



**SECOND SEMESTER 2019-20**  
**COURSE HANDOUT**

**Date: 09.01.2021**

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** : Richa Shrivastava

**1. 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.

**2. 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 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.

**3. Text Books:**

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

**4. Reference Books:**

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

**5. Course Plan:**

Module No.	Lecture Session	Reference (Textbook chapters)	Learning outcomes
1.	Use of statistics in health sciences, what is data, types of data L.S. 1-2	Ch. 1	Introduction to Biostatistics



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		Class notes	
2.	Importance of organization of data, different methods for organization of data, tabular and graphical representation of data L.S. 3-7	Ch. 2 Class notes	To understand organization of data
3.	Measures of description, measures of central tendency, measures of dispersion L.S. 8-11	Ch. 2 Class notes	To understand summarization of data
4.	What is sampling design? Different sampling techniques, randomization in sampling, probability distributions, normal and standard normal distributions L.S. 12-16	Ch. 4, 6 Class notes	To understand sampling
5.	Estimation and confidence interval, hypothesis testing, null and alternate hypothesis L.S. 17-20	Ch. 5 Class notes	To understand statistical inference
6.	Type I error, Type II error, power of study and sample size calculations, L.S. 21-24	Ch. 7 Class notes	To understand errors in statistical hypothesis testing
7.	When do we use parametric tests, different parametric tests like t-test and ANOVA (one way and two way) L.S. 25-30	Ch. 5, 8 Class notes	To understand parametric testing procedures
8.	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 L.S. 31-35	Ch. 15 Class notes	To understand non-parametric testing procedures
9.	How to apply the concept of linear regression analysis and correlation in analytical method development of drug L.S. 36-38	Ch. 7 Class notes	To understand linear regression analysis and correlation
10.	How to compare data obtained from bio-equivalence studies and interpret the results. L.S. 39-40	Ch. 11 Class notes	To understand statistical analysis of bio-equivalence data

**6. Evaluation Scheme:**

Component	Duration	Weightage (%)	Date & Time	Nature of component (Close Book/ Open Book)
Mid-Semester Test	90 Min.	30	<TEST_1>	Closed Book



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Comprehensive Examination	3 h	40	<TEST_C>	Closed Book +Open Book
Pre Mid-Term Assignment	50 mins	15	To be announced in the class	Closed Book
Post Mid-Term Assignment	50 mins	15	To be announced in the class	Open Book

**7. Chamber Consultation Hour:** 6:00 PM-8:00 PM [Email: richa.shrivastava@pilani.bits-pilani.ac.in].

**8. Notices:** Notices concerning the course will be displayed on the Pharmacy Department Notice Board only.

**9. Make-up Policy:** Make-Ups are not given as a routine. It is solely dependent upon the genuineness of the circumstances under which a student fails to appear in a scheduled evaluation component. In such circumstances, prior permission should be obtained from the Instructor-in-Charge. The decision of the Instructor-in-Charge in the above matter will be final.

**10. Note (if any):**

**Instructor-in-charge**  
**Course No. PHA G546**