LJ UNIVERSITY

LJ INSTITUTE OF PHARMACY

SEMESTER: VIII

Subject Name: BIOSTATISTICS AND RESEARCH METHODOLOGY
Subject Code: BP801TP

Scope: This course is designed to impart basic knowledge on important legislations related to the profession of pharmacy in India

Objectives: Upon completion of the course the student shall be able to
1. The Pharmaceutical legislations and their implications in the development and marketing of pharmaceuticals
2. Various Indian pharmaceutical Acts and Laws
3. The regulatory authorities and agencies governing the manufacture and sale of pharmaceuticals
4. The code of ethics during the pharmaceutical practice

Teaching scheme and examination scheme:

Teaching Scheme				Evaluation Scheme			
Theory	Tutorial	Practical	Total	Theory		Practical	
				External	Internal	External	Internal
3	1	0	4	75	25	0	0

Sr. No.	Course Contents	Hours
1	**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	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 methodolog**y: 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.	10
4	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 - Online Statistical Software's to Industrial and Clinical trial approach	08

5	**Design and Analysis of experiments:** **Factorial Design:** Definition, 2^2, 2^3 design. Advantage of factorial design **Response Surface methodology:** Central composite design, Historical design, Optimization Techniques	07
	Total Hours	45

Recommended Books:

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