**Roll No.** | | | | | | | | | | | | | **Total No. of Pages : 02**

**Total No. of Questions : 10**

**M.Sc (Clinical Research) (2018 Batch) (Sem.-1)**

# FUNDAMENTALS OF CLINICAL RESEARCH

**Subject Code : MSCR-102-18**

**M.Code : 75606**

**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 3 clinical trials?

b) What are the provisions of Schedule Y?

c) What are the contents of Schedule M?

d) What is meant by precision during analytical process development?

e) What is meant by 'specificity' in analytical method development?

f) What is a lead compound?

g) What is meant by Phase 0 in clinical trials?

h) What is a placebo and its importance in clinical trials?

i) What is copyright? Give two examples.

j) What is meant by bioavailability?

## SECTION-B

2. What is HTS and its purpose? Write a note on the advantages of HTS.

3. Which is the most bioavailable oral dosage form? Mention the differences of this dosage form with respect to tablets.

4. What is BCS? Mention the different classes with examples.

5. Briefly explain the procedure for filing patent in India.

6. Write a note on Trademarks.

## SECTION-C

7. Discuss the combinatorial chemistry approach for drug design and development with suitable examples.

8. Enlist different IPRs. Discuss the advantages and disadvantages of obtaining a Patent.

9. Discuss cGMP regulations according to Schedule M.

10. Outline different phases of clinical trials and discuss their purpose.

**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**.