

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. Attempt any SIX
2. SECTION-B contain EIGHT questions (Short Essay Type). 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.