QP CODE: 214328 **Reg. No:……**

Second Semester M. Pharm Degree Supplementary Examinations February 2025

M.Pharm (Pharmacology)
Paper IV: Clinical Research and Pharmacovigilance (MPL 204T)
(Common for 2017 and 2019 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. Discuss the ICH-GCP guidelines in clinical trials and summarise about clinical trial protocol.
2. Explain the roles and responsibilities of clinical trial personnel.
3. Elaborate on the Human Ethics Committee, its constitution and role of each member.

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

4. Explain the organization and functions of Poison information centre.
5. Describe the functioning of VigiFlow.
6. Pharmacoeconomics.
7. Vaccine safety surveillance.
8. Elaborate on (a) ICD (b) Argus (c) CDSCO (d) Yellow card scheme
9. Outline the severity and seriousness assessment methods of adverse drug reaction.
10. Cohort and case control studies.
11. Explain the elements of informed consent form.
12. Summarize the essential documents in clinical trial program.

****