

Roll No.

Total No. of Pages : 01

Total No. of Questions : 07

M.Sc. (Clinical Research) (Sem.-3)

QUALITY MANAGEMENT IN CLINICAL TRIALS

Subject Code : MSCR-314-18

M.Code : 77012

Date of Examination : 23-12-22

Time : 2 Hrs.

Max. Marks : 35

INSTRUCTIONS TO CANDIDATES :

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

SECTION-A

1. **Write a note on:**
 - a) GLP
 - b) Quality management
 - c) Audit
 - d) ICH
 - e) Benefit of SOPs

SECTION-B

2. Write a note on good clinical practice.
3. Elaborate on different types of audits.
4. Write a note on role and responsibilities of QA personnel.

SECTION-C

5. Elaborate on relevance of QA and QC in clinical trials. Write a note on their comparison.
6. Discuss in detail about regulatory inspections in clinical trial.
7. Write a note on following :
 - a) Importance of quality management in clinical trials.
 - b) Important aspects of Audit process.

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