QP CODE: 113333 **Reg. No:……**

First Semester M.Pharm Degree Regular Examinations June 2024

M. Pharm Pharmaceutical Regulatory Affairs

PAPER - III – Clinical Research Regulations (MRA 103T)

(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. Explain in detail the requirements of Good clinical practice (ICH GCP) guidelines. Add a note on origin of International Conference on Harmonization (ICH) (7+3)

2. Enumerate the application procedure for approval of ANDA 505 (j) of Federal Food Drug and Cosmetic Act of USA

3. Explain the principles of ICMR Ethical Guidelines for biomedical research

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

4. Write a note on Phase 1 studies

5. Define and explain clinical evaluation of medical devices (1+4)

6. Write a note on role and responsibilities of Institutional Ethics Committee (IEC) (2+3)

7. Describe the informed consent process and documentation requirements (3+2)

8. Write a note on NDA and its approval procedure (2+3)

9. Explain ICH E4 (Studies in support of General Population: Geriatrics) guidelines

10. Discuss the EU Annual report and its regulatory significance (4+1)

11. Enumerate about FDA MedWatch program

12. Write a note on 21 CFR part 320 (Bioavailability and bioequivalence requirements)

****