

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

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