GANPAT UNIVERSITY

FACULTY OF PHARMACY

TEACHING AND EXAMINATION SCHEME

Program	Master of Pharmacy (M.Pharm)	Branch	Pharmacology	Semester	3	Version	2.0.0.0
Effective from	2019-20	Effective for batches admitted onwards		2018-19			

S. N	Subject Code	Subject Name	Theory / Practical	Teaching Scheme						Examination Scheme						
				Credit			Hours Per Week			Theory Marks			Practical Marks			Total Marks
				Le	Pr	Total	Le	Pr	Total	CE	SE	ES	CE	SE	ES	
1	MRM301T	Research Methodology and Biostatistics	Theory	4	-	4	4	-	4	10	15	75	-	-	-	100
2	MJC302T	Journal Club I	Theory	1	-	1	1	-	1	-	25	-	-	-	-	25
3	MRP303T	Research Proposal	Theory	2	-	2	2	-	2	-	50	-	-	-	-	50
4	MDT304D	Dissertation Phase I	Practical	-	14	14	-	28	28	-	-	-	-	50	300	350
			Total	7	14	21	7	28	35	10	90	75	-	50	300	525

GANPAT UNIVERSITY

FACULTY OF PHARMACY

Program	Master of Pharmacy	Branch/Spec.	Pharmacology
Semester	III	Version	2.0.0.0

Effective from Academic Year	2019-20	Effective for the batches Admitted onwards	June 2018
Subject code	MRM301T	Subject Name	Research Methodology and Biostatistics*
Teaching scheme		Examination scheme	

	Le	Tu	Pr	Total	Marks	CE	SE	ES	Total	Duration	SE	ES
Hours	4	-	-	4	Theory	10	15	75	100	Theory	1 hr.	3 hr.
Credit	4	-	-	4	Practical	-	-	-	-	Practical	-	-

Pre-requisites

Nil

Scope and Objectives:

This course aims to guide students for achieving competence and proficiency in the theory and practice for research work, use experimental drug design and aware them about intellectual property rights and patent.

Learning Outcome:

At the end of the course, the students will be able
To understand the fundamental methodology to carry our research.
To learn about experimental design and its importance
To understand IPR and Patents.

Syllabus- Theory

Unit	Content	Hrs
1	**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.	12
2	**Experimental Design:** 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	15

	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 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	
3	**Biostatistics**: Definition, application, statistical tests of significance, type of significance tests, parametric tests (students “t” test, ANOVA, Correlation coefficient, regression), non-parametric tests (wilcoxan 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)	8
4	**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	10
5	**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)	5
6	**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,	10

	Introduction to patent search and important websites, The essential elements of patents, Guidelines for preparations of laboratory notebook, nonobviousness 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” “The Patents Rule 2003”, with special emphasis on the forms to be submitted along with a patent application	

References

1	Research Methodology by C.R. Kothari
2	Patent laws , By P. Narayan. Eastern law house publications
3	Presentation skills - Michael Hallon- Indian Society for Institute education
4	Pharmaceutical Experimental Design By Gareth Lewis and Didier Mathieu
5	www. ipindia.nic.in, www.uspto.gov

GANPAT UNIVERSITY												
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Program	Master of Pharmacy				Branch/Spec.	Pharmacology						
Semester	III				Version	2.0.0.0						
Effective from Academic Year				2019-20	Effective for the batches Admitted onwards					June 2018		
Subject code	MJC302T			Subject Name		Journal Club I						
Teaching scheme					Examination scheme							
	Le	Tu	Pr	Total	Marks	CE	SE	ES	Total	Duration	SE	ES
Hours	1	-	-	1	Theory	-	25	-	25	Theory	1	-
Credit	1	-	-	1	Practical	-	-	-	-	Practical	-	-
Pre-requisites												
Nil												
Scope and Objectives:												
	To critically appraise the literature with help of printed journal and online sources. To choose a journal article that is relevant in answering the research problem. To evaluate the hypothesis, the study design, the method and the results in a systematic fashion. To understand how results of previous study can be used in framing research proposal.											
Learning Outcome:												
	At the end of the course, the students will be able for data mining and come to a right point to design hypothesis.											

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Semester	III				Version	2.0.0.0						
Effective from Academic Year				2019-20	Effective for the batches Admitted onwards					June 2018		
Subject code	MRP303T			Subject Name		Research Proposal						
Teaching scheme					Examination scheme							
	Le	Tu	Pr	Total	Marks	CE	SE	ES	Total	Duration	SE	ES
Hours	2	-	-	2	Theory	-	50	-	50	Theory	2	-
Credit	2	-	-	2	Practical	-	-	-	-	Practical	-	-
Pre-requisites												
Nil												
Scope and Objectives:												
	To horn scientific writing skill of student. To validate research requirement, current need, cost analysis and feasibility of research project. To understand and employ an appropriate statistical tools to design and analyze research proposal.											
Learning Outcome:												
	At the end of the course, students shall be able to identify problems at large and design scientific methodology.											

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Semester	III				Version	2.0.0.0						
Effective from Academic Year				2019-20	Effective for the batches Admitted onwards					June 2018		
Subject code	MDT304D			Subject Name		Dissertation Phase I						
Teaching scheme					Examination scheme							
	Le	Tu	Pr	Total	Marks	CE	SE	ES	Total	Duration	SE	ES
Hours	-	-	28	28	Theory	-	-	-	-	Theory	-	-
Credit	-	-	14	14	Practical	-	50	300	350	Practical	2 hr	6 hr

Pre-requisites

Nil

Scope and Objectives:

The aim of this course is to enable students
To develop an understanding and obtain practical experience of the research process and research skills required to undertake a supervised research project.
To address issues of research design, methodology, ethics and theoretical arguments, and apply these to thier own research.
To execute experiment from proposal and arrive at constructive outcome.

Learning Outcome:

Students will become able to implement hypothesis in laboratory. They gather information and analyzed them scientifically and logically to meet answer.

By the end of the course students will be able to;

- design a research proposal and protocol
- synthesize knowledge and skills previously gained and applied to an in-depth study
- establish links between theory and methods within their field of study
- select from different methodologies, methods and forms of analysis to produce a suitable research design, and justify their design
- present the findings of their project in a written report.