Q.P. Code : 26862

(2½ Hours) **[Total Marks : 60]**

N.B. : (1) **All** questions are **compulsory**.
(2) **All** questions carry **equal marks**.

1. Define clinical trials. Discuss the different types of clinical trials with suitable examples. **12**

OR

1. (a) Give an account of Ethics committee and its role in clinical trials. **06**
(b) State the objectives and importance of Institution ethics committee. **06**

2. Discuss the following preclinical toxicology study :
(a) Single dose and repeat dose toxicity studies. **06**
(b) Teratogenicity studies. **06**

OR

2. Explain the concept of preclinical toxicology and its importance in clinical studies. **12**

3. Explain the process and purpose of new drug discovery. **12**

OR

3. Give a detailed account of :
(a) Thalidomide tragedy. **06**
(b) Post marketing surveillance methods of drug. **06**

4. Describe different types of medical writing. **12**

OR

4. Give an account of :
(a) The process of writing a clinical study report. **06**
(b) Medical report. **06**

5. Write short notes on **any three** of the following : **12**
(a) Cross over design.
(b) Local toxicity test.
(c) Unethical trials of new drugs.
(d) Clinical Data Management.
(e) Phases of clinical trial in drug discovery process.
(f) Interventional studies.

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