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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No. UG/ 68 -A of 2019-20 MUMBAI-400 032 14th August, 2019

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: 5/7/19

Signature :

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

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

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

A candidate is required to put in at least **75 %** 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.

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 – 10: Course of study for (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
MPL102T	Pharmacological and Toxicological Screening Methods-II	4	4	4	100
MPL203T	Principles of Drug Discovery	4	4	4	100
MPL204T	Experimental Pharmacology practical- II	4	4	4	100
MPL205P	Pharmacology Practical II	12	6	12	150
	Seminar/Assignment	7	4	7	100
	Total	**35**	**26**	**35**	**650**

Table – 11: Course of study for M. Pharm. (Pharmacognosy or Pharmacognosy and Phytochemistry)

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
MPG102T	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 – 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

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.

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 – 23: Schemes for internal assessments and end semester examinations (Pharmacology-MPL)

Course Code	Course	Internal Assessment				End Semester Exams		Total Marks
		Continuous Mode	Sessional Exams		Total	Marks	Duration	
			Marks	Duration				
SEMESTER I								
MPL10 1T	Modern Pharmaceutical Analytical Techniques	10	15	1 Hr	25	75	3 Hrs	100
MPL10 2T	Advanced Pharmacology-I	10	15	1 Hr	25	75	3 Hrs	100
MPL10 3T	Pharmacological and Toxicological Screening Methods-I	10	15	1 Hr	25	75	3 Hrs	100
MPL10 4T	Cellular and Molecular Pharmacology	10	15	1 Hr	25	75	3 Hrs	100
MPL10 5P	Experimental Pharmacology - I	20	30	6 Hrs	50	100	6 Hrs	150
-	Seminar /Assignment	-	-	-	-	-	-	100
Total								**650**
SEMESTER II								
MPL20 1T	Advanced Pharmacology II	10	15	1 Hr	25	75	3 Hrs	100
MPL10 2T	Pharmacological and Toxicological Screening Methods-II	10	15	1 Hr	25	75	3 Hrs	100
MPL20 3T	Principles of Drug Discovery	10	15	1 Hr	25	75	3 Hrs	100
MPL20 4T	Clinical research and pharmacovigilance	10	15	1 Hr	25	75	3 Hrs	100
MPL20 5P	Experimental Pharmacology - II	20	30	6 Hrs	50	100	6 Hrs	150
-	Seminar /Assignment	-	-	-	-	-	-	100
Total								**650**

Tables – 24: Schemes for internal assessments and end semester examinations (Pharmacognosy and Phytochemistry-MPG)

Course Code	Course	Internal Assessment				End Semester Exams		Total Marks
		Continuous Mode	Sessional Exams		Total			
			Marks	Duration		Marks	Duration	
SEMESTER I								
MPG10 1T	Modern Pharmaceutical Analytical Techniques	10	15	1 Hr	25	75	3 Hrs	100
MPG10 2T	Advanced Pharmacognosy-1	10	15	1 Hr	25	75	3 Hrs	100
MPG10 3T	Phytochemistry	10	15	1 Hr	25	75	3 Hrs	100
MPG10 4T	Industrial Pharmacognostical Technology	10	15	1 Hr	25	75	3 Hrs	100
MPG10 5P	Pharmacognosy Practical I	20	30	6 Hrs	50	100	6 Hrs	150
-	Seminar /Assignment	-	-	-	-	-	-	100
Total								**650**
SEMESTER II								
MPG20 1T	Medicinal Plant biotechnology	10	15	1 Hr	25	75	3 Hrs	100
MPG10 2T	Advanced Pharmacognosy-II	10	15	1 Hr	25	75	3 Hrs	100
MPG20 3T	Indian system of medicine	10	15	1 Hr	25	75	3 Hrs	100
MPG20 4T	Herbal cosmetics	10	15	1 Hr	25	75	3 Hrs	100
MPG20 5P	Pharmacognosy Practical II	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: Continuousmode

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

PHARMACOLOGY (MPL)

MODERN PHARMACEUTICAL ANALYTICAL TECHNIQUES (MPL 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 60 Hrs

1. 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. 10 Hrs

   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.

   Spectroflourimetry: Theory of Fluorescence, Factors affecting fluorescence (Characterestics of drugs that can be analysed by flourimetry), Quenchers, Instrumentation and Applications of fluorescence spectrophotometer.

   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. 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: j) Thin Layer chromatography k) High Performance Thin Layer Chromatography l) Ion exchange chromatography m) Column chromatography n) Gas chromatography o) High Performance Liquid chromatography p) Ultra High Performance Liquidchromatography q) Affinity chromatography r) Gel Chromatography	10 Hrs
5	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 X ray Crystallography: Production of X rays, Different X ray methods, Bragg's law, Rotating crystal technique, X ray powder technique, Types ofcrystals and applications of X-ray diffraction.	10 Hrs
6	Potentiometry: Principle, working, Ion selective Electrodes and Application of potentiometry. 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.

ADVANCED PHARMACOLOGY - I
(MPL 102T)

Scope

The subject is designed to strengthen the basic knowledge in the field of pharmacology and to impart recent advances in the drugs used for the treatment of various diseases. In addition, this subject helps the students to understand the concepts of drug action and mechanisms involved

Objectives

Upon completion of the course the student shall be able to :

Discuss the pathophysiology and pharmacotherapy of certain diseases

Explain the mechanism of drug actions at cellular and molecular level

Understand the adverse effects, contraindications and clinical uses of drugs used in treatment of diseases

THEORY 60 Hrs

1. General Pharmacology 12 Hrs

a Pharmacokinetics: The dynamics of drug absorption, distribution, biotransformation and elimination. Concepts of linear and non-linear compartment models. Significance of Protein binding.

b Pharmacodynamics: Mechanism of drug action and the relationship between drug concentration and effect. Receptors, structural and functional families of receptors, quantitation of drug receptors interaction and elicited effects.

2 Neurotransmission 12 Hrs

a. Generalaspects and steps involved inneurotransmission.

b. Neurohumoral transmission in autonomic nervous system (Detailed study about neurotransmitters- Adrenaline and Acetyl choline).

c. Neurohumoral transmission in central nervous system (Detailed study about neurotransmitters- histamine, serotonin, dopamine, GABA, glutamate and glycine].

d. Non adrenergic non cholinergic transmission (NANC). Co-transmission

Systemic Pharmacology

A detailed study on pathophysiology of diseases, mechanism of action, pharmacology and toxicology of existing as well as novel drugs used in the following systems

Autonomic Pharmacology

Parasympathomimetics and lytics, sympathomimetics and lytics, agents affecting
neuromuscular junction

3	Central nervous system Pharmacology General and local anesthetics Sedatives and hypnotics, drugs used to treat anxiety. Depression, psychosis, mania, epilepsy, neurodegenerative diseases. Narcotic and non-narcotic analgesics.	12 Hrs
4	Cardiovascular Pharmacology Diuretics, antihypertensives, antiischemics, anti- arrhythmics, drugs for heart failure and hyperlipidemia. Hematinics, coagulants , anticoagulants, fibrinolytics and anti-platelet drugs	12 Hrs
5	Autocoid Pharmacology The physiological and pathological role of Histamine, Serotonin, Kinins Prostaglandins Opioid autocoids. Pharmacology of antihistamines, 5HT antagonists.	12 Hrs

REFEERENCES

1. The Pharmacological Basis of Therapeutics, Goodman and Gillman's
2. Principles of Pharmacology. The Pathophysiologic basis of drug Therapy by David E Golan, Armen H, Tashjian Jr, Ehrin J,Armstrong, April W, Armstrong,Wolters,Kluwer-LippincottWilliams&WilkinsPublishers.
3. Basic and Clinical Pharmacology by B.G Katzung
4. Hand book of Clinical Pharmacokinetics by Gibaldi and Prescott.
5. Applied biopharmaceutics and Pharmacokinetics by Leon Shargel and Andrew B.C.Yu.
6. Graham Smith. Oxford textbook of Clinical Pharmacology.
7. Avery Drug Treatment
8. Dipiro Pharmacology, Pathophysiological approach.
9. Green Pathophysiology for Pharmacists.

10. Robbins & Cortan Pathologic Basis of Disease, 9th Ed. (Robbins Pathology)
11. A Complete Textbook of Medical Pharmacology by Dr. S.K Srivastava published by APC Avichal Publishing Company
12. KD.Tripathi. Essentials of Medical Pharmacology.
13. Modern Pharmacology with Clinical Applications, Craig Charles R. & Stitzel Robert E., Lippincott Publishers.
14. Clinical Pharmacokinetics & Pharmacodynamics : Concepts and Applications – Malcolm Rowland and Thomas N.Tozer, Wolters Kluwer, Lippincott Williams & Wilkins Publishers.
15. Applied biopharmaceutics and Pharmacokinetics, Pharmacodynamics and Drug metabolism for industrial scientists.
16. Modern Pharmacology, Craig CR. & Stitzel RE, Little Brown & Company.

PHARMACOLOGICAL AND TOXICOLOGICAL SCREENING METHODS - I
(MPL 103T)

Scope

This subject is designed to impart the knowledge on preclinical evaluation of drugs and recent experimental techniques in the drug discovery and development. The subject content helps the student to understand the maintenance of laboratory animals as per the guidelines, basic knowledge of various in-vitro and in-vivo preclinical evaluation processes

Objectives

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

Appraise the regulations and ethical requirement for the usage of experimental animals.

Describe the various animals used in the drug discovery process and good laboratory practices in maintenance and handling of experimental animals

Describe the various newer screening methods involved in the drug discovery process

Appreciate and correlate the preclinical data to humans

THEORY 60 Hrs

1. Laboratory Animals 12 Hrs

Common laboratory animals: Description, handling and applications of different species and strains of animals.

Transgenic animals: Production, maintenance and applications

Anaesthesia and euthanasia of experimental animals.

Maintenance and breeding of laboratory animals.

CPCSEA guidelines to conduct experiments on animals

Good laboratory practice.

Bioassay-Principle, scope and limitations and methods

2 Preclinical screening of new substances for the pharmacological activity using in vivo, in vitro, and other possible animal alternative models. 12 Hrs

General principles of preclinical screening. CNS Pharmacology: behavioral and muscle co ordination, CNS stimulants and

depressants, anxiolytics, anti-psychotics, anti epileptics and nootropics. Drugs for neurodegenerative diseases like Parkinsonism, Alzheimers and multiple sclerosis. Drugs acting on Autonomic Nervous System.

3	Preclinical screening of new substances for the pharmacological activity using in vivo, in vitro, and other possible animal alternative models. Respiratory Pharmacology: anti-asthmatics, drugs for COPD and anti allergics. Reproductive Pharmacology: Aphrodisiacs and antifertility agents Analgesics, antiinflammatory and antipyretic agents. Gastrointestinal drugs: anti ulcer, anti -emetic, anti-diarrheal and laxatives.	12 Hrs
4	Preclinical screening of new substances for the pharmacological activity using in vivo, in vitro, and other possible animal alternative models. Cardiovascular Pharmacology: antihypertensives, antiarrythmics, antianginal, antiatherosclerotic agents and diuretics. Drugs for metabolic disorders like anti-diabetic, antidyslipidemic agents. Anti cancer agents. Hepatoprotective screening methods.	12 Hrs
5	Preclinical screening of new substances for the pharmacological activity using in vivo, in vitro, and other possible animal alternative models. Iimmunomodulators, Immunosuppressants and immunostimulants General principles of immunoassay: theoretical basis and optimization of immunoassay, heterogeneous and homogenous immunoassay systems. Immunoassay methods evaluation; protocol outline, objectives and preparation. Immunoassay for digoxin and insulin Limitations of animal experimentation and alternate animal experiments. Extrapolation of in vitro data to preclinical and preclinical to humans	12 Hrs

REFERENCES

1. Biological standardization by J.H. Burn D.J. Finney and I.G. Goodwin
2. Screening methods in Pharmacology by Robert Turner. A
3. Evaluation of drugs activities by Laurence and Bachrach
4. Methods in Pharmacology by Arnold Schwartz.
5. Fundamentals of experimental Pharmacology by M.N.Ghosh
6. Pharmacological experiment on intact preparations by Churchill Livingstone
7. Drug discovery and Evaluation by Vogel H.G.
8. Experimental Pharmacology by R.K.Goyal.
9. Preclinical evaluation of new drugs by S.K. Guta
10. Handbook of Experimental Pharmacology, SK.Kulkarni
11. Practical Pharmacology and Clinical Pharmacy, SK.Kulkarni, 3rd Edition.
12. David R.Gross. Animal Models in Cardiovascular Research, 2nd Edition, Kluwer Academic Publishers, London, UK.
13. Screening Methods in Pharmacology, Robert A.Turner.
14. Rodents for Pharmacological Experiments, Dr.Tapan Kumar chatterjee.
15. Practical Manual of Experimental and Clinical Pharmacology by Bikash Medhi (Author), Ajay Prakash (Author)

CELLULAR AND MOLECULAR PHARMACOLOGY
(MPL 104T)

Scope:

The subject imparts a fundamental knowledge on the structure and functions of cellular components and help to understand the interaction of these components with drugs. This information will further help the student to apply the knowledge in drug discovery process.

Objectives:

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

Explain the receptor signal transduction processes.
Explain the molecular pathways affected by drugs.
Appreciate the applicability of molecular pharmacology and biomarkers in drug discovery process.
Demonstrate molecular biology techniques as applicable for pharmacology

THEORY 60 Hrs

1. Cell biology 12 Hrs

Structure and functions of cell and its organelles

Genome organization. Gene expression and its regulation, importance of siRNA and micro RNA, gene mapping and gene sequencing

Cell cycles and its regulation.

Cell death- events, regulators, intrinsic and extrinsic pathways of apoptosis.

Necrosis and autophagy.

2 Cell signaling 12 Hrs

Intercellular and intracellular signaling pathways.

Classification of receptor family and molecular structure ligand gated ion channels; G-protein coupled receptors, tyrosine kinase receptors and nuclear receptors.

Secondary messengers: cyclic AMP, cyclic GMP, calcium ion, inositol 1,4,5-trisphosphate, (IP3), NO, and diacylglycerol.

Detailed study of following intracellular signaling pathways: cyclic AMP signaling pathway, mitogen-activated protein kinase (MAPK) signaling, Janus kinase (JAK)/signal transducer and activator of transcription (STAT) signaling pathway.

3	Principles and applications of genomic and proteomic tools DNA electrophoresis, PCR (reverse transcription and real time), Gene sequencing, micro array technique, SDS page, ELISA and western blotting. Recombinant DNA technology and gene therapy Basic principles of recombinant DNA technology–Restriction enzymes, various types of vectors. Applications of recombinant DNA technology. Gene therapy– Various types of gene transfer techniques, clinical applications and recent advances in gene therapy.	12 Hrs
4	Pharmacogenomics Gene mapping and cloning of disease gene. Genetic variation and its role in health / pharmacology Polymorphisms affecting drug metabolism Genetic variation in drug transporters Genetic variation in G protein coupled receptors Applications of proteomics science: Genomics, proteomics, metabolomics, functionomics, nutrigenomics Immunotherapeutics Types of immunotherapeutics, humanisation antibody therapy, Immunotherapeutics in clinical practice	12 Hrs
5	a. Cell culture techniques Basic equipments used in cell culture lab. Cell culture media, various types of cell culture, general procedure for cell cultures; isolation of cells, subculture, cryopreservation, characterization of cells and their application. Principles and applications of cell viability assays, glucose uptake assay, Calcium influxassays Principles and applications of flow cytometry b. Biosimilars	12 Hrs

REFERENCES:

1. The Cell, A Molecular Approach. Geoffrey M Cooper.
2. Pharmacogenomics: The Search for Individualized Therapies. Edited by J. Licinio and M –L.Wong
3. Handbook of Cell Signaling (Second Edition) Edited by Ralph A. et.al
4. Molecular Pharmacology: From DNA to Drug Discovery. John Dickenson et.al
5. Basic Cell Culture protocols by Cheril D.Helgason and Cindy L.Miller
6. Basic Cell Culture (Practical Approach) by J. M. Davis (Editor)
7. Animal Cell Culture: A Practical Approach by John R. Masters (Editor)
8. Current porotocols in molecular biology vol I to VI edited by Frederick M.Ausuvel et la.

PHARMACOLOGICAL PRACTICAL - I
(MPL 105P)

1. Analysis of pharmacopoeial compounds and their formulations by UV Vis spectrophotometer
2. Simultaneous estimation of multicomponent 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

Handling of laboratory animals.

1. Various routes of drug administration.
2. Techniques of blood sampling, anesthesia and euthanasia of experimental animals.
3. Functional observation battery tests (modified Irwin test)
4. Evaluation of CNS stimulant, depressant, anxiogenics and anxiolytic, anticonvulsant activity.
5. Evaluation of analgesic, anti-inflammatory, local anesthetic, mydriatic and miotic activity.
6. Evaluation of diuretic activity.
7. Evaluation of antiulcer activity by pylorus ligation method.
8. Oral glucose tolerance test.
9. Isolation and identification of DNA from various sources (Bacteria, Cauliflower, onion, Goat liver).
10. Isolation of RNA from yeast
11. Estimation of proteins by Braford/Lowry's in biological samples.
12. Estimation of RNA/DNA by UV Spectroscopy
13. Gene amplification by PCR.
14. Protein quantification Western Blotting.
15. Enzyme based in-vitro assays (MPO, AChEs, α amylase, α glucosidase).
16. Cell viability assays (MTT/Trypan blue/SRB).
17. DNA fragmentation assay by agarose gel electrophoresis.
18. DNA damage study by Comet assay.
19. Apoptosis determination by fluorescent imaging studies.
20. Pharmacokinetic studies and data analysis of drugs given by different routes of administration using softwares
21. Enzyme inhibition and induction activity
22. Extraction of drug from various biological samples and estimation of drugs in biological fluids using different analytical techniques (UV)
23. Extraction of drug from various biological samples and estimation of drugs in biological fluids using different analytical techniques (HPLC)

REFERENCES

1. CPCSEA, OECD, ICH, USFDA, Schedule Y, EPA guidelines,
2. Fundamentals of experimental Pharmacology by M.N.Ghosh
3. Handbook of Experimental Pharmacology by S.K. Kulkarni.
4. Drug discovery and Evaluation by Vogel H.G.
5. Spectrometric Identification of Organic compounds – Robert M Silverstein,
6. Principles of Instrumental Analysis – Doglas A Skoog, F. James Holler, Timothy A. Nieman,
7. Vogel's Text book of quantitative chemical analysis - Jeffery, Basset, Mendham, Denney,
8. Basic Cell Culture protocols by Cheril D. Helgason and Cindy L.Mille
9. Basic Cell Culture (Practical Approach) by J. M. Davis (Editor)
10. Animal Cell Culture: A Practical Approach by John R. Masters (Editor)
11. Practical Manual of Experimental and Clinical Pharmacology by Bikash Medhi(Author), Ajay Prakash (Author) Jaypee brothers' medical publishers Pvt. Ltd

ADVANCED PHARMACOLOGY - II
(MPL 201T)

Scope

The subject is designed to strengthen the basic knowledge in the field of pharmacology and to impart recent advances in the drugs used for the treatment of various diseases. In addition, the subject helps the student to understand the concepts of drug action and mechanisminvolved

Objectives

Upon completion of the course the student shall be able to:

- Explain the mechanism of drug actions at cellular and molecular level
- Discuss the Pathophysiology and pharmacotherapy of certain diseases
- Understand the adverse effects, contraindications and clinical uses of drugs used in treatment of diseases

	THEORY	60 Hrs
1.	Endocrine Pharmacology Molecular and cellular mechanism of action of hormones such as growth hormone, prolactin, thyroid, insulin and sex hormones Anti-thyroid drugs, Oral hypoglycemic agents, Oral contraceptives, Corticosteroids. Drugs affecting calcium regulation	12 Hrs
2	Chemotherapy Cellular and molecular mechanism of actions and resistance of antimicrobial agents such as ß-lactams, aminoglycosides, quinolones, Macrolide antibiotics. Antifungal, antiviral, and anti-TB drugs.	12 Hrs
3	Chemotherapy Drugs used in Protozoal Infections Drugs used in the treatment of Helminthiasis Chemotherapy of cancer Immunopharmacology Cellular and biochemical mediators of inflammation and immune response. Allergic or hypersensitivity reactions. Pharmacotherapy of asthma and COPD. Immunosuppressants and Immunostimulants	12 Hrs

4	GIT Pharmacology Antiulcer drugs, Prokinetics, antiemetics, anti-diarrheals and drugs for constipation and irritable bowel syndrome. Chronopharmacology Biological and circadian rhythms, applications of chronotherapy in various diseases like cardiovascular disease, diabetes, asthma and peptic ulcer	12 Hrs
5	Free radicals Pharmacology Generation of free radicals, role of free radicals in etiopathology of various diseases such as diabetes, neurodegenerative diseases and cancer. Protective activity of certain important antioxidant Recent Advances in Treatment: Alzheimer's disease, Parkinson's disease, Cancer, Diabetes mellitus	12 Hrs

REFERENCES

1. The Pharmacological basis of therapeutics- Goodman and Gill man's
2. Principles of Pharmacology. The Pathophysiologic basis of drug therapy by David E Golan et al.
3. Basic and Clinical Pharmacology by B.G -Katzung
4. Pharmacology by H.P. Rang and M.M. Dale.
5. Hand book of Clinical Pharmacokinetics by Gibaldi and Prescott.
6. Text book of Therapeutics, drug and disease management by E T. Herfindal and Gourley.
7. Applied biopharmaceutics and Pharmacokinetics by Leon Shargel and Andrew B.C.Yu.
8. Handbook of Essential Pharmacokinetics, Pharmacodynamics and Drug Metabolism for Industrial Scientists
9. Robbins & Cortan Pathologic Basis of Disease, 9th Ed. (Robbins Pathology)
10. A Complete Textbook of Medical Pharmacology by Dr. S.K Srivastava published by APC Avichal Publishing Company.
11. KD.Tripathi. Essentials of Medical Pharmacology
12. Principles of Pharmacology. The Pathophysiologic basis of drug Therapy by David E Golan, Armen H, Tashjian Jr, Ehrin J,Armstrong, April W, Armstrong, Wolters, Kluwer-Lippincott Williams & Wilkins Publishers

PHARMACOLOGICAL AND TOXICOLOGICAL SCREENING METHODS-II
(MPL 202T)

Scope:

This subject imparts knowledge on the preclinical safety and toxicological evaluation of drug & new chemical entity. This knowledge will make the student competent in regulatory toxicological evaluation.

Objectives:

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

Explain the various types of toxicity studies.

Appreciate the importance of ethical and regulatory requirements for toxicity studies.

Demonstrate the practical skills required to conduct the preclinical toxicity studies.

THEORY	60 Hrs
1. Basic definition and types of toxicology (general, mechanistic, regulatory and descriptive) Regulatory guidelines for conducting toxicity studies OECD, ICH, EPA and Schedule Y OECD principles of Good laboratory practice (GLP) History, concept and its importance in drug development	12 Hrs
2 Acute, sub-acute and chronic- oral, dermal and inhalational studies as per OECD guidelines. Acute eye irritation, skin sensitization, dermal irritation & dermal toxicity studies. Test item characterization- importance and methods in regulatory toxicology studies	12 Hrs
3 Reproductive toxicology studies, Male reproductive toxicity studies, female reproductive studies (segment I and segment III), teratogenecity studies (segment II) Genotoxicity studies (Ames Test, *invitro* and *invivo* Micronucleus and Chromosomal aberrations studies) *In vivo* carcinogenicity studies	12 Hrs
4 IND enabling studies (IND studies)- Definition of IND, importance of IND, industry perspective, list of studies needed for IND submission.	12 Hrs

	Safety pharmacology studies- origin, concepts and importance of safety pharmacology. Tier1- CVS, CNS and respiratory safety pharmacology, HERG assay. Tier2- GI, renal and other studies	
5	Toxicokinetics- Toxicokinetic evaluation in preclinical studies, saturation kinetics Importance and applications of toxicokinetic studies. Alternative methods to animal toxicity testing.	12 Hrs

REFERENCES

1. Hand book on GLP, Quality practices for regulated non-clinical research and development (http://www.who.int/tdr/publications/documents/glp-handbook.pdf).
2. Schedule Y Guideline: drugs and cosmetics (second amendment) rules, 2005, ministry of health and family welfare (department of health) New Delhi
3. Drugs from discovery to approval by Rick NG.
4. Animal Models in Toxicology, 3rd Edition, Lower and Bryan
5. OECD test guidelines.
6. Principles of toxicology by Karen E. Stine, Thomas M. Brown.
7. Guidance for Industry M3(R2) Nonclinical Safety Studies for the Conduct of Human Clinical Trials and Marketing Authorization for Pharmaceuticals (http://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm073246.pdf)

PRINCIPLES OF DRUG DISCOVERY
(MPL 203T)

Scope:

The subject imparts basic knowledge of drug discovery process. This information will make the student competent in drug discovery process

Objectives:

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

Explain the various stages of drug discovery.

Appreciate the importance of the role of genomics, proteomics and bioinformatics in drug discovery

Explain various targets for drug discovery.

Explain various lead seeking method and lead optimization

Appreciate the importance of the role of computer aided drug design in drug discovery

THEORY 60 Hrs

1. An overview of modern drug discovery process: Target identification, target validation, lead identification and lead Optimization. Economics of drug discovery. 12 Hrs

   Target Discovery and validation-Role of Genomics, Proteomics and Bioinformatics. Role of Nucleic acid microarrays, Protein microarrays, Antisense technologies, siRNAs, antisense oligonucleotides, Zinc finger proteins. Role of transgenic animals in target validation.

2 Lead Identification- combinatorial chemistry & high throughput screening, in silico lead discovery techniques, Assay development for hit identification. 12 Hrs

   Protein structure

   Levels of protein structure, Domains, motifs, and folds in protein structure. Computational prediction of protein structure: Threading and homology modeling methods. Application of NMR and X-ray crystallography in protein structure prediction

3 Rational Drug Design 12 Hrs

   Traditional vs rational drug design, Methods followed in traditional drug design, High throughput screening, Concepts of Rational Drug Design, Rational Drug Design Methods: Structure and Pharmacophore based approaches

	Virtual Screening techniques: Drug likeness screening, Concept of pharmacophore mapping and pharmacophore based Screening,	
4	Molecular docking: Rigid docking, flexible docking, manual docking; Docking based screening. De novo drug design. Quantitative analysis of Structure Activity Relationship History and development of QSAR, SAR versus QSAR, Physicochemical parameters, Hansch analysis, Fee Wilson analysis and relationship between them.	12 Hrs
5	QSAR Statistical methods – regression analysis, partial least square analysis (PLS) and other multivariate statistical methods. 3D-QSAR approaches like COMFA and COMSIA Prodrug design-Basic concept, Prodrugs to improve patient acceptability, Drug solubility, Drug absorption and distribution, site specific drug delivery and sustained drug action. Rationale of prodrug design and practical consideration of prodrug design	12 Hrs

REFERENCES

1. MouldySioud. Target Discovery and Validation Reviews and Protocols: Volume 2 Emerging Molecular Targetsand Treatment Options. 2007 Humana Press Inc.
2. Darryl León. Scott MarkelIn. Silico Technologies in Drug Target Identification and Validation. 2006 by Taylor and Francis Group, LLC.
3. Johanna K. DiStefano. Disease Gene Identification. Methods and Protocols. Springer New York Dordrecht Heidelberg London.
4. Hugo Kubiny. QSAR: Hansch Analysis and Related Approaches. Methods and Principles in Medicinal Chemistry. Publisher Wiley-VCH
5. Klaus Gubernator, Hans-Joachim Böhm. Structure-Based Ligand Design. Methods and Principles in Medicinal Chemistry. Publisher Wiley-VCH
6. Abby L . Parrill. M . Rami Reddy. Rational Drug Design. Novel Methodology and Practical Applications. ACS Symposium Series; American Chemical Society: Washington, DC, 1999.
7. J. Rick Turner. New drug development design, methodology and, analysis. John Wiley & Sons, Inc., New Jersey.

CLINICAL RESEARCH AND PHARMACOVIGILANCE
(MPL 204T)

Scope:

This subject will provide a value addition and current requirement for the students in clinical research and pharmacovigilance. It will teach the students on conceptualizing, designing, conducting, managing and reporting of clinical trials. This subject also focuses on global scenario of Pharmacovigilance in different methods that can be used to generate safety data. It will teach the students in developing drug safety data in Pre-clinical, Clinical phases of Drug development and post market surveillance.

Objectives:

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

- Explain the regulatory requirements for conducting clinical trial
- Demonstrate the types of clinical trial designs
- Explain the responsibilities of key players involved in clinical trials
- Execute safety monitoring, reporting and close-out activities
- Explain the principles of Pharmacovigilance
- Detect new adverse drug reactions and their assessment
- Perform the adverse drug reaction reporting systems and communication in Pharmacovigilance

THEORY — 60 Hrs

1. Regulatory Perspectives of Clinical Trials: — 12 Hrs

   Origin and Principles of International Conference on Harmonization - Good Clinical Practice (ICH-GCP) guidelines

   Ethical Committee: Institutional Review Board, Ethical Guidelines for Biomedical Research and Human Participant- Schedule Y, ICMR

   Informed Consent Process: Structure and content of an Informed Consent Process Ethical principles governing informed consent process

2 Clinical Trials: Types and Design — 12 Hrs

   Experimental Study- RCT and Non RCT,

   Observation Study: Cohort, Case Control, Cross sectional

   Clinical Trial Study Team

   Roles and responsibilities of Clinical Trial Personnel: Investigator, Study Coordinator, Sponsor, Contract Research Organization and its management

3	Clinical Trial Documentation- Guidelines to the preparation of documents, Preparation of protocol, Investigator Brochure, Case Report Forms, Clinical Study Report Clinical Trial Monitoring- Safety Monitoring in CT Adverse Drug Reactions: Definition and types. Detection and reporting methods. Severity and seriousness assessment.Predictability and preventability assessment, Management of adverse drug reactions; Terminologies of ADR.	12 Hrs
4	Basic aspects, terminologies and establishment of pharmacovigilance History and progress of pharmacovigilance, Significance of safety monitoring, Pharmacovigilance in India and international aspects, WHO international drug monitoring programme, WHO and Regulatory terminologies of ADR, evaluation of medication safety, Establishing pharmacovigilance centres in Hospitals, Industry and National programmes related to pharmacovigilance. Roles and responsibilities in Pharmacovigilance	12 Hrs
5	Methods, ADR reporting and tools used in Pharmacovigilance International classification of diseases, International Non-proprietary names for drugs, Passive and Active surveillance, Comparative observational studies, Targeted clinical investigations and Vaccine safety surveillance. Spontaneous reporting system and Reporting to regulatory authorities, Guidelines for ADRs reporting. Argus, Aris G Pharmacovigilance, VigiFlow, Statistical methods for evaluating medication safety data.	12 Hrs
6	Pharmacoepidemiology, pharmacoeconomics, safety pharmacology	12 Hrs

REFERENCES

1. Central Drugs Standard Control Organization- Good Clinical Practices, Guidelines for Clinical Trials on Pharmaceutical Products in India. New Delhi: Ministry of Health;2001.
2. International Conference on Harmonization of Technical requirements for registration of Pharmaceuticals for human use. ICH Harmonized Tripartite Guideline. Guideline for Good Clinical Practice.E6; May 1996.

3. Ethical Guidelines for Biomedical Research on Human Subjects 2000. Indian Council of Medical Research, New Delhi.
4. Textbook of Clinical Trials edited by David Machin, Simon Day and Sylvan Green, March 2005, John Wiley and Sons.
5. Clinical Data Management edited by R K Rondels, S A Varley, C F Webbs. Second Edition, Jan 2000, Wiley Publications.
6. Handbook of clinical Research. Julia Lloyd and Ann Raven Ed. Churchill Livingstone.
7. Principles of Clinical Research edited by Giovanna di Ignazio, Di Giovanna and Haynes.

PHARMACOLOGICAL PRACTICAL - II
(MPL 205P)

1. To record the DRC of agonist using suitable isolated tissues preparation.
2. To study the effects of antagonist/potentiating agents on DRC of agonist using suitable isolated tissue preparation.
3. To determine to the strength of unknown sample by matching bioassay by using suitable tissue preparation.
4. To determine to the strength of unknown sample by interpolation bioassay by using suitable tissue preparation
5. To determine to the strength of unknown sample by bracketing bioassay by using suitable tissue preparation
6. To determine to the strength of unknown sample by multiple point bioassay by using suitable tissue preparation.
7. Estimation of PA_2 values of various antagonists using suitable isolated tissue preparations.
8. To study the effects of various drugs on isolated heart preparations
9. Recording of rat BP, heart rate and ECG.
10. Recording of rat ECG
11. Drug absorption studies by averted rat ileum preparation.
12. Acute oral toxicity studies as per OECD guidelines.
13. Acute dermal toxicity studies as per OECD guidelines.
14. Repeated dose toxicity studies- Serum biochemical, haematological, urine analysis, functional observation tests and histological studies.
15. Drug mutagenicity study using mice bone-marrow chromosomal aberration test.
16. Protocol design for clinical trial.(3 Nos.)
17. Design of ADR monitoring protocol.
18. In-silico docking studies. (2 Nos.)
19. In-silico pharmacophore based screening.
20. In-silico QSAR studies.
21. ADR reporting

REFERENCES

1. Fundamentals of experimental Pharmacology-by M.N.Ghosh
2. Hand book of Experimental Pharmacology-S.K.Kulakarni
3. Text book of in-vitro practical Pharmacology by Ian Kitchen
4. Bioassay Techniques for Drug Development by Atta-ur-Rahman, Iqbal choudhary and William Thomsen
5. Applied biopharmaceutics and Pharmacokinetics by Leon Shargel and Andrew B.C.Yu.
6. Handbook of Essential Pharmacokinetics, Pharmacodynamics and Drug