QP CODE: 214328 **Reg. No:……**

Second Semester M. Pharm Degree Supplementary Examinations January 2020

M.Pharm (Pharmacology)

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

(2017 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 and classify adverse drug reactions. Elaborate on ADR detection and reporting methods. Mention how ADR could be predicted and prevented.

2. Explain Pharmacovigilance Programme of India

3. Ethical guidelines for biomedical research and human participant

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

4. Significance of post marketing surveillance.

5. Study designs in a clinical trial.

6. Randomization.

7. Role of auditors in clinical trial.

8. GCP.

9. Differentiate phase II and phase III clinical trials.

10. Outline the principles of pharmacoepidemiology

11. Responsibilities of institutional review board

12. Pharmacoeconomics

****