

S. B. Roll. No.....

PHARMACY LAW AND ETHICS
2nd Exam/Pharmacy/3036/Nov'24
(For 2021 Batch Onwards)

Duration: 3Hrs.

M.Marks:80

SECTION-A

Q1. Do as directed.

20x1=20

- a. Define stocking of animals.
- b. Define CDSCO.
- c. Define patent.
- d. Define whole sale of drugs.
- e. Define ANDA.
- f. Define ICMR.
- g. Define trade name concept.
- h. Define ethical principles.
- i. Define NLEM.
- j. Define AICTE.
- k. Health survey and development committee was constituted in _____.
- l. MAPE stands for_____.
- m. Pharmacy bill was passed in year_____.
- n. Schedule M3 deals with_____.
- o. 4th pharmacopoeia was published in the year_____.
- p. CCPA came into force in_____.
- q. 12 weeks of pregnancy for abortion to be certified by _____.
- r. Elected and nominated members of the council can hold office for a period of _____.
- s. Define blood bank.
- t. Schedule P deals with_____.

SECTION-B

Q2. Attempt any ten questions.

10x3=30

- i. Discuss role of different committees in disaster management?
- ii. Discuss manufacturing of new drug in brief?
- iii. What is CPCSEA? Discuss its role in detail?
- iv. Write a detailed note on Medicinal and Toilet Preparation?
- v. Write manufacture of manufactured Psychotropic substances also write their import, export and transshipment?
- vi. Discuss qualification of Drug Analyst along with its functions?
- vii. Discuss categorization of Medical Devices and basic aspects related to its manufacturing and sale?
- viii. Discuss in detail about drug and magic remedies and objectionable advertisements in detail?
- ix. Discuss Clinical Establishments and its aspect related to Pharmacy?
- x. Discuss functions and basic requirements of blood bank?
- xi. Discuss ANDA and NDA in brief along with its role?

SECTION -C

Q3. Attempt any six questions.

6x5=30

- a. How the prices of drugs in the bulk and retail formulations of drugs are calculated under the drug price control order?
- b. What do you mean by Code of Pharmaceutical Ethics? Discuss role of pharmacist in his medical profession and Trade?
- c. What do you mean by GRP? Discuss its role in documentation, licenses, import exports of drugs and medical devices?
- d. Discuss BCS system of classification along with basic concepts of clinical trials?
- e. What is FSSAI? Discuss its role in manufacture, sale and labelling of food supplements.
- f. Discuss role of IPC and CDSCO as pharma regulator bodies?
- g. Discuss role of consumer protection act in the life of a consumer?

