COURSE BOOK M. PHARM PQA I YEAR

(Autonomous)

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CURRICULUM STRUCTURE & SYLLABUS

Effective from the Session: 2024-25

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1. Teaching Scheme of (M. Pharm. Pharm. Quality Assurance I Year)

M.Pharm- PQA 1st Sem

S No.	Course Type	BOS	Course Code	Course Name	Academic Learning (AL)			Continuous Internal Examination (CIE)		Mid Sem Exam (MSE)	End Semester Examination (ESE)		Total Credit
					L	T	P	MSE	CA	TOTAL		CIE+ESE	Cr
1	M.Pharm	KSOP	MQA101T	Modern Pharmaceutical Analytical Techniques	4	0	0	15	10	25	75	100	4
2	M.Pharm	KSOP	MQA102T	Quality Management System	4	0	0	15	10	25	75	100	4
3	M.Pharm	KSOP	MQA103T	Quality Control and Quality Assurance	4	0	0	15	10	25	75	100	4
4	M.Pharm	KSOP	MQA104T	Product Development and Technology Transfer	4	0	0	15	10	25	75	100	4
5	M.Pharm	KSOP	MQA1 305	Soft Skills	1	0	0	10	-	10	40	50	NC
Lab/Internship/Project work/Workshop													
8	M.Pharm	KSOP	MQA105P	Pharmaceutical Quality Assurance Practical I	0	0	12	30	20	50	100	150	6
9	M.Pharm	KSOP	MQA106S	Seminar/Assignment	0	0	7	-	100	100	-	100	4
Total Hours = 36 hrs.					**17**	**0**	**19**					**700**	**26**

M.Pharm-PQA 2nd Sem

S No.	Course Type	BOS	Course Code	Course Name	Academic Learning (AL)			Continuous Internal Examination (CIE)		Mid Sem Exam (MSE)	End Semester Examination (ESE)		Total Credit
					L	T	P	MSE	CA	TOTAL		CIE+ESE	Cr
1	M.Pharm	KSOP	MQA201T	Hazards and Safety Management	4	0	0	15	10	25	75	100	4
2	M.Pharm	KSOP	MQA202T	Pharmaceutical Validation	4	0	0	15	10	25	75	100	4
3	M.Pharm	KSOP	MQA203T	Audits and Regulatory Compliance	4	0	0	15	10	25	75	100	4
4	M.Pharm	KSOP	MQA204T	Pharmaceutical Manufacturing Technology	4	0	0	15	10	25	75	100	4
Lab/Internship/Project work/Workshop													
5	M.Pharm	KSOP	MQA205P	Pharmaceutical Quality Assurance Practical II	0	0	12	30	20	50	100	150	6
6	M.Pharm	KSOP	MQA206S	Seminar/Assignment	0	0	7	-	100	100	-	100	4
7	M.Pharm	KSOP	MQA1 207	Internship on Regulatory Affairs or QbD by CPA/QbD by DPSRU/Any Relevant Industry Internship or 8-12 weeks MOOC Course (NPTEL)	0	0	2	-	25	25	-	25	1
Total Hours: 37 hrs.					**16**	**0**	**21**					**675**	**27**

2. Theory Courses Detail Syllabus

Course Code: MQA101T	Course Name: Modern Pharmaceutical Analytical Techniques	L	T	P	C
Course Offered in: KIET School of Pharmacy		4	0	0	4

Pre-requisite: NA

Course Objectives: After completion of course, student is able to know about chemicals and excipients:

- The analysis of various drugs in single and combination dosage forms.
- Theoretical and practical skills of the instruments

Course Outcome: After completion of the course, the student will be able to

1. Apply the concepts and applications of UV, IR, Fluorimetry, Flame and AAS.
2. Interpret the basics and applications of NMR.
3. Outline the theory, principle, instrumentation and illustrate the applications of Mass spectroscopy.
4. Acquire theory, principle, instrumentation and applications of chromatography and electrophoresis.
5. Apply the theory, principle, instrumentation and applications of X-ray crystallography, Potentiometry, thermal techniques and Immunological assays.

CO-PO Mapping (Scale 1: Low, 2: Medium, 3: High)

CO-PO Mapping	PO1	PO2	PO3	PO4	PO5	PO6
CO1	3	1	2	1	2	-
CO2	3	1	2	1	2	-
CO3	3	1	2	1	2	1
CO4	3	1	2	1	2	-
CO5	3	1	2	1	2	1

Unit 1	UV-Visible, IR, Flame emission spectroscopy	12 hours

a. UV-Visible Spectroscopy: Introduction, theory, laws, instrumentation associated with UV-Visible spectroscopy, choice of solvents and solvent effect. Applications of UV-Visible spectroscopy, Difference/ derivative spectroscopy.
b. IR Spectroscopy: Theory, modes of molecular vibrations, sample handling, Instrumentation of dispersive and Fourier - Transform IR spectrometer, factors affecting vibrational frequencies. Applications of IR spectroscopy and data interpretation.
c. Spectroflourimetry: Theory of fluorescence, factors affecting fluorescence (characteristics of drugs that can be analyzed by flourimetry), quenchers, Instrumentation and applications of fluorescence spectrophotometer.
d. Flame Emission Spectroscopy and Atomic Absorption Spectroscopy: Principle, instrumentation, interferences and applications.

Unit 2	NMR Spectroscopy	12 hours

NMR Spectroscopy: Quantum numbers and their role in NMR, principle, Instrumentation, solvent requirement in NMR, relaxation process, NMR signals in various compounds. Chemical shift, factors influencing chemical shift, spin-spin coupling, coupling constant,
nuclear magnetic double resonance, brief outline of principles of FT-NMR and ^{13}C NMR.
Applications of NMR spectroscopy.

Unit 3	Mass Spectroscopy	12 hours

Mass Spectroscopy: Principle, theory, instrumentation of mass spectroscopy, different types of ionization like electron impact, chemical, field, FAB and MALDI, APCI, ESI, APPI analyzers of quadrupole and time of flight, mass fragmentation and its rules, meta stable ions, isotopic peaks. Applications of mass spectroscopy.

Unit 4	Chromatography	8 hours

Chromatography: Principle, apparatus, instrumentation, chromatographic parameters, factors affecting resolution, isolation of drug from excipients, data interpretation and applications of the following:
• Thin layer chromatography
• High performance thin layer chromatography
• Ion exchange chromatography
• Column chromatography
• Gas chromatography
•High performance liquid chromatography

• Ultra high-performance liquid chromatography
• Affinity chromatography
• Gel chromatography

Unit 5	**Electrophoresis, X-ray Crystallography**	**8 hours**

a. Electrophoresis: Principle, instrumentation, working conditions, factors affecting separation and applications of the following:
a) Paper electrophoresis.
b) Gel electrophoresis.
c) Capillary electrophoresis.
d) Zone electrophoresis.
e) Moving boundary electrophoresis.
f) Isoelectric focusing.
b. X-ray Crystallography: Production of X-rays, different X-ray methods, Bragg's law, rotating crystal technique, X-ray powder technique, types of crystals and applications of X-ray diffraction.

Unit 6	**Potentiometry, Thermal Techniques and Immunological Assays**	**8 hours**

a. Potentiometry: Principle, working, Ion selective electrodes and application of potentiometry.
b. Thermal Techniques: Principle, thermal transitions and Instrumentation (Heat flux and power-compensation and designs), modulated DSC, hyper DSC, experimental parameters (sample preparation, experimental conditions, calibration, heating and cooling rates, resolution, source of errors) and their influence, advantage and disadvantages, pharmaceutical applications.
Differential Thermal Analysis (DTA): Principle, instrumentation and advantage and disadvantages, pharmaceutical applications, derivative differential thermal analysis (DDTA).
TGA: Principle, instrumentation, factors affecting results, advantage and disadvantages, pharmaceutical applications.
c. Immunological Assays: RIA (Radio immune assay), ELISA, bioluminescence assays.

	Total Lecture Hours	**60 hours**

Textbook:

1. Instrumental Methods of Analysis by Willards, 7th edition, CBS Publishers.
2. Practical Pharmaceutical Chemistry by Beckett and Stenlake, Vol II, 4th edition, CBS Publishers, New Delhi, 1997.
3. Organic Spectroscopy by William Kemp, 3rd edition, ELBS, 1991.
4. Quantitative Analysis of Drugs in Pharmaceutical Formulation by P D Sethi, 3rd Edition, CBS Publishers, New Delhi, 1997.
5. Pharmaceutical Analysis - Modern Methods – Part B by J W Munson, Vol 11, Marcel. Dekker Series
6. Spectroscopy of Organic Compounds, 2nd edn., P.S. Kalsi, Wiley Eastern Ltd., Delhi.
7. Undergraduate Instrumental Analysis, Obonson J.W.R., Marcel Dekker Inc, New York.
8. Absorption Spectroscopy of Organic Molecules by Parikh V.H., Addison-Wesley Publishing Co., London.

Reference Books:

1. Spectrometric Identification of Organic compounds by Robert M Silverstein, Sixth edition, John Wiley & Sons, 2004.
2. Principles of Instrumental Analysis by Douglas A Skoog, F. James Holler, Timothy A. Nieman, 5th edition, Eastern press, Bangalore, 1998.
3. Textbook of Pharmaceutical Analysis by KA. Connors, 3rd Edition, John Wiley & Sons, 1982.
4. Introduction to Spectroscopy by Pavia D.L., Lampman G.M. and Kriz G.S., Harcourt College Publishers, Philadelphia
5. Analytical Profile of Drug Substance (All volume) by Florey K., Academic Press, Elsevier, Massachusetts.
6. Thin Layer Chromatography: A Laboratory Handbook, Stahl E., Springer, Berlin.

Mode of Evaluation

MSE		**CA**				**ESE**	**Total**
MSE1	**MSE2**	**CA1**	**CA2**				
60	**60**	**2**	**(ATT)** **8**				
Converted to 15		**10**				**75**	**100**

Course Code: MQA102T	Course Name: Quality Management Systems	L	T	P	C
Course Offered in: KIET School of Pharmacy		4	0	0	4

Pre-requisite: NA

Course Objectives: Upon completion of the course, students shall be able to understand:

- The importance of quality.
- ISO management systems.
- Tools for quality improvement.
- Analysis of issues in quality.
- Quality evaluation of pharmaceuticals.
- Stability testing of drug and drug substances.
- Statistical approaches for quality.

Course Outcome: After completion of the course, the student will be able to

1. Understand concepts & objectives of Quality Management Systems.
2. Apply the basics of inspection models of Quality Management system viz. ISO 9001:2008, 9001:2015, ISO 14001:2004– ICH Q10, OSHAS guidelines, NABL, CFR-21 part 11, WHO-GMP.
3. Validate the Six System Inspection model and its applications.
4. Validate the ICH guidelines for stability testing of drug substances and drug products.
5. Audit for Quality Assurance, Engineering Departments and its maintenance.

CO-PO Mapping (Scale 1: Low, 2: Medium, 3: High)

CO-PO Mapping	PO1	PO2	PO3	PO4	PO5	PO6
CO1	-	1	3	1	2	-
CO2	3	3	2	2	1	1
CO3	2	2	2	2	1	-
CO4	3	2	3	3	-	-
CO5	3	2	3	2	-	-

Unit 1	Introduction to Quality	12 hours

Introduction to Quality: Evolution of quality, definition of quality, dimensions of quality.
Quality as a Strategic Decision: Meaning of strategy and strategic quality management, mission and vision statements, quality policy, quality objectives, strategic planning and implementation, McKinsey 7s model, competitive analysis, management commitment to quality.
Customer Focus: Meaning of customer and customer focus, classification of customers, customer focus, customer perception of quality, factors affecting customer perception, customer requirements, meeting customer needs and expectations, customer satisfaction and customer delight, handling customer complaints, understanding customer behavior, concept of internal and external customers. Case studies. Cost of quality: Categories of cost of quality, models of cost of quality, optimizing costs, preventing cost of quality.

Unit 2	Pharmaceutical Quality Management	12 hours

Basics of quality management, total quality management (TQM), principles of six sigma, ISO 9001:2008, 9001:2015, ISO 14001:2004. Pharmaceutical quality management– ICH Q10, knowledge management, quality metrics, operational excellence and quality management review. OSHAS Guidelines, NABL certification and accreditation, CFR-21 part 11, WHO-GMP requirements.

Unit 3	Six System Inspection Model	12 hours

Six System Inspection Model: Quality management system, production system, facility and equipment system, laboratory control system, materials system, packaging and labeling system. Concept of self-inspection. Quality systems: Change Management/ change control. Deviations, Out of specifications (OOS), out of trend (OOT), Complaints: Evaluation and handling, investigation and determination of root cause, corrective & preventive actions (CAPA), returns and recalls, vendor qualification, annual product reviews, batch review and batch release. concept of IPQC, area clearance/ line clearance.

Unit 4	Drug Stability and Quality risk management	12 hours

Drug Stability: ICH guidelines for stability testing of drug substances and drug products. Study of ICH Q8, quality by design and process development report.
Quality risk management: Introduction, risk assessment, risk control, risk review, risk management tools, HACCP, risk ranking and filtering according to ICH Q9 guidelines.

Unit 5	SPC and Regulatory Compliance through Quality Management and development of Quality Culture Benchmarking	12 hours

Statistical Process Control (SPC): Definition and importance of SPC, quality measurement in manufacturing, statistical control charts: Concepts and general aspects, advantages of statistical control, process capability, estimating inherent or potential capability from a control chart analysis, measuring process control and quality improvement, pursuit of decreased process variability.

Regulatory Compliance through Quality Management and development of Quality Culture Benchmarking: Definition of benchmarking, reasons for benchmarking, types of benchmarking, benchmarking process, advantages of benchmarking, limitations of benchmarking.

Total Lecture Hours	60 hours

Textbook:

1. Organizing for High Performance: Employee Involvement, TQM, Reengineering, and Knowledge Management in the Fortune 1000: The CEO Report by Edward E. Lawler; Susan Albers Mohrman; George Benson, Jossey-Bass, 2001.
2. Corporate Culture and the Quality Organization by James W. Fairfield-Sonn, Quorum Books, 2001
3. The Quality Management Sourcebook: An International Guide to Materials and Resources By Christine Avery; Diane Zabel, Routledge, 1997.
4. The Quality Toolbox, Second Edition, Nancy R. Tague, ASQ Publications.
5. Juran's Quality Handbook, Sixth Edition, Joseph M. Juran and Joseph A. De Feo, ASQ Publications.
6. Root Cause Analysis, The Core of Problem Solving and Corrective Action, Duke Okes, 2009, ASQ Publications.

Reference Books:

1. Implementing Juran's Road Map for Quality Leadership: Benchmarks and Results, By Al Endres, Wiley, 2000.
2. Understanding, Managing and Implementing Quality: Frameworks, Techniques and Cases, By Jiju Antony; David Preece, Routledge, 2002.

Mode of Evaluation

MSE		CA				ESE	Total
MSE1 60	MSE2 60	CA1 2	CA2 (ATT) 8				
Converted to 15		10				75	100

Course Code: MQA103T	Course Name: Quality Control and Quality Assurance	L	T	P	C
Course Offered in: KIET School of Pharmacy		4	0	0	4

Pre-requisite: NA

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

- Understand the cGMP aspects in a pharmaceutical industry.
- To appreciate the importance of documentation.
- To understand the scope of quality certifications applicable to pharmaceutical industries.
- To understand the responsibilities of QA & QC departments.

Course Outcome: After completion of the course, the student will be able to

1. Understand the concepts of Quality Control, Quality Assurance and GLP Pharmaceutical Industry.
2. Apply the principles of cGMP in pharmaceutical manufacturing.
3. Analyze raw materials, finished products, and packaging materials utilizing in process quality control (IPQC) and finished product Quality control testing.
4. Illustrate the concept and submission procedure of various types of documents used in Pharmaceutical Industry.
5. Understand various manufacturing operations and controls in pharmaceutical manufacturing.

CO-PO Mapping (Scale 1: Low, 2: Medium, 3: High)

CO-PO Mapping	PO1	PO2	PO3	PO4	PO5	PO6
CO1	3	-	2	-	-	-
CO2	3	-	-	2	-	-
CO3	3	-	3	-	-	-
CO4	3	-	-	-	-	-
CO5	3	-	-	-	-	-

Unit 1	Quality Control and Quality Assurance	12 hours

Introduction: Concept and evolution and scopes of quality control and quality assurance, good laboratory practice, GMP, overview of ICH Guidelines - QSEM, with special emphasis on Q-series guidelines.
Good Laboratory Practices: Scope of GLP, definitions, quality assurance unit, protocol for conduct of non-clinical testing, control on animal house, report preparation and documentation. CPCSEA guidelines.

Unit 2	cGMP Guidelines	12 hours

cGMP Guidelines according to schedule M, USFDA (inclusive of CDER and CBER), pharmaceutical inspection convention (PIC), WHO and EMEA covering: Organization and personnel responsibilities, training, hygiene and personal records, drug industry location, design, construction and plant lay out, maintenance, sanitation, environmental control, utilities and maintenance of sterile areas, control of contamination and Good warehousing practice.

Unit 3	In process Quality control and Finished product Quality Control	12 hours

Analysis of raw materials, finished products, packaging materials, in process quality control (IPQC), developing specification (ICHQ6 and Q3), purchase specifications and maintenance of stores for raw materials. In process quality control and finished products quality control for following dosage forms in pharma industry according to Indian, US and British pharmacopoeias: tablets, capsules, ointments, suppositories, creams, parenterals, ophthalmic and surgical products (How to refer pharmacopoeias).

Unit 4	Documentation in Pharmaceutical Industry:	12 hours

Three tier documentation, policy, procedures and work instructions, and records (Formats). Basic principles- How to maintain, retention and retrieval etc. Standard operating procedures (How to write), master batch record, batch manufacturing record, quality audit plan and reports. Specification and test procedures, protocols and reports, distribution records, electronic data handling, concepts of controlled and uncontrolled documents. Submission documents for regulators DMFs as common technical document and electronic common technical documentation (CTD, eCTD). Concept of regulated and non regulated markets

Unit 5	Manufacturing Operations and Controls:	12 hours

Sanitation of manufacturing premises, mixups and cross contamination processing of intermediates and bulk products, packaging operations, IPQC, release of finished product, process deviations, charge-in of components, time limitations on production, drug product inspection, expiry date calculation, calculation of yields, production record review, change control, sterile products, aseptic process control, packaging, reprocessing, salvaging, handling of waste and scrap disposal. Introduction, scope and importance of intellectual property rights. Concept of trade mark, copyright and patents.

Total Lecture Hours	60 hours

Textbook:

1. Quality Assurance Guide by Organization of Pharmaceutical Procedures of India, 3rd revised edition, Volume I & II, Mumbai, 1996.
2. Good Laboratory Practice Regulations, 2nd Edition, Sandy Weinberg Vol. 69, Marcel Dekker Series, 1995.
3. Quality Assurance of Pharmaceuticals- A compedium of Guide lines and Related materials Vol I & II, 2nd edition, WHO Publications, 1999.
4. How to Practice GMP's – P P Sharma, Vandana Publications, Agra, 1991.
5. The International Pharmacopoeia – vol I, II, III, IV & V - General Methods of Analysis And Quality Specification for Pharmaceutical Substances, Excepients and Dosage forms, 3rd edition, WHO, Geneva, 2005.
6. Good laboratory Practice Regulations – Allen F. Hirsch, Volume 38, Marcel Dekker Series, 1989.

Reference Books:

1. ISO 9000 and Total Quality Management
2. The drugs and cosmetics act 1940 – Deshpande, Nilesh Gandhi, 4th edition, Susmit Publishers, 2006.
3. QA Manual- D.H. Shah, 1st edition, Business Horizons, 2000.
4. Good Manufacturing Practices for Pharmaceuticals a plan for total quality control – Sidney H. Willig, Vol. 52, 3rd edition, Marcel Dekker Series.
5. Steinborn L. GMP/ISO Quality Audit Manual for Healthcare Manufacturers and Their Suppliers, Sixth Edition, (Volume 1 - With Checklists and Software Package). Taylor & Francis; 2003.
6. Sarker DK. Quality Systems and Controls for Pharmaceuticals. John Wiley & Sons; 2008.
7. Schedule M and Schedule N.

Mode of Evaluation

MSE		CA				ESE	Total	
MSE1 60	MSE2 60	CA1 2	CA2 (ATT) 8					
Converted to 15		10				75	100	

Course Code: MQA104T	Course Name: Product Development and Technology Transfer	L	T	P	C
Course Offered in: KIET School of Pharmacy		4	0	0	4

Pre-requisite: NA

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

- To understand the new product development process.
- To understand the necessary information to transfer technology from R&D to actual manufacturing by sorting out various information obtained during R&D.
- To elucidate necessary information to transfer technology of existing products between various manufacturing places.

Course Outcome: After completion of the course, the student will be able t

1. Apply drug development principles to regulatory processes like IND, NDA, ANDA, sNDA, SUPAC, BACPC, and post-marketing surveillance.
2. Explore and analyze the properties of pre-formulation studies.
3. Evaluate and optimize pilot plant scale-up, manufacturing processes, and quality control strategies for dosage forms.
4. Evaluate packaging materials, systems, and quality control for various dosage forms and modern pharmaceutical needs
5. Apply technology transfer processes from R&D to production, including optimization, modeling, and documentation.

CO-PO Mapping (Scale 1: Low, 2: Medium, 3: High)

CO-PO Mapping	PO1	PO2	PO3	PO4	PO5	PO6
CO1	3	3	2	3	2	-
CO2	3	3	3	3	2	-
CO3	2	3	3	2	2	2
CO4	3	2	2	2	2	-
CO5	2	3	3	2	3	2

Unit 1	Principles of Drug Discovery and Development	12 hours

Introduction, clinical research process. Development and informational content for investigational new drugs application (IND), new drug application (NDA), abbreviated new drug application (ANDA), supplemental new drug application (SNDA), scale up post approval changes (SUPAC) and bulk active chemical post approval changes (BACPAC), post marketing surveillance, product registration guidelines – CDSCO, USFDA.

Unit 2	Pre-Formulation Studies	12 hours

Introduction/concept, organoleptic properties, purity, impurity profiles, particle size, shape and surface area. Solubility, methods to improve solubility of drugs: Surfactants & its importance, co-solvency. Techniques for the study of crystal properties and polymorphism. Pre-formulation protocol, stability testing during product development.

Unit 3	Pilot Plant Scale Up	12 hours

Concept, significance, design, layout of pilot plant scale up study, operations, large scale manufacturing techniques (formula, equipment, process, stability and quality control) of solids, liquids, semisolid and parenteral dosage forms. New era of drug products: Opportunities and challenges.

Unit 4	Pharmaceutical Packaging	12 hours

Pharmaceutical dosage form and their packaging requirements, pharmaceutical packaging materials, medical device packaging, enteral packaging, aseptic packaging systems, container closure systems, issues facing modern drug packaging, selection and evaluation of pharmaceutical packaging materials. Quality control test: Containers, closures and secondary packing materials.

Unit 5	Technology Transfer	12 hours

Development of technology by R & D, technology transfer from R & D to production, optimization and production, qualitative and quantitative technology models. Documentation in technology transfer: Development report, technology transfer plan and exhibit.

	Total Lecture Hours	60 hours

Textbooks

1. The Process of New Drug Discovery and Development. I and II Edition (2006) by Charles G. Smith, James T and O. Donnell. CRC Press, Group of Taylor and Francis.
2. Theory and Practice of Industrial Pharmacy by Leon Lac Lachman, Herbert A. Liberman. Marcel Dekker Inc. New York.
3. Good Manufacturing of Pharmaceuticals (A Plan for total quality control), Sidney H Willing, Murray M, Tuckerman. Williams Hitchings IV, 3rd Edition. Bhalani Publishing House Mumbai.

4. The Pharmaceutical Sciences; the Pharma Path way 'Pure and Applied Pharmacy' by D. A Sawant, Pragati Books Pvt. Ltd.

Reference Books

1. Tablets Vol. I, II, III by Leon Lachman, Herbert A. Liberman, Joseph B. Schwartz, 2nd Edn. (1989) Marcel Dekker Inc. New York.
2. Pharmaceutical Product Development by Vandana V. Patrevale. John I. Disouza. Maharukh T.Rustomji. CRC Press, Group of Taylor and Francis.
3. Pharmaceutical Packaging Technology by D.A. Dean. E.R. Evans, I.H. Hall. 1st Edition (Reprint 2006). Taylor and Francis. London and New York.

Mode of Evaluation

MSE		CA				ESE	Total	
MSE1 60	MSE2 60	CA1 2	CA2 8					
Converted to 15		10				75	100	

Course Code: MQA105P	Course Name: Pharmaceutical Quality Assurance Practical I	L	T	P	C
Course Offered in: KIET School of Pharmacy		0	0	12	6

Pre-requisite: NA

Course Objectives: This course aims to:

- This course imparts skill set in developing complex drug products, conventional and cosmetic formulations. Students will learn to design drug delivery systems based on theoretical concepts, develop prototypes at the nano/microscale, and conduct comparative studies using in silico and in vitro methods.
- It also covers the role of physicochemical characteristics of drugs and excipients in formulation development, optimization, evaluation, and stability studies. Students will learn analytical techniques for drug quantification, characterization, and quality control of pharmaceutical products. Students will get hands-on training in in silico methods to optimize pharmaceutical processes.
- The course also trains students in formulation of cosmetic products and its evaluation. The course equips students in computing pharmacokinetic parameters using various compartment models. The dissolution behavior of drugs and the release mechanisms are also covered in the subject. The experiments are designed in such a way that the students get an understanding of the concepts of miniaturization of delivery systems and complex pharmaceuticals.

Course Outcome: After completion of the course, the student will be able to

1. Perform the quantitative analysis of pharmacopoeial compounds and formulations using UV-Vis spectrophotometry, fluorimetry, flame photometry/AAS, HPLC, and GC techniques.
2. Evaluate multi-drug formulations and carry out pre-formulation studies, including solubility enhancement, determination of pKa and Log P, and the effect of pH on drug solubility.
3. Conduct quality control tests for raw materials, in-process materials, and finished pharmaceutical dosage forms, including tablets, capsules, parenterals, and semisolids, as per official standards.
4. Apply stability testing principles, including accelerated stability studies, and develop stability study protocols to assess product shelf-life and safety.
5. Analyze quality management systems through case studies on TQM, Six Sigma, OOS, OOT, CAPA, and perform process capability estimation and packaging material quality control.

CO-PO Mapping (Scale 1: Low, 2: Medium, 3: High)

CO-PO Mapping	PO1	PO2	PO3	PO4	PO5	PO6
CO1	3	2	3	3	3	1
CO2	3	2	3	3	3	1
CO3	3	2	3	3	3	1

List of Experiments (Indicative & not limited to)

1. Analysis of Pharmacopoeial compounds in bulk and in their formulations (tablet/ capsules/ semisolids) by UV Vis spectrophotometer
2. Simultaneous estimation of multi-drug component containing formulations by UV spectrophotometry
3. Experiments based on HPLC
4. Experiments based on Gas Chromatography
5. Estimation of riboflavin/quinine sulphate by fluorimetry
6. Estimation of sodium/potassium by flame photometry or AAS
7. Case studies on
   - Total Quality Management
   - Six Sigma
   - Change Management/ Change control. Deviations,
   - Out of Specifications (OOS)
   - Out of Trend (OOT)
   - Corrective & Preventive Actions (CAPA)
   - Deviations
8. Development of Stability study protocol

9. Estimation of process capability
10. In process and finished product quality control tests for tablets, capsules, parenterals and semisolid dosage forms.
11. Assay of raw materials as per official monographs
12. Testing of related and foreign substances in drugs and raw materials
13. To carry out pre formulation study for tablets, parenterals (2 experiment).
14. To study the effect of pH on the solubility of drugs, (1 experiment)
15. Quality control tests for Primary and secondary packaging materials
16. Accelerated stability studies (1 experiment)
17. Improved solubility of drugs using surfactant systems (1 experiment)
18. Improved solubility of drugs using co-solvency method (1 experiment)
19. Determination of Pka and Log p of drugs.

Total Lecture Hours: 12 hrs./week

Textbook/ Reference Books:

1. Y Chien, Novel Drug Delivery Systems, 2nd Edn, revised and expanded, Taylor and Francis, Marcel Dekker, Inc., New York, 1992.
2. Shargel, S. Wu-Pong, A. Yu, Applied biopharmaceutics and pharmacokinetics. 7th Edn., Connecticut Appleton Century Crofts, 1985
3. Swarbrick, J. G. Boylan, Encyclopedia of Pharmaceutical Technology, Vol 13, Ist Edn., Marcel Dekker Inc, Taylor & Francis, New York, 1996.
4. Donbrow, Microcapsules and Nanoparticles in Medicine and Pharmacy, CRC Press, 2020.
5. S. Kwon, M. M. de Villiers, P. Aramwit, Nanotechnology in Drug Delivery, Ist Edn., Springer, New York, 2009.
6. L. Wise, R. S. Langer, Medical Applications of Controlled Release, Ist Edn., CRC Press, 2019.
7. Li, B. R. Jasti, Design of Controlled Release Drug Delivery Systems, Ist Edn., McGraw-Hill Education, 2005.

Mode of Evaluation

MSE		CA			ESE	Total
MSE1 30	MSE2 30	CA1 -	CA2 10	CA3 (ATT) 10		
Avg. of MSE1 & MSE2 and converted to 30		20			100	150

Course Code: MQA1 305	Course Name: Soft Skills	L	T	P	C
Course Offered in: KIET School of Pharmacy		1	0	0	NC

Pre-requisite: NA

Course Objectives: This course aims to:

- Enhance communication, interpersonal, and professional skills essential for effective collaboration in healthcare and research environments.
- It also focuses on developing leadership, time management, and problem-solving abilities to prepare students for diverse roles in the pharmaceutical industry and academia.

Course Outcome: After completion of the course, the student will be able to

1. Express themselves well in professional contexts.
2. Enhance their employability quotient.

CO-PO Mapping (Scale 1: Low, 2: Medium, 3: High)

CO-PO Mapping	PO1	PO2	PO3	PO4	PO5	PO6
CO1	-	2	-	-	3	3
CO2	-	2	-	-	3	3

S. No.	Topic Covered	Suggested Activity	Objective of Activity	No. of Hours
1	The ABCDP of Soft Skills	Tagging themselves with an apt adjective	Enhancing self-awareness	1
2	Creating a Professional Introduction using F-B analysis	Writing & narration of the professional introduction	Introduce themselves in formal contexts	1
3	4Ts of GD	GD Sessions	Awareness & Group Dynamics	2
4	Case-based GDs	Team presentations on VUCA, BANI, RUPT, TUNA	Coping with change by enhancing cognitive flexibility (critical thinking & problem-solving)	2
5	Formal Writing	Paragraph writing on topics related to the healthcare/pharma sector	To enhance creativity and written expression abilities	1
6	Image Building	Resume - Traditional & ATS, LinkedIn Profile, E-portfolio	Networking and personal branding	1
7	4Ts of Interview	Mock Interview	Preparing for recruitment interviews	4
8	Public Speaking	JAM/Extempore	To enhance - Communication & Confidence	1
9	Presentation Skills	Individual presentations on topics related to the healthcare/pharma sector	To enhance - Content, communication, & confidence	2
Total number of hours				15

Note: As per the number of weeks available during this semester - common to all three specializations - QA, Pharmacology, and Pharmaceutics

Course Outcomes: The students will be able to -
1) express themselves well in professional contexts
2) enhance their employability quotient

Assessment/Evaluation Methodology: MSE (10 marks) - based on formal introduction; ESE (40 marks) - 20 marks for the interview, 10 marks for the Resume and 10 marks for the presentation.

Course Code: MQA201T	Course Name: Hazards And Safety Management	L	T	P	C
Course Offered in: KIET School of Pharmacy		4	0	0	4

Pre-requisite: NA

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

- Understand about environmental problems among learners.
- Impart basic knowledge about the environment and its allied problems.
- Develop an attitude of concern for the industry environment.
- Ensure safety standards in pharmaceutical industry
- Provide comprehensive knowledge on the safety management.
- Empower ideas to clear mechanism and management in different kinds of hazard management system.
- Teach the method of hazard assessment, procedure, methodology for provide safe industrial atmosphere.

Course Outcome: After completion of the course, the student will be able to

1. Illustrate the multidisciplinary nature of environmental studies and ecosystem.
2. Explore the air-based hazards.
3. Demonstrate the chemical-based hazards.
4. Illustrate the fire and explosion.
5. Review the hazard and risk Management.

CO-PO Mapping (Scale 1: Low, 2: Medium, 3: High)

CO-PO Mapping	PO1	PO2	PO3	PO4	PO5	PO6
CO1	2	2	2	3	2	2
CO2	2	2	2	3	2	2
CO3	2	2	2	3	2	2
CO4	2	2	2	3	2	2
CO5	2	2	2	3	2	2

Unit 1	Multidisciplinary Nature of Environmental Studies	12 hours

Natural resources, renewable and non-renewable resources, natural resources and associated problems, a) Forest resources; b) Water resources; c) Mineral resources; d) Energy resources; e) Land resources Ecosystems: Concept of an ecosystem and structure and function of an ecosystem. Environmental hazards: Hazards based on air, water, soil and radioisotopes.

Unit 2	Air Based Hazards	12 hours

Air Based Hazards: Sources, types of hazards, air circulation maintenance industry for sterile area and non-sterile area, preliminary hazard analysis (PHA). Fire protection system: Fire prevention, types of fire extinguishers and critical hazard management system

Unit 3	Chemical Based Hazards	12 hours

Sources of chemical hazards, hazards of organic synthesis, sulphonating hazard, organic solvent hazard, control measures for chemical hazards, management of combustible gases, toxic gases and oxygen displacing gases management, regulations for chemical hazard, management of over-exposure to chemicals and TLV concept..

Unit 4	Fire and Explosion	12 hours

Introduction, industrial processes and hazards potential, mechanical electrical, thermal and process hazards. Safety and hazards regulations. Fire protection system: Fire prevention, types of fire extinguishers and critical hazard management system mechanical and chemical explosion, multiphase reactions, transport effects and global rates. Preventive and protective management from fires and explosion electricity passivation, ventilation, and sprinkling, proofing, relief systems -relief valves, flares, scrubbers.

Unit 5	Hazard and Risk Management	12 hours

Hazard and Risk Management: Self-protective measures against workplace hazards. Critical training for risk management, process of hazard management, ICH guidelines on risk assessment and risk management methods and tools. Factory act and rules, fundamentals of accident prevention, elements of safety programme and safety management, physicochemical measurements of effluents, BOD, COD, determination of some contaminants, effluent treatment procedure, role of emergency services.

Total Lecture Hours	60 hours

Textbook:

1. Environmental Science, Y.K. Singh, New Age International Pvt, Publishers, Bangalore.

2. "Quantitative Risk Assessment in Chemical Process Industries" American Institute of Chemical Industries, Centre for Chemical Process safety

Reference Books:

1. The Biodiversity of India, Bharucha Erach, Mapin Pu blishing Pvt. Ltd., Ahmedabad – 380 013, India.
2. Hazardous Chemicals: Safety Management and Global Regulations, T.S.S. Dikshith, CRC Press.

Mode of Evaluation

MSE		CA					ESE	Total	
MSE1 60	MSE2 60	CA1 2	CA2 (ATT) 8						
Converted to 15		10					75	100	

Course Code: MQA202T	Course Name: Pharmaceutical Validation	L	T	P	C
Course Offered in: KIET School of Pharmacy		4	0	0	4

Pre-requisite: NA

Course Objectives:

- The concepts of calibration, qualification and validation.
- The qualification of various equipments and instruments.
- Process validation of different dosage forms and validation of analytical method for estimation of drugs.
- Validation of analytical method for estimation of drugs.
- Cleaning validation of equipments employed in the manufacture of pharmaceuticals.

Course Outcome: After completion of the course, the student will be able to

1. Apply the concept of pharmaceutical validation, calibration, qualification and its related aspects including VMP.
2. Analyze the qualification of various manufacturing and laboratory equipments.
3. Evaluate the concept, process & documentation of process validation and analytical method validation, & computerized system validation.
4. Evaluate the cleaning method development, & validation of analytical method used in cleaning.
5. Portray the concepts of Intellectual Property Right.

CO-PO Mapping (Scale 1: Low, 2: Medium, 3: High)

CO-PO Mapping	PO1	PO2	PO3	PO4	PO5	PO6
CO1	-	3	3	2	3	2
CO2	-	3	3	2	-	2
CO3	-	3	3	2	-	2
CO4	3	3	3	3	3	2
CO5	3	3	3	3	3	2

Unit 1	Introduction to Validation	10 hours

Introduction to Validation: Definition of calibration, qualification and validation, scope, frequency and importance. Difference between calibration and validation. Calibration of weights and measures. Advantages of validation, scope of validation, organization for validation, validation master plan, types of validation, streamlining of qualification & validation process and validation master plan.

Qualification: User requirement specification, design qualification, factory acceptance test (FAT)/site acceptance test (SAT), installation qualification, operational qualification, performance qualification, re-qualification (maintaining status- calibration preventive maintenance, change management).

Unit 2	Qualification of Manufacturing Equipment	10 hours

Dry powder mixers, fluid bed and tray dryers, tablet compression (Machine), dry heat sterilization/tunnels, autoclaves, membrane filtration, capsule filling machine. qualification of analytical instruments: UV-Visible spectrophotometer, FTIR, DSC, GC, HPLC, HPTLC, LC-MS.

Unit 3	Qualification of Laboratory Equipments	10 hours

Hardness tester, friability test apparatus, tap density tester, disintegration tester, dissolution test apparatus. Validation of utility systems: Pharmaceutical water system &pure steam, HVAC system, compressed air and nitrogen.

Unit 4	Process Validation	10 hours

Concept, process and documentation of process validation. Prospective, concurrent & retrospective validation, revalidation criteria, process validation of various formulations (Coated tablets, capsules, ointment/creams, liquid orals and aerosols.), aseptic filling: Media fill validation, USFDA guidelines on process validation- A life cycle approach.

Analytical Method Validation: General principles, validation of analytical method as per ICH guidelines and USP.

Unit 5	Cleaning Validation	10 hours

Cleaning method development, validation of analytical method used in cleaning, cleaning of equipment, cleaning of facilities. Cleaning in place (CIP). Validation of facilities in sterile and non-sterile plant.

Computerized System Validation: Electronic records and digital signature - 21 CFR Part 11 and GAMP

Unit 6	General Principles of Intellectual Property	10 hours

Concepts of intellectual property (IP), intellectual property protection (IPP), and intellectual property rights (IPR), economic importance, mechanism for protection of intellectual property- Patents, copyright, trademark. Factors affecting choice of IP protection; Penalties for violation, role of IP in pharmaceutical industry; global ramification and financial implications. Filing a patent application, patent application forms and guidelines. Types patent applications-provisional and non-provisional, PCT

and convention patent applications, international patenting requirement procedures and costs, rights and responsibilities of a patentee, practical aspects regarding maintaining of a patent file, patent infringement meaning and scope. Significance of transfer technology (TOT), IP and ethics-positive and negative aspects of IPP, societal responsibility, avoiding unethical practices

Total Lecture Hours	**60 hours**

Textbook:

1. Pharmaceutical Process Validation, B. T. Loftus & R. A. Nash, Drugs and Pharm Sci. Series, Vol. 129, 3rd Ed., Marcel Dekker Inc., N.Y.
2. The Theory & Practice of Industrial Pharmacy, 3rd edition, Leon Lachman, Herbert A. Lieberman, Joseph. L. Karig, Varghese Publishing House, Bombay.
3. Analytical Method validation and Instrument Performance Verification by Churg Chan, Heiman Lam, Y.C. Lee, Yue. Zhang, Wiley Interscience.
4. Validating Corporate Computer Systems: Good IT Practice for Pharmaceutical Manufacturers. Wingate G. Interpharm Press.

Reference Books:

1. Validation Master Plan by Terveeks or Deeks, Davis Harwood International Publishing.
2. Pharmaceutical Equipment Validation: The Ultimate Qualification Handbook, Phillip A. Cloud, Interpharm Press.

Mode of Evaluation

MSE		CA					ESE	Total	
MSE1 60	MSE2 60	CA1 2	CA2 (ATT) 8						
Converted to 15		10					75	100	

Course Code: MQA203T	Course Name: Audits and Regulatory Compliance	L	T	P	C
Course Offered in: KIET School of Pharmacy		4	0	0	4

Pre-requisite: NA

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

- To understand the importance of auditing.
- To understand the methodology of auditing.
- To carry out the audit process.
- To prepare the auditing report.
- To prepare the check list for auditing.

Course Outcome: After completion of the course, the student will be able to

1. Elaborate concepts & objectives, management of audit, responsibilities, planning process, information gathering, administration, classifications of deficiencies.
2. Analyze role of Quality Systems and audits in Pharmaceutical Manufacturing Environment cGMP Regulations, Quality assurance functions, Quality systems approach, Management responsibilities, Resource, Manufacturing operations, Evaluation activities, Transitioning to quality system approach, Audit checklist for drug industries.
3. Document bulk pharmaceutical chemicals and packaging material vendor audit, warehouse and weighing, dry production: Granulation, tableting, coating, capsules, sterile production and packaging.
4. Audit the manufacturing process, product and process information, general areas of interest in the building raw materials, water, packaging materials.
5. Validate Quality Assurance and Engineering Department & Quality assurance maintenance, critical systems.

CO-PO Mapping (Scale 1: Low, 2: Medium, 3: High)

CO-PO Mapping	PO1	PO2	PO3	PO4	PO5	PO6
CO1	3	2	3	1	1	-
CO2	3	2	3	2	1	-
CO3	3	2	3	2	1	-
CO4	3	2	3	3	1	-
CO5	3	2	3	2	1	-

Unit 1	**Introduction to Audit**	**12 hours**
Objectives, management of audit, responsibilities, planning process, information gathering, administration, classifications of deficiencies		
Unit 2	**Role of Quality Systems and Audits in Pharmaceutical Manufacturing Environment**	**12 hours**
cGMP Regulations, Quality assurance functions, Quality systems approach, Management responsibilities, Resource, Manufacturing operations, Evaluation activities, Transitioning to quality system approach, Audit checklist for drug industries		
Unit 3	**Auditing of Vendors and Production Department**	**12 hours**
Bulk pharmaceutical chemicals and packaging material vendor audit, warehouse and weighing, dry production: Granulation, tableting, coating, capsules, sterile production and packaging.		
Unit 4	**Auditing of Microbiological Laboratory**	**12 hours**
Auditing the manufacturing process, product and process information, general areas of interest in the building raw materials, water, packaging materials.		
Unit 5	**Auditing of Quality Assurance and Engineering Department**	**12 hours**
Quality assurance maintenance, critical systems: HVAC, water, water for injection systems, ETP		
	Total Lecture Hours	**60 hours**

Textbook:

1. Pharmaceutical Manufacturing Handbook, Regulations and Quality by Shayne Cox Gad. Wiley- Interscience, A John Wiley and sons, Inc., Publications.
2. Handbook of microbiological Quality control. Rosamund M. Baird, Norman A.Hodges, Stephen P. Denyar. CRC Press. 2000.
3. Laboratory auditing for quality and regulatory compliance. Donald C. Singer, Raluca-loana Stefan, Jacobus F. Van Staden. Taylor and Francis (2005).

Reference Books:

1. Compliance auditing for Pharmaceutical Manufacturers. Karen Ginsbury and Gil Bismuth,
2. Interpharm/CRC, Boca Raton, London New York,Washington D.C.

Mode of Evaluation

MSE		CA				ESE	Total
MSE1 60	MSE2 60	CA1 2	CA2 (ATT) 8				
Converted to 15		10				75	100

Course Code: MQA204T	Course Name: Pharmaceutical Manufacturing Technology	L	T	P	C
Course Offered in: KIET School of Pharmacy		4	0	0	4

Pre-requisite: NA

Course Objectives: At completion of this course, it is expected that students will be able to understand

- The common practice in the pharmaceutical industry developments, plant layout and production planning.
- Will be familiar with the principles and practices of aseptic process technology, non-sterile manufacturing technology and packaging technology.
- Have a better understanding of principles and implementation of quality by design (QbD) and process analytical technology (PAT) in pharmaceutical manufacturing.

Course Outcome: After completion of the course, the student will be able to

1. Elaborate common practice in the pharmaceutical industry developments, plant layout and production planning.
2. Acquire the knowledge of practices of aseptic process technology, sterile manufacturing technology
3. Acquire the knowledge of practices of non-sterile manufacturing technology and coating technology
4. Elaborate the practices of packaging technology
5. Analyze quality by design (QbD) and process analytical technology (PAT) in pharmaceutical manufacturing.

CO-PO Mapping (Scale 1: Low, 2: Medium, 3: High)

CO-PO Mapping	PO1	PO2	PO3	PO4	PO5	PO6
CO1	2	2	3	2	3	2
CO2	2	2	3	2	3	2
CO3	2	2	3	2	3	2
CO4	1	-	3	-	2	1
CO5	3	2	3	3	3	1

Unit 1 **Pharmaceutical Industry Developments** **12 hours**

Legal requirements and licenses for API and formulation industry, Plant location-Factors influencing. Plant Layout: Factors influencing, special provisions, storage space requirements, sterile and aseptic area layout. Production planning: General principles, production systems, calculation of standard cost, process planning, routing, loading, scheduling, dispatching of records, production control.

Unit 2 **Aseptic Process Technology** **12 hours**

Manufacturing, manufacturing flowcharts, in process-quality control tests for following sterile dosage forms: Ointment, suspension and emulsion, dry powder, solution (Small volume & large volume).
Advanced Sterile Product Manufacturing Technology: Area planning & environmental control, wall and floor treatment, fixtures and machineries, change rooms, personnel flow, utilities & utilities equipment location, engineering and maintenance.
Process Automation in pharmaceutical industry: With specific reference to manufacturing of sterile semisolids, small volume parenterals & large volume parenterals (SVP & LVP), monitoring of parenteral manufacturing facility, cleaning in place (CIP), sterilization in place (SIP), prefilled syringe, powdered jet, needle free injections, and form fill seal technology (FFS).
Lyophilization Technology: Principles, process, equipment.

Unit 3 **Non-Sterile Manufacturing Process Technology, Coating Technology** **12 hours**

Manufacturing, manufacturing flowcharts, in process-quality control tests for following non-Sterile solid dosage forms: Tablets (Compressed & coated), capsules (Hard & soft).
Advance Non-Sterile Solid Product Manufacturing Technology: Process automation in pharmaceutical industry with specific reference to manufacturing of tablets and coated products, improved tablet production: Tablet production process, granulation and pelletization equipments, continuous and batch mixing, rapid mixing granulators, rota granulators, spheronizers and marumerisers, and other specialized granulation and drying equipments. Problems encountered.
Coating Technology: Process, equipments, particle coating, fluidized bed coating, and application techniques. Problems encountered.

Unit 4 **Containers and Closures for Pharmaceuticals** **12 hours**

Types, performance, assuring quality of glass; types of plastics used, drug plastic interactions, biological tests, modification of plastics by drugs, different types of closures and closure liners, film wrapper, blister packs, bubble packs, shrink packaging, foil /plastic pouches, bottle seals, tape seals, breakable seals and sealed tubes, quality control of packaging material and filling equipment, flexible packaging, product package compatibility, transit worthiness of package, stability aspects of packaging. Evaluation of stability of packaging material.

Unit 5	Quality by Design (Qbd) and Process Analytical Technology (PAT)	12 hours
Current approach and its limitations. Why QbD is required, advantages, elements of QbD, terminology: QTPP. CMA, CQA, CPP, RLD, design space, design of experiments, risk assessment and mitigation/minimization. Quality by design, formulations by design, QbD for drug products, QbD for drug substances, QbD for excipients, Aanalytical QbD. FDA initiative on process analytical technology. PAT as a driver for improving quality and reducing costs: Quality by design (QbD), QA, QC and GAMP. PAT guidance, standards and regulatory requirements.		
	Total Lecture Hours	**60 hours**

Textbook:

1. The theory and Practice of Industrial Pharmacy, Lachman L, Lieberman HA, Kanig JL. 3rded., Varghese Publishers, Mumbai 1991.
2. Sinko PJ. Martin's Physical Pharmacy and Pharmaceutical Sciences, 5th ed., B.I. Publications Pvt. Ltd, Noida, 2006.
3. Pharmaceutical Dosage Forms: Tablets, Lieberman HA, Lachman L, Schwartz JB. Vol. I-III, 2 nd ed., CBS Publishers & distributors, New Delhi, 2005.
4. Modern Pharmaceutics, Banker GS, Rhodes CT. 4th ed., Marcel Dekker Inc, New York, 2005.
5. Good Manufacturing of Pharmaceuticals (A Plan for total quality control), Sidney H Willing, MurrayM, Tuckerman. Williams Hitchings IV, 3rd Edition. Bhalani Publishing House Mumbai
6. Indian Pharmacopoeia. Controller of Publication. Delhi, 1996.

Reference Books:

1. British Pharmacopoeia. British Pharmacopoeia Commission Office, London, 2008.
2. United States Pharmacopoeia. United States Pharmacopeial Convention, Inc, USA, 2003.
3. Pharmaceutical Packaging Technology, Dean D A, Evans E R and Hall I H. London, Taylor & Francis, 1st Edition. UK.
4. Pharmaceutical Packaging Handbook. Edward J Bauer. 2009. Informa Health care USA Inc. New York.
5. Pharmaceutical Manufacturing Handbook. Shaybe Cox Gad. John Willey and Sons, New Jersey, 2008.

Mode of Evaluation

MSE		CA				ESE	Total
MSE1	MSE2	CA1	CA2 (ATT)				
60	60	2	8				
Converted to 15		10				75	100

Course Code: MQA205P	Course Name: Pharmaceutical Quality Assurance Practical – II	L	T	P	C
Course Offered in: KIET School of Pharmacy		0	0	12	6

Pre-requisite: NA

Course Objectives: After completion of course, student is able to know:

- To develop competence in the detection, quantification, and analysis of contaminants (organic, metallic, microbial, and environmental) using advanced analytical techniques such as HPLC, TLC, flame photometry, and colorimetry, ensuring regulatory compliance in pharmaceutical manufacturing.
- To impart hands-on training in the qualification and validation of pharmaceutical equipment, analytical instruments, and processing areas, following Good Manufacturing Practices (GMP) and industry standards for equipment like autoclaves, tablet compression machines, and testing apparatus.
- To enhance understanding of regulatory expectations through the preparation and evaluation of checklists for bulk drug vendors, sterile and non-sterile production areas, tableting, and water systems, aligning with WHO, ICH, and FDA guidelines.
- To integrate Quality by Design (QbD) and Process Analytical Technology (PAT) principles into case-based learning, fostering critical thinking and application of quality assurance tools in real-world pharmaceutical development and production scenarios.

Course Outcome: After completion of the course, the student will be able to

1. Perform analysis of organic and metallic contaminants and environmental pollutants using techniques such as HPLC, flame photometry, TLC, and colorimetric methods.
2. Conduct qualification and validation of pharmaceutical equipment (e.g., autoclave, tablet compression machine) and analytical instruments as per regulatory standards.
3. Validate analytical methods, processing areas, and cleaning procedures to ensure compliance with Good Manufacturing Practices (GMP).
4. Develop and implement checklists for pharmaceutical operations, including vendor qualification, tableting, sterile production, and water for injection systems.
5. Apply concepts of Quality by Design (QbD) and Process Analytical Technology (PAT) through case studies and design plant layouts for sterile and non-sterile manufacturing.

CO-PO Mapping (Scale 1: Low, 2: Medium, 3: High)

CO-PO Mapping	PO1	PO2	PO3	PO4	PO5	PO6
CO1	3	3	3	3	3	1
CO2	3	2	3	2	3	1
CO3	-	2	2	3	3	1
CO4	2	3	3	2	3	1
CO5	3	3	3	3	3	1

List of Experiments (Indicative & not limited to)

1. Organic contaminants residue analysis by HPLC
2. Estimation of Metallic contaminants by Flame photometer
3. Identification of antibiotic residue by TLC
4. Estimation of Hydrogen Sulphide in Air
5. Estimation of Chlorine in Work Environment.
6. Sampling and analysis of SO2 using Colorimetric method
7. Qualification of following Pharma equipment
   a. Autoclave
   b. Hot air oven
   c. Powder Mixer (Dry)
   d. Tablet Compression Machine
8. Validation of an analytical method for a drug
9. Validation of a processing area
10. Qualification of at least two analytical instruments
11. Cleaning validation of one equipment
12. Qualification of Pharmaceutical Testing Equipment (Dissolution testing apparatus, Friability Apparatus, Disintegration Tester)
13. Check list for Bulk Pharmaceutical Chemicals vendors
14. Check list for tableting production.

15. Check list for sterile production area
16. Check list for Water for injection.
17. Design of plant layout: Sterile and non-sterile
18. Case study on application of QbD
19. Case study on application of PAT

Total Practical Hours: 12/week

Reference Books:

1. Y Chien, Novel Drug Delivery Systems, 2nd Edn, revised and expanded, Taylor and Francis, Marcel Dekker, Inc., New York, 1992.
2. Shargel, S. Wu-Pong, A. Yu, Applied biopharmaceutics and pharmacokinetics. 7th Edn., Connecticut Appleton Century Crofts, 1985
3. Swarbrick, J. G. Boylan, Encyclopedia of Pharmaceutical Technology, Vol 13, Ist Edn., Marcel Dekker Inc, Taylor & Francis, New York, 1996.
4. Donbrow, Microcapsules and Nanoparticles in Medicine and Pharmacy, CRC Press, 2020.
5. S. Kwon, M. M. de Villiers, P. Aramwit, Nanotechnology in Drug Delivery, Ist Edn., Springer, New York, 2009.
6. L. Wise, R. S. Langer, Medical Applications of Controlled Release, Ist Edn., CRC Press, 2019.
7. Li, B. R. Jasti, Design of Controlled Release Drug Delivery Systems, Ist Edn., McGraw-Hill Education, 2005.

Mode of Evaluation

MSE		CA				ESE	Total
MSE1 30	MSE2 30	CA1	CA2 10	CA3 (ATT) 10			
Average of MSE1 & MSE2 30		20				100	150

Annexure-1

Course Evaluation Structure

The evaluation of the M. Pharm Pharmaceutical Quality Assurance course consists of both theory and lab assessments. The assessments are divided into multiple components as outlined below.

Theory Evaluation Plan

1.Continuous Assessment (CA) of MQA101T, MQA102T, MQA103T, MQA104T, MQA201T, MQA202T, MQA203T, MQA204T - Total Marks: 10

- CA-1: 2 Marks (Based on Assignment/Quiz/Class test/Presentation/GD/Seminar)
- CA-2: 8 Marks (Based on attendance)

2.Mid-Semester and End-Semester Evaluations of MQA101T, MQA102T, MQA103T, MQA104T, MQA201T, MQA202T, MQA203T, MQA204T - Total Marks: 25 Internal, 75 External

- MSE-1: 60 Marks
- MSE-2: 60 Marks } Average of MSE and converted to 15 marks
- CA: 10 Marks (Based on continuous assessment)
- ESE: 75 Marks (externally evaluated)

Practical Evaluation Plan

1.Continuous Assessment (CA) of MQA105P & MQA205P - Total Marks: 20

- CA-1: NA
- CA-2: 10 Marks (Regular lab activities, Quiz, Viva and Lab work)
- CA-3: 10 Marks (Based on attendance)

2. Internal and External Marks Distribution of MQA105P & MQA205P: 50 + 100 = 150 Marks

- MSE-1: 30 Marks
- MSE-2: 30 Marks } Average of MSE1 and MSE2 30 marks
- CA: 20 Marks
- External: 100 Marks (Practical ESE)