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Total No. of Pages : 02

Total No. of Questions : 10

M.Sc. (Clinical Research) (Sem.-1)
FUNDAMENTALS OF CLINICAL RESEARCH

Subject Code : UC-MSCR-102-19

M.Code : 77291

Date of Examintion : 21-01-23

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. Answer briefly :

- a. What are the objectives of Phase I clinical trials?
- b. What is a lead compound?
- c. What is the role of placebo in clinical trials?
- d. What is the role of Phase IV clinical trials?
- e. Differentiate between Validation and Calibration
- f. What is bio-availability?
- g. Differentiate between Acute toxicity and chronic toxicity
- h. What is a formulation and drug delivery system?
- i. Define Bioassay
- j. What is Nocebo?

SECTION-B

2. Discuss in detail the Biopharmaceutical Classification System.
3. What is High Throughput Screening (HTS)? Write a note on the purpose and advantages of HTS.
4. What are the provisions and content of Schedule Y and Schedule M?
5. Using suitable examples, discuss mutagenicity, teratogenicity and carcinogenicity in the context of pre-clinical testing of drugs.
6. Write a detailed note on the GMP and its requirement in the pharmaceutical industry.

SECTION-C

7. What is drug discovery? Write in detail the approaches adopted in the drug discovery process.
8. Write in detail the classification of different drug formulations. Specify the advantages and disadvantages of each type of formulation.
9. Discuss in detail the phases of clinical trials adopted in drug evaluation and clinical development.
10. Discuss the significance of the Sulfonamide tragedy in the drug development process.

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.