

QP CODE: 214328

Reg. No:.....

**Second Semester M. Pharm Degree Regular/Supplementary Examinations  
October 2023**

**M.Pharm (Pharmacology)  
Paper IV: Clinical Research and Pharmacovigilance (MPL 204T)  
(Common for 2017 and 2019 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. Define GCP. Explain the principles of ICH GCP guidelines
2. Discuss various methods of economic evaluation of drug therapies
3. Describe about the constitution, roles and responsibilities of ethical committee

**Short Notes**

**(9x5=45)**

4. Describe about vaccine safety surveillance
5. Discuss on international nonproprietary names of drugs with examples
6. Explain about causality assessment of ADR using various scales
7. Outline about informed consent form
8. Explain about randomization and its relevance in clinical trials
9. Elaborate on vigiflow database
10. Various regulatory authorities for pharmacovigilance in India
11. Brief about case control and cohort studies with examples
12. Pharmacoepidemiology

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