SARDAR PATEL UNIVERSITY

DEPARTMENT OF STATISTICS
FACULTY OF SCIENCE
COURSE OF STUDY

RULES FOR CERTIFICATE COURSE IN BIOSTATISTICS

R.CCBioStat.1: A candidate who has passed the Bachelor's degree examination in any faculty of this University under 10 + 2 + 3 or an examination recognized as equivalent thereto with at least 40 percent of marks will be considered eligible for admission to the "Certificate Course in Biostatistics". In addition, the candidate should have studied biology at XII Std or at later stage of study and should have studied a four credit course in statistics / mathematics. The M.Sc (Semester IV) students are also eligible for the course if they are not offered Biostatistics specialization.

R.CCBioStat.2: In this course the candidates will have to study the courses (i) PS04ESTA03: Bioassays and (ii) PS04ESTA04: Clinical Trials. These two courses are already running in the Department as optional courses in the fourth semester of the M.Sc Programme of the Department. Therefore, the certificate course will be run in the schedule of Semester IV.

R.CCBioStat 3: The course coordinator will be in charge internal examination. Candidates will be examined in each theory paper for 100 marks For deciding result the ratio between the internal assessment and external assessment will be 30:70.For the purpose of internal assessment, the Department concerned will conduct one test.The Department will also arrange Quiz, Seminar etc. for internal assessment in theory course work. The distribution of marks will be as under: -

1. Structure for each theory paper:

a)	Quiz	..	..	..	5 marks
b)	Seminar	..	..	..	5 marks
c)	Test	..	..	..	20 marks

			Total		30 marks

The following grading scheme will be adopted to issue the certificate.

Marks in percentage	Grade
70 and above	A
65-69	B+
60-65	B
55-59	C+
50-54	C
0-49	Attendance Certificate

R.CCBioStat.4: The following are the details of the courses.

PS04ESTA03 - BIOASSAYS

Unit 1	Principles of planning an assay. **Types of biological assays**: Direct assays; Ratio estimators, asymptotic distributions; Fieller's theorem . Quantitative dose response relations: Indirect Assays; the dose response regressions; similarity; Assay validity; Monotony; Linearizing transformations; Essential non-linear relation; a response curve for vitamin B12; Homoscedasticity of variance.	12 L
Unit 2	Parallel line Assays: Unsymmetric designs; Complete Analysis; Symmetric dose structure for parallel assays; complete analysis	12L
Unit 3	Slope ratio Assays Quantal responses; The use of quantal responses; minimal effective dose; median effective dose; Methods of estimation of parameters; Estimation of extreme quantiles; Doseallocation schemes; Polychotomous quantal response;Estimation of points on the quantal response function.	12L
Unit 4	Estimation of safe doses Bayesian approach to bioassay	12L
	Books Recommended:	
	1 Z. Govindarajulu (2000). Statistical Techniques in Bioassay, S. Kargar	
	2 D. J. Finney (1971). Statistical Method in Bioassay, Griffin.	

	3	D. J. Finney (1971). Probit Analysis (3rd Ed.), Griffin.
	4	G. B. Weatherile (1966). Sequential Methodsin Statistics, Methuen.

PS04ESTA04 - CLINICAL TRIALS

Unit 1	**Introduction** to clinical trials, the need, ethics, protocol of clinical trials, Overview of phase 1 – IV and DF, SE, CTE trials, data management and case studies. bias and random error in clinical studies, Endpoints of clinical trials and sample size estimation in SE and CTE trials.		12 L
Unit 2	**Design of clinical trials** parallel vs. cross over designs, cross sectional vs. longitudinal designs, review of factorial designs. Randomization techniques for group allocation.		12L
Unit 3	**Analysis** of outcomes from Phase I- III trials, analysis of survival data from clinical trials, techniques for Interim analysis, intent to treat analysis.		12L
Unit 4	**Application areas** Meta analysis, Multi-center trials, Bioequivalence trials		12L
	Books Recommended		
	1	David Machin, Simon Day. Text Book Of Clinical Trials	
	2	Ton Cleophs, Aeilko Zwinderman. Statistics Applied To Clinical Trials.	
	3	Stephen Senn. Cross – Over Trials In Clinical Research.	
	4	Annpey Pong & Shein- Chung Chow. Hand Book Of Adaptive Designs In Pharmaceutical And Clinical Development	
	5	Effron and Marubini. Analyzing data from CT and Obs studies	
	6	Karl E. Peace. Design And Analysis Of Clinical Trials With Time-To-Event Endpoints	
	7	Geert Molenberghs & Michael G. Kenward. Missing Data In Clinical Studies	
	8	Annpey Pong , Shein- Chung Chow. Handbook Of Adaptive Designs In Pharmaceutical And Clinical Development	
	9	Shein-Chung Chow, Mark Chang. Adaptive Design Methods In Clinical Trials.	
	10	Umakanta Sahoo, Dipti Sawant. Clinical Trial Monitoring A Professional Hand Book	
	11	Diane Fairclough. Design And Analysis Of Quality Of Life Studies In Clinical Trials.	

R.BioStat.5: The total number of seats for the course is 30 and the fee structure of the course is as under.

Collection Head	Amount in Rupees
Information Brochure and application form fee	300.00
Tuition Fee	5000.00
Examination Fee	250.00
Certificate Fee	100.00
Total	5650.00