QP CODE: 214328 **Reg. No:……**

Second Semester M. Pharm Degree Regular/Supplementary Examinations May 2022

M.Pharm (Pharmacology)

Paper IV: Clinical Research and Pharmacovigilance (MPL 204T)

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 ethical guidelines for biomedical research. Explain the role and responsibilities of Institutional Review Board

2. Explain the role and responsibilities of following clinical trial personnel:
   • Chief Investigator • Study Coordinator • Sponsor

3. Define safety pharmacology. Explain various safety pharmacology studies

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

4. Clinical trial documentation

5. Explain the national and international status of pharmacovigilance

6. Vaccine safety surveillance

7. Classify ADRs with suitable examples. Write a note on the management of ADRs

8. Explain the significance of pharmacovigilance

9. Explain the randomized and non-randomized clinical trials.

10. Pharmacoepidemiology

11. WHO international drug monitoring program

12. Explain the tools available for processing, analyzing, and reporting adverse drug events

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