

Paper code

Roll No.....

Examination: B.Sc. (Toxicology), - Semester V semester (2023)

Paper: Drug Regulatory Affairs (Code: BTX-CC-16)

Time: 3 h

MM: 75

This Q paper contains 5 questions, each of 15 marks.

Q1. Choose the correct answer of the following questions [10×1= 15]

- I. The Drugs (Prices Control) Order, 1995, was issued under the Essential Commodities Act to regulate the prices of essential drugs. Which organization is responsible for implementing these price controls?
- a) National Pharmaceutical Pricing Authority (NPPA) b) Department of Pharmaceuticals
c) Ministry of Commerce and Industry d) Bureau of Indian Standards (BIS)
- II. The Drugs and Cosmetics Act, 1940, was amended to include provisions for the regulation of medical devices in which year?
- a) 1955 b) 1966 c) 1982 d) 2005
- III. Which organization is responsible for implementing the provisions of the Narcotic Drugs and Psychotropic Substances Act, 1985, in India?
- a) Central Bureau of Investigation (CBI) b) Central Narcotics Bureau (CNB)
c) Narcotics Control Bureau (NCB) d) Central Intelligence Agency (CIA)
- IV. What is the name of founder of Bengal Chemicals and Pharmaceutical Works, which was one of the first pharmaceutical establishment in India?
- a) Prof. T.K Gajjar b) Acharya Praffula Chandra Ray
c) Mr. Smith Stainstreet and Co. d) Mr. Bathgate
- V. Drug Enquiry Committee is also known as
- a) Wavell Committee b) Hunter Commission
c) Chopra Committee d) Sondhi Committee
- VI. What was the first comprehensive drug legislation enacted in India?
- a) Drugs and Cosmetics Act, 1940 b) Opium Act, 1857
c) Narcotic Drugs and Psychotropic Substances Act, 1985 d) Indian Hemp Drugs Commission Report, 1894
- VII. When was the Indian Patent and Design Act enacted?
- a) 1948 b) 1955 c) 1970 d) 1985
- VIII. Which authority is responsible for granting licenses for the manufacture of drugs and cosmetics in India under the Drugs and Cosmetics Act, 1940?
- a) Ministry of Health and Family Welfare
b) Central Drugs Standard Control Organization (CDSCO)
c) Indian Pharmacopoeia Commission
d) Food Safety and Standards Authority of India (FSSAI)

- IX. Which of the following act is regulating the establishment of a pharmaceutical manufacturing unit?
- Pharmacy Act 1948
 - The Industries (Development and Regulations) Act, 1951
 - Factory Act
 - The Industries (Development and Regulations) Act, 1951
- X. The Narcotic Drugs and Psychotropic Substances Act, 1985, was enacted to fulfill India's obligations under which international convention?
- Geneva Convention
 - Vienna Convention
 - Hague Convention
 - Montreal Convention
- XI. The purpose of Pharmaceutical legislation is to ensure that the patients receive drugs of required quality, tested and evaluated for _____ and efficacy for their intended result.
- XII. Drug bill was introduced in 1940 in legislative assembly, and Drug Bill 1940 was passed, which came to force in _____.
- XIII. The main objective of the Drug Act, 1940 was to regulate the import, manufacture, _____ and sale of drugs and cosmetics in India.
- XIV. The Pharmacy act 1948 was passed with the main objective to regulate the _____ of Pharmacy in India.
- XV. In 1910, Mr. Bathgate established the first _____ in Calcutta.

Q2 Write the short note on any five of the followings

[5×3=15]

- Recent amendments of Drugs and Cosmetics Act 1940
- Three Recommendation of Chopra Committee
- Origin of pharmaceutical legislation in India
- Delhi shops and Establishment Act
- Drug and Cosmetic Rules 1945
- Objective of the NPPA in India

Q3 Attempt any 3 questions

[3×5=15]

- What role does the Central Drug Standard Control Organization (CDSCO) play in the regulation of pharmaceuticals in India?
- Briefly describe the amendments made to the Drugs and Cosmetics Act and their implications for the pharmaceutical industry.
- What is NDPS Act and its main objective?
- Briefly explain the Drugs and Magic Remedies (Objectionable Advertisements) Act.

Q4 How does the drug regulation started in India? Explain the reasons of formation of drug enquiry committee, its recommendation, and implementations. [15]

[OR]

What is Drug Bill 1940? Explain its scopes, objectives, enforcement, and amendments.

Q5 What is Pharmacy Act and why was it enforced? Explain its objectives and implementations. [15]

[OR]

Chronologically enlist the legislative acts regulating the import, manufacture, distribution and sale of drugs and cosmetics in India and briefly explain the Delhi shops and Establishment Act and its implementation in drug regulation.

—End of Question paper—