SARDAR PATEL UNIVERSITY
Vallabh Vidyanagar, Gujarat
(Reaccredited with 'A' Grade by NAAC (CGPA 3.25)
Syllabus with effect from the Academic Year 2021-2022

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

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 - I	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.

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	MQA101T	Modern Pharmaceutical Analytical Techniques	T	4	3	25	75	100/50
Employability, Entrepreneurship	MQA102T	Quality Management System	T	4	3	25	75	100/50
Employability, Entrepreneurship	MQA103T	Quality Control and Quality Assurance	T	4	3	25	75	100/50
Employability, Entrepreneurship	MQA104T	Product Development and Technology Transfer	T	4	3	25	75	100/50
Employability, Entrepreneurship, Skill development	MQA105P	Pharmaceutical Quality Assurance Practical I	P	6	6	50	100	150/75
Employability, Skill development	MQA106S	Seminar/ Assignment	-	4	-	-	-	100/50
				26		150	400	**650/325**

Master of Pharmacy
M. Pharm, Pharmaceutical Quality Assurance, Semester - I

Course Code	MQA101T	Title of the Course	Modern Pharmaceutical Analytical Techniques
Total Credits of the Course	4	Hours per Week	4

Course Objectives:	1. The course is designed to impart the knowledge in the field of Pharmaceutical Analysis. 2. The various modern analytical techniques like UV-Visible, IR, NMR, Maas are taught to enable students to understand and apply principles involved in the determination of pharmaceuticals. 3. Chromatographic methods and other important topics are taught to enable the students to understand and apply the principles involved in the determination of pharmaceuticals

Course Content		
Unit	**Description**	**Hrs**
I	**UV-Visible spectroscopy**: Introduction, Theory, Laws, Instrumentation associated with UV-Visible spectroscopy, Choice of solvents and solvent effect and Applications of UV-Visible spectroscopy. **IR spectroscopy**: Theory, Modes of Molecular vibrations, Sample handling, Instrumentation of Dispersive and Fourier - Transform IR Spectrometer, Factors affecting vibrational frequencies and Applications of IR spectroscopy **Spectroflourimetry:** Theory of Fluorescence, Factors affecting fluorescence, Quenchers, Instrumentation and Applications of fluorescence spectrophotometer. **Flame emission spectroscopy and Atomic absorption spectroscopy**: Principle, Instrumentation, Interferences and Applications.	**10**
II	**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 13C NMR. Applications of NMR spectroscopy.	**10**
III	**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 and Applications of Mass spectroscopy	**10**
IV	**Chromatography**: Principle, apparatus, instrumentation, chromatographic parameters, factors affecting resolution, isolation of drug from excipients, data interpretation and applications of the following: • Thin Layer chromatography	**10**

	• 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	
V	**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) Iso electric focusing **X ray Crystallography**: Production of X rays, Different X ray diffraction methods, Bragg's law, Rotating crystal technique, X ray powder technique, Types of crystals and applications of X- ray diffraction.	**10**
VI	**Potentiometry:** Principle, working, Ion selective Electrodes and Application of potentiometry. **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.	**10**

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: Upon completion of the subject student shall be able to	
1.	Theorize the fundamentals of modern analytical techniques for the analysis of pharmaceuticals
2.	Optimize the experimental conditions of modern pharmaceutical analytical instruments
3.	Analyze or infer the results based on analytical data or observations recorded
4.	Apply modern pharmaceutical analytical techniques for the analysis of pharmaceuticals

Suggested References:	
Sr. No	**References**
1	Spectrometric Identification of Organic compounds - Robert M Silverstein, Sixth edition, John Wiley & Sons, 2004
2	Principles of Instrumental Analysis - Doglas A Skoog, F. James Holler, Timothy A. Nieman, 5th edition, Eastern press, Bangalore, 1998.
3	Instrumental methods of analysis – Willards, 7th edition, CBS publishers
4	Practical Pharmaceutical Chemistry – Beckett and Stenlake, Vol II, 4th edition, CBS Publishers, New Delhi, 1997
5	Organic Spectroscopy - William Kemp, 3rd edition, ELBS, 1991
6	Quantitative Analysis of Drugs in Pharmaceutical formulation - P D Sethi, 3rd Edition, CBS Publishers, New Delhi, 1997.
7	Pharmaceutical Analysis - Modern Methods – Part B - J W Munson, Vol 11, Marcel. Dekker Series
8	Spectroscopy of Organic Compounds, 2nd edn., P.S/Kalsi, Wiley estern Ltd., Delhi
9	Textbook of Pharmaceutical Analysis, KA.Connors, 3rd Edition, John Wiley & Sons, 1982
10	Textbook of Pharmaceutical Analysis, KA.Connors, 3rd Edition, John Wiley & Sons, 1982

Master of Pharmacy
M. Pharm, Pharmaceutical Quality Assurance, Semester - I

Course Code	MQA102T	Title of the Course	Quality Management Systems
Total Credits of the Course	4	Hours per Week	4

Course Objectives:	1. To understand the concept of Quality 2. To understand the Implication of Quality in Pharma industry 3. To Implement Quality Implementation Programs 4. To have exposure to challenges in Quality Improvement Programs and Stability testing of drug and drug substances 5. Statistical approaches for quality

Course Content

Unit	Description	Hrs
I	**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:** Cost of quality, Categories of cost of Quality, Models of cost of quality, Optimising costs, Preventing cost of quality.	**12**
II	**Pharmaceutical quality Management:** 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	**12**
III	**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	**12**

IV	**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	**12**
V	**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	**8**
VI	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	**4**

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:
Upon completion of the subject student shall be able to

1.	Appraise the importance of significance of quality
2.	Deal with quality improvement teams
3.	Identify requirements of quality improvement programs
4.	Comprehend the importance of quality, tools for quality improvement, quality evaluation of pharmaceuticals

Suggested References:	
Sr. No	**References**
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, 200
3	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
4	Corporate Culture and the Quality Organization By James W. Fairfield- Sonn, Quorum Books, 2001
5	The Quality Management Sourcebook: An International Guide to Materials and Resources By Christine Avery; Diane Zabel, Routledge, 1997
6	The Quality Toolbox, Second Edition, Nancy R. Tague, ASQ Publications
7	Juran's Quality Handbook, Sixth Edition, Joseph M. Juran and Joseph A. De Feo, ASQ Publications
8	Root Cause Analysis, The Core of Problem Solving and Corrective Action, Duke Okes, 2009, ASQ Publications

Master of Pharmacy
M. Pharm, Pharmaceutical Quality Assurance, Semester - I

Course Code	MQA103T	Title of the Course	Quality Control and Quality Assurance
Total Credits of the Course	4	Hours per Week	4

Course Objectives:	1. This course deals with the various aspects of quality control and quality assurance aspects of pharmaceutical industries. 2. It covers the important aspects like cGMP, QC tests, documentation, quality certifications, GLP and regulatory affairs. 3. To understand the scope of quality certifications applicable to Pharmaceutical industries 4. To understand responsibility and working of QA and QC departments

Course Content		
Unit	**Description**	**Hrs**
I	**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.	**12**
II	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	**12**
III	Analysis of raw materials, finished products, packaging materials, in process quality control (IPQC), Developing specification (ICH Q6 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).	**12**
IV	**Documentation in pharmaceutical industry:** 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	**12**

	Common Technical Documentation (CTD, eCTD). Concept of regulated and non regulated markets	
V	**Manufacturing operations and controls:** Sanitation of manufacturing premises, mix-ups 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	**12**

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: Upon completion of the subject student shall be able to	
1.	Prepare the cGMP aspects in a pharmaceutical industry
2.	Prepare important documentation
3.	Identify the scope of quality certifications applicable to Pharmaceutical industries
4.	Theorize the responsibilities of QA & QC departments

Suggested References:	
Sr. No	**References**
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
7	ICH guidelines
8	ISO 9000 and total quality management
9	The drugs and cosmetics act 1940 – Deshpande, Nilesh Gandhi, 4th edition, Susmit Publishers, 2006.
10	QA Manual – D.H. Shah, 1st edition, Business Horizons, 2000
11	Good Manufacturing Practices for Pharmaceuticals a plan for total quality control – Sidney H. Willig, Vol. 52, 3rd edition, Marcel Dekker Series
12	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
13	Sarker DK. Quality Systems and Controls for Pharmaceuticals. John Wiley & Sons; 2008
14	Packaging of Pharmaceuticals
15	Schedule M and Schedule N

Master of Pharmacy
M. Pharm, Pharmaceutical Quality Assurance, Semester - I

Course Code	MQA104T	Title of the Course	Product Development and Technology Transfer
Total Credits of the Course	4	Hours per Week	4

Course Objectives:	1. To understand the new product development process 2. To understand the necessary information to transfer technology from R&D to actual manufacturing by sorting out various information obtained during R&D 3. To elucidate necessary information to transfer technology of existing products between various manufacturing places

Course Content

Unit	Description	Hrs.
I	**Principles of Drug discovery and development:** 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	12
II	**Pre-formulation studies:** 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.	12
III	**Pilot plant scale up:** 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	12
IV	**Pharmaceutical packaging:** Pharmaceutical dosage form and their packaging requirments, 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	12
V	**Technology transfer:** 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	12

	plan and Exhibit.	

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: On completion of this course it is expected that students will be able to	
1.	Plan for the scale up and technology transfer process in pharmaceutical industry
2.	Prepare documents for various applications for registration of the pharmaceuticals
3.	Evaluate quality control parameters for pharmaceutical packaging
4.	Evaluate the pre-formulation parameters in product development

Suggested References:	
Sr. No	**References**
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	Leon Lac Lachman, Herbert A. Liberman, Theory and Practice of Industrial Pharmacy. Marcel

	Dekker Inc. New York
3	Sidney H Willing, Murray M, Tuckerman. Williams Hitchings IV, Good manufacturing of pharmaceuticals (A Plan for total quality control) 3rd Edition. Bhalani publishing house Mumbai.
4	Tablets Vol. I, II, III by Leon Lachman, Herbert A. Liberman, Joseph B. Schwartz, 2nd Edn. (1989) Marcel Dekker Inc. New York
5	Text book of Bio- Pharmaceutics and clinical Pharmacokinetics by Milo Gibaldi, 3rd Edn, Lea & Febriger, Philadelphia
6	Pharmaceutical product development. Vandana V. Patrevale. John I. Disouza. Maharukh T.Rustomji. CRC Press, Group of Taylor and Francis
7	Dissolution, Bioavailability and Bio-Equivalence by Abdou H.M, Mack Publishing company, Eastern Pennsylvania
8	Remingtons Pharmaceutical Sciences, by Alfonso & Gennaro, 19th Edn.(1995)OO2C Lippincott; Williams and Wilkins A Wolters Kluwer Company, Philadelphia
9	The Pharmaceutical Sciences; the Pharma Path way 'Pure and applied Pharmacy' by D. A Sawant, Pragathi Books Pvt. Ltd
10	Pharmaceutical Packaging technology by D.A. Dean. E.R. Evans, I.H. Hall. 1st Edition(Reprint 2006). Taylor and Francis. London and New York.

Master of Pharmacy
M. Pharm, Pharmaceutical Quality Assurance, Semester - I

Course Code	MQA105P	Title of the Course	Quality Assurance Practical - I
Total Credits of the Course	6	Hours per Week	12

Course Objectives:	1. Students will learn analytical skills for instrument handlings. 2. Student will learn IPQC, FPQC, quality control testing of samples 3. Student will learn Identify stability study protocol and quality control testing of pharmaceutical packaging. 4. Student will examine the principles of TQM, Six Sigma, Change control/ Deviation Management, Out of Specifications (OOS), Out of Trend (OOT), Corrective & Preventive Actions (CAPA) in pharmaceutical industries

Course Content	
Unit	**Description**
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

Teaching-Learning Methodology	1. Practical training will be facilitated by demonstrations and check-list preparation. 2. Training of instrument or equipment will be imparted with demonstration of components of equipment and standard operating procedure. 3. Students will be instructed for performance of experiment followed by recording of observation, analysis and interpretation of data and discussion on the conclusion. 4. Quiz, viva-voce and performance test will be conducted for evaluation of practical understanding.

Evaluation Pattern		
Sr. No	Details of Evaluation	Marks
1.	Continuous Mode	20
2.	Sessional Examination	30
3.	End Semester Examination	100

Course Outcomes: Upon completion of the course, student shall be able to	
1.	Acquire basic practical knowledge relevant to the analysis of pharmaceuticals
2.	Perform pre-formulation studies, IPQC, FPQC, quality control testing of samples

3.	Apply the skill to perform quality control and tools of quality assurance in pharmaceutical industries.
4.	Implement principles of TQM, Six Sigma, Change control/ Deviation Management, Out of Specifications (OOS), Out of Trend (OOT), Corrective & Preventive Actions (CAPA) in pharmaceutical industries
5.	Prepare and perform stability study protocol and quality control testing of pharmaceutical packaging

SARDAR PATEL UNIVERSITY
Vallabh Vidyanagar, Gujarat
(Reaccredited with 'A' Grade by NAAC (CGPA 3.25)
Syllabus with effect from the Academic Year 2021-2022

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

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 -II	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 interactions 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.

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	MQA201T	Hazards and Safety Management	T	4	3	25	75	100/50
Employability, Entrepreneurship	MQA202T	Pharmaceutical Validation	T	4	3	25	75	100/50
Employability, Entrepreneurship	MQA203T	Audits and Regulatory Compliance	T	4	3	25	75	100/50
Employability, Entrepreneurship	MQA204T	Pharmaceutical Manufacturing Technology	T	4	3	25	75	100/50
Employability, Entrepreneurship, Skill development	MQA205P	Pharmaceutical Quality Assurance Practical II	P	6	6	50	100	150/75
Employability, Skill development	MQA206S	Seminar/Assignment		4	-	-	-	100/50
				26				**650/325**

Master of Pharmacy
M. Pharm, Pharmaceutical Quality Assurance, Semester - II

Course Code	MQA201T	Title of the Course	Hazards and Safety Management
Total Credits of the Course	4	Hours per Week	4

Course Objective:	
1.	Understand about environmental problems among learners and impart basic knowledge about the environment and its allied problems.
2.	Develop an attitude of concern for the industry environment.
3.	Ensure safety standards in pharmaceutical industry
4.	Provide comprehensive knowledge on the safety management
5.	Empower an ideas to clear mechanism and management in different kinds of hazard management system
6.	Teach the method of Hazard assessment, procedure, methodology for provide safe industrial atmosphere

Course Content

Unit	Description	Hrs.
I	**Multidisciplinary nature of environmental studies:** 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	**12**
II	**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	**12**
III	**Chemical based hazards:** Sources of chemical hazards, Hazards of Organic synthesis, sulphonating hazard, Organic solvent hazard, Control measures for chemical hazards,	**12**

	Management of combustible gases, Toxic gases and Oxygen displacing gases management, Regulations for chemical hazard, Management of over-Exposure to chemicals and TLV concept.	
IV	**Fire and Explosion**: 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.	**12**
V	**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.	**12**

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: Upon completion of the subject student shall be able to	
1.	Plan the concept of an ecosystem and structure and function of an ecosystem
2.	Setup about sources and types of air based hazards
3.	Prepare the prevention system of fire hazards and critical hazard risk management
4.	Comply the types of chemical based hazards and their prevention

Suggested References:	
Sr. No	**References**
1	Y.K. Sing, Environmental Science, New Age International Pvt, Publishers, Bangalore
2	Quantitative Risk Assessment in Chemical Process Industries" American Institute of Chemical Industries, Centre for Chemical Process safety
3	Bharucha Erach, The Biodiversity of India, Mapin Pu blishing Pvt. Ltd., Ahmedabad – 380 013, India
4	Hazardous Chemicals: Safety Management and Global Regulations T.S.S. Dikshith, CRC press

Master of Pharmacy
M. Pharm, Pharmaceutical Quality Assurance, Semester - II

Course Code	MQA202T	Title of the Course	Pharmaceutical Validation
Total Credits of the Course	4	Hours per Week	4

Course Objective: The main purpose of the subject is to understand about	
1.	The concepts of calibration, qualification and validation
2.	The qualification of various equipments and instruments
3.	Process validation of different dosage forms
4.	Validation of analytical method for estimation of drugs
5.	Cleaning validation of equipments employed in the manufacture of pharmaceuticals
6.	IPR and its property and filling of Patent application

Course Content

Unit	Description	Hrs
I	**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).	**10**
II	**Qualification of manufacturing equipment:** 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.	**10**
III	**Qualification of laboratory equipments:** Hardness tester, Friability test apparatus, tap	**10**

	density tester, Disintegration tester, Dissolution test apparatus **Validation of Utility systems:** Pharmaceutical water system & pure steam, HVAC system, Compressed air and nitrogen	
IV	**Process Validation:** Concept, Process and documentation of Process Validation. Prospective, Concurrent & Retrospective Validation, Re validation 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	**10**
V	**Cleaning Validation:** 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	**10**
VI	**General Principles of Intellectual Property:** Concepts of Intellectual Property (IP), Intellectual Property Protection (IPP), 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 applications; 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	**10**

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: Upon completion of the subject student shall be able to	
1.	Explain the aspect of validation
2.	Carryout validation of manufacturing processes
3.	Able to validate analytical instrument and processing equipment
4	To perform the validation of analytical method for estimation of drugs and cleaning validation of equipments employed in the manufacture of pharmaceutical
5	Arrange the documentation related to IPR and patent filling.

Suggested References:	
Sr. No	**References**
1	B. T. Loftus & R. A. Nash, "Pharmaceutical Process Validation", 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	Validation Master plan by Terveeks or Deeks, Davis Harwood International publishing
4	Validation of Aseptic Pharmaceutical Processes, 2nd Edition, by Carleton & Agalloco
5	Michael Levin, Pharmaceutical Process Scale-Up", Drugs and Pharm. Sci. Series, Vol. 157,2nd Ed., Marcel Dekker Inc., N.Y
6	Validation Standard Operating Procedures: A Step by Step Guide for Achieving Compliance in the Pharmaceutical, Medical Device, and Biotech Industries, Syed Imtiaz Haider
7	Pharmaceutical Equipment Validation: The Ultimate Qualification Handbook, Phillip A. Cloud, Interpharm Press
8	Validation of Pharmaceutical Processes: Sterile Products, Frederick J. Carlton (Ed.) and James

	Agalloco (Ed.), Marcel Dekker
9	Analytical Method validation and Instrument Performance Verification by Churg Chan, Heiman Lam, Y.C. Lee, Yue. Zhang, Wiley Interscience
10	Huber L. Validation and Qualification in Analytical Laboratories. Informa Healthcare
11	Wingate G. Validating Corporate Computer Systems: Good IT Practice for Pharmaceutical Manufacturers. Interpharm Press
12	LeBlanc DA. Validated Cleaning Technologies for Pharmaceutical Manufacturing. Interpharm Press

Master of Pharmacy
M. Pharm, Pharmaceutical Quality Assurance, Semester - II

Course Code	MQA203T	Title of the Course	Audits and Regulatory Compliance
Total Credits of the Course	4	Hours per Week	4

Course Objective: The main purpose of the subject is to understand about	
1.	To understand the importance of auditing
2.	To understand the methodology of auditing
3.	To carry out the audit process
4.	To prepare the auditing report
5.	To prepare the check list for auditing

Course Content

Unit	Description	Hrs.
I	**Introduction:** Objectives, Management of audit**,** Responsibilities, Planning process, information gathering, administration, Classifications of deficiencies	**12**
II	**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	**12**
III	**Auditing of vendors and production department**: Bulk Pharmaceutical Chemicals and packaging material Vendor audit, Warehouse and weighing, Dry Production: Granulation, tableting, coating, capsules, sterile production and packaging	**12**
IV	**Auditing of Microbiological laboratory:** Auditing the manufacturing process, Product and process information, General areas of interest in the building raw materials, Water, Packaging materials	**12**
V	**Auditing of Quality Assurance and engineering department:** Quality Assurance Maintenance, Critical systems: HVAC, Water, Water for Injection systems, ETP	**12**

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: Upon completion of the subject student shall be able to

1.	Prepare audit objectives, types, procedures and its management and the role of quality systems and audits in pharmaceutical manufacturing environment
2.	Prepare audit checklist for auditing of pharmaceutical industries
3.	Create audit plan and perform audit of different departments in pharmaceutical
4	Evaluate and summarize the content of audit report and post audit activity with corrective and preventive action

Suggested References:

Sr. No	References
1	Compliance auditing for Pharmaceutical Manufacturers. Karen Ginsbury and Gil Bismuth, Interpharm/CRC, Boca Raton, London New York, Washington D.C
2	Pharmaceutical Manufacturing Handbook, Regulations and Quality by Shayne Cox Gad. Wiley-Interscience, A John Wiley and sons, Inc., Publications

3	Handbook of microbiological Quality control. Rosamund M. Baird, Norman A. Hodges, Stephen P. Denyar. CRC Press. 2000
4	Laboratory auditing for quality and regulatory compliance. Donald C. Singer, Raluca-loana Stefan, Jacobus F. Van Staden. Taylor and Francis (2005)

Master of Pharmacy
M. Pharm, Pharmaceutical Quality Assurance, Semester - II

Course Code	MQA204T	Title of the Course	Pharmaceutical Manufacturing Technology
Total Credits of the Course	4	Hours per Week	4

Course Objective: This course is designed to impart knowledge and skills necessary to train the students about	
1.	The common practice in the pharmaceutical industry developments, plant layout and production planning
2.	Will be familiar with the principles and practices of aseptic process technology, non sterile manufacturing technology and packaging technology
3.	Have a better understanding of principles and implementation of Quality by design (QbD) and process analytical technology (PAT) in pharmaceutical manufacturing

Course Content

Unit	Description	Hrs.
I	**Pharmaceutical industry developments:** 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	**12**
II	**Aseptic process technology:** 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).	**12**

	Lyophilization technology: Principles, process, equipment	
III	**Non sterile manufacturing process technology:** 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, application techniques. Problems encountered.	**12**
IV	**Containers and closures for pharmaceuticals:** 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	**12**
V	**Quality by design (QbD) and process analytical technology (PAT):** 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, Analytical 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	**12**

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: Upon completion of the subject student shall be able to	
1.	Plan the common practice in the pharmaceutical industry development, plant layout and production planning
2.	Acquire knowledge of various processes, their applications and problem encounter during non-sterile manufacturing
3.	Apply the knowledge of principles and practices of sterile and non-sterile manufacturing of pharmaceuticals
4	Implementation of PAT and Quality by design (QbD) technique in pharmaceutical manufacturing
5	Evaluate stability aspects of packaging material

Suggested References:	
Sr. No	**References**
1	Lachman L, Lieberman HA, Kanig JL. The theory and practice of industrial pharmacy, 3rd ed., Varghese Publishers, Mumbai 1991
2	Sinko PJ. Martin's physical pharmacy and pharmaceutical sciences, 5th ed., B.I. Publications Pvt. Ltd, Noida, 2006
3	Lieberman HA, Lachman L, Schwartz JB. Pharmaceutical dosage forms: tablets Vol. I-III, 2nd ed., CBS Publishers & distributors, New Delhi, 2005
4	Banker GS, Rhodes CT. Modern Pharmaceutics, 4 th ed., Marcel Dekker Inc, New York, 2005
5	Sidney H Willing, Murray M, Tuckerman. Williams Hitchings IV, Good manufacturing of pharmaceuticals (A Plan for total quality control) 3rd Edition. Bhalani publishing house Mumbai
6	Indian Pharmacopoeia. Controller of Publication. Delhi, 1996
7	British Pharmacopoeia. British Pharmacopoeia Commission Office, London, 2008

8	United States Pharmacopoeia. United States Pharmacopeial Convention, Inc, USA, 2003.
9	Dean D A, Evans E R and Hall I H. Pharmaceutical Packaging Technology. London, Taylor & Francis, 1st Edition. UK
10	Edward J Bauer. Pharmaceutical Packaging Handbook. 2009. Informa Health care USA Inc. New york
11	Shaybe Cox Gad. Pharmaceutical Manufacturing Handbook. John Willey and Sons, New Jersey, 2008

Master of Pharmacy
M. Pharm, Pharmaceutical Quality Assurance, Semester - II

Course Code	MQA205P	Title of the Course	Quality Assurance Practical – II
Total Credits of the Course	4	Hours per Week	4

Course Objective:	
1.	Students will learn analytical skills for instrument handlings
2.	Various checklists for audits and plant lay outs of various manufacturing facilities should be explored
3.	Calibration and Qualifications of various instruments should be performed
4.	Different types of hazards and its preventive action

Course Content	
Unit	**Description**
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) Tablet Compression Machine
8	Validation of an analytical method for a drug
9	Validation of a processing are
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

Teaching-Learning Methodology	1. Practical training will be facilitated by demonstrations and check-list preparation. 2. Training of instrument or equipment will be imparted with demonstration of components of equipment and standard operating procedure. 3. Students will be instructed for performance of experiment followed by recording of observation, analysis and interpretation of data and discussion on the conclusion. 4. Quiz, viva-voce and performance test will be conducted for evaluation of practical understanding.

Evaluation Pattern		
Sr. No	Details of Evaluation	Marks
1.	Continuous Mode	20
2.	Sessional Examination	30
3.	End Semester Examination	100

Course Outcomes: Upon completion of the subject student shall be able to	
1.	To perform validation of analytical methods for drugs and formulations
2.	Prepare plant layout and auditing check list for pharmaceutical manufacturing
3.	Qualify pharmaceutical manufacturing equipments
4.	Differentiate the fire extinguisher and appropriate use of it and also aware of PPE
5.	Prepare and perform the protocol for analysis of pollutant

SARDAR PATEL UNIVERSITY
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Syllabus with effect from the Academic Year 2021-2022

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.

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	MRM301T	Research Methodology and Biostatistics	T	4	3	25	75	100/50
Employability, Skill Development	MQA302J	Journal club	-	1	-	25	-	25/13
Employability, Skill Development	MQA303D	Discussion / Presentation (Proposal Presentation)	-	2	-	50	-	50/25
Employability, Skill Development	MQA304R	Research work	-	14	1		350	350/175
				21				**525/263**

Master of Pharmacy

M. Pharm, Pharmaceutical Quality Assurance, Semester - III

Course Code	MQA301T	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 and the basic concepts of biostatistics
2.	Understand the functions of ethics committees in medical research

Course Content

Unit	Description	Hrs.
I	**General Research Methodology:** Research, objective, requirements, practical difficulties, review of literature, study design, types of studies, strategies to eliminate errors/bias, controls, randomization, crossover design, placebo, blinding techniques	**15**
II	**Biostatistics:** Definition, application, sample size, importance of sample size, factors influencing sample size, dropouts, statistical tests of significance, type of significance tests, parametric tests(students "t" test, ANOVA, Correlation coefficient, regression), non-parametric tests (wilcoxan rank tests, analysis of variance, correlation, chi square test), null hypothesis, P values, degree of freedom, interpretation of P values	**15**
III	**Medical Research:** History, values in medical ethics, autonomy, beneficence, non-maleficence, double effect, conflicts between autonomy and beneficence/non-maleficence, euthanasia, informed consent, confidentiality, criticisms of orthodox medical ethics, importance of communication, control resolution, guidelines, ethics committees, cultural concerns, truth telling, online business practices, conflicts of interest, referral, vendor relationships, treatment of family members, sexual relationships, fatality	**15**
IV	**CPCSEA guidelines for laboratory animal facility:** Goals, veterinary care, quarantine, surveillance, diagnosis, treatment and control of disease, personal hygiene, location of animal facilities to laboratories, anesthesia, euthanasia, physical facilities, environment, animal husbandry, record keeping, SOPs, personnel and training, transport of lab animals	**12**
V	**Declaration of Helsinki:** History, introduction, basic principles for all medical research, and additional principles for medical research combined with medical care.	**03**

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 requirements for laboratory animal facility

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

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

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 - IV	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.

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 Code	Name of Course	Theory/ Practical	Credit	Exam Duration in hrs	Component of Marks		
						Internal	External	Total
Employability, Skill development	MQA401J	Journal club	-	1	-	25	-	25/13
Employability, Skill development	MQA402D	Discussion / Presentation	-	3	-	75	-	75/38
Employability, Skill development	MQA403R	Research work and Colloquium	-	16	1	-	400	400/200
				20		100	400	**500/250**