Birla Institute of Technology & Science, Pilani
Hyderabad Campus

SECOND SEMESTER 2021-2022

Course Handout Part II

Date: 16-Jan-2022

In addition to part-I (General Handout for all courses appended to the time table) this portion gives further specific details regarding the course.

Course No. : *PHA G 546*
Course Title : *Pharmaceutical Biostatistics*
Instructor-in-Charge : *PUNNA RAO RAVI*

Description : Different types of data; methods for data collection; organization and summarization of data; probability distributions; descriptive measures (measures of central tendency and measures of dispersion); sampling and estimation of parameters (point estimates and interval estimates); tests of hypothesis using parametric (t-test and ANOVA) and various non-parametric tests; correlation and linear regression; determination of sample size for a study; estimating bio-equivalence of pharmaceutical products

Scope and Objective of the Course:

The objective of the course is to impart knowledge on various types of data, determining the descriptive measures and estimates for a given data. To provide a detailed understanding of the various types of parametric and non-parametric tests used in statistical analysis of data. The students should be able to select and apply an appropriate parametric/non-parametric test for a given data and interpret the results obtained. The students will also learn how to determine the sample size for a given study and perform statistical analysis and interpretation of data obtained from bio-equivalence studies.

Learning Outcomes:

- Explain different types of data
- Determine descriptive statistics
- Select and apply appropriate statistical techniques for analyzing a given data.
- Determining the sample size for a study
- Perform correlation and linear regression of the given data
- Estimate Bio-equivalence of pharmaceutical products using statistical methods

Course Description:

This course deals with different types of data, methods for data collection, organization and summarization of data, probability distributions, descriptive measures (measures of central tendency and measures of dispersion), sampling and estimation of parameters (point estimates and interval estimates), tests of hypothesis using parametric (T-TEST and ANOVA) and various non-parametric tests, correlation and linear regression. Determining the sample size for a study and estimating Bio-equivalence of pharmaceutical products using statistical methods will also be covered. All the topics covered will be related to the field of pharmaceutical sciences.

Textbook:

1. Pharmaceutical Statistics: Practical and Clinical Applications, ed: Sanford Bolton and Charles Bon. Fifth Edition. (Informa Healthcare, 2007).

Reference Book:

1. Biostatistics: Basic concepts and methodology for the health Sciences, ed: Wayne W. Daniel and Chad L. Cross. Tenth Edition. (Wiley, 2014)

Course Plan:

Lec. No.	Learning objectives	Topics to be covered	Chapter in the Text Book
1-2	Introduction to Biostatistics	Use of statistics in health sciences, what is data, types of data	Ch. 1
3-7	To understand organization of data	Importance of organization of data, different methods for organization of data, tabular and graphical representation of data	Ch. 2
8-11	To understand summarization of data	Measures of description, measures of central tendency, measures of dispersion	Ch. 2
12-16	To understand sampling	What is sampling design? Different sampling techniques, randomization in sampling, probability distributions, normal and standard normal distributions	Ch. 4, 6
17-20	To understand statistical inference	Estimation and confidence interval, hypothesis testing, null and alternate hypothesis	Ch. 5
21-24	To understand errors in statistical hypothesis testing	Type I error, Type II error, power of study and sample size calculations,	Ch. 7
25-28	To understand parametric testing procedures	When do we use parametric tests, different parametric tests like t-test and ANOVA (one way and two way)	Ch. 5, 8
29-33	To understand non-parametric testing procedures	When do we use non-parametric tests, different non-parametric tests like Sign Test, Signed Rank test, Rank Sum Test, Kruskal Wallis Test and Friedman Test	Ch. 15
34-36	To understand linear regression analysis and correlation	How to apply the concept of linear regression analysis and correlation in analytical method development of drug	Ch. 7
37-38	To understand statistical analysis of bio-equivalence data	How to compare data obtained from bio-equivalence studies and interpret the results	Ch. 11

Evaluation Scheme:

Component	Duration	Weightage (%)	Date & Time	Nature of Component
Pre Mid-Term Assignment	50 mins	20	To be announced	CB
Mid-Term Test	90 mins	30	As per Timetable	CB
Post Mid-Term Assignment	50 mins	15	To be announced	OB
Comprehensive Exam	120 mins	35	As per Timetable	CB (15) + OB (20)

CB – Closed Book; OB - Open Book.

Instructor Consultation Hour: To be announce in the class.

Notices: Notices pertaining to this course will be displayed **only on Pharmacy Department Notice Board.**

Make-up Policy: Make-up will be given only for **genuine** reasons. It is expected that students shall avoid misuse of this feature.

Academic Honesty and Integrity Policy: Academic honesty and integrity are to be maintained by all the students throughout the semester and no type of academic dishonesty is acceptable.

INSTRUCTOR-IN-CHARGE