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 Pharmaceutical Quality Assurance
M. Pharm (Pharmaceutical Quality Assurance) Semester: III

Programme Outcome (PO) - For M. Pharm (PQA) Programme	At the end of Master of Pharmacy (M. Pharm) program, the students will be able to: 1. Acquire knowledge and comprehension of the advancements in the core and specialization area of pharmacy. 2. Demonstrate a degree of expertise in laboratory practices, analytical techniques and scientific tools. 3. Independently carry out research/investigation and development work to solve problem. 4. Write and present a substantial scientific document and technical report. 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.
Programme Specific Outcome (PSO) - For M. Pharm (PQA) Semester - III	After completion of the program students are able to: 1. Understand the Quality Assurance, Total Quality Management, and Quality Management concepts, Hazard Management system and technology transfer system. 2. Adopt GMP, Schedule M, ISO 9000 and 14000 standards, NABL accreditation, ICH, USFDA, WHO and other regulatory guidelines and common requirement for product registration and product development. 3. Dealing with different quality concept and use modern pharmaceutical tools, software and equipment to analyze & solve problems with the help of GLP, GCP, QbD, PAT and their documentation. 4. Doing various pharmaceutical product development interaction such as calibration, validation, product complain and recall, corrective and preventive action, documentation and their regulatory requirement. 5. Dealing with various advanced instrumental techniques for identification, characterization, and quantification of drugs and pharmaceuticals. 6. To generate validation protocol for all pharmaceutical operations starting from drug research to development to formulation.

PROGRAMME STRUCTURE
Master of Pharmacy in Pharmaceutical Quality Assurance
M. Pharm (Pharmaceutical Quality Assurance) Semester: III

To Pass	At least 50% Marks in the University Examination in each paper and 50% Marks in the aggregate of University and Internal examination in each course of Theory, Practical & Research work

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	PP03AMQA01	Journal club	J	1	-	25	-	25/13
Employability, Skill Development	PP03CMQA01	Discussion / Presentation (Proposal Presentation)	D	2	-	50	-	50/25
Employability, Skill Development	PP03CMQA02	Research work	R	14	1	-	350	350/175
			Total:	**21**	**-**	**100**	**425**	**525/263**

Master of Pharmacy

M. Pharm, Pharmaceutical Quality Assurance, Semester - III

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

Course Objective: 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.

Course Content

Unit	Description	Hrs.
I	**General Research Methodology** 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	**Biostatistics:** 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: wilcoxan rank tests, analysis of variance, correlation, chi square test. ***Optimization Techniques*** 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**

	Response Surface Method, Contour Plots, Feasibility Search, Grid Search, Regression Summery Interpretation and Graphical representations 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	
III	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. 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.	**15**
IV	***Patent and IPR*** a. Concept of IPR and its type b. Categories, Advantages, registration requirements and validity terms, status in India of various IPRs like Patent, Copyright, Trademark, Geographical Indications, Industrial Designs, Integrated Circuits andTread Secrets 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 d. Paris conventional, World Trade Organization, WIPO and GATT. e. PCT andconvention patent applications; International patenting requirementprocedures and costs; Rights and responsibilities of a patentee; f. Patentinfringement meaning and scope. Significance of transfertechnology (TOT), IP and ethics-positive and negative aspectsof IPP; Societal responsibility, avoiding unethical practices.	**15**

Teaching-Learning Methodology	1. Students will be oriented about the course content in the first session of the course 2. Class-room teaching will be based on interactive sessions using chalk and board teaching method as well as teaching aids such as Powepoint presentations, audio-visual presentations. 3. Virtual teaching and examination will also utilized for the learners of the course. 4. Seminar/assignments on advanced, recent and useful topics related to the course will be an integral part of course teaching and learning methodology. 5. Quiz and Q & A sessions for the topics covered will be conducted at regular interval. 6. Internal theory test will be conducted as a part of regular curriculum. 7. Attendance will be marked for each session as a part of overall evaluation.

	8. Teaching will be facilitated by reading material, discussion forum, task-based learning and case discussions.

Evaluation Pattern		
Sr. No	Details of Evaluation	Marks
1.	Continuous Mode	10
2.	Sessional Examination	15
3.	End Semester Examination	75

Course Outcomes: 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.

Suggested References:	
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