Graphic Era
HILL UNIVERSITY
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University under section 2(f) of UGC Act, 1956

End Term (Even) Semester Examination May-June 2025

Roll no.....

Name of the Course and semester: B.Pharm and VIII
Name of the Subject: Pharmacovigilance
Subject Code: BP-805ET
Time: 3 hour **Maximum Marks: 75**

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

SECTION-A

Multiple choice questions: **20 X 1 = 20 Marks**

1	_____ coordinates the WHO international drug monitoring program? A) FDA B) EMA C) Uppsala Monitoring Centre (UMC) D) CDSCO	(CO1)
2	When was the Pharmacovigilance Programme of India (PvPI) launched? A) 2005 B) 2010 C) 2012 D) 2015	(CO1)
3	Which of the following is a regulatory term in pharmacovigilance? A) MedWatch B) MedDRA C) MedCare D) MedAlert	(CO1)
4	In the context of pharmacovigilance, 'signal' refers to: A) A confirmed adverse reaction B) A hypothesis of a possible causal relationship between an adverse event and a drug C) A marketing strategy D) A communication from the FDA	(CO1)
5	The WHO Drug Dictionary is maintained by: A) Food and Drug Administration (FDA) B) European Medicines Agency (EMA) C) Uppsala Monitoring Centre (UMC) D) Central Drugs Standard Control Organization (CDSCO)	(CO2)

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6	The International Classification of Diseases (ICD) is primarily used to: A) Categorize pharmaceutical companies B) Standardize disease classification globally C) Monitor drug prices D) Define drug manufacturing processes	(CO2)
7	What is the primary function of Contract Research Organisations (CROs)? A) Develop new medicines B) Conduct clinical trials for pharmaceutical companies C) Manufacture drugs D) Market medicines to doctors	(CO2)
8	The establishment of a national program for drug safety is aimed at: A) Reducing the cost of medicines B) Ensuring the safe use of medicines at a national level C) Increasing the number of pharmaceutical companies D) Promoting herbal medicine use	(CO2)
9	What can be a sign of a vaccination failure? A) Mild fever following vaccination B) Inability to develop immunity after receiving a vaccine C) Redness at the injection site D) Temporary swelling around the injection area	(CO3)
10	If an adverse event following immunization (AEFI) occurs, what is the primary step in managing the situation? A) Discontinuing all vaccines immediately B) Investigating the event, identifying causality, and reporting to health authorities C) Changing the vaccine provider D) Increasing the dose of the vaccine	(CO3)
11	Which type of surveillance includes sentinel sites? A) Passive surveillance B) Active surveillance C) Comparative observational studies D) Targeted clinical investigations	(CO3)
12	When dealing with a drug safety crisis, what is a key aspect of communication? A) Ignoring the situation to avoid panic B) Providing clear, timely, and transparent information to the public C) Reducing the number of affected patients D) Only communicating with healthcare professionals	(CO3)

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13	In the pre-clinical phase, safety data is primarily generated by: A) Clinical trials with patients B) Animal studies and laboratory tests C) Patient surveys D) Monitoring healthcare professionals	(CO4)
14	Which of the following is a key element of post-approval safety monitoring? A) Using animal models to test for adverse reactions B) Collecting real-world data on drug safety through spontaneous reporting and registries C) Conducting initial animal studies D) Developing new formulations of the drug	(CO4)
15	What is an Individual Case Safety Report (ICSR)? A) A report detailing all pharmaceutical sales B) A detailed report on a specific adverse event related to a single patient C) A report on drug manufacturing standards D) A report containing market share data	(CO4)
16	The objective of periodic safety update reports (PSURs) is to: A) Update the public about drug prices B) Provide regular safety data and analysis on a drug's risks and benefits post-marketing C) Describe the manufacturing process of the drug D) Provide information on drug distribution channels	(CO4)
17	Genetic variations in pharmacokinetics (PK) can affect: A) The cost of a drug B) How a drug is absorbed, distributed, metabolized, and excreted in the body C) The size of drug doses D) The marketing strategy of a drug	(CO5)
18	Which of the following is a key concern when evaluating drug safety during pregnancy? A) Drugs can cross the placenta and affect fetal development B) Drugs only affect the maternal health and not the fetus C) Only the drug's effectiveness in the mother is important D) Drugs are always cleared faster in pregnancy	(CO5)
19	What does CIOMS Working Groups primarily focus on? A) Organizing clinical trials B) Collaborating on global health issues and creating guidelines in medical sciences C) Conducting sales marketing for pharmaceuticals D) Developing new pharmaceutical formulations	(CO5)

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20	The D&C Act and Schedule Y regulate: A) The prices of pharmaceutical drugs B) The safety, efficacy, and quality of drugs, as well as clinical trials and pharmacovigilance practices C) Drug packaging and labeling only D) Pharmaceutical sales targets	(CO5)

SECTION-B

Short Questions: Attempt any SEVEN questions. **7x5 = 35 Marks**

1	Explain the relationship between the Uppsala Monitoring Centre and the WHO International Drug Monitoring Programme.	(CO1)
2	Define ADRs and describe their classification	(CO1)
3	Explain the anatomical, therapeutic, and chemical classification systems for drugs. How do these classifications help in drug safety monitoring?	(CO2)
4	What are the key steps in establishing a pharmacovigilance program within a hospital?	(CO2)
5	Define vaccine pharmacovigilance. Explain reasons of vaccine failure.	(CO3)
6	Explain pharmacovigilance methods.	(CO3)
7	Discuss safety data generation and give its significance.	(CO4)
8	Give principles of Good clinical practice in pharmacovigilance studies.	(CO4)
9	Name any two CIOMS Working Groups and describe their focus areas briefly.	(CO5)

SECTION-C

Long questions: Attempt any TWO questions **2x10 = 20 Marks**

1	Discuss the history and key milestones in the development of pharmacovigilance.	(CO1)
2	What is the International Classification of Diseases (ICD), and how is it used in pharmacovigilance?	(CO2)
3	Discuss the major amendments made to Schedule Y over the years. How have these amendments impacted the regulation and conduct of clinical trials in India?	(CO5)