## **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.	TITLE OF	THEORY	TOPICS TO BE	DATE	ACTUALLY	REMARK
NO		DAY	COVERED		COVERED	
	CHAPTER					
1.	Introduction	1.	General Principles of Law			
		2.	History and various Acts			
			related to Drugs and			
			Pharmacy profession			
2.	Pharmacy	3.	Objectives, Definitions,			
	Act-1948		Pharmacy Council of			
	and Rules		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	10.	Objectives, Definitions,			
	Cosmetics		Legal definitions of			
	Act 1940 and		schedules to the Act and	1		
	Rules 1945		Rules			
	and New	11.	Import of drugs - Classes			
	Amendment		of drugs and cosmetics	1		
	s		prohibited from import			
		12.	Import under license or			
- 1			permit.			
	Γ	13.	Import under license or			
	1		permit.			
	Γ	14.	Manufacture of drugs -	1		
			Prohibition of	1		
- 1			manufacture and sale of	1		
	-1		certain drugs			
		15.	Conditions for grant of			
	1		license and conditions of			
			license for manufacture of			
			drugs			
		16.	Manufacture of drugs for			
		1	test, examination and			į
		۱:	analysis			
	-	17.	manufacture of new drug,			
			oan license and			
			epacking license.			



		18.	Ct. 1			
		10.	Study of schedule C and			
			C1, G, H, H1, K, P, M, N,			
	H		and X.			
		19.	Study of schedule C and			
			C1, G, H, H1, K, P, M, N,			
			and X.			
		20.				
		20.	Study of schedule C and			
			C1, G, H, H1, K, P, M, N,			
	1		and X.			
		21.	Study of schedule C and			
			C1, G, H, H1, K, P, M, N,			
			and X.			
		22.	Study of schedule C and			
					may of the	
			C1, G, H, H1, K, P, M, N,			
	1		and X.			
		23.	Study of schedule C and			
			C1, G, H, H1, K, P, M, N,		A	
			X.			
		24.	Sale of Drugs - Wholesale			
		25.	Sale of Drugs -Retail sale			
		26.	Sale of Drugs –Restricted			
		20.	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		5	
			manufacture and sale in			
			India			
		29.	Administration of the Act			
		2).	and Rules - Drugs			
			Technical Advisory Board			
		20				
		30.	Central Drugs			
			Laboratory			
		31.	Drugs Consultative			
			Committee		Table 4 of the second	
		32.	Government analysts			
		33.	licensing authorities			
		34.	controlling authorities			
		54.	don't oming authorities			
		35.	Drug Inspectors			
4.	Narcotic	36.	Objectives, Definitions,			
	Drugs and		Authorities and Officers,			
	Psychotropic		Prohibition			
	Substances	37.	Control and Regulation,		<u> </u>	
	Act 1985 and	•	Offences and Penalties.			
	Rules		Officiaces and I chainles.			
5.	<del></del>	20	Objective D. C. ''	-	-	
J.	Drugs and	38.	Objectives, Definitions,			
	Magic		Prohibition of certain			
	Remedies		advertisements			
	(Objectionab	39.	Classes of Exempted			
	1					
			2			_

1				-		
			advertisements, Offences			
1	le		advertisements,			The same and the s
	Advertiseme		and Penalties.			
	nts) Act 1954			1		
	Prevention	40.	Objectives, Definitions,	1		
6.	Prevention		CPCSEA - brief overview,			
	of Cruelty to		Institutional Animal			
	Animals Act-		Ethics Committee,			
	1960:		Ethics Committee,			
			Breeding and Stocking of	}		and the latest and th
			Animals, Performance of		-	
			r animonts			
	l	41.	Transfer and Acquisition			
		41.	of animals for			
			experiment, Records,			
			Power to suspend or			
			revoke registration,			
			Offences and Penalties			
			Introduction, objective,			
7.	Poisons Act-	42.	Introduction, objects			
/•	1919		definition, possession			
	1515	43.	possession for sales and			
			sale of any poison, import			
			Chaicans			
	FSSAI (Food	44.	Brief overview and			
8.	FSSAI (Food		aspects related to			
	Safety and Standards		manufacture			
	Standards	45.	Storage, sale, and			
	Authority of		labelling of Food			
	India) Act and Rules		Supplements			
	National National	46.	Drugs Price Control			
9.	Pharmaceuti		Order (DPCO) - 2013.			
	cal Pricing		Order (DI Co) Objectives, Definitions Sale prices of bulk drugs			
	Authority	47.	Sale prices of built as a			
	Authorny	48.	Retail price of			
			formulations  Retail price and ceiling			
		49.	price of scheduled			
			formulations			
			Pharmaceutical Policy			
		50.	Pharmaceutical 2			
			2002 National List of Essential			
		51.	Medicines (NLEM)			
			Definition, ethical			
10.	Code of	52.	principles			
	Pharmaceuti		Ethical problem solving			
	cal Ethics	53.	Registration			
	1 -	54.	Code of ethics for			
		55.	Pharmacist in relation to			
			his job, trade, medical			Total Miles
			profession and his			
			profession,			
	-	<i>E(</i>	Code of ethics for			
		56.	Pharmacist in relation to			
			his job, trade, medical profession and his			
			profession and his	1		
			profession	i	9	1



		57.	Pharmacist's oath		en degla en procesor en	Address of the books of the boo
11.	Medical	Processor of the Control of the Cont	nemen interview or forecast of the first behalf the majoritation of the contract of the contra	and the second of the		the state of the s
11.	and the same of th	58.	Basic understanding	and a second second second second second	read purples are on a person in a rain	
	Termination	59.	Salient features, and			
	of Pregnancy		Amendments			
	Act and					
or the constant	Rules	of a particular to a manufacture of			period distribution make the format	the same of the same and the sa
12.	Role of all	60.	Central Drugs Standards			
	the		Control Organization			
	government		(CDSCO), Indian			
	pharma		Pharmacopocia	1		
	regulator		Commission (IPC)			
The same sales and	bodies			and the second second second second second	and a second desired in the same self-transfer over such	
13.	Good	61.	(Documentation, licenses,			
	Regulatory		renewals, e-governance)			
	practices		in Community Pharmacy		and addressed the reservoir secure and transcention	
		62.	Hospital pharmacy,			
		63	Pharma Manufacturing Wholesale business,	and the second s		
		63.	inspections, import,			
			export of drugs and			
			medical devices			Company of the Compan
14.	Introduction	64.	Basic concepts of Clinical			
14.	to BCS		Trials, ANDA, NDA			
	system of classification	65.	New Drug development		Alle Berg Steel Victoria Citable	
		66.	New Drugs and Clinical			
			Trials Rules, 2019.		complete with the anapolitic state of	and the second s
		67.	Brand v/s Generic, Trade name concept			
		68.	Introduction to Patent		And the little of the latest and the	
		08.	Law		the second of the second second second second	
		69.	Intellectual Property			
			Rights		the state of the s	and the second s
		70.	Emergency Use			
			Authorization		proprieta de la compansa de la compa	
15.	Blood bank	71.	Basic requirements Functions		A RESIDENCE OF THE PARTY OF	and the second of the second o
		72.	Aspects related to		A STATE OF THE PARTY OF THE PAR	the second secon
16.	Clinical Establishme	73.	Pharmacy			
	nt Act and	74.	Aspects related to			
	Rules	,	Pharmacy			
17.		75.	Basic aspects, and aspects			
	Waste		related to pharma			
	Management		manufacture to disposal			
	Rules 2016	76	of pharma medical waste at homes,			
		76.	pharmacies, and hospitals			
18.	Bioethics	77.	Basic concepts, history			
10.			and principles			
		78.	Brief overview of ICMR's			
			National Ethical			
			Guidelines for Biomedical			
			and Health Research			
			involving human participants			
			participants			

À	native distribution of the Consumer Protection Act	W	Rasic understanding and features		
rik.	Introduction to the Disaster Management Act	\$4.	Exoic understanding and features		
21.	Medical Devices	81.	Categorization, basic aspects related to manufacture and sale		
		82.	basic aspects related to manufacture and sale		

SIGNATURE OF FACULTY