

12526

03 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) Answer as per the latest amendment.

Marks

1. **Attempt any SIX of the following :** **30**
 - a) Give objective of D and C Act, 1940. Give functions of CDL (Any six).
 - b) Define drug inspector. What are the duties of drug inspector in relation to sale of drugs and cosmetics.
 - c) Explain the steps involved in new drug development.
 - d) Discuss the salient features of DPCO and how the retail price of drug is calculated.
 - e) Give constitution of DTAB.
 - f) Explain the code of ethics in relation to job as per code of ethics.
 - g) Discuss the constitution and function of PCI.

2. **Attempt any TEN of the following :** **30**
 - a) Give recommendation of DEC.
 - b) Give conditions for supply of schedule 'X' drugs on retail as per D and C Act, 1940.
 - c) Explain the procedure for registration of the clinical establishment.
 - d) Explain documentation, License and renewals in Pharma manufacturing.
 - e) List the facilities provided and approval of places for termination of pregnancy under MTP act, 1971.
 - f) Give difference between brand name and generic name.
 - g) Give constitution and function of DCC.
 - h) Explain any three phases of clinical trials.
 - i) What are the rules prescribed by State Govt in relation to possession and sale of poison (Any two).
 - j) Define magic remedies and give exempted advertisement under DMR act 1954.
 - k) Give labelling condition for ophthalmic preparations as per D and C Act, 1940.

3. **Attempt ALL of the following :** **20**
 - a) Give principles of bioethics.
 - b) License to sell by retail drugs specified in schedule C and C₁ is issued in which form no?
 - c) What 'Class D' in medical devices stands for — ?
 - d) As per D and C Act, 1940 schedule ff is related with —.

P.T.O.

- e) Central drug laboratory is located at except ——.
- Kasuli
 - Lucknow
 - Kolkata
 - Jaipur
- f) Enlist common bioethical issues. (Any two)
- g) —— is e-governance system to discharge various functions performed by CDSCO under D and C Act, 1940.
- h) Who is the head of the National Disaster Management Authority ?
- FSSAI Stands for ——
- j) Define Ceiling price of Drug.
- k) The WHO Model List of Essential Medicine is updated in ——
- Every 1 year
 - Every 5 year
 - Every 2 year
 - Every 7 year
- l) Define Guardian as per MTP Act, 1971.
- m) Give two functions of Animal Welfare Board of India.
- n) ICMR stands for ——.
- o) For performing animal studies permission has taken from ——.
- IAEC
 - Central Government
 - State Government
 - None of the above.
- p) Head office of CDSCO is located at which place ?
- q) Define 'Ethics'.
- r) The interval between two blood donations should be ——
- 6 weeks
 - 8 weeks
 - 10 weeks
 - 12 weeks
- s) Human Anatomical waste is covered under the provisions of —— Act.
- t) The Consumer Protection was passed in the —— year.
- _____