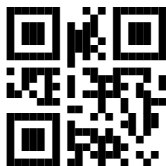


23242

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) 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.

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

- 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'.