**BPHARMA**
**(SEM VIII) THEORY EXAMINATION 2021-22**
**PHARMACOVIGILANCE**

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

**Note:** Attempt all Seetions. 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. |

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