2/31

0205N167

Candidate's Seat No :_____

MSc Sem.-2 Examination

408

Clinical Research

Time : 2-30 Hours] **May-2025** **[Max. Marks : 70**

Instructions:

- **Question-1 to Question-4 are compulsory.**
- **Attempt any fourteen questions in question.5.**

Que. 1 Describe the following:

a) Explain Orphan Drug Application check list & significance. 07

b) Give overview of ANVISA Guideline 07

OR

Que. 1 Describe the following:

a) Short Note: USFDA Guideline. 07

b) Explain Investigation New Drug Application submission Check list. 07

Que. 2 Describe the following:

a) Structure, contents and format for clinical study reports according to NDCT Rule. 07

b) Explain all the principles of ICH-GCP. 07

OR

Que. 2 Describe the following:

a) Explain Manufacturing, Packaging, Labelling, and Coding of Investigational Product(s) 07

b) Explain the Milestones of GCP. 07

Que. 3 Describe the following:

a) Explain Nuremberg code. 07

b) Write a note on MHRA. 07

OR

Que. 3 Describe the following:

a) Explain in brief Intellectual property rights. 07

b) Explain in brief New Drug Application. 07

Que. 4 Describe the following:

a) Explain in brief Abbreviated New Drug Application. 07

b) Write a note on Health and Human Services regulation. 07

OR

Que. 4 Describe the following

a) Explain Indian Council Of Medical Research 07

b) Explain Good Laboratory Practice. 07

P.T.O

M167-2

Module V Regulation In Clinical Research

Que. 5 Answer the following (write any 14 out of 17) **14**

1. Full Form of ICH- GCP?
2. Define: Data monitoring committee
3. Define: Protocol
4. Define: Audit Trail
5. Define: Confidentiality
6. Define: Quality of life trial
7. Define: ADR
8. Define: Investigator Brochure.
9. Full form of TRIPS
10. Full form MHRA.
11. Explain about Validation of Computerized Systems.
12. Full form of FDCs.
13. Define 483 USFDA Form.
14. Define Ethics.
15. Define Non-compliance.
16. Full Form of DHHS.
17. Name two form for IND in USFDA