12425

20226

**03 Hours / 80 Marks**

Seat No. | | | | | | | | |

*Instructions* – (1) All Questions are *Compulsory.*
(2) Answer each next main Question on a new page.
(3) Mobile Phone, Pager and any other Electronic Communication devices are not permissible in Examination Hall.
(4) Incase student has attempted sub-question of question no. 3 more than once, only first attempt should be considered for assessment.

**Marks**

**1. Attempt any SIX of the following:** **30**

a) List ex-officio members and describe the functions of the Pharmacy Council of India.
b) Give objective of D&C Act 1940 and Give constitution of DTAB.
c) Define:
   i) Misbranded drug and
   ii) Adulterated drug as per D&C Act, 1940
d) What does following schedule contains as per Drugs and cosmetic Act 1940:
   i) Schedule A
   ii) Schedule G
   iii) Schedule H
   iv) Schedule N
   v) Schedule R
e) Define 'Bulk drug' as per DPCO and how the retail price of a formulation is calculated?
f) Explain the code of ethics by the PCI for the pharmacist in relation to his Job.
g) Describe the phases of clinical trials.

**2. Attempt any TEN of the following:** **30**

a) Describe the recommendations of the drug enquiry committee.
b) State the classes of drugs prohibited to import as per D&C Act, 1940.
c) Give functions of CDL as per D&C Act, 1940 (Any 6)
d) Write the qualification required to appoint a government analyst as per D&C Act, 1940.
e) Define opium. Addict and coca leaf as per NDPS Act, 1985.
f) Define Magic Remedies? State the objectives of drugs and magic remedies Act, 1954.
g) State the various rules prescribed by State Government for possession, possession for sale and for sale of poisonous substances under Poison Act, 1919.
h) Write any three bonafied reasons for termination of pregnancy under MTP Act, 1971.
i) Discuss the documentation and License required for community pharmacy as per good regulatory practices.
j) Give difference between Brand name drug and Generic drug.
k) Explain the constitution of the national council for clinical establishments.

P.T.O.

Marks

**3. Attempt ALL of the following:** **20**

a) DTAB has _____ Ex-officio members.

b) Examples of schedule 'X' except -

i) Analgin ii) Amobarbital

iii) Pentobarbital iv) Cyclobarbital

c) Indian veterinary research institute is situated at _____ .

d) CPCSEA stands for _____ .

e) According to 'Prevention of cruelty to Animal Act', 'Animal' means any living creature other than _____ .

f) State any two important things should appear on the label of Food Supplements as per FSSAI.

g) What does schedule I prescribe as per DPCO.

h) State any two examples of drug added to the list of NLEM 2021.

i) Hawking of drugs is a part of ethics related to _____

i) Pharmacist in relation to his job

ii) Pharmacist in relation to his trade

iii) Pharmacist in relation to medical profession

iv) Pharmacist in relation to his own profession

j) MTP Act was passed in year _____ .

k) Role of CDSCO except _____

i) Responsible for approval of new drug

ii) Conduct of clinical trials

iii) Amendments of D&C Act and rules

iv) Publish Indian Pharmacopoieu

l) Write the full form of CDER with respect to pharmacy profession.

m) State the function of blood bank.

n) Human Anatomical Waste is discarded in which category as per biomedical waste management schedule.

o) What is the long form of ICMR.

p) What are the common bioethical issues?

i) Eugenics ii) Euthanasia

iii) Organ donation iv) All of these

q) State the name of bioethical principle.

r) The consumer protection act was initiated in India in year _____ .

s) National Institute of Disaster Management authority comes under _____

i) Ministry of Home Affairs ii) Ministry of Environment

iii) Ministry of Pollution iv) Ministry of Foreign Affairs

t) Give two example of medical device.

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