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).