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) PS04ESTA53 : BIOASSAYS and (ii) PS04ESTA54: 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.

Course Code	**PS04ESTA53**	**Title of the Course**	**BIOASSAYS**
Total Credits of the Course	**04**	**Hours per Week**	**04**
Course Objectives:	1. Explain different types of assays and related statistical concept 2. Introduce bioassays with different designed experiments 3. Complete training on different measures related to bioassays and their use. 4. Do some practical on bioassays with real data sets.		

Course Content

Unit	**Description**	**Weightage* (%)**
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.	25
2.	Parallel line Assays: Asymmetric designs; Complete Analysis; Symmetric dose structure for parallel assays; complete analysis.	25
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; Dose allocation schemes; Polychotomous quantal response; Estimation of points on the quantal response function.	25
4.	Estimation of safe doses Bayesian approach to bioassay: safe dose definition,	25

	maximum likelihood estimation of parameters, point estimation and confidence interval for 'safe doses'. Bayesian bioassay, Bayes binomial estimators, Bayes estimate of the median effective dose.	

Teaching-Learning Methodology	

Evaluation Pattern

Sr. No.	Details of the Evaluation	Weightage
1.	Internal Written / Practical Examination (As per CBCS R.6.8.3)	15%
2.	Internal Continuous Assessment in the form of Practical, Viva-voce, Quizzes, Seminars (As per CBCS R.6.8.3)	15%
3.	University Examination	70%

Course Outcomes: Having completed this course, the learner will be able to

1.	understand different types of assays and related statistical concept
2.	distinguish qualitative and quantitative, direct and indirect bioassays
3.	estimate the safe doses.

Suggested References:

Sr. No.	References
1.	Govindarajulu, Z. (2000). Statistical Techniques in Bioassay, S. Kargar.
2.	Finney, D. J. (1971). Statistical Method in Bioassay, Griffin.
3.	Finney, D. J. (1971). Probit Analysis (3rd Ed.), Griffin.
4.	Weatherile, G. B. (1966). Sequential Methodsin Statistics, Methuen

On-line resources to be used if available as reference Masterial

On-line Resources

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Course Code	PS04ESTA54	Title of the Course	CLINICAL TRIALS
Total Credits of the Course	04	Hours per Week	04

Course Objectives:	1. To gain knowledge of bio-statistics techniques used in design and analysis of Clinical trials 2. To train in analysis of commonly conducted pharmaceutical clinical trials 3. To learn some novel contemporary statistical designs, statistical tests and statistical analysis techniques used in clinical trials

Course Content

Unit	Description	Weightage* (%)
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	25
2.	Design of clinical trials parallel vs. cross over designs, cross sectional vs. longitudinal designs, review of factorial designs. Randomization techniques for group allocation.	25
3.	Analysis of outcomes from Phase I- III trials, analysis of survival data from clinical trials, techniques for Interim analysis, intent to treat analysis.	25
4.	Application areas Meta analysis, Multi-center trials, Bioequivalence trials	25

Teaching-Learning Methodology	Interactive Class Lectures, ICT Tools, Problem solving and Group Seminar.

Evaluation Pattern

Sr. No.	Details of the Evaluation	Weightage
1.	Internal Written / Practical Examination (As per CBCS R.6.8.3)	15%
2.	Internal Continuous Assessment in the form of Practical, Viva-voce, Quizzes, Seminars (As per CBCS R.6.8.3)	15%

3.	University Examination	70%

Course Outcomes: Having completed this course, the learner will be able to	
1.	Writing and understanding CT protocol. Understand, differentiate and identify among four Phases of a complete Clinical Trial
2.	Understand study design of published clinical trial. Make choice and carry out randomized allocation of two treatments as specified. Execute clinical trial as per the experimental design.
3.	Given the clinical trial objective and response type, understand the sample size estimation routine or formula and apply to calculate it.
4.	Perform analysis of survival clinical trials, meta-analysis for systematic review of published clinical trials, interim analysis of trials employing group sequential testing.

Suggested References:

Sr. No.	**References**
1.	Shein-Chung Chow and Jen-Pei Liu (2014). Design and Analysis of Clinical Trials, Concepts and Methodologies, 3rd ed., John Wiley
2.	Millard, S. P. and Krause, A. (2010). Applied Statistics in the Pharmaceutical Industry with Case Studies using S-plus, Springer Verlag New York
3.	Senn, S (2002). Cross – Over Trials in Clinical Research, 2nd ed., Statistics in Practice, John Wiley
4.	Jones, B. and Kenward, M. G. (2014). Design and Analysis of Cross-Over Trials, 3rd ed. CRC press
5.	Mike W.-L. Cheung (2015). Meta – Analysis, A Structural Equation Modeling Approach, John Wiley
6.	Piantadosi, S. (2005). Clinical Trials –A Methodological Perspective 3rd ed. Wiley.
7.	Mallinckrodt, C. and Lipkovich, I. (2017). Analyzing Longitudinal Clinical Trial Data, A practical guide, CRC Press, T&F G
8.	Molenberghs, G. and Kenward, M. G. (2007). Missing Data in Clinical Studies, Statistics in Practice, John Wiley
9.	Peace, K. E. (2009). Design and Analysis of Clinical Trials with Time-to-Event Endpoints (Edited), CRC Press, T&F G

10.	Pong, A. and Shein—Chung Chow (2011). Handbook of Adaptive Designs in Pharmaceutical and Clinical Development (Edited), CRC Press T&F G
11.	Atkinson, A. C. and Biswas, A. (2014). Randomised Response-Adaptive Designs in Clinical Trials, Monograph on Statistics and Applied Probability, CRC Press, T&F G

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

Collection Head	**Amount in Rupees**
Information Brochure and application form fee	300.00
Tuition Fee	5,000.00
Examination Fee	250.00
Certificate Fee	100.00
Total	**5,650.00**