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Total No. of Pages : 02

Total No. of Questions : 10

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

CLINICAL STUDY DESIGN

Subject Code : MSCR-302-18

M.Code : 76838

Date of Examination : 14-12-2022

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. Write briefly :

- a. Nocebo
- b. Randomization
- c. Clinical trial end points
- d. Inclusion-exclusion criteria
- e. FDA
- f. Match paired study
- g. Bio-equivalence
- h. Open label study
- i. Bio-availability
- j. Recruitment of subjects.

SECTION-B

2. Discuss various methods of blinding.
3. Write a note on bio-markers with suitable example.
4. Elaborate your views on various types of clinical trials.
5. Write a note on BA-BE studies.
6. How will you design a trial for anticancer drugs? Discuss with suitable examples.

SECTION-C

7. Discuss Phase III clinical trial for anti-diabetic compounds with suitable example.
8. Describe standard format for dossier to trial design for any CVS active new chemical compound as per any regulatory agency.
9. **Write short notes on the following:**
 - a. Clinical trial in pregnancy
 - b. Case control studies.
10. **Discuss the following with suitable diagram/flow charts:**
 - a. Phase II study protocol
 - b. Clinical study protocol in geriatrics.

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.