BPHARMA
(SEM VIII) THEORY EXAMINATION 2021-22
PHARMACOVIGILANCE

Time: 3 Hours ***Total Marks: 75***

Note: 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 is drug event monitoring?
b.	List four drugs contraindicated in pregnant and lactating women.
c.	Suggest the requirements for CIOMS form
d.	What is eudravigilance?
e.	What is teratogenicity? Give examples.
f.	What is post marketing safety?
g.	Narrate the minimum criteria required for a valid report?
h.	What is phase IV of clinical trials?
i.	What are the basic objectives of pharmacovigilance planning?
j.	Mention few examples of predictable adverse drug reactions.

SECTION B

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

a.	Classify adverse drug reaction. How will you detect and report ADR along with causality assessment scales?
b.	Discuss in detail basic and specialized drug information resources in pharmacovigilance
c.	Discuss in detail of Cohort and case control study. Explain the applications of MedDRA and standard MedDra queries.

SECTION C

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

a.	Explain the establishing pharmacovigilance program in the hospital.
b.	What is vaccine safety surveillance? Explain in detail different types of pharmacovigilance methods used for passive and active surveillance.
c.	Discuss in detail establishment and operation of drug safety department in pharmaceutical industry.
d.	Mention the importance aspects of ICH guidelines for expedited reporting.
e.	Write short note on pharmacogenomics in adverse drug reaction
f.	How will you carry out drug safety evaluation in geriatric and pediatric populations?
g.	What is the role of CDSCO in pharmacovigilance? Write a note on ATC classification of drugs.