

Shree H. N. Shukla Institute of Pharmaceutical Education & Research

(Affiliated to Gujarat Technological University, Approved by PCI)

Shree H. N. Shukla College Campus, Nr. Lalpari Lake, B/H. Marketing Yard, Amargadh – Bhichari, Raikot. Mo. 9099063150, 9727753360

Bachelor of Pharmacy Subject Code: BP801TT SEMESTER: VIII Subject Name: Biostatistics and Research Methodology

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

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

Teaching scheme and examination scheme:

Teaching Scheme				Evaluation Scheme			
Theory	Tutorial	Practical	Total	Theory		Practical	
				External	Internal	External	Internal
3	1	0	4	80	20	0	0

Sr No	Topics	%
1.	Introduction: Statistics, Biostatistics, Frequency distributionMeasures of central tendency: Mean, Median, Mode- PharmaceuticalexamplesMeasures of dispersion: Dispersion, Range, standard deviation,Pharmaceutical ProblemsCorrelation: Definition, Karl Pearson's coefficient of correlation, Multiplecorrelation - Pharmaceuticals examples	weightage 10
2.	 Regression: Curve fitting by the method of least squares, fitting the lines y= a + bx and x = a + by, Multiple regression, standard error of regression– Pharmaceutical Examples Probability: Definition of probability, Binomial distribution, Normal distribution Poisson's distribution, properties – problems Sample, Population, large sample, small sample, Null hypothesis, alternative hypothesis, sampling, essence of sampling, types of sampling, Error-I type, Error-II type, Standard error of mean (SEM) - Pharmaceutical examples Parametric test: t-test(Sample, Pooled or Unpaired and Paired), ANOVA, (One way and Two way), Least Significance difference 	10
3.	 Non Parametric tests: Wilcoxon Rank Sum Test, Mann-Whitney U test, Kruskal-Wallis test, Friedman Test Introduction to Research: Need for research, Need for design of Experiments, Experiential Design Technique, plagiarism Graphs: Histogram, Pie Chart, Cubic Graph, response surface plot, Counter Plot graph Designing the methodology: Sample size determination and Power of a study, 	10



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	Report writing and presentation of data, Protocol, Cohorts studies,			
	Observational studies, Experimental studies, Designing clinical trial, various			
	phases.			
	Blocking and confounding system for Two-level factorials	8		
4.	Regression modeling: Hypothesis testing in Simple and Multiple regression			
	models			
	Introduction to Practical components of Industrial and Clinical Trials			
	Problems:			
	Statistical Analysis Using Excel, SPSS, MINITAB®, DESIGN OF			
	EXPERIMENTS, R - Online Statistical Software's to Industrial and Clinical trial			
	approach			
5.	Design and Analysis of experiments:	7		
	Factorial Design: Definition, 22, 23design. Advantage of factorial design			
	Response Surface methodology: Central composite design, Historical design,			
	Optimization Techniques			

Recommended Books (Latest edition):

- 1. Pharmaceutical statistics- Practical and clinical applications, Sanford Bolton, publisher Marcel Dekker Inc. NewYork.
- 2. Fundamental of Statistics Himalaya Publishing House- S.C.Guptha
- 3. Design and Analysis of Experiments -PHI Learning Private Limited, R. Pannerselvam
- 4. Design and Analysis of Experiments Wiley Students Edition, Douglas and C. Montgomery

LEARNING OUTCOMES:

UNIT	LEARNING OUTCOME
1	Introduction of biostatics, measure of tendency & dispersion and correlation.
2	Understand the regression, probability and parametric test
3	Appreciate statistical techniques in solving the problems and various tests.
4	Introduction to Practical components of Industrial and Clinical Trials Problems.
5	Understand the design and analysis of experiments.

BOOK LIST:

Sr. no	Book name	Price (Rs.)
1	Pharmaceutical statistics- Practical and clinical applications, Sanford	4,290 /-
	Bolton, publisher Marcel Dekker Inc. NewYork.	
2	Fundamental of Statistics – Himalaya Publishing House- S.C.Gupta.	825 /-
3	Design and Analysis of Experiments –PHI Learning Private Limited,	252 /-
	R. Pannerselvam.	
4	Design and Analysis of Experiments – Wiley Students Edition,	17,019 /-
	Douglas and C. Montgomery.	