QP CODE: 214328 **Reg. No:……**

Second Semester M. Pharm Degree Regular/Supplementary Examinations February 2021

M.Pharm (Pharmacology)

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

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 ADR. Explain how ADR could be predicted and detected. Mention various methods of reporting ADR.
2. Enumerate contents of clinical trial protocol
3. Elaborate on active and passive surveillance methods in pharmacovigilance

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

4. Roles and responsibilities of an investigator in clinical trial
5. Various databases for ADR reporting
6. Explain various methods to reduce the bias in clinical trials
7. Describe cost effective analysis and cost utility analysis in pharmacoeconomics
8. Outline the ICMR ethical guidelines for biomedical research and human participant
9. Discuss on the evolution of ICH GCP guidelines
10. Brief about various experimental study designs in clinical trials with suitable examples
11. Explain about international classification of diseases
12. Explain about various statistical methods in clinical trials

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