



Shree H. N. Shukla Institute of Pharmaceutical Education & Research

(Affiliated to Gujarat Technological University, Approved by PCI)

Shree H. N. Shukla College Campus, Nr. Lalpari Lake, B/H. Marketing Yard,
Amargadh – Bhichari, Raikot. Mo. 9099063150, 9727753360

M.Pharm SEMESTER: III

Subject Name: RESEARCH METHODOLOGY, BIostatISTICS AND IPR

Subject Code: MRM301T

Teaching scheme and examination scheme:

Teaching Scheme				Evaluation Scheme			
Theory	Tutorial	Practical	Total	Theory		Practical	
				External	Internal	External	Internal
4	0	0	4	80	20	0	0

Sr No	Course Contents	Total Hrs
1	<p>General Research Methodology General Research Methodology: Research, objective, requirements, practical difficulties, Review of literature: Use of Library, books and journals- Medlines-Internet, and reprints of articles as a source for Literature survey. Selecting a problem and preparing Research proposals. The Research Report, Paper writing/ thesis writing, Different parts of the Research paper/Thesis Presentation oral/poster presentation) Importance, types, different skills, content, format of model, Poster, Gestures, eye contact, facial expressions, stage fright, volume- pitch, speed, pause & language, Visual aids & seating, Questionnaire. Sources for procurement research grants –National/ international agencies, Government and private bodies</p>	12
2	<p>Experimental Design (15 hours) Terminology and definitions related to experimental design Study design, types of studies, strategies to eliminate errors/bias, controls, randomization, crossover design, placebo, blinding techniques Sampling Designs: Introduction, types of sample designs, steps, criteria of selection, characteristics, random sampling, drop outs. Advantage and disadvantage of conventional design over experimental design. Basic steps in experimental design. Screening Designs: Screening of factors, General properties for independent factor selected for experimental design, Fractional factorial design(FFD): Purpose advantage and disadvantage of fractional factorial design, Concept of Aliased Effects and Design Aliasing Structure and constructing FFD Analysis of fractional factorial design: Concept of Design Resolution for FFD Case study of factorial design Plackett–Burman designs: Purpose advantage and disadvantage and construction of matrix , Comparison between placket-Burman and FFD design, Case study Full factorial design Optimization techniques and various method of optimization</p>	15



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	<p>Introduction to contour plots Introduction of repose surface design: Classification Characteristic of design Matrix and analysis of design with case study Evolution of full and reduced mathematical models in experimental designs Central composite designs Taguchi and mixture design Application of experimental design in pharmacology for reduction of animal</p>	
3	<p>Biostatistics Definition, application, 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, Kruskal Wallis test, Mann Whitney U test), null hypothesis, P values, degree of freedom, interpretation of P values, post hoc tests for parametric and non-parametric data (Dunnett’s test, Tukey’s test, Dunn’s test)</p>	8
4	<p>Regulatory perspectives of Medical research History of medical research (Nuremberg code, The declaration of Helsinki), initiation of ICH-GCP guidelines, advantages of ICH-GCP, core principles of ICH -GCP guidelines , Ethical Committee: Institutional Review Board, Ethical Guidelines by ICMR for Biomedical Research and Human Participants (ethical issues- informed consent process, confidentiality, payments, conflict of interest, vulnerable participants), Schedule Y, Preparation of clinical protocol, Investigator Brochure, Case Report Forms</p>	10
5	<p>CPCSEA guidelines for laboratory animal facility Objective and functions of IAEC, background and process of evolution of guidelines, statutory provisions regarding scientific experiments of animals, CPCSEA guidelines for animal experimentation and laboratory animal facility 2015, care and handling of animals, concept of 4 R, protocol preparation for Preclinical studies (Form B)</p>	5
6	<p>IPR and Patents Patents: Definition, Need for patenting, scope and importance of patents, Types of Patents, Condition to be satisfied by an invention to be patentable, Introduction to patent search and important websites, The essential elements of patents, Guidelines for preparations of laboratory notebook, non-obviousness in patents, Drafting of patent claims, important patent related websites. Copyrights and Trademark: Brief introduction to trademark protection and WTO patents, Introduction to “The Patents Act 1970” and “The Patents Rule 2003”, with special emphasis on the forms to be submitted along with a patent application</p>	10

REFERENCES:

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. Patent laws , By P. Narayan. Eastern law house publications



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6. Pharmaceutical Experimental Design By Gareth Lewis and Didier Mathieu
7. www.ipindia.nic.in, www.uspto.gov
8. www.cpcsea.nic.in
9. www.icmr.nic.in

LEARNING OUTCOMES:

UNIT	LEARNING OUTCOMES
1	Knowledge about General Research Methodology.
2	Understand Experimental Design.
3	Appreciate the Biostatistics.
4	Knowledge about the Regulatory perspectives of Medical research.
5	Understand the CPCSEA guidelines for laboratory animal facility.
6	Appreciate the IPR and Patents knowledge.

BOOK LIST:

Sr. no	Book name	Price (Rs.)
1	Research Methodology by C.R. Kothari.	314/-
2	Compendium of CPCSEA 2018.	-
3	Presentation skills - Michael Hallon- Indian Society for Institute education.	-
4	Pharmaceutics Statistics by Sanford Bolton, Charles Bon.	7,438/-
5	Patent laws , By P. Narayan. Eastern law house publications.	1,499/-
6	Pharmaceutical Experimental Design By Gareth Lewis and Didier Mathieu.	3,840/-