale of any poison, import of poisons			
8.	FSSAI (Food Safety and Standards Authority of India) Act and Rules	44.	Brief overview and aspects related to manufacture			
		45.	Storage, sale, and labelling of Food Supplements			
9.	National Pharmaceutical Pricing Authority	46.	Drugs Price Control Order (DPCO) - 2013. Objectives, Definitions			
		47.	Sale prices of bulk drugs			
		48.	Retail price of formulations			
		49.	Retail price and ceiling price of scheduled formulations			
		50.	Pharmaceutical Policy 2002			
		51.	National List of Essential Medicines (NLEM)			
10.	Code of Pharmaceutical Ethics	52.	Definition, ethical principles			
		53.	Ethical problem solving			
		54.	Registration			
		55.	Code of ethics for Pharmacist in relation to his job, trade, medical profession and his profession,			
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		57.	Pharmacist's oath			
11.	Medical Termination of Pregnancy Act and Rules	58.	Basic understanding			
		59.	Salient features, and Amendments			
12.	Role of all the government pharma regulator bodies	60.	Central Drugs Standards Control Organization (CDSCO), Indian Pharmacopoeia Commission (IPC)			
13.	Good Regulatory practices	61.	(Documentation, licenses, renewals, e-governance) in Community Pharmacy			
		62.	Hospital pharmacy, Pharma Manufacturing			
		63.	Wholesale business, inspections, import, export of drugs and medical devices			
14.	Introduction to BCS system of classification	64.	Basic concepts of Clinical Trials, ANDA, NDA			
		65.	New Drug development			
		66.	New Drugs and Clinical Trials Rules, 2019.			
		67.	Brand v/s Generic, Trade name concept			
		68.	Introduction to Patent Law			
		69.	Intellectual Property Rights			
		70.	Emergency Use Authorization			
15.	Blood bank	71.	Basic requirements			
		72.	Functions			
16.	Clinical Establishment Act and Rules	73.	Aspects related to Pharmacy			
		74.	Aspects related to Pharmacy			
17.	Biomedical Waste Management Rules 2016	75.	Basic aspects, and aspects related to pharma manufacture to disposal of pharma			
		76.	medical waste at homes, pharmacies, and hospitals			
18.	Bioethics	77.	Basic concepts, history and principles			
		78.	Brief overview of ICMR's National Ethical Guidelines for Biomedical and Health Research involving human participants			

	Introduction to the Consumer Protection Act	78.	Basic understanding and features			
20.	Introduction to the Disaster Management Act	80.	Basic understanding and features			
21.	Medical Devices	81.	Categorization, basic aspects related to manufacture and sale			
		82.	basic aspects related to manufacture and sale			

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