JHARKHAND Rai University
UGC RECOGNISED UNIVERSITY
ACCREDITED BY NAAC

Lesson Plan & Tracking

Programe : D. Pharm	**Session : 2022-2023**	**Year : 2nd Year**	

Course: Pharmacy law & ethics(Theory)

Name of the Faculty: APURWA BHARDWAJ	**Commencement Date: 29.08.2022**	**Date of Closure:**

Lecture No.	Week	Unit	Topics to be Covered	Blended Mode			Date	Duration	Tracking of Lectures	Related Course Outcome	Signature of Faculty	Signature of HoD	Remarks (if any)
				ICT Tool/Platform/ LMS	Resources	Activity							
1	1	Unit-I	Introduction to pharmaceutical legislation in india,Drug enquiry commitee										
2			Health survey & Development committees										
3			Pharmacy act 1948-Objectives,definitions,its constitution & functions.										
4	2	Unit-I	Education regulations										
5			State & joint state pharmacy councils										
6			Registration of pharmacists										
7	3	Unit-I	Offences & penalties under the Act.										
8			Drug & cosmetics Act 1940 -Objectives										

9			Drug & cosmetics Act-definitions										
10	4	Unit-I	Legal definitions of schedule to the Act										
11			Rules import of drugs										
12			Classes of drugs & cosmetics prohibited from import										
13	5	Unit-I	Import under license										
14			Manufacture of drugs ,prohibition & sale .										
15			Conditions for grant of license										
16	6	Unit-I	License for manufacture of drugs										
17			Manufacture of drugs for test										
18			Examination & analysis.										
19	7	Unit-I	Sale of Drugs – Wholesale										
20			Retail sale										
21			Restricted license										

22	8	Unit-I	Records to be kept in a pharmacy										
23			Drugs Prohibited for manufacture and sale in India										
24			Administration of the Act and Rules – Drugs Technical Advisory Board										
25	9	Unit-I	Central Drugs Laboratory, Drugs Consultative Committee										
26			Government analysts, licensing authorities										
27			Controlling authorities, Drug Inspectors.										
28	10	Unit-II	Narcotic drugs & psychotropic substances Act 1985-objectives,definitions,authorities & officers.										
29			Prohibition,control & regulation,offences & penalties.										
30			Drugs & magic remedies Act 1954-objectives,definitions,prohibition of certain advertisements										
31	11	Unit-II	Classes of exempted advertisements,offences & penalties.										
32			Prevention of Cruelty to Animals Act-1960: Objectives,Definitions, CPCSEA - brief overview, Institutional Animal										

33			Ethics Committee,Breeding and Stocking of Animals, Performance of Experiments, Transfer and Acquisition of animals for experiment.										
34			Records, Power to suspend or revoke registration, Offences and Penalties.										
35	12	Unit-II	Poisons Act-1919: Introduction, objective,definition.										
36			Possession, possession for sales and sale of any poison,import of poisons										
37			FSSAI Act & rules-introduction, definition ,functions of FSSAI,rules & regulations										
38	13	Unit-II	Manufacture,storage,packaging of foods,general requirements & labelling requirements a/c FSSAI.										
39			Drugs price control order(DPCO)-2013, introduction,objectives.										
40			DPCO -amendments										
41	14	Unit-II	DPCO -definitions.										
42			DPCO-sale prices of bulk drugs,retail price of formulations,maximum retail price.										
43		Unit-II	DPCO-maximum retail price.										
44	15	Unit-III	Code of Pharmaceutical Ethics: Definition										

45		Unit-III	Ethical principles, ethical problem solving										
46	1	Unit-III	Registration,code of ethics for Pharmacist in relation to his job										
47			Trade, medical profession and his profession.										
48			Pharmacist's oath.										
49	2	Unit-III	Medical Termination of Pregnancy Act and Rules										
50			Basic understanding, salient features, and Amendments OF MTP.										
51			Central Drugs Standards Control Organization (CDSCO)										
52	3	Unit-III	Indian Pharmacopoeia Commission (IPC)										
53			Good Regulatory practices (documentation, licenses,renewals, e-governance) in Community Pharmacy										
54			Hospital pharmacy, Pharma Manufacturing.										
55	4	Unit-III	Wholesale business,inspections, import, export of drugs and medical devices.										
56			Introduction to BCS system of classification										
57			Basic concepts of Clinical Trials										

58	5	Unit-III	ANDA, NDA, New Drug development										
59			New Drugs and Clinical Trials Rules, 2019										
60			Brand v/s Generic,Trade name concept										
61	6	Unit-III	Introduction to Patent Law and Intellectual Property Rights,Emergency Use Authorization.										
62		Unit-IV	Blood bank – basic requirements and functions										
63			Clinical establishment Act & Rules										
64	7	Unit-IV	Biomedical Waste Management Rules 2016 – Basic aspects										
65			Aspects related to pharma manufacture to disposal of pharma / medical waste at homes, pharmacies,and hospitals.										
66			Bioethics - Basic concepts, history										
67	8	Unit-IV	Bioethics-principles.										
68			Brief overview of ICMR’s National Ethical Guidelines for Biomedical.										
69			Health Research involving human participants										

70	9	nit-IV	Introduction to the Consumer Protection Act										
71			Introduction to the Disaster Management Act										
72			Medical Devices – Categorization										
73	10	Unit-IV	Basic aspects related to manufacture										
74			Basic aspects related to sale										
75			REVISION										