Roll No. | | | | | | | | | | | | | **Total No. of Pages : 02**

Total No. of Questions : 07

M.Sc Clinical Research (Sem.-3)

PHARMACOVIGILANCE

Subject Code : UC-MSCR304-19

M.Code : 79930

Date of Examination : 19-12-22

Time : 2 Hrs. **Max. Marks : 35**

INSTRUCTIONS TO CANDIDATES :

1. **SECTION-A is COMPULSORY consisting of FIVE questions carrying ONE marks each.**
2. **SECTION-B contains THREE questions carrying FIVE marks each and students have to attempt any TWO questions.**
3. **SECTION-C contains THREE questions carrying TEN marks each and students have to attempt any TWO questions.**

SECTION-A

1. a) What is Pharmacovigilance?

   b) ……is the governing body of PVPI.

   c) Differentiate between Adverse Reactions and Adverse Event.

   d) Define Herbavigilance.

   e) Define Signal in context to Pharmacovigilance.

SECTION-B

2. Write an elaborative description of adverse drug detection, reporting, and causality assessment.

3. PVPI is bringing many changes in India. Comment on Pharmacovigilance in Indian Perspective.

4. Write briefly about Active and Passive methods of surveillance in Pharmacovigilance.

SECTION-C

5. a. Write a note on the importance of Pharmacovigilance implementation.

   b. Write in detail about the establishment of Pharmacovigilance in India.

6. Using a case study explain in detail post-marketing Signal Detection and Assessment.

7. a. Write in brief about the utility of Pharmacovigilance software.

   b. Write in brief about the key features and benefits of the following software used in Pharmacovigilance :

      i. PvNET

      ii. Oracle Argus Safety.

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