Paper ID : 250380

Roll No: | | | | | | | | | | | | |

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.	Write in short about the importance of safety monitoring of Medicine.
b.	What are CROs ?
c.	Expand PvPI. When did PvPI established in India?
d.	What is vaccination failure?
e.	What is the importance of Schedule Y in Pharmacovigilance?
f.	Write the names of at least *four* International Non-proprietary drugs.
g.	On what basis drugs are classified?
h.	What is cohort analysis?
i.	What is the importance of CIOMS form?
j.	What Good clinical practices to be followed in pharmacovigilance studies?

SECTION B

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

a.	Elaborate Adverse drug reaction reporting systems and communication in pharmacovigilance.
b.	Expand ICH guidelines. Write in detail about the ICH guidelines for Pharmacovigilance.
c.	How safety data is generated at pre-clinical, clinical and post market level under vigilance program in India?

SECTION C

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

a.	Write a note on adverse events following immunization.
b.	Write the mission, objectives, structure, function and reporting methods of PvPI.
c.	Enlist some differences in Indian and global pharmacovigilance requirements.
d.	Write a note on MedDRA.
e.	Enlist some genetics related ADR with example.
f.	What are the parameters for drug safety evaluation in Pregnancy and lactation?
g.	How will you manage and report any adverse drug reaction?