

B.Pharm III Year II Semester (R15) Supplementary Examinations January/February 2023
CLINICAL TRIALS

Time: 3 hours

Max. Marks: 70

PART – A
(Compulsory Question)

- 1 Answer the following: (10 X 02 = 20 Marks)
- (a) What are clinical trial regulations?
 - (b) Name any two ethical issues in clinical trials.
 - (c) What is titration design, when it is needed?
 - (d) What is the goal of phase I study?
 - (e) Name one advantage of randomized withdrawal design.
 - (f) Write a note on factorial design.
 - (g) What is baseline data?
 - (h) What is multi-centre study?
 - (i) Define parametric, nonparametric test.
 - (j) Write the limitations of chi-square test.

PART – B
(Answer all the questions: 05 X 10 = 50 Marks)

- 2 What is the influence ethical committee on conduct of clinical trials?
OR
- 3 Explain the challenges in recruiting the participants for clinical trials.
- 4 Write a note on Bayesian design.
OR
- 5 Describe about up and down design of clinical trials.
- 6 Explain about random permuted blocks.
OR
- 7 Write the distinctive features of phase III clinical trial.
- 8 Discuss about the difficulties of sub group analysis.
OR
- 9 Explain about the baseline assessment comparability.
- 10 Explain analysis of variance with reference to clinical trials.
OR
- 11 (a) What is t-test? Explain the different types of t-test with examples.
(b) Write the significance of t-test.

Code: 15R00606

R15

B.Pharm III Year II Semester (R15) Supplementary Examinations July/August 2022
CLINICAL TRIALS

Time: 3 hours

Max. Marks: 70

PART - A
(Compulsory Question)

- 1 Answer the following: (10 X 02 = 20 Marks)
- (a) Name any two ethical issues in clinical trials
 - (b) Name two major challenges in preclinical research.
 - (c) Define maximum tolerated dose.
 - (d) What is accelerated titration design?
 - (e) Name the types of randomization in clinical trials.
 - (f) Name one advantage of randomized withdrawal design.
 - (g) What is clinical trial recruitment?
 - (h) Why is it important to have similar base line characteristics in clinical trials?
 - (i) How is t-test used in clinical trials?
 - (j) What are nonparametric statistics?

PART - B
(Answer all the questions: 05 X 10 = 50 Marks)

- 2 Explain the challenges in recruiting the participants for clinical trials.
OR
- 3 Write a short note on study population in clinical trials.
- 4 Discuss single patient per cohort design.
OR
- 5 Explain about Bayesian design.
- 6 Write a note on crossover designs in phase III.
OR
- 7 Explain about random permuted blocks.
- 8 Write an essay on the use of baseline data.
OR
- 9 Discuss the difficulties of subgroup analysis.
- 10 Write a note on the applications of Fisher's exact test in clinical trials.
OR
- 11 Explain analysis of variance with reference to clinical trials.

B.Pharm III Year II Semester (R15) Supplementary Examinations March 2022
CLINICAL TRIALS

Time: 3 hours

Max. Marks: 70

PART – A
(Compulsory Question)

- 1 Answer the following: (10 X 02 = 20 Marks)
- (a) What is the need for clinical trials?
 - (b) What are clinical trial regulations?
 - (c) Define titration design.
 - (d) What are randomized control trials?
 - (e) What are historical controls?
 - (f) Define simple randomization.
 - (g) What is baseline data?
 - (h) How patients are enrolled in to clinical trials?
 - (i) What is Fisher's exact test?
 - (j) Write the purpose of regression analysis.

PART – B
(Answer all the questions: 05 X 10 = 50 Marks)

- 2 (a) Write a short note on historical development of clinical trials.
(b) What is the influence ethical committee on conduct of clinical trials?
- OR**
- 3 (a) What are the challenges in conducting clinical trials in any academic centres?
(b) Discuss about the advantages and disadvantages of clinical trials.
- 4 (a) Write a short note on Up and Down designs in finding the dose.
(b) Explain about the randomized cross over design.
- OR**
- 5 (a) Describe about multi stage design.
(b) Write the objectives of phase II clinical trials.
- 6 (a) How double blind and triple blinded studies are carried out?
(b) Write the advantages of factorial designs.
- OR**
- 7 (a) Explain about the types of randomizations.
(b) How permuted block randomization is carried out?
- 8 (a) What is baseline assessment and why it is important in clinical trials?
(b) Explain about the baseline assessment comparability.
- OR**
- 9 (a) Explain the procedures adopted in recruiting the study subjects.
(b) Write the advantages and disadvantages of multi centre studies.
- 10 (a) What are non-parametric analysis and what is its significance?
(b) Describe about ANOVA.
- OR**
- 11 (a) What is student t-test and what are its uses?
(b) Write a note on chi-square test and its applications.

