SARDAR PATEL UNIVERSITY
Vallabh Vidyanagar, Gujarat
(Reaccredited with 'A' Grade by NAAC (CGPA 3.25)
Syllabus with effect from the Academic Year 2022-2023

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

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

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	PP01CMAT01	Modern Pharmaceutical Analytical Techniques	T	4	3	25	75	100/50
Employability, Entrepreneurship	PP01CMQA01	Quality Management System	T	4	3	25	75	100/50
Employability, Entrepreneurship	PP01CMQA02	Quality Control and Quality Assurance	T	4	3	25	75	100/50
Employability, Entrepreneurship	PP01CMQA03	Product Development and Technology Transfer	T	4	3	25	75	100/50
Employability, Entrepreneurship, Skill development	PP01CMQA04	Pharmaceutical Quality Assurance Practical I	P	6	6	50	100	150/75
Skill development	PP01SMQA01	Seminar/ Assignment	S	4	-	100	-	100/50
			Total:	**26**	**-**	**250**	**400**	**650/325**

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

Course Code	PP01CMAT01	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, Mass 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 4. Thermal Techniques and electrophoresis are taught which are essential for the

Course Content		
Unit	**Description**	**60 Hrs**
I	**a. UV-Visible spectroscopy**: Introduction, Theory, Laws, Instrumentation associated with UV-Visible spectroscopy, Choice of solvents and solvent effect and Applications of UV- Visible spectroscopy. Multi Component Methods of analysis **b. 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, Data Interpretation. **c. Spectroflourimetry:** Theory of Fluorescence, Factors affecting fluorescence (Characteristics of the drug that can be analysed by flourimtery), Quenchers, Instrumentation and Applications of fluorescence spectrophotometer. **d. Flame emission spectroscopy and Atomic absorption spectroscopy**: Principle, Instrumentation, Interferences and Applications.	**18**
II	**a. NMR spectroscopy**: 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. **b. 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	**12**

III	**Chromatography**: Principle, apparatus, instrumentation, chromatographic parameters, factors affecting resolution, isolation of drug from excipients, data interpretation and applications of the following: • 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	**15**
IV	**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.	**06**
V	**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.	**09**

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	PP01CMQA01	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.	**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	General introduction to ICH guidelines, History of ICH, Objective of ICH, Overview of all ICH Guidelines - QSEM and Special emphasis given to the Q series Guidelines. **a. ICH Q1** guideline: Drug Stability for stability testing of drug substances and drug products **b. ICH Q8** guideline: Quality by Design and Process development report. **c. ICH Q9** guideline: Quality risk management- Introduction, risk assessment, risk control, risk review, risk management tools, HACCP, risk ranking and filtering.	**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	9. Students will be oriented about the course content in the first session of the course 10. 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. 11. Virtual teaching and examination will also utilized for the learners of the course. 12. Seminar/assignments on advanced, recent and useful topics related to the course will be an integral part of course teaching and learning methodology. 13. Quiz and Q & A sessions for the topics covered will be conducted at regular interval. 14. Internal theory test will be conducted as a part of regular curriculum. 15. Attendance will be marked for each session as a part of overall evaluation. 16. 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	PP01CMQA02	Title of the Course	Quality Control and Quality Assurance
Total Credits of the Course	4	Hours per Week	4

Course Objectives:	6. This course deals with the various aspects of quality control and quality assurance aspects of pharmaceutical industries. 7. It covers the important aspects like cGMP, QC tests, documentation, quality certifications, GLP and regulatory affairs. 8. To understand the scope of quality certifications applicable to Pharmaceutical industries 9. To understand responsibility and working of QA and QC departments

Course Content

Unit	Description	Hrs
I	**Introduction:** Concept, objective and scope of Quality Control and Quality Assurance, Responsibilities of key persons in QA-QC, Difference between QA-QC, Functions of QA, Elements of the Quality Assurance Cycle in Pharmaceutical Manufacturing, Activities of Quality Assurance and Quality Control. **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.	**12**
II	cGMP guidelines according to schedule M, USFDA: 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, Good Distribution Practice. Comparative GMP of USFDA with EMEA, WHO and PIC.	**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, Semisolids, parenterals, ophthalmic and surgical products.	**12**
IV	Documentation in pharmaceutical industry: a. Manufacturing and control documents: BMR, MFR and Routine Records b. Quality Assurance Documents: SOP, Audit Documents c. Store Management documents: Stock reconciliation records for Raw material, finished products and packaging material d. Maintenance and Environmental Control Related documents e. Consumer Related Documents: Product recall, complain traceability document,	**12**

	Preventive Maintenance record	
V	Manufacturing operations and controls: Sanitation of manufacturing premises, mix-ups and cross contamination, processing of intermediates and bulk products, packaging operations, 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.	**12**

Teaching-Learning Methodology	17. Students will be oriented about the course content in the first session of the course 18. 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. 19. Virtual teaching and examination will also utilized for the learners of the course. 20. Seminar/assignments on advanced, recent and useful topics related to the course will be an integral part of course teaching and learning methodology. 21. Quiz and Q & A sessions for the topics covered will be conducted at regular interval. 22. Internal theory test will be conducted as a part of regular curriculum. 23. Attendance will be marked for each session as a part of overall evaluation. 24. 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	PP01CMQA03	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	**Drug Discovery and Development:** Introduction, Drug Discovery and Development Process Outline, Clinical research and its phases. Development and informational contents of following regulatory submission documents/applications Investigational New Drugs Application (IND), Investigator's Brochure (IB), Investigation Medicinal Product Dossier (IMPD) New Drug Application (NDA), CTD, eCTD, DMF Abbreviated New Drug Application (ANDA), Supplemental New Drug Application (SNDA), Scale Up Post Approval Changes (SUPAC) and Bulk active chemical Post approval changes (BACPAC) IVIVC, BA-BE studies	**15**
II	**Pre-formulation studies:** Introduction/concept, Fundamental and derived properties of drug substance in Pre-formulation profiling, Role of Pre-formulation in Drug Discovery and in Drug Development Significance and methods for pre-formulation studies: a. Organoleptic properties, Particle size, shape and surface area, Solid form selection (Amourphous, Crystalline, Polymorph, Solvate, Hydrate, Co-crystal) b. Solubility studies: pH-solubility profile, solubility in pharmaceutical solvents, permeability studies, BCS classification, Methods to improve solubility of Drugs: Surfactants & its importance, co-solvency.	**15**

	c. Stability testing studies, Hygroscopicity, Moisture/Solvent Content d. OVIs and its regulatory limits Dosage form specific Pre-formulation Studies Pre-formulation protocol, Pre-formulation worksheet	
III	**a. Pilot plant scale up:** Concept, Significance, design, scale of batch in product development, layout of pilot plant, organizational structure and personal, operations, Principle of similarities, Geometric/ Kinematic/ Dynamic similarities, 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. **b. Technology transfer:** Development of technology by R & D, Technology transfer from R & D to production, Optimization and Production, Documentation in technology transfer.	**15**
IV	**Pharmaceutical packaging:** 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	**15**

Teaching-Learning Methodology	25. Students will be oriented about the course content in the first session of the course 26. 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. 27. Virtual teaching and examination will also utilized for the learners of the course. 28. Seminar/assignments on advanced, recent and useful topics related to the course will be an integral part of course teaching and learning methodology. 29. Quiz and Q & A sessions for the topics covered will be conducted at regular interval. 30. Internal theory test will be conducted as a part of regular curriculum. 31. Attendance will be marked for each session as a part of overall evaluation. 32. 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	PP01CMQA04	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