



M.Pharm – Pharmaceutical Quality Assurance

PROGRAM OUTCOMES:

PO1	Apply knowledge & skills in documentation of CTD & CAPA.
PO2	To excel in pharmaceutical Quality Assurance through organizing learning.
PO3	To create a hallmark of excellence in pharmaceutical Quality assurance programme.

PROGRAM SPECIFIC OUTCOMES:

PSO1	Acquire knowledge on concepts of calibration, qualification & Validation. Analyze & acquire technical skills in analytical field & drug development as per the requirements of pharmaceutical industry.
PSO2	Apply technical skills and knowledge in documentation & acquire knowledge of various quality management principles & quality certifications, quality audits for quality evaluation QbDPAT in pharmaceutical industry.

COURSE OUTCOMES

I Sem

Course code	Name of the course	Course outcomes
MQA101T	Modern Pharmaceutical Analytical Techniques	<p>The students shall be able to:</p> <p>CO1-Discuss the concepts of various analytical techniques, including UV, NMR, MASS IR, Flame Emission, Atomic Absorption, and spectroscopic methods, to interpret results and data, facilitating the determination of the structure of different categories of drugs.</p> <p>CO2-Explain about the various chromatographic techniques, such as paper chromatography, TLC, HPTLC, Gas Chromatography, HPLC, and electrophoresis, to analyze and separate the components of chemical mixture.</p> <p>CO3-Describe spectrofluorometric, potentiometric, and immune assay techniques to analyze drug concentrations, while employing thermal analysis to investigate how temperature changes affect specific properties of drugs.</p>
MQA102T	Quality Management System	<p>The students shall be able to:</p> <p>CO1-Evaluate the tools for quality improvement in the pharmaceutical industry.</p> <p>CO2-Discuss the quality evaluation and stability testing methods in the pharmaceutical industry for analyzing</p>

		<p>product integrity, assess shelf-life, and ensure compliance with regulatory standards.</p> <p>CO3-Discuss about statistical approaches for quality assessment in the pharmaceutical industry to analyze data.</p>
MQA103T	Quality Control and Quality Assurance	<p>The students shall be able to:</p> <p>CO1-Explain the concepts of quality control and quality assurance, providing an overview of ICH guidelines, and discussing the principles outlined in the QSEM guidelines.</p> <p>CO2-Analyze cGMP aspects within the pharmaceutical industry to understand their significance in ensuring product quality and regulatory compliance</p> <p>CO3-Evaluate the scope of quality certification applicable to the pharmaceutical industry to assess its impact on product quality, regulatory compliance, and overall business operations.</p> <p>CO4-Analyze manufacturing operations and controls within the pharmaceutical industry to understand their role in ensuring product quality, consistency, and compliance with regulatory standards.</p>
MQA104T	Product Development and Technology Transfer	<p>The students shall be able to:</p> <p>CO1-Analyze the new product development process in the pharmaceutical industry to comprehend its stages</p> <p>CO2-Apply critical thinking skills to organize and synthesize the information gathered during R&D, facilitating the transfer of technology to actual manufacturing in the pharmaceutical industry.</p> <p>CO3-Analyze data to clarify essential information for transferring technology between pharmaceutical manufacturing sites.</p>
MQA105P	Pharmaceutical Quality Assurance Practical I	<p>The students shall be able to:</p> <p>CO1-Discuss various components and inspection models of quality management system in pharmaceutical industries.</p> <p>CO2-Discuss the roles and responsibilities of manufacturing, quality control & quality assurance department in pharmaceutical chemistry</p> <p>CO3-Integrate necessary information to transfer technology of existing product between various manufacturing places.</p>
MQA101P	Modern Pharmaceutical Analytical Techniques- Practical	<p>The students shall be able to:</p> <p>CO1-Determine the structure of various categories of drugs by interpreting the results and data obtained from variety of analytical techniques such as UV Visible, IR spectrographic techniques.</p> <p>CO2-Separate the components of chemical mixture by different chromatographic techniques such as TLC, HPLC and electrophoresis.</p> <p>CO3-Analyze various categories of drugs. Multiple and combination dosage form.</p>

	Seminar	<p>The students should be able to:</p> <p>CO1-Facilitate mastery of communication skills by employing effective oral and written presentation strategies, integrating presentation aids and nonverbal communication.</p> <p>CO2-Cultivate the technical writing and critical thinking aptitude through crafting well-structured reports and analyzing technical complexities.</p> <p>CO3-Exhibit the proficiency in presentation by elucidating and interpreting technical topics, receiving constructive feedback to refine their abilities further.</p> <p>CO6-Present effectively and communicate the obtained results for the envisaged research problem.</p>
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II Sem

MQA201T	Hazards and Safety Management	<p>The students shall be able to:</p> <p>CO1-Develop awareness of environmental issues among learners through analysis, evaluation, and synthesis of information.</p> <p>CO2-Explain implementation of safety standards in the pharmaceutical industry through application, analysis, and evaluation of regulatory guidelines and protocols.</p> <p>CO3-Discuss the learning of hazard assessment methods, procedures, and methodologies to establish a safe industrial atmosphere through instruction, application, and evaluation.</p>
MQA202T	Pharmaceutical Validation	<p>The students shall be able to:</p> <p>CO1-Explain the concepts of calibration, qualification, and validation, along with the diverse equipment and instruments used, through understanding, application, and analysis.</p> <p>CO2-Discuss regarding validation processes and the various methods employed in the pharmaceutical industry, employing analysis, evaluation, and synthesis skills.</p> <p>CO3-Evaluate the cleaning validation process for equipment used in pharmaceutical manufacturing, applying analysis, evaluation skills.</p>
MQA203T	Audits and Regulatory Compliance	<p>The students shall be able to:</p> <p>CO1-Explain the significance of auditing and the methodology involved in auditing processes through analysis, evaluation</p> <p>CO2-Outline the audit process and compile auditing reports by applying analysis, synthesis, and evaluation skills.</p> <p>CO3-Develop a checklist for auditing through application, analysis, and evaluation of relevant criteria and standards</p>

MQA204T	Pharmaceutical Manufacturing Technology	<p>The student shall be able to:</p> <p>CO1-Describe common practices in pharmaceutical industry development, plant layout, and production planning through analysis, evaluation.</p> <p>CO2-Comprehend the principles and practices of aseptic process technology, non-sterile manufacturing technology, and packing technology through understanding, application, and analysis.</p> <p>CO3-Develop a deeper comprehension of the principles and implementation of quality by design and process analytical technology in pharmaceutical manufacturing through analysis and evaluation</p>
MQA205P	Pharmaceutical Quality Assurance Practical	<p>The student shall be able to:</p> <p>CO1-Analyze different contaminants and impurities in the given sample</p> <p>CO2-Analyze case study for PAT and QbD</p> <p>CO3-Perform the qualification of various equipment, cleaning validations and validation of analytical methods.</p>
	Seminar	<p>The students shall be able to:</p> <p>CO1-Facilitate mastery of communication skills by employing effective oral and written presentation strategies, integrating presentation aids and nonverbal communication.</p> <p>CO2-Cultivate the technical writing and critical thinking aptitude through crafting well-structured reports and analyzing technical complexities.</p> <p>CO3-Exhibit the proficiency in presentation by elucidating and interpreting technical topics, receiving constructive feedback to refine their abilities further.</p> <p>CO6-Present effectively and communicate the obtained results for the envisaged research problem.</p>
III Sem		
MRM101T (Non University Exam)	Research Methodology and Biostatistics	<p>The students shall be able to:</p> <p>CO1-Articulate the components of research methodology and elucidate the use of biostatistics in research and development processes.</p> <p>CO2-Differentiate between different statistical techniques and evaluate their applications within research contexts.</p> <p>CO3-Demonstrate the ability to choose and execute suitable parametric/ nonparametric tests based on data, employing both manual calculations and statistical software tools.</p> <p>CO4-Elaborate with examples on the ethical considerations involved in pharmaceutical research.</p> <p>CO5-Interpret the standards outlined by CPCSEA for laboratory animal facilities and outline fundamental principles governing the research.</p>

	Research Proposal Presentation	<p>The students shall be able to:</p> <p>CO1-Demonstrate a comprehensive understanding of the research topic, including its significance and relevance to the field.</p> <p>CO2-Communicate effectively the research objectives, methodology, and expected outcomes.</p> <p>CO3-Engage in critical thinking and problem-solving to address potential challenges and limitations of the proposed research.</p> <p>CO4-Seek constructive feedback from peers and mentors to enhance the clarity, feasibility, and impact of the research proposal.</p> <p>CO5-Develop confidence and professionalism in presenting research ideas and defending their scientific merit.</p>
	Journal Club	<p>The students shall be able to:</p> <p>CO1-Analyze critically recent advancements and findings in pharmaceutical research literature.</p> <p>CO2-Enrich literature search and review skills to identify relevant articles and extract key information.</p> <p>CO3-Foster discussion and debate to deepen understanding of methodologies, results, and implications of research studies.</p> <p>CO4-Develop presentation skills to effectively communicate findings and insights to peers.</p> <p>CO5-Promote collaborative learning and peer feedback to broaden perspectives and enhance critical thinking skills.</p>
IV Sem		
	Research Work	<p>The students shall be able to:</p> <p>CO1-Develop a strong work ethic and exhibit critical thinking, analytical skills in conducting independent research.</p> <p>CO2-Exhibit a critical understanding of the research process, such as design of experiments, collection of data, data analysis and interpretation of results.</p> <p>CO3-Learn about the latest advancements in pharmaceutical research, generate novel insights or contribute new knowledge to the existing literature.</p> <p>CO4-Communicate effectively research findings through written reports, presentations, and publications.</p>
	Discussion/Final Presentation	<p>The students shall be able to:</p> <p>CO1-Showcase your in-depth knowledge of the research area planned in a clear, concise, and well-organized manner, including its significance and contribution to pharmacy using visuals and scientific language effectively.</p> <p>CO2-Explain your research methodology, key findings, and their interpretation with clear visuals and data analysis.</p> <p>CO3-Discuss encountered challenges and how they were overcome, demonstrating personal and professional growth leaving room for questions and discussion.</p>