QP CODE: 214328 **Reg. No:……**

Second Semester M. Pharm Degree Supplementary Examinations December 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. Classify various types of ADRs with suitable examples. Write a note on the management of ADRs
2. Explain various types of clinical trials and their designs
3. Explain the various principles of ICH-GCP guidelines

Short Notes **(9x5=45)**

4. Informed consent
5. Explain the rationale and design of cohort studies and potential bias
6. Describe the roles and responsibilities of Institutional Review Board in clinical research
7. Safety pharmacology studies
8. Spontaneous ADR reporting systems
9. Clinical trial documentation
10. Pharmacoeconomics
11. Epidemiology studies
12. Explain the statistical methods for evaluating medication safety data

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