

QP Code: 825006

Reg. No.....

**Eighth Semester B. Pharm Degree Supplementary Examinations
October 2025
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. Discuss the basic and specialized drug information services in pharmacovigilance
2. Explain the clinical trial regulations in India

Short Notes

(7x5=35)

3. Elaborate active and passive surveillance
4. Explain pre and post marketing clinical trials
5. Discuss the process involved in establishment of pharmacovigilance programme in a hospital
6. Write a note on functions of CDSCO in pharmacovigilance
7. Explain periodic safety update reports (PSUR)
8. Discuss the drug safety evaluation in pregnant women
9. What are the factors to be considered while evaluating drug safety in geriatrics

Answer Briefly

(10x2=20)

10. Elaborate CIOMS
11. Role of pharmacist in detecting ADRs
12. Post approval expedited reporting
13. Phases of clinical trials
14. What is vaccine pharmacovigilance
15. Define pharmacogenomics
16. WHO dictionary of drug
17. What is good clinical practice
18. What is eudravigilance
19. Minimum criteria required for a valid report of pharmacovigilance spontaneous report
