GUJARAT TECHNOLOGICAL UNIVERSITY
PHARM.D (PB)
1st Year

Subject Name: Biostatistics & Research Methodology
Subject Code: 818904

Scope: The course is a comprehensive concepts-centric primer for the students to make them ready to conduct clinical and community-based research projects. The focus is on designing, executing, documenting and publishing the project,

Objectives:
On successful completion of the course the student will be able to :

1) Retrieve, read and respond to the scientific literature, including the Methods and Results sections, in public health, medicine, biological science, pharmaceutical science and related fields.
2) analyse a research question of choice, design a study to avail answer to this research question and summarize and analyse the data collected
3) understand the complex clinical trial designs
4) write a scientific report
5) use the computer technology in various hospital activities and in research

Teaching scheme and examination scheme:

Teaching Scheme				Evaluation Scheme				Total Marks
Theory	Tutorial	Practical	Total	Theory		Practical		
				External	Internal	External	Internal	
2	1	0	3	70	30	0	0	100

Detailed syllabus:

Sr.	Topic	Hr	% Weightage
	Research Methodology		
1.	a) Types of clinical study designs: Case studies, observational studies, interventional studies, b) Designing the methodology c) Sample size determination and Power of a study Determination of sample size for simple comparative experiments, determination of sample size to obtain a confidence interval of specified width, power of a study d) Report writing and presentation of data	**10**	**16**
	Biostatistics		
2.	a) Introduction b) Types of data distribution c) Measures describing the central tendency distributions- average, median, mode d) Measurement of the spread of data-range, variation of mean, standard deviation, variance, coefficient of variation, standard error of mean	**5**	**10**
3.	**Data graphics** Construction and labeling of graphs, histogram, piecharts, scatter plots, semilogarthimic plots	**5**	**8**
4.	**Basics of testing hypothesis**	**15**	**24**

	a) Null hypothesis, level of significance, power of test, P value, statistical estimation of confidence intervals. b) Level of significance (Parametric data)- students t test (paired and unpaired), chi Square test, Analysis of Variance (one-way and two-way) c) Level of significance (Non-parametric data)- Sign test, Wilcoxan's signed rank test, Wilcoxan rank sum test, Mann Whitney U test, Kruskal-Wall is test (one way ANOVA) d) Linear regression and correlation- Introduction, Pearsonn's and Spearmann's correlation and correlation co-efficient. e) Introduction to statistical software: SPSS, Epi Info, SAS		
5.	**Statistical methods in epidemiology** Incidence and prevalence, relative risk, attributable risk	**7**	**12**
6.	**Computer applications in pharmacy** Computer System in Hospital Pharmacy: Patterns of Computer use in Hospital Pharmacy – Patient record database management, Medication order entry – Drug labels and list – Intravenous solution and admixture, patient medication profiles, Inventory control, Management report & Statistics. Computer In Community Pharmacy Computerizing the Prescription Dispensing process Use of Computers for Pharmaceutical Care in community pharmacy Accounting and General ledger system Drug Information Retrieval & Storage : Introduction – Advantages of Computerized Literature Retrieval Use of Computerized Retrieval	**18**	**30**

Reference Books:

1. Pharmaceutical statistics- practical and clinical applications, Sanford Bolton latest edition, publisher Marcel Dekker Inc. NewYork
2. Drug Information- A Guide for Pharmacists, Patrick M Malone, Karen L Kier, John E Stanovich , latest edition, McGraw Hill Publications latest edition
3. Khanal AB. Mahajan's methods in biostatistics for medical students and research workers. Jaypee Brothers, latest edition