Exam Date & Time: 09-Mar-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) Schedule P states about.....

1)	Life periods of drugs		2)	Pack sizes of the drugs		3)	List of Dyes, Colors and Pigments		4)	Standards for cosmetics in finished form		(1)

2) Rates of fees charged for analysis by CDL or State Drugs Laboratories are mentioned in .....

(1)

1)	Schedule A		2)	Schedule C		3)	Schedule D		4)	Schedule B	

3) Drugs exempted from certain provisions relating to manufacture of the drugs are mentioned in .....

(1)

1)	Schedule X		2)	Schedule Y		3)	Schedule K		4)	Schedule M	

4) .....is deleted as per Drugs and Cosmetics Act 1940.

(1)

1)	Schedule Y1		2)	Schedule B1		3)	Schedule C1		4)	Schedule L	

5) Schedule T states about.....

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		(1)

6) The regulatory authority of UK is .....

1)	Medicines and Healthcare products Regulatory Agency (MHRA)		2)	Medicines and Healthcare procedure Regulatory Authority (MHRA)		3)	Ministry and Healthcare products Regulatory Agency (MHRA)		4)	Medicines and Health products Recovery Agency (MHRA)		(1)

7) The functions in respect of human blood and human blood products including components to test from freedom of HIV antibodies shall be carried out by.....

1)	National Institute of Disease, Mumbai		2)	National Institute of Virology, Pune		3)	Centre of Research in Virology, Kanpur		4)	Centre of human blood and research, Noida	

(1)

8) Marketing strategies is type of.....

1)	Potential copy right		2)	Potential patent		3)	Potential industrial design		4)	Potential trade secrets	

(1)

9) Manufacturing Licensee number being preceded by the word.....

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

(1)

10) Pack sizes of the drugs are labelled as per.....

1)	Schedule P (I)		2)	Schedule R (II)		3)	Schedule M (III)		4)	Schedule P (II)	

(1)

11) Pharmacy Council of India is reconstituted:

1)	Every 2 years		2)	Every 3 years		3)	Every 5 years		4)	Every 6 years	

12) One of the following Act was passed in 1954:

1)	Narcotic and psychotropic substance Act		2)	Drug and magic Remedies Act		3)	The Medical Termination of pregnancy Act		4)	Poisonous Act.	

(1)

13) Which register is maintained by Central Council? (1)

1)	Subsequent register		2)	Central register		3)	First register		4)	Tribunal register	

14) Which of the following is an objective of Prevention of Cruelty to Animals Act?

1)	To prevent infliction of unnecessary pain or suffering on animals		2)	To prevent cruelty to human subjects		3)	To prevent experiments only on genetically modified microorganisms		4)	To prevent experiments on animals for postgraduate research	

(1)

15) How many drugs were under price control according to DPCO 1995?

1)	74		2)	86		3)	147		4)	347	

(1)

16) Code of Pharmaceutical Ethics is framed by ____

1)	PCI		2)	AICTE		3)	UGC		4)	State Pharmacy Council	

(1)

17) Which committee was established before 1940?

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

(1)

18) The application for the license should be submitted on a prescribed form along with a prescribed fee at least _____before the proposed date of commencement of the manufacture as per the provisions of Medicinal and Toilet Preparations Act.

1)	One Month		2)	Two Months		3)	Three Months		4)	Four Months	

19) In relation to Narcotic Drugs and Psychotropic Substances Act, small quantity of Codeine is _____

1)	25 grams		2)	15 grams		3)	50 grams		4)	10 grams	

(1)

20) Which of following Act is related to Narcotic Drugs and Psychotropic Substances Act? (1)

1)	Narcotic Act		2)	Cannabis Act		3)	Dangerous Drugs Act		4)	D and C Act	

II Long Answers

Answer all the questions.

1) Explain general and restricted license for sale of drugs. Write a note on drugs for personal use and why India is favourable manufacturing destination for many pharmaceutical companies. (5+2+3= 10 Marks) (10)

2) a) What are Education regulations and what they prescribe to pharmacy institutions? What are the qualifications required for making an entry in subsequent register? (2+3=5marks)

b) What is National Fund for Control of Drug Abuse and for what purpose fund can be used? State the offences and penalties in relation to Poppy Straw, Psychotropic Substances and External Dealings in Narcotic Drugs and Psychotropic Substances under The Narcotic Drugs and Psychotropic Substances Act. (10)

III Short Answers

Answer all the questions.

1) Explain various phases of clinical trials. Enlist all good manufacturing practices parameters as per schedule M. (5)

2) Mention the conditions for Termination of Pregnancy as per MTP Act? Mention functions of CDL, DTAB and DCC. (5)

3) Discuss some unfortunate events that catalysed the development of medicine regulations. (5)

4) Define Drug, Cosmetic, New drug, Repacking license and Misbranded drug. (5)

5) What are the functions of National Pharmaceutical Pricing Authority and mention the enforcing authorities of NPPA at National, State and District? (4+1=5marks) (5)

6) What types and classes of advertisements are exempted conditionally under the Drugs and Magic Remedies Act? Differentiate Bonded and Non-Bonded manufactory? (3+2=5Marks) (5)

7) Write short notes on Hathi and Mudaliar Committees. What ethics a pharmacist should follow with respect to Trade. (2½+2½=5marks) (5)

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