Lesson Plan			
Name of faculty :	Mr. Vikas		
Discipline :	DIPLOMA IN PHARMACY		
Semester/Year :	2nd Year		
Subject/Code :	PHARMACY LAW & ETHICS - ER20-26T		
Lession Plan Duration :	39 weeks (Aug. 2023 to July 2024)		
Work Load (Lecture/Practical) per week (in Hours) :			
WEEK	THEORY		PRACTICAL
	LECTURE DAY	**Topic (Including Assignment/Test)**	NOT APPLICABLE
1st	1st	Pharmacy Law & ethics introduction, scope and objective	
	2nd	History and various Acts related to Drugs and Pharmacy profession	
	3rd	Revision	
2st	1st	Pharmacy Act-1948 and Rules Definitions and objective	
	2nd	Pharmacy Council of India; its constitution and functions	
	3rd	Revision	
3rd	1st	Education Regulations, State and Joint state pharmacy councils	
	2nd	Registration of Pharmacists, Offences and Penalties.	
	3rd	Pharmacy Practice Regulations 2015	
4th	1st	Revision	
	2nd	Drugs and Cosmetics Act 1940 and Rules 1945 and New Amendments : Objectives, Definitions	
	3rd	Legal definitions of schedules to the Act	
5th	1st	Import of drugs – Classes of drugs and cosmetics prohibited from import, Import under license or permit	
	2nd	Manufacture of drugs – Prohibition of manufacture and sale of certain drugs	
	3rd	Conditions for grant of license and conditions of license for manufacture of drugs, Manufacture of drugs for test, examination and analysis	
6th	1st	Manufacture of new drug, loan license and repacking license.	
	2nd	Revision	
	3rd	Study of schedule C and C1, G, H, H1, K, P, M, N, and X.	
7th	1st	Sale of Drugs – Wholesale, Retail sale and Restricted license, Records to be kept in a pharmacy	
	2nd	Drugs Prohibited for manufacture and sale in India	
	3rd	Drugs Technical Advisory Board, Central Drugs Laboratory, Drugs	
8th	1st	Revision	
	2nd	Consultative Committee, Government analysts, licensing authorities	

	3rd	Controlling authorities, Drug Inspectors.
9th	1st	Revision
	2nd	Narcotic Drugs and Psychotropic Substances Act 1985 and Rules : Objectives, Definitions
	3rd	Authorities and Officers, Prohibition, Control and Regulation, Offences and Penalties
10th	1st	Revision
	2nd	Revision
	3rd	Revision
11th	1st SESSIONAL EXAMINATION	
12th	1st	Drugs and Magic Remedies Act 1954 : Objectives, Definitions, Prohibition of certain advertisements
	2nd	Classes of Exempted advertisements, Offences and Penalties.
	3rd	Revision
13th	1st	Prevention of Cruelty to Animals Act-1960: Objectives, Definitions, CPCSEA - brief overview, Institutional Animal Ethics Committee, Breeding and Stocking of Animals
	2nd	Performance of Experiments, Transfer and Acquisition of animals for experiment, Records, Power to suspend or revoke registration, Offences and Penalties.
	3rd	Revision
14th	1st	Poisons Act-1919: Introduction, objective, definition
	2nd	Possession, possession for sales and sale of any poison, import of poisons
	3rd	Revision
15th	1st	FSSAI Act and rules : brief overview and aspects related to manufacture
	2nd	Storage, sale, and labelling of Food Supplements
	3rd	Revision
16th	1st	National Pharmaceutical Pricing Authority: Drugs Price Control Order (DPCO) - 2013. Objectives, Definitions, Sale prices of bulk drugs
	2nd	Retail price of formulations, Retail price and ceiling price of scheduled formulations, Pharmaceutical Policy 2002, National List of Essential Medicines (NLEM)
	3rd	Revision
17th	1st	Code of Pharmaceutical Ethics: Definition, ethical principles, ethical problem solving
	2nd	Registration, code of ethics for Pharmacist in relation to his job, trade
	3rd	Medical profession and his profession, Pharmacist's oath
18th	1st	Medical Termination of Pregnancy Act and Rules – basic understanding,
	2nd	Salient features, and Amendments
	3rd	Role of all the government pharma regulator bodies – Central Drugs Standards Control Organization (CDSCO), Indian Pharmacopoeia Commission (IPC)

19th	1st	Good Regulatory practices (documentation, licenses, renewals, e-governance) in Community Pharmacy, Hospital pharmacy
	2nd	Pharma Manufacturing, Wholesale business, inspections, import, export of drugs and medical devices
	3rd	Introduction to BCS system of classification, Basic concepts of Clinical Trials, ANDA, NDA, New Drug development
20th	1st	New Drugs and Clinical Trials Rules, 2019. Brand v/sGeneric, Trade name concept
	2nd	Introduction to Patent Law and Intellectual Property Rights, Emergency Use Authorization
	3rd	Revision
21st	1st	Blood bank – basic requirements and functions
	2nd	Clinical Establishment Act and Rules – Aspects related to Pharmacy
	3rd	Revision
22nd	1st	Biomedical Waste Management Rules 2016 – Basic aspects, and aspects related to pharma manufacture to disposal of pharma
	2nd	Medical waste at homes, pharmacies, and hospitals
	3rd	Revision
23rd	WINTER VACATION	
24th	1st	Revision
	2nd	Revision
	3rd	Revision
25th	2nd SESSIONAL EXAMINATION	
26th	1st	Bioethics - Basic concepts, history and principles.
	2nd	Brief overview of ICMR's National Ethical Guidelines for Biomedical and Health Research involving human participants
	3rd	Revision
27th	1st	Revision
	2nd	Introduction to the Consumer Protection Act
	3rd	Revision
28th	1st	Revision
	2nd	Introduction to the Disaster Management Act
	3rd	Revision
29th	1st	Revision
	2nd	Medical Devices – Categorization

	3rd	Revision
30th	1st	Revision
	2nd	Basic aspects related to manufacture and sale
	3rd	Revision
31st	1st	Revision
	2nd	Revision
	3rd	Revision
32nd	1st	Revision
	2nd	Revision
	3rd	Revision
33rd	1st	Revision
	2nd	Revision
	3rd	Revision
34th	3rd Sessional Examination	
35th	1st	Revision
	2nd	Revision
	3rd	Revision
36th	1st	Revision
	2nd	Revision
	3rd	Revision
37th	1st	Revision
	2nd	Revision
	3rd	Revision
38th	1st	Revision
	2nd	Revision
	3rd	Revision
39th	1st	Revision
	2nd	Revision
	3rd	Revision