22223

3 Hours / 80 Marks

20226

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.

Marks

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

a) Give the procedure for preparing First register and What qualifications required for entry for First register as per pharmacy Act. 1948?

b) Write the qualification for Drug inspector and give the procedure of drug inspector in taking samples.

c) Define the term under D and C Act. 1940
   i) Adulterated Drugs
   ii) Misbranded Drugs.
   Give the functions of CDL as per D and C Act. 1940.

d) State in detail provisions "Schedule N" of D and C Rules 1945.

e) Give the objectives of DPCO, 2013 and define the term under this Act -
   i) Active Pharmaceutical Ingredients
   ii) Formulation
   iii) Maximum Retail price

f) Give two points of difference in law and ethics. Explain the duties of pharmacist in relation to his trade.

g) Explain the steps involved in New Drug Development.

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

a) Explain the general principles of law.

b) Define Drug and New Drug as per the D and C Act. 1940.

c) List licences (with form numbers) for sale of drugs under D and C Act. 1940.

d) Define Repacking of Drugs and state any six conditions for grant of repacking license.

e) Define 'Illicit traffic' under NDPS Act. 1985.

f) Give offences and penalties under Drugs and Magic Remedies (O.A.) Act. 1954.

g) Give provisions for sale and possession of poison under poison Act. 1919.

h) Write the experience and training of Registered Medical Practitioner (RMP) required for termination of pregnancy as per MTP Act. 1971.

i) Explain the documentation, license and renewals in pharma manufacturing.

j) Write the difference between branded and generic drugs (any six)

k) Explain the procedure for registration of the clinical establishment.

Marks

3. Attempt ALL questions: **20**

a) List of diseases and ailments which a drug may not claim to prevent or cure is covered under ..... schedule.

b) As per D and C rules schedule R prescribe.....

c) Which of the following is prohibited to be imported ?

i) Toilet preparations ii) Ayurvedic Drugs

iii) Misbranded Drugs iv) Schedule C, G Drugs

d) CPCSEA stands for .....

e) Define captive animal as per prevention of cruelty to Animal Act. 1960.

f) Out of 22 members of food Authority, the proportion women is .....

i) Half ii) One - Third

iii) One - Fourth iv) Two - Third

g) Which act's prime objective is to make sure that the essential drugs are available to all at a reasonable price.

h) For calculation of price of bulk drugs a return of 12% is allowed on ..... costing.

i) Short term marginal ii) Long term marginal

iii) Periodic iv) Intermediate

i) Code of pharmaceutical ethics developed by.....

j) Define the term minor.

k) The CDSCO is a ..... body.

l) Which authority issue the drug manufacturing license.....

m) Minimum haemoglobin value required for a donor to donate-blood is .....gm/dl

n) Medical devices rules were established in the year .....

i) 1971 ii) 1917

iii) 1997 iv) 1979

o) Head office of National Institute of Disaster Management (NIDM) is situated in which city?

p) Consumer protection Act is significant to ?

i) All goods and services ii) Immovable goods

iii) Movable goods iv) Selected goods and services

q) Define Bioethics

r) As per Bioethics. Enlist the principle of justice.

s) Moral rules to protect and defend the right of patient is mentioned under ..... principle of bioethics.

t) Animal anatomical wastes are categorised under which category of biomedical waste.

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