

Roll No.

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Total No. of Pages : 01

Total No. of Questions : 07

M.Sc CLINICAL RESEARCH (2018 Batch) (Sem.-3)
QUALITY MANAGEMENT IN CLINICAL TRIALS

Subject Code : MSCR314-18

M.Code : 77012

Time : 2 Hrs.

Max. Marks : 35

INSTRUCTIONS TO CANDIDATES :

1. SECTION-A is COMPULSORY consisting of FIVE questions carrying ONE mark 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 briefly :
 - a. GCP
 - b. SOP
 - c. Inspection
 - d. External audit
 - e. ICH

SECTION-B

2. Explain the regulatory requirement of QA and QC in clinical research.
3. Write a note on total quality management in clinical trials.
4. Write a note on clinical inspection procedure.

SECTION-C

5. What is Audit? Describe in detail the audit process and its important aspects.
6. Discuss in detail about the importance of clinical quality assurance department in industry.
7. Write a note on following :
 - a. Different type of SOP's.
 - b. Roles and responsibilities of QA personnel.

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.