Question Paper

Exam Date & Time: 02-Dec-2023 (10:00 AM - 01:00 PM)



MANIPAL ACADEMY OF HIGHER EDUCATION

Pharmaceutical Jurisprudence (PMA-BP505T - S2)

Marks: 75		Duration: 180 mins.
	I Multiple Choice Questions (MCQs)	
Answer all the	questions.	Section Duration: 30 mins
1)	ATENOLOL drug belongs to	(1)
	Schedule X Schedule H Schedule M Schedule V	
2)	The regulatory authority of Europe is	(1)
	European Ministry of Evaluation Authority European Medicines Export Agency Europe Medical Evaluation Authority European Medicines Agency	
3)	The role of Drugs inspectors arein administration.	(1)
	Managerial Analytical Executive Advisory	
4)	Therapeutic exploratory trials is the prime objective of phasetrials.	(1)
	Phase II Phase III Phase IV	
5)	Requirements for the functioning and operation of a blood bank and / or for preparation components are mentioned in schedule	on of blood (1)
	Schedule B Schedule H Schedule N Schedule F	
6)	Requirements of factory premises for manufacture of medical devices are mentioned in	(1)
	Schedule M- IV Schedule M- I	

	Schedule M- II Schedule M- III	
7)	Drug Technical Advisory Board is constituted by	(1)
	Central Government State Government New Delhi Government Ministry of Pharmaceuticals	
8)	List of Dyes, colors and pigments permitted to be used in cosmetics and soaps are mentioned in schedule	(1)
	Schedule S Schedule T Schedule P Schedule Q	
9)	In respect of drugs imported into India by rail from Pakistan is through	(1)
	Jaipur Cantonment Jammu Cantonment Firozpur Cantonment Chandigarh Cantonment	
10)	Drugs exempted from certain provisions relating to manufacture of the drugs are mentioned in schedule	(1)
	Schedule X Schedule Y Schedule K Schedule M	
11)	Pharmacy Council of India is reconstituted every	(1)
	1 year 2 years 4 years 5 years	
12)	The penalty for the person who fails to surrender certificate of registration is	(1)
	INR 50 INR 200 INR 500	
13)	Section 25 of The Narcotic Drugs and Psychotropic Substances Act 1985 deals with	(1)
	Punishment for embezzlement of opium by cultivator Punishment for allowing premises to be used for commission of an offence Punishment for contravention in relation to psychotropic substances. Punishment for contravention in relation to poppy straw	
14)	What is the penalty for consuming the Narcotic Drugs or Psychotropic Substances?	(1)
	Rigorous imprisonment up to 6 months or fine up to Rs 10,000 or both	

Rigorous imprisonment up to 10-20 years and fine not less than to Rs 1-2 lakh. Rigorous imprisonment up to 10 years or fine up to 1 lakh or both Display signboard or notices by a registered medical practitioner on his premises fall under 15) (1) as per Drugs and Magic Remedies Act. Regular advertisement Permitted advertisement Exempted advertisement **Prohibited** advertisement 16) How many drugs were under price control according to DPCO 1979? (1) 74 76 147 347 Code of Pharmaceutical Ethics by Pharmacy Council of India provide framework for....... (1) 17) Community Pharmacists **Industrial Pharmacists Medical Representatives** Pharmacy Technicians 18) Drugs Enquiry Committee was formed under the chairmanship of ____ (1) Sri Ramnath Chopra SL Bhatia Mudaliar Hathi 19) Under the Medicinal and Toilet Preparations (Excise Duties) Act, manufacture of any dutiable goods (1) without a valid licence is punishable with _ imprisonment up to six years or fine of twenty thousand rupees or both imprisonment up to six months or fine of two thousand rupees or both imprisonment up to six months or fine of twenty thousand rupees or both imprisonment up to six years or fine of two thousand rupees or both 20) Animal welfare board is constituted by __ (1)State Government State Council **Central Government Central Council II Long Answers** Answer all the questions. Discuss prohibition of Import of certain drugs. Add a note on imported drugs for personal use and 1) (10)approved places in India for import of drugs through Rail, Sea and Air routes. (4+3+3=10 marks) a) What is the procedure for granting approval to start a pharmacy institution by Pharmacy Council (10) 2) of India. Add a note on Education Regulations. Is PCI's approval mandatory for an institution

Rigorous imprisonment up to 1 year or fine up to Rs. 20,000 or with both

offering pharmacy related courses? Give reason. (2+2+1=5Marks)
b) State the offences and penalties in relation to: a) Poppy Straw b) Prepared Opium c)
Embezzlement of Opium by Cultivators as prescribed under The Narcotic Drugs and Psychotropic Substances Act. What is significance of Small and Commercial quantity of Narcotic Drugs and Psychotropic Substances? (4+1=5Marks)

III Short Answers

Answer all the questions.

1)	Mention the conditions for Termination of Pregnancy as per MTP Act? Enlist functions of CDSCO and various centres of USFDA.	(5)
2)	Explain various phases of clinical trials. Mention the reasons, why tragedies occurred in clinical trials in the past.	(5)
3)	Write briefly about patent and copyright. What are the benefits of geographical indications?	(5)
4)	Discuss various central drugs laboratories in India and add a note on drug consultative committee.	(5)
5)	Enlist various types of price calculations as specified under Drug Price Control Order 2013 and describe the calculation of price of drug of any one type. What were the major changes brought in DPCO 2013 to that of previous DCPO 1995? (2+2+1=5Marks)	(5)
6)	What types and classes of advertisements are exempted conditionally under the Drugs and Magic Remedies Act? Discuss in brief provisions related to "Bonded Manufactory? (2½+2½=5Marks)	(5)
7)	Enlist the recommendations put forwarded by Drugs Enquiry Committee and the actions taken by Government up on the recommendations. What ethics a pharmacist should follow with respect to Medical Profession. (3+2=5Marks)	(5)

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