2211E801

Candidate's Seat No :_____

M.Sc Sem-3 Examination

303

Clinical Research

November-2024

Time : 2-30 Hours] **[Max. Marks : 70**

Instructions:

- **Question-1 to Question-4 are compulsory.**
- **Attempt any fourteen questions in question.5.**

Que. 1 Describe the following:

a) What is Signal? Explain detection of signal in detail. 07
b) Discuss in detail about PV methods. 07

OR

Que. 1 Describe the following:

a) Risk Evaluation & Mitigation Strategy. 07
b) Describe Audit in pharmacovigilance. 07

Que. 2 Describe the following:

a) Discuss General Principles of Expedited reporting Guideline. 07
b) Write PVPI and Pharmacovigilance Centers in India. 07

OR

Que. 2 Describe the following:

a) Discuss ICH E2 E Guideline. 07
b) Write Suspected unaccepted serious adverse reaction. 07

Que. 3 Describe the following:

a) Describe in detail Role of MAH. 07
b) Explain European Risk Management Plan. 07

OR

Que. 3 Describe the following:

a) Write a note on CIOMS program. 07
b) Expedited reporting requirement as per Australian Pharmacovigilance Guideline. 07

Que. 4 Describe the following:

a) Define MedDRA and discuss its structure & content. 07
b) Explain UMC and ICSR in detail. 07

OR

Que. 4 Describe the following

a) PSUR Process for various regulatory. 07
b) Short note on WHO-Adverse Reaction Terminology. 07

(P.T.O)

E801-2

Module IX Pharmacovigilance & Post Marketing Surveillance

Que. 5 Answer the following (write any 14 out of 17) **14**

1. Define: IBD
2. Define: CCSI
3. Full Form of CDSCO
4. Full form of CO-START.
5. Define: De-Challenge.
6. Write a full form of DSUR_____
7. Define: Medication Error
8. Write a full form of DSOB_____
9. Write a full form of NCC-MERP_____
10. ICH E2 D guideline is use for _____
11. Define: Type B ADR
12. Who can report ADRs? (Any 3)
13. Define: CAPA.
14. Enlist places to find information on ADRs.
15. Write a full form of DAPs_____
16. Differentiate between Medwatch 3500 & Medwatch 3500 A
17. Submission of MEDWATCH report is done by all of the following except
    (A) Online (B) Phone (C) Fax (D) By Person