Duration: 3 hrs **Total marks: 75**

N.B. : 1. All questions are compulsory.
2. Figures to right indicate full marks.

Q.1 Choose the appropriate option for following multiple choice based questions. (Write the correct option and the correct answer.) **20**

1 What is adulterated drug
a) Whole or in part of any filthy, putrid or decomposed substance
b) Misbranded drug
c) Drug in Phase I trial
d) Drug in Phase II trial

2 Condition to be fulfilled for import of Schedule X drugs (Narcotics & Psychotropic substances) by the importer is-
a) The licence granted even before should not be suspended or cancelled
b) Must have good source of income
c) Must have good relationship with drug inspector
d) Only patented products are sanctioned to import

3 Requirements and guidelines of factory premises, plants, and equipment are found in_____ of Drug and Cosmetic Act'1940.
a) Schedule P
b) Schedule Q
c) Schedule L
d) Schedule M

4 A person (applicant) who does not have his own arrangement (factory) for manufacture but who wish to use manufacturing facilities own by another licences is called as-
a) Manufacturing licence
b) Repackaging licence
c) Loan licence
d) Proprietary licence

5 For the wholesale of drug specified in schedule C & CI licence is issued in form?
a) 20 A
b) 20 B
c) 21 B
d) 21 C

6 The Schedule H on the label denotes
a) Biologicals
b) Ophthalmic
c) To be sold by retail on the prescription of registered medical practitioner only
d) Good manufacturing Practices

7 Which of the following is the advisory administrative body appointed by the Central government for execution of Drug and cosmetic act 1940?
a) Drug Consultative committee
b) Central drug laboratory
c) licensing authority
d) drug analyst

8 The functions of the CDL in respect of Homoeopathy medicines carried out at
a) Homoeopathic pharmacopoeia laboratory Ghaziabad
b) Homoeopathic pharmacopoeia laboratory Noida
c) National institute of virology
d) Central drug laboratory at kolkata

9 As per Pharmacy Act, First register of state for Pharmacist was prepared by?
a) Drugs controller of India
b) central government
c) local FDA
d) Dr. B. Mukerjee

10 Find the odd one out with reference to the MTP (ED) Act 1955?
a) Azithromycin Tablets
b) Deodorants and perfumes
c) Skin products
d) Hair products

11 Medicinal cannabis is also known as
a) Opium
b) Hemp
c) Heroin
d) Charas

12 The Drugs and magic remedy (OA) Act was passed in _____.
a) 1954
b) 1948
c) 1985
d) 1972

13 Animal welfare board is established by
- a) Central council
- b) State council
- c) PCI
- d) Central government

14 NLEM stands for —--
- a) National laboratory of essential medicines
- b) National list of essential medicines
- c) New list of essential medicines
- d) New laboratory of essential medicines

15 R. N. Chopra was the chairperson of
- a) DEC
- b) Hathi Committee
- c) Mudaliar Committee
- d) Study of drugs enquiry committee

16 Pharmacy ethics provide a framework for
- a) Pharmacist, pharmacy technician
- b) IT
- c) Deputy commissioner
- d) Registar

17 What is MTP an abbreviation for
- a) Medical Termination of Pregnancy
- b) Menstrual Termination of pregnancy
- c) Medical Term of Pregnancy
- d) Medical testing of pregnancy

18 _____act focuses on building better informed citizens
- a) Right to information
- b) Indian penal code
- c) Drug and cosmetic act 1940
- d) National list of laboratory testing

19 Patent protects
- a) New Invention
- b) Discovery
- c) Experiment
- d) Invention

20 Which of the following is the geographical indication property right
- a) Bandhani print
- b) Textile printing
- c) Tatoo making
- d) Research publication

Q. 2	Answer **any two** questions	**20**
I a.	Define Drug and misbranded drugs as per D and C Act 1940 and discuss the classes of drugs which are prohibited for manufacture and sale.	**6**
b.	Give composition and function of PCI.	**4**
II a.	Define Opium derivative. Describe power of the central government to control certain operations w.r.t. opium.	**5**
b.	Elaborate on procedure to conduct experiments on animals as per Prevention of cruelty to animals act.	**5**
III a.	Enlist required qualifications for Drug inspector and elaborate powers and duties of drug inspector as per D and C act 1940.	**6**
b.	Elaborate about the minimum requirements to run a Pharmacy as per schedule N of D & C Act.	**4**
Q. 3	Answer **any seven** questions.	**35**
I	Discuss about the conditions to be fulfilled by the importer of the drug to issue an import licence.	**5**
II	What do you mean by Loan licence? Describe the forms and provisions required to issue a loan licence.	**5**
III	Give legislative intent of DMR (OA) Act. Define advertisement and magic remedy under DMR (OA) Act.	**5**
IV	a) Describe the constitution and functions of the institutional animals ethics committee.	**2.5**
	b) Explain the ceiling price fixation for scheduled formulations and elaborate on the maximum retail price.	**2.5**
V	What is DEC and discuss the recommendations given by Drug enquiry committee.	**5**
VI	Define ethics and elaborate the role and responsibilities of Pharmacists in society.	**5**
VII	Discuss the provisions made for termination of pregnancy as per MTP Act.	**5**
VIII	Define the term "Right to Information". What are the obligations of public authorities towards the right to information	**5**
IX	Define Invention and discuss the inventions which are not patentable as per the provisions of Indian Patent Act.	**5**

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