Time: 3 Hours **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 A drug said to be _____ as per the Drug and cosmetic act If it contains filthy, putrid drug.
a) Misbranded drug
b) Spurious drug
c) Adulterated drug
d) Substandard drug

2 Which of the following schedule to rule to D and C Act. provides minimum equipment requirement to run the pharmacy
a. Schedule M
b. Schedule O
c. Schedule N
d. Schedule B

3 Which of the following is artificial colour
a)Annattod
b)carotin
c)Caramel
d) Lake colour

4 Which of the following schedule to rule to D and C Act provided the manufacturing requirement for Ayurvedic drugs
a)Schedule B
b)Schedule T
c)Schedule X
d)Schedule H

5 The DTAB committee is the ……..committee appointed by central and state government as per D and C act 1940.
a) Advisory
b) Supervisory
c) Analytical
d) Executive

6 Permission to initiate clinical trial with new drug may be obtained by applying in _____ for a test licence to import or manufacture of drug
a) Form 12
b) Form 15
c) Form 10 AA
d) Form 21

7 Central council means_____
- a) DCC
- b) Education council
- c) PCI
- d) Registration tribunal

8 Upto _____ may be imported without any permit, if it is part of passanger's luggage.
- a) 10 average doses
- b) 100 average doses
- c) 500 average doses
- d) 250 average doses

9 Repacking license can be granted for
- a) Polio vaccine
- b) Boric Acid
- c) Glibenclamide tablets
- d) Tamoxifen citrate injection

10 The objective of the DMR (OA) Act 1954 is
- a) To control sale of drugs
- b) To prohibit certain types of advertisements relating to magic remedies which falsely claim and mislead public
- c) To market the drugs
- d) To analyze the drugs

11 Which of the following committees was formed by the Central Government for efficient administration of NDPS Act 1985?
- a) Local Committee
- b) Narcotic drug and Psychotropic substances Consultative committee
- c) Authorities and officers
- d) DTAB

12 As D and C act, which of the following is a spurious drug.
- a) Tablet formulations
- b) Genetically modified product
- c) Lacking authenticity, substitution or imitation
- d) Excipient

13 PCT stands for
- a) Patent cooperative treaty
- b) Partial cooperative treaty
- c) Product cooperative treaty
- d) Process cooperative treaty

14 Gliclazide comes under _____
- a) Schedule G
- b) Schedule B
- c) Schedule J
- d) Schedule H

15 Animal welfare board is established by
a)PCI ,
b) state council
c) Central council
d) Central government

16 Which price is fixed by the Government for scheduled formulations in accordance with the provisions of DPCO order 2013?
a) Ceiling Price
b) MRP
c) Discounted price
d) Manufacturing cost

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 Who initiated the revolution to control the import of standard and non-effective drugs.
a) R. N. Chopra
b) Haroon Jafer
c) S. Bosh
d) D Ghosh

19 The _____ has provided the system facilitating the access to information to every citizen.
a)Right to Information act
b)Indian penal code
c)Indian patent act
d)Right to declaration act

20 A artistic work can be also registered under __
a) trademark
b) Geographical indication
c) Copyright
d) patent

Q. 2 Answer any two questions **20**

Ia Define 'Drug' and 'misbranded drugs' as per D and C Act 1940 and discuss the process of sample dispatch to the Central drug laboratory **6**

Ib What are the provisions for import of drugs for personal use and give examples of any two drugs prohibited for import as per D and C Act. **4**

II	a) Define 'Advertisement' What are the prohibited advertisements as per DMR(OA) Act?	6
	b) Discuss composition and functions of PCI as per Pharmacy Act.	4
III a	Enlist and discuss the types of licenses granted for the manufacturing of drugs for sale as per D and C act 1940.	6
b	Elaborate on the requirements to be satisfied for the blood bank as per D & C Act.	4
Q. 3	**Answer any seven questions.**	**35**
I	Explain the labeling requirements for the ophthalmic preparation.	5
II	Give the constitution and functions of the DTAB committee as per the Drug and Cosmetic Act 1940.	5
III	Define 'dutiable goods' and discuss the procedure to be followed for obtaining license for manufacture in bond.	5
IV	a) Define 'scheduled formations'. Discuss objectives of DPCO 2013.	5
	b) Discuss provisions of the prevention of cruelty to animal act regarding breeding and stocking of animals.	
V	Write a short note on the health survey and development committee.	5
VI	Discuss the ethics pharmacists should follow in relation to his/her trade and in relation to the medical profession.	5
VII	Define 'minor' and discuss conditions under which the pregnancy can be terminated medically as per MTP Act.	5
VIII	Define 'record' as per RTI and State the objectives of "Right to Information"and enlist any four types of information which may be refused.	5
IX	Define 'patent' and discuss the criteria to be satisfied for an invention to be patentable as per the provisions of Indian Patent Act.	5