

22223

3 Hours / 80 Marks



20226

Seat No.

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- 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.

P.T.O.

**3. Attempt ALL questions:**

- 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 isgm/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.