23242

3 Hours / 80 Marks

20226

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

Instructions – (1) All Questions are Compulsory.

(2) Answer each next main Question on a new page.

(3) Illustrate your answers with neat sketches wherever necessary.

(4) Figures to the right indicate full marks.

(5) Assume suitable data, if necessary.

(6) Mobile Phone, Pager and any other Electronic Communication devices are not permissible in Examination Hall.

Marks

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

a) Define education regulation. Describe it in detail and define 'Central Register'.

b) Give the constitution and functions of Drugs Technical Advisory Board.

c) Discuss the ethics of pharmacists in relation to his job as per the code of pharmaceutical ethics.

d) Give the functions of Central Drug Laboratory (CDL).

e) Give the formula for calculation of retail price of drug formulation and explain the terms involved in it as per DPCO, 1995 and define 'Ceilling Price'.

f) What is clinical trial and explain various phases of clinical trials.

g) Define government analyst. State qualifications for appointment of government analyst as per D and C Act,1940.

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

a) Write the classes of drugs and cosmetics prohibited for manufacture as per D and C Act and Rules.

b) Give any three bonafide reasons for termination of pregnancy under Medical Termination of Pregnancies Act, 1971.

c) Describe documentation, licenses and renewals of pharma manufacturing as per good regulators practices.

d) Write recommendation of 'Drug Enquiry Committee'.

e) State the classes of prohibited advertisements as per DMR Act, 1954. (any three)

f) What are the labelling particulars required to appear on label of 'Ophthalmic preparations'.

g) Define 'Poison' as per Poison Act, 1919 and name any two poisons specified in list 'A' and list 'B' each.

h) Write penalties for punishment for contravention in relation to coca plant under NDPS Act and the rules.

i) Define 'Repacking of drugs' and state any four conditions for grant of repacking licence.

j) Differentiate Brand name and Generic name of drugs.

k) What are the functions of the National Council for clinical establishments?

P.T.O.

Marks

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

a) Define 'Chemist and Druggist'.

b) Clandestine arrangements as per code of pharmaceutical ethics means.
   i) Secret agreements
   ii) Pharmacist may render first aid to victim
   iii) Link between medical profession and public
   iv) All of the above

c) CPCSEA stands for _____.

d) What does schedule G to the rules prescribes?

e) Give function of Food Authority.

f) What is the objective of DPCO. (any two)

g) Name of local body which allow experiments on small animals?
   i) CPCSEA ii) IAEC
   iii) IACE iv) IECC

h) Medical termination of Pregnancy Act was passed in _____.

i) For production from basic stage post tax return of _____ on net worth is considered.
   i) 10% ii) 20%
   iii) 8% iv) 18%

j) Give two examples of schedule J.

k) State the principles of biethics.

l) Mention different classes of medical devices.

m) GRP stand for _____.

n) 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

o) Who is the head of the Central Authority's Investigation wing?
   i) Police Inspector ii) Director General
   iii) Magistrate iv) Police Commissioner

p) ICMR stands for _____.

q) Who is the head of Central Drugs Standards Control Organization. (CDSCO)

r) Human Anatomical waste is categorised in which colour bag as per Biomedical Waste Management Act.

s) Minimum haemoglobin require to donate blood is _____.

t) Define 'Bioethics'.

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