QP CODE: 214328 **Reg. No:……**

Second Semester M. Pharm Degree Supplementary Examinations August 2021

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 structure and content of informed consent form. Outline ethical principles governing informed consent process

2. Explain the significance of safety monitoring in clinical trials

3. Define and classify adverse drug reactions. Elaborate on ADR detection and reporting methods. Mention how ADR could be product and prevented

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

4. Explain the role responsibilities of Institutional review broad

5. Define • Pharmacovigilance • Case control study

6. Pharmacoepidemiology

7. Pharmacoeconomics

8. ICH – GCP guidelines

9. Safety pharmacology

10. Explain the difference between adverse event and adverse drug reaction

11. Progress of Pharmacovigilance in India

12. Passive and active surveillance

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