Question Paper

Exam Date & Time: 04-Jan-2024 (10:00 AM - 01:00 PM)

MANIPAL ACADEMY OF HIGHER EDUCATION

Pharmaceutical Jurisprudence [PMA-BP505T - S3]

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

I Multiple Choice Questions (MCQs)

Answer all the questions. Section Duration: 30 mins

1) RANITIDINE drug belongs to schedule ..... (1)

- Schedule X
- Schedule H
- Schedule K
- Schedule V

2) The regulatory authority of Thailand is---------- (1)

- Ministry of Public Health
- Ministry of Health
- Medical Products Agency (MPA)
- Ministry of Thailand Welfare and Health

3) The role of Drug Technical Advisory Board is .....in administration. (1)

- Managerial
- Analytical
- Executive
- Advisory

4) The requirements and guidelines for import and/or manufacture of new drugs for sale or for clinical trials are mentioned in..... (1)

- New Drugs and Clinical Trials Rules, 2023.
- New Drugs and Clinical Trials Rules, 2019.
- New Drugs and Clinical Trials Rules, 2020.
- New Drugs and Clinical Trials Rules, 2018.

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

- Schedule B
- Schedule H
- Schedule N
- Schedule F

6) Requirements of factory premises for manufacture of cosmetics are mentioned (1)

in.....

- Schedule M - IV
- Schedule M - I
- Schedule M - II
- Schedule M - III

7) Drug Technical Advisory Board is constituted by ..... Government to advice on technical matters arising out of the administration. (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) Standards for condoms made of rubber latex intended for single use and other mechanical contraceptives are mentioned in schedule..... (1)

- Schedule S
- Schedule R
- Schedule P
- Schedule Q

10) " Warning: If irritation persists or increases discontinue the use and consult the physician" is Special Labeling Requirements for..... (1)

- Hair ointments
- Ear ointments
- Ophthalmic ointments
- External ointments

11) _____ is not an ex-officio member of Pharmacy Council of India (1)

- Director General of Health Services
- Director of Central Drug Laboratory
- Drugs Controller General of India
- Director Central Drug Research Institute

12) Printing of register of Pharmacist (in the State) is done after which date of the year? (1)

- After 1st January
- After 1st March
- After 1st April
- After 1st June

13) When did The Narcotic Drugs and Psychotropic Substances Act 1985, come into force? (1)

- 01 April 1986
- 01 March 1986

14 November 1985
23 April 1985

14) Which of following is one of the oldest Act before Narcotic Drugs and Psychotropic Substances Act was established? (1)

Dangerous Drugs Act
Opium Act
Poisons Act
Insecticide Act

15) Advertisement of drugs claiming cure of disease mentioned in Schedule-J is _____ as per Drugs and Magic Remedies Act. (1)

Granted
Prohibited
Exempted
Exempted with condition

16) Who regulate the Drug Prices in India? (1)

National Pharmaceutical Pricing Authority
Drugs Controller General of India
Essential Commodities Act
Pharmacy Council of India

17) Code of ethics are framed first by _____ (1)

Medical Council of India
Pharmacy Council of India
All India Council for Technical Education
National Institute of Pharmaceutical Education and Research

18) Drugs Enquiry Committee is also known as? (1)

Bhatia Committee
Mudaliar Committee
Therapeutic Committee
Chopra Committee

19) A non-bonded manufactory shall be inspected by the officer at least _____ (1)

once every month
once every two months
once every six months
once every year

20) When was the Prevention of Cruelty to Animals Act passed? (1)

1960
1961
1955
1954

II Long Answers

Answer all the questions.

1)	Explain the GMP as per Schedule M. Add a note on clinical trials. (5+5= 10 marks)	(10)
2)	a) What are first and subsequent registers? Mention the qualification required to enter the name in to the subsequent register. (2+3=5Marks) b) State the offences and penalties in relation to a) Psychotropic Substances b) Illegal Import, Export or Transshipment of Narcotic Substances c) External Dealings in Narcotic Drugs & Psychotropic Substances prescribed under The Narcotic Drugs and Psychotropic Substances Act.	(10)

III Short Answers

Answer all the questions.

1)	Discuss functions of CDSCO. Mention the conditions for Termination of Pregnancy as per Medical Termination of Pregnancy Act?	(5)
2)	What are the general labelling requirement for drugs? Draw a specimen label for Schedule X drug.	(5)
3)	Write briefly about trademark and types of copyright. What are the benefits of geographical indications?	(5)
4)	Write duties and qualifications of drug inspector and Government. analyst.	(5)
5)	Discuss the functions of National Pharmaceutical Pricing Authority.	(5)
6)	What types and classes of advertisements are exempted under the Drugs and Magic Remedies Act? Differentiate Bonded and Non-Bonded manufactory provisions? (3+2=5Marks)	(5)
7)	Write short notes on drugs enquiry committee (Chopra Committee). What ethics a pharmacist should follow with respect to his Trade. (3+2=5Marks)	(5)

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