

Vallabh Vidyanagar, Gujarat (Reaccredited with 'A' Grade by NAAC (CGPA 3.25) Syllabus with effect from the Academic Year 2022-2023

#### PROGRAMME STRUCTURE

Master of Science in Statistics MSc (Statistics) Semester: IV

| Programme Outcome (PO) - For MSc Statistics Programme | Master of Science program provides extended theoretical and practical knowledge of different science subjects. Master of Science programme at Sardar Patel University is designed keeping the overall back ground preparation in mind for the student to either seek a job or to become an entrepreneur. The students, after completion of Bachelor of Science can select—the master's programme in the subject they have had at—the final year or in a related discipline (depending upon eligibility criteria prescribed by university).  Programme outcomes: At the end of the program, the students will be able to  1. Have a deep understanding of both the theoretical and practical—concepts in the respective subject.  2. Understand laboratory processes—and use scientific equipments and work independently.  3. Develop research temperament as a consequence of their theory and practical learning.  4. Communicate scientific information in oral and written form.  5. Understand the issues related to nature and environmental contexts and think rationally for sustainable development.  6. The students are able to handle unexpected situations by critically analyzing the problem. |
|---|--|
| Programme Specific Outcome                            | 1.   |
| (PSO) - For MSc <b>Statistics</b>                     | 2.   |
| Semester - IV   |  |

| To | Pass  |
|----|-------|
| 10 | 1 abb |

At least 40% Marks in the University Examination in each paper and 40% Marks in the aggregate of University and Internal examination in each course of Theory, Practical & 40% Marks in Viva-voce.





|                    |             | Name Of Course                         | Theory/<br>Practical | Credit | Exam     | Component of Marks |          |       |
|--------------------|-------------|--|----------------------|--------|----------|--------------------|----------|-------|
| Course Type        | Course Code |  |                      |        | Duration | Internal           | External | Total |
|                    |             |  |                      |        | in hrs   | Total              | Total    | Total |
|                    | PS04CSTA51  | Computer Oriented Statistical Methods  | T                    | 4      | 3        | 30                 | 70       | 100   |
| Core Course        | PS04CSTA52  | Statistical Quality Control Techniques | T                    | 4      | 3        | 30                 | 70       | 100   |
| Cole Course        | PS04CSTA53  | Practicals                             | P                    | 4      | 3        | 30                 | 70       | 100   |
|                    | PS04CSTA54  | Project Work                           | P                    | 1      | 3        | 30                 | 70       | 100   |
|                    | PS04ESTA51  | Econometrics and Time Series Analysis  | T                    | 4      | 3        | 30                 | 70       | 100   |
| Elective<br>Course | PS04ESTA52  | Actuarial Statistics                   | T                    | 4      | 3        | 30                 | 70       | 100   |
|                    | PS04ESTA53  | Bioassays                              | T                    | 4      | 3        | 30                 | 70       | 100   |
|                    | PS04ESTA54  | Clinical Trials                        | T                    | 4      | 3        | 30                 | 70       | 100   |





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| Course Code                 | PS04CSTA51 | Title of the<br>Course | COMPUTER ORIENTED<br>STATISTICAL METHODS |
|-----------------------------|------------|------------------------|--|
| Total Credits of the Course | 04         | Hours per<br>Week      | 04                                       |

| Course<br>Objectives: | Develop understanding of generating samples from a specified distribution as input to a simulation model.  |  |  |  |
|-----------------------|--|--|--|--|
|                       | 2. Illustrate some widely-used techniques for generating random variates: Inverse-transform technique, Acceptance-rejection technique, Special properties. |  |  |  |
|                       | 3. To introduce various multivarite techniques for reduction and extraction of multivariate data.  |  |  |  |
|                       | 4. To study interdependency and inter-relationship among the variables.  |  |  |  |

| Cours | Course Content  |            |  |
|-------|---|------------|--|
| Unit  | Description   | Weightage* |  |
| 1.    | Generation of Random Numbers From Uniform, Binomoial, Poisson, Exponential, Weibull, Normal, Gamma, T, F, Multivariate Normal Distribution and Different Stochastic Processes Using Pseudo Random Number Generation Algorithms Like Linear Congruential Method (Lcg), Inverse Method, Rejection Method, etc.                                    | 25         |  |
| 2.    | Simulation Principles: Rejection Method; Variance Reduction; Importance Sampling. Simulation of Probability Distribution of Different Statistics Using Monte Carlo and Similar Techniques. Estimation of Bias, MSE and other Statistics using Bootstrap and Similar Techniques. MCMC Algorithms: Metropolis-Hastings Algorithm; Gibbs Sampling. | 25         |  |
| 3.    | Logistic Regression Models: Introduction; The Multiple Logistic Regression Model; Fitting The Logistic Regression Model; Testing for The Significance of The Model. Application of Logistic Regression in study of Matched Case Control Data. Cox's Regression Model:   | 25         |  |





|    | Proportional Hazard Model. Estimation and tests of parameters of the proportional Hazard Model. Use of this in comparison of two or more life distributions. Discriminant analysis. |    |
|----|---|----|
| 4. | Multivariate Techniques: (I) Principal Component Analysis (II) Factor Analysis (III) Canonical Correlation (IV) Cluster Analysis.   | 25 |

| Teaching- Learning Methodology  Discussion and question answers based learning Black board/Multimedia projector using ICT Tools Learning through Problem solving approach Assignments and seminars are given for development of confidence among students |
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| Evalu      | Evaluation Pattern   |           |  |
|------------|--|-----------|--|
| Sr.<br>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, Assignments, Attendance (As per CBCS R.6.8.3) | 15%       |  |
| 3.         | University Examination   | 70%       |  |

| Cou | Course Outcomes: Having completed this course, the learner will be able to               |  |
|-----|--|--|
| 1.  | generate random variables or samples using various methods of random variable generation |  |
| 2.  | know various methods for simulation  |  |
| 3.  | use appropriate multivariate technique for data analysis depending of objectives         |  |

| Suggested References: |            |
|-----------------------|------------|
| Sr. No.               | References |





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| 1.  | Anderson, T.W. (2003). An Introduction to Multivariate Statistical Analysis, Ed. IV, Wiley   |  |
|-----|--|--|
| 2.  | Bhuyan, K.C. (2004). Multivariate Analysis and its Applications, New Central Book Agency   |  |
| 3.  | Efron, B. and Tibshirani. R.J. (1993); An Introduction to the Bootstrap, Chapman and Hall.   |  |
| 4.  | Gemerman, D. and Lopes, H.F. (2006). Markov Chain Monte Carlo: Stochastic Simulation for Bayesian Inference, Ed. II, Chapman and Hall  |  |
| 5.  | Hair, J. F., Black, W.C., Babin, B. J., Anderson, R.E. and Tatham, R. L. (2006). Multivariate Data Analysis, Ed, VI, Pearson Education |  |
| 6.  | Hardle, W. and Simar, L. (2007) Applied Multivariate Statistical Analysis, Springer  |  |
| 7.  | Johnson, R. A. and Wichern, D. W. (2007). Applied Multivariate Statistical Analysis, Prentice-Hall International                       |  |
| 8.  | Kroese, D. P., Taimre, T. and Botev, Z. I. (2011). Handbook of Monte Carlo Method, Wiley   |  |
| 9.  | Manly, B.F. and Navarro Alberto, J.A. (2017). Multivariate Statistical Methods, Ed. IV, CRC Press                                      |  |
| 10. | McLachlan, G.J. and Krishnan, T. (1997) The EM Algorithms and Extensions.(Wiley.)  |  |

| On-line resources to be used if available as reference material |
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| On-line Resources   |
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| Course Code                 | PS04CSTA52 | Title of the<br>Course | STATISTICAL QUALITY CONTROL<br>TECHNIQUES |
|-----------------------------|------------|------------------------|---|
| Total Credits of the Course | 04         | Hours per<br>Week      | 04  |

| Objectives: | The goal of this course is to introduce statistical quality control (SQC) emphasizing various aspects which are relevant for SQC's practical implementation |
|-------------|---|
|             |   |

| Course Content |   |            |
|----------------|---|------------|
| Unit           | Description   | Weightage* |
| 1.             | Basic Concepts of quality control. Process control and process capability. Relation between theory of testing hypotheses and charts. choice of control limits, rational subgroup principle, allocating sampling effort, average run length. Purpose of capability Indices. Determining the process capability using, , charts. The role of normality in determining defective parts per million. One sided specification, non-normal distributions. | 25         |
| 2.             | Process capability analysis: potential capability, actual capability, definitive analysis. Testing of potential capability, confidence interval of potential capability and actual capability. Gage and measurement system capability study. Setting specification limits on discret components (linear and non linear combination). Estimation of natural tolerance limit of a process.  | 25         |
| 3.             | CUSUM charts, EWMA chart –Use of these charts for prediction. CUSUM, EWMA for controlling process variability. Comparison of these charts with Shewart charts. Acceptance control charts Acceptance sampling plan, chain sampling, continuous sampling plans, Skip –lot sampling plans. Fundamental of experimental design, one factor, two factor, blocking. Concept of interaction.   | 25         |
| 4.             | Process Design and Improvement with designed experiments. Use of Design of 2k- factorial design with k≥1. 2k-p fractional factorial design in SPC. Taguchi's contribution to Quality Engineering. Elements and principle of quality engineering. Steps in robust design; signal to noise ratio.   | 25         |
|                |   |            |





| Teaching-   | On-line/off-line lectures. |
|-------------|----------------------------|
| Learning    |                            |
| Methodology |                            |

| Evaluation Pattern |  |           |
|--------------------|--|-----------|
| Sr.<br>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, Assignments, Attendance (As per CBCS R.6.8.3) | 15%       |
| 3.                 | University Examination   | 70%       |

| Cou | Course Outcomes: Having completed this course, the learner will be able to               |  |  |
|-----|--|--|--|
| 1.  | Can address conformance and impotence on target in context of societal loss.             |  |  |
| 2.  | Use control chart capable to detect shift of magnitude of $L\sigma$ ; $L \leq 3\sigma$ . |  |  |
| 3.  | Can apply design of experiment to improve process.                                       |  |  |
| 4.  | Can perform potential capability, actual capability, definitive analysis.                |  |  |
| 5.  | Can practice gage and measurement system capability study.                               |  |  |

| Sugges     | Suggested References:  |  |  |
|------------|--|--|--|
| Sr.<br>No. | References   |  |  |
| 1.         | Montgomery, D. C. (1985) Introduction to Statistical Quality Control.(Wiley).      |  |  |
| 2.         | Montgomery, D.C. (1985) Design and Analysis of Experiments; Wiley.                 |  |  |
| 3.         | Rayon, T.P(1989) Statistical Methods for quality improvement. John Wiley and sons. |  |  |
| 4.         | Ott, E.R. (1975) Process Quality Control; McGraw Hill.                             |  |  |





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| 5. | Wetherill, G.B. (1977) Sampling Inspection and Quality Control; Halsted Press.                             |
|----|--|
| 6. | Wetherill, G.B. and Brown, D.W. (1991) Statistical Process Control, Theory and Practice; Chapman and Hall. |
| 7. | Phadke, M.S. (1989) Quality Engineering through Robust Design; Prentice Hall.                              |

| On-line resources to be used if available as reference material |
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| On-line Resources   |
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| Course Code                 | PS04CSTA53 | Title of the Course | PRACTICALS |
|-----------------------------|------------|---------------------|------------|
| Total Credits of the Course | 04         | Hours per<br>Week   | 04         |

| Course      | 1. |
|-------------|----|
| Objectives: | 2. |
|             |    |

| Course | Course Content |            |  |
|--------|----------------|------------|--|
| Unit   | Description    | Weightage* |  |
| 1.     |                | 25         |  |
| 2.     |                | 25         |  |
| 3.     |                | 25         |  |
| 4.     |                | 25         |  |
|        |                |            |  |

| Teaching-<br>Learning<br>Methodology |  |  |
|--------------------------------------|--|--|
|--------------------------------------|--|--|

| Evalu      | Evaluation Pattern   |     |  |  |
|------------|--|-----|--|--|
| Sr.<br>No. | Details of the Evaluation Weightage  Output  Details of the Evaluation   |     |  |  |
| 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, Assignments, Attendance (As per CBCS R.6.8.3) | 15% |  |  |
| 3.         | University Examination   | 70% |  |  |





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| Course Outcomes: Having completed this course, the learner will be able to |
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| 1.   |
| 2.   |
| 3.   |
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| Suggested References:  |
| Sr. References No.   |
| 1.   |
| 2.   |
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| On-line resources to be used if available as reference material            |
| On-line Resources  |
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| Course Code                 | PS04CSTA54 | Title of the Course | PROJECT |
|-----------------------------|------------|---------------------|---------|
| Total Credits of the Course | 04         | Hours per<br>Week   | 08      |

| Course      | 1. |
|-------------|----|
| Objectives: | 2. |
|             |    |

| Course | Course Content |            |  |
|--------|----------------|------------|--|
| Unit   | Description    | Weightage* |  |
| 1.     |                | 25         |  |
| 2.     |                | 25         |  |
| 3.     |                | 25         |  |
| 4.     |                | 25         |  |
|        |                |            |  |

| Teaching-<br>Learning<br>Methodology |  |
|--------------------------------------|--|
|--------------------------------------|--|

| Evalu      | Evaluation Pattern               |     |  |
|------------|----------------------------------|-----|--|
| Sr.<br>No. | $\epsilon$                       |     |  |
| 1.         | Project Presentation             | 30% |  |
| 2.         | Project Reports and Presentation | 70% |  |





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| Cours      | se Outcomes: Having completed this course, the learner will be able to |
|------------|--|
| 1.         |  |
| 2.         |  |
| 3.         |  |
|            |  |
|            |  |
| Sugge      | ested References:  |
| Sr.<br>No. | References   |
| 1.         |  |
| 2.         |  |
|            |  |
|            |  |
| On-lii     | ne resources to be used if available as reference material             |
| On-lii     | ne Resources   |
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| Course Code                 | PS04ESTA51 | Title of the Course | ECONOMETRICS AND TIME SERIES ANALYSIS |
|-----------------------------|------------|---------------------|---------------------------------------|
| Total Credits of the Course | 04         | Hours per<br>Week   | 04                                    |

| Course<br>Objectives: | <ol> <li>Students have concise knowledge of basic regression analysis so that they are able to understand its applications in different fields in economics.</li> <li>To provide students with some useful tools of econometrics which help in analysis of economic data.</li> <li>To equip students with various forecasting techniques and knowledge on modern statistical methods for analyzing time series data</li> </ol> |
|-----------------------|--|
|-----------------------|--|

| Cours | Course Content  |            |  |
|-------|---|------------|--|
| Unit  | Description   | Weightage* |  |
| 1.    | Econometrics: Definition, Methodology, Examples, Nature and Source of Data;  Classical Linear Regression Model (CLRM): Assumptions, estimation of parameters through Maximum Likelihood Method and Ordinary Least Square Method, Properties of Estimator; Testing of Hypothesis and confidence intervals, Testing of Subset of Regressors, Point Predictor, Model Selection Criterion; $R^2$ , Adj $R^2$ , AIC, BIC Mallow's $C_p$ Statistic; Significance Test and Confidence Interval; Dummy Variable: Nature, introduction, examples, Chow Test, Seasonal Adjustment | 25         |  |
| 2.    | Hetroscedasticity: Reason of Hetroscedasticity; Consequences of using OLS in presence of Hetroscedasticity; Detection: Informal Method, Formal Method; Park Test, Goldfield-Quant Test; Remedial Measures, Method of Generalized Least Squares (GLS), Autocorrelation: Nature of the Problem, Consequences of Autocorrelation, Detection: Graphical Method; Durbin-Watson d Test, A General Test of Autocorrelation, The Breusch-Goldfrey (BG) Test; GLS when correlation coefficient is known as well as unknown;  |            |  |





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| 3. | Multicolinearity Problem, Its implications and tools for handling the problem; Detection of Multicolinearity; Remedial Measures; Ridge Regression; Use of Principle Component Analysis; Introduction to Simultaneous Equation Models; The identification Problem  | 25 |
|----|---|----|
| 4. | Introduction to Time Series Analysis; Some Basic Concepts: white noise, stationary, non stationary time series, ACF and PACF plot; Unit Root Test (Augmented Dickey-Fuller Test); Forecasting: Exponential Smoothing Methods, AR Process, MA Process, ARMA Process, ARIMA Process; The Box-Jenkins (BJ) Methodology; VAR Model; Auto Regressive Conditional Hetroscedasticity (ARCH) and Generalized Autoregressive Conditional Hetroscedasticity (GARH) Model; | 25 |

| Teaching- Discussion and question answers based learning |  |
|--|--|
| Learning   | Black board/Multimedia projector using ICT Tools                 |
| Methodology  | Learning through Problem solving approach                        |
|  | Assignments and seminars are given for development of confidence |
|  | among students   |

| Evalu      | Evaluation Pattern   |           |  |  |
|------------|--|-----------|--|--|
| Sr.<br>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, Assignments, Attendance (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. to specify assumptions, formulate and estimate appropriate models, interpret the results and test their statistical significance.





| 2. | explain core concepts and techniques in econometrics with special focus on the classical linear regression model. |
|----|---|
| 3. | understand the assumptions upon which different econometric methods are based and their implications.             |
| 4. | distinguish regression analysis model and time series model.  |
| 5. | understand various components of time series and various time series models.                                      |

| Suggest | ggested References:  |  |  |
|---------|--|--|--|
| Sr. No. | References   |  |  |
| 1.      | Cameron, A.C. and Trivedi, P.K. (2005). Microeconometrics Methods and Applications, Cambridge University Press   |  |  |
| 2.      | Cooray, T.M.J.A. (2008). Applied Time Series Analysis and Forecasting, Narosa Publishing House, New Delhi        |  |  |
| 3.      | Green, W. H. (1993). Econometric Analysis, Ed. II, MACMILLAN Publishing  |  |  |
| 4.      | Greene, W.H. (2003) Econometric Analysis. Ed. V, Pearson Education   |  |  |
| 5.      | Gourieroux, C and Jasiak, J. (2007). Financial Econometrics: Problems, Models and Methods, New Age International |  |  |
| 6.      | Gujarathi, D.N., Porter, D.C. and Sangeetha (2012). Basic Econometrics, Ed. V , Tata MacGraw Hill, New Delhi     |  |  |
| 7.      | Johnston, J. and Dinardo, J (1997). Econometric methods, Ed. IV, McGraw Hill                                     |  |  |
| 8.      | Ruppert, D.(2004). Statistics and Finance: An Introduction , Springer (India) Pvt. Ltd.                          |  |  |
| 9.      | Shumway, R.H. (1988). Applied Statistical time Series Analysis, Prentice Hall, New Jersey                        |  |  |
| 10.     | Theil, H. (1982): Introduction to the theory and practice of Econometrics, John Wiley.                           |  |  |

| On-line resources to be used if available as reference material |
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| On-line Resources   |





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| Course Code                 | PS04ESTA52 | Title of the<br>Course | ACTUARIAL STATISTICS |
|-----------------------------|------------|------------------------|----------------------|
| Total Credits of the Course | 04         | Hours per<br>Week      | 04                   |

| Cours | Course Content  |    |  |
|-------|---|----|--|
| Unit  | Init Description  |    |  |
| 1.    | <ol> <li>Utility theory, insurance and utility theory, models for individual claims and their sums, survival function, curtate future lifetime, force of mortality Life table and its relation with survival function, examples, assumptions for fractional ages, some analytical laws of mortality, select and ultimate tables. Multiple life functions, joint life and last survivor status, insurance and annuity benefits through multiple life functions evaluation for special mortality laws.</li> <li>Multiple decrement models, deterministic and random survivorship groups, associated single decrement tables, central rates of multiple decrement, net single premiums and their numerical evaluations. Distribution of aggregate claims, compound Poisson distribution and its applications. Distribution of aggregate claims, compound Poisson distribution and its applications.</li> </ol> |    |  |
| 2.    |   |    |  |
| 3.    | Principles of compound interest: Nominal and effective rates of interest and discount, force of interest and discount, compound interest, accumulation factor, continuous compounding. Life insurance: Insurance payable at the moment's of death and at the end of the year of death-level benefit insurance, endowment insurance, differed insurance and varying benefit insurance, recursions, commutation functions. Life annuities: Single payment, continuous life annuities, discrete life annuities, life annuities with monthly payments, commutation functions, varying annuities, recursions, complete annuities-immediate and apportion able annuities-due.   | 25 |  |





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| 4. | Net Premiums: Continuous and discrete premiums, true monthly payment premiums, apportionable premiums, commutation functions, accumulation type benefits. Payment premiums, apportionable premiums, commutation functions accumulation type benefits. Net premium reserves: Continuous and discrete net premium reserve, reserves on a semi continuous basis, reserves based on true monthly premiums, reserves on an apportion able or discounted continuous basis, reserves at fractional durations, allocations of loss to policy years, recursive formulas and differential equations for reserves, commutation functions. Some practical considerations: Premiums that include expenses-general expenses types of expenses, per policy expenses. Claim amount distributions, approximating the individual model, stop-loss insurance. | 25 |
|----|--|----|
|    |  |    |

| Teaching-<br>Learning |  |
|-----------------------|--|
| Methodology           |  |

| Evaluation Pattern |  |           |
|--------------------|--|-----------|
| Sr.<br>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, Assignments, Attendance (As per CBCS R.6.8.3) | 15%       |
| 3.                 | University Examination   | 70%       |

| Cou | Course Outcomes: Having completed this course, the learner will be able to                 |  |  |
|-----|--|--|--|
| 1.  | 1. calculations related to lifer insurance policies and finance.                           |  |  |
| 2.  | 2. know statistical concepts exclusively used in the design insurance related instruments. |  |  |
| 3.  | 3. know reliability and survival analysis concepts being used in insurance sector.         |  |  |





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| Sugges     | Suggested References:   |  |
|------------|---|--|
| Sr.<br>No. | References  |  |
| 1.         | Deshmukh, S. R. (2009). Actuarial Statistics: An Introduction using R. University Press Pvt. Ltd Hyderabad (Text Book).   |  |
| 2.         | . Bowers, N. L., Gerber, H. U., Hickman, J. C., Jones D. A. and Nesbitt, C. J. (1986). Actuarial Mathematics', Society of Actuaries, Itasca, III inois, U. S. A. Second Edition (1997) Section I – Chapters: 1, 2, 3, 8, 9, and 11, Section II – Chapters: 4, 5, 6, 7, 13, and 14 |  |
| 3.         | Spurgeon E. T. (1972), Life Contingencies, Cambridge University Press.  |  |
| 4.         | Neill, A. (1977). Life Contingencies, Heinemann   |  |

| On-line resources to be used if available as reference material |
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| On-line Resources   |
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| Course Code                 | PS04ESTA53 | Title of the Course | BIOASSAYS |
|-----------------------------|------------|---------------------|-----------|
| Total Credits of the Course | 04         | Hours per<br>Week   | 04        |

| Course<br>Objectives: | <ol> <li>Explain different types of assays and related statistical concept</li> <li>Introduce bioassays with different designed experiments</li> <li>Complete training on different measures related to bioassays and their use.</li> <li>Do some practical on bioassays with real data sets.</li> </ol> |
|-----------------------|--|
|-----------------------|--|

| 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, maximum likelihood estimation of parameters, point estimation and confidence interval for safe doses; Bayesian Bioassay, Bayes binomial estimators, Bayes estimator of the median effective dose.   | 25             |
|                |   |                |

| Teaching-<br>Learning<br>Methodology |  |  |  |  |
|--------------------------------------|--|--|--|--|
|--------------------------------------|--|--|--|--|





| Evaluation Pattern |  |     |
|--------------------|--|-----|
| Sr.<br>No.         |  |     |
| 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, Assignments, Attendance (As per CBCS R.6.8.3) | 15% |
| 3.                 | University Examination   | 70% |

| Cou | 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.  | 3. estimate the safe doses.  |  |
|     |  |  |

| Suggested References: |  |  |
|-----------------------|--|--|
| Sr.<br>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 material |
|---|
| On-line Resources   |
|   |





# Vallabh Vidyanagar, Gujarat

(Reaccredited with 'A' Grade by NAAC (CGPA 3.25) Syllabus with effect from the Academic Year 2022-2023





#### Vallabh Vidyanagar, Gujarat

(Reaccredited with 'A' Grade by NAAC (CGPA 3.25) Syllabus with effect from the Academic Year 2022-2023

| Course Code                 | PS04ESTA54 | Title of the Course | CLINICAL TRIALS |
|-----------------------------|------------|---------------------|-----------------|
| Total Credits of the Course | 04         | Hours per<br>Week   | 04              |

| Course<br>Objectives: | <ol> <li>To gain knowledge of bio-statistics techniques used in design and analysis of Clinical trials</li> <li>To train in analysis of commonly conducted pharmaceutical clinical trials</li> <li>To learn some novel contemporary statistical designs, statistical tests and statistical analysis techniques used in clinical trials</li> </ol> |
|-----------------------|---|
|-----------------------|---|

| Course | 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-               | Interactive | Class | Lectures, | ICT | Tools, | Problem | solving | and | Group |
|-------------------------|-------------|-------|-----------|-----|--------|---------|---------|-----|-------|
| Learning<br>Methodology | Seminar.    |       |           |     |        |         |         |     |       |





| Evaluation Pattern |  |           |  |
|--------------------|--|-----------|--|
| Sr.<br>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, Assignments, Attendance (As per CBCS R.6.8.3) | 15%       |  |
| 3.                 | University Examination   | 70%       |  |

| Cou | Course Outcomes: Having completed this course, the learnerwill 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.              |  |  |

| Sugges     | sted References:   |
|------------|--|
| Sr.<br>No. | References   |
| 1.         | Shein-Chung Chow and Jen-Pei Liu (2014). Design and Analysis of Clinical Trials, Concepts and Methodologies, 3 <sup>rd</sup> 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, 2 <sup>nd</sup> ed., Statistics in Practice, John Wiley                                |
| 4.         | Jones, B. and Kenward, M. G. (2014). Design and Analysis of Cross-Over Trials, 3 <sup>rd</sup>   |





## Vallabh Vidyanagar, Gujarat

(Reaccredited with 'A' Grade by NAAC (CGPA 3.25) Syllabus with effect from the Academic Year 2022-2023

|     | ed. CRC press   |
|-----|---|
| 5.  | Mike WL. Cheung (2015). Meta – Analysis, A Structural Equation Modeling Approach, John Wiley  |
| 6.  | Piantadosi, S. (2005). Clinical Trials –A Methodological Perspective 3 <sup>rd</sup> 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 |

