QP CODE: 214328 **Reg. No:……**

Second Semester M. Pharm Degree Regular/Supplementary Examinations November 2024

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. Explain the roles and responsibilities of investigators, contract research organizations and its management in clinical trials

2. Distinguish between adverse event and adverse drug reactions. Explain various scales used for assessment of causality. Outline important guide lines for ADRs reporting

3. Explain the different observational study designs.

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

4. Differentiate Phase-II and Phase –III trails

5. Explain Pharmaco-economics

6. Safety pharmacology

7. Guideline to the preparation of protocol and investigator brochure

8. Role and responsibilities of study coordinator in clinical trials.

9. Write the Ethical principle governing informed consent process

10. International classification of disease

11. Pharmacoepidemiology

12. Pharmacovigilance in India

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