

**NIRMA UNIVERSITY**  
**Institute of Pharmacy**  
**(B. Pharm.)**  
**(Semester - VIII)**

		<b>L</b>	<b>T</b>	<b>P</b>	<b>C</b>
		<b>3</b>	<b>1</b>	<b>-</b>	<b>4</b>
<b>Course Code</b>	<b>BP801T</b>				
<b>Course Title</b>	<b>Biostatistics and Research Methodology - Theory</b>				

**Scope:**

To understand the applications of Biostatistics 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 this course the student should be able to:

5. Know the operation of MS Excel, SPSS, R and MINITAB, DoE (Design of Experiment)
6. Know the various statistical techniques to solve statistical problems
7. Appreciate statistical techniques in solving the problems.

**Course Learning Outcomes (CLO):**

At the end of the course, students will be able to -

1. Remember various statistical formulas used for pharmaceutical sciences.
2. Understand the basic concepts of various statistical test for data analysis.
3. Describe fundamentals in research methodology, data presentations and interpretation of graphs.
4. Apply appropriate statistical test for pharmaceutical data treatment.
5. Illustrate the operation of various software for experimental designs.
6. Analyze scientific data using suitable experimental design.

**Syllabus:**

**Teaching hours:**

**45 Hours**

**UNIT I**

**10 Hours**

**Introduction:** Statistics, Biostatistics, Frequency distribution.

**Measures of central tendency:** Mean, Median, Mode- Pharmaceutical examples.

**Measures of dispersion:** Dispersion, Range, standard deviation, Pharmaceutical problems.

**Correlation:** Definition, Karl Pearson's coefficient of correlation, Multiple correlation - Pharmaceuticals examples.

**UNIT II**

**10 Hours**

**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.

**Non Parametric tests:** Wilcoxon Rank Sum Test, Mann-Whitney U test, Kruskal-Wallis test, Friedman Test.

### UNIT – III

**10 Hours**

**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, Report writing and presentation of data, Protocol, Cohorts studies, Observational studies, Experimental studies, Designing clinical trial, various phases.

### UNIT – IV

**08 Hours**

**Factors:** Blocking and confounding system for Two-level factorials.

**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, etc. Online Statistical Software's to Industrial and Clinical trial approach

### UNIT – V

**07 Hours**

**Design and Analysis of experiments:**

Factorial Design: Definition,  $2^2$  design,  $2^3$  design. Advantage of factorial design.

Response Surface methodology: Central composite design, Historical design, Optimization Techniques.

### Tutorials Teaching hours:

**15 Hours**

Tutorials will be based on above syllabus

### Suggested Readings^: (Latest edition)

14. Bolton, S. *Pharmaceutical Statistics - Practical and Clinical Applications*, New York, Marcel Dekker Inc Publishers.
15. Gupta, S.C. *Fundamental of Statistics*, Mumbai, Himalaya Publishing House.
16. Panneerselvam, R. *Design and Analysis of Experiments*, New Delhi, PHI Learning Pvt. Ltd.
17. Montgomery, D.C. *Design and Analysis of Experiments*, New Jersey, Wiley Students Choice Publishers

L= Lecture, T= Tutorial, P= Practical, C= Credit

^ this is not an exhaustive list

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