ADMISSION & EXAMINATION

BYE-LAWS

FOR

MASTER OF PHARMACY

IN

QUALITY ASSURANCE

Program Code: MQA

SCHOOL OF PHARMACEUTICAL EDUCATION AND RESEARCH

JAMIA HAMDARD

(DEEMED TO BE UNIVERSITY)

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CONTENTS

BOS MEETING DETAILS

- **Approval date of the BOS/School Board meeting for the present syllabus:**

Name of the program	Department	Board of School (BOS) Approval Date
M. Pharm	Quality Assurance	21.04.2017

- **Approval date of the Academic Council meeting for the present syllabus**

Name of the program	Program Code	Dates of Revision
M. Pharm	MQA	31.05.2017

VISION AND MISSION STATEMENTS

Vision Statement: To create an atmosphere for quality education and research enabling students to excel in drug and drug delivery systems

Mission Statements:

MS 1: To support infrastructure for research through grants and industry academia interaction

MS 2: To provide an environment for the conduct of academic activities required to transform student's calibre.

MS 3: To create a learning environment where the faculty and students can discover, examine, embrace and comprehend technological changes for self-reliance.

MS 4: To strengthen education policies and programs for creating ideals representative of a democratic society.

PROGRAM EDUCATIONAL OBJECTIVES (PEOs)

After completion of the M. Pharm (Quality Assurance), the post graduates will be able to:

PEO1: Apply basic tools of a quality system and its continuous management.

PEO2: Communicate effectively at every stage of the drug development process.

PEO3: Assist in systematic development of a quality system based on generation of standard operating procedures and control programs.

PEO4: Assess strong interpersonal skills required for a team work.

PEO5: Adapt to ambitious professional skills as a pharmacist.

PEO6: Engage in lifelong learning and delivering personal skills required for a professional attitude.

Mapping Program Educational Objectives (PEOs) with Mission Statements (MS)

	MS-1	MS-2	MS-3	MS-4
PEO-1	3	2	3	3
PEO-2	3	3	3	2
PEO-3	3	3	3	3
PEO-4	2	2	3	3
PEO-5	3	3	3	2
PEO-6	3	3	2	3

Level of Mapping: '3' is for 'high-level' mapping, 2 for 'Medium-level' mapping, 1 for 'Low-level' mapping.

PROGRAMME SPECIFIC OUTCOME (PSO)

After completion of the M. Pharm (Pharmaceutics), the post graduates will be able to:

PSO1: Able to exhibit skills in a blended environment of teaching and research.

PSO2: Describe student's aptitude in Educational Establishments, Government Departments, Hospitals & Clinics, Manufacturing Companies, Pharmaceutical Companies, Drug Processing Companies, Service Industries, Medical Writing, etc.

PSO3: Develop entrepreneurial skills with innovation and creativity for persistence.

PROGRAM OUTCOMES (POs)

After going through the two years Master Program in Pharmaceutics, graduates will exhibit the ability to:

PO1: Apply Pharmacy Knowledge: Develop knowledge related to quality control in pharmaceutical industries especially covering topics such as cGMP, product quality test, documentation, quality certification, GLP, and regulatory affairs for the evaluation of novel drug delivery systems**.**

PO2: Research and development: Able to apply the new product development process by knowing the necessary information to transfer technology from R&D

PO3: Problem analysis: Establish an ability to ensure that the product is designed and implemented with correct procedures.

PO4: Modern tool usage: Utilize different quality assurance tools to assist in monitoring and managing the quality initiatives of the products.

PO5: Communication: Understand the basic knowledge about the different quality management principles.

PO6: Professional identity: Establish a Profession that is committed to delivering quality services. Also developing expertise as required by Pharmaceutical Industry and Academia.

PO7: Leadership skills: Ensure that the research and manufacturing projects are completed in time and within budget.

PO8: Planning abilities: Plan, manage, and implement activities related to product development processes, as per international guidelines.

PO9: Pharmaceutical ethics: Assure the safety, efficacy and quality of drug products with faithfulness and loyalty.

PO10: Environmental sustainability: Develop a responsible attitude towards industry environment.

Also, empower ideas related to clean and green environment.

PO11: Life-long learning: Able to apply reasoning and learning for a healthy societal impact.

Mapping of Program Outcomes (POs) and Program Specific Outcomes (PSOs) with Program Educational Objectives (PEOs)

	PEO-1	**PEO-2**	**PEO-3**	**PEO-4**	**PEO-5**	**PEO-6**
PO-1	3	3	3	2	3	3
PO-2	2	2	3	3	2	3
PO-3	2	3	3	3	2	1
PO-4	3	3	3	2	1	2
PO-5	2	3	3	3	3	3
PO-6	2	3	3	2	3	3
PO-7	2	2	2	3	2	1
PO-8	2	2	3	3	3	3
PO-9	2	2	3	3	3	3
PO-10	3	2	3	3	2	1
PO-11	3	3	3	3	3	3
PSO-1	3	3	3	2	2	3
PSO-2	3	3	3	2	2	3
PSO-3	3	3	3	2	2	3

Level of Mapping: ‘3’ is for ‘high-level’ mapping, 2 for ‘Medium-level’ mapping, 1 for ‘Low-level’ mapping.

CONSOLIDATED SEMESTER WISE PROGRAMME DETAILS

Table-I: Schemes for internal assessments and end semester examinations semester wise

Semester I

Course code	Name of the course	Internal Assessment				Credits points	End Semester Exams		Total Marks
		Continuous Mode	Sessional Exams		Total Marks		Marks	Duration	
			Marks	Duration					
MQA 101T	Modern Pharmaceutical Analytical Techniques	10	15	1 Hr	25	4	75	3 Hrs	100
MQA 102T	Quality Management System	10	15	1 Hr	25	4	75	3 Hrs	100
MQA 103T	Quality Control and Quality Assurance	10	15	1 Hr	25	4	75	3 Hrs	100
MQA 104T	Product Development and Technology Transfer	10	15	1 Hr	25	4	75	3 Hrs	100
MQA 105P	Pharmaceutical Quality Assurance Practical I	20	30	6 Hr	50	6	100	6 Hrs	150
	Seminar /Assignment	-	-	-	100	4	-	-	100
Total						**26**			**650**

Semester II

Course code	Name of the course	Internal Assessment				Credits points	End Semester Exams		Total Marks
		Continuous Mode	Sessional Exams		Total Marks		Marks	Duration	
			Marks	Duration					
MQA201T	Hazards and Safety Management	10	15	1 Hr	25	4	75	3 Hrs	100
MQA202T	Pharmaceutical Validation	10	15	1 Hr	25	4	75	3 Hrs	100
MQA203T	Audits and Regulatory Compliance	10	15	1 Hr	25	4	75	3 Hrs	100
MQA204T	Pharmaceutical Manufacturing Technology	10	15	1 Hr	25	4	75	3 Hrs	100
MQA205P	Pharmaceutical Quality Assurance Practical II	20	30	6 Hr	50	6	100	6 Hrs	150
	Seminar/Assignment	-	-	-	100	4	-	-	100
Total						**26**			**650**

Semester III

Course Code	Course	Credit Hours	Credit Points
MRM 301T	Research Methodology and Biostatistics*	4	4
-	Journal club	1	1
-	Discussion / Presentation (Proposal Presentation)	2	2
-	Research Work	28	14
Total		**35**	**21**

* Non University Exam

Semester IV

Course Code	Course	Credit Hours	Credit Points
-	Journal Club	1	1
-	Research Work	31	16
-	Discussion/Final Presentation	3	3
Total		**35**	**20**

Table II-Semester wise credits distribution

Semester	Credit Points
I	26
II	26
III	21
IV	20
Co-curricular Activities (Attending Conference, Scientific Presentations and Other Scholarly Activities)	Minimum=02 Maximum=07*
Total Credit Points	Minimum=95 Maximum=100*

*Credit Points for Co-curricular Activities

Guidelines for Awarding Credit Points for Co-curricular Activities

Name of the Activity	Maximum Credit Points Eligible / Activity
Participation in National Level Seminar/Conference/Workshop/Symposium/ Training Programs (related to the specialization of the student)	01
Participation in international Level Seminar/Conference/Workshop/Symposium/ Training Programs (related to the specialization of the student)	02
Academic Award/Research Award from State Level/National Agencies	01
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

Note: International Conference: Held Outside India; International Journal: The Editorial Board Outside India

*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. The criteria to acquire this credit point shall be defined by the colleges from time to time.

Program Committee

The M. Pharm. programme shall have a Programme Committee constituted by the Head of the institution in consultation with all the Heads of the departments.

The composition of the Programme Committee shall be as follows:

A teacher at the cadre of Professor shall be the Chairperson; One Teacher from each M. Pharm specialization and four student representatives (two from each academic year), nominated by the Head of the institution.

Duties of the Programme Committee:

1. Periodically reviewing the progress of the classes.
2. Discussing the problems concerning curriculum, syllabus and the conduct of classes.
3. 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.
4. Communicating its recommendation to the Head of the institution on academic matters.
5. The Programme Committee shall meet at least twice in a semester preferably at the end of each sessional exam and before the end semester exam.

Examinations/Assessments

The schemes for internal assessment and end semester examinations are given in Table I.

End semester examinations

The End Semester Examinations for each theory and practical course through semesters I to II shall be conducted by the respective university except for the subject with asterix symbol (*) in table I for which examinations shall be conducted by the subject experts at college level and the marks/grades shall be submitted to the university.

RULES AND REGULATIONS

1. Short Title and Commencement

These regulations shall be called as "The Revised Regulations for the Master of Pharmacy (M. Pharm.) Degree Program - Credit Based Semester System (CBSS) of the Pharmacy Council of India, New Delhi". They shall come into effect from the Academic Year 2016-17. The regulations framed are subject to modifications from time to time by the authorities of the university.

2. Minimum qualification for admission

A Pass in the following examinations

a) B. Pharm Degree examination of an Indian university established by law in India from an institution approved by Pharmacy Council of India and has scored not less than 55 % of the maximum marks (aggregate of 4 years of B.Pharm.)

b) Every student, selected for admission to post graduate pharmacy program in any PCI approved institution should have obtained registration with the State Pharmacy Council or should obtain the same within one month from the date of his/her admission, failing which the admission of the candidate shall be cancelled.

Note: It is mandatory to submit a migration certificate obtained from the respective university where the candidate had passed his/her qualifying degree (B. Pharm.)

3. Duration of the program

The program of study for M. Pharm. shall extend over a period of four semesters (two academic years). The curricula and syllabi for the program shall be prescribed from time to time by Pharmacy Council of India, New Delhi.

4. Medium of instruction and examinations

Medium of instruction and examination shall be in English.

5. Working days in each semester

Each semester shall consist of not less than 100 working days. The odd semesters shall be conducted from the month of June/July to November/December and the even semesters shall be conducted from the month of December/January to May/June in every calendar year.

6. Attendance and progress

A candidate is required to put in at least 80% attendance in individual courses considering theory and practical separately. The candidate shall complete the prescribed course satisfactorily to be eligible to appear for the respective examinations.

7. Program/Course credit structure

As per the philosophy of Credit Based Semester System, certain quantum of academic work viz. theory classes, practical classes, seminars, assignments, etc. are measured in terms of credits. On satisfactory completion of the courses, a candidate earns credits. The amount of credit associated with a course is dependent upon the number of hours of instruction per week in that course. Similarly, the credit associated with any of the other academic, co/extracurricular activities is dependent upon the quantum of work expected to be put in for each of these activities per week/per activity.

8 Credit assignment

Theory and Laboratory courses

Courses are broadly classified as Theory and Practical. Theory courses consist of lecture (L) and Practical (P) courses consist of hours spent in the laboratory. Credits (C) for a course is dependent on the number of hours of instruction per week in that course and is obtained by using a multiplier of one (1) for lecture and a multiplier of half (1/2) for practical (laboratory) hours. Thus, for example, a theory course having four lectures per week throughout the semester carries a credit of 4. Similarly, a practical having four laboratory hours per week throughout semester carries a credit of 2. The contact hours of seminars, assignments and research work shall be treated as that of practical courses for the purpose of calculating credits. i.e., the contact hours shall be multiplied by 1/2. Similarly, the contact hours of journal club, research work presentations and discussions with the supervisor shall be considered as theory course and multiplied by 1.

9. Minimum credit requirements

The minimum credit points required for the award of M. Pharm. degree is 95. However based on the credit points earned by the students under the head of co-curricular activities, a student shall earn a maximum of 100 credit points. These credits are divided into Theory courses, Practical, Seminars, Assignments, Research work, Discussions with the supervisor, Journal club and Co-Curricular activities over the duration of four semesters. The credits 3 are distributed semester-wise as shown in Table 14. Courses generally progress in sequence, building competencies and their positioning indicates certain academic maturity on the part of the learners. Learners are expected to follow the semester-wise schedule of courses given in the syllabus.

10. Academic work

A regular record of attendance both in Theory, Practical, Seminar, Assignment, Journal club, Discussion with the supervisor, Research work presentation and Dissertation shall be maintained by the department / teaching staff of respective courses.

11. Course of study

The course of study for M. Pharm shall include Semester Wise Theory & Practical as given in Table- III-IV. The number of hours to be devoted to each theory and practical course in any semester shall not be less than that shown in Table –III-IV

Table III-: Course of study for Semester I

Course code	Name of the course	No. of hours	Tutorial	Credit points
MQA 101T	Modern Pharmaceutical Analytical Techniques	4	-	4
MQA 102T	Quality Management System	4	-	4
MQA 103T	Quality Control and Quality Assurance	4	-	4
MQA 104T	Product Development and Technology Transfer	4	-	4
MQA 105P	Pharmaceutical Quality Assurance Practical I	12	-	6
	Seminar /Assignment	7	-	4
	Total	**35**		**26**

Table IV-: Course of study for semester II

Course code	Name of the course	No. of hours	Tutorial	Credit points
MQA201T	Hazards and Safety Management	4	-	4
MQA 202T	Pharmaceutical Validation	4		4
MQA 203T	Audits and Regulatory Compliance	4	-	4
MQA 204T	Pharmaceutical Manufacturing Technology	4	-	4
MQA 205P	Pharmaceutical Quality Assurance Practical II	12	-	6
	Seminar /Assignment	7	-	4
	Total	**35**		**26**

12. Program Committee

1. The 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 teacher at the cadre of Professor shall be the Chairperson; One Teacher from each M. Pharm specialization and four student representatives (two from each academic year), nominated by the Head of the institution.

3. Duties of the Programme Committee:
   i. Periodically reviewing the progress of the classes.
   ii. Discussing the problems concerning curriculum, syllabus and the conduct of classes.
   iii. 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.
   iv. Communicating its recommendation to the Head of the institution on academic matters.
   v. The Programme Committee shall meet at least twice in a semester preferably at the end of each sessional exam and before the end semester exam.

13. Examinations/Assessments

The scheme for internal assessment and end semester examinations is given in Table V- VI

End semester examinations

The End Semester Examinations for each theory and practical course through semesters I to IV shall beconducted by the university except for the subjects with asterix symbol (*) in table I and II for which examinations shall be conducted by the subject experts at college level and the marks/grades shall be submitted to the university.

Internal assessment: Continuous mode

The marks allocated for Continuous mode of Internal Assessment shall be awarded as per the scheme given below.

Table V: Scheme for awarding internal assessment: Continuous mode

Theory	
Criteria	Maximum Marks
Attendance (Refer Table – VI)	8
Student – Teacher interaction	2
Total	**10**

Practical	
Attendance (Refer Table – VI)	10
Based on Practical Records, Regular viva voce, etc.	10
Total	**20**

Table VI: Guidelines for the allotment of marks for attendance

Percentage of Attendance	**Theory**	**Practical**
95 – 100	8	10
90 – 94	6	7.5
85 – 89	4	5
80 – 84	2	2.5
Less than 80	0	0

Sessional Exams

Two sessional exams shall be conducted for each theory / practical course as per the schedule fixed by the college(s). The scheme of question paper for theory and practical sessional examinations is given in the table. The average marks of two sessional exams shall be computed for internal assessment as per the requirements given in tables.

Promotion and award of grades

A student shall be declared PASS and eligible for getting grade in a course of M. Pharm programme if he/she secures at least 50% marks in that particular courseincluding internal assessment.

Carry forward of marks

In case a student fails to secure the minimum 50% in any Theory or Practical course as specified in 12, then he/she shall reappear for the end semester examination of that course. However his/her

marks of the Internal Assessment shall be carried over and he/she shall be entitled for grade obtained by him/her on passing.

Improvement of internal assessment

A student shall have the opportunity to improve his/her performance only once in the sessional exam component of the internal assessment. The re-conduct of the sessional exam shall be completed before the commencement of next end semester theory examinations.

Re-examination of end semester examinations

Re examination of end semester examination shall be conducted as per the schedule given in table VII. The exact dates of examinations shall be notified from time to time.

Table VII: Tentative schedule of end semester examinations

Semester	For Regular Candidates	For Failed Candidates
I and III	November / December	May / June
II and IV	May / June	November / December

Allowed to keep terms (ATKT):

No student shall be admitted to any examination unless he/she fulfills the norms given in 6. ATKT rules are applicable as follows:

A student shall be eligible to carry forward all the courses of I and IIsemesters till the III semester examinations. However, he/she shall not be eligible to attend the courses of IV semester until all the courses of I, II and III semesters are successfully completed.
A student shall be eligible to get his/her CGPA upon successful completion of the courses of I to IV semesters within the stipulated time period as per the norms.

Note: Grade AB should be considered as failed and treated as one head for deciding ATKT. Such rules are also applicable for those students who fail to register for examination(s) of any course in any semester.

Grading of performances

Letter grades and grade points allocations:

Based on the performances, each student shall be awarded a final letter grade at the end of the semester for each course.The letter grades and their corresponding grade points are given in Table – VIII.

Table VIII: Letter grades and grade points equivalent to Percentage of marks and performances

Percentage of Marks Obtained	Letter Grade	Grade Point	Performance
90.00 – 100	O	10	Outstanding
80.00 – 89.99	A	9	Excellent
70.00 – 79.99	B	8	Good
60.00 – 69.99	C	7	Fair
50.00 – 59.99	D	6	Average
Less than 50	F	0	Fail
Absent	AB	0	Fail

A learner who remains absent for any end semester examination shall be assigned a letter grade of AB and a corresponding grade point of zero. He/she should reappear for the said evaluation/examination in due course.

The Semester grade point average (SGPA)

The performance of a student in a semester is indicated by a number called 'Semester Grade Point Average' (SGPA). The SGPA is the weighted average of the grade points obtained in all the courses by the student during the semester. For example, if a student takes five courses (Theory/Practical) in a semester with credits C1, C2, C3 and C4 and the student's grade points in these courses are G1, G2, G3 and G4, respectively, and then students' SGPA is equal to:

$$SGPA = \frac{C_1G_1 + C_2G_2 + C_3G_3 + C_4G_4}{C_1 + C_2 + C_3 + C_4}$$

The SGPA is calculated to two decimal points. It should be noted that, the SGPA for any semester shall take into consideration the F and ABS grade awarded in that semester. For example if a learner has a F or ABS grade in course 4, the SGPA shall then be computed as:

$$SGPA = \frac{C_1G_1 + C_2G_2 + C_3G_3 + C_4 * ZERO}{C_1 + C_2 + C_3 + C_4}$$

Cumulative Grade Point Average (CGPA)

The CGPA is calculated with the SGPA of all the IV semesters to two decimal points and is indicated in final grade report card/final transcript showing the grades of all IV semesters and their courses. The CGPA shall reflect the failed status in case of F grade(s), till the course(s) is/are passed. When the course(s) is/are passedby obtaining a pass grade on subsequent examination(s) the CGPA shall only reflect the new grade and not the fail grades earned earlier.The CGPA is calculated as:

$$CGPA = \frac{C_1S_1 + C_2S_2 + C_3S_3 + C_4S_4}{C_1 + C_2 + C_3 + C_4}$$

where C1, C2, C3,…. is the total number of credits for semester I,II,III,…. and S1,S2, S3,….is the SGPA of semester I,II,III,…. .

Declaration of class

The class shall be awarded on the basis of CGPA as follows: First Class with Distinction = CGPA of. 7.50 and above

First Class = CGPA of 6.00 to 7.49

Second Class = CGPA of 5.00 to 5.99

Project work

All the students shall undertake a project under the supervision of a teacher in Semester III to IV and submit a report. 4 copies of the project report shall be submitted (typed & bound copy not less than 75 pages).

The internal and external examiner appointed by the University shall evaluate the project at the time of the Practical examinations of other semester(s). The projects shall be evaluated as per the criteria given below.

Evaluation of Dissertation Book:

Objective(s) of the work done	50 Marks
Methodology adopted	150 Marks
Results and Discussions	250 Marks
Conclusions and Outcomes	50 Marks
Total	500 Marks

Evaluation of Presentation:

Presentation of work	100 Marks
Communication skills	50 Marks
Question and answer skills	100 Marks
Total	250 Marks

Award of Ranks

Ranks and Medals shall be awarded on the basis of final CGPA. However, candidates who fail in one or more courses during the M.Pharm program shall not be eligible for award of ranks. Moreover, the candidates should have completed the M. Pharm program in minimum prescribed number of years, (two years) for the award of Ranks.

Award of degree

Candidates who fulfill the requirements mentioned above shall be eligible for award of degree during the ensuing convocation.

Duration for completion of the program of study

The duration for the completion of the program shall be fixed as double the actual duration of the program and the students have to pass within the said period, otherwise they have to get fresh Registration.

Revaluation I Re-totaling of answer papers

There is no provision for revaluation of the answer papers in any examination. However, the candidates can apply for retotaling by paying prescribed fee.

Re-admission after break of study

Candidate who seeks re-admission to the program after break of study has to get the approval from the university by paying a condonation fee.

SYLLABUS

M.PHARM. SEMESTER I

Course Code MQA 101T	**Title of the course: Modern Pharmaceutical Analytical Techniques (MAT)**
Course Code: MQA 102T	**Title of the Course: Quality Management Systems (Theory)**
Course Code: MQA 103T	**Title of the Course: Quality Control and Quality Assurance (Theory)**
Course Code: MQA 104T	**Title of the Course: Product Development and Technology Transfer (Theory)**
Course Code: MQA 105P	**Title of the Course: Quality Assurance Practical – I**

Name of the Academic Program: M. Pharm Quality Assurance I Sem.

Course Code: MQA-102T

Title of the Course: Quality Management Systems

L-T-P: 4-0-0 **Credits: 4**

(L=Lecture hours, T= Tutorial hours, P: Practical hours)

COURSE OUTCOMES (COs)

After completing this Course, the students should be able to:

CO-1: Identify various quality management principles and systems utilized in manufacturing of novel drug delivery systems. **(Cognitive level: Remember)**

CO-2: Explain the quality evaluation tools and methods used in pharmaceutical manufacturing. **(Cognitive level: Understand)**

CO-3: Solve the problems and issues in manufacturing and quality evaluation. **(Cognitive level: Apply)**

CO-4: Analyze statistical process control parameters in various operations. **(Cognitive level: Analyze)**

CO-5: Evaluate stability of drugs and pharmaceuticals. **(Cognitive level: Evaluate).**

Mapping of Course Outcomes (COs) with Program Outcomes (POs) and Program Specific Outcomes (PSOs)

	PO1	PO2	PO3	PO4	PO5	PO6	PO7	PO8	PO9	PO10	PO11	PO12	PSO1	PSO2	PSO3
CO1	2				3						1		3	2	1
CO2	2			3							2		3	2	1
CO3	3		3						1		2		3	2	1
CO4	3							2			2		3	2	1
CO5	3			2					2		2		3	2	1

Each Course Outcome (CO) may be mapped with one or more Program Outcomes (POs). Write '3' in the box for 'High-level' mapping, 2 for 'Medium-level' mapping, 1 for 'Low'-level' mapping.

Detailed Syllabus **(Total: 60 Hrs)**

Unit 1: **12Hrs**

Introduction to Quality: Evolution of Quality, Definition of Quality, Dimensions of 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.

Unit 2 **12Hrs**

Pharmaceutical quality Management: Basics of Quality Management, Total Quality Management (TQM), Principles of Six sigma, ISO 9001:2008, 9001:2015, ISO 14001:2004, Pharmaceutical Quality Management – ICH Q10, Knowledge management, Quality Metrics, Operational Excellence and Quality Management Review. OSHAS guidelines, NABL certification and accreditation, CFR-21 part 11, WHO-GMP requirements.

Unit 3 **12Hrs**

Six System Inspection model: Quality Management system, Production system, Facility and Equipment system, Laboratory control system, Materials system, Packaging and labelling system. Concept of self-inspection. Quality systems: Change Management/ Change control. Deviations, Out of Specifications (OOS), Out of Trend (OOT), Complaints - evaluation and handling, Investigation and determination of root cause, Corrective & Preventive Actions (CAPA), Returns and Recalls, Vendor Qualification, Annual Product Reviews, Batch Review and Batch Release. Concept of IPQC, area clearance/ Line clearance.

Unit 4 **12Hrs**

Drug Stability: ICH guidelines for stability testing of drug substances and drug products. Study of ICH Q8, Quality by Design and Process development report Quality risk management:

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

Unit 5 **8 Hrs**

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.

Unit 6 **4 Hrs**

Regulatory Compliance through Quality Management and development of Quality Culture Benchmarking: Definition of benchmarking, Reasons for bench marking, Types of Benchmarking, Benchmarking process, Advantages of benchmarking, Limitations of benchmarking.

Reference Books:

1. Joseph M. Juran and Joseph A. De Feo, (2010), Juran's Quality Handbook, Sixth Edition, ASQ Publications, New York.
2. Jiju Antony and David Preece, (2002). Understanding, Managing and Implementing Quality: Frameworks, Techniques and Cases, Routledge, London.
3. James W. Fairfield-Sonn, (2001), Corporate Culture and the Quality Organization, Quorum Books, Muscat.
4. Christine Avery and Diane Zabel, (1997), The Quality Management Sourcebook: An International Guide to Materials and Resources ¸ Routledge, London.
5. Nancy R. Tague (2005), The Quality Toolbox, Second Edition, ASQ Publications, New York.
6. Duke Okes (2009), Root Cause Analysis, the Core of Problem Solving and Corrective Action, ASQ Publications New York.
7. Christine Avery and Diane Zabel (1997), The Quality Management Sourcebook: An International Guide to Materials and Resources, Routledge, London.

Teaching-Learning Strategies in brief

Various pedagogic strategies are followed including classroom teaching in chalk-board as well as audio-visual mode, learning through discussion among the peer group, classroom interaction, discussion of research papers published in journals related to topics (Journal Club), assignments, seminar power point presentations, Q & A session and reflective learning.

Assessment methods and weightages in brief

There are two components of assessment: Internal assessment (25 marks) and End semester examination (75 marks). Internal assessment consists of continuous mode (10 marks) and sessional examinations (15 marks). There are two sessional tests (each conducted for 30 marks and computed for 15 marks) and one improvement test. The average marks of two best sessional tests are computed out of 15 marks. Continuous mode evaluation is of 10 marks comprising attendance-8 marks and Student- Teacher interaction: 2 marks.

Name of the Academic Program: M. Pharm Quality Assurance I Sem.

Course Code: MQA-103T

Title of the Course: Quality Control and Quality Assurance (QCQA)

L-T-P: 4-0-0 **Credits: 4**

(L=Lecture hours, T= Tutorial hours, P: Practical hours)

COURSE OUTCOMES (COs)

After completing this Course, the students should be able to:

CO-1: Recognize the concepts and evolution of Quality Control and Quality Assurance. Discuss and enlist GMP, GLP guidelines associated with various national and international regulatory bodies (USFDA) **(Cognitive level: Remember and understand)**

CO-2: Explain and discuss Responsibilities of QC and QA Departments (Cognitive level: Understand)

CO-3: Understand the best practices in quality documentation needed in a pharmaceutical industry and get acquainted to creation of Common Technical document (eCTD) **(Cognitive level: Understand, Create and Apply)**

CO-4: Understand the analysis of raw, finished and packaging material according to ICH guidelines **(Cognitive level: Understand Analyse)**

CO-5: Appraise manufacturing operations and controls and the flow of material inside a pharmaceutical industry. Learn the nuances of good documentation for quality processes **(Cognitive level: Understand, Evaluate and Apply)**

CO-6: Learn basic concept of Intellectual property rights, copyrights, trademarks, and patents **(Cognitive level: Understand).**

Mapping of Course Outcomes (COs) with Program Outcomes (POs) and Program Specific Outcomes (PSOs)

	PO1	PO2	PO3	PO4	PO5	PO6	PO7	PO8	PO9	PO10	PO11	PO12	PSO1	PSO2	PSO3
CO1	3				2					3	3		3	2	1
CO2	3			3	2						3		3	2	1
CO3	3	3			2	2				2	3		3	2	1
CO4	2				2	2			2		3		3	1	1
CO5	2		3		2	2		2	2	3	3		3	2	1
CO6	3	3			2	2					3		3	3	2

Each Course Outcome (CO) may be mapped with one or more Program Outcomes (POs). Write '3' in the box for 'High-level' mapping, 2 for 'Medium-level' mapping, 1 for 'Low'-level' mapping.

Detailed Syllabus **(Total: 60 Hrs)**

Unit 1 **12 Hrs**

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 Qseries guidelines.

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

Unit 2 **12 Hrs**

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

Unit 3 **12 Hrs**

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).

Unit 4 **12 Hrs**

Documentation in pharmaceutical industry: Three tier documentation, Policy, Procedures and Work instructions, and records (Formats), Basic principles- How to maintain, retention and retrieval etc. Standard operating procedures (How to write), Master Batch Record, Batch Manufacturing Record, Quality audit plan and reports. Specification and test procedures, Protocols and reports. Distribution records. Electronic data handling. Concepts of controlled and

uncontrolled documents. Submission documents for regulators DMFs, as Common Technical Document and Electronic Common Technical Documentation (CTD, eCTD). Concept of regulated and non-regulated markets.

Unit 5 **12 Hrs**

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

Reference Books

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. 127
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.

Teaching-Learning Strategies in brief

Various pedagogic strategies are used including classroom teaching in chalk-board as well as audio-visual mode, learning through discussion among the peer group, classroom interaction, discussion of research papers published in journals related to topics (Journal Club), assignments, seminar power point presentations, Q & A session and reflective learning.

Assessment methods and weightages in brief

There are two components of assessment: Internal assessment (25 marks) and End semester examination (75 marks). Internal assessment consists of continuous mode (10 marks) and sessional examinations (15 marks). There are two sessional tests (each conducted for 30 marks and computed for 15 marks) and one improvement test. The average marks of two best sessional tests are computed out of 15 marks. Continuous mode evaluation is of 10 marks comprising attendance- 8 marks and Student- Teacher interaction: 2 marks.

Name of the Academic Program: M. Pharm Quality Assurance I Sem

Course Code: MQA 104T

Title of the Course: Product Development and Technology Transfer (Theory)

L-T-P: 4-0-0 **Credits: 4**

(L=Lecture hours, T=Tutorial hours, P=Practical hours)

COURSE OUTCOMES (COs)

After completing this Course, the students should be able to:

CO1: Practice the whole process of drug discovery **(Cognitive level: Apply)**

CO2: Analyze and comply preformulation strategies for a formulation development **(Cognitive level: Analyze/ Create)**

CO3: Outline the pilot plant production of various dosage forms **(Cognitive level: Analyze)**.

CO4: Develop technology transfer for various pharmaceuticals **(Cognitive level: Create)**.

CO5: Discuss regulatory requirements for pharmaceutical packaging material **(Cognitive level: Understand).**

Mapping of Course Outcomes (COs) with Program Outcomes (POs) and Program Specific Outcomes (PSOs)

	PO1	PO2	PO3	PO4	PO5	PO6	PO7	PO8	PO9	PO10	PO11	PSO1	PSO2	PSO3
CO1	3	2	1	2	1	1	1	2	1	2	1	3	2	1
CO2	3	2	3	2	1	1	1	1	2	1	1	2	3	1
CO3	3	2	3	2	1	1	2	1	1	1	1	2	3	1
CO4	1	3	2	2	2	1	1	2	1	1	1	2	2	3
CO5	3	1	2	1	1	3	2	2	1	1	1	3	2	1

Each Course Outcome (CO) may be mapped with one or more Program Outcomes (POs). Write '3' in the box for 'High-level'mapping, 2 for 'Medium-level'mapping, 1 for 'Low'-level'mapping.

Detailed Syllabus **(Total: 60 Hrs)**

Chapter 1 **12 Hrs**

Principles of Drug discovery and development: Introduction, Clinical research process. Development and informational content for Investigational New Drugs Application (IND), New Drug Application (NDA), Abbreviated New Drug Application (ANDA), Supplemental New Drug

Application (SNDA), Scale Up Post Approval Changes (SUPAC) and Bulk active chemical Post approval changes (BACPAC), Post marketing surveillance, Product registration guidelines – CDSCO, USFDA. Approval changes (BACPAC), Post marketing surveillance, Product registration guidelines – CDSCO, USFDA.

Chapter 2 **12 Hrs**

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.

Chapter 3 **12 Hrs**

Pilot plant scale up: 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.

Chapter 4 **12 Hrs**

Pharmaceutical packaging: Pharmaceutical dosage form and their packaging requirments, Pharmaceutical packaging materials, Medical device packaging, Enteral Packaging, Aseptic packaging systems, Container closure systems, Issues facing modern drug packaging, Selection and evaluation of Pharmaceutical packaging materials.
Quality control test: Containers, closures and secondary packing materials.

Chapter 5 **12 Hrs**

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.

Reference Books

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
3. Pharmacy. Marcel Dekker Inc. New York.
4. 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.
5. Tablets Vol. I, II, III by Leon Lachman, Herbert A. Liberman, Joseph B. Schwartz, 2nd Edn. (1989) Marcel Dekker Inc. New York.
6. Text book of Bio- Pharmaceutics and clinical Pharmacokinetics by Milo Gibaldi, 3rd Edn, Lea & Febriger, Philadelphia.

7. Pharmaceutical product development. Vandana V. Patrevale. John I. Disouza. Maharukh T.Rustomji. CRC Press, Group of Taylor and Francis.

8. Dissolution, Bioavailability and Bio-Equivalence by Abdou H.M, Mack Publishing company, Eastern Pennsylvania.

9. Remingtons Pharmaceutical Sciences, by Alfonso & Gennaro, 19th Edn.(1995)OO2C Lippincott; Williams and Wilkins A Wolters Kluwer Company, Philadelphia.

10. The Pharmaceutical Sciences; the Pharma Path way 'Pure and applied Pharmacy' by D. A Sawant, Pragathi Books Pvt. Ltd.

11. Pharmaceutical Packaging technology by D.A. Dean. E.R. Evans, I.H. Hall. 1st Edition(Reprint 2006). Taylor and Francis. London and New York.

Teaching-Learning Strategies in brief

The teaching learning strategies, followed are board and chalk teaching, Learning through discussion among the peer group, classroom interaction, discussion of research papers of Journals related to topics, power point presentation, Q & A session and reflective learning.

Assessment methods and weightages in brief

There are two components of assessment: Internal assessment (25 marks) and End semester examination (75 marks). Internal assessment consists of continuous mode (10 marks) and sessional examinations (15 marks). There are two Sessional exams (each conducted for 30 marks and computed for 15 marks) and one improvement exam. The average marks of two best sessional exams are computed out of 15 marks. Continuous mode evaluation is of 10 marks comprising of attendance- 8 marks (calculated as: Percentage of Attendance: Allotment of marks- Less than 80: 0 marks; 80-84: 2 marks; 85-89: 4 marks; 90-94: 6 marks and 95-100: 8 marks) and Student-Teacher interaction: 2 marks.

Total Marks are 100 for the subject (Internal Assessment: 25 marks and End Semester Examination: 75 Marks).

Name of the Academic Program: M. Pharm Quality Assurance I Sem

Course Code: MQA 105P

Title of the Course: Quality Assurance Practical – I

L-T-P: 0-0-12 **Credits: 6**

(L=Lecture hours, T=Tutorial hours, P=Practical hours)

COURSE OUTCOMES (COs)

After completing this Course, the students should be able to:

CO-1: Explain the basic techniques and methods for Analysis of Pharmacopoeial compounds in bulk and in their formulations (tablet/ capsules/ semisolids) by spectrophotometry. **(Cognitive level: Understand)**.

CO-2: Understand about basic analysis and instrumentation for HPLC, Gas Chromatography, fluorimetry **(Cognitive level: Understand)**

CO-3: To understand about 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 **(Cognitive level: Create and Apply)**

CO-4: Use of Techniques and practices of in process and finished products **(Cognitive level: Understand and Apply)**

CO-5: Understand quality control tests for tablets, capsules, parenterals and semisolid dosage forms. **(Cognitive level: Understand and Apply)**

Mapping of Course Outcomes (COs) with Program Outcomes (POs) and Program Specific Outcomes (PSOs)

	PO1	PO2	PO3	PO4	PO5	PO6	PO7	PO8	PO9	PO10	PO11	PSO1	PSO2	PSO3
CO1	3	1	2	3	1	1	1	1	1	1	2	2	1	2
CO2	3	1	2	3	1	1	1	1	1	1	2	2	1	2
CO3	3	1	3	2	1	2	2	2	1	2	3	3	1	2
CO4	3	2	3	3	2	2	1	1	2	2	2	2	2	3
CO5	3	2	3	2	1	1	1	2	3	2	1	3	2	2

Each Course Outcome (CO) may be mapped with one or more Program Outcomes (POs). Write '3' in the box for 'High-level'mapping, 2 for 'Medium-level'mapping, 1 for 'Low'-level'mapping.

Detailed Syllabus **12 Hours/Week**

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 Strategies in brief

The teaching learning strategies followed are board and chalk teaching, Learning through discussion among the peer group, classroom interaction, quiz, presentations, Q & A session and reflective learning.

Assessment methods and weightages in brief

There are two components of assessment: Internal assessment and End semester examination. Internal assessment consists of continuous mode and sessional practical exams. There are two Sessional exams and one improvement exam. The average marks of two Sessional exams are computed for internal assessment. Sessional practical exam is conducted for 30 marks. Continuous mode evaluation is of 20 marks comprising of Attendance (10 marks), Practical records and Viva voce (10 marks). End semester exams is of 100 marks.

M.PHARM. SEMESTER II

Course Code MQA 201T	**Title of the course: Hazards and Safety Management (Theory)**
Course Code: MQA 202T	**Title of the Course: Pharmaceutical Validation (Theory)**
Course Code: MQA 203T	**Title of the Course: Audits and Regulatory Compliance (Theory)**
Course Code: MQA 204T	**Title of the Course: Pharmaceutical Manufacturing Technology (Theory)**
Course Code: MQA 205P	**Title of the Course: Quality Assurance Practical – II**

Name of the Academic Program: M. Pharm Quality Assurance II Sem

Course Code: MQA 201T

Title of the Course: Hazards and Safety Management (Theory)

L-T-P: 4-0-0 Credits: 4

(L=Lecture hours, T=Tutorial hours, P=Practical hours)

COURSE OUTCOMES (COs)

After completing this Course, the students should be able to:

CO1: Collect information about our natural resources **(Cognitive level: Create)**

CO2: **A**nalyze the impact of various types of hazards to environment **(Cognitive level: Analyze)**

CO3: Discriminate the potential risks to environment **(Cognitive level: Evaluate)**.

CO4: Demonstrate the techniques to handle fire explosions **(Cognitive level: Apply)**.

CO5: Appraise of the global requirement for a green environment **(Cognitive level: Evaluate)**

Mapping of Course Outcomes (COs) with Program Outcomes (POs) and Program Specific Outcomes (PSOs)

	PO1	PO2	PO3	PO4	PO5	PO6	PO7	PO8	PO9	PO10	PO11	PSO1	PSO2	PSO3
CO1	3	1	1	2	2	1	2	1	1	1	1	3	2	1
CO2	3	1	1	2	2	2	1	2	1	3	2	2	3	1
CO3	3	1	3	2	1	1	1	2	1	1	1	2	3	1
CO4	3	3	2	2	1	1	1	1	2	1	1	2	3	1
CO5	3	2	1	1	1	1	2	1	1	1	1	3	2	1

Each Course Outcome (CO) may be mapped with one or more Program Outcomes (POs). Write '3' in the box for 'High-level'mapping, 2 for 'Medium-level'mapping, 1 for 'Low'-level'mapping.

Detailed Syllabus **(Total: 60 Hrs)**

Chapter 1 **12 Hrs**

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.

Chapter 2 **12 Hrs**

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.

Chapter 3 **12 Hrs**

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.

Chapter 4 **12 Hrs**

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.

Chapter 5 **12 Hrs**

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.

Reference Books

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 Publishing Pvt. Ltd., Ahmedabad – 380 013, India.
4. Hazardous Chemicals: Safety Management and Global Regulations, T.S.S. Dikshith, CRC press.

Teaching-Learning Strategies in brief

The teaching learning strategies, followed are board and chalk teaching, Learning through discussion among the peer group, classroom interaction, quiz, presentations, Q & A session and reflective learning.

Assessment methods and weightages in brief

There are two components of assessment: Internal assessment and End semester examination. Internal assessment consists of continuous mode and sessional exams. There are two Sessional exams and one improvement exam. The average marks of two Sessional exams are computed for internal assessment. Sessional exam is conducted for 30 marks and are computed for 15 marks. Continuous mode evaluation is of 10 marks comprising of Attendance (4 marks), Academic activities (Average of any 3 activities e.g. Quiz, assignment, open book test, field work, group discussion and seminar) (3 marks) and student teacher interaction (3 marks). End semester exams is of 75 marks.

Total Marks are 100 for the subject (Internal Assessment: 25 Marks and End semester examination: 75 Marks).

Name of the Academic Program: M. Pharm. Pharmaceutical Quality Assurance Sem II

Course Code: MQA 202T

Title of the Course: Pharmaceutical Validation (Theory)

L-T-P: 4-0-0 **Credits: 4**

(L=Lecture hours, T= Tutorial hours, P: Practical hours)

COURSE OUTCOMES (COs)

After completing this Course, the students should be able to:

CO-1: Explain the principles of analytical method and different process validations **(Cognitive level: Understand)**.

CO-2: Distinguish different levels of qualification of equipments and instruments **(Cognitive level: Understand)**.

CO-3: Describe Cleaning validation of equipments at manufacturing level **(Cognitive level: Understand)**.

CO-4: Discuss the aspects of intellectual property pertaining to Pharmaceuticals **(Cognitive level: Understand)**

Mapping of Course Outcomes (COs) with Program Outcomes (POs) and Program Specific Outcomes (PSOs)

	PO1	PO2	PO3	PO4	PO5	PO6	PO7	PO8	PO9	PO10	PO11	PSO1	PSO2	PSO3
CO1	3	3		1		2			3			2	2	
CO2	3	2			1	1					1	2	3	
CO3	3			2		1		1		1				
CO4		2	1			1		1	2		2	2		3

Each Course Outcome (CO) may be mapped with one or more program Outcomes (POs). Write '3' in the box for 'High-level' mapping, '2' for 'Medium-level' mapping, '1' for 'low-level' mapping

Detailed Syllabus **(Total: 60 Hrs)**

Chapter 1 **10 Hrs**

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).

Chapter 2 **10 Hrs**

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.

Chapter 3 **10 Hrs**

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.

Chapter 4 **10 Hrs**

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.

Chapter 5 **10 Hrs**

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 Part11 and GAMP

Chapter 6 **10 Hrs**

General Principles of Intellectual Property: Concepts of Intellectual Property (IP), Intellectual Property Protection (IPP), Intellectual Property Rights (IPR); Economic importance, mechanism for protection of Intellectual Property– patents, Copyright, Trademark; Factors affecting choice of IP protection; Penalties for violation; Role of IP in pharmaceutical industry; Global ramification and financial implications. Filing a patent applications; patent application forms and guidelines. Types patent applications - provisional and non-provisional, PCT and convention patent applications; International patenting requirement procedures and costs; Rights and responsibilities of a patentee; Practical aspects regarding maintaining of a Patent file; Patent infringement meaning and scope. Significance of transfer technology (TOT), IP and ethics-positive and negative aspects

of IPP; Societal responsibility, avoiding unethical practices.

Reference Books

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 & Agallo co, (Marcel Dekker).
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, Inter pharm 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. InterpharmPress
12. LeBlanc DA. Validated Cleaning Technologies for Pharmaceutical Manufacturing. Interpharm Press

Teaching-Learning Strategies in Brief

The teaching learning strategies, followed are board and chalk teaching, Learning through discussion among the peer group, classroom interaction, discussion of research papers of Journals related to topics/ICH guidelines, power point presentation, Q & A session and reflective learning.

Assessment methods and weightages in brief

There are two components of assessment: Internal assessment (25 marks) and End semester examination (75 marks). Internal assessment consists of continuous mode (10 marks) and sessional

examinations (15 marks). There are two sessional exams (each conducted for 30 marks and computed for 15 marks) and one improvement exam. The average marks of two best sessional exams are computed out of 15 marks. Continuous mode evaluation is of 10 marks comprising of attendance- 8 marks (calculated as: Percentage of Attendance: Allotment of marks- Less than 80: 0 marks; 80-84: 2 marks; 85-89: 4 marks; 90-94: 6 marks and 95-100: 8 marks) and Student-Teacher interaction: 2 marks.

Total Marks are 100 for the subject (Internal Assessment: 25 marks and End Semester Examination: 75 Marks).

Name of the Academic Program: M. Pharm Quality Assurance II Sem

Course Code: MQA 203T

Title of the Course: Audits and Regulatory Compliance (Theory)

L-T-P: 4-0-0 Credits: 4

(L=Lecture hours, T=Tutorial hours, P=Practical hours)

COURSE OUTCOMES (COs)

After completing this Course, the students should be able to:

CO1: Collect information about the auditing process in pharmaceutical firms. **(Cognitive level: Create)**

CO2: Analyze the impact of various types of audits in industries **(Cognitive level: Analyze)**

CO3: Identify the potential drawbacks in audit reports **(Cognitive level: Analyze)**

CO4: Indicate the reasons for regulatory non-compliance **(Cognitive level: Understand)**.

CO5: Evaluate various methodologies for auding **(Cognitive level: Evaluate)**.

Mapping of Course Outcomes (COs) with Program Outcomes (POs) and Program Specific Outcomes (PSOs)

	PO1	PO2	PO3	PO4	PO5	PO6	PO7	PO8	PO9	PO10	PO11	PSO1	PSO2	PSO3
CO1	3	2	5	2	2	3	1	1	1	1	1	3	2	1
CO2	3	1	3	2	1	1	1	1	1	3	2	2	3	2
CO3	3	1	3	2	1	2	1	2	2	1	1	2	3	1
CO4	2	3	1	2	1	1	2	1	1	1	1	2	3	1
CO5	2	3	3	1	2	1	1	2	2	1	1	3	2	1

Each Course Outcome (CO) may be mapped with one or more Program Outcomes (POs). Write '3' in the box for 'High-level'mapping, 2 for 'Medium level'mapping, 1 for 'Low'-level'mapping.

Detailed Syllabus **(Total: 60 Hrs)**

Chapter 1 **12 Hrs**

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

Chapter 2 **12 Hrs**

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.

Chapter 3 **12 Hrs**

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.

Chapter 4 **12 Hrs**

Auditing of Microbiological laboratory: Auditing the manufacturing process, Product and process information, General areas of interest in the building raw materials, Water, Packaging materials.

Chapter 5 **12 Hrs**

Auditing of Quality Assurance and engineering department: Quality Assurance Maintenance, Critical systems: HVAC, Water, Water for Injection systems, ETP.

Reference Books

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).

Teaching-Learning Strategies in brief

The teaching learning strategies, followed are board and chalk teaching, Learning through discussion among the peer group, classroom interaction, quiz, presentations, Q & A session and reflective learning.

Assessment methods and weightages in brief

There are two components of assessment: Internal assessment and End semester examination. Internal assessment consists of continuous mode and sessional exams. There are two Sessional exams and one improvement exam. The average marks of two Sessional exams are computed for internal assessment. Sessional exam is conducted for 30 marks and are computed for 15 marks. Continuous mode evaluation is of 10 marks comprising of Attendance (4 marks), Academic activities (Average of any 3 activities e.g. Quiz, assignment, open book test, field work, group

discussion and seminar) (3 marks) and student teacher interaction (3 marks). End semester exams is of 75 marks.

Total Marks are 100 for the subject (Internal Assessment: 25 Marks and End semester examination: 75 Marks).

Name of the Academic Program: M. Pharm. Quality Assurance Sem. I

Course Code: MQA 204 T.

Title of the Course: Pharmaceutical Manufacturing Technology (Theory)

L-T-P: 4-0-0 **Credits: 4**

(L=Lecture hours, T= Tutorial hours, P: Practical hours)

COURSE OUTCOMES (COs)

After completing this Course, the students should be able to:

CO1: Explain various practices in the pharmaceutical industry and recent developments **(Cognitive level: Understand)**.

CO2: Know the practices of aseptic processing technology and non-sterile manufacturing practices **(Cognitive level: Understand)**

CO3: Understand basics principles and implementation of Quality by design (QbD) and its software **(Cognitive level: Create and Apply)**

CO4: Use of the concepts of process analytical technology (PAT) in pharmaceutical industrial processes **(Cognitive level: Understand)**

CO5: Design different packaging technology **(Cognitive level: Understand and Apply)**

Mapping of Course Outcomes (COs) with Program Outcomes (POs) and Program Specific Outcomes (PSOs)

	PO1	PO2	PO3	PO4	PO5	PO6	PO7	PO8	PO9	PO10	PO11	PSO1	PSO2	PSO3
CO1	3			3					3					2
CO2	3	2	2	2					3	3	3		2	2
CO3	3	2	3	2					1	2	3	3		2
CO4	3		3	3	2				2	2	2		2	2
CO5	3	3	2	3		2			2	3			3	2

Each Course Outcome (CO) may be mapped with one or more program Outcomes(POs). Write ‘3’ in the box for ‘High-level’ mapping, ‘2’ for ‘Medium-level’ mapping, ‘1’ for ‘low-level’ mapping

Detailed Syllabus **(Total: 60 Hrs)**

Chapter 1 **12 Hrs**

Pharmaceutical industry developments: Legal requirements and Licenses for API and formulation industry, Plant location- Hours 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.

Chapter 2 **12 Hrs**

Aseptic process technology: Manufacturing, manufacturing 12 flowcharts, in process-quality control tests for following sterile Hrs dosage forms: Ointment, S uspension and Emulsion, Dry powder, Solution (S mall Volume & large Volume). Advanced sterile product manufacturing technology: Area planning & environmental control, wall and floor treatment, fixtures and machineries, change rooms, personnel flow, utilities & utilities equipment location, engineering and maintenance. Process Automation in Pharmaceutical Industry: With specific reference to manufacturing of sterile semisolids, Small Volume Parenterals & Large Volume Parenterals (SVP & LVP), Monitoring of Parenteral manufacturing facility, Cleaning in Place (CIP), Sterilization in Place (SIP), Prefilled Syringe, Powdered Jet, Needle Free Injections, and Form Fill Seal Technology (FFS). Lyophilization technology: Principles, process, equipment.

Chapter 3 **12 Hrs**

Non sterile manufacturing process technology: 12 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. P roblems encountered.
Coating technology: Process, equipments, particle coating, fluidized bed coating, application techniques. Problems encountered.

Chapter 4 **12 Hrs**

Containers and closures for pharmaceuticals: Types, 12 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.

Chapter 5 **12 Hrs**

Quality by design (QbD) and process analytical technology 12 (P AT): 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 E 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.

Reference Books

1. Lachman L, Lieberman HA,KanigJ L.The theory and practice of industrial pharmacy, 3rd ed., Varghese Publishers, Mumbai 1991.
2. Sinko PJ. Martin's physical pharmacy and pharmaceutical sciences, 5 ed., B.I. Publications P vt. Ltd, Noida, 2006.
3. Lieberman HA, Lachman L, Schwartz J B. Pharmaceutical dosage forms: and tablets Vol. I-III, 2 ed., CBS Publishers & distributors, New Delhi, 2005.
4. Banker GS, Rhodes CT. Modern Pharmaceutics, 4th 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 E dition. B halani publishing house Mumbai.
6. Indian Pharmacopoeia. Controller of Publication. Delhi,1996.
7. British P harmacopoeia. B ritish P harmacopoeia 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 st Technology. London, Taylor & Francis, 1 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 J ersey, 2008.

Teaching-Learning Strategies in Brief

The teaching learning strategies, followed are board and chalk teaching, Learning through discussion among the peer group, classroom interaction, discussion of research papers of Journals related to topics, power point presentation, Q & A session and reflective learning.

Assessment methods and weightages in brief

There are two components of assessment: Internal assessment (25 marks) and End semester examination (75 marks). Internal assessment consists of continuous mode (10 marks) and sessional examinations (15 marks). Continuous mode evaluation is of 10 marks comprising of attendance- 8 marks (calculated as: Percentage of Attendance: Allotment of marks- Less than 80: 0 marks; 80-84: 2 marks; 85-89: 4 marks; 90-94: 6 marks and 95-100: 8 marks) and Student- Teacher interaction- 2 marks. There are two Sessional exams (each conducted for 30 marks and computed

for 15 marks) and one improvement exam (30 marks and computed for 15 marks). The average marks of two best sessional exams are computed out of 15 marks.

Total Marks are 100 for the subject (Internal Assessment: 25 marks and End Semester Examination: 75 Marks)

Name of the Academic Program: M. Pharm Quality Assurance II Sem

Course Code: MQA 205P

Title of the Course: Quality Assurance Practical – II

L-T-P: 0-0-12 **Credits: 6**

(L=Lecture hours, T=Tutorial hours, P=Practical hours)

COURSE OUTCOMES (COs)

After completing this Course, the students should be able to:

CO1: Analyze various organic contaminants **(Cognitive level: Analyze)**

CO2: Identify matallic contaminants and antibiotic residues **(Cognitive level: Understand)**

CO3: Develop method of estimation of Chlorine and Hydrogen sulphide in the work environment **(Cognitive level: Create)**.

CO4: Demonstrate the techniques to study qualification of equipments **(Cognitive level: Apply)**.

CO5: Interpret the validation methods for drugs and their processing area **(Cognitive level: Evaluate)**

Mapping of Course Outcomes (COs) with Program Outcomes (POs) and Program Specific Outcomes (PSOs)

	PO1	PO2	PO3	PO4	PO5	PO6	PO7	PO8	PO9	PO10	PO11	PSO1	PSO2	PSO3
CO1	3	3	1	2	1	1	1	1	1	1	1	3	2	1
CO2	3	3	1	1	1	1	1	1	1	3	2	2	3	1
CO3	2	3	3	1	1	1	1	2	1	1	1	2	3	1
CO4	3	3	1	2	1	2	1	2	1	2	1	2	3	1
CO5	3	2	1	3	3	1	1	2	1	1	2	1	2	3

Each Course Outcome (CO) may be mapped with one or more Program Outcomes (POs). Write '3' in the box for 'High-level'mapping, 2 for 'Medium-level'mapping, 1 for 'Low'-level'mapping.

Detailed Syllabus **12 Hours/Week**

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

Teaching-Learning Strategies in brief

The teaching learning strategies followed are board and chalk teaching, Learning through discussion among the peer group, classroom interaction, quiz, presentations, Q & A session and reflective learning.

Assessment methods and weightages in brief

There are two components of assessment: Internal assessment and End semester examination. Internal assessment consists of continuous mode and sessional practical exams. There are two Sessional exams and one improvement exam. The average marks of two Sessional exams are computed for internal assessment. Sessional practical exam is conducted for 30 marks. Continuous mode evaluation is of 20 marks comprising of Attendance (10 marks), Practical records and Viva voce (10 marks). End semester exams is of 100 marks.