Exam Date & Time: 06-Jan-2022 (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) DTAB is constituted by ..... to advice on technical matters arising out of the administration. (1)

1)	Central Government		2)	State Government		3)	New Delhi Government		4)	Ministry of Pharmaceuticals	

2) 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	

3) As per Schedule M (MFR) stands for-------- (1)

1)	Master Formula Receipt		2)	Manufacture Formula Records		3)	Master Finish Records		4)	Master Formula Records	

4) Therapeutic exploratory trials are objective of ---------- trials. (1)

1)	Phase I		2)	Phase II		3)	Phase III		4)	Phase IV	

5) 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		2)	Misbranded		3)	Substandard		4)	Adulterated	

	drug			drug			drug			drug	

6) Requirements of factory premises for manufacture of medical devices are mentioned in..... (1)

1)	Schedule M (IV)		2)	Schedule M (I)		3)	Schedule M (III)		4)	Schedule M (II)	

7) In respect of drugs imported into India by Air route is through..... (1)

1)	New Delhi		2)	Jaipur		3)	Indore		4)	Kanpur	

8) The containers of all the drugs including patent or proprietary medicine are to be labelled in accordance with --------- (1)

1)	The Drugs and Cosmetics Act 1940 and Rules 1945		2)	The Indian Contract Act		3)	The Drugs and Magic Remedies Act		4)	The Poisonous Act	

9) List of substances that are required to be used only under medical supervision and which are to be labelled accordingly are stated in..... (1)

1)	Schedule M		2)	Schedule V		3)	Schedule J		4)	Schedule G	

10) One of the following country is among semi regulated markets in case of pharmaceutical industry. (1)

1)	Germany		2)	France		3)	India		4)	South Africa	

11) The Education Regulation is published in official gazette by ____

1)	Ministry of Education		2)	Central Government		3)	Drugs Controller General of India		4)	Pharmacy Council of India	

(1)

12) Who has the power to constitute State Pharmacy Council?

1)	Central Government		2)	Central Council		3)	State Government		4)	Pharmacy Council of India	

(1)

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

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

14) Which Act's prime objective is to make sure that the essential drugs are available to all at a reasonable prices? (1)

1)	DMRA		2)	DPCO		3)	D and C		4)	NDPS	

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 Year		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 of the following committee has dealt with Price Control and Role of foreign sector among others? (1)

1)	Hathi		2)	Mudaliar		3)	Chopra		4)	Bhatia	

19) Which of the following statements is correct? (1)

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	

20) Which of the following is the class of exempted advertisement as per DMR(OA) Act? (1)

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	

II Long Answers

Answer all the questions.

1) Explain Good Manufacturing Practices mentioned for premises and materials under Drugs and Cosmetics Act. Briefly write various centers of USFDA and functions of CDSCO. (6+4=10 marks) (10)

2) a) Describe the functions of Pharmacy Council of India. What is the procedure used for the registration of pharmacist by state pharmacy council? (3+2=5marks)
b) Define Coca Derivative, Opium Poppy and Opium Derivative as per Narcotic Drugs and Psychotropic Substances. State the offences and penalties in relation to prepared opium, cannabis plant and cannabis. What is the significance 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 CDL, DTAB and DCC. (5)

2) Why tragedies occurred due to clinical trials in the past? Explain the reasons. (5)

3) Write briefly about patent. What are the benefits of geographical indications? (5)

4) Define "Manufacture" and "Loan license" as per Drugs and Cosmetics Act. What is difference between Law, Rules and Regulation? (5)

5) Define "Generic Version of a Medicine" and "Market Share" as per DPCO. Enlist types of price calculations as specified under DPCO 2013. Is price control on drugs bad? Give reason. (2+2+1=5marks) (5)

6) What types and classes of advertisements are prohibited under the Drugs and Magic Remedies Act? What do you mean by Non-Bonded manufactory? (4+1=5marks) (5)

7) Write short notes on DEC. What ethics a pharmacist should follow with respect to Medical Profession? (5)
(4+1=5Marks)

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