Duration: 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 deemed to be _____ as per the Drug and cosmetic act If it is not labelled in the prescribed manner.
a) Misbranded drug
b) Spurious drug
c) Adulterated drug
d) Substandard drug

2. Which of the following schedule drugs require an import license in form 10 A
a) Schedule X
b) Schedule P
c) Schedule O
d) Schedule M

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

4. Who is the *ex officio* member of the DTAB?
a) The Director of the central drug laboratory,Kolkatta
b) Director of Finance ministry
c) Executive member of disaster control team
d) Independent director

5. Function of DCC is _____
a) To analyse samples sent
b) To grant permission for sale of drugs
c) To inspect manufacturing premises
d) To advice central and state government and DTAB

6. Which of the following drugs are prohibited to manufacture for sale under D and C Act
a) Any drug of standard quality
b) Drug labelled in prescribed manner
c) Any drug with import licence
d) Any drug which claims to cure or prevent any disease or ailments specified in schedule J

7. GMP requirements of factory premises and for manufacture of Ayurvedic (including Siddha) and Unani drugs is given in
   a) Schedule M II
   b) Schedule M
   c) Schedule T
   d) Schedule U

8. If the manufacturer does not hold a separate licence for test, analysis or examination the licence is obtained in _____.
   a) Form 28
   b) Form 29
   c) Form 10
   d) Form 12

9. Which of the following is a prohibited advertisement?
   a) Advertisements of magic remedies for the treatment of certain of certain diseases and disorders
   b) Advertisements by Government
   c) Leaflets or literature along with packing of drugs
   d) Therapeutic index published by licenced manufacturer

10. Cannabis means
   a) Charas
   b) Opium
   c) Medicinal preparation
   d) Manufactured drug

11. Pharmacy act was passed in
   a) 1978
   b) 1948
   c) 1971
   d) 1955

12. Nominated members of IAEC includes
   a) Two members of Indian council of medical Research
   b) Drugs controller of India
   c) Two Pharmacists
   d) One member of IPA

13. Restricted preparations are
   a) Preparations used for hair care
   b) Capable of being misused as ordinary alcoholic beverages
   c) Preparations which can be repacked without licence
   d) Preparations which can be manufactured in absence of excise commissioner

14. 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

15. Health and survey committee was established under chairmanship of _____
   a) Mr. Jaisukhlal Haathi
   b) Sir. Joseph Bhore
   c) R. N. Chopra
   d) Dr. Mashelkar

16. As per MTP act _____is mandatory for termination of pregnancy.
   a) Consent form of Pregnant woman
   b) Consent form of relatives
   c) Consent form of parents
   d) Consent form of in laws

17. Acyclovir comes under _____
   a) Schedule G
   b) Schedule B
   c) Schedule J
   d) Schedule H

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

19. What is the meaning of "novelty" in relation to a product or a process?
   a) Not Presented
   b) Not published
   c) Not performed
   d) Non existent

20. Which of the following is the geographical indication property right?
   a) Sanganeri Hand Block Print
   b) Coding programme
   c) Paper making
   d) Algorithm

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

I a) Define 'Drug' and 'spurious drugs' as per D and C Act 1940 and discuss the classes of drugs which are prohibited for manufacture and sale. **6**

b) Write a note on education regulations and enlist the offences and under Pharmacy Act 1948. **4**

II	a)	Define 'Coca Leaf' under NDPS Act. What are the operations controlled under NDPS act? Enlist any two offences under NDPS Act .	**6**
	b)	Give the objectives of prevention of cruelty to animals act. Elaborate on procedure to be followed for Performance of experiments on animals	**4**
III	a)	Enlist required qualifications for Drug inspector and elaborate on powers and duties of drug inspector as per D and C act 1940.	**6**
	b)	Discuss the standard operating procedure(SOPs) as per schedule M as given in Drugs and Cosmetic act 1940.	**4**

Q.3 Answer any seven questions. **35**

I.	Discuss the labelling requirements for drugs other than homoeopathic medicines as per the drugs and cosmetic act 1940.	**5**
II.	What do you mean by Loan licence? Describe the forms and provisions required to issue a loan licence.	**5**
III.	Write note on Schedule N	**5**
IV.	a) Define 'Advertisement' and describe the objective of DMR(OA) Act. b) What are the objectives of DPCO 2013 and differentiate between DPCO 1995 and DPCO 2013	**5**
V.	Discuss the recommendations given by the Drug enquiry committee.	**5**
VI.	What ethics a pharmacist should follow in relation to his job and in relation to his/her profession.	**5**
VII.	a) Differentiate between bonded laboratory and non bonded laboratory. b) Discuss the provisions made for termination of pregnancy as per MTP Act.	**5**
VIII.	Define the term "Right to Information". What are the duties 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**