Exam Date & Time: 07-Dec-2022 (10:00 AM - 01:00 PM)

MANIPAL ACADEMY OF HIGHER EDUCATION

Pharmaceutical Jurisprudence [PMA-BP505T]

Marks: 75 **Duration: 180 mins.**

I Multiple Choice Questions (MCQs)

Answer all the questions. Section Duration: 30 mins

1) List of Psychotropic substances whose import, manufacture and sale, labelling and packaging are governed by special provisions as per schedule..... (1)

1)	Schedule H		2)	Schedule X		3)	Schedule C		4)	Schedule M	

2) If drug is colored, coated, powdered or polished that damage is concealed or if it is made to appear of better or greater therapeutic value than it really is, then the drug is..... (1)

1)	Spurious drug		2)	Misbranded drug		3)	Substandard drug		4)	Adulterated drug	

3) Requirements of factory premises for manufacture of cosmetics are mentioned in..... (1)

1)	Schedule M - I		2)	Schedule M - II		3)	Schedule M - III		4)	Schedule M	

4) Manufacturing Licensee number being preceded by the word..... (1)

1)	"Mfg.Lic.No."		2)	"Muf.Lic.No."		3)	"Mln.Lic.No."		4)	"Mgf.Lic.No."	

5) The regulatory authority of Europe is---------- (1)

1)	European Ministry of Evaluation Authority		2)	European Medicines Export Agency		3)	Europe Medical Evaluation Authority		4)	European Medicines Evaluation Agency	

6) Schedule T states about..... (1)

1)	Good Manufacturing Practices for Ayurvedic, Allopathy and Unani Medicines		2)	Good Manufacturing Practices for Ayurvedic, and Unani Medicines		3)	Good Manufacturing Practices for Ayurvedic, Siddha and Unani Medicines		4)	Good Manufacturing Practices for Siddha and Unani Medicines	

7) The role of Drugs inspectors are.....in administration of the Act. (1)

1)	Advisory		2)	Analytical		3)	Executive		4)	Managerial	

8) List of Dyes, colors and pigments permitted to be used in cosmetics and soaps are mentioned in schedule..... (1)

1)	Schedule S		2)	Schedule T		3)	Schedule P		4)	Schedule Q	

9) Requirements for the functioning and operation of a blood bank and / or for preparation of blood components are mentioned in schedule------ (1)

1)	Schedule B		2)	Schedule H		3)	Schedule N		4)	Schedule F	

10) As per Schedule M- SOPs means..... (1)

1)	Science Operating Procedures		2)	Standard Operating Practical's		3)	Standard Operation Process		4)	Standard Operating Procedures	

11) The Education Regulation is published in official gazette by _____ (1)

1)	Respective state pharmacy council		2)	Central Government		3)	Drugs Controller General of India		4)	Pharmacy Council of India	

12) State Pharmacy Councils were established for _____ (1)

1)	Regulation of drug manufacturing in the state		2)	Registration of Pharmacists		3)	Registration of approval of certain drugs		4)	Approval of certain drugs and Registration of pharmacists	

13) Name of the local body which allows experiments on small animals is _____ (1)

1)	IECC		2)	IACE		3)	IAEC		4)	CPCSEA	

14) Which of the following DPCO is replaced by DPCO 2013? (1)

1)	DPCO 1995		2)	DPCO 2000		3)	DPCO 2005		4)	DPCO 2010	

15) What is the penalty for consuming Narcotic Drug or Psychotropic Substances? (1)

1)	Rigorous imprisonment up to 6 months or fine up to Rs 10,000 or both		2)	Rigorous imprisonment up to 1 year or fine up to Rs. 20,000 or with both		3)	Rigorous imprisonment up to 10-20 years and fine not less than to Rs 1-2 lakh.		4)	Rigorous imprisonment up to 10 years or fine up to 1 lakh or both	

16) Dutiable goods may be kept in a warehouse initially for a maximum period of _____ (1)

1)	1 Years		2)	2 Years		3)	3 Years		4)	4 Years	

17) Which of the following Act was established in the year 1985? (1)

1)	Narcotic and Psychotropic Substance Act		2)	Drug and Magic Remedies Act		3)	The Medical Termination of pregnancy Act		4)	DPCO	

18) Which one of the following aspect did SL Bhatia associated with? (1)

1)	Training courses in		2)	Working of pharmaceutical		3)	Licensing Drugs		4)	Price control	

	Pharmacy			industry						of drugs	

19) Which of the following statements is correct?

1)	While weighing and measuring ingredients visual estimation can be adopted		2)	Self-service method is permissible to sell medicines now		3)	It is the responsibility of pharmacist to provide practical training to trainees		4)	Pharmacists can vary prices of drugs based on the affordability of the patients		(1)

20) Which of the following is the class of exempted advertisement as per DMR(OA) Act?

1)	Advertisement published by Government		2)	Advertisement related to Schedule J diseases/conditions		3)	Advertisements of magic remedies for the treatment of certain diseases and disorders.		4)	Kavach possessing miraculous powers		(1)

II Long Answers

Answer all the questions.

1) Explain good manufacturing practices mentioned for premises and materials under Drug and Cosmetics Act. What are types of copyright and benefits of geographical indications? Mention classification of Global market.(5+3+2=10marks) (10)

2) a) Discribe functions of Pharmacy Council of India and State Pharmacy Council. What are the qualification criteria to enter name in the subsequent registers? (3+2=5 marks)
b) Define Coca Plant, Coca Leaf and Coca Derivative. State the offences and penalties in relation to Poppy Straw and Prepared Opium. What is the importance of Small and Commercial Quantity? (2+2+1=5marks) (10)

III Short Answers

Answer all the questions.

1) Mention the conditions for Termination of Pregnancy as per MTP Act? Mention functions of central drugs laboratory, drug technical advisory committe and drug consultative committee. (5)

2) What are Clinical Trials? Explain the reasons, why tragedies occurred in process of clinical trials in the past.(2+3=5) (5)

3) Mention all the places through which drugs may be imported into India. Add note on Import of drugs for personal use. (5)

4) Define Manufacture and loan license. What is difference between Law, Rules and Regulation? (5)

5) Enlist types of pricing according to DPCO and describe any one. Add a note on NLEM. (4+1=5marks) (5)

6) What types and classes of advertisements that are exempted with a condition under the Drugs and Magic Remedies Act? With what objective Medicinal and Toilet Preparations Act was established? Add a note on Non-Bonded manufactory? (3+2=5marks) (5)

7) Discuss in brief recommendations put forwarded by DEC. What ethics a pharmacist should follow with respect to his Job? (3+2=5Marks) (5)

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