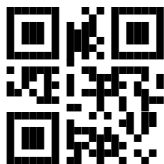


12425

03 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) Mobile Phone, Pager and any other Electronic Communication devices are not permissible in Examination Hall.
 - (4) Incase 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) List ex-officio members and describe the functions of the Pharmacy Council of India.
- b) Give objective of D&C Act 1940 and Give constitution of DTAB.
- c) Define:
 - i) Misbranded drug and
 - ii) Adulterated drug as per D&C Act, 1940
- d) What does following schedule contains as per Drugs and cosmetic Act 1940:
 - i) Schedule A
 - ii) Schedule G
 - iii) Schedule H
 - iv) Schedule N
 - v) Schedule R
- e) Define 'Bulk drug' as per DPCO and how the retail price of a formulation is calculated?
- f) Explain the code of ethics by the PCI for the pharmacist in relation to his Job.
- g) Describe the phases of clinical trials.

2. Attempt any TEN of the following:

30

- a) Describe the recommendations of the drug enquiry committee.
- b) State the classes of drugs prohibited to import as per D&C Act, 1940.
- c) Give functions of CDL as per D&C Act, 1940 (Any 6)
- d) Write the qualification required to appoint a government analyst as per D&C Act, 1940.
- e) Define opium. Addict and coca leaf as per NDPS Act, 1985.
- f) Define Magic Remedies? State the objectives of drugs and magic remedies Act, 1954.
- g) State the various rules prescribed by State Government for possession, possession for sale and for sale of poisonous substances under Poison Act, 1919.
- h) Write any three bonafied reasons for termination of pregnancy under MTP Act, 1971.
- i) Discuss the documentation and License required for community pharmacy as per good regulatory practices.
- j) Give difference between Brand name drug and Generic drug.
- k) Explain the constitution of the national council for clinical establishments.

P.T.O.

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

- a) DTAB has _____ Ex-officio members.
- b) Examples of schedule 'X' except -
 - i) Analgin
 - ii) Amobarbital
 - iii) Pentobarbital
 - iv) Cyclobarbitol
- c) Indian veterinary research institute is situated at _____ .
- d) CPCSEA stands for _____ .
- e) According to 'Prevention of cruelty to Animal Act', 'Animal' means any living creature other than _____ .
- f) State any two important things should appear on the label of Food Supplements as per FSSAI.
- g) What does schedule I prescribe as per DPCO.
- h) State any two examples of drug added to the list of NLEM 2021.
- i) Hawking of drugs is a part of ethics related to _____
 - i) Pharmacist in relation to his job
 - ii) Pharmacist in relation to his trade
 - iii) Pharmacist in relation to medical profession
 - iv) Pharmacist in relation to his own profession
- j) MTP Act was passed in year _____ .
- k) Role of CDSCO except _____
 - i) Responsible for approval of new drug
 - ii) Conduct of clinical trials
 - iii) Amendments of D&C Act and rules
 - iv) Publish Indian Pharmacopoeia
- l) Write the full form of CDER with respect to pharmacy profession.
- m) State the function of blood bank.
- n) Human Anatomical Waste is discarded in which category as per biomedical waste management schedule.
- o) What is the long form of ICMR.
- p) What are the common bioethical issues?
 - i) Eugenics
 - ii) Euthanasia
 - iii) Organ donation
 - iv) All of these
- q) State the name of bioethical principle.
- r) The consumer protection act was initiated in India in year _____ .
- s) 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
- t) Give two example of medical device.
