

BIOSTATISTICS AND RESEARCH METHODOLOGY

(Theory BP801T) (As per PCI Syllabus)



- Prof. Rushikesh Chandrakant Sorate Dr. Amol Tanaji Ubale
- Prof. Varsha Gajanan Rane
- Prof. Megha Sanjay Jadhav
- Prof. Shardul Sanjay Kalyankar

BIOSTATISTICS AND RESEARCH METHODOLOGY (THEORY BP801T)

Prof. Rushikesh Chandrakant Sorate

Asst. Professor, Yuvak Kalyan Sangh's Vijayrao Naik College of Pharmacy, Shirval-Kankavli Maharashtra.

Dr. Amol Tanaji Ubale

Asso. Professor, Y. K. S.'S Vijayrao Naik College of Pharmacy, Kankavli Maharashtra.

Prof. Varsha Gajanan Rane

Assistant Professor, V P College of Pharmacy, Madkhol-Sawantwadi, Maharashtra.

Prof. Megha Sanjay Jadhav

Asst. Professor, Shaneshwar Shikshan Prasarak Mandal, V P College of Pharmacy Madkhol Sawantwadi Maharashtra.

Prof. Shardul Sanjay Kalyankar

Assistant Professor, Y. K. S.'S Vijayrao Naik College of Pharmacy, Kankavli, Maharashtra. Book Title: **Biostatistics and Research Methodology**

(Theory BP801T)

Authored By: **Prof. Rushikesh Chandrakant Sorate**,

Dr. Amol Tanaji Ubale,

Prof. Varsha Gajanan Rane, Prof. Megha Sanjay Jadhav, Prof. Shardul Sanjay Kalyankar

Price: ₹699

1st Edition

ISBN: 978-93-48091-94-9

9 789348 091949

Published: March 2025

Publisher:



Kripa-Drishti Publications

A/ 503, Poorva Height, SNO 148/1A/1/1A,

Sus Road, Pashan-411021, Pune, Maharashtra, India.

Mob: +91-8007068686

Email: editor@kdpublications.in
Web: https://www.kdpublications.in

© Copyright Prof. Rushikesh Chandrakant Sorate, Dr. Amol Tanaji Ubale, Prof. Varsha Gajanan Rane, Prof. Megha Sanjay Jadhav, Prof. Shardul Sanjay Kalyankar

All Rights Reserved. No part of this publication can be stored in any retrieval system or reproduced in any form or by any means without the prior written permission of the publisher. Any person who does any unauthorized act in relation to this publication may be liable to criminal prosecution and civil claims for damages. [The responsibility for the facts stated, conclusions reached, etc., is entirely that of the author. The publisher is not responsible for them, whatsoever.]

PREFACE

Research methodology and statistical techniques are combined in the book "Biostatistics and Research Methodology." For research scholars and working researchers, this book might serve as a workbook. For students pursuing degrees and postgraduate programs in pharmacy, biology, biotechnology, medicine, and home science, this book covers the course "Biostatistics and Research Methodology." There are five units in this book.

This book is also meant to be used as a textbook for P.G. and U.G. pharmacy students. Important This book's features include: Written in an easy-to-understand style for students who are not mathematicians. With basic examples, the SPSS data analysis process is demonstrated for the majority of widely used statistical tools. great assistance to professors who mentor M.Sc. and Ph.D. students on their projects.

Scope: To understand the applications of Biostatics in Pharmacy. This subject deals with descriptive statistics, Graphics, Correlation, Regression, logistic regression Probability theory, Sampling technique, Parametric tests, Non-Parametric tests, ANOVA, Introduction to Design of Experiments, Phases of Clinical trials and Observational and Experimental studies, SPSS, R and MINITAB statistical software's, analyzing the statistical data using Excel.

Objectives: Upon completion of the course the student shall be able to

- Know the operation of M.S. Excel, SPSS, R and MINITAB®, DoE (Design of Experiment)
- Know the various statistical techniques to solve statistical problems Appreciate statistical techniques in solving problems.

Abbreviations

Alternative Hypothesis (H1)
Analysis of Variance (ANOVA)
Arithmetic Mean (AM)
Box-Behnken Design (BBD)
Bureau of Labor Statistics (BLS)
Capital Asset Pricing Model (CAPM)
Central Composite Design (CCD)
Clinical Research Unit (CRU)
Coefficient of variation (CV)
Completely randomized design (CRD)
Design of Experiments (DOE)
European Medicines Agency (EMA)
Genetic algorithms (GANs)
Genetic Algorithms (GCRs)
Genetic Algorithms (GMOs)
Gross Domestic Product (GDP)
Independent variables (IVs)
Institutional Review Board (IRB)
Interquartile Range (IQR)
Investigational Medicinal Product (IMP)

Least Significant Difference (LSD)

Least-Squares Regression Line (LSRL)

Linear Programming (LP)

Mean Absolute Deviation (MAD)

Multivariate analysis of variance (MANOVA)

Null Hypothesis (H0)

Ordinary Least Squares (OLS)

Pharmaceuticals and Medical Devices Agency (PMDA)

Pharmacodynamics (PD)

Pharmacokinetics (PK)

Probability Density Function (PDF)

Recursive Feature Elimination (RFE)

Response Surface Methodology (RSM)

Scholastic Assessment Test (SAT)

Standard Error (SE)

Standard Error of Mean (SEM)

Statistical Analysis System (SAS)

Statistical Package for The Social Sciences (SPSS)

Statistical process control (SPC)

Therapeutic Goods Administration (TGA)

US Food and Drug Administration (FDA)

US Food and Drug Administration's (USFDA)

Variance Inflation Factor (VIF)

INDEX

Unit-1:	1
	1
1.1 Introduction:	
1.1.1 Descriptive Statistics:	
1.1.2 Inferential Statistics:	
1.1.3 Biostatistics:	
1.1.4 Frequency Distribution:	
1.2 Measures of Central Tendency:	
1.2.1 Mean:	
1.2.2 Median:	
1.2.3 Mode:	
1.2.4 Relationship between Mean, Median and Mode:	
1.2.5 Pharmaceutical Examples:	
1.3 Measures of Dispersion:	
1.3.1 Dispersion:	
1.3.2 Range:	
1.3.3 Standard Deviation:	
1.3.4 Solved Examples:	
1.4 Correlation:	
1.4.1 Definition:	
1.4.2 Karl Pearson's Coefficient of Correlation:	
1.4.3 Multiple Correlation:	28
1.4.4 Example on Coefficient of Correlation:	29
Unit-2	34
2.1 Regression Introduction:	34
2.1.1 Curve Fitting by the Method of Least Squares:	
2.1.2 Fitting the Lines $y=a+bx$ and $x=a+by$, Multiple Regression: .	
2.1.3 Standard Error of Regression:	
2.1.4 Pharmaceutical Examples:	
2.2 Probability:	
2.2.1 Binomial Distribution:	
2.2.2 Normal Distribution:	55
2.2.3 Poisson's Distribution:	
2.2.4 Sample Distribution:	
2.2.5 Population:	
2.2.6 Null Hypothesis:	
2.2.7 Alternative Hypothesis (H _a):	
2.2.8 Sampling:	
2.2.9 Types of Sampling:	

2.2.10 Essence of Sampling:	72
2.2.11 Error-I type:	72
2.2.12 Type II Error:	
2.2.13 Standard Error of Mean (SEM):	
2.2.14 Pharmaceutical Examples:	
2.3 Parametric Test: t-test (Sample, Pooled or Unpaired and Paired):	
2.3.1 T-test:	
2.3.2 ANOVA:	
2.3.4 Least Significance Difference:	
Unit-3:	100
3.1 Introduction:	100
3.1.1 Wilcoxon Rank Sum Test:	
3.1.2 Mann-Whitney U test:	
3.1.3 Kruskal-Wallis test:	
3.1.4 Friedman Test:	
3.2 Introduction to Research:	
3.2.1 Need for Research:	
3.2.2 Need for design of Experiments:	
3.2.3 Experiential Design Technique:	
3.2.4 Plagiarism:	
3.3 Graphs:	
3.3.1 Histogram:	
3.3.2 Pie Chart:	
3.3.3 Cubic Graph:	
3.3.4 Response Surface Plot:	
3.3.5 Counter Plot Graph:	
3.4 Designing the methodology:	
3.4.1 Sample size determination:	
3.4.2 Report writing and presentation of data:	
3.4.3 Protocol:	
3.4.4 Cohorts Studies:	
3.4.5 Observational studies:	144
3.4.6 Experimental Studies:	147
3.4.6 Designing Clinical Trial:	
3.4.7 Various Phases:	
Unit- 4	154
4.1 Introduction:	154
4.1.1 Blocking:	
4.1.2 Confounding:	
4.2 Regression Modeling:	
4.2.1 Hypothesis Testing On Linear Regression:	157
4.2.2 Hypothesis Testing in Simple Regression Models:	

4.2.3 Hypothesis Testing in the Multiple Regression Model:	161
4.3 Introduction to Practical Components of Industrial and Clinical Trials	Problems:
-	162
4.3.1 Statistical Analysis Using Excel:	163
4.3.2 SPSS:	
4.3.3 Statistical Analysis Using Minitab:	168
4.3.4 Design of Experiments:	
4.3.5 Statistical Analysis Using R Programming Language:	170
4.3.6 Online Statistical Software's to Industrial and Clinical Trial	Approach:
	172
4.3.7 R- Online Statistical Software's to Industrial and Clin	ical Trial
Approach:	174
Unit -5	176
5 1 Total hard's as	176
5.1 Introduction:	
5.1.1 Analysis of Variance:	
5.2 Factorial Design:	
5.2.1 22, 23d Design:	
5.2.2 Advantage of Factorial Design:	
5.3 Response Surface Methodology:	
5.3.1 Central Composite Design (CCD):	
5.3.2 Historical Design:	194
5.3.3 Optimization Techniques:	195
References:	198
	170

List of Figures

	Figures Name	Page No
Figure 1.1:	Frequency Distribution	4
Figure 1.2:	Frequency Distribution Graphs	5
Figure 1.3:	Central Tendency	7
Figure 1.4:	Measures of Central Tendency	7
Figure 2.1:	Curve Fitting by The Method of Least Squares	35
Figure 2.2:	List Square Method	36
Figure 2.3:	List Square Method Graph	37
Figure 2.4:	Probability density function (P.D.F.)	56
Figure 2.5:	Standard Normal Distribution	57
Figure 2.6:	The probability Mass function for Poisson distribution	60
Figure 2.7:	Population and Sample	67
Figure 2.8:	Probability of Making a Type I error	73
Figure 2.9:	Probability of Making a Type II error	74
Figure 2.10:	Trade-off between Type I and Type II errors	75
Figure 2.11:	T-Test and A Z-Test	86
Figure 2.12:	Probability Plot	89
Figure 3.1:	QQ Plot and Box Plots for data in Example 1	103
Figure 3.2:	Wilcoxon Rank-Sum Test for Example 1	104
Figure 3.3:	Wilcoxon Rank-Sum Test for Example 2	105
Figure 3.4:	Calculation of W' using reverse ranks	106
Figure 3.5:	As a result, when the t-test's normal distribution condition is not met, the Mann-Whitney U test is utilized instead.	107
Figure 3.6:	The variables do not have to follow a distribution curve.	108
Figure 3.7:	Test subjects awaiting a pulmonary function test. Credit: Technology Networks.	117
Figure 3.8:	Experimental design	122
Figure 3.9:	Section of the river Pregal in Koenigsberg and Euler's graph.	126
Figure 3.10:	5 vertices and 6 edges	127
Figure 3.11:	Histogram vs. Bar Charts	128
Figure 3.12:	Pie chart	128
Figure 3.13:	skeletons of polyhedral	129
Figure 3.14:	Response Surface Plot	130
Figure 3.15:	Rectangular Contour Plot	132
Figure 3.16.	Polar Contour Plot	132

	Figures Name	Page No.
Figure 3.17:	Ternary Contour Plot	133
Figure 3.18:	An experimental study, used to answer interventional RQs	147
Figure 3.19:	True experimental studies	148
Figure 4.1:	Linear regression model example with number of clicks and emails sent as axes.	156
Figure 4.2:	Hypothesis Testing on Linear Regression	157
Figure 4.3:	Scatter Plot	158
Figure 4.4:	linear regression on this dataset in Python	159
Figure 5.1:	A sample layout of a completely randomized design with four treatments (A, B, C and D) each replicated five times	180
Figure 5.2:	Optimizing the extraction parameters of fruit tea polysaccharides and polyphenols using RSM (doi.org)	192
Figure 5.3:	Controlled biosynthesis of gold nanoparticles with Coffee Arabica using factorial design (doi.org)	193

List of Tables

Table Name	Page No.
Table 1.1: The following is a synopsis of each of these graphs	5
Table 1.2: Frequency array or discrete series	6
Table 1.3: r value variation	27
Table 1.4: The coefficient of multiple correlation	28
Table 2.1: Probability of getting a head($P(X)$)	49
Table 2.2: The following is the Z Table for the Standard Normal Distribution	57
Table 2.3: Population vs Sample	66
Table 2.4: To better grasp the difference between a null hypothesis and an alternative hypothesis, consider the following examples.	70
Table 2.5: The following table lists some of the main distinctions between Type I and Type II errors	77
Table 2.6: We'll start off by reading our csv into a data frame	88
Table 2.7: To determine the mean and standard deviations of the before and after columns, use the describe () method.	92
Table 2.8: The restraint (untreated) groups were these fours	96
Table 2.9: For simplicity, let's first tabulate those figures	97
Table 3.1 Data for Example 1	103
Table 3.2: Calculate Mann-Whitney U-Test	109
Table 3.3: Example	114
Table 3.4: Sort the data for all groups in ascending order and assign them rankings	114
Table 3.5: Arrange back according to the levels an calculate the sum of ranks for each level	115
Table 3.6: Pulmonary function test results for 12 patients at 3 time points, and their ranks in ascending order.	118
Table 3.7: Graph and Nodes	129
Table 3.8: Comparing experimental designs (descriptive studies do not have any comparison or connection groups)	147
Table 3.9: Phases of Clinical Trials	150
Table 4.1: The Results of the test can be summarized in a special ANOVA table:	161
Table 4.2: Functions for central tendency and variability:	164
Table 4.3: Functions for correlation and regression	164
Table 4.4: Excel Array Functions for Statistical Analysis	164

Table 4.5: Excel Data Analysis Tools	165
Table 4.6: Statistical Functions for Central Tendency and Variability R	170
Table 4.7: Base R Statistical Functions for Relative Standing	171
Table 4.8: T-Test Functions for Statistical Analysis with R	171
Table 5.1: For our example, the 20 random numbers are ranked from the smallest to the largest, as shown in the following:	179
Table 5.2: For our example, the 20 ranks are divided into four groups, each consisting of five numbers, as follows:	179
Table 5.3: Mycelial growth in terms of diameter of the colony (mm) of R. solani isolates on PDA medium after 14 hours of incubation.	181
Table 5.4: Schematic representation of ANOVA of CRD with unequal replications.	181
Table 5.5 ANOVA of mycelial growth data of Table 5.3.	182

ABOUT THE AUTHORS



Prof. Rushikesh Chandrakant Sorate He is currently working as an Asst. Professor at Yuvak Kalyan Sangh's Vijayrao Naik College of Pharmacy, Shirval-Kankavli Maharashtra. He has completed his Master of Pharmacy (Pharmaceutics) from Shivaji University Kolhapur. He pursuing his Ph. D. in Shivaji University Kolhapur. He has 05-year experience of Academics. His research interests include nanoparticles & herbal formulations. He applied for a Design Patent in India. He has published 02 Review articles in Scopus indexed journals. He is an Active IJCRT RMS(Reviewer) Member of the esteemed Journal (International Journal of Creative Research Thoughts). He worked as a jury member in state level competition. He has attended International & National conferences.



Dr. Amol Tanaji Ubale He is currently working as currently working as an Asso.Professor at Y. K. S.'S Vijayrao Naik College of Pharmacy, Kankavli Maharashtra. He has completed his Master of Pharmacy (Q.A.) from Shivaji University Kolhapur. He has completed his PhD in Sunrise University Rajasthan. He has 12 years of Academic & Administrative experience. His research interests include nanoparticles & herbal formulations. He applied for patents in India & South Africa. He also worked as Jury for Maharashtra Students Innovation Challenge 2023 organized by Govt of Maharashtra's District Skill Development, Employment & Entrepreneurship Guidance Centre, Satara. He is a life Member of Association of Pharmaceutical Teachers of India. He is Member of All India Council for Technical Skill Development. He is Resource person in Intellect Institute of Education & Research Pune. His book Pharmacist Practical Training Report Book as per PCI ER 2020 by KD Publications Pune in 2023. His book Pharmaceutical Biotechnology for B. PHARM students of Sixth Semester published by Gyan Publications in 2023. His book D. Pharmacy multiple choice questions as per PCI ER-2020 Diploma in pharmacy first year published by Brilliant Publication in 2023. His book D. Pharmacy multiple choice questions as per PCI ER-2020 Diploma in pharmacy Second year published by Brilliant Publication in 2023. He has published 3 research papers & 10 Review articles in reputed journals. He is RMS (Reviewer) Member of the IJRAR - International Research Journal. He is a Member of the RMS (Reviewer) of the TIJER- International Research Journal. He a section editor in STM Journals: research & reviews: a journal of drug formulation, development and production. He is an editorial board member in STM Journals- Research & Reviews: A Journal of Drug Design & Discovery. He is Editorial team member in Kripa Drishti Publications Pune. He is an Editorial Advisory Board member in Scientific Publications Universal Journal of Pharmacy and Pharmacology. He is a Global Outreach -Po



Prof. Varsha Gajanan Rane is currently working as an Assistant Professor at V P College of Pharmacy, Madkhol-Sawantwadi, Maharashtra. She completed her Master of Pharmacy (Pharmaceutics) from Mumbai University and has 3 years of academic experience. She is an expert in teaching all subjects of Pharmaceutics and has command over other subjects such as Medicinal Chemistry, Pharmaceutical Organic Chemistry, and Pharmaceutical Biochemistry. Her research interests include nanoparticle formulations. She has guided more than 15 graduate students and is currently involved in research on ethosomal formulations. She has published more than 5 national and international papers and has attended and presented several papers at international and national conferences, including IPC 72.



Prof. Megha Sanjay Jadhav she is currently working as an Asst. Professor at Shaneshwar Shikshan Prasarak Mandal, V P College of Pharmacy Madkhol Sawantwadi Maharashtra. She has completed her B. Pharm from Shivaji University, Kolhapur and M. Pharm (Pharmaceutics) from Mumbai University. Her research interests include nanoparticles formulation. She has total 2 years 6 months experience of Academic fields. She is expert in teaching all subject of Pharmaceutics including Pharmaceutical Organic Chemistry, Herbal Drug Technology. She has guided more than 13 B. Pharm students and their publication including review articles and their presentation. She has Published 02 Review article and 02 research article in Scopus indexed journals. She has attended International & National Conferences such as IPC 72 Nagpur.



Prof. Shardul Sanjay Kalyankar He is currently working as an Assistant Professor at Y. K. S.'S Vijayrao Naik College of Pharmacy, Kankavli, Maharashtra. He has completed his Master of Pharmacy (Pharmaceutics) from Shivaji University Kolhapur. He has 1.8 years of Industrial Experience and 1 year of Academic experience. His research interests include Crystal engineering, Cocrystal development & herbal formulations. He applied copyright on the cocrystal development also applied for patents in India. He has published 1 research papers & 2 Review articles in reputed journals.



Kripa-Drishti Publications

A-503 Poorva Heights, Pashan-Sus Road, Near Sai Chowk,

Pune - 411021, Maharashtra, India.

Mob: +91 8007068686

Email: editor@kdpublications.in Web: https://www.kdpublications.in and pholistical problematic and information and

Price: ₹699

ISBN: 978-93-48091-94-9

