PAPER ID-410825

Subject Code: BP805ET

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

BPHARM

(SEM VIII) THEORY EXAMINATION 2023-24

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.	Name the different levels of ATC system.
b.	Discuss the applications of MedDRA.
c.	Examine the role of CRO in Pharmacovigilance.
d.	Discuss the purpose of INN.
e.	Explain the term “vaccination failure”.
f.	Give the characteristics of a cross-sectional study.
g.	Define ICSR and PSUR.
h.	Distinguish between Type A and Type B ADRs citing examples.
i.	State the aims and objectives of PvPI.
j.	Name the drug regulatory authorities of India, USA, Japan and Australia.

SECTION B

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

a.	Discuss the steps in establishing a national pharmacovigilance programmed.
b.	Explain the passive and active surveillance methods in pharmacovigilance.
c.	Describe the various methods used in causality assessment.

SECTION C

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

a.	Elaborate on the management of adverse drug reactions.
b.	Discuss drug safety evaluation in geriatrics.
c.	Elaborate on various types of AEFIs.
d.	Summarize WHO International drug monitoring program and its functions.
e.	Explain different types of information resources in pharmacovigilance.
f.	Write a detailed note on communication in drug safety crisis management.
g.	Describe genetics-related ADRs citing examples.