

Roll No.

Total No. of Pages : 02

Total No. of Questions : 13

B.Pharmacy (Sem.-8)  
**PHARMACOVIGILANCE**  
Subject Code : BP-805-ET  
M.Code : 79768  
Date of Examination : 11-07-22

Time : 3 Hrs.

Max. Marks : 75

**INSTRUCTIONS TO CANDIDATES :**

1. SECTION-A is COMPULSORY consisting of TEN questions carrying TWO marks each.
2. SECTION-B contains THREE questions carrying TEN marks each and student has to attempt any TWO questions.
3. SECTION-C contains NINE questions carrying FIVE marks each and student has to attempt any SEVEN questions.

**SECTION-A**

1. Write briefly :

- a) Define Pharmacovigilance and enlist its various objectives.
- b) Define spontaneous and mandatory reporting.
- c) Describe the significance of Vigimed and Vigiflow?
- d) Define the term '*Daily defined doses*'.
- e) Define adverse events following immunization.
- f) Define active and passive surveillance.
- g) Define Eudravigilance.
- h) Enlist the major roles of CDSCO (India) in pharmacovigilance.
- i) Define pharmacogenomics.
- j) Enlist primary and secondary sources of drug information.

## SECTION-B

2. Describe the process of establishment of pharmacovigilance Programme in a hospital.
3. Describe the design and methodology of retrospective and prospective observational studies.
4. Describe the ICH guidelines for Pharmacovigilance.

## SECTION-C

5. Describe the components and functioning of Pharmacovigilance Program of India.
6. Describe the various methods of causality assessment of ADR.
7. Describe the advantages and limitations of International Classification of Diseases (ICD).
8. Describe the specialized resources for adverse drug reactions.
9. Describe the ways of effective communication in pharmacovigilance system.
10. Explain the differences in Indian and Global pharmacovigilance requirements.
11. Describe the GCP guidelines for conducting pharmacovigilance studies.
12. Draw and explain MedDRA hierarchy.
13. Explain the concept of drug safety evaluation in geriatrics.

**NOTE : Disclosure of Identity by writing Mobile No. or Making of passing request on any page of Answer Sheet will lead to UMC against the Student.**