Revised Regulations for the Master of Pharmacy Degree Program (w.e.f. June 2016)

Credit Based Semester System

M. PHARM. PHARMACOLOGY (MPC)

Pharmacy Council of India
Combined Council's Building, Kotla Road,
Aiwan-E-Ghalib Marg,
New Delhi-110 002
CHAPTER – I: REGULATIONS

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

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

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

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

3. Duration of the program
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 Phamacy 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 semesters shall consist of not less than 100 working days. The odd semesters shall be conducted from the month of June/July to November/December and the even semesters shall be conducted from the month of December/January to May/June in every calendar year.
6. Attendance and progress
A candidate is required to put in at least 80% attendance in individual courses considering theory and practical separately. The candidate shall complete the prescribed course satisfactorily to be eligible to appear for the respective examinations.

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

7.1. Credit assignment
7.1.1. Theory and Laboratory courses
Courses are broadly classified as Theory and Practical. Theory courses consist of lecture (L) and Practical (P) courses consist of hours spent in the laboratory. Credits (C) for a course is dependent on the number of hours of instruction per week in that course, and is obtained by using a multiplier of one (1) for lecture and a multiplier of half (1/2) for practical (laboratory) hours. Thus, for example, a theory course having four lectures per week throughout the semester carries a credit of 4. Similarly, a practical having four laboratory hours per week throughout semester carries a credit of 2.

The contact hours of seminars, assignments and research work shall be treated as that of practical courses for the purpose of calculating credits. i.e., the contact hours shall be multiplied by 1/2. Similarly, the contact hours of journal club, research work presentations and discussions with the supervisor shall be considered as theory course and multiplied by 1.

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

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

9. Course of study
The specializations in M.Pharm program is given in Table I.

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

<table>
<thead>
<tr>
<th>S. No.</th>
<th>Specialization</th>
<th>Code</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>Cosmeceutics</td>
<td>MCC</td>
</tr>
<tr>
<td>2.</td>
<td>Industrial Pharmacy</td>
<td>MIP</td>
</tr>
<tr>
<td>3.</td>
<td>Pharmaceutical Analysis</td>
<td>MPA</td>
</tr>
<tr>
<td>4.</td>
<td>Pharmaceutical Biotechnology</td>
<td>MPB</td>
</tr>
<tr>
<td>5.</td>
<td>Pharmaceutical Chemistry</td>
<td>MPC</td>
</tr>
<tr>
<td>6.</td>
<td>Pharmaceutics</td>
<td>MPH</td>
</tr>
<tr>
<td>7.</td>
<td>Pharmacognosy</td>
<td>MPG</td>
</tr>
<tr>
<td>8.</td>
<td>Pharmacology</td>
<td>MPL</td>
</tr>
<tr>
<td>9.</td>
<td>Pharmacy Practice</td>
<td>MPP</td>
</tr>
<tr>
<td>10.</td>
<td>Pharmaceutical Quality Assurance</td>
<td>MQA</td>
</tr>
<tr>
<td>11.</td>
<td>Pharmaceutical Regulatory Affairs</td>
<td>MRA</td>
</tr>
</tbody>
</table>

The course of study for M.Pharm specializations shall include Semester wise Theory & Practical as given in Table – II to XIII. 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 to XIII.
<table>
<thead>
<tr>
<th>Course Code</th>
<th>Course</th>
<th>Credit</th>
<th>Credit</th>
<th>Hrs./wk</th>
<th>Marks</th>
</tr>
</thead>
<tbody>
<tr>
<td>MPA101T</td>
<td>Modern Pharmaceutical Analytical Techniques</td>
<td>4</td>
<td>4</td>
<td>4</td>
<td>100</td>
</tr>
<tr>
<td>MPL101T</td>
<td>Advanced Pharmacology-I</td>
<td>4</td>
<td>4</td>
<td>4</td>
<td>100</td>
</tr>
<tr>
<td>MPL102T</td>
<td>Pharmacological and Toxicological Screening Methods-I</td>
<td>4</td>
<td>4</td>
<td>4</td>
<td>100</td>
</tr>
<tr>
<td>MPL103T</td>
<td>Cellular and Molecular Pharmacology</td>
<td>4</td>
<td>4</td>
<td>4</td>
<td>100</td>
</tr>
<tr>
<td>MPL104P</td>
<td>Pharmacology Practical I</td>
<td>12</td>
<td>6</td>
<td>12</td>
<td>150</td>
</tr>
<tr>
<td></td>
<td>Seminar/Assignment</td>
<td>7</td>
<td>4</td>
<td>7</td>
<td>100</td>
</tr>
<tr>
<td></td>
<td><strong>Total</strong></td>
<td><strong>35</strong></td>
<td><strong>26</strong></td>
<td><strong>35</strong></td>
<td><strong>650</strong></td>
</tr>
</tbody>
</table>

**Semester II**

<table>
<thead>
<tr>
<th>Course Code</th>
<th>Course</th>
<th>Credit</th>
<th>Credit</th>
<th>Hrs./wk</th>
<th>Marks</th>
</tr>
</thead>
<tbody>
<tr>
<td>MPL201T</td>
<td>Advanced Pharmacology II</td>
<td>4</td>
<td>4</td>
<td>4</td>
<td>100</td>
</tr>
<tr>
<td>MPL102T</td>
<td>Pharmacological and Toxicological Screening Methods-II</td>
<td>4</td>
<td>4</td>
<td>4</td>
<td>100</td>
</tr>
<tr>
<td>MPL203T</td>
<td>Principles of Drug Discovery</td>
<td>4</td>
<td>4</td>
<td>4</td>
<td>100</td>
</tr>
<tr>
<td>MPL204T</td>
<td>Experimental Pharmacology practical- II</td>
<td>4</td>
<td>4</td>
<td>4</td>
<td>100</td>
</tr>
<tr>
<td>MPL205P</td>
<td>Pharmacology Practical II</td>
<td>12</td>
<td>6</td>
<td>12</td>
<td>150</td>
</tr>
<tr>
<td></td>
<td>Seminar/Assignment</td>
<td>7</td>
<td>4</td>
<td>7</td>
<td>100</td>
</tr>
<tr>
<td></td>
<td><strong>Total</strong></td>
<td><strong>35</strong></td>
<td><strong>26</strong></td>
<td><strong>35</strong></td>
<td><strong>650</strong></td>
</tr>
</tbody>
</table>
### Table – 13: Course of study for M. Pharm. III Semester
(Common for All Specializations)

<table>
<thead>
<tr>
<th>Course Code</th>
<th>Course</th>
<th>Credit Hours</th>
<th>Credit Points</th>
</tr>
</thead>
<tbody>
<tr>
<td>MRM101T</td>
<td>Research Methodology and Biostatistics*</td>
<td>4</td>
<td>4</td>
</tr>
<tr>
<td>-</td>
<td>Journal club</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>-</td>
<td>Discussion / Presentation</td>
<td>2</td>
<td>2</td>
</tr>
<tr>
<td>-</td>
<td>(Proposal Presentation)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>-</td>
<td>Research Work</td>
<td>28</td>
<td>14</td>
</tr>
<tr>
<td></td>
<td><strong>Total</strong></td>
<td><strong>35</strong></td>
<td><strong>21</strong></td>
</tr>
</tbody>
</table>

*Non University Exam

### Table – 14: Course of study for M. Pharm. IV Semester
(Common for All Specializations)

<table>
<thead>
<tr>
<th>Course Code</th>
<th>Course</th>
<th>Credit Hours</th>
<th>Credit Points</th>
</tr>
</thead>
<tbody>
<tr>
<td>-</td>
<td>Journal Club</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>-</td>
<td>Research Work</td>
<td>31</td>
<td>16</td>
</tr>
<tr>
<td>-</td>
<td>Discussion/Final Presentation</td>
<td>3</td>
<td>3</td>
</tr>
<tr>
<td></td>
<td><strong>Total</strong></td>
<td><strong>35</strong></td>
<td><strong>20</strong></td>
</tr>
</tbody>
</table>

### Table – 15: Semester wise credits distribution

<table>
<thead>
<tr>
<th>Semester</th>
<th>Credit Points</th>
</tr>
</thead>
<tbody>
<tr>
<td>I</td>
<td>26</td>
</tr>
<tr>
<td>II</td>
<td>26</td>
</tr>
<tr>
<td>III</td>
<td>21</td>
</tr>
<tr>
<td>IV</td>
<td>20</td>
</tr>
<tr>
<td>Co-curricular Activities (Attending Conference, Scientific Presentations and Other Scholarly Activities)</td>
<td>Minimum=02 Maximum=07*</td>
</tr>
<tr>
<td>Total Credit Points</td>
<td>Minimum=95 Maximum=100*</td>
</tr>
</tbody>
</table>

*Credit Points for Co-curricular Activities
Table – 16: Guidelines for Awarding Credit Points for Co-curricular Activities

<table>
<thead>
<tr>
<th>Name of the Activity</th>
<th>Maximum Credit Points Eligible / Activity</th>
</tr>
</thead>
<tbody>
<tr>
<td>Participation in National Level Seminar/Conference/Workshop/Symposium/Training Programs (related to the specialization of the student)</td>
<td>01</td>
</tr>
<tr>
<td>Participation in international Level Seminar/Conference/Workshop/Symposium/Training Programs (related to the specialization of the student)</td>
<td>02</td>
</tr>
<tr>
<td>Academic Award/Research Award from State Level/National Agencies</td>
<td>01</td>
</tr>
<tr>
<td>Academic Award/Research Award from International Agencies</td>
<td>02</td>
</tr>
<tr>
<td>Research / Review Publication in National Journals (Indexed in Scopus / Web of Science)</td>
<td>01</td>
</tr>
<tr>
<td>Research / Review Publication in International Journals (Indexed in Scopus / Web of Science)</td>
<td>02</td>
</tr>
</tbody>
</table>

Note: International Conference: Held Outside India
International Journal: The Editorial Board Outside India

* The credit points assigned for extracurricular and or co-curricular activities shall be given by the Principals of the colleges and the same shall be submitted to the University. The criteria to acquire this credit point shall be defined by the colleges from time to time.

10. Program Committee

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

2. The composition of the Programme Committee shall be as follows:

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

3. Duties of the Programme Committee:

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

11. Examinations/Assessments
The schemes for internal assessment and end semester examinations are given in Table – XVII.

11.1. End semester examinations
The End Semester Examinations for each theory and practical course through semesters I to IV shall be conducted by the respective university except for the subject with asterix symbol (*) in table I and II for which examinations shall be conducted by the subject experts at college level and the marks/grades shall be submitted to the university.
### Tables – 24: Schemes for internal assessments and end semester examinations (Pharmacology)

<table>
<thead>
<tr>
<th>Course Code</th>
<th>Course</th>
<th>Internal Assessment</th>
<th>End Semester Exams</th>
<th>Total Marks</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Continuous Mode</td>
<td>Sessional Exams</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Marks</td>
<td>Duration</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>SEMESTER I</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>MPA101T</td>
<td>Modern Pharmaceutical Analytical Techniques</td>
<td>10</td>
<td>15</td>
<td>25</td>
</tr>
<tr>
<td></td>
<td></td>
<td>1 Hr</td>
<td>3 Hrs</td>
<td>100</td>
</tr>
<tr>
<td>MPL101T</td>
<td>Advanced Pharmacology-I</td>
<td>10</td>
<td>15</td>
<td>25</td>
</tr>
<tr>
<td></td>
<td></td>
<td>1 Hr</td>
<td>3 Hrs</td>
<td>100</td>
</tr>
<tr>
<td>MPL102T</td>
<td>Pharmacological and Toxicological Screening Methods-I</td>
<td>10</td>
<td>15</td>
<td>25</td>
</tr>
<tr>
<td></td>
<td></td>
<td>1 Hr</td>
<td>3 Hrs</td>
<td>100</td>
</tr>
<tr>
<td>MPL103T</td>
<td>Cellular and Molecular Pharmacology</td>
<td>10</td>
<td>15</td>
<td>25</td>
</tr>
<tr>
<td></td>
<td></td>
<td>1 Hr</td>
<td>3 Hrs</td>
<td>100</td>
</tr>
<tr>
<td>MPL104P</td>
<td>Pharmacology Practical I</td>
<td>20</td>
<td>30</td>
<td>50</td>
</tr>
<tr>
<td></td>
<td></td>
<td>6 Hrs</td>
<td>6 Hrs</td>
<td>150</td>
</tr>
<tr>
<td>-</td>
<td>Seminar /Assignment</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td></td>
<td></td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>100</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td><strong>Total 650</strong></td>
</tr>
</tbody>
</table>

| **SEMESTER II** |                                             |                     |                    |             |
| MPL201T       | Advanced Pharmacology II                    | 10                  | 15                 | 25          |
|             |                                             | 1 Hr                | 3 Hrs              | 100         |
| MPL102T      | Pharmacological and Toxicological Screening Methods-II | 10                  | 15                 | 25          |
|             |                                             | 1 Hr                | 3 Hrs              | 100         |
| MPL203T      | Principles of Drug Discovery               | 10                  | 15                 | 25          |
|             |                                             | 1 Hr                | 3 Hrs              | 100         |
| MPL204T      | Experimental Pharmacology practical-II     | 10                  | 15                 | 25          |
|             |                                             | 1 Hr                | 3 Hrs              | 100         |
| MPL205P      | Pharmacology Practical II                  | 20                  | 30                 | 50          |
|             |                                             | 6 Hrs               | 6 Hrs              | 150         |
| -           | Seminar /Assignment                         | -                   | -                  | -           |
|             |                                             | -                   | -                  | -           |
|             |                                             |                     |                    | 100         |
|             |                                             |                     |                    | **Total 650** |
### Tables – 28: Schemes for internal assessments and end semester examinations (Semester III& IV)

<table>
<thead>
<tr>
<th>Course Code</th>
<th>Course</th>
<th>Internal Assessment</th>
<th>End Semester Exams</th>
<th>Total Marks</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Continuous Mode</td>
<td>Sessional Exams</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Marks</td>
<td>Duration</td>
<td>Total Marks</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>SEMESTER III</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>MRM101T</td>
<td>Research Methodology and Biostatistics*</td>
<td>10</td>
<td>15</td>
<td>1 Hr</td>
</tr>
<tr>
<td></td>
<td>- Journal club</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>- Discussion / Presentation (Proposal Presentation)</td>
<td>25</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td></td>
<td>- Research work*</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>SEMESTER IV</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>- Journal club</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>- Discussion / Presentation (Proposal Presentation)</td>
<td>75</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td></td>
<td>- Research work and Colloquium</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

*Non University Examination
11.2. Internal assessment: Continuous mode
The marks allocated for Continuous mode of Internal Assessment shall be awarded as per the scheme given below.

Table – 29: Scheme for awarding internal assessment: Continuous mode

<table>
<thead>
<tr>
<th>Criteria</th>
<th>Theory</th>
<th>Maximum Marks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Attendance (Refer Table – 30)</td>
<td></td>
<td>8</td>
</tr>
<tr>
<td>Student – Teacher interaction</td>
<td></td>
<td>2</td>
</tr>
<tr>
<td>Total</td>
<td></td>
<td>10</td>
</tr>
</tbody>
</table>

**Practical**

<table>
<thead>
<tr>
<th>Criteria</th>
<th></th>
<th>10</th>
</tr>
</thead>
<tbody>
<tr>
<td>Attendance (Refer Table – 30)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Based on Practical Records, Regular viva voce, etc.</td>
<td></td>
<td>10</td>
</tr>
<tr>
<td>Total</td>
<td></td>
<td>20</td>
</tr>
</tbody>
</table>

Table – 30: Guidelines for the allotment of marks for attendance

<table>
<thead>
<tr>
<th>Percentage of Attendance</th>
<th>Theory</th>
<th>Practical</th>
</tr>
</thead>
<tbody>
<tr>
<td>95 – 100</td>
<td>8</td>
<td>10</td>
</tr>
<tr>
<td>90 – 94</td>
<td>6</td>
<td>7.5</td>
</tr>
<tr>
<td>85 – 89</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>80 – 84</td>
<td>2</td>
<td>2.5</td>
</tr>
<tr>
<td>Less than 80</td>
<td>0</td>
<td>0</td>
</tr>
</tbody>
</table>

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

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

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

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

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

<table>
<thead>
<tr>
<th>Table – 31: Tentative schedule of end semester examinations</th>
</tr>
</thead>
<tbody>
<tr>
<td>Semester</td>
</tr>
<tr>
<td>----------</td>
</tr>
<tr>
<td>I and III</td>
</tr>
<tr>
<td>II and IV</td>
</tr>
</tbody>
</table>

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

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

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

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

17. Grading of performances
17.1. Letter grades and grade points allocations:
Based on the performances, each student shall be awarded a final letter grade at the end of the semester for each course. The letter grades and their corresponding grade points are given in Table – 32:
Table – 32: Letter grades and grade points equivalent to Percentage of marks and performances

<table>
<thead>
<tr>
<th>Percentage of Marks Obtained</th>
<th>Letter Grade</th>
<th>Grade Point</th>
<th>Performance</th>
</tr>
</thead>
<tbody>
<tr>
<td>90.00 – 100</td>
<td>O</td>
<td>10</td>
<td>Outstanding</td>
</tr>
<tr>
<td>80.00 – 89.99</td>
<td>A</td>
<td>9</td>
<td>Excellent</td>
</tr>
<tr>
<td>70.00 – 79.99</td>
<td>B</td>
<td>8</td>
<td>Good</td>
</tr>
<tr>
<td>60.00 – 69.99</td>
<td>C</td>
<td>7</td>
<td>Fair</td>
</tr>
<tr>
<td>50.00 – 59.99</td>
<td>D</td>
<td>6</td>
<td>Average</td>
</tr>
<tr>
<td>Less than 50</td>
<td>F</td>
<td>0</td>
<td>Fail</td>
</tr>
<tr>
<td>Absent</td>
<td>AB</td>
<td>0</td>
<td>Fail</td>
</tr>
</tbody>
</table>

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

18. The Semester grade point average (SGPA)
The performance of a student in a semester is indicated by a number called ‘Semester Grade Point Average’ (SGPA). The SGPA is the weighted average of the grade points obtained in all the courses by the student during the semester. For example, if a student takes five courses (Theory/Practical) in a semester with credits 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, the SGPA shall then be computed as:

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

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

$$\text{CGPA} = \frac{C_1 S_1 + C_2 S_2 + C_3 S_3 + C_4 S_4}{C_1 + C_2 + C_3 + C_4}$$

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

20. **Declaration of class**
The class shall be awarded on the basis of CGPA as follows:
- First Class with Distinction = CGPA of 7.50 and above
- First Class = CGPA of 6.00 to 7.49
- Second Class = CGPA of 5.00 to 5.99

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

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

<table>
<thead>
<tr>
<th>Component</th>
<th>Marks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Objective(s) of the work done</td>
<td>50</td>
</tr>
<tr>
<td>Methodology adopted</td>
<td>150</td>
</tr>
<tr>
<td>Results and Discussions</td>
<td>250</td>
</tr>
<tr>
<td>Conclusions and Outcomes</td>
<td>50</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>500</strong></td>
</tr>
</tbody>
</table>

### Evaluation of Presentation:

<table>
<thead>
<tr>
<th>Component</th>
<th>Marks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Presentation of work</td>
<td>100</td>
</tr>
<tr>
<td>Communication skills</td>
<td>50</td>
</tr>
<tr>
<td>Question and answer skills</td>
<td>100</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>250</strong></td>
</tr>
</tbody>
</table>

22. **Award of Ranks**

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

23. **Award of degree**

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

24. **Duration for completion of the program of study**

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

25. **Revaluation / Retotaling of answer papers**

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

26. **Re-admission after break of study**

Candidate who seeks re-admission to the program after break of study has to get the approval from the university by paying a condonation fee.
PHARMACOLOGY
(MPC)
**SEMESTER I**

1. MODERN PHARMACEUTICAL ANALYSIS
2. ADVANCED PHARMACOLOGY-I
3. PHARMACOLOGICAL AND TOXICOLOGICAL SCREENING METHODS-I
4. CELLULAR AND MOLECULAR PHARMACOLOGY

Practicals

**SEMESTER I**

1. ADVANCED PHARMACOLOGY-II
2. TOXICOLOGICAL SCREENING METHODS
3. PRINCIPLES OF DRUG DISCOVERY
4. CLINICAL RESEARCH AND PHARMACOVIGILANCE
5. EXPERIMENTAL PHARMACOLOGY-II

Practicals

*Soft skills should be added in research methodology and biostatistics paper in semester III

*Practical in Modern pharmaceutical with emphasis on analysis case study
MODERN PHARMACEUTICAL ANALYSIS (MPA101T)

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,

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

THEORY HOURS

1. UV-Visible spectroscopy: Introduction, Theory, Laws, Instrumentation 12 Hrs
   associated with UV-Visible spectroscopy, Choice of solvents and solvent effect and Applications of UV-Visible spectroscopy.
   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
   Spectrofluorimetry: Theory of Fluorescence, Factors affecting fluorescence, 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, 12 Hrs
   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.

3 Mass Spectroscopy: Principle, Theory, Instrumentation of Mass 12 Hrs
   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
4 Chromatography: Principle, apparatus, instrumentation, chromatographic parameters, factors affecting resolution and applications of the following:
   a) Paper chromatography b) Thin Layer chromatography
c) Ion exchange chromatography d) Column chromatography
e) Gas chromatography f) High Performance Liquid chromatography
g) Affinity chromatography

12 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 of crystals and applications of X-ray diffraction.

REFERENCES
ADVANCED PHARMACOLOGY-I (MPL101T)

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:

1. Discuss the pathophysiology and pharmacotherapy of certain diseases
2. Explain the mechanism of drug actions at cellular and molecular level
3. Understand the adverse effects, contraindications and clinical uses of drugs used in treatment of diseases

THEORY 60 HOURS
UNIT-I
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. 06 hrs
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. 06 hrs

UNIT-II
12 Hrs
Neurotransmission
06 Hrs
a. General aspects and steps involved in neurotransmission.
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
06 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.
a. Autonomic Pharmacology
Parasympathomimetics and lytics, sympathomimetics and lytics, agents affecting neuromuscular junction

UNIT-III

12 Hrs
Central nervous system Pharmacology
General and local anesthetics 02 hrs
Sedatives and hypnotics, drugs used to treat anxiety. 02 hrs
Depression, psychosis, mania, epilepsy, neurodegenerative diseases. 05 hrs
Narcotic and non-narcotic analgesics. 03 hrs

UNIT-IV
Cardiovascular Pharmacology
12 Hrs
Diuretics, antihypertensives, antiischemics, anti- arrhythmics, drugs for heart failure and hyperlipidemia. 07 hrs
Hematinics, coagulants, anticoagulants, fibrinolytics and anti-platelet drugs 05 hrs

UNIT- V
Autocoid Pharmacology
12 Hrs
The physiological and pathological role of Histamine, Serotonin, Kinins Prostaglandins Opioid autocoids. 08 hrs
Pharmacology of antihistamines, 5HT antagonists. 04 hrs

REFERENCES
1. The Pharmacological basis of therapeutics- Goodman and Gill man’s
3. Basic and Clinical Pharmacology by B.G -Katzung
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
PHARMACOLOGICAL AND TOXICOLOGICAL SCREENING METHODS-I  
(MPL102T)

**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 HOURS**

**Unit-I**

12 Hrs

**Laboratory Animals**

Common lab animals: Description, handling and applications of different species and strains of animals. 02 hrs

Transgenic animals: Production, maintenance and applications 02 hrs

Anaesthesia and euthanasia of experimental animals. 03 hrs

Maintenance and breeding of laboratory animals. 02 hrs

CPCSEA guidelines to conduct experiments on animals 02 hrs

Good laboratory practice. 01 hrs

**Unit-II**

12 Hrs

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 coordination, CNS stimulants and depressants, anxiolytics, anti-psychotics, anti epileptics

Unit-III
12 Hrs
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.

Unit-IV
12 hrs
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, antihyperlipidemic, and agents. Anti cancer agents

Unit V
12 hrs
Preclinical screening of new substances for the pharmacological activity using *in vivo*, *in vitro*, and other possible animal alternative models.
Immunosuppressants and immunomodulators 02 hrs
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 08 hrs
Limitations of animal experimentation and alternate animal experiments. 01 hr
Extrapolation of *in vitro* data to preclinical and preclinical to humans. 01 hr

REFERENCES

1. Biological standardization by J.H. Burn D.J. Finney and I.G. Goodwin
2. Indian Pharmacopeia and other Pharmacopeias
3. Screening methods in Pharmacology by Robert Turner. A
4. Evaluation of drugs activities by Laurence and Bachrach
7. Pharmacological experiment on intact preparations by Churchill Livingstone
8. Drug discovery and Evaluation by Vogel H.G.
CELLULAR AND MOLECULAR PHARMACOLOGY (MPL103T)

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.

Unit I
12 Hrs
Cell biology
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.

Unit II
12 Hrs
Cell signaling
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.

Unit III
12 Hrs
Principles and applications of genomic and proteomic tools 06 hrs
DNA electrophoresis, PCR (reverse transcription and real time), Gene sequencing, microarray technique, SDS page, ELISA and western blotting,

**Recombinant DNA technology and gene therapy**  
06 hrs
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**
12Hrs

**Pharmacogenomics**  
08 hrs
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**  
04 hrs
Types of immunotherapeutics, humanisation antibody therapy, Immunotherapeutics in clinical practice

**Unit V**
12Hrs

**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 influx assays
Principles and applications of flow cytometry

**Unit VI**

Biosimilars

**References:**

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)

Experimental Pharmacology- I (MPL104P)
1. Analysis of pharmacopoeial compounds and their formulations by UV Vis spectrophotometer
2. Simultaneous estimation of multi component containing formulations by UV spectrophotometry
3. Experiments based on HPLC
4. Experiments based on Gas Chromatography
5. Estimation of riboflavin/quinine sulphate by fluorimetry
6. Estimation of sodium/potassium by flame photometry

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.
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).
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
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)
ADVANCED PHARMACOLOGY-II (MPL201T)

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 mechanism involved.

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

UNIT-I
Endocrine Pharmacology
12 Hrs
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
12 Hrs
Cellular and molecular mechanism of actions and resistance of antimicrobial agents such as β-lactams, aminoglycosides, quinolones, Macrolide antibiotics. Antifungal, antiviral, and anti-TB drugs.

UNIT-III
Chemotherapy
06 Hrs
Drugs used in Protozoal Infections
Drugs used in the treatment of Helminthiasis
Chemotherapy of cancer
Immunopharmacology
06 Hrs
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
08 Hrs
Antiulcer drugs, Prokinetics, antiemetics, anti-diarrheals and drugs for constipation and irritable bowel syndrome.

Chronopharmacology
04 Hrs
Biological and circadian rhythms, applications of chronotherapy in various diseases like cardiovascular disease, diabetes, asthma and peptic ulcer

UNIT-V
Free radicals Pharmacology
04 Hrs
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:
08 Hrs
Alzheimer ’s disease, Parkinson’s disease , Cancer, Diabetes mellitus

References
1. The Pharmacological basis of therapeutics- Goodman and Gill man’s
3. Basic and Clinical Pharmacology by B.G -Katzung
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
TOXICOLOGICAL SCREENING METHODS (MPL202T)

Scope:
The 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.

Unit I
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

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

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

REFERENCES
1. Hand book on GLP, Quality practices for regulated non-clinical research and
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.
5. OECD test guidelines.
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/guidanceregulatoryinformation/guidances/ucm073246.pdf)
PRINCIPLES OF DRUG DISCOVERY (MPL203T)

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

Unit-I 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.

Unit-II 12 Hrs
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-III 12 Hrs
Rational Drug Design

Virtual Screening techniques: Drug likeness screening, Concept of pharmacophore mapping and pharmacophore based Screening,
Unit-IV 12 Hrs
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-V 12 Hrs
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

References


2. Darryl León. Scott MarkellIn. Silico Technologies in Drug Target Identification and Validation. 2006 by Taylor and Francis Group, LLC.


CLINICAL RESEARCH AND PHARMACOVIGILANCE
(MPL204T)

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

UNIT-I  
12 hours

Regulatory Perspectives of Clinical Trials:

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

UNIT- II  
12 hours

Clinical Trials: Types and Design
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

UNIT- III
12 hours

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


UNIT-IV
12 hours

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


UNIT-VI

Pharmacoepi Dermatology, pharmacoconomics, safety pharmacology

References:

**Experimental Pharmacology-II (MPL205P)**

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 the strength of unknown sample by matching bioassay by using suitable tissue preparation.
4. To determine the strength of unknown sample by interpolation bioassay by using suitable tissue preparation.
5. To determine the strength of unknown sample by bracketing bioassay by using suitable tissue preparation.
6. To determine 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.
15. Drug mutagenicity study using mice bone-marrow chromosomal aberration test.
17. Protocol design for clinical trial.
18. Protocol design for clinical trial.
20. In silico docking studies.
21. In silico pharmacophore based screening.
22. In silico QSAR studies.
23. ADR reporting
24. In silico docking studies.

References
1. Fundamentals of experimental Pharmacology-by M.N.Ghosh
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.