P.T.O.

3 Hours / 80 Marks

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- (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.

Seat No.

Marks

2022

Attempt any SIX of the following: 1.

- Give the procedure for preparing First register and What qualifications a) 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.
- Explain the steps involved in New Drug Development. g)

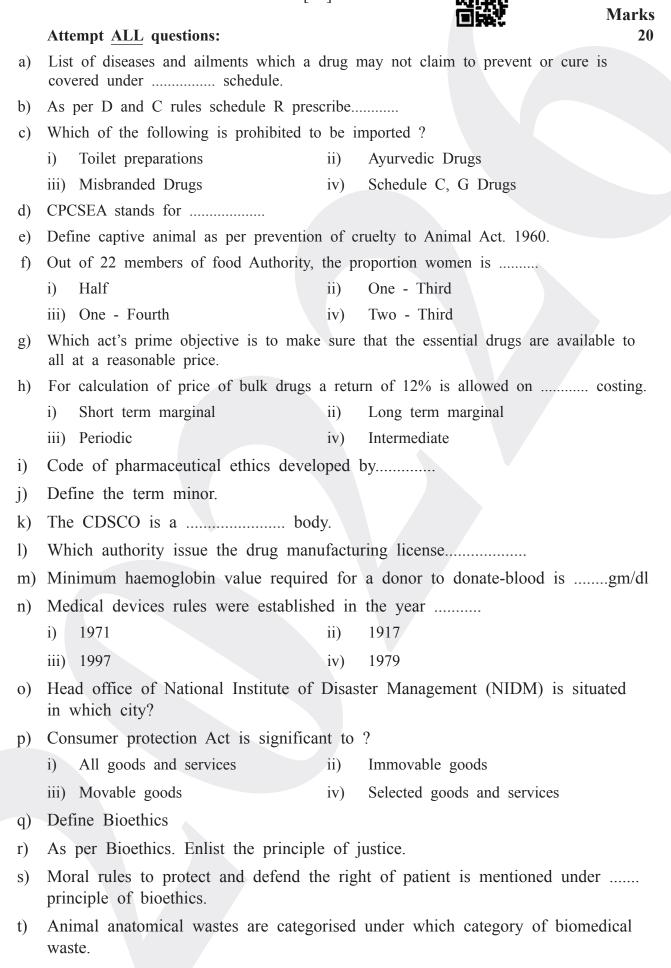
Attempt any TEN of the following: 2.

- Explain the general principles of law. a)
- Define Drug and New Drug as per the D and C Act. 1940. b)
- List licences (with form numbers) for sale of drugs under D and C Act. 1940. c)
- Define Repacking of Drugs and state any six conditions for grant of repacking license. d)
- Define 'Illicit traffic' under NDPS Act. 1985. e)
- Give offences and penalties under Drugs and Magic Remedies (O.A.) Act. 1954. f)
- Give provisions for sale and possession of poison under poison Act. 1919. **g**)
- Write the experience and training of Registered Medical Practitioner (RMP) h) required for termination of pregnancy as per MTP Act. 1971.
- Explain the documentation, license and renewals in pharma manufacturing. i)
- Write the difference between branded and generic drugs (any six) i)
- Explain the procedure for registration of the clinical establishment. k)

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3.