Code: 15R00606 **R15**

B.Pharm III Year II Semester (R15) Regular 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) Define clinical trials.
(b) Classify various phases of clinical trials.
(c) Define cohort design of clinical trials.
(d) What is up & down design?
(e) Define Bayesian design.
(f) What is randomized titration design?
(g) What are uncontrolled trials? Give an example.
(h) What is blinding in clinical trials?
(i) What are multicentre trials?
(j) What are parametric tests? Give an example.

PART – B

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

UNIT – I

2 What are the challenges in the modern clinical trials?

OR

3 Classify various phases of clinical trials with the elements evaluated in each phase.

UNIT – II

4 What are up and down design in phase 1 clinical trials? How do you calculate the maximum tolerated dose?

OR

5 Explain about dose escalation design in phase 1 clinical trials.

UNIT – III

6 Write about cross over designs in phase-III trials.

OR

7 What are factorial designs? Give examples. Explain about main and interaction effects.

UNIT – IV

8 What is patient recruitment? Give a detailed note on safety monitoring in clinical trials.

OR

9 What is subgroup? Explain the problems associated in conducting multiple subgroup analysis.

UNIT – V

10 Give example of non parametric statistical tests. Write a note on any two non parametric statistical tests.

OR

11 Write a detailed description of student ‘t’ test and ANOVA.

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