



MPHARM PHARMACEUTICAL QUALITY ASSURANCE

SEMESTER I COURSE OUTCOMES (COs)

PQA-MQA 101T: Modern Pharmaceutical Analytical Techniques

This course deals with various advanced analytical instrumental techniques for identification, characterization and quantification of drugs. Instruments dealt are NMR, Mass spectrometer, IR, HPLC, GC etc.

After completion of the course, a student will be able to understand:

CO1: The theory and working of sophisticated analytical instruments for quality control of drugs and pharmaceuticals.

CO2: The analysis of various drugs in single and combination dosage forms.

CO3: Applications of various analytical techniques for drug analysis.

PQA-MQA 102T: Quality Management System

This course is designed to impart fundamental knowledge and concepts about various quality management principles and systems utilized in the manufacturing industry. It also aids in understanding the quality evaluation of drug substance and drug product.

After completion of this course it is expected that students will be able to understand-

CO1: The importance of quality

CO2: ISO management systems

CO3: Tools for quality improvement

CO4: Analysis of issues in quality

CO5: Stability testing of drug substance and drug product

CO6: Statistical approaches for quality pharmaceutical industries.

PQA-MQA 103T: Quality Control and Quality Assurance

This course deals with the various aspects of quality control and quality assurance in pharmaceutical industry. It covers the important aspects like cGMP, QC tests, documentation, quality certifications, GLP and regulatory affairs.

Upon completion of this course the student should be able to

CO1: Understand the cGMP aspects in a pharmaceutical industry

CO2: Appreciate the importance of documentation

CO3: Understand the scope of quality certifications applicable to Pharmaceutical industries

CO4: Understand the responsibilities of QA & QC departments



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PQA-MQA 104T: Product Development and Technology Transfer

This course deals with activities related to drug product development and Technology transfer.

Upon completion of this course the student should be able to understand:

CO1: The new drug development process and related regulations.

CO2: The concept of pre-formulation studies, solubility studies, crystal properties and polymorphism.

CO3: Learn the quality control tests for containers and closures.

CO3: The necessary information to transfer technology from R&D to actual manufacturing and related documentation

PQA-MQA 105P: Pharmaceutical Quality Assurance Practical- I

This course is designed to gain practical skills on assay of drugs, formulations, quality control of packaging materials, pre-formulation studies and QA case studies.

Upon completion of this course the student should be able to:

CO1: Analyze the API and formulations using various analytical instruments

CO2: Solve the case studies on QA related issues

CO3: Perform the Pre-formulation studies

PQA-MQA 106S: Seminar in Pharmaceutical Quality Assurance

The course is designed to create an environment where student gather information about an assigned topic in the relevant field. Students will develop writing skills, presentation skills and defend their presentation effectively.

Upon completion of the course the student shall be able to:

CO1: Acquire knowledge to gather, organize, deliver information, and defend a given topic in the Pharmaceutical Quality Assurance area.

CO2: Acquire knowledge on concepts using audio-visual aids.

CO3: Acquire communication and presentation skills.

CO4: Effectively defend the presentation.

CO5: Develop a write-up about seminar topic.



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SEMESTER II COURSE OUTCOMES (COs)

PQA-MQA 201T: Hazard and Safety Management

This course involves basic theoretical and practical discussions integrating the proficiency to handle the emergency in the pharmaceutical product development process and provides the principle based approach to solve the complex tribulations.

After completion of this course it is expected that students will be able to:

CO1: Impart basic knowledge about the environment and its allied problems.

CO2: Develop an attitude of concern for the industry environment.

CO3: Ensure safety standards in pharmaceutical industry.

CO4: Provide comprehensive knowledge on the safety management.

CO5: Implement the Hazard assessment procedure, methodology to provide safe industrial atmosphere.

PQA-MQA 202T: Pharmaceutical Validation

The course covers the complete information about validation, types, methodology and application.

Upon completion of this course the student should be able to understand:

CO1: The concepts of calibration, qualification and validation.

CO2: The qualification of various equipment.

CO3: Process validation of different dosage forms and analytical method validation.

CO4: Cleaning validation of equipment employed in the manufacture of pharmaceuticals and validation of computer systems.

PQA-MQA 203T: Audit and Regulatory Compliance

This course deals with the process of auditing in pharmaceutical industries.

Upon completion of this course the student should be able:

CO1: To understand the importance of auditing

CO2: To understand the methodology of auditing

CO3: To carry out the audit process

CO4: To prepare the auditing report

CO5: To prepare the check list for auditing



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SEMESTER II COURSE OUTCOMES (COs)

PQA-MQA 204T: Pharmaceutical Manufacturing Technology

This course is designed to impart knowledge and skills necessary to train the students with the industrial activities during Pharmaceutical Manufacturing.

After completion of this course it is expected that students will be able to:

CO1: The common practice in the pharmaceutical industry developments, plant layout and production planning.

CO2: The principles and practices of aseptic process technology, non-sterile manufacturing technology and packaging technology.

CO3: The principles and implementation of Quality by design (QbD) and process analytical technology (PAT) in pharmaceutical manufacturing.

PQA-MQA 205P: Pharmaceutical Quality Assurance-II

This course is designed to gain practical skills on qualification of analytical instruments, estimation of contaminants, and design of audit check lists.

Upon completion of this course the student should be able to:

CO1: Analyze the contamination in pharmaceutical products using various analytical instruments

CO2: Design audit check list for various pharmaceutical activities.

CO3: Understand the Qualification of analytical instruments, and importance of QbD and PAT.

PQA-MQA 206S: Seminar in Pharmaceutical Quality Assurance

The course is designed to create an environment where student gather information about an assigned topic in the relevant field. Students will develop writing skills, presentation skills and defend their presentation effectively.

Upon completion of the course the student shall be able to:

CO1: Acquire knowledge to gather, organize, deliver information, and defend a given topic in the Pharmaceutical Quality Assurance area.

CO2: Acquire knowledge on concepts using audio-visual aids.

CO3: Acquire communication and presentation skills.

CO4: Effectively defend the presentation.

CO5: Develop a write-up about seminar topic.



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SEMESTER III COURSE OUTCOMES (COs)

PHA-MRM 301T: Research Methodology and Biostatistics

This subject is designed to understand the advanced knowledge for research methodology, ethics in research, medical research, design, conduct and interpretation of results. This subject deals with descriptive statistics principles and their applications in biostatistics involving parametric tests, non-parametric tests, correlation, regression, probability theory and statistical hypotheses.

Upon completion of the course the student shall be able to

CO1: Know the various components of research design and methodology.

CO2: Appreciate advanced statistical techniques in solving the research problems.

PQA-MJC 302P: Journal Club in Pharmaceutical Quality Assurance

The course is designed to create an environment where students present a published research paper, and critically analyze it, that would enhance the communication, presentation and analytical skills of the students.

Upon completion of the course the student shall be able to:

CO1: Learn to organize complex research concepts using audio-visual aids.

CO2: Acquire communication and presentation skills.

CO3: Effectively respond to the questions raised by peers and stand scientific scrutiny.

MPHARM – Choice Based Interdisciplinary Courses

The following electives are offered by the departments to provide pharmaceutical research and development oriented knowledge in various topics such as

- PQA-001E: Theory and Practice of Analytical and Bioanalytical Method Development and Validation
- PQA-003E: Trouble Shooting in High Performance Liquid Chromatography