ADMISSION & EXAMINATION BYE-LAWS

FOR

MASTER OF PHARMACY IN PHARMACOLOGY

Program Code: MPL

SCHOOL OF PHARMACEUTICAL EDUCATION AND RESEARCH
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CONTENTS

BOS MEETING DETAILS

- **Approval date of the BOS/School Board meeting for the present syllabus:**

Name of the program	Department	Board of School (BOS) Approval Date
M. Pharm	Pharmacology	21.04.2017

- **Approval date of the Academic Council meeting for the present syllabus**

Name of the program	Program Code	Dates of Revision
M. Pharm	MPL	31.05.2017

VISION AND MISSION STATEMENTS

Vision Statement: To train and develop competent pharmacologists with rigorous scientific attitude who can become academicians, professionals and researchers and generate useful and contemporary knowledge to meet the needs of society, industry and research organizations in India and abroad.

Mission Statements:

MS1: To impart knowledge of basic and clinical pharmacology to meet the academic, industrial, and public health requirements.

MS 2: To inculcate research skills in the students to make them intellectual contributors to address healthcare challenge through creation of new knowledge.

MS3: To provide a platform for students to develop critical thinking, teamwork, and communication abilities so as to become a competent professional.

PROGRAM EDUCATIONAL OBJECTIVES (PEOs)

After completion of the M. Pharm (Pharmacology), the postgraduates will be able to:

PEO1: Apply knowledge in solving industry-relevant programs.

PEO2: Carryout quality research in different facets of the program including higher education.

PEO3: Foster abilities to design and fabricate new products or techniques, benefiting the society at large.

PEO4: Combine practical pharmaceutical knowledge and abilities with research ability for a better output.

PEO5: Inculcate entrepreneurial skills in aspiring pharmacy professionals

PEO6: Develop leadership skills to be applied in R&D, production, and other facets of the profession

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

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

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

PROGRAMME SPECIFIC OUTCOME (PSO)

After completion of the M. Pharm (Pharmacology), the postgraduates will be able to:

PSO1: Apply the knowledge of pathophysiology of various diseases for helping in design of rational and personalized pharmacotherapeutic approach.

PSO2: Demonstrate understanding of safety aspects of drugs in relation to public health.

PSO3: Design and conduct research experiments for drug discovery and development

PSO4: Analyze and critically evaluate the role of pharmacology in relation to other branches of biomedical sciences.

PSO5: Communicate effectively on the scientific aspects of drugs both at community and professional levels.

PROGRAM OUTCOMES (POs)

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

PO1: **Pharmacology Knowledge:** Apply the knowledge of basic and clinical pharmacology and pharmacotherapeutics for the treatment of diseases using modern scientific approach

PO2: **Planning Abilities:** Apply the principles of pharmacokinetics for finding effective doses and dosage regiments for effective treatment of special populations using appropriate models.

PO3: **Problem Analysis:** Develop scientific temperament and critical reasoning abilities to evaluate challenges and gaps in the drug therapy and formulate solutions for the effective pharmacological management of disease using inter and multidisciplinary approaches.

PO4: **Modern tool Usage:** Demonstrate understanding of drug discovery process and clinical research and carry out experiments for preclinical and clinical evaluation of new drugs using contemporary technology.

PO5: **Leadership Skills:** Participate effectively and demonstrate leadership skills in multidisciplinary and multicultural teams.

PO6: **Professional Identity:** Appreciate and analyze the role of medicines in improving public health and understand the responsibility of pharmacologists in the same through scientific research and community engagement.

PO7: **Pharmaceutical Ethics:** Demonstrate ethics in one's practices in personal, professional, and social spheres of life.

PO8: **Communication:** Demonstrate ability to effectively communicate on challenges and solution of pharmacological aspects of healthcare using available verbal and written media at local as well as global level.

PO9: **The Pharmacologist and Society**: Demonstrate skills of analyzing and promoting rational use of drugs on the basis of scientific as well as economic factors.

PO10: **Environment and Sustainability:** Understand the importance of sustainable development and develop perspective on role of pharmacologists towards sustainable development.

PO11: **Lifelong Learning:** Understand the importance of and use available resources for lifelong learning and continuing professional development for advancement of science in general and pharmacology for the benefit of mankind.

Mapping of Program Outcomes (POs) and Program Specific Outcomes (PSOs) with Program Educational Objectives (PEOs)

	PEO-1	PEO-2	PEO-3	PEO-4	PEO-5	PEO-6
PO-1	3	3	3	3	3	2
PO-2	3	3	3	3	3	2
PO-3	3	3	3	3	3	2
PO-4	3	3	3	3	2	2
PO-5	3	3	3	3	3	3
PO-6	3	3	3	3	3	3
PO-7	3	3	3	3	2	2
PO-8	3	3	3	3	3	3
PO-9	3	3	3	3	3	3

PO-10	3	3	3	3	3	3
PO-11	3	3	3	3	3	3
PSO-1	3	3	3	3	3	3
PSO-2	3	3	2	3	3	3
PSO-3	3	3	3	3	3	3
PSO-4	3	3	3	3	3	3
PSO-5	3	3	2	3	3	3

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

CONSOLIDATED SEMESTER WISE PROGRAMME DETAILS

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

Semester I

Course code	Name of the course	Internal Assessment				End Semester Exams		Total Marks	Credit points
		Continuous mode	Sessional Exams		Total	Marks	Duration		
			Marks	Duration					
MPL101T	Modern Pharmaceutical Analytical Techniques	10	15	1 Hr	25	75	3 Hrs	100	4
MPL102T	Advanced Pharmacology-I	10	15	1 Hr	25	75	3 Hrs	100	4
MPL103T	Pharmacological and Toxicological Screening Methods-I	10	15	1 Hr	25	75	3 Hrs	100	4
MPL104T	Cellular and Molecular Pharmacology	10	15	1 Hr	25	75	3 Hrs	100	4
MPL105P	Experimental Pharmacology - I	20	30	6 Hrs	50	100	6 Hrs	150	6
-	Seminar/Assignment	-	-	-	-			100	4
	Total							**650**	**26**

Semester II

Course code	Name of the course	Internal Assessment				End Semester Exams		Total Marks	Credit points
		Continuous Mode	Sessional Exams		Total	Marks	Duration		
			Marks	Duration					
MPL201T	Advanced Pharmacology-II	10	15	1 Hr	25	75	3 Hrs	100	4
MPL 202T	Pharmacological and Toxicological Screening Methods-II	10	15	1 Hr	25	75	3 Hrs	100	4
MPL 203T	Principles of Drug Discovery	10	15	1 Hr	25	75	3 Hrs	100	4
MPL 204T	Clinical Research and Pharmacovigilance	10	15	1 Hr	25	75	3 Hrs	100	4
MPL 205P	Experimental Pharmacology - II	20	30	6 Hrs	50	100	6 Hrs	150	6
-	Seminar/Assignment							100	4
Total								**650**	**26**

Semester III

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

* Non-University Exam

Semester IV

Course code	Name of the course	Internal Assessment				End Semester Exams		Total Marks	Credit points
		Continuous Mode	Sessional Exams		Total	Marks	Duration		
			Marks	Duration					
-	Journal club	-	-	-	25	-	-	25	1
-	Discussion / Presentation (Proposal Presentation	-	-	-	75	-	-	75	16
-	Research work and Colloquium	-	-	-	-	400	1 Hr	400	3
Total								**500**	**20**

RULES AND REGULATIONS

1. Short Title and Commencement

These regulations shall be called as "The Revised Regulations for the Master of Pharmacy (M. Pharm.) Degree Program - Credit Based Semester System (CBSS) of the Pharmacy Council of India, New Delhi". They shall come into effect from the Academic Year 2016-17. The regulations framed are subject to modifications from time to time by the authorities of the university.

2. Minimum qualification for admission

A Pass in the following examinations

a) B. Pharm Degree examination of an Indian university established by law in India from an institution approved by Pharmacy Council of India and has scored not less than 55 % of the maximum marks (aggregate of 4 years of B.Pharm.)

b) Every student, selected for admission to post graduate pharmacy program in any PCI approved institution should have obtained registration with the State Pharmacy Council or should obtain the same within one month from the date of his/her admission, failing which the admission of the candidate shall be cancelled.

Note: It is mandatory to submit a migration certificate obtained from the respective university where the candidate had passed his/her qualifying degree (B. Pharm.)

3. Duration of the program

The program of study for M. Pharm. shall extend over a period of four semesters (two academic years). The curricula and syllabi for the program shall be prescribed from time to time by Pharmacy Council of India, New Delhi.

4. Medium of instruction and examinations

Medium of instruction and examination shall be in English.

5. Working days in each semester

Each semester shall consist of not less than 100 working days. The odd semesters shall be conducted from the month of June/July to November/December and the even semesters shall be conducted from the month of December/January to May/June in every calendar year.

6. Attendance and progress

A candidate is required to put in at least 80% attendance in individual courses considering theory and practical separately. The candidate shall complete the prescribed course satisfactorily to be eligible to appear for the respective examinations.

7. Program/Course credit structure

As per the philosophy of Credit Based Semester System, certain quantum of academic work viz. theory classes, practical classes, seminars, assignments, etc. are measured in terms of credits. On satisfactory completion of the courses, a candidate earns credits. The amount of credit associated with a course is dependent upon the number of hours of instruction per week in that course. Similarly, the credit associated with any of the other academic, co/extracurricular activities is dependent upon the quantum of work expected to be put in for each of these activities per week/per activity.

8 Credit assignment

Theory and Laboratory courses

Courses are broadly classified as Theory and Practical. Theory courses consist of lecture (L) and Practical (P) courses consist of hours spent in the laboratory. Credits (C) for a course is dependent on the number of hours of instruction per week in that course and is obtained by using a multiplier of one (1) for lecture and a multiplier of half (1/2) for practical (laboratory) hours. Thus, for example, a theory course having four lectures per week throughout the semester carries a credit of 4. Similarly, a practical having four laboratory hours per week throughout semester carries a credit of 2. The contact hours of seminars, assignments and research work shall be treated as that of practical courses for the purpose of calculating credits. i.e., the contact hours shall be multiplied by 1/2. Similarly, the contact hours of journal club, research work presentations and discussions with the supervisor shall be considered as theory course and multiplied by 1.

9. Minimum credit requirements

The minimum credit points required for the award of M. Pharm. degree is 95. However based on the credit points earned by the students under the head of co-curricular activities, a student shall earn a maximum of 100 credit points. These credits are divided into Theory courses, Practical, Seminars, Assignments, Research work, Discussions with the supervisor, Journal club and Co-Curricular activities over the duration of four semesters. The credits 3 are distributed semester-wise as shown in Table 14. Courses generally progress in sequence, building competencies and their positioning indicates certain academic maturity on the part of the learners. Learners are expected to follow the semester-wise schedule of courses given in the syllabus.

10. Academic work

A regular record of attendance both in Theory, Practical, Seminar, Assignment, Journal club, Discussion with the supervisor, Research work presentation and Dissertation shall be maintained by the department / teaching staff of respective courses.

11. Course of study

The course of study for M. Pharm shall include Semester Wise Theory & Practical as given in Table– II-III. The number of hours to be devoted to each theory, and practical course in

any semester shall not be less than that shown in Table –II-III

Table II-: Course of study for Semester I

Course code	Name of the course	No. of hours	Tutorial	Credit points
MPL101T	Modern Pharmaceutical Analytical Techniques	4	-----	4
MPL102T	Advanced Pharmacology-I	4	-----	4
MPL 103T	Pharmacological and Toxicological Screening Methods-I	4	----	4
MPL 104T	Cellular and Molecular Pharmacology	4	----	4
MPL 105P	Experimental Pharmacology - I	12	----	6
-	Seminar/Assignment	7	----	4
	Total	**35**		**26**

Table III-: Course of study for Semester II

Course code	Name of the course	No. of hours	Tutorial	Credit points
MPL201T	Advanced Pharmacology-II	4	-	4
MPL 202T	Pharmacological and Toxicological Screening Methods-II	4		4
MPL 203T	Principles of Drug Discovery	4	-	4
MPL 204T	Clinical Research and Pharmacovigilance	4	-	4
MPL 205P	Experimental Pharmacology - II	12	-	6
	Seminar/Assignment	7	-	4
	Total	**35**		**26**

Table-IV: Semester wise credits distribution

Semester	Credit Points
I	**26**
II	26
III	21
IV	20
Co-curricular Activities (Attending Conference, Scientific Presentations and Other Scholarly Activities)	Minimum=02 Maximum=07*
Total credit points	Minimum=95 Maximum=10*

* Credit Points for Co-curricular Activities

12. Program Committee

1. The M. Pharm. programme shall have a Programme Committee constituted by the Head of the institution in consultation with all the Heads of the departments.

2. The composition of the Programme Committee shall be as follows: A teacher at the cadre of Professor shall be the Chairperson; One Teacher from each M. Pharm specialization and four student representatives (two from each academic year), nominated by the Head of the institution.

3. Duties of the Programme Committee:
   i. Periodically reviewing the progress of the classes.
   ii. Discussing the problems concerning curriculum, syllabus and the conduct of classes.
   iii. Discussing with the course teachers on the nature and scope of assessment for the course and the same shall be announced to the students at the beginning of respective semesters.
   iv. Communicating its recommendation to the Head of the institution on academic matters.
   v. The Programme Committee shall meet at least twice in a semester preferably at the end of each sessional exam and before the end semester exam.

13. Examinations/Assessments

The scheme for internal assessment and end semester examinations is given in Table IV- VII

End semester examinations

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

Internal assessment: Continuous mode

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

Table IV: Scheme for awarding internal assessment: Continuous mode

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

Table V: Guidelines for the allotment of marks for attendance

Percentage of Attendance	Theory	Practical
95 – 100	8	10
90 – 94	6	7.5
85 – 89	4	5
80 – 84	2	2.5
Less than 80	0	0

Sessional Exams

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

Promotion and award of grades

A student shall be declared PASS and eligible for getting grade in a course of M.Pharm.programme if he/she secures at least 50% marks in that particular courseincluding internal assessment.

Carry forward of marks

In case a student fails to secure the minimum 50% in any Theory or Practical course as specified in 12, then he/she shall reappear for the end semester examination of that course. However his/her marks of the Internal Assessment shall be carried over and he/she shall be entitled for grade obtained by him/her on passing.

Improvement of internal assessment

A student shall have the opportunity to improve his/her performance only once in the sessional exam component of the internal assessment. The re-conduct of the sessional exam shall be completed before the commencement of next end semester theory examinations.

Reexamination of end semester examinations

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

Table VI: Tentative schedule of end semester examinations

Semester	For Regular Candidates	For Failed Candidates
I and III	November / December	May / June
II and IV	May / June	November / December

Allowed to keep terms (ATKT):

No student shall be admitted to any examination unless he/she fulfills the norms given in 6. ATKT rules are applicable as follows:

A student shall be eligible to carry forward all the courses of I and IIsemesters till the III semester examinations. However, he/she shall not be eligible to attend the courses of IV semester until all the courses of I, II and III semesters are successfully completed.

A student shall be eligible to get his/her CGPA upon successful completion of the courses of I to IV semesters within the stipulated time period as per the norms.

Note: Grade AB should be considered as failed and treated as one head for deciding ATKT. Such rules are also applicable for those students who fail to register for examination(s) of any course in any semester.

Grading of performances

Letter grades and grade points allocations:

Based on the performances, each student shall be awarded a final letter grade at the end of the semester for each course.The letter grades and their corresponding grade points are given in Table – VII.

Table VII: Letter grades and grade points equivalent to Percentage of marks and performances

Percentage of Marks Obtained	Letter Grade	Grade Point	Performance
90.00 – 100	O	10	Outstanding
80.00 – 89.99	A	9	Excellent
70.00 – 79.99	B	8	Good
60.00 – 69.99	C	7	Fair
50.00 – 59.99	D	6	Average

Less than 50	F	0	Fail
Absent	AB	0	Fail

A learner who remains absent for any end semester examination shall be assigned a letter grade of AB and a corresponding grade point of zero. He/she should reappear for the said evaluation/examination in due course.

The Semester grade point average (SGPA)

The performance of a student in a semester is indicated by a number called 'Semester Grade Point Average' (SGPA). The SGPA is the weighted average of the grade points obtainedin all the courses by the student during the semester. For example, if a student takes five courses (Theory/Practical) in a semester with credits C1, C2, C3 and C4 and the student's grade points in these courses

are G1, G2, G3 and G4, respectively, and then students' SGPA is equal to:

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

The SGPA is calculated to two decimal points. It should be noted that, the SGPA for any semester shall take into consideration the F and ABS grade awarded in that semester. For example if a learner has a F or ABS grade in course 4, theSGPA shall then be computed as:

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

Cumulative Grade Point Average (CGPA)

The CGPA is calculated with the SGPA of all the IV semesters to two decimal points and is indicated in final grade report card/final transcript showing the grades of all IV semesters and their courses. The CGPA shall reflect the failed statusin case of F grade(s), till the course(s) is/are passed. When the course(s) is/are passedby obtaining a pass grade on subsequent examination(s) theCGPAshall only reflect the new grade and not the fail grades earned earlier.The CGPA is calculated as:

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

where C1, C2, C3,…. is the total number of credits for semester I,II,III,…. and S1,S2, S3,….is the SGPA of semester I,II,III,…. .

Declaration of class

The class shall be awarded on the basis of CGPA as follows: First Class with Distinction = CGPA of. 7.50 and above

First Class = CGPA of 6.00 to 7.49

Second Class = CGPA of 5.00 to 5.99

Project work

All the students shall undertake a project under the supervision of a teacher in Semester III to IV and submit a report. 4 copies of the project report shall be submitted (typed & bound copy not less than 75 pages).

The internal and external examiner appointed by the University shall evaluate the project at the time of the Practical examinations of other semester(s). The projects shall be evaluated as per the criteria given below.

Evaluation of Dissertation Book:

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

Evaluation of Presentation:

Presentation of work	100 Marks
Communication skills	50 Marks
Question and answer skills	100 Marks
Total	250 Marks

Award of Ranks

Ranks and Medals shall be awarded on the basis of final CGPA. However, candidates who fail in one or more courses during the M.Pharm program shall not be eligible for award of ranks. Moreover, thecandidates should have completed the M. Pharm program in minimum prescribed number of years, (two years) for the award of Ranks.

Award of degree

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

Duration for completion of the program of study

The duration for the completion of the program shall be fixed as double the actual duration of the program and the students have to pass within the said period, otherwise they have to get freshRegistration.

Revaluation I Re-totaling of answer papers

There is no provision for revaluation of the answer papers in any examination. However, the candidates can apply for retotaling by paying prescribed fee.

Re-admission after break of study

Candidate who seeks re-admission to the program after break of study has to get the approval from the university by paying a condonationfee.

SYLLABUS

M.PHARM. SEMESTER I

Course Code MPL 101T	**Title of the course: Modern Pharmaceutical Analytical Techniques (MAT)**
Course Code: MPL 102T	**Title of the Course: Advanced Pharmacology-I (Theory)**
Course Code: MPL 103T	**Title of the Course: Pharmacological and Toxicological Screening Methods I (Theory)**
Course Code: MPL 104T	**Title of the Course: Cellular and Molecular Pharmacology (Theory)**
Course Code: MPL 105P	**Title of the Course: Pharmacological Practical I**

Name of the Academic Program: M. Pharm (Pharmacology)

Course Code: MPL 102T

Title of the Course: Advanced Pharmacology-I

L-T-P: 4-0-0 **Credits: 4**

(L=Lecture hours, T=Tutorial hours, P=Practical hours)

COURSE OUTCOMES (COs)

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

CO-1: To possess comprehensive advance knowledge and basic principles regarding the pathophysiology/ etiology of various diseases **(Cognitive levels: Understand)**.

CO-2: To comprehend the molecular basis of the mechanism of action of drugs **(Cognitive levels: Understand)**.

CO-3: To identify the physiological and pathophysiological role of various neurotransmitters and autocoids **(Cognitive levels: Understand)**.

CO-4: To integrate knowledge of pharmacokinetics and pharmacodynamics of drugs to pharmacotherapeutics. Learners would be able to categorize, compare and contrast multiple determinants of disease/pathology **(Cognitive levels: Apply)**.

CO-5: To analyze drugs recommended/approved/ under clinical trial phases for each category of system and compare the data of all the drugs with respect to efficacy and adverse effects/contradictions **(Cognitive levels: Analyze)**.

CO-6: To assess, in detail, the concept of pharmacology and toxicology and apply principles of pharmacology to plan practical research problems and for their future research projects **(Cognitive levels: Apply)**.

CO-7: To ask questions concerning concept of drug action with confidence and seek effective help from reference source **(Cognitive levels: Evaluate)**.

CO-8: Learning outcomes would allow faculty and set the standards by which success of the course will be evaluated **(Cognitive levels: Create)**.

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

	PO1	PO2	PO3	PO4	PO5	PO6	PO7	PO8	PO9	PO10	PO11	PSO1	PSO2	PSO3	PSO4	PSO5
CO1	3					2		3	2	2	3	3				3
CO2	3				2	2		3	3	2	3	3	3			
CO3	3										3	3		2		
CO4	3	3	3		3	2		3	3		3	3	2		2	
CO5	3	3		3				3		2	3	3	3			3
CO6	3		3	3	3		3	3		2	3	3		3	3	
CO7	3	3		2	3			3	3		3	3	3		3	3
CO8	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3

Each Course Outcome (CO) may be mapped with one or more Program Outcomes (POs). Write '3' in the box for 'High-level'mapping, 2 for 'Medium-level'mapping, 1 for 'Low'-level'mapping. Mapping with PSOs, where applicable.

Detailed Syllabus:

Unit 1: General Pharmacology 12Hrs

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.

Unit 2: Neurotransmission 12Hrs

a. General aspects and steps involved in neurotransmission.
b. Neurohumoral transmission in autonomic nervous system (Detailed study about neurotransmitters- Adrenaline and Acetylcholine).
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). Cotransmission.

Unit 3: Systemic Pharmacology 12 Hrs

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.

Unit 4: Cardiovascular Pharmacology 12 Hrs

Diuretics, antihypertensives, antiischemics, anti- arrhythmics, drugs for heart failure and hyperlipidemia. Hematinics, coagulants, anticoagulants, fibrinolytics and antiplatelet
Drugs.

Unit 5: Autocoid Pharmacology **12 Hrs**

The physiological and pathological role of Histamine, Serotonin, Kinins Prostaglandins Opioid autocoids. Pharmacology of antihistamines, 5HT antagonists.

Reference Books:

1. Goodman and Gilman's, The Pharmacological Basis ofTherapeutics, Mc Graw-Hill.
2. David E Golan, Armen H, Tashjian Jr, Ehrin J,Armstrong, April W,Armstrong, Principles of Pharmacology. The Pathophysiologic basis of drug Therapy by Wolters, Kluwer-Lippincott Williams & Wilkins Publishers.
3. Katzung B. G Basic. Basic and Clinical Pharmacology, TataMc Graw-Hill.
4. Gibaldi and Prescott.Hand book of Clinical Pharmacokinetics.
5. Leon Shargel and Andrew B.C.Yu.Applied biopharmaceutics and Pharmacokinetics.
6. Graham Smith. Oxford textbook of Clinical Pharmacology.
7. Avery Drug Treatment
8. Dipiro Pharmacology, Pathophysiological approach.
9. Green Pathophysiology for Pharmacists.
10. Annual review of Pharmacology
11. Trends in Pharmacological sciences (TIPS)

(Number of Units may be decided by the School/Department/Centre)

Teaching-Learning Strategies in brief (4 to 5 sentences)

The teaching learning strategies, followed are board and chalk teaching, Learning through discussion among the peer group, classroom interaction, discussion of research papers of Journals related to topics, power point presentation, Q & A session and reflective learning.

Assessment methods and weightages in brief

There are two components of assessment: Internal assessment (25 marks) and End semester examination (75 marks). Internal assessment consists of continuous mode (10 marks) and sessional examinations (15 marks). There are two Sessional exams (each conducted for 30 marks and computed for 15 marks) and one improvement exam. The average marks of two best sessional exams are computed out of 15 marks. Continuous mode evaluation is of 10 marks comprising of attendance- 8 marks (calculated as: Percentage of Attendance: Allotment of marks- Less than 80: 0 marks; 80-84: 2 marks; 85-89: 4 marks; 90-94: 6 marks and 95-100: 8 marks) and Student- Teacher interaction: 2 marks.
Total Marks are 100 for the subject (Internal Assessment: 25 marks and End Semester Examination: 75 Marks).

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Name of the Academic Program: M. Pharm. (Pharmacology)

Course Code: MPL103T.

Title of the Course: Pharmacological and Toxicological Screening Methods I.

L-T-P4-0-0 **Credits.** 4

(L=Lecture hours, T=Tutorial hours, P=Practical hours)

COURSE OUTCOMES (COs)

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

CO-1: Describe the various animals used in the drug discovery process and good laboratory practices in maintenance and handling of experimental animals

CO-2: Appraise the regulations and ethical requirement for the usage of experimental animals.

CO-3: Acquired fundamental knowledge of various *in-vitro* and *in-vivo* preclinical evaluation of drugs and recent experimental techniques in the drug discovery and development.

CO-4: Describe the various newer screening methods involved in the drug discovery process

CO-5: Appreciate and correlate the preclinical data to humans

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

	PO1	PO2	PO3	PO4	PO5	PO6	PO7	PO8	PO9	PO10	PO11	PSO1	PSO2	PSO3	PSO4
CO1			3	2				2				3			
CO2			3	3									2		
CO3	2	2	3	3											
CO4	2	2	3	2							3				
CO5	1	2	3	2											2
…..															
…..															

Each Course Outcome (CO) may be mapped with one or more Program Outcomes (POs). Write '3' in the box for 'High-level'mapping, 2 for 'Medium-level'mapping, 1 for 'Low'-level'mapping.

Mapping with PSOs, where applicable.

Detailed Syllabus:

Unit I **12 hrs**

1. Laboratory Animals: 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

Unit II **12 hrs**

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

Unit III **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 formetabolic disorders like anti-diabetic, antidyslipidemic agents. Anti cancer agents. Hepatoprotective screening methods.

Unit IV **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

Reference Books:

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. Gupta
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 BikashMedhi, Ajay Prakash

Teaching-Learning Strategies in Brief

The teaching learning strategies, followed are board and chalk teaching, Learning through discussion among the peer group, classroom interaction, discussion of research papers of Journals related to topics, power point presentation, Q & A session and reflective learning.

Assessment methods and weightages in brief

There are two components of assessment: Internal assessment (25 marks) and End semester examination (75 marks). Internal assessment consists of continuous mode (10 marks) and sessional examinations (15 marks). There are two Sessional exams (each conducted for 30 marks and computed for 15 marks) and one improvement exam. The average marks of two best sessional exams are computed out of 15 marks. Continuous mode evaluation is of 10 marks comprising of attendance- 8 marks (calculated as: Percentage of Attendance: Allotment of marks- Less than 80: 0 marks; 80-84: 2 marks; 85-89: 4 marks; 90-94: 6 marks and 95-100: 8 marks) and Student- Teacher interaction: 2 marks.
Total Marks are 100 for the subject (Internal Assessment: 25 marks and End Semester Examination: 75 Marks).

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Name of the Academic Program: M. Pharm (Pharmacology)

Course Code: MPL104T

Title of the Course: Cellular and Molecular Pharmacology (Theory)

L-T-P: 4-0-0 **Credits –** 4 (theory)

(L=Lecture hours, T=Tutorial hours, P=Practical hours)

COURSE OUTCOMES (COs)

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

CO-1: Explain the cell biology and cell signalling pathways **(Cognitive level: Understand)**

CO-2: Discuss the molecular pathways affected by drugs **(Cognitive level: Understand)**

CO-3: Describe immunotherapeutics, gene therapy and biosimilars **(Cognitive level: Understand)**

CO-4: Relate the applicability of molecular pharmacology and biomarkers to drug discovery process **(Cognitive level: Apply)**

CO-5: Demonstrate molecular and cell biology techniques as applicable for pharmacology **(Cognitive level: Apply)**

CO-6: Appraise the role of pharmacogenomics and genetic variation in pharmacology **(Cognitive level: Analyze)**

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

	PO1	PO2	PO3	PO4	PO5	PO6	PO7	PO8	PO9	PO10	PO11	PSO1	PSO2	PSO3	PSO4	PSO5
CO1	3		2	2		1					3	2		3	3	2
CO2	3		2	2		2					3	3	2	3	3	2
CO3	3		2	2		2	2		2		3	2	3	3	3	3
CO4	3		3	3	2	3			2		3	3	2	3	3	2
CO5	2		2	3	2	3					3	2	2	3	3	2
CO6	3		2	2	1	3	1		2		3	3	3	3	3	3

Each Course Outcome (CO) may be mapped with one or more Program Outcomes (POs). Write '3' in the box for 'High-level'mapping, 2 for 'Medium-level' mapping, 1 for 'Low-level' mapping.

Mapping with PSOs, where applicable.

Detailed Syllabus

UNIT-I **12 hours**

Cell Biology

Structure and functions of cells 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.

UNIT-II **12 hours**

Cell Signalling
Intercellular and Intracellular signalling 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.

UNIT-III **12 hours**

Principles and applications of genomic and proteomic tools
DNA electrophoresis, PCR (reverse transcription and real time), Gene sequencing, microarray 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.

UNIT-IV **12 hours**

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 proteomic Science and others
Genomics, proteomics, metabolomics, functionomics, nutrigenomics

Immunotherapeutics
Types of immunotherapeutics, humanization antibody therapy, Immunotherapeutics in clinical practice

UNIT-V **12 hours**

Cell Culture techniques

Basic equipment 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 influx assays
Principles and applications of flow cytometry

Biosimilars

Reference Books (Latest Editions)

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 CherilD.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 protocols in molecular biology vol I to VI edited by Frederick M. Ausuvel et la.

Teaching-Learning Strategies in Brief

The teaching learning strategies, followed are board and chalk teaching, Learning through discussion among the peer group, classroom interaction, discussion of research papers of Journals related to topics, power point presentation, Q & A session and reflective learning.

Assessment methods and weightages in brief

There are two components of assessment: Internal assessment (25 marks) and End semester examination (75 marks). Internal assessment consists of continuous mode (10 marks) and sessional examinations (15 marks). There are two Sessional exams (each conducted for 30 marks and computed for 15 marks) and one improvement exam. The average marks of two best sessional exams are computed out of 15 marks. Continuous mode evaluation is of 10 marks comprising of attendance- 8 marks (calculated as: Percentage of Attendance: Allotment of marks- Less than 80: 0 marks; 80-84: 2 marks; 85-89: 4 marks; 90-94: 6 marks and 95-100: 8 marks) and Student- Teacher interaction: 2 marks.

Total Marks are 100 for the subject (Internal Assessment: 25 marks and End Semester Examination: 75 Marks).

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Name of the Academic Program: M. Pharm Pharmacology

Course Code: MPL 105 P

Title of the Course: Pharmacological Practical I

L-T-P: 0-0-12 **Credits: 6**

(L=Lecture hours, T=Tutorial hours, P=Practical hours)

COURSE OUTCOMES (COs)

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

CO-1: Attain 'hands on' various spectroscopic and chromatographic techniques **(Cognitive level: Apply)**

CO-2: Analyze various drugs in single and combination dosage forms using advanced instrumental techniques **(Cognitive level: Analyze)**

CO-3: Experience the handling of laboratory animals used in Experimental Pharmacology **(Cognitive level: Apply)**

CO-4: Demonstrate various screening methods used in preclinical research **(Cognitive level: Apply)**

CO-5: Illustrate various *in vitro* methods of estimating molecules at cellular level **(Cognitive level: Analyze)**

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

	PO1	PO2	PO3	PO4	PO5	PO6	PO7	PO8	PO9	PO10	PO11	PSO1	PSO2	PSO3	PSO4	PSO5
CO1				2							3				3	
CO2				3							3				3	
CO3							3									
CO4				3						2	2			2		
CO5				3						2	3			3		

Each Course Outcome (CO) may be mapped with one or more program Outcomes (POs). Write '3' in the box for 'High-level' mapping, '2' for 'Medium-level' mapping, '1' for 'low-level' mapping

Detailed Syllabus:

1. Analysis of pharmacopeial 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

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 analyticaltechniques (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

Teaching-Learning Strategies in Brief

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Assessment methods and weightages in brief

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Total Marks are 100 for the subject (Internal Assessment: 25 marks and End Semester Examination: 75 Marks).

M.PHARM. SEMESTER II

Course Code MPL 201T	**Title of the course: Advanced Pharmacology-II (Theory)**
Course Code: MPL202T	**Title of the Course: Pharmacological and Toxicological Screening Methods II(Theory)**
Course Code: MPL203T	**Title of the Course: Principles of Drug discovery (Theory)**
Course Code: MPL204T	**Title of the Course: Clinical Research and Pharmacovigilance (Theory)**
Course Code: MPL205P	**Title of the Course: Pharmacological Practical II**

Name of the Academic Program: M. Pharm. (Pharmacology)

Course Code: MPL 201T

Title of the Course: Advanced Pharmacology-II

L-T-P: 4-0-0 **Credits: 4**

(L=Lecture hours, T=Tutorial hours, P=Practical hours)

COURSE OUTCOMES (COs)

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

CO-1: To possess comprehensive advance knowledge and basic principles regarding the pathophysiology/ etiology of various diseases **(Cognitive levels: Understand)**.

CO-2: To comprehend the molecular basis of the mechanism of action of drugs **(Cognitive levels: Understand)**.

CO-3: To analyze drugs recommended/approved/ under clinical trial phases for each category of system and compare the data of all the drugs with respect to efficacy and adverse effects/contradictions **(Cognitive levels: Analyze)**.

CO-4: To assess, in detail, the concept of pharmacology and toxicology and apply principles of pharmacology to plan practical research problems and for their future research projects **(Cognitive levels: Apply)**.

CO-5: To ask questions concerning concept of drug action with confidence and seek effective help from reference source **(Cognitive levels: Evaluate)**.

CO-6: Learning outcomes would allow faculty and set the standards by which success of the course will be evaluated **(Cognitive levels: Create)**.

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

	PO1	PO2	PO3	PO4	PO5	PO6	PO7	PO8	PO9	PO10	PO11	PSO1	PSO2	PSO3	PSO4	PSO5
CO1	3					2		3	2	2	3	3				3
CO2	3				2	2		3	3	2	3	3	3			-
CO3	3	3		3					3	2	3	3	3			3
CO4	3		3	3	3		3	3		2	3	3		3	3	
CO5	3	3		2	3			3			3		3		3	3
CO6	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3
…..																

Each Course Outcome (CO) may be mapped with one or more Program Outcomes (POs). Write '3' in the box for 'High-level'mapping, 2 for 'Medium-level'mapping, 1 for 'Low'-level'mapping.

Mapping with PSOs, where applicable.

Detailed Syllabus:

Unit I. Endocrine Pharmacology 12Hrs

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

Unit II: Chemotherapy 12Hrs

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

Unit III: Chemotherapy 12Hrs

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

Unit IV: GIT Pharmacology 12Hrs

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

Unit V: Free radicals Pharmacology 12Hrs

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

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
13. Annual review of Pharmacology
14. Trends in Pharmacological sciences (TIPS)

(Number of Units may be decided by the School/Department/Centre)

Teaching-Learning Strategies in Brief

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Assessment methods and weightages in brief

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Total Marks are 100 for the subject (Internal Assessment: 25 marks and End Semester Examination: 75 Marks).

Name of the Academic Program: M Pharm (Pharmacology)

Course Code: MPL202T.

Title of the Course: Pharmacological and Toxicological Screening Methods II.

L-T-P4-0-0 **Credits**: 4

(L=Lecture hours, T=Tutorial hours, P=Practical hours)

COURSE OUTCOMES (COs)

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

CO-1: Explain the various types of toxicity studies **(Cognitive Level: Understand)**.

CO-2: Acquire fundamental knowledge on the preclinical*in vitro* and *in vivo* safety and toxicological evaluation of drug & new chemical entity **(Cognitive level: Apply)**

CO-3: Describe the various newer toxicity screening methods, by different regulatory authorities, involved in the drug discovery process **(Cognitive level: Explain)**

CO-4: Appreciate the different regulatory authorities, guidelines, and importance of ethical and regulatory requirements for toxicity studies **(Cognitive level: Analyze)**

CO-5: Demonstrate the practical skills required to conduct the preclinical toxicity studies **(Cognitive level: Evaluate)**

CO-6: Appreciate and correlate the preclinical toxicological data to humans **(Cognitive level: Analyze)**

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

	PO1	PO2	PO3	PO4	PO5	PO6	PO7	PO8	PO9	PO10	PO11	PSO1	PSO2	PSO3	PSO4
CO1			3	2			3					2			
CO2			3	3					2		3				
CO3	2	2	3	3									1		
CO4	2	2	3	2							1				3
CO5	1	2	3	2							2			2	

Each Course Outcome (CO) may be mapped with one or more Program Outcomes (POs). Write '3' in the box for 'High-level'mapping, 2 for 'Medium-level'mapping, 1 for 'Low'-level'mapping.

Mapping with PSOs, where applicable.

Detailed Syllabus:

Unit I **12Hrs**

Basic definition and types of toxicology (general, mechanistic, regulatory and descriptive) Regulatory guidelines for conducting toxicity studies OECD, ICH, EPA and Schedule YOECD principles of Good laboratory practice (GLP)

History, concept and its importance in drug development

Unit II: 12Hrs

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

Unit III: 12Hrs

Reproductive toxicology studies, Male reproductive toxicity studies, female reproductive studies (segment I and segment III), teratogenecity studies (segment II). Genotoxicity studies (Ames Test, in vitro and in vivo Micronucleus and Chromosomal aberrations studies)
In vivo carcinogenicity studies

Unit IV: 12 Hrs

IND enabling studies (IND studies)- Definition of IND, importance of IND, industry perspective, list of studies needed for IND submission. 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

Unit V: 12 Hrs

Toxicokinetics- Toxicokinetic evaluation in preclinical studies, saturation kinetics Importance and applications of toxicokinetic studies. Alternative methods to animal toxicity testing.

Reference Books:

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
8. (http://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm073246.pdf)

Teaching-Learning Strategies in Brief

The teaching learning strategies, followed are board and chalk teaching, Learning through discussion among the peer group, classroom interaction, discussion of research papers of Journals related to topics, power point presentation, Q & A session and reflective learning.

Assessment methods and weightages in brief

There are two components of assessment: Internal assessment (25 marks) and End semester examination (75 marks). Internal assessment consists of continuous mode (10 marks) and sessional examinations (15 marks). There are two Sessional exams (each conducted for 30 marks and computed for 15 marks) and one improvement exam. The average marks of two best sessional exams are computed out of 15 marks. Continuous mode evaluation is of 10 marks comprising of attendance- 8 marks (calculated as: Percentage of Attendance: Allotment of marks- Less than 80: 0 marks; 80-84: 2 marks; 85-89: 4 marks; 90-94: 6 marks and 95-100: 8 marks) and Student- Teacher interaction: 2 marks.

Total Marks are 100 for the subject (Internal Assessment: 25 marks and End Semester Examination: 75 Marks).

Name of the Academic Program: M Pharm (Pharmacology)

Course Code: MPL203T.

Title of the Course: Principles of Drug Discovery

L-T-P4-0-0 **Credits: 4**

(L=Lecture hours, T=Tutorial hours, P=Practical hours)

COURSE OUTCOMES (COs)

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

CO-1: Explain the various stages of drug discovery **(Cognition level: Understand)**

CO-2: Relate the importance of the role of genomics, proteomics and bioinformatics in drug discovery **(Cognition level: Apply)**

CO-3: Explain various targets for drug discovery **(Cognition level: Understand)**

CO-4: Show various lead seeking method and lead optimization **(Cognition level: Apply)**

CO-5: Develop the importance of the role of computer aided drug design in drug discovery **(Cognition level: Create)**

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

	PO1	PO2	PO3	PO4	PO5	PO6	PO7	PO8	PO9	PO10	PO11	PSO1	PSO2	PSO3	PSO4
CO1	3	2	3	2	2			2	2		2			3	
CO2	3		3	3					2		2			3	
CO3	3		2	3		2			2					3	
CO4	3		3	2			1				1			3	
CO5	3	2		3	2	2		2			2			3	

Each Course Outcome (CO) may be mapped with one or more Program Outcomes (POs). Write '3' in the box for 'High-level'mapping, 2 for 'Medium-level'mapping, 1 for 'Low'-level'mapping.

Mapping with PSOs, where applicable.

Detailed Syllabus:

Unit I: **12Hrs**

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

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.

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

Unit II: 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,

Unit III: Molecular Docking **12Hrs**

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.

Unit IV: QSAR Statistical methods **12Hrs**

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

Reference Books:

1. Mouldy Sioud. Target Discovery and Validation Reviews and Protocols: Volume 2 Emerging Molecular Targets and Treatment Options. 2007 Humana Press Inc.
2. Darryl León. Scott Markel In. 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.

Teaching-Learning Strategies in Brief

The teaching learning strategies, followed are board and chalk teaching, Learning through discussion among the peer group, classroom interaction, discussion of research papers of Journals related to topics, power point presentation, Q & A session and reflective learning.

Assessment methods and weightages in brief

There are two components of assessment: Internal assessment (25 marks) and End semester examination (75 marks). Internal assessment consists of continuous mode (10 marks) and sessional examinations (15 marks). There are two Sessional exams (each conducted for 30 marks and computed for 15 marks) and one improvement exam. The average marks of two best sessional exams are computed out of 15 marks. Continuous mode evaluation is of 10 marks comprising of attendance- 8 marks (calculated as: Percentage of Attendance: Allotment of marks- Less than 80: 0 marks; 80-84: 2 marks; 85-89: 4 marks; 90-94: 6 marks and 95-100: 8 marks) and Student- Teacher interaction: 2 marks.

Total Marks are 100 for the subject (Internal Assessment: 25 marks and End Semester Examination: 75 Marks).

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Name of the Academic Program M. Pharm. (Pharmacology)

Course Code: MPL204T

Title of the Course: Clinical Research and Pharmacovigilance (Theory)

L-T-P: 4-0-0 Credits – 4 (theory)

(L=Lecture hours, T=Tutorial hours, P=Practical hours)

COURSE OUTCOMES (COs)

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

CO-1: Explain the regulatory requirements for conducting and reporting clinical trials **(Cognitive level: Understand)**

CO-2: Demonstrate the types of clinical trial designs **(Cognitive level: Apply)**

CO-3: Discuss the responsibilities of key players involved in clinical trials **(Cognitive level: Understand)**

CO-4: Execute safety monitoring, reporting and close-out activities **(Cognitive level: Apply)**

CO-5: Explain the principles of Pharmacovigilance, Pharmacoepidemiology and Pharmacoeconomics **(Cognitive level: Understand)**

CO-6: Assess new adverse drug reactions and their severity **(Cognitive level: Evaluate)**

CO-7: Practice the adverse drug reaction reporting systems and communication in Pharmacovigilance **(Cognitive level: Apply)**

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

	PO1	PO2	PO3	PO4	PO5	PO6	PO7	PO8	PO9	PO10	PO11	PSO1	PSO2	PSO3	PSO4	PSO5
CO1	1	1		2		2	3				3			3	2	
CO2	1	2	2	2		2	2				3			3	2	
CO3				2	2	2	2				3			3		
CO4	1			2		2	2				3		3		2	
CO5	1	1	3	2	2	2	2		2		3		3		2	2
CO6	1		2	2		2	2				3		3			
CO7				2		2	2	3			3		3		2	2

Each Course Outcome (CO) may be mapped with one or more Program Outcomes (POs). Write '3' in the box for 'High-level'mapping, 2 for 'Medium-level' mapping, 1 for 'Low-level' mapping.

Detailed Syllabus

UNIT-I **12 hours**

Regulatory Perspectives of Clinical Trials

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

Ethical Committees – Institutional Review Board, ICMR National Ethical guidelines for biomedical research involving human participants, Schedule Y
Informed Consent Process: Structure and content of an Informed Consent Process, Ethical principles governing informed consent process

UNIT-II **12 hours**

Clinical Trials

Clinical Trials: Types and Design,
Experimental Study-RCT and Non-RCT
Observational 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

UNIT-III **12 hours**

Clinical Trial Documentation

Guidelines to the preparation of documents, Preparation of protocol, Investigator's 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.

UNIT-IV **12 hours**

Pharmacovigilance

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

UNIT-V **12 hours**

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.

UNIT-VI **12 hours**

Pharmacoepidemiology, Pharmacoeconomics, Safety Pharmacology

Reference Books & Guidelines (Latest Editions)

1. International Conference on Harmonization of Technical requirements for registration of Pharmaceuticals for human use. ICH Harmonized Tripartite Guideline. Guideline for Good Clinical Practice. E6 (R2), May 1996 and further amendments
2. National Ethical Guidelines for Biomedical Research Involving Human Participants 2017, Indian Council of Medical Research, New Delhi
3. Central Drugs Standard Control Organization- Good Clinical Practices, Guidelines for Clinical Trials on Pharmaceutical Products in India. New Delhi: Ministry of Health; 2001.
4. New Drugs & Clinical Trial Rule, 2018, CDSCO, New Delhi.
5. Textbook of Clinical Trials, 2nd edition, edited by David Machin, Simon Day and Sylvan Green, November 2006, John Wiley and Sons.
6. Pharmaceutical Medicine and Translational Clinical Research, Edited by Divya Vohora, Gursharan Singh, November 2017, Academic Press, Elsevier, USA.
7. Handbook of Clinical Research. Julia Lloyd and Ann Raven Ed. Churchill Livingstone.
8. Principles of Clinical Research, edited by Giovannadi Ignazio, Di Giovanna and Haynes.

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Total Marks are 100 for the subject (Internal Assessment: 25 marks and End Semester Examination: 75 Marks).

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Name of the Academic Program: M. Pharm Pharmacology

Course Code: MPL 205 P

Title of the Course: Pharmacological Practical II

L-T-P: 0-0-12 **Credit: 12**

(L=Lecture hours, T=Tutorial hours, P=Practical hours)

COURSE OUTCOMES (COs)

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

CO-1: Estimate the potency of test samples using various bioassay procedures **(Cognitive level: Evaluate)**

CO-2: Acquire the technique of recording Blood Pressure, Heart rate and ECG in rats **(Cognitive level: Apply)**

CO-3: Demonstrate toxiciy studies as preclinical evaluation in drug discovery and develpoment **(Cognitive level: Apply)**

CO-4: Comprehend screening of drugs based on *in-silico* Pharmacophore modeling and Docking studies **(Cognitive level: Apply)**

CO-5: Design protocols for clinical trial and Adverse Drug Reaction (ADR) monitoring **(Cognitive level: Create)**

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

	PO1	PO2	PO3	PO4	PO5	PO6	PO7	PO8	PO9	PO10	PO11	PSO1	PSO2	PSO3	PSO4	PSO5
CO1	2			2			3									
CO2				3			3			2						
CO3				3			3						3			
CO4	3			3	3					2				3		
CO5				3									3	3		

Each Course Outcome (CO) may be mapped with one or more program Outcomes (POs). Write '3' in the box for 'High-level' mapping, '2' for 'Medium-level' mapping, '1' for 'low-level' mapping

Detailed Syllabus:

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 Metabolism for Industrial Scientists.

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