QP CODE: 214328 **Reg. No:……**

Second Semester M.Pharm Degree Examinations August 2018

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. Discuss the various types of clinical studies and designs. Explain the list of research design for clinical studies.
2. Explain the various structural and functional aspects of ADR monitoring system.
3. Describe the various methods of pharmacoeconomic evaluation process

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

4. Discuss the practices and assessment in safety pharmacology.
5. The principles of ICH-GCP in clinical trials.
6. The contents of investigators brochure in clinical trials.
7. Describe the importance of pharmaco- epidemiological studies.
8. Discuss the various elements of consent form and add a note on the basic principles of informed consent.
9. The objectives and implementation of pharmacovigilance programme in India.
10. Discuss the various statistical techniques involved in evaluating medication safety data.
11. Schedule Y in clinical trials.
12. Describe the composition and functions of institutional review board

****