Revised syllabus as per AICTE
received mail dt. 17.2.2020

University of Mumbai

No. UG/ 68 of 2019-20

CIRCULAR:-

Attention of the Principals of the Affiliated Colleges, Directors of the recognized Institutions in Science & Technology Faculty is invited to this office Circular No. UG/193 of 2016-17, dated 3rd December, 2016 relating to the Credit System Manual revised syllabus for B. Pharm. & M. Pharm. (Sem. I to IV).

They are hereby informed that the recommendations made by the Ad-hoc Board of Studies in Pharmacy at its meeting held on 14th June, 2019 have been accepted by the Academic Council at its meeting held on 26th July, 2019 **vide** item No. 4.38 and that in accordance therewith, the Manual and Revised Scheme and Syllabus as per the (CBCS) for the Master of Pharmacy (Sem.I to IV) has been brought into force with effect from the academic year 2019-20, accordingly. (The same is available on the University's website www.mu.ac.in).

(Dr. Ajay Deshmukh)
REGISTRAR

MUMBAI – 400 032
14th August, 2019

To
The Principals of the affiliated Colleges, and Directors of the recognized Institutions in Science & Technology Faculty. (Circular No. UG/334 of 2017-18 dated 9th January, 2018.)

A.C/4.38/26/07/2019

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MUMBAI-400 032

14th August, 2019

No. UG/ 68 -A of 2019-20

Copy forwarded with Compliments for information to:-

1) The I/c Dean, Faculty of Science & Technology,
2) The Chairman, Board of Studies in Pharmacy,
3) The Director, Board of Examinations and Evaluation,
4) The Director, Board of Students Development,
5) The Co-ordinator, University Computerization Centre,

(Dr. Ajay Deshmukh)
REGISTRAR

Cover Page

AC 26/07/2019
Item No. 4.38

UNIVERSITY OF MUMBAI

Syllabus for Approval

Sr. No.	Heading	Particulars
1	Title of the Course	Master of Pharmacy (M. Pharm.)
2	Eligibility for Admission	B. Pharm. / GPAT
3	Passing Marks	50%
4	Ordinances / Regulations (if any)	
5	No. of Years / Semesters	2 (two) years / 4 (four) Semesters
6	Level	P.G. / ~~U.G.~~/ ~~Diploma~~ / ~~Certificate~~ (Strike out which is not applicable)
7	Pattern	~~Yearly~~ / Semester (Strike out which is not applicable)
8	Status	~~New~~ / Revised (Strike out which is not applicable)
9	To be implemented from Academic Year	From Academic Year 2019-20

Date: 17/7/19 Signature :

Name of BOS Chairperson / Dean : KRISHNA IYER Ph.D

UNIVERSITY OF MUMBAI

Manual on

CHOICE BASED CREDIT SYSTEM

for

Postgraduate Program

(Master of Pharmacy, M. Pharm.)

in

PHARMACY

Revised Course (Revised 2019)

(from the academic year 2019–2020)

1

INTRODUCTION

RECOMMENDATIONS OF NATIONAL REGULATORY AUTHORITIES

The University Grants Commission (UGC), the **National Assessment and Accreditation Council (NAAC),** the **Distance Education Council (DEC)** and the **National Knowledge Commission (NKC)** have time and again come out with recommendations for improving the quality and effectiveness of Higher education provisions in the country. The ministry of Human Resource Development at the Central level and the Ministry of Higher & Technical Education, Govt. of Maharashtra have also repeatedly stressed on the need for universities to pay prompt attention to improve the quality of education. **T**he **National Knowledge Commission (NKC)**, in its report to the Prime Minister on 29th November 2006) has also reiterated the importance of higher education and the contribution it has made to economic development, social progress and political democracy in independent India.

An important concern voiced more strongly in recent times, is the need to develop a Choice-Based Credit System (CBCS) in tune with global trends and the adoption of a sound grading system for reflecting learner performance. This is in line with the **recommendation of the UGC** in its *Action Plan for Academic and Administrative Reforms* (Ref. UGC letters January 2008; March 2009) "……. *Curricular flexibility and learners' mobility are issues that warrant our urgent attention. These can be addressed by introducing credit based courses and credit accumulation. In order to provide with some degree of flexibility to learners, we need to provide flexibility in course selection and also a minimum as well as a maximum permissible span of time in which a course can be completed by a learner… The Choice-Based Credit System (CBCS) imminently fits into the emerging socioeconomic milieu, and could effectively respond to the educational and occupational aspirations of the upcoming generations. In view of this, institutions of higher education in India would do well to invest thought and resources into introducing CBCS. Aided by modern communication and information technology, CBCS has a high probability to be operationalized efficiently and effectively — elevating learners, institutions and higher education system in the country to newer heights…".*

RATIONALE FOR INTRODUCTION OF CREDIT AND GRADING SYSTEM

The UGC while outlining the several unique features of the Choice-Based Credit System (CBCS) has, in fact, given in a nutshell, the rationale for its introduction. Among the features

highlighted by the UGC are: *Enhanced learning opportunities, ability to match learners' scholastic needs and aspirations, inter-institution transferability of learners (following the completion of a semester), part-completion of an academic programme in the institution of enrolment and part-completion in a specialized (and recognized) institution, improvement in educational quality and excellence, flexibility for working learners to complete the programme over an extended period of time, standardization and comparability of educational programmes across the country, etc.*

This Choice Based Credit System enables a much-required shift in focus from teacher-centric to learner-centric education since the workload estimated is based on the investment of time in learning, not in teaching. It also focuses on continuous evaluation which will enhance the quality of education. It can be concluded from the above discussion that it is very much essential to implement the Choice Based Credit System in higher education in India. Course credit structure, examination/assessment and grading are mainly focused aspects of this manual and discussed in subsequent chapters.

DIRECTIVES OF PHARMACY COUNCIL OF INDIA

The Pharmacy Council of India (PCI) in exercise of the powers conferred to it under the sections 10 and 18 of the Pharmacy Act 1948 (8 of 1948), with the approval of the Central Government, had made the Bachelor of Pharmacy (B. Pharm.) Course Regulations, 2014 and Master of Pharmacy (M. Pharm.) Course regulations vide Gazette dated December 10, 2014. Further as per regulations 6 and 8 of the above course regulations the PCI has also prescribed the Rules and Syllabus for B. Pharm. course and Scheme and Syllabus for M. Pharm., its letter Ref 14-136/2016-PCI and Ref 14-154/2015 PCI dated December 21, 2016, with the subject heading "Statutory Scheme/Rules and syllabus for B. Pharm and M. Pharm. courses". It is thus mandatory to implement the directives of PCI with regard to the Rules/Regulations/Syllabus for recognition and extension of approval of B. Pharm. and M. Pharm. programs of institutes/Universities by the PCI

1. ADMISSION CRITERIA

Admission to the M. Pharm. program of University of Mumbai is governed by the rules and regulations of University of Mumbai and as per norms of the Govt. of Maharashtra through State CET Cell and the Directorate of Technical Education (DTE) and the All India Council for Technical Education (AICTE, New Delhi) in force at the time of admission and as amended from time to time.

In general, a learner who has passed the examination for the B. Pharm. Degree from All India Council for Technical Education or Pharmacy Council of India or Central or State Government approved institutions, with at least **55 %** marks (at least **50%** marks in case of SC or ST category and persons with disability belonging to Maharashtra state only.) and obtained Score in Graduate pharmacy Aptitude Test conducted by All India Council of Technical Education may be admitted to the M. Pharm. Program (Partly by Papers and Partly by Research). However, the rules/regulations and qualifications for admission be those in effect at the day and time of admission.

2. COURSE STRUCTURE

2.1 Duration of the program

The program of study for M. Pharm. shall extend over a period of four semesters (two academic years). The medium of instruction shall be English.

2.2 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 July to November/December and the even semesters shall be conducted from the month of December/January to May/June in every calendar year.

As the requirements for a particular degree (undergraduate or postgraduate), a certain quantum of academic work measured in terms of credits is laid down in general. Learner earns credits every semester by satisfactorily clearing courses/other academic activities. 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 activities is dependent upon the quantum of work expected to be put in for each of the other activity per week.

2.3 Attendance and progress

According to ordinance O.6086 (repealing O.119, O.120 and O.125), it is mandatory for every learner to have minimum 50% attendance for each course and average attendance of all the courses together has to be 75% in each semester. The candidate shall complete the prescribed course satisfactorily to be eligible to appear for the respective examinations.

2.4 Credit assignment

2.4.1 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 by1.

2.5 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 are distributed semester-wise as shown in Table 13. 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.

3. 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.

4. COURSE OF STUDY

The specializations in M. Pharm program is given in Table 1.

Table – 1: List of M. Pharm. Specializations and their Code

S. No.	Specialization	Code
1.	Pharmaceutics	MPH
2.	Industrial Pharmacy	MIP
3.	Pharmaceutical Chemistry	MPC
4.	Pharmaceutical Analysis	MPA
5.	Pharmaceutical Quality Assurance (Quality Assurance)	MQA
6.	Pharmaceutical Regulatory Affairs	MRA
7.	Pharmaceutical Biotechnology	MPB
8.	Pharmacy Practice	MPP
9.	Pharmacology	MPL
10.	Pharmacognosy (Pharmacognosy and Phytochemistry)	MPG

The course of study for M. Pharm. specializations shall include Semester wise Theory & Practical as given in Tables – 2 to 11. 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 – 2 to 11.

Table – 2: Course of study for M. Pharm. (Pharmaceutics)

Course Code	Course	Credit Hours	Credit Points	Hrs./wk	Marks
Semester I					
MPH101T	Modern Pharmaceutical Analytical Techniques	4	4	4	100
MPH102T	Drug Delivery System	4	4	4	100
MPH103T	Modern Pharmaceutics	4	4	4	100
MPH104T	Regulatory Affair	4	4	4	100
MPH105P	Pharmaceutics Practical I	12	6	12	150
-	Seminar/Assignment	7	4	7	100
	Total	**35**	**26**	**35**	**650**
Semester II					
MPH201T	Molecular Pharmaceutics (Nano Tech and Targeted DDS)	4	4	4	100
MPH202T	Advanced Biopharmaceutics& Pharmacokinetics	4	4	4	100
MPH203T	Computer Aided Drug Delivery System	4	4	4	100
MPH204T	Cosmetic and Cosmeceuticals	4	4	4	100
MPH205P	Pharmaceutics Practical II	12	6	12	150
-	Seminar/Assignment	7	4	7	100
	Total	**35**	**26**	**35**	**650**

Table – 12: Course of study for M. Pharm. III and IV Semesters (Common for All Specializations)

Course Code	Course	Credit Hours	Credit Points
MRM301T	Research Methodology and Biostatistics*	4	4
-	Journal club	2	2
-	Discussion / Presentation (Proposal Presentation)	5	5
-	Research Work	30	30
Total		**41**	**41**

***** Non University Exam

Table – 13: Semester wise credits distribution

Semester	Credit Points
I	26
II	26
III and IV	41
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

Table – 14: 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

*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.

5. 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.

6. Examinations/Assessments

The schemes for internal assessment and end semester examinations are given in Tables – 15 to 25.

Tables – 15: Schemes for internal assessments and end semester examinations (Pharmaceutics- MPH)

Course Code	Course	Internal Assessment				End Semester Exams		Total Marks
		Continuous Mode	Sessional Exams		Total	Marks	Duration	
			Marks	Duration				
SEMESTER I								
MPH101T	Modern Pharmaceutical Analytical Techniques	10	15	1 Hr	25	75	3 Hrs	100
MPH102T	Drug Delivery System	10	15	1 Hr	25	75	3 Hrs	100
MPH103T	Modern Pharmaceutics	10	15	1 Hr	25	75	3 Hrs	100
MPH104T	Regulatory Affair	10	15	1 Hr	25	75	3 Hrs	100
MPH105P	Pharmaceutics Practical I	20	30	6 Hrs	50	100	6 Hrs	150
-	Seminar /Assignment	-	-	-	-	-	-	100
Total								**650**
SEMESTER II								
MPH201T	Molecular Pharmaceutics (Nano Tech and Targeted DDS)	10	15	1 Hr	25	75	3 Hrs	100
MPH202T	Advanced Biopharmaceutics & Pharmacokinetics	10	15	1 Hr	25	75	3 Hrs	100
MPH203T	Computer Aided Drug Delivery System	10	15	1 Hr	25	75	3 Hrs	100
MPH 204T	Cosmetic and Cosmeceuticals	10	15	1 Hr	25	75	3 Hrs	100
MPH205P	Pharmaceutics Practical I	20	30	6 Hrs	50	100	6 Hrs	150
-	Seminar /Assignment	-	-	-	-	-	-	100
TOTAL								**650**

Tables – 25: Schemes for internal assessments and end semester examinations (Semester III& IV)

Course Code	Course	Internal Assessment				End Semester Exams		Total Marks
		Continuous Mode	Sessional Exams		Total	Marks	Duration	
			Marks	Duration				
SEMESTER III								
MRM 30 1T	Research Methodology and Biostatistics*	10	15	1 Hr	25	75	3 Hrs	100
-	Journal club	-	-	-	25	-	-	25
-	Discussion / Presentation (Proposal Presentation)	-	-	-	50	-	-	50
-	Research work and colloquium	-	-	-	-	-	-	-
Total								**175**
SEMESTER IV								
-	Journal club	-	-	-	25	-	-	25
-	Discussion / Presentation (Proposal Presentation)	-	-	-	75	-	-	75
-	Research work and Colloquium	-	-	-	-	750	1 Hr	850
Total								**1025**

***Non-University Examination**

6.1 Internal assessment: Continuous mode

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

Table – 26: Scheme for awarding internal assessment: Continuous mode

Theory	
Criteria	**Maximum Marks**
Attendance (Refer Table – 27)	8
Student – Teacher interaction	2
Total	**10**
Practical	
Attendance (Refer Table – 27)	10
Based on Practical Records, Regular viva voce, etc.	10
Total	**20**

Table – 27: Guidelines for the allotment of marks for attendance

Percentage of Attendance	**Theory**	**Practical**
90 – 100	8	10
85 – 89	6	7.5
80 – 84	4	5
75– 79	2	2.5
Less than 75	0	0

6.2 Sessional Exams

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

6.3 End Semester Exam:

The End Semester Examinations in Semesters I and II (Theory Courses) of the M. Pharm. degree, and the *viva-voce* examination of the thesis at the end of Semester IV for the M. Pharm. Degree course will be conducted by the university.

A time-table and question papers for all the theory examinations of Semesters I and II will be prepared/set by the university as per the procedure.

The question papers for the Theory courses in Semesters I and II will be set by examiners and paper-setters appointed by the University.

The assessment and moderation of the answer booklets for the examinations in Theory courses in Semesters I and II will be carried out by examiners and moderators appointed by the ad-hoc Board of Studies in Pharmacy and approved by the University.

The assessment and moderation of the answer booklets of the Theory courses in Semesters I and II will be conducted by the University through Central Assessment Programme (CAP).

The evaluation of the End Semester Examination in the Practical subjects and Seminar/assignment in Semester I and II will be conducted at the college/institutional level by PG teachers recognized as research guides by the university

7. 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 course including internal assessment.

8. Carry forward of marks

In case a student fails to secure the minimum **50%** in any Theory or Practical course, 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.

9. 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.

10. Reexamination of end semester examinations

Reexamination of end semester examination shall be conducted as per the schedule given in table 28. The exact dates of examinations shall be notified from time to time.

Table – 28: 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

11. Allowed to keep terms(ATKT):

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

A student shall be eligible to carry forward all the courses of I, II and III. The submission of synopsis and the holding of the viva voce examination shall be permitted only if the student has successfully cleared semester I, II and III.

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.

12. Grading of performances

a. 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 – 29.

Table – 29: 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.

13. 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:

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

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:

$$\text{SGPA} = \frac{C1G1 + C2G2 + C3G3 + C4 * 0}{C1 + C2 + C3 + C4}$$

14. 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 passed by 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:

$$CGPA = \frac{C1S1 + C2S2 + C3S3 + C4S4}{C1 + C2 + C3 + C4}$$

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,…. .

15. Declaration of class

Although the GPA system is a stand-alone system of grading and not amenable to facile conversion to percent marks, in general, the conversion of CGPA to percent marks is:

CGPA x 9.5 = Percent marks.

The class shall be awarded on the basis of CGPA as follows:

- First Class with Distinction = CGPA of. 7.37 and above
- First Class = CGPA of 6.32 to 7.36
- Second Class = CGPA of 6.00 to 6.31

16. Project work

All the students shall undertake a project under the supervision of a teacher in Semester III to IV and submit a report. Four copies of the project report shall be submitted.

- **Writing the thesis**

The thesis will be typed using Times New Roman font, size 11, 1.5 line spacing, with all headings/subheadings in bold.

The thesis will be of maximum 125 pages and composed in the following manner:

Chapter 1 – Introduction. This should be limited to about 30 pages and will describe all background information of the research described in the thesis.

Chapter 2 – Aims and objectives, limited to 2 pages.

Chapter 3 – Plan of Work, limited to 4 pages

Chapter 4 – Experimental. This section should preferably include only the optimized experiments from which the inferences and conclusions were drawn.

Chapter 5 – Results and Discussion, this should constitute 40 to 50 pages of the thesis.

Chapter 6 – References. This should be in ACS format. Refer to Ch. 14 *In The ACS Style Guide*; Coghill, A., et al.; American Chemical Society: Washington, DC, 2006.

If any deviations are found in the style of writing the thesis, the thesis is liable to be rejected by the University.

Scheme of assessment for Thesis

Assessment	External Examiner	Internal (Guiding Teacher)	Total
	50% of marks	50% of marks	100%

The assessment of the thesis submitted at the end of Semester IV will done by both the internal (guiding) teacher and an external examiner chosen from the industry with established competence in the field or may be any recognized research guide from another recognized university. It is proposed that every learner will submit a synopsis of the research work carried out by him/her during Semesters III and IV which forms the content of the thesis. A learner will be permitted to submit his/her synopsis no earlier than 20 months (after 20 months) from the beginning of the M. Pharm. program as instructed by the

Government/Regulatory Authority for the respective year, BUT will have to submit the final thesis by the end of 24 months from the beginning of the M. Pharm program as instructed by the Government/Regulatory Authority. The time between submission of synopsis and thesis should be at least one month. The learner must submit his thesis to the University in a format as prescribed by the University. The university will take all steps to conduct the *viva-voce* examination at the earliest after the submission of the thesis. It is expected that only the synopsis of the thesis submitted by the learner will be forward by the university to the external examiner at least one week before the conduct of the *viva-voce* examination. Only at the time of the *viva-voce* examination, the external examiner will be presented the thesis submitted by the candidate for the award of the degree.

The evaluation will be done by a pair of examiners (research guide and external examiner), appointed by and at the University, based on the report and a viva-voce. Final Grade reports are to be sent by the Institute to the respective section of university on completion of the viva-voce. The criteria of evaluation of Dissertation are given in the curriculum manual.

Any late submission of synopsis or thesis will result in the learner requiring to keep terms for the next semester and any subsequent semester/s till the learner finishes his/her degree.

The internal and external examiner appointed by the University shall evaluate the project. The projects shall be evaluated as per the criteria given below.

Evaluation of Dissertation Book:

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

Evaluation of Presentation:

Presentation of work		**100**
Communication skills		**50**
Question and answers kills		**100**
	Total	**250 Marks**

17. Award of degree

Candidates who fulfill the requirements mentioned above shall be eligible for award of

degree during the ensuing convocation.

18. Duration for completion of the program of study

The duration for the completion of the program shall be fixed as per the norms of the University of Mumbai

UNIVERSITY OF MUMBAI

Scheme and Syllabus For

CHOICE BASED CREDIT SYSTEM

for

Postgraduate Program

(Master of Pharmacy, M. Pharm.)

in

PHARMACY

Revised Course (Revised 2019)

(from the academic year 2019–2020)

1. Course of study

The specializations in M.Pharm program is given in Table 1.

Table – 1: List of M.Pharm. Specializations and their Code

S. No.	Specialization	Code
1.	Pharmaceutics	MPH
2.	Industrial Pharmacy	MIP
3.	Pharmaceutical Chemistry	MPC
4.	Pharmaceutical Analysis	MPA
5.	Pharmaceutical Quality Assurance	MQA
6.	Pharmaceutical Regulatory Affairs	MRA
7.	Pharmaceutical Biotechnology	MPB
8.	Pharmacy Practice	MPP
9.	Pharmacology	MPL
10.	Pharmacognosy	MPG

The course of study for M.Pharm specializations shall include Semester wise Theory & Practical as given in Table – 2 to 11. 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 – 2 to 11.

Table – 2: Course of study for M. Pharm. (Pharmaceutics)

Course Code	Course	Credit Hours	Credit Points	Hrs./wk	Marks
Semester I					
MPH101T	Modern Pharmaceutical Analytical Techniques	4	4	4	100
MPH102T	Drug Delivery System	4	4	4	100
MPH103T	Modern Pharmaceutics	4	4	4	100
MPH104T	Regulatory Affair	4	4	4	100
MPH105P	Pharmaceutics Practical I	12	6	12	150
-	Seminar/Assignment	7	4	7	100
Total		**35**	**26**	**35**	**650**
Semester II					
MPH201T	Molecular Pharmaceutics (Nano Tech and Targeted DDS)	4	4	4	100
MPH202T	Advanced Biopharmaceutics & Pharmacokinetics	4	4	4	100
MPH203T	Computer Aided Drug Delivery System	4	4	4	100
MPH204T	Cosmetic and Cosmeceuticals	4	4	4	100
MPH205P	Pharmaceutics Practical II	12	6	12	150
-	Seminar/Assignment	7	4	7	100
	Total	**35**	**26**	**35**	**650**

PHARMACEUTICS (MPH)

MODERN PHARMACEUTICAL ANALYTICAL TECHNIQUES (MPH 101T)

Scope

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

Objectives

After completion of course student is able to know,

- Chemicals and Excipients
- The analysis of various drugs in single and combination dosage forms
- Theoretical and practical skills of the instruments

THEORY ***60 HOURS***

1. 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. — 11 Hrs

   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

   c. **Spectroflourimetry:** 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.

2 **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. — 11 Hrs

3	**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	11 Hrs
4	**Chromatography**: Principle, apparatus, instrumentation, chromatographic parameters, factors affecting resolution and applications of the following: a) Paper chromatography b) Thin Layer chromatography c) Ion exchange chromatography d) Column chromatography e) Gas chromatography f) High Performance Liquid chromatography g) Affinity chromatography	11 Hrs
5	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) Iso electric 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 X-ray diffraction.	11 Hrs
6	**Immunological assays :** RIA (Radio immuno assay), ELISA, Bioluminescence assays.	5 Hrs

REFERENCES

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

DRUG DELIVERY SYSTEMS
(MPH 102T)

SCOPE

This course is designed to impart knowledge on the area of advances in novel drug delivery systems.

OBJECTIVES

Upon completion of the course, student shall be able to understand

- The various approaches for development of novel drug delivery systems.
- The criteria for selection of drugs and polymers for the development of delivering system
- The formulation and evaluation of Novel drug delivery systems..

THEORY ***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, Telepharmacy.	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	**Occular 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

REFERENCES

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 WileyInterscience 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

JOURNALS

1. Indian Journal of Pharmaceutical Sciences (IPA)
2. Indian drugs (IDMA)
3. Journal of controlled release (Elsevier Sciences) desirable
4. Drug Development and Industrial Pharmacy (Marcel & Decker) desirable

MODERN PHARMACEUTICS
(MPH 103T)

Scope

Course designed to impart advanced knowledge and skills required to learn various aspects and concepts at pharmaceutical industries

Objectives

Upon completion of the course, student shall be able to understand

- The elements of preformulation studies.
- The Active Pharmaceutical Ingredients and Generic drug Product development
- Industrial Management and GMP Considerations.
- Optimization Techniques & Pilot Plant Scale Up Techniques
- Stability Testing, sterilization process & packaging of dosage forms.

THEORY ***60 HRS***

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
2	**Validation :** Introduction to Pharmaceutical Validation, Scope & merits of Validation, Validation and calibration of Master plan, ICH & WHO guidelines for calibration and validation of equipments, Validation of specific dosage form, Types of validation. Government regulation, Manufacturing Process Model, URS, DQ, IQ, OQ & P.Q. of facilities.	10 Hrs
3	**cGMP & Industrial Management**: Objectives and policies of current good manufacturing practices, layout of buildings, services, equipments 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

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

REFERENCES

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.

REGULATORY AFFAIRS
(MPH 104T)

Scope

Course designed to impart advanced knowledge and skills required to learn the concept of generic drug and their development, various regulatory filings in different countries, different phases of clinical trials and submitting regulatory documents : filing process of IND, NDA and ANDA

- To know the approval process of
- To know the chemistry, manufacturing controls and their regulatory importance
- To learn the documentation requirements for
- To learn the importance and

Objectives:

Upon completion of the course, it is expected that the students will be able to understand

- The Concepts of innovator and generic drugs, drug development process
- The Regulatory guidance's and guidelines for filing and approval process
- Preparation of Dossiers and their submission to regulatory agencies in different countries
- Post approval regulatory requirements for actives and drug products
- Submission of global documents in CTD/ eCTD formats
- Clinical trials requirements for approvals for conducting clinical trials
- Pharmacovigilence and process of monitoring in clinical trials.

THEORY ***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

   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

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

REFERENCES

1. Generic Drug Product Development, Solid Oral Dosage forms, Leon Shargel and IsaderKaufer,Marcel Dekker series, Vol.143
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

PHARMACEUTICS PRACTICALS - I
(MPH 105P)

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 Heckal plot, Higuchi and peppas plot and determine similarity factors.

MOLECULAR PHARMACEUTICS (NANO TECHNOLOGY & TARGETED DDS) (NTDS)
(MPH 201T)

Scope

This course is designed to impart knowledge on the area of advances in novel drug delivery systems.

Objectives

Upon completion of the course student shall be able to understand

- The various approaches for development of novel drug delivery systems.
- The criteria for selection of drugs and polymers for the development of NTDS
- The formulation and evaluation of novel drug delivery systems.

THEORY ***60 Hrs***

1.	**Targeted Drug Delivery Systems: C**oncepts, 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, Electrosomes.	12 Hrs
4	**Pulmonary Drug Delivery Systems** : Aerosols, propellents, ContainersTypes, 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.	12 Hrs

REFERENCES

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, VallabhPrakashan, New Delhi, First edition 2002.
3. N.K. Jain, Controlled and Novel Drug Delivery, CBS Publishers & Distributors, NewDelhi, First edition 1997 (reprint in 2001).

ADVANCED BIOPHARMACEUTICS & PHARMACOKINETICS (MPH 202T)

Scope

This course is designed to impart knowledge and skills necessary for dose calculations, dose adjustments and to apply biopharmaceutics theories in practical problem solving. Basic theoretical discussions of the principles of biopharmaceutics and pharmacokinetics are provided to help the students' to clarify the concepts.

Objectives

Upon completion of this course it is expected that students will be able understand,

- The basic concepts in biopharmaceutics and pharmacokinetics.
- The use raw data and derive the pharmacokinetic models and parameters the best describe the process of drug absorption, distribution, metabolism and elimination.
- The critical evaluation of biopharmaceutic studies involving drug product equivalency.
- The design and evaluation of dosage regimens of the drugs using pharmacokinetic and biopharmaceutic parameters.
- The potential clinical pharmacokinetic problems and application of basics of pharmacokinetic

THEORY ***60 Hrs***

1. **Drug Absorption from the Gastrointestinal Tract**: Gastrointestinal tract, Mechanism of drug absorption, Factors affecting drug absorption, pH–partition theory of drug absorption. Formuulation 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. 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 testingperformance 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 modeling: 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 of k_{max} and v_{max}. 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. biopharmaceutics classification system, methods. Permeability: In-vitro, in-situ and In-vivo methods.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 pharmacodynamic, drug interactions. Pharmacokinetics and pharmacodynamics of biotechnology drugs. Introduction, Proteins and peptides, Monoclonal antibodies, Oligonucleotides, Vaccines (immunotherapy), Gene therapies.	12 Hrs

REFERENCES

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., VallabPrakashan, 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, Leaand Febiger, Philadelphia, 1970
7. Clinical Pharmacokinetics, Concepts and Applications 3rd edition by MalcolmRowland and Thom~ N. Tozer, Lea and Febiger, Philadelphia, 1995
8. Dissolution, Bioavailability and Bioequivalence, Abdou. H.M, Mack PublishingCompany, 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 JambhekarandPhilip J Breen,pharmaceutical press, RPS Publishing,2009.
13. Absorption and Drug Development- Solubility, Permeability, and Charge State, Alex Avdeef, John Wiley & Sons, Inc,2003.

COMPUTER AIDED DRUG DEVELOPMENT
(MPH 203T)

Scope

This course is designed to impart knowledge and skills necessary for computer Applications in pharmaceutical research and development who want to understand the application of computers across the entire drug research and development process. Basic theoretical discussions of the principles of more integrated and coherent use of computerized information (informatics) in the drug development process are provided to help the students to clarify the concepts.

Objectives

Upon completion of this course it is expected that students will be able to understand,

- History of Computers in Pharmaceutical Research and Development
- Computational Modeling of Drug Disposition
- Computers in Preclinical Development
- Optimization Techniques in Pharmaceutical Formulation
- Computers in Market Analysis
- Computers in Clinical Development
- Artificial Intelligence (AI) and Robotics
- Computational fluid dynamics(CFD)

THEORY		***60 Hrs***
1.	a. **Computers in Pharmaceutical Research and 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 b. **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 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	a. **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 b. **Computer Simulations in Pharmacokinetics and Pharmacodynamics:** Introduction, Computer Simulation: Whole Organism, Isolated Tissues, Organs, Cell, Proteins and Genes. c. **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.	12 Hrs

REFERENCES

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

COSMETICS AND COSMECEUTICALS
(MPH 204T)

Scope

This course is designed to impart knowledge and skills necessary forthefundamental need for cosmetic and cosmeceutical products.

Objectives

Upon completion of the course, the students shall be able to understand

- Key ingredients used in cosmetics and cosmeceuticals.
- Key building blocks for various formulations.
- Current technologies in the market
- Various key ingredients and basic science to develop cosmetics and cosmeceuticals
- Scientific knowledge to develop cosmetics and cosmeceuticals with desired Safety, stability, and efficacy.

THEORY ***60 Hrs***

1. **Cosmetics – Regulatory :** Definition of cosmetic products as per Indian regulation. Indian regulatory requirements for labeling 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. — 12 Hrs

2 **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. — 12 Hrs

3 **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 syndetbars. — 12 Hrs

Perfumes; Classification of perfumes. Perfume ingredients listed as allergens in EU regulation.

	Controversial ingredients: Parabens, formaldehyde liberators, dioxane.	
4	**Design of cosmeceutical products:** Sun protection, sunscreens classification and regulatory aspects. Addressing dry skin, acne, sun-protection, pigmentation, prickly heat, wrinkles, body odor., dandruff, dental cavities, bleeding gums, mouth odor and sensitive teeth through cosmeceutical formulations.	12 Hrs
5	**Herbal Cosmetics :** Herbal ingredients used in Hair care, skin care 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.	12 Hrs

REFERENCES

1. Harry's Cosmeticology. 8th edition.
2. Poucher'sperfumecosmeticsandSoaps,10th edition.
3. Cosmetics - Formulation, Manufacture and quality control, PP.Sharma,4th edition
4. Handbook of cosmetic science and Technology A.O.Barel, M.Paye and H.I. Maibach. 3 rd edition
5. Cosmetic and Toiletries recent suppliers catalogue.
6. CTFA directory.

PHARMACEUTICS PRACTICALS - II
(MPH 205P)

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

Semester III
MRM 301T - Research Methodology & Biostatistics

UNIT – I

General Research Methodology: Research, objective, requirements, practical difficulties, review of literature, study design, types of studies, strategies to eliminate errors/bias, controls, randomization, crossover design, placebo, blinding techniques.

UNIT – II

Biostatistics: Definition, application, sample size, importance of sample size, factors influencing sample size, dropouts, statistical tests of significance, type of significance tests, parametric tests(students "t" test, ANOVA, Correlation coefficient, regression), non-parametric tests (wilcoxan rank tests, analysis of variance, correlation, chi square test), null hypothesis, P values, degree of freedom, interpretation of P values.

UNIT – III

Medical Research: History, values in medical ethics, autonomy, beneficence, non-maleficence, double effect, conflicts between autonomy and beneficence/non-maleficence, euthanasia, informed consent, confidentiality, criticisms of orthodox medical ethics, importance of communication, control resolution, guidelines, ethics committees, cultural concerns, truth telling, online business practices, conflicts of interest, referral, vendor relationships, treatment of family members, sexual relationships, fatality.

UNIT – IV

CPCSEA guidelines for laboratory animal facility: Goals, veterinary care, quarantine, surveillance, diagnosis, treatment and control of disease, personal hygiene, location of animal facilities to laboratories, anesthesia, euthanasia, physical facilities, environment, animal husbandry, record keeping, SOPs, personnel and training, transport of lab animals.

UNIT – V

Declaration of Helsinki: History, introduction, basic principles for all medical research, and additional principles for medical research combined with medical care.