PAPER ID-310789

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. | 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. |

QP25DP1_145 | 22-Jan-2025 1:55:55 PM | 115.244.153.242


QP25DP1_145 | 22-Jan-2025 1:55:55 PM | 115.244.153.242