ADMISSION & EXAMINATION BYE-LAWS

FOR

MASTER OF PHARMACY IN PHARMACEUTICS

Program Code: MPH

(With effect from 2017-18)

SCHOOL OF PHARMACEUTICAL EDUCATION AND RESEARCH
JAMIA HAMDARD
(DEEMED TO BE UNIVERSITY)
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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	Pharmaceutics	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	MPH	31.05.2017

VISION AND MISSION STATEMENTS

Vision Statement: Consistent striving for excellence in development of clinically translational novel drug delivery systems

Mission Statements:

MS 1: To be a catalyst for positive benchmark change for sustainable and commercially viable pharmaceutical research
MS 2: To advance the practice of innovative research and outcome-based education, to achieve excellence in career avenues.
MS 3: To mark the highest standards of scientific rigors with updated knowledge and technology for fruitful scientific outcomes.

PROGRAM EDUCATIONAL OBJECTIVES (PEOs)

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

PEO1: Apply knowledge in solving industry-relevant programs.
PEO2: Carry out quality research in different facets of the program including higher education.
PEO3: Foster abilities to design and fabricate new products or techniques, benefiting the society at large.
PEO4: Combine practical pharmaceutical knowledge and abilities with research ability for a better output.
PEO5: Inculcate entrepreneurial skills in aspiring pharmacy professionals
PEO6: Develop leadership skills to be applied in R&D, production and other facets of the profession

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

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

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

PROGRAM OUTCOMES (POs)

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

PO1: **Applied Pharmacy Knowledge:** Use knowledge of the fundamental elements in sync with updated technologies, tailored biopharmaceutical application and regulatory requirements pertaining to the development of innovative drug delivery systems.

PO2: **Research and development:** Utilize skills to create novel medicine delivery strategies for the available range of active therapeutic substances. Good understanding of the computer- based tools required for the product development research.

PO3: **Problem analysis:** Cultivate the problem solving skills that are generally encountered during pharmaceutical product development, including scale-ups and meeting the expectations of regulation by applying the concept of critical thinking and in-depth analysis.

PO4: **Modern tool usage:** Use latest product optimization tools along with statistical analysis during the novel product development, like computer aided drug design techniques and *in silico* studies.

PO5: **Communication:** Prepare quality documents, reports and effective presentation. Hone communication skills and the ability to successfully carry out obligations related to the development of knowledge in accordance with the demands of the academia and industry.

PO6: **Professional identity:** Create a profession that is dedicated to providing quality services that exceed the stakeholder's expectations like customers, industries, academia, regulatory bodies and to give direction and contribute to the improvement of services and technologies.

PO7: **Leadership skills**: Organize and execute the objectives related to research and development within a set timeline. Nurturing the skills from the beginning to manage and utilize the available resources judiciously.

PO8: **Planning abilities:** Implement the knowledge and **s**kills for proper planning and running different steps which are involved in the time bound deliverables like R&D, production, regulatory submissions and product life cycle management.

PO9: **Pharmaceutical ethics:** Show a high level of morality, honesty and integrity. Implement ethical principles when drawing conclusions and accept responsibility for the repercussions is any.

PO10: **Environmental sustainability:** Use expertise and skills to solve the issues of environmental pollution, harmful industrial waste, along with wastage and also improve manufacturing processes while maintaining the sustainability practices.

PO11: **Life-long learning:** Readily engage in independent and ongoing learning processes in response to evolving needs and scientific advances. Using input from other professionals and identifying learning needs for life-long learning improvement. Recognize the importance of conferences, seminars, and workshops in the advancement of knowledge.

PROGRAMME SPECIFIC OUTCOME (PSOs)

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

PSO1: Analyse different departments of the pharmaceutical industry like manufacturing, R&D, quality assurance, intellectual property rights and regulatory affairs

PSO2: Design and develop interfaces for entrepreneurship particularly in field of formulation research and development, pharmaceutical production, pharmaceutical consulting services, medicine sales, and distribution.

PSO3: Comprehend knowledge as drug analyst, research scientist, drug inspector and qualified teachers in the public and private organizations.

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

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

Semester I

Course code	Name of the course	Internal Assessment				End Semester Exams		Total Marks	Credit points
		Continuous mode	Sessional Exams		Total	Marks	Duration		
			Marks	Duration					
MPH101T	Modern Pharmaceutical Analytical Techniques	10	15	1 Hr	25	75	3 Hrs	100	4
MPH102T	Drug Delivery System	10	15	1 Hr	25	75	3 Hrs	100	4
MPH 103T	Modern Pharmaceutics	10	15	1 Hr	25	75	3 Hrs	100	4
MPH 104T	Regulatory Affair	10	15	1 Hr	25	75	3 Hrs	100	4
MPH 105P	Pharmaceutics Practical I	20	30	6 Hrs	50	100	6 Hrs	150	6
MPH 106S	Seminar/Assignment	-	-	-	-			100	4
Total								**650**	**26**

Semester II

Course code	Name of the course	Internal Assessment				End Semester Exams		Total Marks	Credit points
		Continuous Mode	Sessional Exams		Total	Marks	Duration		
			Marks	Duration					
MPH201T	Molecular Pharmaceutics (Nano Tech and Targeted DDS)	10	15	1 Hr	25	75	3 Hrs	100	4
MPH 202T	Advanced Biopharmaceutics & Pharmacokinetics	10	15	1 Hr	25	75	3 Hrs	100	4
MPH 203T	Computer Aided Drug Delivery System	10	15	1 Hr	25	75	3 Hrs	100	4
MPH 204T	Cosmetic and Cosmeceuticals	10	15	1 Hr	25	75	3 Hrs	100	4
MPH 205P	Pharmaceutics Practical II	20	30	6 Hrs	50	100	6 Hrs	150	6
MPH 206S	Seminar/Assignment							100	4
Total								**650**	**26**

Semester III

Course code	Name of the course	Internal Assessment				End Semester Exams		Total Marks	Credit points
		Continuous Mode	Sessional Exams		Total	Marks	Duration		
			Marks	Duration					
MPH 301T	Research Methodology and Biostatistics*	10	15	1 Hr	25	75	3 Hrs	100	4
MPHJC 302	Journal club	-	-	-	25		3 Hrs	25	1
MPHDP 303	Discussion / Presentation (Proposal Presentation)	-	-	-	50		3 Hrs	50	2
MPHRW 304	Research Work	-	-	-	-	350	1 Hrs	350	14
Total								**525**	**21**

* Non University Exam

Semester IV

Course code	Name of the course	Internal Assessment				End Semester Exams		Total Marks	Credit points
		Continuous Mode	Sessional Exams		Total	Marks	Duration		
			Marks	Duration					
MPHJC 401	Journal club	-	-	-	25	-	-	25	1
MPHDP 402	Discussion / Presentation (Proposal Presentation	-	-	-	75	-	-	75	16
MPHRW 403	Research work and Colloquium	-	-	-	-	400	1 Hr	400	3
MPHCA 404	Co-curricular Activities	-	-	-	50	-	-	50	Minimum=02 Maximum=07
Total								**550**	**20**

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– II-V. 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 –II-V

Table II-: Course of study for Semester I

Course code	Name of the course	No. of Hours	Tutorial	Credit points
MPH101T	Modern Pharmaceutical Analytical Techniques	4	-----	4
MPH102T	Drug Delivery System	4	-----	4
MPH 103T	Modern Pharmaceutics	4	----	4
MPH 104T	Regulatory Affair	4	----	4
MPH 105P	Pharmaceutics Practical I	12	----	6
MPH 106S	Seminar/Assignment	7	----	4
	Total	**35**		**26**

Table III-: Course of study for Semester II

Course code	Name of the course	No. of Hours	Tutorial	Credit points
MPH 201T	Molecular Pharmaceutics (Nano Tech and Targeted DDS)	4	-	4
MPH 202T	Advanced Biopharmaceutics & Pharmacokinetics	4		4
MPH 203T	Computer Aided Drug Delivery System	4	-	4
MPH 204T	Cosmetic and Cosmeceuticals	4	-	4
MPH 205P	Pharmaceutics Practical II	12	-	6
MPH 206S	Seminar/Assignment	7	-	4
	Total	**35**		**26**

Table IV-: Course of study for Semester III

Course Code	Course	Credit Hours	Credit Points
MPH 301T	Research Methodology and Biostatistics*	4	4
MPHJC 302	Journal club	1	1
MPHDP 303	Discussion / Presentation (Proposal Presentation)	2	2
MPHRW 304	Research Work	28	14
Total		**35**	**21**

* Non University Exam

Table V-: Course of study for Semester IV

Course Code	Course	Credit Hours	Credit Points
MPHJC 401	Journal Club	1	1
MPHDP 402	Discussion/Final Presentation	3	3
MPHRW 403	Research work and Colloquium	31	16
MPHCA 404	Co-curricular Activities	-	Minimum=02 Maximum=07
Total		**35**	Minimum=22 Maximum=27

Table-VI: 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=10*

* 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.

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 IV- VII

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 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 VII: Scheme for awarding internal assessment: Continuous mode

Theory	
Criteria	**Maximum Marks**
Attendance (Refer Table – VIII)	8
Student – Teacher interaction	2
Total	10
Practical	
Attendance (Refer Table – VIII)	10
Based on Practical Records, Regular viva voce, etc.	10
Total	20

Table VIII: 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 IX. The exact dates of examinations shall be notified from time to time.

Table IX: 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 – X.

Table X: 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 obtainedin 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, theSGPA shall then be computed as:

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

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 statusin 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 MPH 101T	**Title of the course: Modern Pharmaceutical Analytical Techniques (MAT)**
Course Code: MPH 102T	**Title of the Course: Drug Delivery Systems (Theory)**
Course Code: MPH 103T	**Title of the Course: Modern Pharmaceutics (Theory)**
Course Code: MPH 104T	**Title of the Course: Regulatory Affairs (Theory)**
Course Code: MPH 105P	**Title of the Course: Pharmaceutics Practical -I**

Name of the Academic Program: M. Pharm. Pharmaceutics Sem I
Course Code: MPH101T
Title of the Course: Modern Pharmaceutical Analytical Techniques (Theory)
L-T-P: 4-0-0 **Credits: 4**
(L=Lecture hours, T=Tutorial hours)

COURSE OUTCOMES (COs)

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

CO1: Recognize the principle, instrumentation and applications of different chromatographic techniques **(Cognitive level: Remember and Understand)**
CO2: Investigate the pharmaceutical substance by Nuclear Magnetic spectroscopy techniques. **(Cognitive level: Remember and Understand)**
CO3: Investigate the pharmaceutical substance by Mass spectroscopy Techniques. **(Cognitive level: Remember and Understand)**
CO4: The analysis of various drugs in single and combination dosage forms **(Cognitive level: Remember and Understand)**
CO5: Recognize the principle, instrumentation and applications of electrophoresis and X ray crystallography. delivery systems **(Cognitive level: Remember and 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	1	2	2	3	2	1	1	1	1	1	2	1	1	2
CO2	1	2	2	3	2	1	1	1	1	1	2	1	1	2
CO3	1	2	2	3	2	1	1	1	1	1	2	1	1	1
CO4	1	2	2	3	1	1	1	1	1	1	2	1	1	3
CO5	1	2	2	3	2	1	1	1	1	1	2	1	1	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 Hours)**

Unit I **12 Hrs**

a. UV-Visible spectroscopy: Introduction, Theory, Laws, Instrumentation associated with UV-Visible spectroscopy, Choice of solvents and solvent effect and Applications of UV Visible spectroscopy.

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

c. Spectrofluorimetry: Theory of Fluorescence, Factors affecting fluorescence, Quenchers, Instrumentation and Applications of fluorescence spectrophotometer.

d. Flame emission spectroscopy and Atomic absorption spectroscopy: Principle, Instrumentation, Interferences and Applications.

Unit II **12 Hrs**

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

Unit III **12 Hrs**

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

Unit IV **12 Hrs**

Chromatography: Principle, apparatus, instrumentation, chromatographic parameters, factors affecting resolution, isolation of drug from excipients, data interpretation and applications of the following:

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

Unit V **12 Hrs**

a. Electrophoresis: Principle, Instrumentation, working conditions, factors affecting separation and applications of the following:

a) Paper electrophoresis b) Gel electrophoresis c) Capillary electrophoresis d) Zone electrophoresis e) Moving boundary electrophoresis f) Isoelectric focusing

b. 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 Xray diffraction.

Unit VI **12 Hrs**

a. **Potentiometry:** Principle, working, ions selective electrodes, and application of potentiometry.
b. **Thermal techniques:** Principle, thermal transitions, and instrumentation (Heat flux and Power-compensation and designs), Modulated DSC, Hyper DSC, Experimental parameters (Sample preparation, experimental condition, calibration, heating and cooling rates, resolution, sources of errors) and their influence, advantages and disadvantages, pharmaceutical applications.
c. **Differential Thermal Analysis (DTA):** Principle, instrumentation, advantages, disadvantages, pharmaceutical application, derivative differential thermal analysis (DDTA).
d. TGA: Principle, instrumentation, factors affecting results, advantages and disadvantages, pharmaceutical application.

Reference Books

1. Spectrometric Identification of Organic compounds - Robert M Silverstein, Sixth edition, John Wiley & Sons, 2004.
2. Principles of Instrumental Analysis - Doglas A Skoog, F. James Holler, Timothy A. Nieman, 5th edition, Eastern press, Bangalore, 1998.
3. Instrumental methods of analysis – Willards, 7th edition, CBS publishers.
4. Practical Pharmaceutical Chemistry – Beckett and Stenlake, Vol II, 4th edition, CBS Publishers, New Delhi, 1997.
5. Organic Spectroscopy - William Kemp, 3rd edition, ELBS, 1991.
6. Quantitative Analysis of Drugs in Pharmaceutical formulation - P D Sethi, 3rd Edition, CBS Publishers, New Delhi, 1997.
7. Pharmaceutical Analysis- Modern methods – Part B - J W Munson, Volume 11, Marcel Dekker Series

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).

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Name of the Academic Program: M. Pharm. Pharmaceutics Sem I
Course Code: MPH 102T
Title of the Course: Drug Delivery Systems (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 various approaches for development of novel drug delivery Systems. **(Cognitive Level: Understand)**.
CO-2: Know the criteria for selection of drugs and polymers for the development of delivering systems **(Cognitive level: Understand)**
CO-3: To formulate and evaluate the Novel drug delivery systems **(Cognitive level: Create and Apply)**
CO-4: Use the concepts of Personalized medicine, Bioelectronic Medicine, 3 D printing of pharmaceuticals and Tele pharmacy **(Cognitive level: Understand)**
CO-5: Design different rate controlled novel delivery systems for protein/peptide and Vaccine delivery systems (Cognitive level: Understand and Apply)

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

	PO 1	PO 2	PO 3	PO 4	PO 5	PO 6	PO 7	PO 8	PO 9	PO 10	PO 11	PSO 1	PSO 2	PSO 3
CO1	3	2	3	2	2	3	3	3	3	1	3	1	3	3
CO2	3	2	2	2	2	3	2	3	2	3	3	1	2	2
CO3	3	2	3	2	2	3	2	3	1	2	3	3	3	2
CO4	3	3	3	3	2	3	2	3	2	2	2	1	2	2
CO5	3	3	2	2	2	2	2	3	2	3	3	1	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)**

1. **Sustained Release (SR) and Controlled Release (CR)formulations:** Introduction & basic concepts, advantages/disadvantages, factors influencing, Physicochemical & biological approaches for SR/CR formulation, Mechanism of Drug Delivery from SR/CR formulation. Polymers: introduction, definition, classification, properties and application, Dosage Forms for Personalized Medicine: Introduction, Definition, Pharmacogenetics, Categories of Patients for Personalized Medicines: Customized drug delivery systems, Bioelectronic Medicines, 3D printing of pharmaceuticals, Tele pharmacy. **10 Hrs**
2. **Rate Controlled Drug Delivery Systems:** Principles & Fundamentals, Types, Activation; Modulated Drug Delivery Systems; Mechanically activated, pH activated, Enzyme activated, and Osmotic activated Drug Delivery Systems, Feedback regulated Drug Delivery Systems; Principles & Fundamentals. **10 Hrs**

3. **Gastro-Retentive Drug Delivery Systems:** Principle, concepts, advantages and disadvantages, Modulation of GI transit time approaches to extend GI transit. Buccal Drug Delivery Systems: Principle of muco adhesion, advantages and disadvantages, Mechanism of drug permeation, Methods of formulation and its evaluations. **10 Hrs**

4 **Ocular Drug Delivery Systems**: Barriers of drug permeation, Methods to overcome barriers. **06 Hrs**

5 **Transdermal Drug Delivery Systems:** Structure of skin and barriers, Penetration enhancers, Transdermal Drug Delivery Systems, Formulation and evaluation.**10 Hrs**

6. **Protein and Peptide Delivery**: Barriers for protein delivery. Formulation and Evaluation of delivery systems of proteins and other macromolecules. **08 Hrs**

7 **Vaccine delivery systems**: Vaccines, uptake of antigens, single shot vaccines, mucosal and transdermal delivery of vaccines. **06 Hrs**

Reference Books & Journals

1. Y W. Chien, Novel Drug Delivery Systems, 2nd edition, revised and expanded, Marcel Dekker, Inc., New York, 1992.
2. Robinson, J. R., Lee V. H. L, Controlled Drug Delivery Systems, Marcel Dekker, Inc., New York, 1992.
3. Encyclopedia of Controlled Delivery, Editor- Edith Mathiowitz, Published by Wiley Interscience Publication, John Wiley and Sons, Inc, New York! Chichester/Weinheim
4. N.K. Jain, Controlled and Novel Drug Delivery, CBS Publishers & Distributors, New Delhi, First edition 1997 (reprint in 2001).
5. S.P.Vyas and R.K.Khar, Controlled Drug Delivery - concepts and advances, Vallabh Prakashan, New Delhi, First edition 2002
6. Indian Journal of Pharmaceutical Sciences (IPA)
7. Indian drugs (IDMA)
8. Journal of controlled release (Elsevier Sciences) desirable
9. Drug Development and Industrial Pharmacy (Marcel & Decker) desirable

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. Pharmaceutics Sem I
Course Code: MPH 103T
Title of the Course: Modern Pharmaceutics (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: Define the elements of preformulation studies concerning various types of dosage forms. **(Cognitive level: Remember and understand)**
CO-2: Know Active Pharmaceutical Ingredients and Generic Drug Product development **(Cognitive level: Understand)**
CO-3: Explain Industrial Management and GMP Considerations (**Cognitive level: Understand and Remember)**
CO-4: Distinguish between various Optimization Techniques & Pilot Plant Scale Up Techniques **(Cognitive level: Understand and apply)**
CO-5: Learn about the principles of stability testing, sterilization process & packaging of dosage forms **(Cognitive level: Understand, Evaluate and Apply)**

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

	PO1	PO 2	PO 3	PO 4	PO 5	PO 6	PO 7	PO 8	PO 9	PO1 0	PO1 1	PSO1	PSO 2	PSO 3
CO1	3	1	3	2	2	1	2	2	1	1	2	3	2	3
CO2	3	1	3	2	2	2	2	3	3	2	3	3	2	3
CO3	3	2	3	2	3	2	2	3	3	3	3	3	3	3
CO4	3	2	3	3	3	2	2	2	2	2	2	2	2	2
CO5	3	2	3	2	3	2	2	2	2	2	2	2	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 **(Total:60 Hrs)**

Unit 1
a. Preformation Concepts – Drug Excipient interactions - different methods, kinetics of stability, Stability testing. Theories of dispersion and pharmaceutical Dispersion (Emulsion and Suspension, SMEDDS) preparation and stability large and small volume parental – physiological and formulation consideration, Manufacturing and evaluation. **10 Hrs**

b. Optimization techniques in Pharmaceutical Formulation: Concept and parameters of optimization, Optimization techniques in pharmaceutical formulation and processing. Statistical design, Response surface method, Contour designs, Factorial designs and application in formulation. **10 Hrs**

Unit 2

Validation: Introduction to Pharmaceutical Validation, Scope & merits of Validation, Validation and calibration of Master plan, ICH & WHO guidelines for calibration and validation of equipment's, Validation of specific dosage form, Types of validation. Government regulation, Manufacturing Process Model, URS, DQ, IQ, OQ & P.Q. of facilities. **10 Hrs**

Unit 3

cGMP & Industrial Management: Objectives and policies of current good manufacturing practices, layout of buildings, services, equipment's and their maintenance Production management: Production organization, materials management, handling and transportation, inventory management and control, production and planning control, Sales forecasting, budget and cost control, industrial and personal relationship. Concept of Total Quality Management. **10 Hrs**

Unit 4

Compression and compaction: Physics of tablet compression, compression, consolidation, effect of friction, distribution of forces, compaction profiles. Solubility. **10 Hrs**

Unit 5

Study of consolidation parameters: Diffusion parameters, Dissolution parameters and Pharmacokinetic parameters, Heckel plots, Similarity factors – f2 and f1, Higuchi and Peppas plot, Linearity Concept of significance, Standard deviation, Chi square test, students T-test, ANOVA test. **10 Hrs**

Reference Books

1. Theory and Practice of Industrial Pharmacy By Lachmann and Libermann
2. Pharmaceutical dosage forms: Tablets Vol. 1-3 by Leon Lachmann.
3. Pharmaceutical Dosage forms: Disperse systems, Vol, 1-2; By Leon Lachmann.
4. Pharmaceutical Dosage forms: Parenteral medications Vol. 1-2; By Leon Lachmann.
5. Modern Pharmaceutics; By Gillbert and S. Banker.
6. Remington's Pharmaceutical Sciences.
7. Advances in Pharmaceutical Sciences Vol. 1-5; By H.S. Bean & A.H. Beckett.
8. Physical Pharmacy; By Alfred martin
9. Bentley's Textbook of Pharmaceutics – by Rawlins.
10. Good manufacturing practices for Pharmaceuticals: A plan for total quality control, Second edition; By Sidney H. Willig.
11. Quality Assurance Guide; By Organization of Pharmaceutical producers of India.
12. Drug formulation manual; By D.P.S. Kohli and D.H.Shah. Eastern publishers, New Delhi.
13. How to practice GMPs; By P.P.Sharma. Vandhana Publications, Agra.
14. Pharmaceutical Process Validation; By Fra. R. Berry and Robert A. Nash.
15. Pharmaceutical Preformulations; By J.J. Wells.
16. Applied production and operations management; By Evans, Anderson, Sweeney and Williams.
17. Encyclopaedia of Pharmaceutical technology, Vol I – III.

Teaching-Learning Strategies in Brief

Various pedagogic strategies are employed including classroom teaching in chalk-board mode as well as audio-visual mode, peer group learning and discussions, classroom interactions, review/research papers published in journals related to topics (Journal Club) evaluation through

peer discussion, 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 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).

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Name of the Academic Program: M. Pharm. Pharmaceutics Sem I
Course Code: MPH 104T
Title of the Course: Regulatory Affairs
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: Discuss the concept of innovator drugs, generic drugs, and drug development process. **(Cognitive level: Understand)**

CO2: Discuss the regulatory process and guidelines for filing applications for approval process. **(Cognitive level: Remember)**

CO3: Differentiate between the guidelines for filing and approval process of regulatory agencies in different countries. **(Cognitive level: Create)**

CO4: Evaluate the post approval regulatory requirements for actives and drug products. **(Cognitive level: Evaluate)**

CO5: Analyze the global documents in Common Technical Document / eCTD formats **(Cognitive level: Analyze).**

CO6: Discuss the regulatory procedures involved in non-clinical drug development **(Cognitive level: Remember).**

CO7: Apply the regulatory requirements for approvals for conducting clinical trials **(Cognitive level: Apply).**

CO8: Discuss the pharmacovigilance and monitoring of clinical trials **(Cognitive level: Remember).**

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	1	1	2	1	2	2	2	3	3	2	1
CO2	3	1	2	1	2	2	1	3	2	1	3	2	2	2
CO3	3	1	3	1	2	2	1	3	2	1	3	3	1	2
CO4	3	1	3	2	2	2	1	2	2	1	3	3	2	2
CO5	3	1	3	1	1	3	1	2	2	1	3	1	1	2
CO6	3	1	1	2	2	2	3	2	2	1	3	1	2	1
CO7	3	1	2	1	2	2	2	2	2	1	3	3	2	1
CO8	3	1	2	1	2	3	1	2	3	2	3	1	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 **60 Hrs**

1. a. Documentation in Pharmaceutical industry: Master formula record, DMF (Drug Master File), distribution records. Generic drugs product development Introduction, Hatch-Waxman act and amendments, CFR (CODE OF FEDERAL REGULATION), drug product performance, in-vitro, ANDA regulatory approval process, NDA approval process, BE and

drug product assessment, in –vivo, scale up process approval changes, post marketing surveillance, outsourcing BA and BE to CRO. **12 Hrs**

1. b. Regulatory requirement for product approval: API, biologics, novel, therapies obtaining NDA, ANDA for generic drugs ways and means of US registration for foreign drugs **12 Hrs**

2. CMC, post approval regulatory affairs. Regulation for combination products and medical devices. CTD and ECTD format, industry and FDA liaison. ICH - Guidelines of ICH-Q, S E, M. Regulatory requirements of EU, MHRA, TGA and ROW countries. **12 Hrs**

3. Non clinical drug development: Global submission of IND, NDA, ANDA. Investigation of medicinal products dossier, dossier (IMPD) and investigator brochure (IB). **12 Hrs**

4. Clinical trials: Developing clinical trial protocols. Institutional review board/ independent ethics committee Formulation and working procedures informed Consent process and procedures. HIPAA- new, requirement to clinical study process, pharmacovigilance safety monitoring in clinical trials. **12 Hrs**

Reference Books & Websites

1 Javed Ali and Sanjula Baboota Regulatory Affairs in the Pharmaceutical Industry. Academic Press is an imprint of Elsevier Inc., USA**.** 2022. ISBN: 978-0-12-822211-9
2. The Pharmaceutical Regulatory Process, Second Edition Edited by Ira R. Berry and Robert P.Martin, Drugs and the Pharmaceutical Sciences,Vol.185, Informa Health care Publishers.
3. New Drug Approval Process: Accelerating Global Registrations By Richard A Guarino, MD,5th edition, Drugs and the Pharmaceutical Sciences, Vol.190.
4. Guidebook for drug regulatory submissions / Sandy Weinberg. By John Wiley & Sons. Inc.
5. FDA regulatory affairs: a guide for prescription drugs, medical devices, and biologics/edited By Douglas J. Pisano, David Mantus.
6. Clinical Trials and Human Research: A Practical Guide to Regulatory Compliance By Fay A. Rozovsky and Rodney K. Adams
7. www.ich.org/
8. www.fda.gov/
9. europa.eu/index_en.htm
10. https://www.tga.gov.au/tga-basics.
11. Generic Drug Product Development, Solid Oral Dosage forms, Leon Shargel and Isader Kaufer,Marcel Dekker series, Vol.143

Teaching-Learning Strategies in brief

The teaching learning strategies, followed are board and chalk teaching, presentations, Learning through discussion among the peer group, classroom interaction, quiz, 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). 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. Pharmaceutics Sem I
Course Code: MPH 105P
Title of the Course: Pharmaceutics Practical -1
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: Analyse therapeutic agents by various instrumental analytical techniques namely UV/VIS spectrophotometry, HPLC, Gas chromatography, fluorimetry and flame photometry (**Cognitive level: Analyze)**

CO-2: Explain the various elements of preformulation studies before commencing with formulation development **(Cognitive level: Evaluate)**

CO-3: Design, formulate and evaluate various novel drug delivery systems namely SR matrix tablets, osmotic controlled systems, floating formulations, mucoadhesive tablets and transdermal systems **(Cognitive level: Create)**

CO-4: Analyse various factors affecting drug disintegration and dissolution **(Cognitive level: Analyze)**

CO-5: Understand the importance of *in vitro* dissolution studies for predicting drug release **(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	2	2	3	1	1	3	3	1	3	2	2	2
CO2	3	3	3	2	3	2	1	3	3	1	3	2	2	2
CO3	3	3	3	3	3	3	1	3	3	3	3	3	3	2
CO4	3	3	2	2	3	2	1	3	3	1	3	1	2	2
CO5	3	3	3	2	3	2	1	3	3	1	3	1	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

1. Analysis of Pharmacopoeial compounds and their formulations by UV Vis spectrophotometer
2. Simultaneous estimation of multi 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
7. To perform In-vitro dissolution profile of CR/ SR marketed formulation
8. Formulation and evaluation of sustained release matrix tablets
9. Formulation and evaluation osmotically controlled DDS
10. Preparation and evaluation of Floating DDS- hydro dynamically balanced DDS
11. Formulation and evaluation of Muco adhesive tablets.

12. Formulation and evaluation of trans dermal patches.
13. To carry out preformulation studies of tablets.
14. To study the effect of compressional force on tablets disintegration time.
15. To study Micromeritic properties of powders and granulation.
16. To study the effect of particle size on dissolution of a tablet.
17. To study the effect of binders on dissolution of a tablet.
18. To plot Heckel plot, Higuchi and peppas plot and determine similarity factors.

Reference Books

1. United States of pharmacopoeia, USP-24, NF-19. Asian edition, 2000.
2. Indian pharmacopoeia - Govt. of Indian Ministry of Health, 2018.
3. Lachman Leon, Liebermann, H.A; Kanig, J.L. The Theory and Practice of Industrial Pharmacy, IV edition, 2013.
4. Aulton, M.E; Pharmaceutics – The science of dosage form design, II edition, Churchill living stone, 2002.
5. Banker, G.S.; Rhodes, C.T.; Drugs and the Pharmaceutical science – Modern Pharmaceutics, IV edition, Marcel Dekker Inc., 2002
6. Martindale, Extra Pharmacopoeia
7. Dissolution, Bioavailability and Bioequivalence, Abdou. H.M, Mack Publishing Company, Pennsylvania 1989
8. Biopharmaceutics and Relevant Pharmacokinetics by John. G Wagner and M. Pemarowski,1st edition, Drug Intelligence Publications, Hamilton, Illinois, 1971.
9. Encyclopedia of Pharmaceutical Technology, Vol 13, James Swarbrick, James. G. Boylan,
   Marcel Dekker Inc, New York, 1996.
10. Sanjula Baboota and Javed Ali, Novel Drug Delivery Systems as per New B. Pharm. PCI Syllabus. Birla Publications, New Delhi, India, 2022.

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. Finally learning by doing i.e., performing the experiment, discussing the observations and interpretation among peers.

Assessment methods and weightages in brief

There are two components of assessment: Internal assessment (50 marks) and End semester examination (100 marks). Internal assessment consists of continuous mode (20 marks) and sessional examinations (30 marks). Continuous mode evaluation is of 10 marks comprising of Attendance- 10 marks (calculated as: Percentage of Attendance: Allotment of marks- Less than 80: 0 marks; 80-84: 2.5 mark; 85-89:5 mark; 90-94: 7.5 marks and 95-100: 10 marks) and based on practical records, regular viva voce, etc. -10 marks. There are two Sessional exams (each conducted for 40 marks and computed for 30 marks) and one improvement exam (40 marks and computed for 30 marks). The average marks of two best sessional exams are computed out of 30 marks.

Total Marks are 150 for the subject (Internal Assessment: 50 marks and End Semester Examination: 100 Marks).

M. PHARM. SEMESTER II	
Course Code: MPH 201T	**Title of the Course: Molecular Pharmaceutics (Nanotechnology and Targeted DDS (NTDS) (Theory)**
Course Code: MPH 202T	**Title of the Course: Advanced Biopharmaceutics & Pharmacokinetics (Theory)**
Course Code: MPH 203T	**Title of the Course: Computer Aided Drug Delivery (Theory)**
Course Code: MPH 204T	**Title of the Course: Cosmetics and Cosmeceuticals (Theory)**
Course Code: MPH 205P	**Title of the Course: Pharmaceutics Practical - II (Practical)**

Name of the Academic Program: M. Pharm. Pharmaceutics Sem II
Course Code: MPH 201T
Title of the Course: Molecular Pharmaceutics Nanotechnology &Targeted DDS (NTDS)
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: Define the various terminologies used in development of novel drug delivery system. Explain various approaches for drug targeting. **(Cognitive level: Remember and Understand)**
CO-2: Apprise about the concepts Targeted drug delivery, method and evaluation. **(Cognitive level: Remember and Understand)**
CO-3: Distinguish and establish the criteria for selection of drugs and polymers for the development of NTDS. **(Cognitive level: Understand and Apply)**
CO-4: To formulate and evaluate the novel drug delivery systems. **(Cognitive level: Create and Apply)**
CO-5: Design and evaluate different rate controlled novel delivery systems eg microcapsules/microspheres, pulmonary drug delivery and Nucleic acid based therapeutic delivery systems. **(Cognitive level: Understand and Apply)**

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

	PO 1	PO 2	PO 3	PO 4	PO 5	PO 6	PO 7	PO 8	PO 9	PO1 0	PO1 1	PSO 1	PSO 2	PSO 3
CO1	3	3	3	1	1	2	2	3	3	1	1	3	3	3
CO2	3	2	3	2	1	2	2	3	2	3	3	3	2	2
CO3	3	2	3	2	1	2	2	2	1	2	3	3	2	2
CO4	3	2	3	2	1	2	2	3	2	2	3	3	3	3
CO5	3	2	3	2	1	2	2	3	2	2	3	3	3	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)**

1. **Drug Delivery Systems**: Concepts, Events and biological process involved in drug targeting. Tumor targeting and Brain specific delivery. **12 Hrs**

2. **Targeting Methods:** introduction preparation and evaluation. Nano Particles & Liposomes: Types, preparation and evaluation. **12 Hrs**

3. **Micro Capsules / Micro Spheres:** Types, preparation and evaluation, Monoclonal Antibodies; preparation and application, preparation and application of Niosomes, Aquasomes, Phytosomes, Electrosome. **12 Hrs**

4. **Pulmonary Drug Delivery Systems:** Aerosols, propellents, Containers Types, preparation and evaluation, Intra Nasal Route Delivery systems; Types, preparation and evaluation. **12 Hrs**

5. **Nucleic acid based therapeutic delivery system:** Gene therapy, introduction (ex-vivo & in-vivo gene therapy). Potential target diseases for gene therapy (inherited disorder and cancer). Gene expression systems (viral and nonviral gene transfer). Liposomal gene delivery systems. Biodistribution and Pharmacokinetics. knowledge of therapeutic antisense molecules and aptamers as drugs of future. **12Hrs**

Reference Books

1. Y W. Chien, Novel Drug Delivery Systems, 2nd edition, revised and expanded, Marcel Dekker, Inc., New York, 1992.
2. S.P. Vyas and R.K. Khar, Controlled Drug Delivery - concepts and advances, Vallabh Prakashan, New Delhi, First edition 2002.
3. N.K. Jain, Controlled and Novel Drug Delivery, CBS Publishers & Distributors, New Delhi, First edition 1997 (reprint in 2001).

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).

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Name of the Academic Program: M. Pharm. Pharmaceutics Sem II
Course Code: MPH 202 T
Title of the Course: Advanced Biopharmaceutics & Pharmacokinetics
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: Discuss basic concepts of Biopharmaceutics and pharmacokinetics **(Cognitive level: Understand)**
CO-2: Apply raw data for deriving the pharmacokinetic models and parameters to best describe the process of drug absorption, distribution, metabolism and elimination. **(Cognitive level: Apply)**
CO-3: Critically evaluate Biopharmaceutics studies involving drug product equivalency. **(Cognitive level: Evaluate)**
CO-4: Design and evaluate dosage regimens of the drugs using pharmacokinetic and biopharmaceutic parameters. **(Cognitive level: Create)**
CO-5: Learn knowledge and skills necessary for dose calculations and dose adjustments. **(Cognitive level: Apply)**
CO-6: Analyze the Bioavailability and Bioequivalence studies to help in assessing the drug product performance *in vivo*. **(Cognitive level: Analyze)**

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

	PO 1	PO 2	PO 3	PO 4	PO 5	PO 6	PO 7	PO 8	PO 9	PO 10	PO 11	PS O1	PS O2	PS O3
CO 1	3	2	2	1	3	1	1	1	1	1	3	1	1	1
CO 2	3	3	3	2	2	3	2	1	2	2	3	2	2	2
CO 3	3	3	3	3	2	3	2	2	2	2	3	2	2	2
CO 4	3	3	3	3	2	3	1	2	2	2	3	2	2	2
CO 5	3	3	3	2	3	1	3	2	2	3	3	3	3	3
CO 6	3	3	3	2	2	3	1	2	2	3	3	2	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)**

1. **Drug Absorption from The Gastrointestinal Tract:** Gastrointestinal tract, Mechanism of drug absorption, Factors affecting, pH–partition theory, Formulation and physicochemical factors: Dissolution rate, Dissolution process, Noyes–Whitney equation and drug dissolution, Factors affecting the dissolution rate. Gastrointestinal absorption: role of the dosage form: Solution (elixir, syrup and solution) as a dosage form, Suspension as a dosage form, Capsule as a dosage form, Tablet as a dosage form, Dissolution methods, Formulation and processing factors, Correlation of in vivo data with in vitro dissolution data. Transport model: Permeability-Solubility-Charge State and the pH Partition Hypothesis, Properties of the Gastrointestinal Tract (GIT), pH Microclimate Intracellular pH Environment, Tight-Junction Complex. Solubility: Experimental methods. Permeability: In-vitro, in-situ and In-vivo methods. **12 Hrs**

2. **Biopharmaceutic Considerations in Drug Product Design and In Vitro Drug Product Performance:** Introduction, Biopharmaceutic Factors Affecting Drug Bioavailability, Rate-Limiting Steps in Drug Absorption, Physicochemical Nature of the Drug Formulation Factors Affecting Drug Product Performance, In Vitro: Dissolution and Drug Release Testing, Compendial Methods of Dissolution, Alternative Methods of Dissolution Testing, Meeting Dissolution Requirements, Problems of Variable Control in Dissolution Testing Performance of Drug Products: In Vitro–In Vivo Correlation, Dissolution Profile Comparisons, Drug Product Stability, Considerations in the Design of a Drug Product. **12 Hrs**

3. **Pharmacokinetics:** Basic considerations, Pharmacokinetic models, Compartment modelling: One compartment model- IV bolus, IV infusion, Extra-vascular; Multi Compartment model: Two compartment - model in brief, Non-Linear Pharmacokinetics: Cause of non-linearity, Michaelis – Menten equation, Estimation Kmax and Vmax. Drug interactions: Introduction, the effect of protein-binding interactions, The effect of tissue-binding interactions, Cytochrome P450-based drug interactions, Drug interactions linked to transporters. **12 Hrs**

4. **Drug Product Performance, In Vivo:** Bioavailability and Bioequivalence: Drug Product Performance, Purpose of Bioavailability Studies, Relative and Absolute Availability, Methods for Assessing Bioavailability, Bioequivalence Studies, Design and Evaluation of Bioequivalence Studies, Study Designs, Crossover Study Designs, Evaluation of the Data, Bioequivalence Example, Study Submission and Drug Review Process, The Biopharmaceutics Classification System, Generic Biologics (Biosimilar Drug Products),Clinical Significance of Bioequivalence Studies, Special Concerns in Bioavailability and Bioequivalence Studies, Generic Substitution. **12 Hrs**

5. **Application of Pharmacokinetics:** Modified-Release Drug Products, Targeted Drug Delivery Systems and Biotechnological Products. Introduction to pharmacokinetics and pharmacodynamics, drug interactions. Pharmacokinetics and pharmacodynamics of biotechnology drugs: Introduction, Proteins and peptides, Monoclonal antibodies, Oligonucleotides, Vaccines (immunotherapy), Gene therapies.

12 Hrs

Reference Books

1. Biopharmaceutics and Clinical Pharmacokinetics by Milo Gibaldi, 4th edition, Philadelphia, Lea and Febiger, 1991

2. Biopharmaceutics and Pharmacokinetics, A. Treatise, D M. Brahmankar and Sunil B. Jaiswal., Vallab Prakashan, Pitampura, Delhi
3. Applied Biopharmaceutics and Pharmacokinetics by Shargel. Land YuABC, 2nd edition, Connecticut Appleton Century Crofts, 1985
4. Textbook of Biopharmaceutics and Pharmacokinetics, Dr. Shobha Rani R. Hiremath, Prism Book.
5. Pharmacokinetics by Milo Gibaldi and D. Perrier, 2nd edition, Marcel Dekker Inc., New York, 1982.
6. Current Concepts in Pharmaceutical Sciences: Biopharmaceutics, Swarbrick. J, Lea and Febiger, Philadelphia, 1970
7. Clinical Pharmacokinetics, Concepts and Applications 3rd edition by Malcolm Rowland and Thom~ N. Tozer, Lea and Febiger, Philadelphia, 1995
8. Dissolution, Bioavailability and Bioequivalence, Abdou. H.M, Mack Publishing Company, Pennsylvania 1989
9. Biopharmaceutics and Clinical Pharmacokinetics, An Introduction, 4th edition, revised and expande by Robert. E. Notari, Marcel Dekker Inc, New York and Basel,1987.
10. Biopharmaceutics and Relevant Pharmacokinetics by John. G Wagner and M.Pemarowski, 1st edition, Drug Intelligence Publications, Hamilton, Illinois, 1971.
11. Encyclopedia of Pharmaceutical Technology, Vol 13, James Swarbrick, James. G. Boylan, Marcel Dekker Inc, New York, 1996.
12. Basic Pharmacokinetics,1 st edition, Sunil S Jambhekar and Philip J Breen, pharmaceutical press, RPS Publishing,2009.
13. Absorption and Drug Development- Solubility, Permeability, and Charge State, Alex Avdeef, John Wiley & Sons, Inc,2003.

Teaching-Learning Strategies in brief

The teaching learning strategies, followed are board and chalk teaching, presentations, 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 (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)

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Name of the Academic Program: M. Pharm. Pharmaceutics Sem II
Course Code: MPH 203T
Title of the Course: Computer Aided Drug Development (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 the various stages of drug discovery **(Cognitive level: Understand)**
CO2: Learn the concept of bio-isosterism and drug resistance. **(Cognitive level: Understand)**
CO3: Describe physicochemical Properties and the techniques involved in QSAR. **(Cognitive level: Understand)**
CO4: Learn introduction to Bioinformatics and Cheminformatics. **(Cognitive level: Understand)**
CO5: Learn methods in molecular and quantum mechanics **(Cognitive level: Create and Apply)**
CO6: Explain various structure-based drug design methods (Molecular docking, Denovo drug design) **(Cognitive level: Create and Apply)**
CO7: Learn the concept of pharmacophore and modelling techniques **(Cognitive level: Understand)**
CO8: Explain the various techniques in Virtual Screening **(Cognitive level: Understand)**

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

	PO 1	**PO 2**	**PO 3**	**PO 4**	**PO 5**	**PO 6**	**PO 7**	**PO 8**	**PO9**	**PO1 0**	**PO1 1**	**PSO 1**	**PSO 2**	**PSO 3**
CO1	3	2	1	3	1	2	1	2	3	1	3	1	1	2
CO2	3	2	3	2	1	2	1	1	3	3	3	1	2	2
CO3	3	2	3	2	1	2	1	1	1	2	3	3	1	2
CO4	3	2	3	3	2	2	1	1	2	2	2	1	2	2
CO5	3	3	2	3	1	2	1	1	2	3	2	1	3	2
CO6	3	3	3	3	1	2	1	1	2	1	2	1	1	1
CO7	3	3	2	3	1	2	1	1	1	1	3	1	1	1
CO8	3	3	2	3	1	2	1	1	1	2	3	1	1	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)**

1. **Computers in Pharmaceutical Research Development:** A General Overview: History of Computers in Pharmaceutical Research and Development. Statistical modeling in Pharmaceutical research and development: Descriptive versus Mechanistic Modeling, Statistical Parameters, Estimation, Confidence Regions, Nonlinearity at the Optimum, Sensitivity Analysis, Optimal Design, Population Modeling Quality-by-Design in

Pharmaceutical Development: Introduction, ICH Q8 guideline, Regulatory and industry views on QbD, Scientifically based QbD -examples of application. **12 Hrs**

2. **Computational Modeling of Drug Disposition:** Introduction, Modeling Techniques: Drug Absorption, Solubility, Intestinal Permeation, Drug Distribution, Drug Excretion, Active Transport;P-gp, BCRP, Nucleoside Transporters, hPEPT1, ASBT, OCT, OATP, BBB-Choline Transporter. **12 Hrs**

3. **Computer-aided formulation development:** Concept of 12 optimization, Optimization parameters, Factorial design, Optimization technology & Screening design. Computers in Pharmaceutical Formulation: Development of pharmaceutical emulsions, microemulsion drug carriers Legal Protection of Innovative Uses of Computers in R&D, The Ethics of Computing In Pharmaceutical Research, Computers in Market analysis **12 Hrs**
4. **Computer-aided biopharmaceutical characterization:** Gastrointestinal absorption simulation. Introduction, Theoretical background, Model construction, Parameter sensitivity analysis, Virtual trial, Fed vs. fasted state, In vitro dissolution and in vitro-in vivo correlation, Biowaiver considerations Computer Simulations in Pharmacokinetics and Pharmacodynamics: Introduction Computer Simulation: Whole Organism, Isolated Tissues, Organs, Cell, Proteins and Genes. Computers in Clinical Development: Clinical Data Collection and Management, Regulation of Computer Systems. **12 Hrs**

5. **Artificial Intelligence (AI), Robotics and Computational fluid dynamics:** General overview, Pharmaceutical Automation, Pharmaceutical applications, Advantages and Disadvantages. Current Challenges and Future Directions.
12Hrs

References

1. Computer Applications in Pharmaceutical Research and Development, Sean E kins, 2006, John Wiley & Sons.
2. Computer-Aided Applications in Pharmaceutical Technology, 1 Edition, Jelena Djuris, Woodhead Publishing
3. Encyclopedia of Pharmaceutical Technology, Vol 13, James Swarbrick,
4. James. G. Boylan, Marcel Dekker Inc, New York, 1996.

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 Pharmaceutics Sem II

Course Code: MPH 204T

Title of the Course: Cosmetics and Cosmeceuticals

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: Define cosmetics and cosmeceuticals; describe the regulation of import, sale and manufacture of cosmetics in India. **(Cognitive level: Remember)**

CO-2: Explain and discuss the basic structure of skin and hair; hair growth cycle. **(Cognitive level: Understand)**

CO-3: Predict and choose the formulation building blocks of skin and hair care products. **(Cognitive level: Apply)**

CO-4: Distinguish and criticize controversial ingredients used in cosmetic products **(Cognitive level: Analyze)**

CO-5: Appraise the ingredients used in hair care, skin care and oral care; review the guidelines and assess the challenges in formulating herbal cosmetics. **(Cognitive level: Evaluate)**

CO-6: Design various cosmeceutical products for dry skin, sun burn, hair, gum and dental problems **(Cognitive level: Create)**

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	1	2	2	1	1	2	1	1	1	1	3	3	2	1
CO2	1	2	1	1	2	1	1	1	1	1	3	3	2	1
CO3	3	3	3	2	1	2	1	2	2	2	3	3	2	1
CO4	2	2	3	1	1	1	1	2	2	2	3	3	1	1
CO5	2	2	3	1	1	1	1	2	2	2	3	3	2	1
CO6	3	3	3	2	1	1	1	2	2	1	3	3	3	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: **12 Hrs**

Cosmetics- Regulatory: Definition of cosmetic products as per Indian regulation. Indian regulatory requirements for labelling of cosmetics Regulatory provisions relating to import of cosmetics. Misbranded and spurious cosmetics. Regulatory provisions relating to manufacture of cosmetics – Conditions for obtaining license, prohibition of manufacture and sale of certain cosmetics, loan license, offences and penalties.

Unit 2: **12 Hrs**

Cosmetics- Biological aspects: Structure of skin relating to problems like dry skin, acne, pigmentation, prickly heat, wrinkles and body odor. Structure of hair and hair growth cycle.

Common problems associated with oral cavity. Cleansing and care needs for face, eye lids, lips, hands, feet, nail, scalp, neck, body and under-arm.

Unit 3: 12 Hrs

Formulation Building blocks: Building blocks for different product formulations of cosmetics/cosmeceuticals. Surfactants –Classification and application. Emollients, rheological additives: classification and application. Antimicrobial used as preservatives, their merits and demerits. Factors affecting microbial preservative efficacy. Building blocks for formulation of a moisturizing cream, vanishing cream, cold cream, shampoo and toothpaste. Soaps and syndet bars. Perfumes; Classification of perfumes. Perfume ingredients listed as allergens in EU regulation. Controversial ingredients: Parabens, formaldehyde liberators, dioxane.

Unit 4: 12 Hrs

Design of cosmeceutical products: Sun protection, sunscreens classification and regulatory aspects. Addressing dry skin, acne, sun-protection, pigmentation, prickly heat, wrinkles, and body odor. Dandruff, dental cavities, bleeding gums, mouth odor and sensitive teeth through cosmeceutical formulations.

Unit 5 12 Hrs

Herbal Cosmetics: Herbal ingredients used in Hair care, skincare and oral care. Review of guidelines for herbal cosmetics by private bodies like cosmos with respect to preservatives, emollients, foaming agents, emulsifiers and rheology modifiers. Challenges in formulating herbal cosmetics.

Reference Books

1. J.B. Wilkinson, R.J. Moore, *Harry's Cosmeticology,* Seventh edition, George Godwin (Publisher), London.
2. Poucher, Perfume cosmetics and Soaps, 10th edition, Springer, New York.
3. PP. Sharma, Cosmetics - Formulation, Manufacture and quality control, 4th edition, Vandana Publications Pvt. Ltd., Delhi.
4. A.O. Barel, M. Paye and H.I. Maibach, *Handbook of cosmetic science and Technology*, 3rd edition, Informa Healthcare, USA.

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). Total Marks for the subject are 100. 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. Pharmaceutics Sem II
Course Code: MPH 205P
Title of the Course: Pharmaceutics 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:

CO-1: Prepare and evaluate novel formulations **(Cognitive level: Remember)**.
CO-2: Discuss the concept of dissolution with respect to various parameters **(Cognitive level: Understand).**
CO-3: Apply design tools for formulation optimization **(Cognitive level: Apply)**.
CO-4: Formulate and evaluate cosmetic preparations **(Cognitive level: Evaluate)**.
CO-5: Apply Biopharmaceutics concepts in practical problem solving **(Cognitive level: Apply)**.

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

	PO 1	PO 2	PO 3	PO 4	PO 5	PO 6	PO 7	PO 8	PO 9	PO 10	PO 11	PSO 1	PSO 2	PSO 3
CO1	3	3	3	3	2	3	1	3	3	3	3	3	3	2
CO2	3	3	3	3	2	3	1	3	3	2	3	3	2	1
CO3	3	3	3	3	2	3	1	3	3	2	3	3	3	2
CO4	3	3	3	3	2	3	1	3	3	3	3	3	3	2
CO5	3	3	3	2	2	3	1	3	3	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

1. To study the effect of temperature change, non-solvent addition, incompatible polymer addition in microcapsules preparation
2. Preparation and evaluation of Alginate beads
3. Formulation and evaluation of gelatin /albumin microspheres
4. Formulation and evaluation of liposomes/niosomes
5. Formulation and evaluation of spherules
6. Improvement of dissolution characteristics of slightly soluble drug by Solid dispersion technique.
7. Comparison of dissolution of two different marketed products /brands
8. Protein binding studies of a highly protein bound drug & poorly protein bound drug
9. Bioavailability studies of Paracetamol in animals.
10. Pharmacokinetic and IVIVC data analysis by Winnoline R software
11. In vitro cell studies for permeability and metabolism

12. DoE Using Design Expert Software
13. Formulation data analysis Using Design Expert Software
14. Quality-by-Design in Pharmaceutical Development
15. Computer Simulations in Pharmacokinetics and Pharmacodynamics
16. Computational Modeling of Drug Disposition
17. To develop Clinical Data Collection manual
18. To carry out Sensitivity Analysis, and Population Modeling.
19. Development and evaluation of Creams
20. Development and evaluation of Shampoo and Toothpaste base
21. To incorporate herbal and chemical actives to develop products
22. To address Dry skin, acne, blemish, Wrinkles, bleeding gums and dandruff

Reference Books

1. United States of pharmacopoeia, USP-24, NF-19. Asian edition, 2000.
2. Indian pharmacopoeia - Govt. of Indian Ministry of Health, 2018.
3. Lachman Leon, Liebermann, H.A; Kanig, J.L. The Theory and Practice of Industrial Pharmacy, IV edition, 2013.
4. Aulton, M.E; Pharmaceutics – The science of dosage form design, II edition, Churchill living stone, 2002.
5. Banker, G.S.; Rhodes, C.T.; Drugs and the pharmaceutical science – Modern Pharmaceutics, IV edition, Marcel Dekker Inc., 2002
6. Martindale, Extra Pharmacopoeia
7. Dissolution, Bioavailability and Bioequivalence, Abdou. H.M, Mack Publishing Company, Pennsylvania 1989
8. Biopharmaceutics and Relevant Pharmacokinetics by John. G Wagner and M.Pemarowski, 1st edition, Drug Intelligence Publications, Hamilton, Illinois, 1971.
9. Encyclopedia of Pharmaceutical Technology, Vol 13, James Swarbrick, James. G.Boylan, Marcel Dekker Inc, New York, 1996.
10. Sanjula Baboota and Javed Ali, Novel Drug Delivery Systems as per New B. Pharm. PCI Syllabus. Birla Publications, New Delhi, India, 2022.

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. Finally learning by doing i.e., performing the experiment, discussing the observations and interpretation among peers.

Assessment methods and weightages in brief

There are two components of assessment: Internal assessment (50 marks) and End semester examination (100 marks). Internal assessment consists of continuous mode (20 marks) and sessional examinations (30 marks). Continuous mode evaluation is of 10 marks comprising of Attendance- 10 marks (calculated as: Percentage of Attendance: Allotment of marks- Less than 80: 0 marks; 80-84: 2.5 mark; 85-89:5 mark; 90-94: 7.5 marks and 95-100: 10 marks) and based on practical records, regular viva voce, etc. -10 marks. There are two

Sessional exams (each conducted for 40 marks and computed for 30 marks) and one improvement exam (40 marks and computed for 30 marks). The average marks of two best sessional exams are computed out of 30 marks.

Total Marks are 150 for the subject (Internal Assessment: 50 marks and End Semester Examination: 100 Marks).

ADMISSION & EXAMINATION
BYE-LAWS

FOR

MASTER OF PHARMACY
IN
PHARMACEUTICAL QUALITY ASSURANCE

Program Code: MQA

(with effect from 2017-18)

SCHOOL OF PHARMACEUTICAL EDUCATION AND RESEARCH
JAMIA HAMDARD
(DEEMED TO BE UNIVERSITY)
Hamdard Nagar, New Delhi-110 062
Ph. 011 26059688, Extn.- 5600

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	Pharmaceutical 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: Consistent striving for excellence in development of clinically translational novel drug delivery systems

Mission Statements:

MS 1: To be a catalyst for positive benchmark change for sustainable and commercially viable pharmaceutical research
MS 2: To advance the practice of innovative research and outcome based education, to achieve excellence in career avenues.
MS 3: To mark the highest standards of scientific rigors with updated knowledge and technology for fruitful scientific outcomes.

PROGRAM EDUCATIONAL OBJECTIVES (PEOs)

After completion of the M. Pharm (Pharmaceutical 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
PEO-1	2	2	2
PEO-2	3	3	3
PEO-3	2	2	3
PEO-4	2	2	3
PEO-5	3	3	3
PEO-6	3	3	2

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

PROGRAM OUTCOMES (POs)

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

PO1: **Applied Pharmacy Knowledge:** Use knowledge of the fundamental elements in sync with updated technologies, tailored biopharmaceutical application and regulatory requirements pertaining to the development of innovative drug delivery systems.

PO2: **Research and development:** Utilize skills to create novel medicine delivery strategies for the available range of active therapeutic substances. Good understanding of the computer- based tools required for the product development research.

PO3: **Problem analysis:** Cultivate the problem solving skills that are generally encountered during pharmaceutical product development, including scale-ups and meeting the expectations of regulation by applying the concept of critical thinking and in-depth analysis.

PO4: **Modern tool usage:** Use latest product optimization tools along with statistical analysis during the novel product development, like computer aided drug design techniques and *in silico* studies.

PO5: **Communication:** Prepare quality documents, reports and effective presentation. Hone communication skills and the ability to successfully carry out obligations related to the development of knowledge in accordance with the demands of the academia and industry.

PO6: **Professional identity:** Create a profession that is dedicated to providing quality services that exceed the stakeholder's expectations like customers, industries, academia, regulatory bodies and to give direction and contribute to the improvement of services and technologies.

PO7: **Leadership skills**: Organize and execute the objectives related to research and development within a set timeline. Nurturing the skills from the beginning to manage and utilize the available resources judiciously.

PO8: **Planning abilities:** Implement the knowledge and **s**kills for proper planning and running different steps which are involved in the time bound deliverables like R&D, production, regulatory submissions and product life cycle management.

PO9: **Pharmaceutical ethics:** Show a high level of morality, honesty and integrity. Implement ethical principles when drawing conclusions and accept responsibility for the repercussions is any.

PO10: **Environmental sustainability: U**se expertise and skills to solve the issues of environmental pollution, harmful industrial waste, along with wastage and also improve manufacturing processes while maintaining the sustainability practices.

PO11: **Life-long learning:** Readily engage in independent and ongoing learning processes in response to evolving needs and scientific advances. Using input from other professionals and identifying learning needs for life-long learning improvement. Recognize the importance of conferences, seminars, and workshops in the advancement of knowledge.

PROGRAMME SPECIFIC OUTCOME (PSOs)

After completion of the M. Pharm (Pharmaceutical Quality Assurance), 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.

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	1	2	2	2	3	3
PSO-2	2	2	3	3	3	3
PSO-3	2	2	3	3	3	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
MQA 106S	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					
MQA 201T	Hazards and Safety Management	10	15	1 Hr	25	4	75	3 Hrs	100
MQA 202T	Pharmaceutical Validation	10	15	1 Hr	25	4	75	3 Hrs	100
MQA 203T	Audits and Regulatory Compliance	10	15	1 Hr	25	4	75	3 Hrs	100
MQA 204T	Pharmaceutical Manufacturing Technology	10	15	1 Hr	25	4	75	3 Hrs	100
MQA 205P	Pharmaceutical Quality Assurance Practical II	20	30	6 Hr	50	6	100	6 Hrs	150
MQA 206S	Seminar/Assignment	-	-	-	100	4	-	-	100
Total						**26**			**650**

Semester III

Course code	Name of the course	Internal Assessment				End Semester Exams		Total Marks	Credit points
		Continuous Mode	Sessional Exams		Total	Marks	Duration		
			Marks	Duration					
MQA301T	Research Methodology and Biostatistics*	10	15	1 Hr	25	75	3 Hrs	100	4
MQAJC302	Journal club	-	-	-	25		3 Hrs	25	1
MQADP303	Discussion / Presentation (Proposal Presentation)	-	-	-	50		3 Hrs	50	2
MQARW304	Research Work	-	-	-	-	350	1 Hrs	350	14
Total								**525**	**21**

* Non University Exam

Semester IV

Course code	Name of the course	Internal Assessment				End Semester Exams		Total Marks	Credit points
		Continuous Mode	Sessional Exams		Total	Marks	Duration		
			Marks	Duration					
MQAJC 401	Journal club	-	-	-	25	-	-	25	1
MQADP 402	Discussion / Presentation (Proposal Presentation	-	-	-	75	-	-	75	16
MQARW 403	Research work and Colloquium	-	-	-	-	400	1 Hr	400	3
MQACA 404	Co-curricular Activities	-	-	-	50	-	-	50	Minimum=02 Maximum=07
Total								**550**	**20**

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- II-V. 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 –II-V

Table II-: 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

MQA 106S	Seminar /Assignment	7	-	4
Total		**35**		**26**

Table III-: Course of study for semester II

Course code	Name of the course	No. of hours	Tutorial	Credit points
MQA 201T	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
MQA 206S	Seminar /Assignment	7	-	4
Total		**35**		**26**

Table IV-: Course of study for Semester III

Course Code	Course	Credit Hours	Credit Points
MQA 301T	Research Methodology and Biostatistics*	4	4
MQAJC302	Journal club	1	1
MQADP303	Discussion / Presentation (Proposal Presentation)	2	2
MQARW304	Research Work	28	14
Total		**35**	**21**

* Non University Exam

Table V-: Course of study for Semester IV

Course Code	Course	Credit Hours	Credit Points
MQAJC 401	Journal Club	1	1
MQADP 402	Discussion/Final Presentation	3	3
MQARW 403	Research work and Colloquium	31	16
MQACA 404	Co curricular Activities	-	Minimum=02 Maximum=07
Total		**35**	Minimum=22 Maximum=27

Table VI-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.

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 VII: Scheme for awarding internal assessment: Continuous mode

Theory	
Criteria	Maximum Marks
Attendance (Refer Table – VIII)	8
Student – Teacher interaction	2
Total	**10**
Practical	
Attendance (Refer Table – VIII)	10
Based on Practical Records, Regular viva voce, etc.	10
Total	**20**

Table VIII: 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 IX. The exact dates of examinations shall be notified from time to time.

Table IX: 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 – X.

Table X: 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.

Re-evaluation I Re-totaling of answer papers

There is no provision for re-evaluation 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: Pharmaceutical Quality Assurance Practical – I**

Name of the Academic Program: M. Pharm. Pharmaceutical Quality Assurance Sem I
Course Code: MQA101T
Title of the Course: Modern Pharmaceutical Analytical Techniques (Theory)
L-T 4-0 **Credits: 4**
(L=Lecture hours, T=Tutorial hours)

COURSE OUTCOMES (COs)

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

CO1: Recognize the principle, instrumentation and applications of different chromatographic techniques **(Cognitive level: Remember and Understand)**

CO2: Investigate the pharmaceutical substance by Nuclear Magnetic spectroscopy techniques. **(Cognitive level: Remember and Understand)**

CO3: Investigate the pharmaceutical substance by Mass spectroscopy Techniques. **(Cognitive level: Remember and Understand)**

CO4: The analysis of various drugs in single and combination dosage forms **(Cognitive level: Remember and Understand)**

CO5: Recognize the principle, instrumentation and applications of electrophoresis and X ray crystallography. delivery systems **(Cognitive level: Remember and Understand)**

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

	PO 1	PO 2	PO3	PO 4	PO 5	PO 6	PO7	PO 8	PO9	PO1 0	PO1 1	PSO 1	PSO 2	PSO 3
CO1	1	2	2	3	2	1	1	1	1	1	2	3	1	2
CO2	1	2	2	3	2	1	1	1	1	1	2	2	1	2
CO3	1	2	2	3	2	1	1	1	1	1	2	2	1	2
CO4	1	2	2	3	1	1	1	1	1	1	2	2	1	2
CO5	1	2	2	3	2	1	1	1	1	1	2	2	1	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.

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.

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

Unit I **12 Hrs**

a. UV-Visible spectroscopy: Introduction, Theory, Laws, Instrumentation associated with UV-Visible spectroscopy, Choice of solvents and solvent effect and Applications of UV Visible spectroscopy.

b. IR spectroscopy: Theory, Modes of Molecular vibrations, Sample handling, Instrumentation of Dispersive and Fourier - Transform IR Spectrometer, Factors affecting vibrational frequencies and Applications of IR spectroscopy, Data interpretation.
c. Spectrofluorimetry: Theory of Fluorescence, Factors affecting fluorescence, Quenchers, Instrumentation and Applications of fluorescence spectrophotometer.
d. Flame emission spectroscopy and Atomic absorption spectroscopy: Principle, Instrumentation, Interferences and Applications.

Unit II **12 Hrs**

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

Unit III **12 Hrs**

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

Unit IV **12 Hrs**

Chromatography: Principle, apparatus, instrumentation, chromatographic parameters, factors affecting resolution, isolation of drug from excipients, data interpretation and applications of the following:

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

Unit V **12 Hrs**

a. Electrophoresis: Principle, Instrumentation, working conditions, factors affecting separation and applications of the following:
a) Paper electrophoresis b) Gel electrophoresis c) Capillary electrophoresis d) Zone electrophoresis e) Moving boundary electrophoresis f) Isoelectric focusing
b. 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 Xray diffraction.

Unit VI **12 Hrs**

a. **Potentiometry:** Principle, working, ions selective electrodes, and application of potentiometry.

b. **Thermal techniques:** Principle, thermal transitions, and instrumentation (Heat flux and Power-compensation and designs), Modulated DSC, Hyper DSC, Experimental parameters (Sample preparation, experimental condition, calibration, heating and cooling rates, resolution, sources of errors) and their influence, advantages and disadvantages, pharmaceutical applications.
c. **Differential Thermal Analysis (DTA):** Principle, instrumentation, advantages, disadvantages, pharmaceutical application, derivative differential thermal analysis (DDTA).
d. TGA: Principle, instrumentation, factors affecting results, advantages and disadvantages, pharmaceutical application.

References Books

1. Spectrometric Identification of Organic compounds - Robert M Silverstein, Sixth edition, John Wiley & Sons, 2004.
2. Principles of Instrumental Analysis - Doglas A Skoog, F. James Holler, Timothy A. Nieman, 5th edition, Eastern press, Bangalore, 1998.
3. Instrumental methods of analysis – Willards, 7th edition, CBS publishers.
4. Practical Pharmaceutical Chemistry – Beckett and Stenlake, Vol II, 4th edition, CBS Publishers, New Delhi, 1997.
5. Organic Spectroscopy - William Kemp, 3rd edition, ELBS, 1991.
6. Quantitative Analysis of Drugs in Pharmaceutical formulation - P D Sethi, 3rd Edition, CBS Publishers, New Delhi, 1997.
7. Pharmaceutical Analysis- Modern methods – Part B - J W Munson, Volume 11, Marcel Dekker Series

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 Pharmaceutical 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	PSO1	PSO2	PSO3
CO1	2	3	3	2	3	3	3	2	2	1	1	3	3	2
CO2	2	3	3	3	2	3	3	2	2	1	2	3	2	2
CO3	3	3	3	3	2	3	3	3	1	1	2	3	3	2
CO4	3	3	2	3	2	3	3	2	2	1	2	3	2	1
CO5	3	3	2	2	2	3	2	2	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 Pharmaceutical 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	PSO1	PSO2	PSO3
CO1	3	1	1	2	2	3	2	2	2	3	3	3	2	2
CO2	3	1	1	3	2	3	2	2	2	3	3	2	2	1
CO3	3	3	2	2	2	2	2	2	2	2	3	3	3	3
CO4	2	1	2	2	2	2	2	2	2	3	3	2	3	3
CO5	2	1	3	2	2	2	2	2	2	3	3	3	3	3
CO6	3	3	2	2	2	2	2	2	2	3	3	2	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 Pharmaceutical 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	3	3
CO2	3	2	3	2	1	1	1	1	2	1	1	3	3	3
CO3	3	2	3	2	1	1	2	1	1	1	1	3	3	3
CO4	1	3	2	2	2	1	1	2	1	1	1	3	3	3
CO5	3	1	2	1	1	3	2	2	1	1	1	3	3	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)**

Unit 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.

Unit 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.

Unit 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.

Unit 4 **12 Hrs**

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.

Unit 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 Pharmaceutical Quality Assurance I Sem
Course Code: MQA 105P
Title of the Course: Pharmaceutical 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)

	PO 1	PO 2	PO 3	PO 4	PO 5	PO 6	PO 7	PO 8	PO 9	PO1 0	PO11	PSO 1	PSO 2	PSO 3
CO 1	3	1	2	3	1	1	1	1	1	1	2	2	2	2
CO 2	3	1	2	3	1	1	1	1	1	1	2	2	2	1
CO 3	3	1	3	2	1	2	2	2	1	2	3	3	2	2
CO 4	3	2	3	3	2	2	1	1	2	2	2	3	2	3
CO 5	3	2	3	2	1	1	1	2	3	2	1	3	3	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. 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, discussion of research papers of Journals related to topics, power point presentation, Q & A session and reflective learning. Finally learning by doing i.e., performing the experiment, discussing the observations and interpretation among peers.

Assessment methods and weightages in brief

There are two components of assessment: Internal assessment (50 marks) and End semester examination (100 marks). Internal assessment consists of continuous mode (20 marks) and sessional examinations (30 marks). Continuous mode evaluation is of 10 marks comprising of Attendance- 10 marks (calculated as: Percentage of Attendance: Allotment of marks- Less than 80: 0 marks; 80-84: 2.5 mark; 85-89:5 mark; 90-94: 7.5 marks and 95-100: 10 marks) and based on practical records, regular viva voce, etc. -10 marks. There are two Sessional exams (each

conducted for 40 marks and computed for 30 marks) and one improvement exam (40 marks and computed for 30 marks). The average marks of two best sessional exams are computed out of 30 marks.

Total Marks are 150 for the subject (Internal Assessment: 50 marks and End Semester Examination: 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: Pharmaceutical Quality Assurance Practical – II**

Name of the Academic Program: M. Pharm Pharmaceutical 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	2	1
CO3	3	1	3	2	1	1	1	2	1	1	1	2	2	1
CO4	3	3	2	2	1	1	1	1	2	1	1	2	2	1
CO5	3	2	1	1	1	1	2	1	1	1	1	2	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 **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.

Unit 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.

Unit 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.

Unit 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.

Unit 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)

	PO 1	PO 2	PO 3	PO 4	PO 5	PO 6	PO 7	PO 8	PO 9	PO1 0	PO1 1	PSO 1	PSO 2	PSO 3
CO 1	3	3	1	1	1	2	1	1	3	1	2	2	2	2
CO 2	3	2	1	2	1	1	1	1	1	1	1	2	3	2
CO 3	3	2	1	2	1	1	1	1	1	1	2	1	1	2
CO 4	3	2	1	2	1	1	1	1	2	1	2	2	1	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)**

Unit 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).

Unit 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.

Unit 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.

Unit 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.

Unit 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

Unit 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 Pharmaceutical 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 auditing **(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	1	2	2	3	1	1	1	1	1	2	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	3
CO4	2	3	1	2	1	1	2	1	1	1	1	2	3	2
CO5	2	3	3	1	2	1	1	2	2	1	1	3	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)**

Unit 1 **12 Hrs**
Introduction: Objectives, Management of audit, Responsibilities, Planning process, information gathering, administration, Classifications of deficiencies.

Unit 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.

Unit 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.

Unit 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.

Unit 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. Pharmaceutical 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	PO 2	PO 3	PO 4	PO 5	PO 6	PO 7	PO 8	PO 9	PO1 0	PO1 1	PSO 1	PSO 2	PSO 3
CO1	3	1	2	3	2	2	1	1	3	1	1	2	2	2
CO2	3	2	2	2	2	1	1	1	3	3	3	2	2	2
CO3	3	2	3	2	1	1	1	1	1	2	3	3	2	2
CO4	3	2	3	3	2	1	1	1	2	2	2	2	2	2
CO5	3	3	2	3	1	2	1	1	2	3	1	2	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**
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.

Unit 2 **12 Hrs**

Aseptic process technology: Manufacturing, manufacturing 12 flowcharts, in process-quality control tests for following sterile Hrs dosage forms: Ointment, Suspension 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.

Unit 3 **12 Hrs**

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. P roblems encountered.
Coating technology: Process, equipments, particle coating, fluidized bed coating, application techniques. Problems encountered.

Unit 4 **12 Hrs**

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.

Unit 5 **12 Hrs**

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 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 Pharmaceutical Quality Assurance II Sem
Course Code: MQA 205P
Title of the Course: Pharmaceutical 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)

	PO 1	**PO 2**	**PO 3**	**PO 4**	**PO 5**	**PO 6**	**PO 7**	**PO 8**	**PO 9**	**PO1 0**	**PO1 1**	**PSO 1**	**PSO 2**	**PSO 3**
CO 1	3	3	1	2	1	1	1	1	1	1	1	2	1	1
CO 2	3	3	1	1	1	1	1	1	1	3	2	2	1	1
CO 3	2	3	3	1	1	1	1	2	1	1	1	1	2	1
CO 4	3	3	1	2	1	2	1	2	1	2	1	2	2	2
CO 5	3	2	1	3	3	1	1	2	1	1	2	1	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. 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, discussion of research papers of Journals related to topics, power point presentation, Q & A session and reflective learning. Finally learning by doing i.e., performing the experiment, discussing the observations and interpretation among peers.

Assessment methods and weightages in brief

There are two components of assessment: Internal assessment (50 marks) and End semester examination (100 marks). Internal assessment consists of continuous mode (20 marks) and sessional examinations (30 marks). Continuous mode evaluation is of 10 marks comprising of Attendance- 10 marks (calculated as: Percentage of Attendance: Allotment of marks- Less than 80: 0 marks; 80-84: 2.5 mark; 85-89:5 mark; 90-94: 7.5 marks and 95-100: 10 marks) and based on practical records, regular viva voce, etc. -10 marks. There are two Sessional exams (each conducted for 40 marks and computed for 30 marks) and one improvement exam (40 marks and computed for 30 marks). The average marks of two best sessional exams are computed out of 30 marks.

Total Marks are 150 for the subject (Internal Assessment: 50 marks and End Semester Examination: 100 Marks).

PCI

Annexure II –

MINUTES OF 02.269th EXECUTIVE COMMITTEE (EC) MEETING OF THE COUNCIL HELD ON 28th & 29th FEBRUARY, 2016 AT BHUABANESWAR, ODISHA.

Item No.56 to 61 : * Consideration of the approval of Diploma / Degree / Pharm.D / Pharm.D (Post Baccalaureate) course and examination in pharmacy at the undermentioned institutions

Item No. Course IR No.	State/ File No. Name of institutions	For admns. Limited to	Approved for conduct of course/ u/s 12 / extension upto academic session	Name of the Examining Authority
Item No.56 Degree IR No.6th (Dec.,2015)	DELHI 32-213/2015-PCI Faculty of Pharmacy (SFS Course), Jamia Hamdard (Hamdard University), Hamdard Nagar, New Delhi - 110 062.	60	extension upto 2017-2018	The Registrar, Jamia Hamdard (Hamdard University), Hamdard Nagar, New Delhi-110 062.

The PCI inspection of our B Pharm (SFS) course was held in Dec 2015. Compliance was submitted well in time. Now the above result have come and our B Pharm (SFS) course have been approved by PCI for a period of 3 years (upto 2017-18 ie 2015-16, 2016-17 and 2017-18) which is a maximum limit of approval on the part of PCI

This is for your kind information

28/4/16
Dean
F/O Pharmacy

PS to Vice Chancellor – for information

PHARMACY COUNCIL OF INDIA

E-mail : registrar@pci.nic.in
Website : www.pci.nic.in
Contact : 011-61299900/01/02/03

NBCC Centre, 3rd Floor Plot No.2, Community Centre
Maa Anandamai Marg Okhla Phase I
NEW DELHI - 110020

DECISION LETTER

Institute Name / Inst ID :Faculty Of Pharmacy Sfs Course Jamia Hamdard Hamdard University Hamdard Nagar Newdelhi/PCI-630

State :DELHI

District :SOUTH

Sub-District :Saket

Village/Town/City :

Pin Code :110062

Sir / Madam

With reference to the subject cited above i am directed to convey the approval of PCI as per Following Details

Course	Name of Affiliation	Decision	Approval Status
B.Pharm	The Secretary Jamia Hamdard Hamdard University Hamdard NagarNew Delhi	Extension of approval under section 12 upto 2022-2023 academic session for 60 admissions	Approved

Date : 10th April 2020

For Archna Mudgal
Registrar-cum-Secretary
PCI

Copy to:

i) Registrar of the University

ii) Principal of the college

iii) Secretary/Chairman of the Trust/Society

iv) Guard File (PCI)

Note: Validity of the course details may be verified at www.pci.nic.in.

PHARMACY COUNCIL OF INDIA

E-mail : registrar@pci.nic.in
Website : www.pci.nic.in
Contact : 011-61299900/01/02/03

NBCC Centre, 3rd Floor Plot No.2, Community Centre
Maa Anandamai Marg Okhla Phase I
NEW DELHI - 110020

DECISION LETTER

Institute Name / Inst ID :Faculty Of Pharmacy Sfs Course Jamia Hamdard Hamdard University Hamdard Nagar Newdelhi/PCI-630

State :DELHI

District :SOUTH

Sub-District :Saket

Village/Town/City :

Pin Code :110062

Sir / Madam

With reference to the subject cited above i am directed to convey the approval of PCI as per Following Details

Course	Name of Affiliation	Decision	Approval Status
B.Pharm	The Secretary Jamia Hamdard Hamdard University Hamdard NagarNew Delhi	111 CC Decision (6th & 7th April 2021) is as under- B.Pharm course is already approved upto 2022-2023 academic session for 60 admissions.	Approved

Date : 14th Jul 2021

For Archna Mudgal
Registrar-cum-Secretary
PCI

Copy to:

i) Registrar of the University

ii) Principal of the college

iii) Secretary/Chairman of the Trust/Society

iv) Guard File (PCI)

Note: Validity of the course details may be verified at www.pci.nic.in.

PHARMACY COUNCIL OF INDIA

A Statutory body under Ministry of Health and Family Welfare
Government of India

E - MAIL : registrar@pci.nic.in
WEBSITE : www.pci.nic.in
Telephone : 011-61299900
011 - 61299901, 011 - 61299902
011-61299903

NBCC Centre, 3rd Floor
Plot No.2, Community Centre
Maa Anandamai Marg
Okhla Phase I
NEW DELHI - 110020

DECISION LETTER

Institute Name / Inst ID Faculty Of Pharmacy Sfs Course Jamia Hamdard Hamdard University Hamdard Nagar Newdelhi / PCI-630
State DELHI
District SOUTH
Sub-District Saket
Village/Town/City
Pin Code 110062

Sir / Madam

With reference to the subject cited above i am directed to convey the approval of PCI as per Following Details

Course	Name of Affiliation body/University	Decision	Approval Status	Approval Upto	Approval Intake
B.Pharm	The Secretary Jamia Hamdard Hamdard University Hamdard NagarNew Delhi	116th CC (July, 2022) B.Pharm course is already approved upto 2022-2023 academic session for 60 admissions.	Approved	2022-2023	60

Date 02nd Feb 2023

For
(I/C) Registrar-cum-Secretary
PCI

Copy to

i) Registrar of the University

ii) Principal of the college

iii) Secretary/Chairman of the Trust/Society

iv) Guard File (PCI)

Note: Validity of the course details may be verified at www.pci.nic.in

PHARMACY COUNCIL OF INDIA

A Statutory body under Ministry of Health and Family Welfare
Government of India

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011-61299903

NBCC Centre, 3rd Floor
Plot No.2, Community Centre
Maa Anandamai Marg
Okhla Phase I
NEW DELHI - 110020

DECISION LETTER

Institute Name / Inst ID Faculty Of Pharmacy Sfs Course Jamia Hamdard Hamdard University Hamdard Nagar Newdelhi / PCI-630
State DELHI
District SOUTH
Sub-District Saket
Village/Town/City
Pin Code 110062

Sir / Madam

With reference to the subject cited above i am directed to convey the approval of PCI as per Following Details

Course	Name of Affiliation body/University	Decision	Approval Status	Approval Upto	Approval Intake
B.Pharm	The Secretary Jamia Hamdard Hamdard University Hamdard NagarNew Delhi	B.Pharm Extend approval upto 2023-2024 academic session for 60 admissions for B.Pharm course	Approved	2023-2024	60

Date 08th May 2023

For
(I/C) Registrar-cum-Secretary
PCI

Copy to

i) Registrar of the University

ii) Principal of the college

iii) Secretary/Chairman of the Trust/Society

iv) Guard File (PCI)

Note: Validity of the course details may be verified at www.pci.nic.in

PHARMACY COUNCIL OF INDIA

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NBCC Centre, 3rd Floor Plot No.2, Community Centre
Maa Anandamai Marg Okhla Phase I
NEW DELHI - 110020

DECISION LETTER

Institute Name / Inst ID :Faculty Of Pharmacy Jamia Hamdard Hamderd University Hamdard Nagar New Delhi/PCI-624

State :DELHI

District :SOUTH

Sub-District :Saket

Village/Town/City :

Pin Code :110062

Sir / Madam

With reference to the subject cited above i am directed to convey the approval of PCI as per Following Details

Course	Name of Affiliation	Decision	Approval Status
B.Pharm	The Secretary Jamia Hamdard Hamdard University Hamdard NagarNew Delhi	Extension of approval upto 2023-2024 (B.Pharm) for 60 admissions	Approved
D.Pharm	The Secretary Jamia Hamdard Hamdard University Hamdard NagarNew Delhi	Extension of approval upto 2023-2024 (D.Pharm) for 60 admissions	Approved
M.Pharm Pharmaceutics	The Secretary Jamia Hamdard Hamdard University Hamdard NagarNew Delhi	15	Approved
M.Pharm Pharmaceutical Chemistry	The Secretary Jamia Hamdard Hamdard University Hamdard NagarNew Delhi	10	Approved
M.Pharm Pharmaceutical Analysis	The Secretary Jamia Hamdard Hamdard University Hamdard NagarNew Delhi	08	Approved

M.Pharm Pharmaceutical Quality Assurance	The Secretary Jamia Hamdard Hamdard University Hamdard NagarNew Delhi	08	Approved
M.Pharm Pharmaceutical Biotechnology	The Secretary Jamia Hamdard Hamdard University Hamdard NagarNew Delhi	05	Approved
M.Pharm Pharmacy Practice	The Secretary Jamia Hamdard Hamdard University Hamdard NagarNew Delhi	08	Approved
M.Pharm Pharmacology	The Secretary Jamia Hamdard Hamdard University Hamdard NagarNew Delhi	15	Approved
M.Pharm Pharmacognosy	The Secretary Jamia Hamdard Hamdard University Hamdard NagarNew Delhi	08	Approved

Date : 10th April 2020

For Archna Mudgal
Registrar-cum-Secretary
PCI

Copy to:

i) Registrar of the University

ii) Principal of the college

iii) Secretary/Chairman of the Trust/Society

iv) Guard File (PCI)

Note: Validity of the course details may be verified at www.pci.nic.in.

PHARMACY COUNCIL OF INDIA

E-mail : registrar@pci.nic.in
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NBCC Centre, 3rd Floor Plot No.2, Community Centre
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NEW DELHI - 110020

DECISION LETTER

Institute Name / Inst ID :Faculty Of Pharmacy Jamia Hamdard Hamderd University Hamdard Nagar New Delhi/PCI-624

State :DELHI

District :SOUTH

Sub-District :Saket

Village/Town/City :

Pin Code :110062

Sir / Madam

With reference to the subject cited above i am directed to convey the approval of PCI as per Following Details

Course	Name of Affiliation	Decision	Approval Status
B.Pharm	The Secretary Jamia Hamdard Hamdard University Hamdard NagarNew Delhi	111 CC Decision (6th & 7th April 2021) is as under- B.Pharm course is already approved upto 2023-2024 academic session for 60 admissions.	Approved
D.Pharm	The Secretary Jamia Hamdard Hamdard University Hamdard NagarNew Delhi	111 CC Decision (6th & 7th April 2021) is as under- D.Pharm course is already approved upto 2023-2024 academic session for 60 admissions.	Approved
M.Pharm Pharmaceutics	The Secretary Jamia Hamdard Hamdard University Hamdard NagarNew Delhi	111 CC Decision (6th & 7th April 2021) is as under- M.Pharm (Pharmaceutics)-15	Approved
M.Pharm Pharmaceutical Chemistry	The Secretary Jamia Hamdard Hamdard University Hamdard NagarNew Delhi	111 CC Decision (6th & 7th April 2021) is as under- M.Pharm (Pharmaceutical Chemistry)-10	Approved

M.Pharm Pharmaceutical Analysis	The Secretary Jamia Hamdard Hamdard University Hamdard NagarNew Delhi	111 CC Decision (6th & 7th April 2021) is as under- M.Pharm (Pharmaceutical Analysis)-08	Approved
M.Pharm Pharmaceutical Quality Assurance	The Secretary Jamia Hamdard Hamdard University Hamdard NagarNew Delhi	111 CC Decision (6th & 7th April 2021) is as under- M.Pharm, (Pharmaceutical Quality Assurance)-08	Approved
M.Pharm Pharmaceutical Biotechnology	The Secretary Jamia Hamdard Hamdard University Hamdard NagarNew Delhi	111 CC Decision (6th & 7th April 2021) is as under- M.Pharm (Pharmaceutical Biotechnology)-05	Approved
M.Pharm Pharmacy Practice	The Secretary Jamia Hamdard Hamdard University Hamdard NagarNew Delhi	111 CC Decision (6th & 7th April 2021) is as under- M.Pharm (Pharmacy Practice)-08	Approved
M.Pharm Pharmacology	The Secretary Jamia Hamdard Hamdard University Hamdard NagarNew Delhi	111 CC Decision (6th & 7th April 2021) is as under- M.Pharm (Pharmacology)-15	Approved
M.Pharm Pharmacognosy	The Secretary Jamia Hamdard Hamdard University Hamdard NagarNew Delhi	111 CC Decision (6th & 7th April 2021) is as under- M.Pharm (Pharmacognosy)-08	Approved

Date : 14th Jul 2021

For Archna Mudgal
Registrar-cum-Secretary
PCI

Copy to:

i) Registrar of the University

ii) Principal of the college

iii) Secretary/Chairman of the Trust/Society

iv) Guard File (PCI)

Note: Validity of the course details may be verified at www.pci.nic.in.

PHARMACY COUNCIL OF INDIA

A Statutory body under Ministry of Health and Family Welfare
Government of India

E - MAIL : registrar@pci.nic.in
WEBSITE : www.pci.nic.in
Telephone : 011-61299900
011 - 61299901, 011 - 61299902
011-61299903

NBCC Centre, 3rd Floor
Plot No.2, Community Centre
Maa Anandamai Marg
Okhla Phase I
NEW DELHI - 110020

DECISION LETTER

Institute Name / Inst ID Faculty Of Pharmacy Jamia Hamdard Hamderd University Hamdard Nagar New Delhi / PCI-624
State DELHI
District SOUTH
Sub-District Saket
Village/Town/City
Pin Code 110062

Sir / Madam

With reference to the subject cited above i am directed to convey the approval of PCI as per Following Details

Course	Name of Affiliation body/University	Decision	Approval Status	Approval Upto	Approval Intake
B.Pharm	The Secretary Jamia Hamdard Hamdard University Hamdard NagarNew Delhi	116th CC (July, 2022) B.Pharm course is already approved upto 2023-2024 academic session for 60 admissions.	Approved	2023-2024	60
D.Pharm	The Secretary Jamia Hamdard Hamdard University Hamdard NagarNew Delhi	116th CC (July, 2022) D.Pharm course is already approved upto 2023-2024 academic session for 60 admissions.	Approved	2023-2024	60
M.Pharm Pharmaceutics	The Secretary Jamia Hamdard Hamdard University Hamdard NagarNew Delhi	116th CC (July, 2022) M.Pharm (Pharmaceutics)-15	Approved	2022-2023	15
M.Pharm Pharmaceutical Chemistry	The Secretary Jamia Hamdard Hamdard University Hamdard NagarNew Delhi	116th CC (July, 2022) M.Pharm (Pharmaceutical Chemistry)-10	Approved	2022-2023	10
M.Pharm Pharmaceutical Analysis	The Secretary Jamia Hamdard Hamdard University Hamdard NagarNew Delhi	116th CC (July, 2022) M.Pharm (Pharmaceutical Analysis)-08	Approved	2022-2023	8
M.Pharm Pharmaceutical Quality Assurance	The Secretary Jamia Hamdard Hamdard University Hamdard NagarNew Delhi	116th CC (July, 2022) M.Pharm (Pharmaceutical Quality Assurance)-08	Approved	2022-2023	8
M.Pharm Pharmaceutical Biotechnology	The Secretary Jamia Hamdard Hamdard University Hamdard NagarNew Delhi	116th CC (July, 2022) M.Pharm (Pharmaceutical Biotechnology)-05	Approved	2022-2023	5
M.Pharm Pharmacy Practice	The Secretary Jamia Hamdard Hamdard University Hamdard NagarNew Delhi	116th CC (July, 2022) M.Pharm (Pharmacy Practice)-08	Approved	2022-2023	8
M.Pharm Pharmacology	The Secretary Jamia Hamdard Hamdard University Hamdard NagarNew Delhi	116th CC (July, 2022) M.Pharm (Pharmacology)-15	Approved	2022-2023	15
M.Pharm Pharmacognosy	The Secretary Jamia Hamdard Hamdard University Hamdard NagarNew Delhi	116th CC (July, 2022) M.Pharm (Pharmacognosy)-08	Approved	2022-2023	8

Date 02nd Feb 2023

For
(I/C) Registrar-cum-Secretary
PCI

Copy to

i) Registrar of the University

ii) Principal of the college

iii) Secretary/Chairman of the Trust/Society

iv) Guard File (PCI)

Note: Validity of the course details may be verified at www.pci.nic.in

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NBCC Centre, 3rd Floor
Plot No.2, Community Centre
Maa Anandamai Marg
Okhla Phase I
NEW DELHI - 110020

DECISION LETTER

Institute Name / Inst ID Faculty Of Pharmacy Jamia Hamdard Hamderd University Hamdard Nagar New Delhi / PCI-624
State DELHI
District SOUTH
Sub-District Saket
Village/Town/City
Pin Code 110062

Sir / Madam

With reference to the subject cited above i am directed to convey the approval of PCI as per Following Details

Course	Name of Affiliation body/University	Decision	Approval Status	Approval Upto	Approval Intake
B.Pharm	The Secretary Jamia Hamdard Hamdard University Hamdard NagarNew Delhi	B.Pharm B.Pharm course is already approved upto 2023-2024 academic session for 60 admissions.	Approved	2023-2024	60
D.Pharm	The Secretary Jamia Hamdard Hamdard University Hamdard NagarNew Delhi	D.Pharm D.Pharm course is already approved upto 2023-2024 academic session for 60 admissions.	Approved	2023-2024	60
M.Pharm Pharmaceutics	The Secretary Jamia Hamdard Hamdard University Hamdard NagarNew Delhi	M.Pharm (Pharmaceutics)-15	Approved	2023-2024	15
M.Pharm Pharmaceutical Chemistry	The Secretary Jamia Hamdard Hamdard University Hamdard NagarNew Delhi	M.Pharm (Pharmaceutical Chemistry)-10	Approved	2023-2024	10
M.Pharm Pharmaceutical Analysis	The Secretary Jamia Hamdard Hamdard University Hamdard NagarNew Delhi	M.Pharm (Pharmaceutical Analysis)-08	Approved	2023-2024	8
M.Pharm Pharmaceutical Quality Assurance	The Secretary Jamia Hamdard Hamdard University Hamdard NagarNew Delhi	M.Pharm(Pharmaceutical Quality Assurance)-08	Approved	2023-2024	8
M.Pharm Pharmaceutical Biotechnology	The Secretary Jamia Hamdard Hamdard University Hamdard NagarNew Delhi	M.Pharm (Pharmaceutical Biotechnology)-05	Approved	2023-2024	5
M.Pharm Pharmacy Practice	The Secretary Jamia Hamdard Hamdard University Hamdard NagarNew Delhi	M.Pharm (Pharmacy Practice)-08	Approved	2023-2024	8
M.Pharm Pharmacology	The Secretary Jamia Hamdard Hamdard University Hamdard NagarNew Delhi	M.Pharm (Pharmacology)-15	Approved	2023-2024	15
M.Pharm Pharmacognosy	The Secretary Jamia Hamdard Hamdard University Hamdard NagarNew Delhi	M.Pharm (Pharmacognosy)-08	Approved	2023-2024	8

Date 08th May 2023

For
(I/C) Registrar-cum-Secretary
PCI

Copy to

i) Registrar of the University

ii) Principal of the college

iii) Secretary/Chairman of the Trust/Society

iv) Guard File (PCI)

Note: Validity of the course details may be verified at www.pci.nic.in

D Pharm
B Pharm approved upto 2020-21
page no 7

भारतीय भेषजी परिषद्

(भेषजी अधिनियम, 1948 के अंतर्गत स्थापित)

PHARMACY COUNCIL OF INDIA

(CONSTITUTED UNDER THE PHARMACY ACT, 1948)

तार	Telegram	: 'फार्मकाउंसिल' 'FARMCOUNCIL'	संयुक्त परिषद् भवन	Combined Councils' Building
दूरभाष	Telephone	: 23239184, 23231348	कोटला रोड	Kotla Road
फैक्स	Fax	: 011-23239184	ऐवान-ए-ग़ालिब मार्ग	Aiwan-E-Ghalib Marg
ई-मेल	E-Mail	: pci@ndb.vsnl.net.in	पोस्ट बॉक्स नं. 7020	Post Box No. 7020
वेबसाईट	Website	: www.pci.nic.in	नई दिल्ली - 110002	New Delhi - 110002

Ref. No:17-1/2017-PCI | 17385-562

Speed Post

29 NOV 2018

The Controller of Publications
Govt. of India
Deptt. of Publications
Civil Lines, Behind Old Sectt.
Delhi- 110 054.

Sub: Pharmacy Council of India- Publication of resolutions passed under section 12 of the Pharmacy Act, 1948 by the –

Sir,

I am directed to forward herewith the following resolution (English & Hindi) passed by the Pharmacy Council of India in 101th Central Council meeting held on 6th & 7th April, 2017 for publication in Part-III, Section 4 of Gazette of India as required under section 12 of the Pharmacy Act (8 of 1948):

- Resolution No. ~~100~~ 101/PCI/1434 pertains to Diploma, Degree, Pharm.D, Pharm.D & Pharm.D(PB) and M.Pharm in Pharmacy (both in English & Hindi)

A copy of the notification when published, together with the bill, in duplicate may please be forwarded to this office for payment.

Kindly acknowledge its receipt.

Yours faithfully

Dear / HOD

(ARCHNA MUDGAL)
Registrar-cum-Secretary

12-12

...2

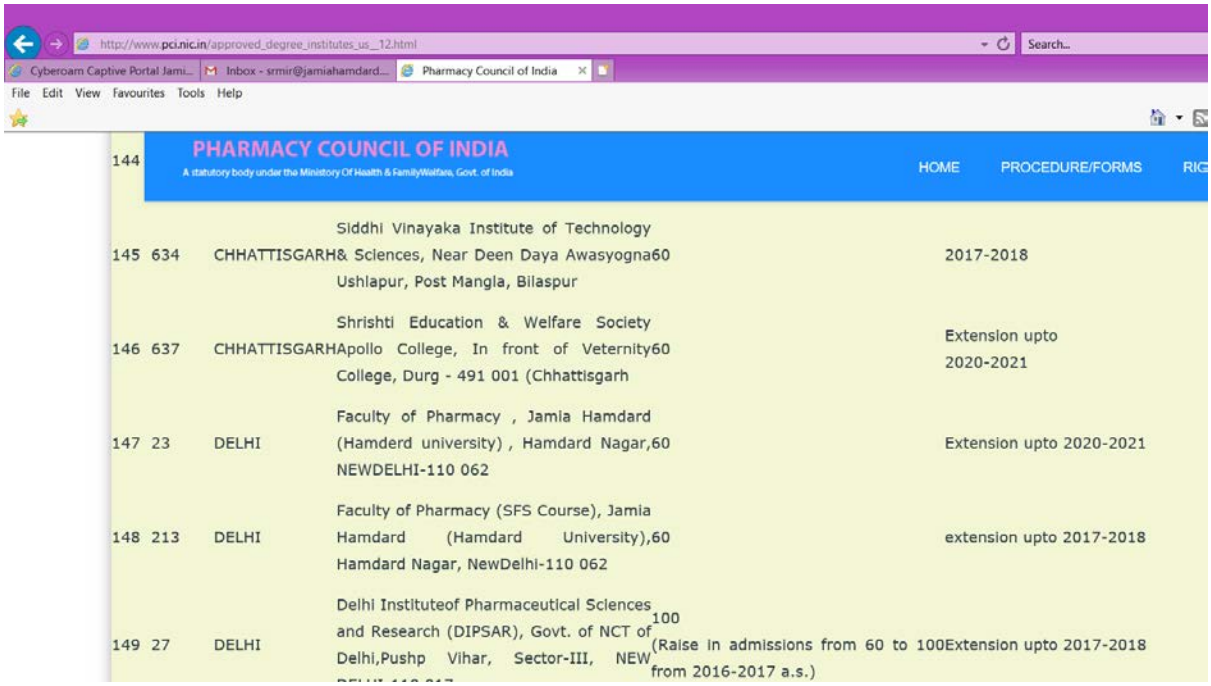
12/12/18

101 CC Item No. Course IR No.	State/ File No. Name of institutions	For admns. Limited to	Approved for conduct of course/ u/s 12/extension upto academic session	Name of the Examining Authority
101 CC Item No.482 Degree IR No.5th (Jan.,2017)	**GUJARAT** 32-711/2014-PCI Ratnamani College of Pharmacy Ratnamani Education Campus, Shankhalpur Ta-Becharaji, Road to- Becharaji Distt. Mehsana - 384 210.	60	Extension upto 2017-2018	The Registrar Gujarat Technological University, L.D. College of Engineering Campus, 2nd Floor, ACPC Building, Navrangpura Ahmedabad - 380 015.
101 CC Item No.484 Diploma IR No.12th Surprise (Dec.,2016)	**DELHI** 17-31/2016-PCI Faculty of Pharmacy Jamia Hamdard (Hamdard University) Hamdard Nagar - 110 062.	60	Extension upto 2020-2021	The Secretary Jamia Hamdard (Hamdard University) Hamdard Nagar New Delhi - 110 062.
Degree IR No.11th Surprise (Dec.,2016)	32-23/2016-PCI Faculty of Pharmacy Jamia Hamdard (Hamdard University) Hamdard Nagar - 110 062.	60	Extension upto 2020-2021.	The Registrar Jamia Hamdard (Hamdard University) Hamdard Nagar New Delhi - 110 062.

101 CC Item No. Course IR No.	State/ File No. Name of institutions	Specialization approved by PCI	No. of admns. approved	Name of the Examining Authority
101 CC Item No.505 M.Pharm IR No.1st (Dec.,2016)	**KARNATAKA** **M.Pharm** 60-11/2016-PCI Manipal College of Pharmaceutical Sciences Madhav Nagar, Manipal - 576 104.	1. Pharmaceutics	15	The Registrar Manipal University (Deemed University) University Building Madhav Nagar, Manipal - 576 104.
		2. Industrial Pharmacy	15	
		3. Pharmaceutical Chemistry	15	
		4. Pharmaceutical Quality Assurance	15	
		5. Drug Regulatory Affairs	15	
		6. Pharmaceutical Biotechnology	15	
		7. Pharmacy Practice	15	
		8. Pharmacology	15	
		9. Pharmacognosy	15	
		10. Pharmaceutical Administration	15	
		11. Pharmaceutical Marketing	15	

Registrar-cum-Secretary
Pharmacy Council of India
New Delhi - 110002

Approval letter for B. Pharm and B. Pharm (SFS)



http://www.pci.nic.in/approved_degree_institutes_us_12.html

Pharmacy Council of India

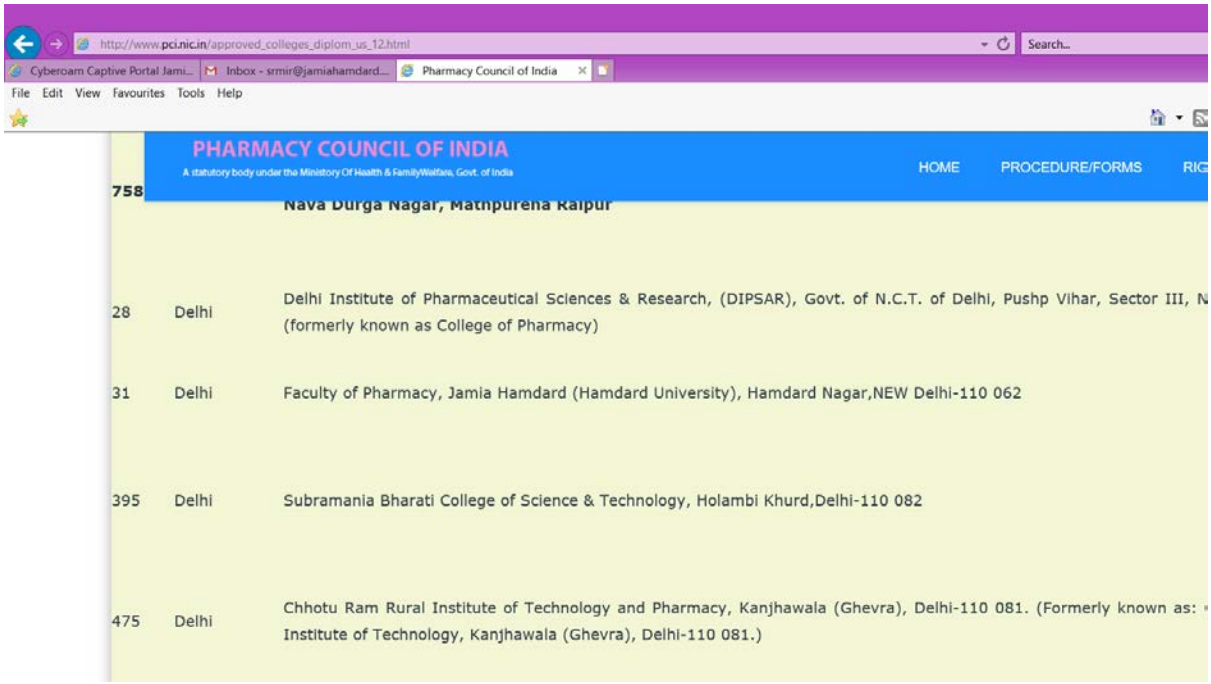
PHARMACY COUNCIL OF INDIA

A statutory body under the Ministry Of Health & FamilyWelfare, Govt. of India

HOME PROCEDURE/FORMS

144					
145	634	CHHATTISGARH	Siddhi Vinayaka Institute of Technology & Sciences, Near Deen Daya Awasyogna Ushlapur, Post Mangla, Bilaspur	60	2017-2018
146	637	CHHATTISGARH	Shrishti Education & Welfare Society Apollo College, In front of Veternity College, Durg - 491 001 (Chhattisgarh	60	Extension upto 2020-2021
147	23	DELHI	Faculty of Pharmacy , Jamia Hamdard (Hamderd university) , Hamdard Nagar, NEWDELHI-110 062	60	Extension upto 2020-2021
148	213	DELHI	Faculty of Pharmacy (SFS Course), Jamia Hamdard (Hamdard University), Hamdard Nagar, NewDelhi-110 062	60	extension upto 2017-2018
149	27	DELHI	Delhi Instituteof Pharmaceutical Sciences and Research (DIPSAR), Govt. of NCT of Delhi,Pushp Vihar, Sector-III, NEW	100 (Raise in admissions from 60 to 100 from 2016-2017 a.s.)	Extension upto 2017-2018

Approval letter for D. Pharm



http://www.pci.nic.in/approved_colleges_diplom_us_12.html

Pharmacy Council of India

PHARMACY COUNCIL OF INDIA

A statutory body under the Ministry Of Health & FamilyWelfare, Govt. of India

HOME PROCEDURE/FORMS

758		Nava Durga Nagar, Mathpurena Raipur
28	Delhi	Delhi Institute of Pharmaceutical Sciences & Research, (DIPSAR), Govt. of N.C.T. of Delhi, Pushp Vihar, Sector III, N (formerly known as College of Pharmacy)
31	Delhi	Faculty of Pharmacy, Jamia Hamdard (Hamdard University), Hamdard Nagar,NEW Delhi-110 062
395	Delhi	Subramania Bharati College of Science & Technology, Holambi Khurd,Delhi-110 082
475	Delhi	Chhotu Ram Rural Institute of Technology and Pharmacy, Kanjhawala (Ghevra), Delhi-110 081. (Formerly known as: Institute of Technology, Kanjhawala (Ghevra), Delhi-110 081.)