

Roll No.

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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 : 07-01-2023

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.
- b) Define passive surveillance and post-marketing surveillance.
- c) Define case report and case series.
- d) Give an example of immunization error related adverse reaction associated with vaccination.
- e) Define pharmacogenetics and pharmacogenomics.
- f) Define contract research organizations.
- g) Describe the significance of Vigimed and Vigiflow?
- h) Enlist tertiary sources of drug information.
- i) Define WHO drug dictionary.
- j) Define adverse drug reaction and adverse drug event.

SECTION-B

2. Describe basic sources of drug information and specialized resources for adverse drug reactions.
3. Describe the detection, reporting and management of adverse drug reactions.
4. Describe pharmacogenetic variations attributed to CYP450 isoenzymes inhibition and induction.

SECTION-C

5. Describe the mission and objectives of WHO international drug monitoring programme.
6. Classify adverse drug reactions.
7. Describe the principles for assigning daily defined doses.
8. Describe the classification and significance of adverse events following immunization programme.
9. Describe the concept of post marketing surveillance.
10. Briefly describe safety evaluation at pre-clinical and clinical trial phase.
11. Describe the anatomical, therapeutic and chemical classification of drugs.
12. Describe the issues of drug safety evaluation in paediatric population.
13. Describe the process of establishment of pharmacovigilance Programme in a hospital.

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.