`Roll No. | | | | | | | | | | | | Total No. of Pages : 02

Total No. of Questions : 10

M.Sc. (Clinical Research) (Sem.-2)

CLINICAL RESEARCH REGULATIONS

Subject Code : MSCR-202-18

M.Code : 75939

Date of Examination : 06-07-22

Time : 3 Hrs. Max. Marks : 70

INSTRUCTIONS TO CANDIDATES :

1. **SECTION-A is COMPULSORY consisting of TEN questions carrying TWO marks each.**
2. **SECTION-B contains FIVE questions carrying FIVE marks each and students have to attempt any FOUR questions.**
3. **SECTION-C contains FOUR questions carrying TEN marks each and students have to attempt any THREE questions.**

SECTION-A

1. Briefly discuss the following :

a) Define GLP.

b) Thalidomide tragedy.

c) Schedule Y.

d) Define IND and NDA.

e) Nuremberg's code.

f) What do you mean by ICH?

g) Short note on declaration of Helsinki.

h) What are GLP and GCP?

i) What do you mean by TGA? Write its role.

j) ANVISA and OECD.

SECTION-B

2. Discuss about the different methods of post marketing surveillance.

3. Expand forms of the following MHRA, CRO, CRF, MAH, EMEA, CTA, GLP, CFR. Add a note on marketing authorization holder (MAH).

4. Write a note on basic methodology and study designs of BA/BE studies.

5. What do you mean by format of dossier?

6. Write a detailed note on regulation of medical devices and vaccines.

SECTION-C

7. Discuss the principles of ICH-GCP guidelines in detail.

8. What do you mean by expedited reporting in clinical trial? Discuss the safety reporting as per schedule V.

9. Explain in detail about regulation of prescription and non- prescription drugs.

10. Discuss in detail about safety reports filings. Explain with example.

NOTE : Disclosure of Identity by writing Mobile No. or Making of passing request on any page of Answer Sheet will lead to UMC against the Student.