QP CODE: 113333 **Reg. No:……**

First Semester M.Pharm Degree Supplementary Examinations August 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 responsibilities composition and function of independent ethics committee as per ICMR guidelines.
2. Describe on clinical investigation and evaluation of medical devices and IVDs.
3. Discuss in detail about schedule Y of Drug and Cosmetics Act for the conduct of clinical trial on new drugs in India

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

4. Write briefly about ICH E6 guidelines.
5. Informed consent process
6. List out the contents of EU Annual Safety Report
7. Write the Scope of ISO 14155
8. Discuss the responsibilities of sponsor in clinical trial
9. ICH E10 Guidelines
10. Discuss on clinical trial requirements for approval of NDA 505(b)(2) application.
11. Financial disclosure by clinical investigator as per 21 CFR part54
12. Explain in brief about Nuremberg code

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