



**SARDAR PATEL UNIVERSITY**  
**Vallabh Vidyanagar, Gujarat**  
**(Reaccredited with 'A' Grade by NAAC (CGPA 3.25)**  
**Syllabus with effect from the Academic Year 2022-2023**

**PROGRAMME STRUCTURE**  
**Master of Pharmacy in Pharmaceutics**  
**M. Pharm (Pharmaceutics) Semester: III**

Programme Outcome (PO) - For M. Pharm (MPH) Programme	At the end of Master of Pharmacy (M. Pharm) program, the students will be able to: <ol style="list-style-type: none"><li>1. Acquire knowledge and comprehension of the advancements in the core and specialization area of pharmacy.</li><li>2. Demonstrate a degree of expertise in laboratory practices, analytical techniques and scientific tools.</li><li>3. Independently carry out research/investigation and development work to solve problem.</li><li>4. Write and present a substantial scientific document and technical report.</li><li>5. Apply reasoning by contextual knowledge to assess societal impact, environmental impact, health, safety and legal issues and the consequent responsibilities relevant to the pharmacy profession.</li></ol>
Programme Specific Outcome (PSO) - For M. Pharm (MPH) Semester - III	After completion of the program students are able to: <ol style="list-style-type: none"><li>1. Students will learn the concept of literature review and research writings.</li><li>2. Students will understand various research tools for data analysis and the way to apply</li><li>3. Students will learn various guidelines related to animal experimentation for their developed formulations and other regulatory aspects of clinical-nonclinical studies</li><li>4. Students will learn how to present and improve their scientific presentations</li><li>5. Students will understand the way of writing research proposals</li><li>6. Students will also gain the practical skill and knowledge to do research</li></ol>





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**M. Pharm (Pharmaceutics) Semester: III**

Course Type	Course Code	Name of Course	Theory/ Practical	Credit	Exam Duration in hrs	Component of Marks			
						Internal	External	Total	
Employability, Entrepreneurship	PP03CMRM01	Research Methodology and Biostatistics	T	4	3	25	75	100/50	
Employability, Skill Development	PP03AMPH01	Journal club	J	1	-	25	-	25/13	
Employability, Skill Development	PP03CMPH01	Discussion / Presentation (Proposal Presentation)	D	2	-	50	-	50/25	
Employability, Skill Development	PP03CMPH02	Research work	R	14	1		350	350/175	
				<b>Total:</b>	<b>21</b>	<b>-</b>	<b>100</b>	<b>425</b>	<b>525/263</b>





Master of Pharmacy

M. Pharm, Pharmaceutics, Semester - III

Course Code	PP03CMRM01	Title of the Course	Research Methodology & Biostatistics
Total Credits of the Course	4	Hours per Week	4

<b>Course Objective:</b> Upon completion of the course student shall be able to understand	
1.	Learn general research methodology concept
2.	Understand the functions of ethics committees in medical research
3.	Learn the different Biostatistics calculation and optimization techniques
4.	Understand the process of patent and IPR.

<b>Course Content</b>		
Unit	Description	Hrs.
I	<b>General Research Methodology</b> Research, objective of Research, requirements, study design, types of studies, strategies to eliminate errors/bias, controls, randomization, crossover design, placebo, blinding techniques. Review of literature: Use of Library, books and journals/Medlines-Internet, and reprints of articles as a source for Literature survey, E Resources. 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.	15
II	<b>Biostatistics:</b> a. Definition, application, sample size, importance of sample size, factors influencing sample size, dropouts, statistical tests of significance, type of significance tests, Null hypothesis, P values, degree of freedom, interpretation of P values, parametric tests: various t test, ANOVA, Correlation coefficient, regression, non-parametric tests: wilcoxon rank tests, analysis of variance, correlation, chi square test. <b>Optimization Techniques</b> a. General principles, optimization and its parts, application, advantages, variables and constrains, various strategies and classification of optimization techniques b. Various Mathematical Models, Simulation and Search methods – Steepest Ascent,	15





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	<p>Response Surface Method, Contour Plots, Feasibility Search, Grid Search, Regression Summery Interpretation and Graphical representations</p> <p>b. Randomized complete block design, Plackett-Burman design, Full Factorial and Fractional Factorial Designs, Central Composite Design, Box Behnken Design, Mixture and Simplex Designs, Taguchi Design, D-Optimal design, Case studies</p>	
<b>III</b>	<p>a. Medical Research: History – Nuremberg Code, The Helsinki Declaration, Belmont Report, Ethical considerations – values in medical ethics, autonomy, beneficence, non-maleficence, Informed consent, Justice and access, autonomy and human dignity, conflicts between autonomy and beneficence/non-maleficence, GCP- ICH guideline and principles, ICMR guidelines for Biomedical Research, Ethical committees – IEC, IRB, Ethical issues – conflict of interest, informed consent process, confidentiality, referral, payments, vulnerable participation.</p> <p>b. Regulations in animal experimentation – History, Scope and Importance, and Elements of – CPCSEA guidelines for laboratory animal facility, OECD-GLP guidelines for non-clinical safety studies.</p>	<b>15</b>
<b>IV</b>	<p><b><i>Patent and IPR</i></b></p> <p>a. Concept of IPR and its type</p> <p>b. Categories, Advantages, registration requirements and validity terms, status in India of various IPRs like Patent, Copyright, Trademark, Geographical Indications, Industrial Designs, Integrated Circuits and Tread Secrets</p> <p>c. Patents in India – The patent act, 1970, Various Amendments in Patent Act, Stages of Patenting, Patent Opposition, Maintenance and Conditions of Patent rights, Patent search and various resources</p> <p>d. Paris conventional, World Trade Organization, WIPO and GATT.</p> <p>e. PCT and convention patent applications; International patenting requirement procedures and costs; Rights and responsibilities of a patentee;</p> <p>f. Patent infringement meaning and scope. Significance of transfertechnology (TOT), IP and ethics-positive and negative aspects of IPP; Societal responsibility, avoiding unethical practices.</p>	<b>15</b>

<b>Teaching-Learning Methodology</b>	<ol style="list-style-type: none"> <li>1. Students will be oriented about the course content in the first session of the course</li> <li>2. Class-room teaching will be based on interactive sessions using chalk and board teaching method as well as teaching aids such as Poweppoint presentations, audio-visual presentations.</li> <li>3. Virtual teaching and examination will also utilized for the learners of the course.</li> <li>4. Seminar/assignments on advanced, recent and useful topics related to the course will be an integral part of course teaching and learning methodology.</li> <li>5. Quiz and Q &amp; A sessions for the topics covered will be conducted at regular interval.</li> <li>6. Internal theory test will be conducted as a part of regular curriculum.</li> <li>7. Attendance will be marked for each session as a part of overall evaluation.</li> </ol>
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	8. Teaching will be facilitated by reading material, discussion forum, task-based learning and case discussions.
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<b>Evaluation Pattern</b>		
Sr. No	Details of Evaluation	Marks
1.	Continuous Mode	10
2.	Sessional Examination	15
3.	End Semester Examination	75

<b>Course Outcomes:</b> Students will be able to	
1.	Theorize the elements of research methodology
2.	Apply statistical methodology for data analysis
3.	Practice ethical principles and regulatory considerations in medical research
4.	Acquire knowledge of Patent and IPR.

<b>Suggested References:</b>	
Sr. No	References
1	Research in Education- John V. Best, John V. Kahn 7th edition
2	Thesis & Assignment – Jonathan Anderson
3	Writing a technical paper- Donald Menzel
4	Pharmaceutical Statistics , Practical and Clinical Applications, Fifth Edition, Sanford Bolton, Charles Bon
5	ICMR guidelines for medical research
6	Principle and Practice of Clinical Trial Medicine, Richard Chin, Bruce Y. Lee, Academic Press
7	CPCSEA guideline for laboratory animal care and handling

