QP CODE: 214328 **Reg. No:……**

Second Semester M.Pharm Degree Examinations July 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. Explain various aspects of clinical trial documentation with focus on preparation of protocols and case report forms

2. Explain the various functions of national pharmacovigilance programme.

3. Describe the various clinical trial designs and add a note on good clinical practice

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

4. Describe the compositions and functions of IEC in clinical trials.

5. The method of reporting serious adverse event in clinical trial.

6. Discuss various study design in pharmaco-epidemiology.

7. The various types of cost measurement in pharmacoeconomic study.

8. Explain various elements and key components in informed consent.

9. Active and passive surveillance.

10. Describe the statistical challenges in the evaluating medication safety data.

11. Explain the role of ICMR in clinical research.

12. Discuss the assessment in safety pharmacology

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