



PAPER ID-310789

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Subject Code: BP805ET

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BPHARM
(SEM VIII) THEORY EXAMINATION 2024-25
PHARMACOVIGILANCE

TIME: 3 HRS**M.MARKS: 75**

Note: 1. Attempt all Sections. If require any missing data; then choose suitably.

SECTION A

1. Attempt all questions in brief.**10 x 2 = 20**

a.	What are ICSR and PSUR?
b.	Outline importance of drug safety monitoring.
c.	Define CRF and SUSAR
d.	Write about primary purpose of MedDRA.
e.	Compare cross sectional study and case control study.
f.	Give objectives of ICH.
g.	Differentiate passive surveillance and active surveillance.
h.	Explain inform consent process.
i.	Enlist various factors affecting ADRs of vaccine.
j.	Compute the importance of ICD.

SECTION B

2. Attempt any two parts of the following:**2 x 10 = 20**

a.	Classify adverse drug reactions. Discuss their management.
b.	Explain drug safety evaluation in pregnancy and paediatric population.
c.	Write a note on schedule Y.

SECTION C

3. Attempt any five parts of the following:**7 x 5 = 35**

a.	Define preclinical studies. Explain phases of clinical trial.
b.	Discuss the role of GCP in Pharmacovigilance studies.
c.	Illustrate CIOMS in detail.
d.	Explain role of Pharmacogenomics in adverse drug reactions.
e.	Write a detailed note on Eudravigilance medicinal product dictionary.
f.	Elaborate the Pharmacovigilance programme of India.
g.	Give an explanation on vaccine safety surveillance.