Roll No. | | | | | | | | | | | | |

Total No. of Pages : 02

Total No. of Questions : 18

Pharm. D (Sem.–5)

CLINICAL RESEARCH

Subject Code : 5.1

M.Code : 72490

Time : 3 Hrs. **Max. Marks : 70**

INSTRUCTION TO CANDIDATES :

1. **SECTION-A contain SEVEN questions. Attempt any FIVE questions. Each question will carry TWO marks each.**
2. **SECTION-B contain EIGHT questions (Short Essay Type). Attempt any SIX questions. Each question will carry FIVE marks.**
3. **SECTION-C contain THREE questions (Long Essay Type). Attempt any TWO questions. Each question will carry FIFTEEN marks.**

SECTION-A

1. Write salient features of RCT.
2. Define placebo and its significance.
3. Write about mutagenic toxicity in new drug discovery process.
4. Write a brief note on Schedule Y.
5. Write briefly about declaration of Helsinki.
6. Write a brief note on parallel and cross over clinical trials.
7. Define therapeutic exploratory and therapeutic confirmatory clinical trials.

SECTION-B

8. Discuss about various phases of clinical trials.
9. Describe about abbreviated New Drug Application.
10. Discuss about role and responsibilities of sponsor in a clinical trial.

11. Discuss about role and responsibilities of investigator in a clinical trial.

12. Discuss about informed consent process and informed consent form.

13. Write a note on overview of regulatory requirements for new drug approval in US.

14. Write a note on pharmacovigilance programme of India.

15. Write a note on various toxicological studies conducted during new drug discovery process.

SECTION-C

16. Discuss in detail about composition, responsibilities and procedures of IRB.

17. Discuss in detail ICH - GCP guidelines and its basic principles.

18. Discuss in detail about designing of a clinical trial protocol and CRF.

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.