



Gyanmanjari
Innovative University

Course Syllabus
Gyanmanjari Pharmacy College
Semester-3 (M. Pharm.)

Subject: Research Methodology and Biostatistics - MPHXX13513

Type of course: Major

Prerequisite: Biostatistics

Rationale: This subject is designed to impart knowledge and skills of Research Methodology and Biostatistics, their applications in pharmaceutical development, design of dose and dosage regimen and in solving the problems raised therein.

Teaching and Examination Scheme:

Teaching Scheme			Credits	Examination Marks					Total Marks
CI	T	P	C	Theory Marks		Practical Marks		CA	
				ESE	MSE	V	P	ALA	
4	-	-	4	75	25	-	-	50	150

Legends: CI-Class Room Instructions; T – Tutorial; P - Practical; C – Credit; ESE - End Semester Examination; MSE- Mid Semester Examination; V – Viva; CA - Continuous Assessment; ALA- Active Learning Activities.

Course Content:

Chapter No.	Course content	Hrs.	% Weightage
1.	General Research Methodology: General Research Methodology: Research, objective, requirements, practical difficulties, review of literature, study design, types of studies, strategies to eliminate errors/bias, controls, randomization, crossover design, placebo, blinding techniques.	10	25



2.	Biostatistics: Definition, application, sample size, importance of sample size, factors influencing sample size, dropouts, statistical tests of significance, type of significance tests, parametric tests (students "t" test, ANOVA, Correlation coefficient, regression), non-parametric tests (wilcoxon rank tests, analysis of variance, correlation, chi square test), null hypothesis, P values, degree of freedom, interpretation of P values.	10	20
3.	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, online business practices, conflicts of interest, referral, vendor relationships, treatment of family members, sexual relationships, fatality.	10	25
4.	CPCSEA guidelines for laboratory animal facility: Goals, veterinary care, quarantine, surveillance, diagnosis, treatment and control of disease, personal hygiene, location of animal facilities to laboratories, anesthesia, euthanasia, physical facilities, environment, animal husbandry, record keeping, SOPs, personnel and training, transport of lab animals.	08	15
5.	Declaration of Helsinki: History, introduction, basic principles for all medical research, and additional principles for medical research combined with medical care.	07	15

Continuous Assessment:

Sr. No	Active Learning Activities	Marks
1.	Research Proposal Simulation The faculty will Divide students into small groups. Each group selects a research problem, formulates objectives, a hypothesis, study design, sampling technique, and data collection tools. Students will present their proposal to the class as if applying for a research grant, and students make the report and submit on GMIU web portal.	10
2.	Biostatistics Data Analysis Workshop The faculty will Provide Data handling, statistical analysis, and interpretation to students with raw data sets (e.g., survey or clinical data). Ask them to apply statistical tests (mean, SD, t-test, chi-square, etc.) using Excel/SPSS. Students create the report and submit it on the GMIU web portal.	10
3.	Thesis Writing and Group Discussion Assign the students to thesis writing for the research area, including biostatistics and research methodology. Encourage active participation by asking students to present key findings, pose questions, and challenge assumptions. Make a report and upload it on the GMIU portal.	10
4.	Journal Club / Article Critique The faculty will assign students to read and present a scientific research article. They must critique the study design, methodology, and statistical analysis used. students	10



	make the report and submit it on the GMIU web portal.	
5.	Simulation of Statistical Tests Utilize statistical software (e.g., SPSS, R) to simulate data and perform statistical tests based on real-world scenarios. Students can simulate data for a clinical trial comparing two treatments, then perform a t-test to compare the means and interpret the p-value. Prepare the report and submit it on the GMIU web portal.	10
Total		50

Suggested Specification table with Marks (Theory):75

Distribution of Theory Marks (Revised Bloom's Taxonomy)						
Level	Remembrance (R)	Understanding (U)	Application (A)	Analyze (N)	Evaluate (E)	Create (C)
Weightage	30%	35 %	20%	05%	05%	05%

Note: This specification table shall be treated as a general guideline for students and teachers. The actual distribution of marks in the question paper may vary slightly from above table.

Course Outcome:

After learning the course, the students should be able to:	
CO1	Demonstrate understanding of general research methodology and scientific writing.
CO2	Apply parametric and non-parametric tests, interpret statistical outcomes such as P-values, and conduct post hoc tests to validate research findings.
CO3	Apply principles of experimental design for scientific research
CO4	Interpret and apply CPCSEA guidelines for ethical animal experimentation.
CO5	Comprehend ethical and regulatory guidelines in medical and clinical research.

Instructional Method:

The course delivery method will depend upon the requirement of content and need of students. The teacher in addition to conventional teaching method by black board, may also use any of tools such as demonstration, role play, Quiz, brainstorming, MOOCs etc.

From the content 10% topics are suggested for flipped mode instruction.

Students will use supplementary resources such as online videos, NPTEL/SWAYAM videos, e-courses, Virtual Laboratory

The internal evaluation will be done on the basis of Active Learning Assignment

Practical/Viva examination will be conducted at the end of semester for evaluation of performance of students in laboratory.



Reference Books:

- [1]. Research Methodology by C.R. Kothari
- [2]. Compendium of CPCSEA 2018
- [3]. Presentation skills - Michael Hallon- Indian Society for Institute education
- [4]. Pharmaceutics Statistics by Sanford Bolton, Charles Bon
- [5]. Pharmaceutical Experimental Design By Gareth Lewis and Didier Mathieu
- [6]. [www. ipindia.nic.in](http://www.ipindia.nic.in), www.uspto.gov
- [7]. www.cpcsea.nic.in
- [8]. www.icmr.nic.in

