

QP Code: 825006

Reg. No.....

**Eighth Semester B. Pharm Degree Regular/Supplementary
Examinations March 2026
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 History and development of Pharmacovigilance. Write notes on Pharmacovigilance program of India.
2. Explain in detail about ICH guidelines for Pharmacovigilance. Write about safety data generation.

Short Notes

(7x5=35)

3. Classification and management of adverse drug reactions.
4. Establishment of Pharmacovigilance programme in Industry
5. Different sources of drug information.
6. Write a note on anatomical therapeutic and chemical classification of drugs.
7. Discuss the principles of Pharmacovigilance communication
8. Describe the steps and procedures involved in drug discovery and drug development
9. Elaborate about vaccination failure, types and causes in detail.

Answer Briefly

(10x2=20)

10. Define Clinical trials
11. Drug safety monitoring program
12. Post marketing surveillance
13. Write any four terminologies used in pharmacovigilance.
14. What do you mean by defined daily dose.
15. Write a short note on individual case safety reports.
16. What do you understand by term Vaccine Pharmacovigilance
17. List out objectives for ICH in Pharmacovigilance
18. List out members of CIOMS.
19. WHO drug dictionary.

CORRECTION / NO-CORRECTION FILE
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QPCODE: 825006

Dated: 12-03-2026

Question No.8

Replaced with "Describe passive surveillance methods."

Question No.15

The word 'care' Corrected as "case"

Question No.17

Replaced with "Importance of Cohort studies."

Corrections/Modifications/Replacement of Questions if any shall be made available to all students. Take the print out of the Correction File in such cases and distribute to all students.

(Sd/-)

CONTROLLER OF EXAMINATIONS