Scheme and Syllabus

M. Pharmacy
Pharmaceutical Quality Assurance

Batch 2017 onwards

PTU

ਆਈ. ਕੇ. ਗੁਜਰਾਲ ਪੰਜਾਬ ਟੈਕਨੀਕਲ ਯੂਨੀਵਰਸਿਟੀ

By
Board of Studies Pharmacy
Department of Academics

First Semester

Course Code	Course Name	L	P	Marks			Credits
				Internal	External	Total	
MQA101T	Modern Pharmaceutical Analytical Techniques	4	-	25	75	100	4
MQA102T	Quality Management Systems	4	-	25	75	100	4
MQA103T	Quality Control & Quality Assurance	4	-	25	75	100	4
MQA104T	Product Development & Technology Transfer	4		25	75	100	4
MQA105P	Pharmaceutical Quality Assurance Practical I	-	12	50	100	150	6
-	Seminar/Assignment#	-	7	-	-	100	4
	Total	**16**	**19**	**150**	**400**	**650**	**26**

- # Minimum five seminar/assignment each of 20 marks per semester

Second Semester

Course Code	Course Name	L	P	Marks			Credits
				Internal	External	Total	
MQA201T	Hazards & Safety Management	4	-	25	75	100	4
MQA202T	Pharmaceutical Validation	4	-	25	75	100	4
MQA203T	Audits & Regulatory Compliance	4	-	25	75	100	4
MQA204T	Pharmaceutical Manufacturing Technology	4		25	75	100	4
MQA205P	Pharmaceutical Quality Assurance Practical II	-	12	50	100	150	6
-	Seminar/Assignment#	-	7	-	-	100	4
	Total	**16**	**19**	**150**	**400**	**650**	**26**

- # Minimum five seminar/assignment each of 20 marks per semester

Third Semester

Course Code	Course Name	L	P	Marks			Credits
				Internal	**External**	**Total**	
MRM301T	Research Methodology & Biostatistics*	4	-	25	75	100	4
-	Journal Club	1	-	25	-	25	1
-	Discussion / Presentation (Proposal Presentation)	2	-	50	-	50	2
-	Research Work*	-	28	-	350	350	14
	Total	**7**	**28**	**100**	**425**	**525**	**21**

- *Non -University Exam

Fourth Semester

Course Code	Course Name	L	P	Marks			Credits
				Internal	External	Total	
-	Journal Club	1	-	25	-	25	1
-	Research Work	-	31	-	400	400	16
-	Discussion/Final Presentation	3	-	75	-	75	3
-	Co-curricular Activities	-	-	Satisfactory/Unsatisfactory			2*
Total		**4**	**31**	**100**	**400**	**500**	**22**

**Note: Required credit points 02 for satisfactory; Less than 02 credit points unsatisfactory*

***Credits not included towards calculation of CGPA**

Semester Wise Credits Distribution

Semester	Credit Points
I	26
II	26
III	21
IV	20
Co-curricular Activities (Attending Conference, Scientific Presentations & Other Scholarly Activities)	02*
Total Credit Points	**93 + 2* = 95**

- *Credit Points for Co-curricular Activities
- *Credits not included towards calculation of CGPA
- *The credit points assigned for extracurricular and or co-curricular activities shall be given by the Principals of the colleges and the same shall be submitted to the University

Guidelines for Awarding Credit Points for Co-curricular Activities

Name of the Activity	Maximum Credit Points
Participation in National Level Seminar/ Conference/ Workshop/ Symposium/ Training Programs (related to the specialization of the student) OR Academic Award/Research Award from State Level/National Agencies	02
Participation in International Level Seminar/ Conference/ Workshop/ Symposium / Training Programs (related to the specialization of the student) #	02
Academic Award/Research Award from International Agencies	02
Research / Review Publication in National Journals (Indexed in Scopus / Web of Science)*	01
Research / Review Publication in International Journals (Indexed in Scopus / Web of Science)*$	02

- #International Conference held even in India will be considered for award of Credit Points.
- *Only those research / review publications will be considered which have been published during the tenure of M. Pharm. Course.
- $ International Journal: The Editorial Board outside India.

Academic Work

The department / teaching staff of respective courses shall maintain a regular record of attendance in Theory, Practical, Seminar, Assignment, Journal Club, and Discussion with the supervisor, Research work presentation and Dissertation.

Program Committee

1. M. Pharm. Programme shall have a Programme Committee constituted by the Head of the Institution in consultation with all the Heads of the departments.
2. The composition of the Programme Committee shall be as follows:
   a. A teacher at the cadre of Professor shall be the Chairperson
   b. One Teacher from each M. Pharm. Specialization
   c. Four student representatives (two from each academic year), nominated by the Head of the Institution
3. Duties of the Programme Committee:
   a. Periodically review the progress of the classes.
   b. Discuss the problems concerning curriculum, syllabus and the conduct of classes.
   c. Discussing with the course teachers on the nature and scope of assessment for the course and the same shall be announced to the students at the beginning of respective semesters.

Sessional Exams

- Two sessional exams shall be conducted for each theory/practical course
- The average marks of two sessional exams shall be computed for internal assessment
- Sessional exam shall be **conducted for 30 marks** for theory and shall be **computed for 15 marks**.
- Sessional exam for practical shall be **conducted for 40 marks** and shall be **computed for 30 marks**.

Question Paper Pattern for Theory Sessional Examinations

Multiple Choice Questions (MCQs) **OR** Objective Type Questions (5 x 2) (Answer all the questions)	10 x 1 = 10 **OR** 05 x 2 = 10
Short Answers (Answer 2 out of 3)	2 x 5 = 10
Long Answers (Answer 1 out of 2)	1 x 10 = 10
Total	**30 Marks**

Question Paper Pattern for Practical Sessional Examinations

Synopsis	10
Experiments	25
Viva voce	05
Total	**40 Marks**

Internal Assessment

- The internal assessment will have two components i.e. **Continuous Mode** and **Sessional Exams**

1. Theory Courses having Internal of 25 Marks the scheme of internal award is:
    - Sessional Exams: 15 Marks
    - Continuous Mode: 10 Marks

Continuous Mode Scheme

Criteria	Maximum Marks
*Attendance (as per table given below)	08
Student – Teacher interaction	02
Total	**10**

2. Practical Courses having Internal of 50 Marks the scheme of internal award is:
    - Sessional Exams: 30 Marks
    - Continuous Mode: 20 Marks

Continuous Mode Scheme

Criteria	Maximum Marks
*Attendance (as per table given below)	10
Based on Practical Records, Regular viva voce, etc.	10
Total	**20**

***Guidelines for the Allotment of Marks for Attendance**

Percentage of Attendance	Theory (Maximum Marks 08)	Practical (Maximum Marks 10)
95 – 100	08	10
90 – 94	06	7.5
85 – 89	04	5
80 – 84	02	2.5
Less than 80	0	0

1st SEMESTER

Course Code	Course Title	Teaching Load		Marks		Exam (hrs)		Credits
		L	P	Int.	Ext.	Int.	Ext.	
MQA101T	Modern Pharmaceutical Analytical Techniques	4	-	25	75	1	3	4

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

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

1. Chemicals and Excipients.
2. The analysis of various drugs in single and combination dosage forms.
3. Theoretical and practical skills of the instruments.

Module 01 **10 Hour**

UV-Visible Spectroscopy

- Introduction, Theory, Laws, and Instrumentation associated with UV-Visible spectroscopy
- Choice of solvents and solvent effect
- Applications of UV- Visible spectroscopy, Difference/ Derivative spectroscopy

IR Spectroscopy

- Theory, Modes of Molecular vibrations, Sample handling
- Instrumentation of Dispersive and Fourier - Transform IR Spectrometer
- Factors affecting vibrational frequencies
- Applications of IR spectroscopy, Data Interpretation

Spectroflourimetry

- Theory of Fluorescence
- Factors affecting fluorescence (characteristics of drugs that can be analysed by flourimetry), Quenchers, Instrumentation
- Applications of fluorescence spectrophotometer

Flame Emission Spectroscopy and Atomic Absorption Spectroscopy

- Principle, Instrumentation, Interferences and Applications

Module 02 **10 Hours**

NMR Spectroscopy

- Quantum numbers and their role in NMR
- Principle, Instrumentation, Solvent requirement in NMR
- Relaxation process, NMR signals in various compounds
- Chemical shift, Factors influencing chemical shift, Spin-Spin coupling, Coupling constant, Nuclear magnetic double resonance
- Brief outline of principles of FT-NMR and ^{13}C NMR
- Applications of NMR spectroscopy

Module 03 **10 Hours**

Mass Spectroscopy

- Principle, Theory, Instrumentation of Mass Spectroscopy
- Different types of ionization like electron impact, chemical, field, FAB and MALDI, APCI, ESI, APPI Analyzers of Quadrupole and Time of Flight
- Mass fragmentation and its rules
- Meta stable ions
- Isotopic peaks
- Applications of Mass spectroscopy

Module 04 **10Hours**

Chromatography

Principle, apparatus, instrumentation, chromatographic parameters, factors affecting resolution and applications of the following:

- Thin Layer chromatography
- High Performance Thin Layer Chromatography
- Ion exchange chromatography
- Column chromatography
- Gas chromatography
- High Performance Liquid chromatography
- Ultra High Performance Liquid chromatography
- Affinity chromatography
- Gel Chromatography

Module 05 **10Hours**

Electrophoresis

Principle, Instrumentation, Working conditions, factors affecting separation and applications of the following:

- Paper electrophoresis
- Gel electrophoresis
- Capillary electrophoresis
- Zone electrophoresis
- Moving boundary electrophoresis
- Isoelectric 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

Module 06 **10 Hours**

Potentiometry

- Principle, working, ion selective electrodes
- 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
- Advantage and disadvantages
- Pharmaceutical applications
- Derivative differential thermal analysis (DDTA)

TGA

- Principle, instrumentation
- Factors affecting results
- Advantage and disadvantages
- Pharmaceutical applications

Recommended Books (Latest editions)

1. Spectrometric Identification of Organic Compounds - Robert M Silverstein, John Wiley & Sons.
2. Principles of Instrumental Analysis - Doglas A Skoog, F. James Holler, Timothy A. Nieman, Eastern press, Bangalore.
3. Instrumental methods of analysis – Willards, CBS publishers.
4. Practical Pharmaceutical Chemistry – Beckett and Stenlake, Vol II, CBS Publishers, New Delhi.
5. Organic Spectroscopy - William Kemp, ELBS.
6. Quantitative Analysis of Drugs in Pharmaceutical formulation - P D Sethi,CBS Publishers, New Delhi.
7. Pharmaceutical Analysis- Modern methods – Part B - J W Munson, Volume 11, Marcel Dekker Series.
8. Spectroscopy of Organic Compounds, P.S. Kalsi, Wiley Estern Ltd., Delhi.
9. Textbook of Pharmaceutical Analysis, K. A. Connors, John Wiley & Sons.

Course Code	Course Title	Teaching Load		Marks		Exam (hrs)		Credits
		L	P	Int.	Ext.	Int.	Ext.	
MQA102T	Quality Management Systems	4	-	25	75	1	3	4

Scope: This course is designed to impart fundamental knowledge and concepts about various quality management principles and systems utilized in the manufacturing industry. It also aids in understanding the quality evaluation in the pharmaceutical industries.

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

1. The importance of quality.
2. ISO management systems.
3. Tools for quality improvement.
4. Analysis of issues in quality.
5. Quality evaluation of pharmaceuticals.
6. Stability testing of drug and drug substances.
7. Statistical approaches for quality.

Module 01 **12Hours**

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

Module 02 **12Hours**

Pharmaceutical Quality Management

- Basics of Quality Management, Total Quality Management (TQM), Principles of Six sigma
- ISO 9001:2008, 9001:2015, ISO14001:2004
- 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

Module 03 **12Hours**

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

Module 04 **12 Hours**

Drug Stability

- ICH guidelines for stability testing of drug substances and drug products
- Study of ICH Q8, Quality by Design and Process development report

Quality Risk Management

- Introduction, risk assessment, risk control, risk review, risk management tools, HACCP, risk ranking and filtering according to ICH Q9 guidelines

Module 05 **08Hours**

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

Module 06 **04 Hours**

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

Recommended Books (Latest editions)

1. Implementing Juran's Road Map for Quality Leadership: Benchmarks and Results, By Al Endres, Wiley.
2. Understanding, Managing and Implementing Quality: Frameworks, Techniques and Cases, By Jiju Antony; David Preece, Routledge.
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.
4. Corporate Culture and the Quality Organization by James W. Fairfield- Sonn, Quorum Books.
5. The Quality Management Sourcebook: An International Guide to Materials and Resources by Christine Avery; Diane Zabel, Routledge.
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, ASQ Publications.

Course Code	Course Title	Teaching Load		Marks		Exam (hrs)		Credits
		L	P	Int.	Ext.	Int.	Ext.	
MQA103T	Quality Control & Quality Assurance	4	-	25	75	1	3	4

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

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

1. Understand the cGMP aspects in a pharmaceutical industry.
2. To appreciate the importance of documentation.
3. To understand the scopeof quality certifications applicable to Pharmaceutical industries.
4. To understand the responsibilities of QA & QC departments.

Module 01 **12 Hours**

Introduction

- Concept and evolution and scopes of Quality Control and Quality Assurance, Good Laboratory Practice, GMP, Overview of ICH Guidelines - QSEM, with special emphasis on Q- series guidelines

Good Laboratory Practices

- Scope of GLP, Definitions, Quality assurance unit, protocol for conduct of non-clinical testing, control on animal house, report preparation and documentation
- CPCSEA guidelines

Module 02 **12 Hours**

- cGMP guidelines according to schedule M, USFDA (inclusive of CDER and CBER), Pharmaceutical Inspection Convention(PIC), WHO and EMEA covering: Organization and personnel responsibilities, training, hygiene and personal records, drug industry location, design, construction and plant lay out, maintenance, sanitation, environmental control, utilities and maintenance of sterile areas, Control of contamination, Good Warehousing Practice

Module 03 **12 Hours**

- 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)

Module 04 **12 Hours**

Documentation in Pharmaceutical Industry

- Three tier documentation, Policy, Procedures and Work instructions
- Records (Formats) Basic principles- How to maintain, retention etc
- Standard operating procedures (How to write), Master Batch Record, Batch Manufacturing Record, Quality audit plan and reports
- Specification and test procedures, Protocols and reports
- Distribution Records
- Electronic data handling
- Concepts of controlled and uncontrolled documents
- Submission documents for regulators DMFs, as Common Technical Document and Electronic Common Technical
- Documentation (CTD, eCTD)
- Concept of regulated and non regulated markets

Module 05 **12 Hours**

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
- Introduction, scope and importance of intellectual property rights

Recommended Books (Latest editions)

1. Quality Assurance Guide by organization of Pharmaceutical Procedures of India, Volume I & II, Mumbai.
2. Good Laboratory Practice Regulations, Sandy Weinberg Vol. 69, Marcel Dekker Series.
3. Quality Assurance of Pharmaceuticals- A compedium of Guide lines and Related materials Vol I & II, WHO Publications.
4. How to Practice GMP's – P P Sharma, Vandana Publications, Agra.
5. The International Pharmacopoeia – vol I, II, III, IV & V - General Methods of Analysis and Quality specification for Pharmaceutical Substances, Excepients and Dosage forms, WHO, Geneva.
6. Good laboratory Practice Regulations – Allen F. Hirsch, Volume 38, Marcel Dekker Series.
7. ICH guidelines
8. ISO 9000 and total quality management.
9. The drugs and cosmetics act 1940 – Deshpande, Nilesh Gandhi, Susmit Publishers.
10. QA Manual – D.H. Shah, 1st edition, Business Horizons.

11. Good Manufacturing Practices for Pharmaceuticals a plan for total quality control – Sidney H. Willig, Vol. 52, Marcel Dekker Series.
12. Steinborn L. GMP/ISO Quality Audit Manual for Healthcare Manufacturers and Their Suppliers, (Volume 1 - With Checklists and Software Package), Taylor & Francis.
13. Sarker DK. Quality Systems and Controls for Pharmaceuticals, John Wiley & Sons.
14. Packaging of Pharmaceuticals.
15. Schedule M and Schedule N.

Course Code	Course Title	Teaching Load		Marks		Exam (hrs)		Credits
		L	P	Int.	Ext.	Int.	Ext.	
MQA104T	Product Development & Technology Transfer	4	-	25	75	1	3	4

Scope: This deal with technology transfer covers the activities associated with Drug Substance, Drug Product and analytical tests and methods, required following candidate drug selection to completion of technology transfer from R&D to the first receiving site and technology transfer related to post-marketing changes in manufacturing places.

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

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.

Module 01 **12 Hours**

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)
- Bulk active chemical Post approval changes (BACPAC)
- Post marketing surveillance
- Product registration guidelines – CDSCO, USFDA

Module 02 **12 Hours**

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

Module 03 **12 Hours**

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

Module 04 **12 Hours**

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

Module 05 **12 Hours**

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 plan and Exhibit
- Legislation regulations of food products with special emphasis on BIS, Agmark, FDA and US-FDA

Recommended Books (Latest editions)

1. The process of new drug discovery and development, 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), Bhalani publishing house Mumbai.
4. Tablets Vol. I, II, III by Leon Lachman, Herbert A. Liberman, Joseph B. Schwartz, Marcel Dekker Inc. New York.
5. Text book of Bio- Pharmaceutics and clinical Pharmacokinetics by Milo Gibaldi, 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, 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, Taylor and Francis, London and New York.

Course Code	Course Title	Teaching Load		Marks		Exam (hrs)		Credits
		L	P	Int.	Ext.	Int.	Ext.	
MQA105P	Pharmaceutical Quality Assurance Practical - I	-	12	50	100	6	6	6

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
    a) Total Quality Management
    b) Six Sigma
    c) Change Management/ Change control. Deviations
    d) Out of Specifications (OOS)
    e) Out of Trend (OOT)
    f) Corrective & Preventive Actions (CAPA)
    g) 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

2nd SEMESTER

Course Code	Course Title	Teaching Load		Marks		Exam (hrs)		Credits
		L	P	Int.	Ext.	Int.	Ext.	
MQA201T	Hazards & Safety Management	4	-	25	75	1	3	4

Scope: This course is designed to convey the knowledge necessary to understand issues related to different kinds of hazard and their management. Basic theoretical and practical discussions integrate the proficiency to handle the emergency situation in the pharmaceutical product development process and provides the principle based approach to solve the complex tribulations.

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

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

Module 01 **12 Hours**

Multidisciplinary Nature of Environmental Studies

- Natural Resources
- Renewable and non-renewable resources
- Natural resources and associated problems: Forest resources; Water resources; Mineral resources; Energy resources; Land resources

Ecosystems

- Concept of an ecosystem and Structure and function of an ecosystem

Environmental Hazards

- Hazards based on Air, Water, Soil and Radioisotopes

Module 02 **12 Hours**

Air Based hazards

- Sources, Types of Hazards
- Air circulation maintenance industry for sterile area and non sterile area
- Preliminary Hazard Analysis (PHA)

Fire Protection System

- Fire prevention, types of fire extinguishers
- Critical Hazard management system

Module 03 **12 Hours**

Chemical Based Hazards

- Sources of chemical hazards
- Hazards of Organic synthesis, sulphonating hazard
- Organic solvent hazard, Control measures for chemical hazards
- Management of combustible gases
- Toxic gases and Oxygen displacing gases management
- Regulations for chemical hazard
- Management of over-Exposure to chemicals and TLV concept

Module 04 **12 Hours**

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
- 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

Module 05 **12 Hours**

Hazard and Risk Management

- Self- protective measures against workplace hazards
- Critical training for risk management
- Process of hazard management
- ICH guidelines on risk assessment
- 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

Recommended Books (Latest editions)

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.

Course Code	Course Title	Teaching Load		Marks		Exam (hrs)		Credits
		L	P	Int.	Ext.	Int.	Ext.	
MQA202T	Pharmaceutical Validation	4	-	25	75	1	3	4

Scope: The main purpose of the subject is to understand about validation and how it can be applied to industry and thus to improve the quality of the products. The subject covers the complete information about validation, types, methodology and application.

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

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

Module 01 **10 Hours**

Introduction

- Definition of Calibration, Qualification and Validation
- Scope, frequency and importance
- Difference between calibration and validation
- Calibration of weights and measures
- Advantage of Validation
- Scope of Validation
- Organization for Validation, Validation Master plan, Types of Validation
- Streamlining of Qualification & Validation process
- 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)

Module 02 **10 Hours**

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

Module 03 **10 Hours**

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

Module 04 **10 Hours**

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

Module 05 **10 Hours**

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

Module 06 **10 Hours**

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 application - patent application forms and guidelines

- Types patent applications-provisional and non-provisional, PCT and convention patent applications
- International patenting requirement procedures and costs
- Rights and responsibilities of a patentee
- Practical aspects regarding maintaining of a Patent file
- Patent infringement meaning and scope
- Significance of transfer technology (TOT), IP and ethics-positive and negative aspects of IPP
- Societal responsibility, avoiding unethical practices

Recommended Books (Latest editions)

1. B. T. Loftus & R. A. Nash, "Pharmaceutical Process Validation, Drugs and Pharm Sci. Series, Vol. 129, Marcel Dekker Inc., N.Y.
2. The Theory & Practice of Industrial Pharmacy, 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, by Carleton & Agalloco, Marcel Dekker.
5. Michael Levin, Pharmaceutical Process Scale-Up, Drugs and Pharm. Sci. Series, Vol. 157, 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 Inter Science.
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.

Course Code	Course Title	Teaching Load		Marks		Exam (hrs)		Credits
		L	P	Int.	Ext.	Int.	Ext.	
MQA203T	Audits & Regulatory Compliance	4	-	25	75	1	3	4

Scope: This course deals with the understanding and process for auditing in pharmaceutical industries. This subject covers the methodology involved in the auditing process of different in pharmaceutical industries.

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

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 checklist for auditing.

Module 01 **12 Hours**

Introduction

- Objectives, Management of audit, Responsibilities, Planning process, information gathering, administration, Classifications of deficiencies

Module 02 **12 Hours**

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

Module 03 **12 Hours**

Auditing of Vendors and Production Department

- Bulk Pharmaceutical Chemicals and packaging material Vendor audit
- Warehouse and weighing
- Dry Production: Granulation, tableting, coating, capsules, sterile

Module 04 **12 Hours**

Auditing of Microbiological Laboratory

- Auditing the manufacturing process
- Product and process information
- General areas of interest in the building raw materials, Water, Packaging materials

Module 05 **12 Hours**

Auditing of Quality Assurance and Engineering Department

- Quality Assurance Maintenance, Critical systems: HVAC, Water, Water for Injection systems, ETP

Recommended Books (Latest editions)

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.
4. Laboratory auditing for quality and regulatory compliance. Donald C. Singer, Raluca-loana Stefan, Jacobus F. Van Staden. Taylor and Francis.

Course Code	Course Title	Teaching Load		Marks		Exam (hrs)		Credits
		L	P	Int.	Ext.	Int.	Ext.	
MQA204T	Pharmaceutical Manufacturing Technology	4	-	25	75	1	3	4

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

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

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.

Module 01 **12 Hours**

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

Module 02 **12 Hours**

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)

Lyophilisation Technology

- Principles, process, equipment

Module 03 **12 Hours**

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

Module 04 **12 Hours**

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

Module 05 **12 Hours**

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

Recommended Books (Latest editions)

1. Lachman L, Lieberman HA, Kanig JL. The theory and practice of industrial pharmacy, Varghese Publishers, Mumbai.
2. Sinko PJ. Martin's physical pharmacy and pharmaceutical sciences, B.I. Publications Pvt. Ltd, Noida.
3. Lieberman HA, Lachman L, Schwartz JB. Pharmaceutical dosage forms: tablets Vol. I-III, CBS Publishers & distributors, New Delhi.
4. Banker GS, Rhodes CT. Modern Pharmaceutics, 4 Inc, New York. ed., Marcel Dekker.
5. Sidney H Willing, Murray M, Tuckerman. Williams Hitchings IV, Good manufacturing of pharmaceuticals (A Plan for total quality control), Bhalani publishing house Mumbai.
6. Indian Pharmacopoeia. Controller of Publication. Delhi.
7. British Pharmacopoeia. British Pharmacopoeia Commission Office, London.
8. United States Pharmacopoeia. United States Pharmacopeial Convention, Inc, USA.
9. Dean D A, Evans E R and Hall I H. Pharmaceutical Packaging Technology. London, Taylor & Francis, UK.
10. Edward J Bauer. Pharmaceutical Packaging Handbook. Informa Health care USA Inc. New york.
11. Shaybe Cox Gad. Pharmaceutical Manufacturing Handbook. John Willey and Sons, New Jersey.

Course Code	Course Title	Teaching Load		Marks		Exam (hrs)		Credits
		L	P	Int.	Ext.	Int.	Ext.	
MQA205P	Pharmaceutical Quality Assurance Practical - II	-	12	50	100	6	6	6

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

3rd SEMESTER

Course Code	Course Title	Teaching Load		Marks		Exam (hrs)		Credits
		L	P	Int.	Ext.	Int.	Ext.	
MRM301T	Research Methodology & Biostatistics	4	-	25	75	1	3	4

Module 01 **12 Hours**

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

Module 02 **12 Hours**

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

Module 03 **12 Hours**

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

Module 04 **12 Hours**

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

Module 05 **12 Hours**

Declaration of Helsinki

- History, introduction, basic principles for all medical research, and additional principles for medical research combined with medical care

Recommended Books (Latest editions)

1. Basic & Clinical Biostatistics, Beth Dawson and Robert G. Trapp. Lange Medical Books/McGraw-Hill Medical Publishing Division.
2. Research Methdology, R. Panneerselvam, PHI Learning Pvt. Limited, Delhi.
3. Methods in Biostatistics, B.K. Mahajan. JAYPEE Brothers Medical Publishers (P) Ltd.
4. CPCSEA Guidelines.
   A Handbook of Applied Statistics in Pharmacology, Katsumi Kobayashi and K. Sadasivan Pillai. CRC Press, Taylor & Francis Group.