

QP Code: 825006

Reg. No.....

**Eighth Semester B. Pharm Degree Supplementary Examinations
November 2022
Pharmacovigilance
(2017 Scheme)**

Time: 3 Hours

Max. Marks: 75

- *Answer all questions to the point neatly and legibly • Do not leave any blank pages between answers • Indicate the question number correctly for the answer in the margin space*
- *Answer all parts of a single question together • Leave sufficient space between answers*
- *Draw diagrams wherever necessary*

Essays

(2x10=20)

1. Explain about ICH guidelines for Pharmacovigilance
2. Discuss in detail about i) cross sectional study ii) Case control study iii) Cohort study

Short Notes

(7x5=35)

3. Explain the establishment of pharmacovigilance program in a hospital
4. History and development of Pharmacovigilance
5. Passive surveillance
6. Mention about effective communication in Drug safety crisis management
7. Discuss about Differences in Indian and Global Pharmacovigilance requirement
8. Role of CDSCO in Pharmacovigilance
9. Explain in brief about Post approval phase of safety data generation

Answer Briefly

(10x2=20)

10. Explain PvPI
11. Classify ADR
12. Spontaneous reporting system
13. What are CIOMS working groups
14. What is International classification of diseases. Give one example
15. Schedule Y
16. Mention the Role of ICH in Pharmacovigilance
17. Pre-clinical phase of safety data generation
18. What are Sentinel sites
19. Name statistical Methods for evaluating Medication safety Data
