03 Hours / 80 Marks

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

Instructions – (1) All Questions are *Compulsory.*
(2) Answer each next main Question on a new page.
(3) Figures to the right indicate full marks.
(4) Mobile Phone, Pager and any other Electronic Communication devices are not permissible in Examination Hall.
(5) In case student has attempted sub-question of question no. 3 more than once, only first attempt should be considered for assessment.
(6) Answer as per latest amendment.

Marks

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

a) Write the constitution and functions of state pharmacy council.
b) Discuss the code of ethics of pharmacist in relation to his trade as per code of ethics.
c) Explain in detail schedule N under D&C Act 1940.
d) What is clinical trials. Discuss in brief phases of clinical trials.
e) Write qualifications and powers of Drug Inspector under D&C Act 1940.
f) Give constitution and functions of Drugs Technical Advisory Board.
g) State any two objectives of DPCO 1995. Describe the formula for calculating retail price of formulation.

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

a) Give important recommendations of Drug Enquiry Committee and its significance.
b) Discuss the functions of Central Drug Laboratory. (Any three)
c) Describe the labelling requirement of ophthalmic preparations under D&C Act 1940.
d) Explain in brief provision related to import of drugs under D&C Act 1940.
e) Write any three offences and penalties under NDPS Act 1985.
f) Give bonafied reasons for termination of pregnancies as per MTP Act 1971.
g) What are Good Regulatory Practices? Write documentation and licenses in community pharmacy.
h) Define patent. Enlist various types of Intellectual Properties. (IPR)
i) Explain registration of clinical establishments as per act.
j) State the classes of Exempted Advertisements as per Drugs and Magic Remedies Act 1954.
k) Define "Poison". Give the objectives of Poisons Act 1919 with two examples.

Marks

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

a) Define Chemist and Druggist under D&C Act 1940.

b) As per D&C Act "Schedule" O is related to _____

c) List of drugs used by patient under medical supervision is covered under _____

i) Schedule G ii) Schedule H
iii) Schedule I iv) Schedule J

d) CPCSEA has headquarter at _____

e) A price fixed by the Government for scheduled formulations according to the provisions of DPCO is,

i) Ceiling Price ii) Retail Price
iii) Buying Price iv) Maximum Retail Price

f) Post tax return on net worth under DPCO 1995 is _____ .

g) Hawking of drugs is a part of ethics of Pharmacist in relation to which code of ethics?

h) Define Lunatic under MTP Act 1971.

i) Registration of breeders, permission has to be taken from

i) Central Government ii) IAEC
iii) CPCSEA iv) No permission required

j) IPC stand for

i) Indian Pharmaceutical Congress
ii) International Pharmacy Council
iii) Indian Pharmaceutical Council
iv) Indian Pharmacopoeia Commission

k) The Principle of Bioethics is essentially derived from religious books. State True or False.

l) What is SUGAM portal?

m) Enlist the steps for a waste treatment method for biomedical waste

n) How often the blood can be donated?

o) The core principles of bioethics are the following except.

i) Justice ii) Autonomy
iii) Beneficence iv) Maleficence

p) Enlist any two rights of consumer as per consumer protection Act, 2019.

q) Write full form of NDRF.

r) The high-risk medical devices are classified under which class?

s) Headquarter of FSSAI is located in, _____

t) State any one guideline of ICMR

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