

**CLINICAL TRIALS**

Time: 3 hours

Max. Marks: 70

**PART – A**

(Compulsory Question)

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- 1 Answer the following: (10 X 02 = 20 Marks)
- (a) Name the factors that reduce the extent to which a drug is absorbed after oral administration.
  - (b) Name any two uses of pharmacoeconomics.
  - (c) Define 'Ethics'.
  - (d) Name any two responsibilities of ILC.
  - (e) What is preclinical toxicology?
  - (f) Classify carcinogens.
  - (g) What is a clinical trial protocol?
  - (h) What is an interventional study?
  - (i) What is the aim of phase – II trials?
  - (j) Name any two functions of clinical data manager.

**PART – B**

(Answer all five units, 5 X 10 = 50 Marks)

**UNIT – I**

- 2 Outline the importance of pharmacokinetic studies in drug development.

**OR**

- 3 Discuss the role of preclinical studies in drug development.

**UNIT – II**

- 4 Explain the role of institutional ethics committee in clinical trials.

**OR**

- 5 Independent ethics committees are charged with protecting the rights and safety of clinical trial participants – comment.

**UNIT – III**

- 6 Discuss the requirements for carcinogenicity and mutagenicity testing in drug development.

**OR**

- 7 Explain the general principles of local toxicity, genotoxicity and animal toxicity studies.

**UNIT – IV**

- 8 Outline the main steps involved in new drug discovery process.

**OR**

- 9 Write short notes on:
- (a) Principles of sampling.
  - (b) Informed consent process.

**UNIT – V**

- 10 What are the various types of clinical trials? Explain each in detail.

**OR**

- 11 Explain the concept of blinding in clinical trials in detail.

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