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 density tester, Disintegration tester, Dissolution test apparatus **Validation of Utility systems:** Pharmaceutical water system & pure steam, HVAC system, Compressed air and nitrogen	**15**
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	**15**
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**

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):** a. Introduction, objectives, elements, benefits and current status b. Aspects of QbD to product development – QTPP, CQA, CMA, CPP, Risk Assessment, Design Space, Control Strategy, Product Life Cycle Management and Continuous Improvement c. Implementation of QbD in product development (Case Studies) d. 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