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

Total No. of Pages : 02

Total No. of Questions : 18

Pharm. D (Sem.–5)

CLINICAL RESEARCH

Subject Code : 5.1

Paper ID : [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 Define phase IV clinical trials.

2 Define pharmacovigilance.

3 Define protocol deviations.

4 Briefly describe the composition of IEC.

5 Define case report form.

6 Define GCP.

7 Write two major responsibilities of clinical research associate.

SECTION-B

8 Describe the importance of various phases of clinical trials.

9 Discuss the composition and functions of IRB.

10 Describe the process of IND application.

11 Briefly describe the various pharmacological approaches to drug discovery.

12 Briefly describe the CDSCO guidelines for good clinical practice.

13 Describe the major content of case report form.

14 Describe the informed consent process.

15 Briefly describe the designing of protocol.

SECTION-C

16 Describe the role & responsibilities of sponsor, investigator and trial coordinator as per ICH GCP.

17 Write short notes on the following :

a) Safety monitoring in clinical trials

b) Regulatory authority

18 Write short notes on the following :

a) Data management

b) Post marketing surveillance