

M.Sc. Sem.-3 Examination
303

Clinical Research
November-2025

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) Define Phramacovigilance & explain its method. 07
b) Discuss in detail Periodic Safety Update Report. 07
OR

Que. 1 Describe the following:

- a) Explain REMS. Give its Importance. 07
b) Discuss case series development as per GPP. 07

Que. 2 Describe the following:

- a) Discuss General Principles of ICH E2 C Guideline. 07
b) Work flow of National Pharmacovigilance of India. 07
OR

Que. 2 Describe the following:

- a) Discuss General Principles of ICH E2A Guideline 07
b) Structure of Pharmacovigilance Plan according to ICH E2D guideline. 07

Que. 3 Describe the following:

- a) Write a note on Yellow card scheme. 07
b) Write a note on Eudravigilance. 07
OR

Que. 3 Describe the following:

- a) Write a note on MEDWATCH program. 07
b) Requirements of reporting in special situation- EU Specifications. 07

Que. 4 Describe the following:

- a) Role of Uppsala Monitoring Center. 07
b) Explain in detail structure of WHOART. 07
OR

Que. 4 Describe the following

- a) Explain Pharmacovigilance Dictionaries:CO-START. 07
b) Enlist adverse reaction reporting form according to region & discuss individual case safety report. 07

P.T.O

Module IX Pharmacovigilance & Post Marketing Surveillance**Que. 5 Answer the following (write any 14 out of 17)****14**

1. Define : Vigisearch.
2. Which regulatory runs yellow card scheme?
3. Write a full form of OMA_____
4. Define SUSAR.
5. Define:Re-challenge
6. Full Form NPP.
7. Naranjo Probability scale used for_____.
8. Enlist any 3 characteristics of Good Case Report
9. Define: Unlisted AEs
10. Differentiate between Expected Adverse Events & Unexpected Adverse Events
11. Define: Registries
12. What is the timeline for PSUR submission in EU.
13. Give PSUR reporting requirement in U.S region.
14. Define: RiskMAP
15. Write a full form of ICSR_____
16. Define: CCDS.
17. FDA form 3500 include information except
(A)Product Name (B) Patient name (C) Event description (D) Reporter Name

