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2024

D.Pharm. Part II (Regular) End-Term Examination

PHARMACY LAW AND ETHICS

Full Marks – 80

Time – Three hours

The figures in the margin indicate full marks  
for the questions.

1. Objective type (Answer all *twenty*) : (20 × 1 = 20)
- (i) The Central drug laboratory is situated at \_\_\_\_\_.
  - (ii) Schedule P is related to \_\_\_\_\_.
  - (iii) What are some common food safety standards set by FSSAI?
  - (iv) What are the penalties for false warning of disaster?
  - (v) Who is the chairperson of the National Disaster Management Authority (NDMA)?
  - (vi) What are the key steps involved in blood donation and processing at a blood bank?
  - (vii) Where is the Government Opium factory is situated?
  - (viii) Name the schedule under which Phenobarbitone comes under the D and C Act.
  - (ix) What is another name of Phase IV clinical trial?
  - (x) What is the expanded form of CDSCO?
  - (xi) Where is the Headquarters of the National Pharmaceutical Pricing Authority situated?
  - (xii) Father of pharmacy education in India is \_\_\_\_\_.
  - (xiii) Registered medicinal practitioner is approved by act \_\_\_\_\_.

[Turn over



- (xiv) Poisons Act was passed in year \_\_\_\_\_.
- (xv) "Drug Enquiry Committee" (DEC) under the chairmanship of Lt. Col R.N. Chopra in the year
- (a) 1932 (b) 1931  
(c) 1948 (d) 1952
- (xvi) If the length of pregnancy exceeds 12 weeks but does not exceed 20 weeks, it can be terminated only if at least \_\_\_\_\_ medical practitioners are of the opinion that termination is necessary.
- (a) One (b) Two  
(c) Three (d) Four
- (xvii) The consumer protection act was enacted in the year
- (a) 1986 (b) 1984  
(c) 1982 (d) 1988
- (xviii) The disaster management act was made effective from
- (a) Dec. 23, 2005 (b) Dec. 24, 2005  
(c) Dec. 22, 2004 (d) Dec. 21, 2004
- (xix) The first department of pharmaceuticals was started at BHU \_\_\_\_\_.
- (a) 1932 (b) 1922  
(c) 1942 (d) 1952
- (xx) Which of the following is not a provision under the Prevention of Cruelty to Animals Act 1960?
- (a) Prohibition of animal fights  
(b) Protection of animals from unnecessary pain or suffering  
(c) Regulation of transportation of animals  
(d) Licensing of individuals for hunting endangered species

2. Short answer (Answer *ten* out of *eleven*) : (10 × 3 = 30)

- (a) Explain CCSEA's role in ensuring ethical treatment of animals in research.  
(b) What are the duties of a Drug Inspector?  
(c) Outline the process of developing a new drug.  
(d) What classes of drugs and cosmetics are prohibited from import without a license or permit?  
(e) Write short notes on the offenses and corresponding penalties as per the Pharmacy Act of 1948 and its accompanying rules.



- (f) What are the categories of advertisements exempted from regulation under the Drugs and Magic Remedies (Objectionable Advertisements) Act, 1954?
- (g) Explain the role of FSSAI in ensuring food safety standards and its impact on public health in India.
- (h) Discuss the key provisions of the Poison Act and regulations governing the import of poisons, highlighting their significance in safeguarding public health.
- (i) Discuss the role of the National Pharmaceutical Pricing Authority (NPPA) in regulating drug prices in India.
- (j) Explain the significance of good regulatory practices in community pharmacy and wholesale businesses.
- (k) Summarize the core principles of the ICMR's National Ethical Guidelines regarding biomedical and health research with human participants.
3. Long answer questions (Answer six out of seven) : (6 × 5 = 30)
- (a) Explain the necessary conditions for importing medical devices into India.
- (b) Describe the process involved in obtaining and renewing a license for a wholesale pharmacy.
- (c) Provide an overview of the membership and duties of the Pharmacy Council of India.
- (d) Discuss the significance of ANDA, IND, clinical trials and the overall process of new drug development in ensuring drug safety, efficacy and regulatory approval.
- (e) Explain the key provisions and significance of the Disaster Management Act, highlighting its role in disaster preparedness, response, and mitigation strategies in India.
- (f) Explain the Consumer Protection Act's main objectives and its role in protecting consumer rights.
- (g) Write short notes on the functions and significance of blood banks within the healthcare system, emphasizing their pivotal role in maintaining a stable supply of safe and compatible blood for transfusions.