

Time : 2-00 Hours]

[Max. Marks : 50

Instructions: All Questions in **Section I** carry equal marks.Attempt any **THREE** questions in **Section I**Question IX in **Section II** is **COMPULSORY****SECTION I****Que. 1 Answer in Detail**

- (i) Write a brief note on Sulfanilamide Disaster. 07
- (ii) Explain the history of Thalidomide Tragedy and its Impact. 07

Que. 2 Answer in Detail

- (i) Enlist types of Clinical Trials and write a note on any 3 types. 07
- (ii) Write a note on Phases of Drug Development 07

Que. 3 Answer in Detail

- (i) Explain in brief Study designs for assessing dose-response as per E4 Guideline 07
- (ii) Explain Dose Response relationship curve along with its various interpretations. 07

Que. 4 Answer in Detail

- (i) Write a brief note on S7A guidelines. 07
- (ii) Explain important highlights of S9 Guidelines. 07

Que. 5 Answer in Detail

- (i) Explain Preamble and General Principles of Declaration of Helsinki 07
- (ii) Write a brief note on Part C basic applications of Belmont Report 07

Que. 6 Answer in Detail

- (i) Draw a Typical Organogram of Clinical Research Organisation and explain key functions of Quality assurance and Medical Writing department. 07
- (ii) Explain Parallel and Crossover Designs with suitable examples 07

Que. 7 Answer in Detail

- (i) Write a note on Factorial designs and equivalence Trials 07
- (ii) Explain Different types of Blinding in Clinical Trials. 07

Que. 8 Answer in Detail

- (i) Explain the Typical flow of Clinical Study through various departments in CRO. 07
- (ii) Explain Protocol Deviation and SOP Deviation with suitable examples

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and actions taken in response to them

07

SECTION II

Que.9 Answer in short (Any eight)

08

- A. When was Belmont Report first Published?
- B. Define Null Hypothesis
- C. Define End Point Parameters
- D. What is Orange book?
- E. What are cross over designs?
- F. Define Meta analysis
- G. Which governing body regulates clinical trials in india?
- H. What is full form of SMO?.
- I. Can we use healthy volunteers in Anti Cancer drug trials? Why?
- J. What is therapeutic index?

— X —