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HILL UNIVERSITY
Established by an Act of the State Legislature of Uttarakhand (Adhiniyam Sankhya 12 of 2011)
University under section 2(f) of UGC Act, 1956

Sessional I (Even) Semester Examination March 2025

Roll no.....

Name of the Course: B.Pharm
Semester: VIII
Name of the Paper: Pharmacovigilance
Paper Code: BP-805ET
Time: 1.5 hour **Maximum Marks: 30**

Note:
(i) This question paper contains three sections
(iI) All the sections are compulsory

SECTION-A (Multiple Choice Questions)

Note: All questions are compulsory (10x1=10)

1	Which of the following best describes the primary purpose of pharmacovigilance? A) To discover new drugs B) To monitor and ensure the safety of medicines C) To market drugs to the public D) To reduce drug prices	(CO1)
2	What term refers to the serious consequences of an ADR that leads to death or hospitalization? A) Severity B) Causality C) Seriousness D) Predictability	(CO1)
3	Which of the following is included in the regulatory terminology for ADRs? A) Clinical trial evaluation B) Risk communication C) Market analysis D) Drug patenting	(CO1)

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4	How does the pharmacovigilance system assess predictability of an ADR? A) By analyzing the drug's marketability B) By reviewing clinical trials and prior knowledge C) By reducing drug production costs D) By limiting drug accessibility	(CO1)
5	Which of the following is an example of a method used in causality assessment of ADRs? A) Market research B) Post-marketing surveillance C) Algorithm-based evaluation D) Statistical analysis of drug prices	(CO1)
6	What does the WHO's International Non-Proprietary Names (INN) system provide? A) Drug patent information B) Common generic names for drugs C) Clinical trial outcomes D) Market prices of drugs	(CO2)
7	Which system is used to define daily defined doses (DDD) of medications? A) Anatomical Classification B) International Classification of Diseases C) WHO Drug Dictionary D) International Drug Monitoring Programme	(CO2)
8	How does the WHO Drug Dictionary assist in pharmacovigilance? A) By creating new clinical trial designs B) By providing a standardized classification for drugs C) By evaluating drug market trends D) By establishing marketing regulations	(CO2)
9	What is one of the main benefits of establishing a national pharmacovigilance program? A) Reducing the number of new drugs approved B) Improving public health through better monitoring of drug safety C) Limiting drug distribution globally D) Encouraging pharmaceutical companies to increase drug prices	(CO2)

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10	The role of Contract Research Organizations (CROs) in pharmacovigilance is..... A) To manufacture drugs B) To conduct safety monitoring and drug testing C) To reduce drug development costs D) To establish clinical trials for new drugs	(CO2)

SECTION-B (Short Answer Type Questions)

Note: Attempt any TWO (2x5=10)

1	Define pharmacovigilance and explain its significance in ensuring drug safety.	CO1
2	Describe the WHO International Drug Monitoring Programme and its role in global pharmacovigilance.	CO1
3	Outline the Anatomical Therapeutic Chemical (ATC) classification system and its application in pharmacovigilance.	CO2

SECTION-C (Long Answer Type Questions)

Note: Attempt any ONE (1x10=10)

1	Discuss the various methods used in causality assessment of adverse drug reactions (ADRs) and their importance in pharmacovigilance.	CO1
2	Analyze the role of Contract Research Organizations (CROs) in pharmacovigilance, focusing on their contributions to drug safety monitoring and reporting.	CO2