

KSV PhD Pharmaceutical Sciences: Course Work 2024

Paper subject and	Marks	Credit	Teaching /Self study	Evaluator
Paper I Research Methodology	100 Marks	4	15 Hrs Teaching	Any Phd Guide

Paper-I RESEARCH METHODOLOGY 100 Marks 15 Hrs (4 Credits)

Unit 1: General Research Methodology, Data Base and Research Metrics:

- Research, objective, Characteristics, Steps of research, Methods of research, Types of research – Descriptive vs. Analytical, Applied vs. Fundamental, Quantitative vs. Qualitative, Conceptual vs. Empirical, requirements, practical difficulties, review of literature
- Research Problem and Research Design Introduction to Research Problem, Necessity of Defining the Problem, Selecting the Problem, Techniques Involved in Defining a Problem, Meaning and
- Recent Advances in Research Methodology, Case Studies and Practical Applications
- Introduction to Databases in Research, Types of Research Databases: Bibliographic, Full-text, and Specialized, Database Searching Techniques and Strategies, Database Management and Data Integrity
- Indexing database and citation database: Utilization of PubMed, Scopus, Web of Science, and other relevant databases, Citation Management Software: EndNote, Mendeley, etc.
- Research Metrics: Impact factor of Journal as per citation report, Site score, h-index, I index, g index Citation Counts and Ethical Use of Research Metrics

Unit 2: Biostatistics:

- Introduction to Biostatistics: Definition and scope of biostatistics, Importance of biostatistics in pharmacy and healthcare, Basic concepts: Population, Sample, Variables, and Data types
- Descriptive Statistics: Fundamental and application Measures of central tendency: Mean, Median, and Mode, Measures of dispersion: Range, Variance, Standard deviation, SEM
- Statistical Inference: Estimation: Point estimation and Interval estimation, Hypothesis testing: Null hypothesis, Alternative hypothesis, Type I and Type II errors, Parametric tests: t-tests, ANOVA (Analysis of Variance), Correlation coefficient, regression, non-parametric tests (Wilcoxon signed-rank tests, analysis of variance, correlation, chisquare test), null hypothesis, P values, degree of freedom, interpretation of P values, etc. in pharmaceutical research with its interpretations.
- Statistical Software Applications: Utilization of statistical software packages in biostatistics: SPSS, SAS, R, STATA, Hands-on experience with statistical software for data analysis and interpretation
- Ethical and Regulatory Considerations: Ethical principles in the design and conduct of biostatistical studies, Regulatory requirements for data management and analysis in pharmaceutical research
- Definition, application of sample size, importance of sample size, Factors influencing sample size, drop outs, statistical tests of significance, type of significance tests

Unit 3: Intellectual property rights:

- Introduction to Intellectual property rights IPR, Types of Intellectual Property Rights (IPRs), Patents: Definition, Requirements, and Patentability Criteria, patent laws, process of patenting and research finding, conflicts of interest
- Commercialisation, copy right and ethical of research, cyber laws Ethical issues in research, and Royalty, Plagiarism software like Turnitin, Urkund Software and other open-source software tools, Citation, Referencing style and acknowledgement,
- Trademarks, Copyrights, Trade Secrets: Definition, Registration Process, Duration of Protection, and Enforcement
- Professional Protection of environment and biodiversity NBA, Environmental impacts and Ethical issues.
- Application of Intellectual Property Rights in Pharmacy Research and Innovation

Unit 4: Information and Communication Technology in Research with Scientific communication skills:

- Utilization of ICT Tools for Literature Review, Ethical Considerations in ICT Use in Research
- Definition of Scientific communication with its different types and Listening Skills, Development of communication skills in presentation of scientific seminars, eye to eye contact, facing to audience, question & answer session etc.
- Scientific presentations in Oral paper presentation and poster paper presentation.
- Art of scientific writing: Steps to better writing, flow method, organisation of material and style, drawing figures, graphs, table, footnotes, references etc. in a research paper
- Internet Searching and E-journals: Use of internet networks in research activities in searching materials, paper, downloading and submission of papers in different scientific journals
- Professional Communication Etiquette and Communication in Teamwork and Collaboration

Unit 5: Ethical and Scientific Research Design:

- Types of Research Design, Important Concepts Relating to Research Design, types of studies, strategies and importance of randomization, crossover design, placebo, blinding techniques.
- CCSEA guidelines for laboratory animal facility: Goals, veterinary care, quarantine, surveillance, diagnosis, treatment and control of disease, personal hygiene, location of animal to laboratories, facilities, anaesthesia, euthanasia, environment, animal husbandry, record keeping, SOPs, personnel and training, transport of lab animals.
- Data Collection and Analytical Methods of Data Collection- Observation (Interpretation and Presentation of Data), Interview, Questionnaires, Schedules, Survey and Experimental.
- Declaration of Helsinki: History, introduction, basic principles for all medical research, and additional principles for medical research combined with medical care.
- Medical Research: History, values in medical ethics, autonomy, beneficence, non-maleficence, double effect, conflicts between autonomy and beneficence/non-maleficence, euthanasia, informed consent, confidentiality, criticisms of orthodox medical ethics, importance of communication, control resolution, guidelines, ethics committees, cultural concerns, truth telling, conflicts of interest.
- Importance of GLP, GMP, GCP, GPVP and Regulatory Affairs in Research

References: Latest Editions of following Books

- 1) Kothari, C.R., Research Methodology (Methods and Techniques), New Age Publisher
- 2) Fundamentals of modern statistical methods By Rand R. Wilcox

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3) Power Analysis for Experimental Research A Practical Guide for the Biological,
Medical and Social Sciences by R. Barker Bausell, Yu-Fang Li Cambridge University
Press

4) Design of Experiments: Statistical Principles of Research Design and Analysis, by
Robert O. Kuehl Brooks/Cole
