Your Roll Number.....

Jamia Hamdard (Deemed to be University)

Examination:M.Sc. **Clinical Research**, Semester: **I (2023)**

PaperCodeand Title:**MCR-DCC 102, Regulatory Affairs in Clinical Research**

Time: 3 hours Maximum Marks:75

Write the roll number at the top immediately on receipt of this question paper. Attempt ALL questions. All parts of a question must be attempted in continuation. Start answering each question on new page.

1. Define the following: **[1 x10=10]**

i) Emergency IND

ii) ICH

iii) Bioequivalence

iv) PMS

v) Safety Report filing

vi) Sulphanilamide tragedy

vii) CTD

viii) ICH E6 guideline

ix) ANDA

x) TGA

Section B Attempt ANY TWO **[15x2=30 marks]**

3. What is GLP and Explain GLP guidelines?

4. Explain Wiley act. Explain with historical events how USA regulatory evolves?

5. Describe regulatory system of Japan?

6. What is OECD guidelines and explain in brief.

Section C Write Short note on ANY FOUR **[5x4=20 marks]**

7. Indian Regulatory system for Drugs

8. GCP principles

9. Nuremberg's Code

10. Regulation of Prescription drugs.

11. Waxman Hatch Act

**********END OF QUESTION PAPER**********