PAPER ID-310661

Subject Code: **BP805ET**

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

BPHARM

(SEM VIII) THEORY EXAMINATION 2023-24

PHARMACOVIGILANCE

TIME: 3 HRS **M.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 adverse drug reaction?
b.	Mention the differences between drug toxicity and drug abuse.
c.	What is eudravigilance?
d.	What is drug event monitoring?
e.	List four drugs contraindicated in padiatric patients.
f.	What is post marketing safety?
g.	Narrate the minimum criteria required for a valid report.
h.	Mention the salient features of Phase III of clinical trial.
i.	What do you mean by teratogenicity?
j.	What is ATC classification of drugs?

SECTION B

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

a.	Discuss the importance of safety monitoring of medicine. Highlight the salient features of the Pharmacovigilance Program of India (PvPI)
b.	How will you set up the establishment & operation of drug safety department in industry? Mention its rationale of such set up.
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.	Suggest some examples of vaccination failure. How will you control such failures in future?
b.	Mention the importance aspects of ICH guidelines for expedited reporting
c.	What is the role of CDSCO in pharmacovigilance? Write a note on ATC classification of drugs
d.	How will you carry out drug safety evaluation in pregnant woman and geriatric patients?
e.	Write short notes on CIOMS
f.	Suggest the role of genetics related ADR with examples
g.	Write short note on pharmacogenomics on adverse drug reaction