GANPAT UNIVERSITY

FACULTY OF PHARMACY

TEACHING AND EXAMINATION SCHEME

Program	Master of Pharmacy (M.Pharm)	Branch	Quality Assurance	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

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FACULTY OF PHARMACY												
Program	Master of Pharmacy				Branch/Spec.	Quality Assurance						
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:

- Learn objectives of research for preparing research proposal, techniques & importance of documentation, methods of literature survey and technical writing, and presentation skill
- Learn various experimental designs and their applications in various areas of pharmaceutical research
- Know the various statistical methods to solve different types of problems
- Understand various regulatory norms and guidance for medical research
- Understand know-how IPR and Patents
- Design newer suitable methodology to answer the hypothesis.

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 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	15

	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, 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	10
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	

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FACULTY OF PHARMACY												
Program	Master of Pharmacy				Branch/Spec.	Quality Assurance						
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:	
	Acquire knowledge to critically appraise the literature with the help of printed journal or online sources.
	Understanding of how to choose journal article that is relevant in answering the research problem.
	Apply the area of evolutionary research in the article addresses.
	Analyze the research results in systemic way.
	Evaluate the hypothesis, the study design and the method in systemic fashion.
	Create skills to draw significant conclusions from the different resaerch articles.

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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:

	Knowledge of literature to select appropriate research proposal
	Understand methodology for selection of appropriate proposal, preparation of content, presentations, submission, tests, viva voce etc.
	Applications of various statistical tools for designing suitable research proposal
	Analyse various research schemes available from government and non-government sectors
	Evaluate and identify problems at large and design scientific methodology for preparation of quality proposal
	Create skills to strengthen ability for scientific writing and presentations

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Program	Master of Pharmacy				Branch/Spec.	Quality Assurance						
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:

	Knowledge about information gathering from literature reviews and selects the title of project.
	Understand and design a research proposal and protocol.
	Synthesize knowledge and skills previously gained and applied to an in-depth study.
	Analyse and establish links between theory and methods within their field of study.
	Evaluate different methodologies, methods and forms of analysis to produce a suitable research design, and justify their design.
	Create skill to present the findings of their project in a written report.