

QP Code: 825006

Reg. No.....

**Eighth Semester B. Pharm Degree Supplementary Examinations
December 2023
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 in detail about Pharmacovigilance program of India
2. Describe in detail about drug safety evaluation in a) Paediatrics b) Geriatrics

Short Notes

(7x5=35)

3. Discuss about importance of safety monitoring of medicines
4. Discuss about the methods used in causality assessment
5. Describe about MedDRA and its standardised queries
6. Mention about the drug information resources
7. Explain about vaccine safety surveillance
8. Comparative observational study
9. International non-proprietary names of drugs

Answer Briefly

(10x2=20)

10. Compare and contrast ADE and ADR
11. Benefit-Risk analysis
12. Uppsala monitoring centre
13. What are the Lowest level terms in MedDRA Hierarchy
14. WHO-Adverse reaction terminologies
15. CIOMS
16. Drug event monitoring
17. D & C Act
18. What are Periodic Safety Update Reports (PSUR)
19. What is defined daily doses
