Code: 13R00606 **R13**

B.Pharm III Year II Semester (R13) Supplementary Examinations May/June 2018

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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