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

Sessional II (Even) Semester Examination May 2025

Roll no.....

Name of the Course and semester: 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: **10 X 1 = 10 Marks**

1	An example of active surveillance is_____ a) Spontaneous reporting b) Prescription event monitoring c) Cohort event monitoring d) Case-control studies	(CO3)
2	Key component of communication in pharmacovigilance is: a) Suppressing information about adverse drug reactions b) Delaying the dissemination of safety information c) Transparent and timely sharing of risk information with stakeholders d) Limiting information to regulatory authorities only	(CO3)
3	Passive surveillance method in pharmacovigilance is: a) Cohort event monitoring b) Prescription event monitoring c) Spontaneous reporting d) Sentinel surveillance	(CO3)
4	In vaccine pharmacovigilance, 'sentinel surveillance' refers to: a) Monitoring all adverse events in the general population b) Monitoring specific adverse events in selected healthcare settings c) Passive reporting of adverse events d) Monitoring only serious adverse events	(CO3)
5	The aim of spontaneous reporting in pharmacovigilance is to: a) Establish causality between drug and adverse event b) Perform benefit-risk analysis c) Conduct clinical trials d) Monitor drug efficacy	(CO3)

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6	Which type of safety data is generated during the pre-clinical phase? a) Clinical trial data b) Post-marketing surveillance data c) Laboratory and animal study data d) Epidemiological study data	(CO4)
7	What is the purpose of periodic safety update reports (PSURs) in pharmacovigilance? a) To report serious adverse events to regulatory agencies b) To provide a comprehensive review of a product's safety profile c) To monitor vaccine efficacy d) To improve vaccine distribution	(CO4)
8	Good clinical practice (GCP) is important in pharmacovigilance studies because a) It ensures the quality and integrity of clinical trial data b) It improves vaccine efficacy c) It reduces adverse events following immunization d) It increases vaccine distribution	(CO4)
9	What is informed consent in a clinical trial? a) Subjects do not know which study treatment they receive b) Patients injected with placebo and active doses c) Fake treatment d) Signed document of the recruited patient for the clinical trial procedures	(CO4)
10	How many people are typically selected for a Phase II trial? a) The whole market will be under surveillance b) 500–3000 people c) 100–300 people d) 20-50 people	(CO4)

SECTION-B

Short Questions: Attempt any TWO questions. **2x5 = 10 Marks**

1	What is vaccine pharmacovigilance? Give reasons of vaccine failure.	CO3
2	Discuss pharmacovigilance methods.	CO3
3	What are the objectives of ICH guidelines for pharmacovigilance. Give its structure.	CO4

SECTION-C

Long questions: Attempt any ONE question **1x10 = 10 Marks**

1	Discuss safety data generation.	CO3
2	Write a note on Good Clinical Practice in pharmacovigilance studies.	CO4