

**Ordinance Governing
Master of Pharmacy
M. Pharm. Degree Course**

**Syllabus / Curriculum
2017 - 18**



Accredited 'A' Grade by NAAC
Placed in Category 'A' by MHRD(GoI)

KLE UNIVERSITY

JNMC Campus, Nehru Nagar, Belgaum - 590 010. Karnataka, INDIA.
Phone : +91 0831-2472777, 2493779 FAX : +91 0831-2493777
E-mail : info@kleuniversity.edu.in Website : www.kleuniversity.edu.in

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© Registrar

E-mail: registrar@kleuniversity.edu.in

Director, Academic Affairs

Email: diracademic@kleuniversity.edu.in

KLE University

JNMC Campus, Nehru Nagar,

Belgaum-590010

Ph: 0831-2472777

e-mail:info@kleuniversity.edu.in

Price Rs: 170/-only

Printed at:

OMEGA OFFSET

4574, Shetty Galli, Belgaum.

☎ : 2424124, 2433429

Fax : 4204124

VISION

To be an outstanding University of excellence ever in pursuit of newer horizons to build self reliant global citizens through assured quality educational programs.

MISSION

- To promote sustainable development of higher education consistent with statutory and regulatory requirements.
- To plan continuously provide necessary infrastructure, learning resources required for quality education and innovations.
- To stimulate to extend the frontiers of knowledge, through faculty development and continuing education programs.
- To make research a significant activity involving staff, students and society.
- To promote industry / organization, interaction/collaborations with regional/national / international bodies.
- To establish healthy systems for communication among all stakeholders for vision oriented growth.
- To fulfill the national obligation through rural health missions.

OBJECTIVES

The objectives are to realize the following at university and its constituent institutions:

- To implement effectively the programs through creativity and innovation in teaching, learning and evaluation.
- To make existing programs more careers oriented through effective system of review and redesign of curriculum.
- To impart spirit of enquiry and scientific temperament among students through research oriented activities.
- To enhance reading and learning capabilities among faculty and students and inculcate sense of life long learning.
- To promulgate process for effective, continuous, objective oriented student performance evaluation.
- To ordinate periodic performance evaluation of the faculty.
- To incorporate themes to build values. Civic responsibilities & sense of national integrity.
- To ensure that the academic, career and personal counseling are in-built into the system of curriculum delivery.
- To strengthen, develop and implement staff and student welfare programs.
- To adopt and implement principles of participation, transparency and accountability in governance of academic and administrative activities.
- To constantly display sensitivity and respond to changing educational, social, and community demands.
- To promote public-private partnership.

INSIGNIA



The Emblem of the University is a Philosophical statement in Symbolic.

The Emblem...

A close look at the emblem unveils a pillar, a symbol of the “University of Excellence” built on strong values & principles.

The Palm and the Seven Stars...

The Palm is the palm of the teacher- the hand that acts, promises & guides the students to reach for the Seven Stars...

The Seven Stars signify the ‘Saptarishi Dnyanamandal’, the Great Bear-a constellation made of Seven Stars in the sky, each signifying a particular Domain. Our culture says: The true objective of human birth is to master these Knowledge Domains.

The Seven Stars also represent the Saptarishis, the founders of KLE Society whose selfless service and intense desire for “Dnyana Dasoha” laid the foundation for creating the knowledge called KLE Society.

Hence another significance of the raised palm is our tribute to these great Souls for making this University a possibility.

Empowering Professionals...

‘Empowering Professionals’, inscription at the base of the Emblem conveys that our Organization with its strength, maturity and wisdom forever strive to empower the student community to become globally competent professionals. It has been a guiding force for many student generations in the past, and will continue to inspire many forth coming generations.



KLE UNIVERSITY

(Formerly known as KLE Academy of Higher Education & Research)

[Established under Section 3 of the UGC Act, 1956 vide Government of India Notification No. F. 9-19/2000-U.3(A)]

Accredited 'A' Grade by NAAC

Office of the Registrar, KLE University,

JNMC Campus, Nehru Nagar, Belgaum-590 010, Karnataka State, India

Ph: 0831-2472777/2493779 Fax : 0831-2493777 Web: [http:// www.kleuniversity.edu.in](http://www.kleuniversity.edu.in) E-mail:

info@kleuniversity.edu.in

Ref. No. KLEU/AC/10-11/

3rd April 2010

NOTIFICATION

Sub : **Ordinance governing the syllabus/curriculum for
Master of Pharmacy Course**

Ref : Minutes of the meeting of the Academic Council of the University
held on 13th March 2010.

In exercise of the powers conferred under Rule A-04 (i) of the Memorandum of Association of the University, the Academic Council of the University is pleased to approve the Ordinance governing the syllabus / curriculum for the following **Master of Pharmacy Course** in its meeting held on 13th March 2010.

The Ordinance shall be effective for the students admitted to **Master of Pharmacy Course** under the Faculty of Pharmacy in the constituent college of the University viz. KLEs College of Pharmacy, Belgaum from the academic session 2009-10 onwards.

By Order

REGISTRAR

To

The Dean,
Faculty of Pharmacy
KLEs College of Pharmacy
BELGAUM.

CC to :

1. The Secretary, University Grants Commission, New Delhi.
2. The PA to Hon. Chancellor, KLE University, Belgaum.
3. The Special Officer to Hon. Vice-Chancellor, KLE University, Belgaum.
4. All Officers of the University - Academic Affairs / Examination Branch.

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CHAPTER – I:

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

1. 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/extra-curricular activities is dependent upon the quantum of work expected to be put in for each of these activities per week/per activity.

7.1. Credit assignment

7.1.1. 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 by 1.

7.2. 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 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.

8. 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.

9. Course of study

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

S.No.	Specialization	Code
1.	Pharmaceutics	MPH
2.	Pharmaceutical Chemistry	MPC
3.	Pharmaceutical Quality Assurance	MQA
4.	Pharmacy Practice	MPP
5.	Pharmacology	MPL
6.	Pharmacognosy	MPG

The course of study for M.Pharm. specializations shall include Semester wise Theory & Practical as given in Table – 2 to 7. 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 7.

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

Course Code	Course	Credit Hours	Credit Points	Hrs./Week	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 – 3: Course of study for M. Pharm.

(Pharmaceutical Chemistry)

Course Code	Course	Credit Hours	Credit Points	Hrs./Wk	Marks
Semester I					
MPC101T	Modern Pharmaceutical Analytical Techniques	4	4	4	100
MPC102T	Advanced Organic Chemistry-I	4	4	4	100
MPC103T	Advanced Medicinal Chemistry	4	4	4	100
MPC104T	Chemistry of Natural Products	4	4	4	100
MPC105P	Pharmaceutical Chemistry Practical I	12	6	12	150
-	Seminar/Assignment	7	4	7	100
Total		35	26	35	650
Semester II					
MPC201T	Advanced Spectral Analysis	4	4	4	100
MPC202T	Advanced Organic Chemistry -II	4	4	4	100
MPC203T	Computer Aided Drug Design	4	4	4	100
MPC204T	Pharmaceutical Process Chemistry	4	4	4	100
MPC205P	Pharmaceutical Chemistry Practical II	12	6	12	150
-	Seminar/Assignment	7	4	7	100
Total		35	26	35	650

**Table – 4: Course of study for M. Pharm.
(Pharmaceutical Quality Assurance)**

Course Code	Course	Credit Hours	Credit Points	Hrs./Week	Marks
Semester I					
MQA101T	Modern Pharmaceutical Analytical Techniques	4	4	4	100
MQA102T	Quality Management System	4	4	4	100
MQA103T	Quality Control and Quality Assurance	4	4	4	100
MQA104T	Product Development and Technology Transfer	4	4	4	100
MQA105P	Pharmaceutical Quality Assurance Practical I	12	6	12	150
-	Seminar/Assignment	7	4	7	100
Total		35	26	35	650
Semester II					
MQA201T	Hazards and Safety Management	4	4	4	100
MQA202T	Pharmaceutical Validation	4	4	4	100
MQA203T	Audits and Regulatory Compliance	4	4	4	100
MQA204T	Pharmaceutical Manufacturing Technology	4	4	4	100
MQA205P	Pharmaceutical Quality Assurance Practical II	12	6	12	150
-	Seminar/Assignment	7	4	7	100
Total		35	26	35	650

**Table – 5: Course of study for M. Pharm.
(Pharmacy Practice)**

Course Code	Course	Credit Hours	Credit Points	Hrs./Wk	Marks
Semester I					
MPP101T	Clinical Pharmacy Practice	4	4	4	100
MPP102T	Pharmacotherapeutics-I	4	4	4	100
MPP103T	Hospital & Community Pharmacy	4	4	4	100
MPP104T	Clinical Research	4	4	4	100
MPP105P	Pharmacy Practice Practical I	12	6	12	150
-	Seminar/Assignment	7	4	7	100
Total		35	26	35	650
Semester II					
MPP201T	Principles of Quality Use of Medicines	4	4	4	100
MPP202T	Pharmacotherapeutics II	4	4	4	100
MPP203T	Clinical Pharmacokinetics and Therapeutic Drug Monitoring	4	4	4	100
MPP204T	Pharmacoepidemiology & Pharmacoconomics	4	4	4	100
MPP205P	Pharmacy Practice Practical II	12	6	12	150
-	Seminar/Assignment	7	4	7	100
Total		35	26	35	650

Table – 6: Course of study for M. Pharm. (Pharmacology)

Course Code	Course	Credit Hours	Credit Points	Hrs./Wk	Marks
Semester I					
MPL101T	Modern Pharmaceutical Analytical Techniques	4	4	4	100
MPL102T	Advanced Pharmacology-I	4	4	4	100
MPL103T	Pharmacological and Toxicological Screening Methods-I	4	4	4	100
MPL104T	Cellular and Molecular Pharmacology	4	4	4	100
MPL105P	Pharmacology Practical I	12	6	12	150
-	Seminar/Assignment	7	4	7	100
Total		35	26	35	650
Semester II					
MPL201T	Advanced Pharmacology II	4	4	4	100
MPL202T	Pharmacological and Toxicological Screening Methods-II	4	4	4	100
MPL203T	Principles of Drug Discovery	4	4	4	100
MPL204T	Clinical Research and Pharmacovigilance	4	4	4	100
MPL205P	Pharmacology Practical II	12	6	12	150
-	Seminar/Assignment	7	4	7	100
Total		35	26	35	650

**Table – 7: Course of study for M. Pharm.
(Pharmacognosy)**

Course Code	Course	Credit Hours	Credit Points	Hrs./Wk	Marks
Semester I					
MPG101T	Modern Pharmaceutical Analytical Techniques	4	4	4	100
MPG102T	Advanced Pharmacognosy-1	4	4	4	100
MPG103T	Phytochemistry	4	4	4	100
MPG104T	Industrial Pharmacognostical Technology	4	4	4	100
MPG105P	Pharmacognosy Practical I	12	6	12	150
-	Seminar/Assignment	7	4	7	100
Total		35	26	35	650
Semester II					
MPG201T	Medicinal Plant biotechnology	4	4	4	100
MPG202T	Advanced Pharmacognosy-II	4	4	4	100
MPG203T	Indian system of medicine	4	4	4	100
MPG204T	Herbal cosmetics	4	4	4	100
MPG205P	Pharmacognosy Practical II	12	6	12	150
-	Seminar/Assignment	7	4	7	100
Total		35	26	35	650

**Table – 8: Course of study for M. Pharm. III Semester
(Common for All Specializations)**

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

* Non University Exam

**Table – 9: Course of study for M. Pharm. IV Semester
(Common for All Specializations)**

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

Table – 10: Semester wise credits distribution

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

*Credit Points for Co-curricular Activities

Table – 11: 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.

10. 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 sessionalexam and before the end semester exam.

11. Examinations/Assessments

The schemes for internal assessment and end semester examinations are given in Table – 12.

11.1. End semester examinations

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

**Table – 12: 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	1Hr	25	75	3Hrs	100
MPH102T	Drug Delivery System	10	15	1Hr	25	75	3Hrs	100
MPH103T	Modern Pharmaceutics	10	15	1Hr	25	75	3Hrs	100
MPH104T	Regulatory Affairs	10	15	1Hr	25	75	3Hrs	100
MPH105P	Pharmaceutics Practical I	20	30	6Hrs	50	100	6Hrs	150
-	Seminar/Assignment	-	-	-	-	-	-	100
Total								650
Semester II								
MPH201T	Molecular Pharmaceutics (Nano Tech and Targeted DDS)	10	15	1Hr	25	75	3Hrs	100
MPH202T	Advanced Biopharmaceutics & Pharmacokinetics	10	15	1Hr	25	75	3Hrs	100
MPH203T	Computer Aided Drug Delivery System	10	15	1Hr	25	75	3Hrs	100
MPH204T	Cosmetic and Cosmeceuticals	10	15	1Hr	25	75	3Hrs	100
MPH205P	Pharmaceutics Practical II	20	30	6Hrs	50	100	6Hrs	150
-	Seminar/Assignment	-	-	-	-	-	-	100
Total								650

**Table – 13: Schemes for internal assessments and end semester examinations
(Pharmaceutical Chemistry-MPC)**

Course Code	Course	Internal Assessment				End Semester Exams		Total Marks	
		Continuous Mode	Sessional Exams		Total	Mar ks	Durati on		
			Marks	Durati on					
Semester I									
MPC101T	Modern Pharmaceutical Analytical Techniques	10	15	1Hr	25	75	3Hrs	100	
MPC1012T	Advanced Organic Chemistry-I	10	15	1Hr	25	75	3Hrs	100	
MPC103T	Advanced Medicinal Chemistry	10	15	1Hr	25	75	3Hrs	100	
MPC104T	Chemistry of Natural Products	10	15	1Hr	25	75	3Hrs	100	
MPC105P	Pharmaceutical Chemistry Practical I	20	30	6Hrs	50	100	6Hrs	150	
-	Seminar/Assignment	-	-	-	-	-	-	100	
Total									650
Semester II									
MPC201T	Advanced Spectral Analysis	10	15	1Hr	25	75	3Hrs	100	
MPC202T	Advanced Organic Chemistry -II	10	15	1Hr	25	75	3Hrs	100	
MPC203T	Computer Aided Drug Design	10	15	1Hr	25	75	3Hrs	100	
MPC204T	Pharmaceutical Process Chemistry	10	15	1Hr	25	75	3Hrs	100	
MPC205P	Pharmaceutical Chemistry Practical II	20	30	6Hrs	50	100	6Hrs	150	
-	Seminar/Assignment	-	-	-	-	-	-	100	
Total									650

**Table – 14: Schemes for internal assessments and end semester examinations
(Pharmaceutical Quality Assurance-MQA)**

Course Code	Course	Internal Assessment				End Semester Exams		Total Marks
		Continuous Mode	Sessional Exams		Total	Marks	Duration	
			Marks	Duration				
Semester I								
MQA101T	Modern Pharmaceutical Analytical Techniques	10	15	1Hr	25	75	3Hrs	100
MQA102T	Quality Management System	10	15	1Hr	25	75	3Hrs	100
MQA103T	Quality Control and Quality Assurance	10	15	1Hr	25	75	3Hrs	100
MQA104T	Product Development and Technology Transfer	10	15	1Hr	25	75	3Hrs	100
MQA105P	Pharmaceutical Quality Assurance Practical I	20	30	6Hrs	50	100	6Hrs	150
-	Seminar/Assignment	-	-	-	-	-	-	100
Total								650
Semester II								
MQA201T	Hazards and Safety Management	10	15	1Hr	25	75	3Hrs	100
MQA202T	Pharmaceutical Validation	10	15	1Hr	25	75	3Hrs	100
MQA203T	Audits and Regulatory Compliance	10	15	1Hr	25	75	3Hrs	100
MQA204T	Pharmaceutical Manufacturing Technology	10	15	1Hr	25	75	3Hrs	100
MQA205P	Pharmaceutical Quality Assurance Practical II	20	30	6Hrs	50	100	6Hrs	10
-	Seminar/Assignment	-	-	-	-	-	-	100
Total								650

**Table – 15: Schemes for internal assessments and end semester examinations
(Pharmacy Practice)**

Course Code	Course	Internal Assessment				End Semester Exams		Total Marks
		Continuous Mode	Sessional Exams		Total	Marks	Duration	
			Marks	Duration				
Semester I								
MPP101T	Clinical Pharmacy Practice	10	15	1Hr	25	75	3Hrs	100
MPP102T	Pharmacotherapeutics-I	10	15	1Hr	25	75	3Hrs	100
MPP103T	Hospital & Community Pharmacy	10	15	1Hr	25	75	3Hrs	100
MPP104T	Clinical Research	10	15	1Hr	25	75	3Hrs	100
MPP105P	Pharmacy Practice Practical I	20	30	6Hrs	50	100	6Hrs	150
-	Seminar/Assignment	-	-	-	-	-	-	100
Total							650	
Semester II								
MPP201T	Principles of Quality Use of Medicines	10	15	1Hr	25	75	3Hrs	100
MPP202T	Pharmacotherapeutics II	10	15	1Hr	25	75	3Hrs	100
MPP203T	Clinical Pharmacokinetics and Therapeutic Drug Monitoring	10	15	1Hr	25	75	3Hrs	100
MPP204T	Pharmacoepidemiology & Pharmacoconomics	10	15	1Hr	25	75	3Hrs	100
MPP205P	Pharmacy Practice Practical II	20	30	6Hrs	50	100	6Hrs	150
-	Seminar/Assignment	-	-	-	-	-	-	100
Total							650	

Table – 16: Schemes for internal assessments and end semester examinations (Pharmacology)

Course Code	Course	Internal Assessment				End Semester Exams		Total Marks
		Continuous Mode	Sessional Exams		Total	Marks	Duration	
			Marks	Duration				
Semester I								
MPL101T	Modern Pharmaceutical Analytical Techniques	10	15	1Hr	25	75	3Hrs	100
MPL102T	Advanced Pharmacology-I	10	15	1Hr	25	75	3Hrs	100
MPL103T	Pharmacological and Toxicological Screening Methods-I	10	15	1Hr	25	75	3Hrs	100
MPL104T	Cellular and Molecular Pharmacology	10	15	1Hr	25	75	3Hrs	100
MPL105P	Pharmacology Practical I	20	30	6Hrs	50	100	6Hrs	150
-	Seminar/Assignment	-	-	-	-	-	-	100
Total								650
Semester II								
MPL201T	Advanced Pharmacology II	10	15	1Hr	25	75	3Hrs	100
MPL202T	Pharmacological and Toxicological Screening Methods-II	10	15	1Hr	25	75	3Hrs	100
MPL203T	Principles of Drug Discovery	10	15	1Hr	25	75	3Hrs	100
MPL204T	Clinical Research and Pharmacovigilance	10	15	1Hr	25	75	3Hrs	100
MPL205P	Pharmacology Practical- II	20	30	6Hrs	50	100	6Hrs	150
-	Seminar/Assignment	-	-	-	-	-	-	100
Total								650

Table – 17: Schemes for internal assessments and end semester examinations (Pharmacognosy)

Course Code	Course	Internal Assessment				End Semester Exams		Total Marks	
		Continuous Mode	Sessional Exams		Total	Marks	Duration		
			Marks	Duration					
Semester I									
MPG101T	Modern Pharmaceutical Analytical Techniques	10	15	1Hr	25	75	3Hrs	100	
MPG102T	Advanced Pharmacognosy-1	10	15	1Hr	25	75	3Hrs	100	
MPG103T	Phytochemistry	10	15	1Hr	25	75	3Hrs	100	
MPG104T	Industrial Pharmacognostical Technology	10	15	1Hr	25	75	3Hrs	100	
MPG105P	Pharmacognosy Practical I	20	30	6Hrs	50	100	6Hrs	150	
-	Seminar/Assignment	-	-	-	-	-	-	100	
Total									650
Semester II									
MPG201T	Medicinal Plant biotechnology	10	15	1Hr	25	75	3Hrs	100	
MPG202T	Advanced Pharmacognosy-II	10	15	1Hr	25	75	3Hrs	100	
MPG203T	Indian system of medicine	10	15	1Hr	25	75	3Hrs	100	
MPG204T	Herbal cosmetics	10	15	1Hr	25	75	3Hrs	100	
MPG205P	Pharmacognosy Practical II	20	30	6Hrs	50	100	6Hrs	150	
-	Seminar/Assignment	-	-	-	-	-	-	100	
Total									650

Table – 18: 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								
MRM301T	Research Methodology and Biostatistics*	10	15	1Hr	25	75	3Hrs	100
	Journal club	-	-	-	25	-	-	25
	Discussion / Presentation (Proposal Presentation)	-	-	-	50	-	-	50
	Research work*	-	-	-	-	350	1Hr	350
Total							525	
Semester IV								
-	Journal club	-	-	-	25	-	-	25
-	Discussion / Presentation (Proposal Presentation)	-	-	-	75	-	-	75
-	Research work and Colloquium	-	-	-	-	400	1Hr	400
Total							500	

***Non University Examination**

11.2. Internal assessment: Continuous mode

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

Table – 19: Scheme for awarding internal assessment: Continuous mode

Theory	
Criteria	Maximum Marks
Attendance (Refer Table – 28)	8
Student – Teacher interaction	2
Total	10
Practical	
Attendance (Refer Table – 28)	10
Based on Practical Records, Regular viva voce, etc.	10
Total	20

Table – 20: 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

11.2.1. 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.

12. 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.

13. 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.

14. 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.

15. Reexamination of end semester examinations

Reexamination of end semester examination shall be conducted as per the schedule given in table 29. The exact dates of examinations shall be notified from time to time.

Table – 21: 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

16. 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 II semesters 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.

17. Grading of performances

17.1. 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 – 22.

Table – 22: 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.

18. 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 C_1, C_2, C_3 and C_4 and the student's grade points in these courses are G_1, G_2, G_3 and G_4 , 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:

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

19. 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:

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

where C_1, C_2, C_3, \dots is the total number of credits for semester I, II, III, \dots and S_1, S_2, S_3, \dots is the SGPA of semester I, II, III, \dots

20. 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

21. 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
	<hr/>
Total	250 Marks

22. 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.

23. Award of degree

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

24. 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.

25. Revaluation / Retotaling 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.

26. 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.

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 Hrs

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.

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. 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. **11Hrs**

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 **11Hrs**

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 **11Hrs**

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 **11Hrs**

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 - Douglas 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

(MPH102T)

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. **10Hrs**
- 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**

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. **10Hrs**
5. **Study of consolidation parameters;** Diffusion parameters, Dissolution parameters and Pharmacokinetic parameters, Heckel plots, Similarity factors – f_2 and f_1 , 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 new drug, Investigational new drug and abbreviated new drug
- To know the chemistry, manufacturing controls and their regulatory importance
- To learn the documentation requirements for IND, NDA and ANDA

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
- Pharmacovigilance 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. **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**

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:** Concepts, Events and biological process involved in drug targeting. Tumor targeting and Brain specific delivery. **12Hrs**
- 2. Targeting Methods:** Introduction preparation and evaluation. Nano Particles & Liposomes: Types, preparation and evaluation. **12Hrs**
- 3. Micro Capsules / Micro Spheres:** Types, preparation and evaluation, Monoclonal Antibodies ; preparation and application, Hrs preparation and application of Niosomes, Aquasomes, Phytosomes, Electrosomes. **12Hrs**
- 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.

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.

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 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. Brahmarkar and Sunil B. Jaiswal., VallabPrakashan, Pitampura, Delhi
3. Applied Biopharmaceutics and Pharmacokinetics by Shargel. Land YuABC, 2ndedition, 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. **12 Hrs**
- b. Quality-by-Design in Pharmaceutical Development:** Introduction, ICH Q8 guideline, Regulatory and industry views on QbD, Scientifically based QbD - examples of application.
- 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 for the fundamental 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.

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

Controversial ingredients: Parabens, formaldehyde liberators, dioxane.

12 Hrs

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, emulsifier and rheology modifiers. Challenges in formulating herbal cosmetics. **12 Hrs**

REFERENCES

1. Harry's Cosmeticology. 8th edition.
2. Poucher's perfume cosmetics and Soaps, 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. 3rd 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[®] 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

PHARMACEUTICAL CHEMISTRY (MPC)
MODERN PHARMACEUTICAL ANALYTICAL TECHNIQUES
(MPC 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 about chemicals and excipients

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

THEORY

60Hrs

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, Difference/ Derivative 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 (Characteristics of drugs that can be analysed by fluorimetry), Quenchers, Instrumentation and Applications of fluorescence spectrophotometer. **d. Flame emission spectroscopy and Atomic absorption spectroscopy:** Principle, Instrumentation, Interferences and Applications. **10 Hrs**
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. **10 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. **10 Hrs**

4. Chromatography: Principle, apparatus, instrumentation, chromatographic parameters, factors affecting resolution, isolation of drug from excipients, data interpretation and applications of the following: a) Thin Layer chromatography b) High Performance Thin Layer Chromatography c) Ion exchange chromatography d) Column chromatography e) Gas chromatography f) High Performance Liquid chromatography g) Ultra High Performance Liquid chromatography h) Affinity chromatography i) Gel Chromatography. **10 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 methods, Bragg's law, Rotating crystal technique, X ray powder technique, Types of crystals and applications of X-ray diffraction. **10 Hrs**

6. a. Potentiometry: Principle, working, Ion 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 conditions, calibration, heating and cooling rates, resolution, source of errors) and their influence, advantage and disadvantages, pharmaceutical applications. Differential Thermal Analysis (DTA): Principle, instrumentation and advantage and disadvantages, pharmaceutical applications, derivative differential thermal analysis (DDTA). TGA: Principle, instrumentation, factors affecting results, advantage and disadvantages, pharmaceutical applications. **10 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, Vol 11, Marcel. Dekker Series
8. Spectroscopy of Organic Compounds, 2nd edn., P.S/Kalsi, Wiley estern Ltd., Delhi.
9. Textbook of Pharmaceutical Analysis, KA.Connors, 3rd Edition, John Wiley & Sons, 1982.