

Roll No.

Total No. of Pages : 02

Total No. of Questions : 10

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

Subject Code : MSCR-102-18

M.Code : 75606

Date of Examination : 17-01-23

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. Write briefly :

- a) Target- centered drug design
- b) Exclusive marketing rights
- c) High Throughput Screening
- d) Trade marks and trade secrets
- e) Lead compounds
- f) Importance of phase zero in clinical trials
- g) Importance of Biopharmaceutical Classification Systems
- h) Advantages of placebo response
- i) Sulfonamide tragedy
- j) Single blind study in clinical trials.

SECTION-B

2. Explain lead optimization.
3. What are the conditions to get any patent by an applicant and discuss the offences and penalty in cases of infringement of the patents?
4. Discuss the TRIPS and its impact in Indian Pharmaceutical companies, while developing any new drug molecule.
5. Discuss the types, advantages and disadvantages of Exclusive Marketing Rights.
6. Explain the advantages and disadvantages of the solid dosage forms over liquid dosage forms.

SECTION-C

7. Explain in detail the importance of combinatorial chemistry in the development of any new drug molecule.
8. What is the difference between quality control tests and quality assurance tests? Discuss various quality control tests for any solid dosage forms.
9. Discuss the role of drug regularity affairs in the development of any new drug molecule.
10. Explain in detail, the requirements of Good Manufacturing Practices (GMPs) for any finished pharmaceutical products.

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.