QP CODE: 214328 **Reg. No:……**

Second Semester M.Pharm Degree Supplementary Examinations January 2019

M.Pharm (Pharmacology)

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

(2017 Scheme)

Time: 3 Hours **Total Marks: 75**

- Answer all Questions.
- Draw Diagrams wherever necessary.

Essays **(3x10=30)**

1. Define adverse drug reaction. Discuss in detail on its management along with its causality assessment scales.

2. Define the term pharmacoeconomics, the need for pharmacoeconomics in Indian scenario.

3. Discuss the various phases of clinical trials

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

4. Structure of informed consent.

5. Roles and responsibility of a study coordinator.

6. WHO international drug monitoring programme.

7. Preparation of case report forms.

8. Statistical methods for evaluating medication safety data.

9. Vaccine safety surveillance.

10. Safety monitoring in clinical trial.

11. Schedule Y

12. Institutional review board

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