

Roll No _____

END-TERM EXAMINATION
Odd Semester 2024-25

Course Code BP505T

Course Name: Pharmaceutical Jurisprudence

Programme Name: B. Pharmacy

Time: 3 Hours

Maximum Marks : 75



Instructions: The question paper consists of 32 questions divided into three-part A, B and C. Attempt all questions from section-A comprises 20 MCQs, Any seven questions out of Nine from section-B and Any two questions out of three from section-C

Section-A (20 X 1 = 20 Marks)

1	What is the primary objective of the Drugs and Cosmetics Act, 1940 ? a) To regulate the production of medical devices b) To ensure the safety, efficacy, and quality of drugs and cosmetics c) To oversee the sale of food products d) To control the sale of tobacco	CO 1	L 2
2	Which of the following schedules under the Drugs and Cosmetics Act, 1940 governs the sale of prescription drugs? a) Schedule X b) Schedule- H c) Schedule G d) Schedule M	CO 1	L 1
3	Who is responsible for enforcing compliance with the Drugs and Cosmetics Act, 1940 regarding the labeling and sale of drugs? a) Drug Inspector b) Sales representative c) Retail Pharmacy owner d) Hospital Administrators	CO 2	L 2
4	Which of the following schedules under the Drugs and Cosmetics Act, 1940 lists the drugs whose import is prohibited without a license? a) Schedule M b) Schedule X c) Schedule H d) Schedule N	CO 3	L 4
5	Under the Pharmacy Act, 1948, who is responsible for the registration of pharmacists in India? a) Central Government b) Drug Inspectors c) State Health Department d) Pharmacy Council of India	CO 5	L 1
6	Which of the following is prohibited under the Narcotic Drugs and Psychotropic Substances Act, 1985? a) Cultivation of opium poppy for medicinal use b) Sale of heroin for medical purposes c) Unlicensed production or sale of narcotic drugs d) Use of medical marijuana under prescription	CO 4	L 5
7	Which of the following bodies is responsible for overseeing the ethical treatment of animals used for experiments under the Prevention of Cruelty to Animals Act, 1960? a) CPCSEA b) Drugs Technical Advisory Board c) Indian Medical Association d) State Veterinary Council	CO 3	L 3
8	What is the role of the National Pharmaceutical Pricing Authority (NPPA) under the Drug Price Control Order (DPCO), 2013? a) To regulate drug patents b) To fix retail prices of medicines c) To oversee drug manufacturing quality d) To approve new drug formulations	CO 5	L 2
9	Which of the following is a primary objective of the Medical Termination of Pregnancy Act? a) To regulate abortion only in government hospitals b) To prohibit the sale of abortion pills c) To legalize the termination of pregnancy under certain conditions d) To mandate counseling for pregnant women	CO 1	L 2
10	Which of the following is not an example of Intellectual Property Rights (IPR) in the pharmaceutical industry? a) Drug patents b) Trademarks for pharmaceutical brands c) Manufacturing licenses d) Copyright for drug formulations	CO 5	L 1
11	Which schedule of the Drugs and Cosmetics Act, 1940 covers narcotic drugs?	CO	L

1	a) Schedule G	b) Schedule FF	c) Schedule P	d) Schedule X	1	1
1 2	Which of the following drugs requires a repacking license under the Drugs and Cosmetics Act, 1940? a) Imported Bulk Drugs b) Prescription-only medicines c) Non Prescription Herbal supplement d) OTC analgesic				CO 2	L 3
1 3	The Drugs Technical Advisory Board advises the government primarily on: a) Determining standards for drugs and cosmetics b) Licensing of pharmaceutical companies c) Consumer drug safety d) Pharmacist's professional ethics				CO 3	L 2
1 4	Biological and microbiological tests are conducted at- a) Kolkata b) Chennai c) Kasauli d) Mumbai				CO 3	L 2
1 5	The labeling requirements for drugs under the Drugs and Cosmetics Act, 1940 do NOT include: a) Wholesale distributor details b) Manufacturer details c) Batch number d) Instructions for use				CO 2	L 3
1 6	What is the primary function of the Drugs Consultative Committee under the Drugs and Cosmetics Act, 1940? a) Licensing pharmaceutical companies b) Examining the quality of drugs c) Advising on drug-related policies d) Conducting clinical trial				CO 3	L 2
1 7	DTAB contains _____ Ex-Officio members. a) 6 b) 7 c) 8 d) 9				CO 3	L 4
1 8	Life period of drugs is dealt in a) Schedule P b) Schedule R c) Schedule Q d) schedule T				CO 2	L 1
1 9	Medical Termination of Pregnancy Act was passed in a) 1954 b) 1985 c) 1971 d) 1991				CO 2	L 2
2 0	Schedule X prescribe the drugs of -----category a) Analgesics b) Antibiotics c) Biological products d) Habit forming drugs				CO 3	L 3

Section C (2 X 10 = 20 Marks)

1	Discuss the provisions of the Drugs and Magic Remedies Act and its role in regulating advertisements related to pharmaceutical products. Explain the penalties for violating this Act.	CO1 CO2	L 2
2	Evaluate the importance of Intellectual Property Rights (IPR) in the pharmaceutical industry. Discuss the impact of patent laws on drug innovation and access to affordable medicines in India.	CO5	L 5
3	Describe the key provisions of the Pharmacy Act, 1948, with a focus on the role of the Pharmacy Council of India and the State Pharmacy Councils. Discuss the importance of pharmacist registration and the legal framework for pharmaceutical education in India.	CO1 , CO2 ,	L 2

Section B (7 X 5 = 35 Marks)

1	What are the primary objectives of the Drugs and Cosmetics Act, 1940? Explain how these objectives aim to ensure the safety, efficacy, and quality of pharmaceutical products in India.	CO1	L2
2	Explain how a drug manufacturer can apply for a loan license under the Drugs and Cosmetics Act. What are the key conditions involved in obtaining and maintaining such a license?	CO2	L3
3	Analyze the significance of the provisions related to prohibited drugs under the Drugs and Cosmetics Act, 1940. What are the potential risks associated with these drugs, and how does the Act mitigate these risks?	CO3	L4
4	What are the primary provisions in Schedule G of the Drugs and Cosmetics Act, 1940? Explain its importance in regulating the sale and distribution of drugs.	CO1	L2
5	Evaluate the significance of Schedule Y for the approval and clinical trial regulations of new drugs in India. How does this schedule ensure the safety and efficacy of new pharmaceutical products?	CO4	L5
6	Explain the key provisions of the Medicinal and Toilet Preparations Act, 1955. How does this Act regulate the manufacture and sale of medicinal and toilet preparations?	CO1	L2
7	What are the primary objectives of the Pharmacy Act 1948? How does this Act contribute to the regulation of the pharmacy profession in India?	CO2	L3
8	What are the primary objectives of the Drugs and Magic Remedies Act? How does	CO1	L2

	this Act help in protecting the public from misleading advertisements and claims regarding drugs?		
9	Briefly explain the objectives and contributions of the Drugs Enquiry Committee, Health Survey and Development Committee, Hathi Committee, and Mudaliar Committee. How did these committees influence the development of pharmaceutical legislations in India?	CO1	L2