Code: 13R00606 **R13**

B.Pharm III Year II Semester (R13) Supplementary Examinations December 2017

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) Define bioavailability.
(b) What are prodrugs? Give few examples.
(c) Write the role of FDA in clinical trials.
(d) Expand OECD.
(e) Write the importance of mutagenicity studies.
(f) Write the use of cell lines in pharmacology.
(g) Write a note on informed consent process.
(h) Give a note on phase-II clinical trials.
(i) Define single blind study and its advantages.
(j) What is a crossover design?

PART – B

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

UNIT – I

2 Define drug discovery and development. Explain in detail the various stages in the modern drug discovery pipeline in pharmacological perspective.

OR

3 Explain different pharmacokinetic drug-drug interactions with an example.

UNIT – II

4 Explain in detail the principle, responsible conduct and supervision of ethics in clinical trials.

OR

5 Give a detailed note on the care and use of non-human animals in research.

UNIT – III

6 Discuss in detail the study design and importance of mutagenicity studies.

OR

7 Write notes on:

(a) Chronic toxicity testing.
(b) Ocular toxicity testing.

UNIT – IV

8 Give a detailed note on safety monitoring in clinical trials.

OR

9 Write about the various methods in post-marketing surveillance.

UNIT – V

10 Write a detailed note on data management and its components in clinical development.

OR

11 Give short notes on the following:

(a) Randomized trials.
(b) Principles of sampling.

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