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

Credit Based Semester System

M. PHARM. PHARMACEUTICS (MPH)

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 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 semestershall 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 1.

<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 – 7: Course of study for M. Pharm. (Pharmaceutics)

<table>
<thead>
<tr>
<th>Course Code</th>
<th>Course</th>
<th>Credit Hours</th>
<th>Credit Points</th>
<th>Hrs/wk</th>
<th>Marks</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Semester I</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<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>MPH101T</td>
<td>Modified Release Drug Delivery System</td>
<td>4</td>
<td>4</td>
<td>4</td>
<td>100</td>
</tr>
<tr>
<td>MPH102T</td>
<td>Modern Pharmaceutics</td>
<td>4</td>
<td>4</td>
<td>4</td>
<td>100</td>
</tr>
<tr>
<td>MPH103T</td>
<td>Pharmaceutical Regulatory Affair</td>
<td>4</td>
<td>4</td>
<td>4</td>
<td>100</td>
</tr>
<tr>
<td>MPH104P</td>
<td>Pharmaceutics 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><strong>Total</strong></td>
<td></td>
<td>35</td>
<td>26</td>
<td>35</td>
<td>650</td>
</tr>
<tr>
<td><strong>Semester II</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>MPH201T</td>
<td>Molecular Pharmaceutics (Nano Tech and Targeted DDS)</td>
<td>4</td>
<td>4</td>
<td>4</td>
<td>100</td>
</tr>
<tr>
<td>MPH202T</td>
<td>Advanced Biopharmaceutics &amp; Pharmacokinetics</td>
<td>4</td>
<td>4</td>
<td>4</td>
<td>100</td>
</tr>
<tr>
<td>MPH203T</td>
<td>Computer Aided Drug Delivery System</td>
<td>4</td>
<td>4</td>
<td>4</td>
<td>100</td>
</tr>
<tr>
<td>MPH204T</td>
<td>Cosmetic and Cosmeceuticals</td>
<td>4</td>
<td>4</td>
<td>4</td>
<td>100</td>
</tr>
<tr>
<td>MPH205P</td>
<td>Pharmaceutics 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><strong>Total</strong></td>
<td></td>
<td>35</td>
<td>26</td>
<td>35</td>
<td>650</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 (Proposal Presentation)</td>
<td>2</td>
<td>2</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 – 22: Schemes for internal assessments and end semester examinations (Pharmaceutics)

<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><strong>Continuous Mode</strong></td>
<td><strong>Sessional Exams</strong></td>
<td><strong>Total</strong></td>
</tr>
<tr>
<td></td>
<td></td>
<td><strong>Marks</strong></td>
<td><strong>Duration</strong></td>
<td><strong>Marks</strong></td>
</tr>
</tbody>
</table>

**SEMESTER I**

<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>MPA101T</td>
<td>Modern Pharmaceutical Analytical Techniques</td>
<td>10 15 1 Hr 25 75 3 Hrs</td>
<td>100</td>
<td></td>
</tr>
<tr>
<td>MPH101T</td>
<td>Modified Release Drug Delivery System</td>
<td>10 15 1 Hr 25 75 3 Hrs</td>
<td>100</td>
<td></td>
</tr>
<tr>
<td>MPH102T</td>
<td>Modern Pharmaceutics</td>
<td>10 15 1 Hr 25 75 3 Hrs</td>
<td>100</td>
<td></td>
</tr>
<tr>
<td>MPH103T</td>
<td>Pharmaceutical Regulatory Affair</td>
<td>10 15 1 Hr 25 75 3 Hrs</td>
<td>100</td>
<td></td>
</tr>
<tr>
<td>MPH104P</td>
<td>Pharmaceuticals Practical I</td>
<td>20 30 6 Hrs 50 100 6 Hrs</td>
<td>150</td>
<td></td>
</tr>
<tr>
<td>-</td>
<td>Seminar /Assignment</td>
<td>- - - - - -</td>
<td>100</td>
<td></td>
</tr>
</tbody>
</table>

**SEMESTER II**

<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>MPH201T</td>
<td>Molecular Pharmaceutics(Nano Tech and Targeted DDS)</td>
<td>10 15 1 Hr 25 75 3 Hrs</td>
<td>100</td>
<td></td>
</tr>
<tr>
<td>MPH202T</td>
<td>Advanced Biopharmaceutics &amp; Pharmacokinetics</td>
<td>10 15 1 Hr 25 75 3 Hrs</td>
<td>100</td>
<td></td>
</tr>
<tr>
<td>MPH203T</td>
<td>Computer Aided Drug Delivery System</td>
<td>10 15 1 Hr 25 75 3 Hrs</td>
<td>100</td>
<td></td>
</tr>
<tr>
<td>MPH204T</td>
<td>Cosmetic and Cosmeceuticals</td>
<td>10 15 1 Hr 25 75 3 Hrs</td>
<td>100</td>
<td></td>
</tr>
<tr>
<td>MPH205P</td>
<td>Pharmaceuticals Practical I</td>
<td>20 30 6 Hrs 50 100 6 Hrs</td>
<td>150</td>
<td></td>
</tr>
<tr>
<td>-</td>
<td>Seminar /Assignment</td>
<td>- - - - - -</td>
<td>100</td>
<td></td>
</tr>
</tbody>
</table>

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><strong>SEMESTER III</strong></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>Discussion / Presentation (Proposal Presentation)</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>-</td>
<td>Research work*</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td></td>
<td><strong>Total</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>SEMESTER IV</strong></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>-</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><strong>Total</strong></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><strong>Total</strong></td>
<td></td>
<td><strong>10</strong></td>
</tr>
</tbody>
</table>

**Practical**

| Attendance (Refer Table – 30)                        |        | 10            |
| Based on Practical Records, Regular viva voce, etc.   |        | 10            |
| **Total**                                            |        | **20**        |

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 – 31: Tentative schedule of end semester examinations

<table>
<thead>
<tr>
<th>Semester</th>
<th>For Regular Candidates</th>
<th>For Failed Candidates</th>
</tr>
</thead>
<tbody>
<tr>
<td>I and III</td>
<td>November / December</td>
<td>May / June</td>
</tr>
<tr>
<td>II and IV</td>
<td>May / June</td>
<td>November / December</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:

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

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

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

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

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

where \(C_1, C_2, C_3, \ldots\) 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:**

| 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

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.
M. PHARM. PHARMACEUTICS (MPH)
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 of the instruments

THEORY 60 HOURS


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, 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 $^{13}$C NMR. Applications of NMR 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

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) Isoelectric 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.

6 **Immunological assays**: RIA (Radio immuno assay), ELISA, Bioluminescence assays.

**REFERENCES**
DRUG DELIVERY SYSTEM (MPH101T)

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

OBJECTIVES

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

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

THEORY


4. **Ocular Drug Delivery Systems**: Barriers of drug permeation, Methods to overcome barriers.


6. **Protein and Peptide Delivery**: Barriers for protein delivery. Formulation and Evaluation of delivery systems of proteins and other macromolecules.
7. **Vaccine delivery systems**: Vaccines, uptake of antigens, single shot vaccines, mucosal and transdermal delivery of vaccines.

**REFERENCES**
5. S.P.Vyas and R.K.Khar, Controlled Drug Delivery - concepts and advances, Vallabh Prakashan, New Delhi, First edition 2002

**JOURNALS**
1. Indian Journal of Pharmaceutical Sciences (IPA)
2. Indian drugs (IDMA)
3. Journal of controlled release (Elsevier Sciences) desirable
4. Drug Development and Industrial Pharmacy (Marcel & Decker) desirable
MODERN PHARMACEUTICS (MPH102T)

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

Objectives
Upon completion of the course, student shall be able to understand
- To understand the elements of preformulation studies.
- To understand the Active Pharmaceutical Ingredients and Generic drug Product development
- To learn Industrial Management and GMP Considerations.
- To understand Optimization Techniques & Pilot Plant Scale Up Techniques
- To study Stability Testing, sterilization process & packaging of dosage forms.

THEORY
60 HRS

10 hrs
1. **Preformation Concepts** – Drug Excipient interactions - different methods, kinetics of stability, Stability testing.
   Theories of dispersion and pharmaceutical Dispersion (Emulsion and Suspension, SMEDDS) preparation and stability
   Large and small volume parental – physiological and formulation consideration, Manufacturing and evaluation

2. **Optimization techniques in Pharmaceutical Formulation**: Concept and parameters of optimization, Optimization techniques in pharmaceutical formulation and processing. Statistical design, Response surface method, Contour designs, Factorial designs and application in formulation.

3. **Validation** : Introduction to Pharmaceutical Validation, Scope & merits of Validation, , Validation and calibration of Master plan, ICH & WHO guidelines for calibration and validation of equipments, Validation of specific dosage form, Types of validation. Government regulation, Manufacturing Process Model, URS, DQ, IQ, OQ & P.Q. of facilities

10 Hrs
4. **cGMP & Industrial Management**: Objectives and policies of current good manufacturing practices, layout of buildings, services, equipments and their maintenance Production management: Production organization, materials
management, handling and transportation, inventory management and control, production and planning control, Sales forecasting, budget and cost control, industrial and personal relationship. Concept of Total Quality Management


REFERENCES
1. Theory and Practice of Industrial Pharmacy By Lachmann and Libermann
3. Pharmaceutical Dosage forms: Disperse systems, Vol, 1-2; By Leon Lachmann.
4. Pharmaceutical Dosage forms: Parenteral medications Vol. 1-2; By Leon Lachmann.
5. Modern Pharmaceutics; By Gillbert and S. Banker.
8. Physical Pharmacy; By Alfred martin
11. Quality Assurance Guide; By Organization of Pharmaceutical producers of India.
13. How to practice GMPs; By P.P.Sharma. Vandhana Publications, Agra.
15. Pharmaceutical Preformulations; By J.J. Wells.
16. Applied production and operations management; By Evans, Anderson, Sweeney and Williams.
REGULATORY AFFAIRS (MPH103T)

Scope

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

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

Objectives:

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

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

THEORY

60 Hr

1. **Documentation in pharmaceutical industry**: Master formula record, DMF (Drug Master File), distribution records. Generic drugs product development Introduction, Hatch-Waxman act and amendments, CFR (CODE OF FEDERAL REGULATION), drug product performance, in-vitro, ANDA regulatory approval process, NDA approval process, BE and drug product assessment, in-vivo, scale up process approval changes, post marketing surveillance, outsourcing BA and BE to CRO

2. **Regulatory requirement for product approval**: API, biologics, novel, therapies obtaining NDA, ANDA for generic drugs ways and means of US registration for foreign drugs
3. CMC, post approval regulatory affairs. Regulation for combination products and medical devices. CTD and ECTD format, industry and FDA liaison. ICH - Guidelines of ICH-Q,S,E,M. Regulatory requirements of EU, MHRA, TGA and ROW countries.

12 hrs

4. Non clinical drug development: Global submission of IND, NDA, ANDA. Investigation medicinal products dossier, dossier (IMPD) and investigator brochure (IB)

12 hrs


12 hrs

REFERENCES

7. www.ich.org/
8. www.fda.gov/
9. europa.eu/index_en.htm
PRACTICALS (MPH104P)

1. Analysis of pharmacopoeial compounds and their formulations by UV Vis spectrophotometer
2. Simultaneous estimation of multi component containing formulations by UV spectrophotometry
3. Experiments based on HPLC
4. Experiments based on Gas Chromatography
5. Estimation of riboflavin/quinine sulphate by fluorimetry
6. Estimation of sodium/potassium by flame photometry
7. To perform *In-vitro* dissolution profile of CR/ SR marketed formulation
8. Formulation and evaluation of sustained release matrix tablets
9. Formulation and evaluation osmotically controlled DDS
10. Preparation and evaluation of Floating DDS- hydro dynamically balanced DDS
11. Formulation and evaluation of Muco adhesive tablets.
12. Formulation and evaluation of trans dermal patches.
13. To carry out preformulation studies of tablets.
14. To study the effect of compressional force on tablets disintegration time.
15. To study Micromeritic properties of powders and granulation.
16. To study the effect of particle size on dissolution of a tablet.
17. To study the effect of binders on dissolution of a tablet.
18. To plot Heckal plot, Higuchi and peppas plot and determine similarity factors.
MOLECULAR PHARMACEUTICS (NANO TECHNOLOGY & TARGETED DDS) (NTDS)(MPH201T)

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

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

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

THEORY
60 Hrs

12 hrs
1. **Targeted Drug Delivery Systems:** Concepts, Events and biological process involved in drug targeting. Tumor targeting and Brain specific delivery.

12 hrs
2. **Targeting Methods:** introduction preparation and evaluation. Nano Particles & Liposomes: Types, preparation and evaluation

12 hrs
3. **Micro Capsules / Micro Spheres:** Types, preparation and evaluation, Monoclonal Antibodies; preparation and application, preparation and application of Niosomes, Aquasomes, Phytosomes, Electrosomes.

12 hrs
4. **Pulmonary Drug Delivery Systems:** Aerosols, propellents, ContainersTypes, preparation and evaluation, Intra Nasal Route Delivery systems; Types, preparation and evaluation

12 hrs
5. **Veterinary Drug Delivery Systems:** Tablets and bolus, Feed additives, Drinking water medication, Oral paste and gels, Drenchers and Tubing product

REFERENCES:
1. Y W. Chien, Novel Drug Delivery Systems, 2nd edition, revised and expanded, Marcel

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

**ADVANCED BIOPHARMACEUTICS & PHARMACOKINETICS (MPH202T)**

**Scope**

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

**Objectives**

At completion of this course it is expected that students will be able understand –

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

**THEORY**

**60 Hrs**

**12hrs**


12Hrs


12Hrs


12Hrs


12Hrs


REFERENCES:

2. Biopharmaceutics and Pharmacokinetics, A. Treatise, D. M. Brahmankar and Sunil B. Jaiswal, VallabPrakashan, Pitampura, Delhi
4. Textbook of Biopharmaceutics and Pharmacokinetics, Dr. Shobha Rani R. Hiremath,Prism Book
COMPUTER AIDED DRUG DEVELOPMENT (MPH203T)

Scope

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

Objectives

At completion of this course it is expected that students will be able to understand-

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

THEORY 60Hrs


Quality-by-Design In Pharmaceutical Development: Introduction, ICH Q8 guideline, Regulatory and industry views on QbD, Scientifically based QbD - examples of application 12Hrs


4. **Computer-aided biopharmaceutical characterization**: Gastrointestinal absorption simulation
   - Introduction, Theoretical background, Model construction, Parameter sensitivity analysis, Virtual trial, Fed vs. fasted state, In vitro dissolution and *in vitro-in vivo* correlation, Biowaiver considerations
   - **Computer Simulations in Pharmacokinetics and Pharmacodynamics**: Introduction, Computer Simulation: Whole Organism, Isolated Tissues, Organs, Cell, Proteins and Genes.
   - **Computers in Clinical Development**: Clinical Data Collection and Management, Regulation of Computer Systems


REFERENCES:

COSMETICS AND COSMECEUTICALS (MPH204T)

Scope

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

Objectives: Upon completion of the course, the students will be able to understand

- The key ingredients used in cosmetics and cosmeceuticals.
- The key building blocks for various formulations.
- The current technologies in the market
- The various key ingredients and basic science to develop cosmetics and cosmeceuticals
- The scientific knowledge to develop cosmetics and cosmeceuticals with desired Safety, sensory, stability, and efficacy.

THEORY

60Hrs

12Hrs

1. Formulations approaches and Requirements
   Definition of cosmetic products as per EU guidelines. Structure of skin relating to problems like dry skin, acne, pigmentation, prickly heat, wrinkles and body odor. Structure of hair and hair growth cycle. Common problems associated with oral cavity. Cleansing and care needs for face, eye lids, lips, hands, feet, nail, scalp, neck, body and under-arms. Formulation requirements for ethnic needs.

2. Plant Lay out, factory requirements and commonly used cosmetics raw materials
   Perfumes: Classification of perfumes. Perfume ingredients listed as allergens in EU regulation.
   Controversial ingredients: Parabens, formaldehyde liberators, dioxane.

3. Design of special purpose cosmeceutical products
   Sun protection, sunscreens classification and regulatory aspects. addressing dry skin, acne,
sun-protection, pigmentation, prickly heat, wrinkles, body odor. Dandruff, dental cavities, bleeding gums, mouth odor and sensitive teeth.

12Hrs

3. **Herbal Cosmetics**

Herbal ingredients used in Hair care, skin care and oral care. Review of guidelines for herbal cosmetics by private bodies like cosmos with respect to preservatives, emollients, foaming agents, emulsifiers and rheology modifiers. Challenges in formulating herbal cosmetics.

12Hrs

4. **Formulation of Lip care products and Cosmetic Safety**

Chemistry and formulation of paraphylene diamine based hair colorants. Soaps and syndet bars Labelling requirements for cosmetics Study of salient features of cosmetic safety data base developed by private body, and International Nomenclature of Cosmetic Ingredients (INCI). Review of the list of ingredients on the labels of cosmetics, cosmeceuticals, baby care and men’s range of the products in the market and conduct comparative study of the formulations.

RECOMMENDED BOOKS:

1. Harry’s Cosmeticology. 8th edition
2. Poucher’s perfume cosmetics and Soaps, 10th edition
3. Cosmetics - Formulation, manufacture and quality control PP.Sharma, 4th edition
4. Handbook of cosmetic science and Technology A.O.Barel, M.Paye and H.I.Maibach. 3rd edition
5. Cosmetic and Toiletries recent suppliers catalogue.
6. CTFA directory.
PRACTICAL (MPH205P)

1. To study the effect of temperature change, non solvent addition, incompatible polymer addition in microcapsules preparation
2. Preparation and evaluation of Alginate beads
3. Formulation and evaluation of gelatin/albumin microspheres
4. Formulation and evaluation of liposomes
5. Formulation and evaluation of niosomes
6. Formulation and evaluation of spheruls
7. Improvement of dissolution characteristics of slightly soluble drug by solid dispersion technique.
8. Comparison of dissolution of two different marketed products/brands
9. Protein binding studies of a highly protein bound drug & poorly protein bound drug
11. Pharmacokinetic and IVIVC data analysis by Winnoline® software
12. In vitro cell studies for permeability and metabolism
14. Formulation data analysis Using Design Expert® Software
15. Quality-by-Design in Pharmaceutical Development
16. Computer Simulations in Pharmacokinetics
17. Computer Simulations Pharmacodynamics
18. Computational Modeling Of Drug Disposition
19. To develop Clinical Data Collection manual
21. Development and evaluation of Creams
22. Development and evaluation of Shampoo and Toothpaste base
23. To incorporate herbal and chemical actives to develop products
24. To address Dry skin, acne, blemish, Wrinkles, bleeding gums and dandruff