

RE-ORGANIZATION OF SYLLABUS

Old Syllabus of Biostatistics & Research Methodology as per PCI:

Unit 1	<p>Introduction: Statistics, Biostatistics, Frequency distribution</p> <p>Measures of central tendency: Mean, Median, Mode- Pharmaceutical examples</p> <p>Measures of dispersion: Dispersion, Range, standard deviation, Pharmaceutical problems</p> <p>Correlation: Definition, Karl Pearson's coefficient of correlation, Multiple correlation - Pharmaceuticals examples</p>	10 Hours
Unit 2	<p>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</p> <p>Probability: Definition of probability, Binomial distribution, Normal distribution, Poisson's distribution, properties - problems</p> <p>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</p> <p>Parametric test: t-test(Sample, Pooled or Unpaired and Paired) , ANOVA, (One way and Two way), Least Significance difference</p>	10 Hours
Unit 3	<p>Non Parametric tests: Wilcoxon Rank Sum Test, Mann-Whitney U test, Kruskal-Wallis test, Friedman Test</p> <p>Introduction to Research: Need for research, Need for design of Experiments, Experiential Design Technique, plagiarism</p> <p>Graphs: Histogram, Pie Chart, Cubic Graph, response surface plot, Counter Plot graph</p> <p>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.</p>	10 Hours
Unit 4	<p>Blocking and confounding system for Two-level factorials</p> <p>Regression modeling: Hypothesis testing in Simple and Multiple regression models</p> <p>Introduction to Practical components of Industrial and Clinical Trials Problems</p> <p>Statistical Analysis Using Excel, SPSS, MINITAB®, DESIGN OF EXPERIMENTS, R - Online Statistical Software's to Industrial and Clinical trial approach</p>	08 Hours
Unit 5	<p>Design and Analysis of experiments:</p> <p>Factorial Design: Definition, 2², 2³ design. Advantage of factorial design</p> <p>Response Surface methodology: Central composite design, Historical design, Optimization Techniques</p>	07 Hours

**Re-Organization Syllabus of Biostatistics & Research Methodology**

Unit No.	Contents	Time Allotted	Rationale
Unit I	<p>Introduction & Methodologies of Research</p> <p>a. Introduction to Research: Need for research, Need for design of Experiments, Experiential Design Technique and plagiarism.</p> <p>b. Graphs: Histogram, Pie Chart, Cubic Graph, response surface plot, Counter Plot graph</p> <p>c. 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.</p>	8 hrs.	Sequence is changed because, before knowing the use & importance of biostatistics in product development, it is important to have the prior knowledge of research & the methodologies involved in pharmaceutical product development.
Unit II	<p>Experiential Designing & Analysis Techniques</p> <p>a. Design and Analysis of experiments: Factorial Design: Definition, 2^2, 2^3 designs. Advantage of factorial design</p> <p>b. Blocking and confounding system for Two-level factorials</p> <p>c. Response Surface methodology: Central composite design, Historical design, Optimization Techniques</p>	8 hrs.	Considering all relevant concept of research methodologies it is important to study the design of experiments for product development, So it is kept in unit II.
Unit III	<p>Descriptive Statistics</p> <p>a. Introduction: Statistics, Biostatistics, Frequency distribution</p> <p>Measures of central tendency: Mean, Median, Mode-Pharmaceutical examples</p>	12 hrs.	Once the student know the, What is research & its different relevant methodologies. It's important to study the basics of biostatistics, as well as pharmaceutical information gathering & their summarizes features from a collection of information during



	<p>b. Measures of dispersion: Dispersion, Range, standard deviation, Pharmaceutical problems</p> <p>c. Probability: Definition of probability, Binomial distribution, Normal distribution, Poisson's distribution, properties – problems Sample, Population, large sample, small sample - Pharmaceutical examples</p>		the development study.
Unit IV	<p>Inferential Statistics</p> <p>a. Correlation: Definition, Karl Pearson's coefficient of correlation, Multiple correlation - Pharmaceuticals examples</p> <p>b. 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</p> <p>c. Regression modeling: Hypothesis testing in Simple and Multiple regression models, Null hypothesis, alternative hypothesis, sampling, essence of sampling, types of sampling, Error-I type, Error-II type, Standard error of mean (SEM) - Pharmaceutical examples</p> <p>d. Parametric test: t-test(Sample, Pooled or Unpaired and Paired) , ANOVA, (One way and Two way), Least Significance difference</p> <p>e. Non Parametric tests: Wilcoxon Rank Sum Test, Mann-Whitney U test, Kruskal-Wallis test, Friedman Test</p>	12 hrs.	In the previous units, all the relevant concept of research methodologies & descriptive statistics are covered. To maintain the dependent relationship between those points this unit is taken in similar sequence.

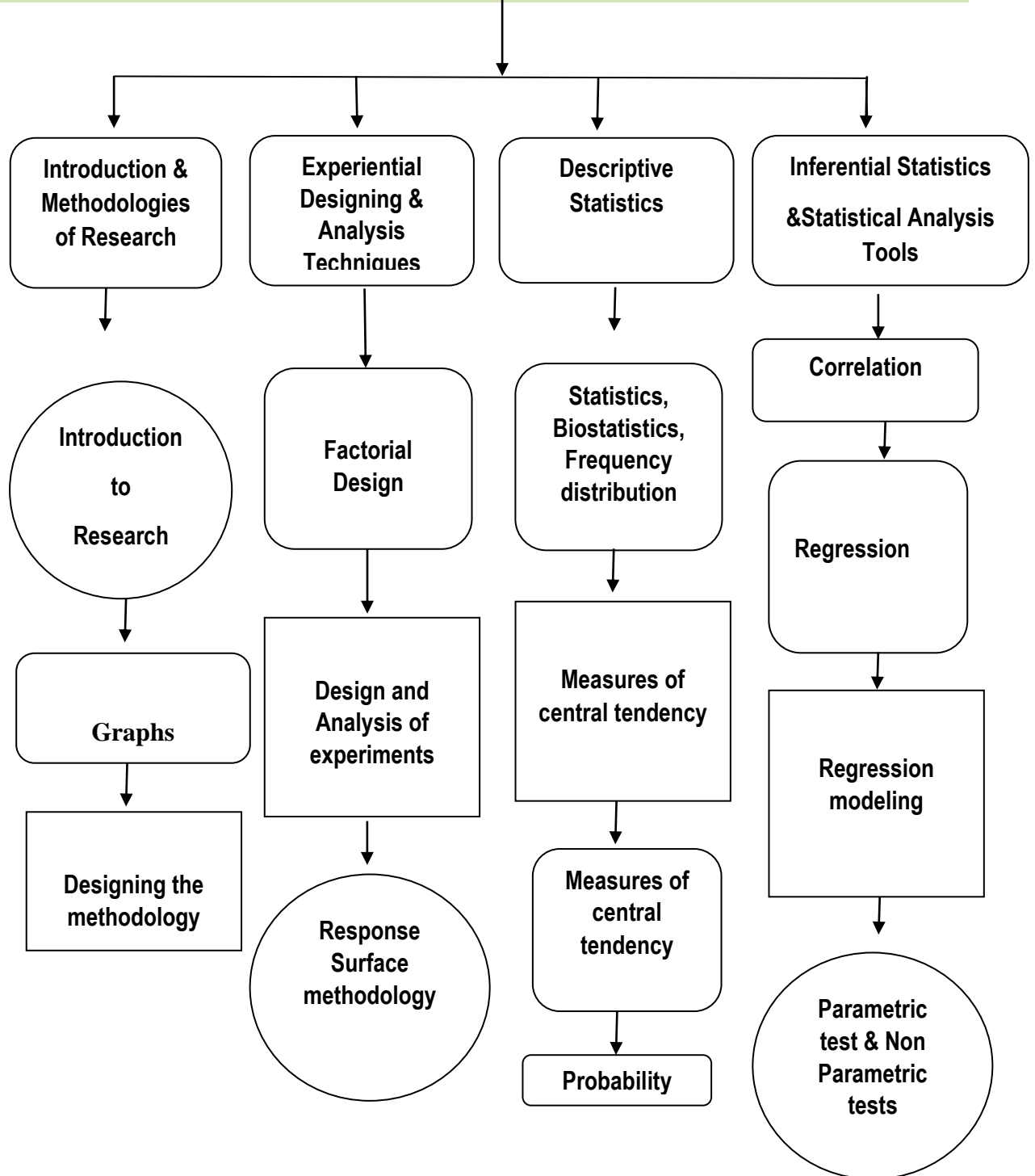


Unit V	Statistical Analysis Tools a. Introduction to Practical components of Industrial and Clinical Trials Problems: Statistical Analysis Using Excel, SPSS, MINITAB [®] , DESIGN OF EXPERIMENTS, R - Online Statistical Software's to Industrial and Clinical trial approach	5 hrs.	After studying descriptive statistics & Inferential Statistics, it is easy to understand the statistical analysis tools used in Industrial and Clinical Trials problems, so taken in sequence of dependent relationship.
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GRAPHICAL SYLLABUS

BIostatistics and RESEARCH METHODOLOGY



Embedded Formative Assessments 1

Class: Final Year B. Pharm

Semester: VIII

Subject: Biostatistics & Research Methodology

Topic Covered: Unit No 1

Date of Activity: 12.05.2022

Submission Date: 22.05.2022

Que. no.	Questions	CO
Low Achiever (0-6 Marks)		
1	Explain the importance of pharmaceutical research.	CO801.3
2	Explain the importance of graphs (histogram, pie chart, cubic graph, response surface plot, counter plot graph) involved in research.	CO801.3
3	Explain the importance of plagiarism in pharmaceutical research.	CO801.3
Medium Achiever (07-11 Marks)		
1	Explain importance & advantages of cohort study design in research.	CO801.3
2	Write a short review report on solid oral dosage forms used as pharmaceuticals.	CO801.3
3	Graphical representation of research data is helpful for better understanding & conclusive, Justify view with appropriate explanation.	CO801.3
High Achiever High Achiever (12-15 Marks)		
1	Researcher is going to develop the herbal formulation, Identify & enlist the different stages involved in designing the research methodology.	CO801.3
2	Prepare pharmaceutical research strategy for XYZ drug (BCS class II).	CO801.3

Embedded Formative Assessments 2

Class: Final Year B. Pharm

Subject: Biostatistics & Research Methodology

Date of Activity: 14.05.2022

Semester: VIII

Topic Covered: Unit No 2

Submission Date: 24.05.2022

Que. no.	Questions	CO
Low Achiever (0-6 Marks)		
1	Explain the importance of research design in pharmaceutical research.	CO801.4
2	Explain the dependant & independent variables, extraneous variables, confounded relationship, research hypothesis, experimental & non-experimental hypothesis-testing research, experimental control groups, treatments, control, experiment & experimental units concepts regarding research design.	CO801.4
Medium Achiever (0-6 Marks)		
1	Explain the Historical study & their advantages.	CO801.4
2	Explain the types, importance & advantages of response surface methodology.	CO801.4
3	Brief any four optimization techniques.	CO801.4
High Achiever High Achiever (12-15 Marks)		
1	Discuss the difference between historical study and cohort study along with their applications	CO801.4
2	Define blocking and confounding in factorial design. Explain the confounding 2k factorial design.	CO801.4