

QP CODE: 214328

Reg. No:.....

**Second Semester M. Pharm Degree Regular/Supplementary Examinations
November 2025**

**M.Pharm (Pharmacology)
Paper IV: Clinical Research and Pharmacovigilance (MPL 204T)
(Common for 2019 and 2024 Scheme)**

Time: 3 Hours

Total 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 table/diagrams/flow charts wherever necessary*

Essays

(3x10=30)

1. Discuss the importance of WHO's international drug monitoring programme and drug safety monitoring in India.
2. Classify adverse drug reactions with suitable examples and mention the role of pharmacist in management of ADR.
3. Explain the composition and functions of Institutional Review Board.

Short Notes

(9x5=45)

4. Compare and contrast adverse event and adverse drug reaction.
5. Elaborate on the international classification of disease.
6. Appraise the applications and need of Pharmacoeconomics.
7. Explain in detail about case report forms in clinical trials.
8. Recall the comparative observational studies and ICH guidelines.
9. Explain the importance and contents of Investigator Brochure.
10. Define: a) Aris G b) Causality assessment c) Pharmacoepidemiology
 d) ICD e) Argus
11. Discuss in brief on the industry and national programmes related to pharmacovigilance.
12. Summarize the roles and responsibilities of principle investigator in clinical trial.

CORRECTION / NO-CORRECTION FILE
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QPCODE: 214328

Dated: 14-11-2025

Question No.7

Corrected as "Explain in detail about case report forms in clinical trials."

Question No.10(d)

Replaced with "randomised control trial."

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