Syllabus & Regulations

for

1. M.Pharm. (Pharmaceutics)
2. M.Pharm. (Pharmaceutical Chemistry)
3. M.Pharm. (Pharmacology)
4. M.Pharm. (Pharmacognosy)

From 2018-19 onwards
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 Pondicherry University, Puducherry. They shall come into effect from the Academic Year 2018–19 onwards. 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 Pondicherry University, Puducherry.

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 14. Courses generally progress in sequence, building competencies and their positioning indicates certain academic maturity on the part of the learners. Learners are expected to follow the semester-wise schedule of courses given in the syllabus.

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

9. Course of study
The specializations in M.Pharm program is given in Table 1.

<table>
<thead>
<tr>
<th>S. No.</th>
<th>Specialization</th>
<th>Code</th>
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<th>Hrs./wk</th>
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## Course of Study for (Pharmacology)

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## Course of study for M. Pharm. (Pharmacognosy)

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### Course of study for M. Pharm. III Semester
(Common for All Specializations)

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*Non University Exam

### Course of study for M. Pharm. IV Semester
(Common for All Specializations)

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### Semester wise credits distribution

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<td>II</td>
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<td>III</td>
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<td>IV</td>
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Co-curricular Activities
(Attending Conference, Scientific Presentations and Other Scholarly Activities)

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<th>Maximum=07*</th>
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**Total Credit Points**

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<th>Minimum=95</th>
<th>Maximum=100*</th>
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*Credit Points for Co-curricular Activities
Guidelines for Awarding Credit Points for Co-curricular Activities

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

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 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.
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<th>Internal Assessment</th>
<th>End Semester Exams</th>
<th>Total Marks</th>
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<td>MPH 104T</td>
<td>Regulatory Affair</td>
<td>10</td>
<td>15</td>
<td>25</td>
</tr>
<tr>
<td>MPH 105P</td>
<td>Pharmaceutics Practical I</td>
<td>20</td>
<td>30</td>
<td>50</td>
</tr>
<tr>
<td></td>
<td>Seminar / Assignment</td>
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<td>Total</td>
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<tr>
<td>MPH 201T</td>
<td>Molecular Pharmaceutics (Nano Tech and Targeted DDS)</td>
<td>10</td>
<td>15</td>
<td>25</td>
</tr>
<tr>
<td>MPH 202T</td>
<td>Advanced Biopharmaceutics &amp; Pharmacokinetics</td>
<td>10</td>
<td>15</td>
<td>25</td>
</tr>
<tr>
<td>MPH 203T</td>
<td>Computer Aided Drug Delivery System</td>
<td>10</td>
<td>15</td>
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</tr>
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<td>MPH</td>
<td>Cosmetic</td>
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<td>Course Title</td>
<td>Credits</td>
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<tr>
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</tr>
<tr>
<td>204T</td>
<td>and Cosmeceuticals</td>
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<td>MPH</td>
<td>Pharmacetics Practical I</td>
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<td>205P</td>
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**Total**: 650
### (Pharmaceutical Chemistry-MPC)

<table>
<thead>
<tr>
<th>Course Code</th>
<th>Course</th>
<th>Continuous Mode</th>
<th>Sessional Exams</th>
<th>Internal Assessment</th>
<th>End Semester Exams</th>
<th>Total Marks</th>
</tr>
</thead>
<tbody>
<tr>
<td>MPC101T</td>
<td>Modern Pharmaceutical Analytical Techniques</td>
<td>10</td>
<td>15</td>
<td>1 Hr</td>
<td>25</td>
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<tr>
<td>MPC102T</td>
<td>Advanced Organic Chemistry -I</td>
<td>10</td>
<td>15</td>
<td>1 Hr</td>
<td>25</td>
<td>75</td>
</tr>
<tr>
<td>MPC103T</td>
<td>Advanced Medicinal chemistry</td>
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<td>15</td>
<td>1 Hr</td>
<td>25</td>
<td>75</td>
</tr>
<tr>
<td>MPC104T</td>
<td>Chemistry of Natural Products</td>
<td>10</td>
<td>15</td>
<td>1 Hr</td>
<td>25</td>
<td>75</td>
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<td>MPC105P</td>
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<td>-</td>
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### SEMESTER II

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<th>Total Marks</th>
</tr>
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<tbody>
<tr>
<td>MPC201T</td>
<td>Advanced Spectral Analysis</td>
<td>10</td>
<td>15</td>
<td>1 Hr</td>
<td>25</td>
<td>75</td>
</tr>
<tr>
<td>MPC202T</td>
<td>Advanced Organic Chemistry -II</td>
<td>10</td>
<td>15</td>
<td>1 Hr</td>
<td>25</td>
<td>75</td>
</tr>
<tr>
<td>MPC203T</td>
<td>Computer Aided Drug Design</td>
<td>10</td>
<td>15</td>
<td>1 Hr</td>
<td>25</td>
<td>75</td>
</tr>
<tr>
<td>MPC204T</td>
<td>Pharmacetical Process Chemistry</td>
<td>10</td>
<td>15</td>
<td>1 Hr</td>
<td>25</td>
<td>75</td>
</tr>
<tr>
<td>MPC205P</td>
<td>Pharmacetical Chemistry</td>
<td>20</td>
<td>30</td>
<td>6 Hrs</td>
<td>50</td>
<td>100</td>
</tr>
<tr>
<td>Practical II</td>
<td>Seminar/Assignment</td>
<td>100</td>
<td></td>
<td></td>
<td></td>
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<td>Total 650</td>
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### Schemes for internal assessments and end semester examinations (Pharmacology–MPL)

<table>
<thead>
<tr>
<th>Course Code</th>
<th>Course</th>
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<th>End Semester Exams</th>
<th>Total Marks</th>
</tr>
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<td>Sessional Exams</td>
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<td></td>
<td>Mar</td>
<td>ks</td>
<td>Duration</td>
</tr>
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<td>SEMESTER I</td>
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<tr>
<td>MPL10 1T</td>
<td>Modern Pharmaceutical Analytical Techniques</td>
<td>10</td>
<td>15</td>
<td>1 Hr</td>
</tr>
<tr>
<td>MPL10 2T</td>
<td>Advanced Pharmacology–I</td>
<td>10</td>
<td>15</td>
<td>1 Hr</td>
</tr>
<tr>
<td>MPL10 3T</td>
<td>Pharmacological and Toxicological Screening Methods–I</td>
<td>10</td>
<td>15</td>
<td>1 Hr</td>
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<tr>
<td>MPL10 4T</td>
<td>Cellular and Molecular Pharmacology</td>
<td>10</td>
<td>15</td>
<td>1 Hr</td>
</tr>
<tr>
<td>MPL10 5P</td>
<td>Experimental Pharmacology – I</td>
<td>20</td>
<td>30</td>
<td>6 Hrs</td>
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<tr>
<td></td>
<td>Seminar (Optional)</td>
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<td>-</td>
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<tr>
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<td>Total</td>
<td>650</td>
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<td></td>
</tr>
<tr>
<td>SEMESTER II</td>
<td></td>
<td></td>
<td></td>
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</tr>
<tr>
<td>MPL20 1T</td>
<td>Advanced Pharmacology II</td>
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<td>15</td>
<td>1 Hr</td>
</tr>
<tr>
<td>MPL10 2T</td>
<td>Pharmacological and Toxicological Screening Methods–II</td>
<td>10</td>
<td>15</td>
<td>1 Hr</td>
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<tr>
<td>MPL20 3T</td>
<td>Principles of Drug Discovery</td>
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<td>1 Hr</td>
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<td>MPL20 4T</td>
<td>Clinical research and pharmacovigilance</td>
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<td>15</td>
<td>1 Hr</td>
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<tr>
<td>MPL20 5P</td>
<td>Experimental Pharmacology – II</td>
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<td>30</td>
<td>6 Hrs</td>
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<tr>
<td></td>
<td>Seminar (Optional)</td>
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<td>-</td>
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### Schemes for internal assessments and end semester examinations (Pharmacognosy–MPG)

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<thead>
<tr>
<th>Course Code</th>
<th>Course</th>
<th>Internal Assessment</th>
<th>End Semester Exams</th>
<th>Total Marks</th>
</tr>
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<td>Continuous Mode</td>
<td>Sessional Exams</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Mar ks</td>
<td>Durati on</td>
<td></td>
</tr>
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<td></td>
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<td></td>
</tr>
<tr>
<td><strong>SEMIESTER I</strong></td>
<td></td>
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<tr>
<td>MPG101T</td>
<td>Modern Pharmaceutical Analytical Techniques</td>
<td>10</td>
<td>15</td>
<td>1 Hr</td>
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<tr>
<td>MPG102T</td>
<td>Advanced Pharmacognosy–I</td>
<td>10</td>
<td>15</td>
<td>1 Hr</td>
</tr>
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<td>MPG103T</td>
<td>Phytochemistry</td>
<td>10</td>
<td>15</td>
<td>1 Hr</td>
</tr>
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<td>MPG104T</td>
<td>Industrial Pharmacognostical Technology</td>
<td>10</td>
<td>15</td>
<td>1 Hr</td>
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<td>MPG105P</td>
<td>Pharmacognosy Practical I</td>
<td>20</td>
<td>30</td>
<td>6 Hrs</td>
</tr>
<tr>
<td></td>
<td>Seminar Assignment</td>
<td>-</td>
<td>-</td>
<td>-</td>
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<td>Total</td>
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<td></td>
<td></td>
</tr>
<tr>
<td><strong>SEMIESTER II</strong></td>
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<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>MPG201T</td>
<td>Medicinal Plant biotechnology</td>
<td>10</td>
<td>15</td>
<td>1 Hr</td>
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<tr>
<td>MPG102T</td>
<td>Advanced Pharmacognosy–II</td>
<td>10</td>
<td>15</td>
<td>1 Hr</td>
</tr>
<tr>
<td>MPG203T</td>
<td>Indian system of medicine</td>
<td>10</td>
<td>15</td>
<td>1 Hr</td>
</tr>
<tr>
<td>MPG204T</td>
<td>Herbal cosmetics</td>
<td>10</td>
<td>15</td>
<td>1 Hr</td>
</tr>
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<td>Pharmacognosy Practical II</td>
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<td>6 Hrs</td>
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<td></td>
<td>Seminar Assignment</td>
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<td></td>
<td>Total</td>
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### Schemes for internal assessments and end semester examinations (Semester III& IV)

<table>
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<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>Mark</td>
<td>Duration</td>
<td></td>
</tr>
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<td>Duration</td>
<td>Mark</td>
</tr>
<tr>
<td>SEMESTER III</td>
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<td></td>
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<tr>
<td>MRM301T</td>
<td>Research Methodology</td>
<td>10</td>
<td>15</td>
<td>1 Hr</td>
</tr>
<tr>
<td></td>
<td>and Biostatistics*</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>- Journal club</td>
<td>-</td>
<td>-</td>
<td>25</td>
</tr>
<tr>
<td></td>
<td>- Discussion / Presentation</td>
<td>-</td>
<td>-</td>
<td>50</td>
</tr>
<tr>
<td></td>
<td>(Proposal Presentation)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>- Research work*</td>
<td>-</td>
<td>-</td>
<td>350</td>
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<tr>
<td></td>
<td>Total</td>
<td></td>
<td></td>
<td>525</td>
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</table>

| SEMESTER IV |                               |                    |                    |             |
|             | - Journal club                | -                  | -                  | 25          | -           | - | 25   |
|             | - Discussion / Presentation   | -                  | -                  | 75          | -           | - | 75   |
|             | (Proposal Presentation)       |                    |                    |             |
|             | - Research work and           | -                  | -                  | 400         | 1 Hr        | 400 |
|             | Colloquium                    |                    |                    |             |
|             | Total                         |                    |                    | 500         |

*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.

**Scheme for awarding internal assessment: Continuous mode**

<table>
<thead>
<tr>
<th>Criteria</th>
<th>Maximum Marks</th>
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<tbody>
<tr>
<td>Attendance</td>
<td>8</td>
</tr>
<tr>
<td>Student – Teacher interaction</td>
<td>2</td>
</tr>
<tr>
<td>Total</td>
<td>10</td>
</tr>
<tr>
<td><strong>Practical</strong></td>
<td></td>
</tr>
<tr>
<td>Attendance (Refer Table – 28)</td>
<td>10</td>
</tr>
<tr>
<td>Based on Practical Records, Regular viva voce, etc.</td>
<td>10</td>
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<tr>
<td><strong>Total</strong></td>
<td>20</td>
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</tbody>
</table>

**Guidelines for the allotment of marks for attendance**

<table>
<thead>
<tr>
<th>Percentage of Attendance</th>
<th>Theory</th>
<th>Practical</th>
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</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>
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</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 in the table. The average marks of two sessional exams shall be computed for internal assessment as per the requirements given in tables.

12. Promotion and award of grades

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

13. Carry forward of marks

In case a student fails to secure the minimum 50% in any Theory or Practical course as specified in 12, then he/she shall reappear for the end semester examination of that course. However his/her marks of the Internal Assessment shall be carried over and he/she shall be entitled for grade obtained by him/her on passing.
14. Improvement of internal assessment
A student shall have the opportunity to improve his/her performance only once in the sessional exam component of the internal assessment. The re-conduct of the sessional exam shall be completed before the commencement of next end semester theory examinations.

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

<table>
<thead>
<tr>
<th>Tentative schedule of end semester examinations</th>
</tr>
</thead>
<tbody>
<tr>
<td>Semester</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 below.
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:

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

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 I 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.
Scope
This subject deals with various advanced analytical instrumental techniques for identification, characterization and quantification of drugs. Instruments dealt are NMR, Mass spectrometer, IR, HPLC, GC etc.

Objectives
After completion of course student is able to know,
   Chemicals and Excipients
   The analysis of various drugs in single and combination dosage forms Theoretical and practical skills of the instruments

THEORY 60 HOURS

b. IR spectroscopy: Theory, Modes of Molecular vibrations, Sample handling, Instrumentation of Dispersive and Fourier – Transform IR Spectrometer, Factors affecting vibrational frequencies and Applications of IR spectroscopy


2 NMR spectroscopy: Quantum numbers and their role in NMR, 11 Principle, Instrumentation, Solvent requirement in NMR, Hrs 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.
Mass Spectroscopy: Principle, Theory, Instrumentation of Mass 11
Spectroscopy, Different types of ionization like electron impact, Hrs 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

Chromatography: Principle, apparatus, instrumentation, 11 chromatographic parameters, factors affecting resolution and Hrs 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

Electrophoresis: Principle, Instrumentation, Working 11 conditions, factors affecting separation and applications of the Hrs following:
a) Paper electrophoresis b) Gel electrophoresis c) Capillary electrophoresis d) Zone electrophoresis e) Moving boundary electrophoresis f) Iso electric focusing
b. X ray Crystallography: Production of X rays, Different X ray diffraction methods, Bragg's law, Rotating crystal technique, X ray powder technique, Types of crystals and applications of X-ray diffraction.

Immunological assays: RIA (Radio immuno assay), ELISA, 5 Hrs Bioluminescence assays.

REFERENCES
DRUG DELIVERY SYSTEMS  
(MPH 102T)

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

OBJECTIVES
Upon completion of the course, student shall be able to understand
- The various approaches for development of novel drug delivery systems.
- The criteria for selection of drugs and polymers for the development of delivering system.
- The formulation and evaluation of Novel drug delivery systems.

THEORY  
60 Hrs

1. Sustained Release(SR) and Controlled Release (CR) formulations: 10 Hrs
   - Dosage Forms for Personalized Medicine: Introduction, Definition, Pharmacogenetics, Categories of Patients for Personalized Medicines: Customized drug delivery systems, Bioelectronic Medicines, 3D printing of pharmaceuticals, Telepharmacy.

2. Rate Controlled Drug Delivery Systems: Principles & 10 Fundamentals, Types, Activation; Modulated Drug Delivery Hrs


6 Protein and Peptide Delivery: Barriers for protein delivery. 08 Formulation and Evaluation of delivery systems of proteins and Hrs other macromolecules.

7 Vaccine delivery systems: Vaccines, uptake of antigens, single 06 shot vaccines, mucosal and transdermal delivery of vaccines. Hrs

REFERENCES

JOURNALS
1. Indian Journal of Pharmaceutical Sciences (IPA)
2. Indian drugs (IDMA)
3. Journal of controlled release (Elsevier Sciences) desirable
4. Drug Development and Industrial Pharmacy (Marcel & Decker) desirable
MODERN PHARMACEUTICS
(MPH 103T)

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

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

THEORY 60 HRS
   b. Optimization techniques in Pharmaceutical Formulation: 10 Concept and parameters of optimization, Optimization techniques Hrs in pharmaceutical formulation and processing. Statistical design, Response surface method, Contour designs, Factorial designs and application in formulation
3. cGMP & Industrial Management: Objectives and policies of 10 current good manufacturing practices, layout of buildings, Hrs 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.
4 Compression and compaction: Physics of tablet compression, 10 compression, consolidation, effect of friction, distribution of Hrs forces, compaction profiles. Solubility.

5 Study of consolidation parameters; Diffusion parameters, 10 Dissolution parameters and Pharmacokinetic parameters, Heckel Hrs plots, Similarity factors – f2 and f1, Higuchi and Peppas plot, Linearity Concept of significance, Standard deviation, Chi square test, students T-test, ANOVA test.

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.
17. Encyclopaedia of Pharmaceutical technology, Vol I – III.
REGULATORY AFFAIRS
(MPH 104T)

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

To know the approval process of
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

b. Regulatory requirement for product approval: API, biologics, novel, therapies obtaining NDA, ANDA for generic drugs ways and means of US registration for foreign drugs
2 CMC, post approval regulatory affairs. Regulation for combination 12 products and medical devices.CTD and ECTD format, industry Hrs and FDA liaison. ICH – Guidelines of ICH–Q, S E, M. Regulatory requirements of EU, MHRA, TGA and ROW countries.

3 Non clinical drug development: Global submission of IND, 12 Hrs NDA,ANDA.Investigation of medicinal products dossier, dossier (IMPD) and investigator brochure (IB).

4 Clinical trials: Developing clinical trial protocols. Institutional 12 review board/ independent ethics committee Formulation and Hrs working procedures informed Consent process and procedures. HIPAA– new, requirement to clinical study process, pharmacovigilance safety monitoring in clinical trials.

REFERENCES
7. www.ich.org/
8. www.fda.gov/
9. europa.eu/index_en.htm
PHARMACEUTICS PRACTICALS - I
(MPH 105P)

1. Analysis of pharmacopoeial compounds and their formulations by UV
Vis spectrophotometer
2. Simultaneous estimation of multi component containing
formulations by UV spectrophotometry
3. Experiments based on HPLC
4. Experiments based on Gas Chromatography
5. Estimation of riboflavin/quinine sulphate by fluorimetry
6. Estimation of sodium/potassium by flame photometry
7. To perform In-vitro dissolution profile of CR/ SR marketed formulation
8. Formulation and evaluation of sustained release matrix tablets
9. Formulation and evaluation osmotically controlled DDS
10. Preparation and evaluation of Floating DDS– hydro dynamically balanced
DDS
11. Formulation and evaluation of Muco adhesive tablets.
12. Formulation and evaluation of trans dermal patches.
13. To carry out preformulation studies of tablets.
14. To study the effect of compressional force on tablets disintegration time.
15. To study Micromeritic properties of powders and granulation.
16. To study the effect of particle size on dissolution of a tablet.
17. To study the effect of binders on dissolution of a tablet.
18. To plot Heckal plot, Higuchi and peppas plot and determine
similarity factors.
MOLECULAR PHARMACEUTICS (NANO TECHNOLOGY & TARGETED DDS) (NTDS)  
(MPH 201T)

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

Objectives
Upon completion of the course student shall be able to understand
The various approaches for development of novel drug delivery systems.
The criteria for selection of drugs and polymers for the development of NTDS
The formulation and evaluation of novel drug delivery systems.

THEORY


REFERENCES
ADVANCED BIOPHARMACEUTICS & PHARMACOKINETICS (MPH 202T)

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

Objectives
Upon completion of this course it is expected that students will be able understand,

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

THEORY 60 Hrs
1. Drug Absorption from the Gastrointestinal Tract: 12 Hrs


4 Drug Product Performance, In Vivo: Bioavailability and Bioequivalence: drug product performance, purpose of bioavailability studies, relative and absolute availability. methods for assessing bioavailability, bioequivalence studies, design and evaluation of bioequivalence studies, study designs, crossover study designs, evaluation of the data, bioequivalence example, study submission and drug review process. biopharmaceutics classification system, methods. Permeability: In–vitro, in–situ and In–vivo methods. generic biologics (biosimilar drug products), clinical significance of bioequivalence studies, special concerns in bioavailability and bioequivalence studies, generic substitution.

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
(MPH 203T)

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

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

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

THEORY 60 Hrs


c. Computers in Clinical Development: Clinical Data Collection and Management, Regulation of Computer Systems


REFERENCES


COSMETICS AND COSMECEUTICALS  
(MPH 204T)

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

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

- Key ingredients used in cosmetics and cosmeceuticals.
- Key building blocks for various formulations.
- Current technologies in the market
- Various key ingredients and basic science to develop cosmetics and cosmeceuticals
- Scientific knowledge to develop cosmetics and cosmeceuticals with desired Safety, stability, and efficacy.

THEORY 60 Hrs


Controversial ingredients: Parabens, formaldehyde liberators, dioxane.

Sun-protection, pigmentation, pricky heat, wrinkles, body odor., dandruff, dental cavities, bleeding gums, mouth odor and sensitive teeth through cosmeceutical formulations.

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

REFERENCES
4. Handbook of cosmetic science and Technology A.O.Barel, M.Paye and H.I. Maibach. 3rd edition
5. Cosmetic and Toiletries recent suppliers catalogue.
6. CTFA directory.
PHARMACEUTICS PRACTICALS - II  
(MPH 205P)  

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

MODERN PHARMACEUTICAL ANALYTICAL TECHNIQUES (MPC 101T)

Scope
This subject deals with various advanced analytical instrumental techniques for identification, characterization and quantification of drugs. Instruments dealt are NMR, Mass spectrometer, IR, HPLC, GC etc.

Objectives
After completion of course student is able to know about chemicals and excipients

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

THEORY

60 Hrs

1. a. UV-Visible spectroscoPy: Introduction, Theory,Laws, 10
   b. IR spectroscopy: Theory, Modes of Molecular vibrations, Sample handling, Instrumentation of Dispersive and Fourier – Transform IR Spectrometer, Factors affecting vibrational frequencies and Applications of IR spectroscopy, Data Interpretation.
   c. Spectrofluorimetry: Theory of Fluorescence, Factors affecting fluorescence (Characterestics of drugs that can be analysed by flourimetry), Quenchers, Instrumentation and Applications of fluorescence spectrophotometer.

2  NMR spectroscopy: Quantum numbers and their role in NMR, 10
   Principle, Instrumentation, Solvent requirement in NMR, Hrs 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.

4 Chromatography: Principle, apparatus, instrumentation, 10 chromatographic parameters, factors affecting resolution, isolation Hrs of drug from excipients, data interpretation and applications of the following:
   a) Thin Layer chromatography
   b) High Performance Thin Layer Chromatography
   c) Ion exchange chromatography
   d) Column chromatography
   e) Gas chromatography
   f) High Performance Liquid chromatography
   g) Ultra High Performance Liquid chromatography
   h) Affinity chromatography
   i) Gel Chromatography

5 a. Electrophoresis: Principle, Instrumentation, Working 10 conditions, factors affecting separation and applications of the Hrs following:
   a) Paper electrophoresis b) Gel electrophoresis c) Capillary electrophoresis d) Zone electrophoresis e) Moving boundary electrophoresis f) Iso electric focusing
   b. X ray Crystallography: Production of X rays, Different X ray methods, Bragg’s law, Rotating crystal technique, X ray powder technique, Types of crystals and applications of X-ray diffraction.

   b. Thermal Techniques: Principle, thermal transitions and Instrumentation (Heat flux and power–compensation and designs), Modulated DSC, Hyper DSC, experimental parameters (sample preparation, experimental conditions, calibration, heating and cooling rates, resolution, source of errors) and their influence, advantage and disadvantages, pharmaceutical applications. Differential Thermal Analysis (DTA): Principle, instrumentation
and advantage and disadvantages, pharmaceutical applications, derivative differential thermal analysis (DDTA).

TGA: Principle, instrumentation, factors affecting results, advantage and disadvantages, pharmaceutical applications.

REFERENCES
ADVANCED ORGANIC CHEMISTRY - I
(MPC 102T)

Scope
The subject is designed to provide in-depth knowledge about advances in organic chemistry, different techniques of organic synthesis and their applications to process chemistry as well as drug discovery.

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

The principles and applications of retrosynthesis
The mechanism & applications of various named reactions
The concept of disconnection to develop synthetic routes for small target molecule.
The various catalysts used in organic reactions
The chemistry of heterocyclic compounds

THEORY 60 Hrs
1. Basic Aspects of Organic Chemistry:
   2. Types of reaction mechanisms and methods of determining them,
   3. Detailed knowledge regarding the reactions, mechanisms and their relative reactivity and orientations. Addition reactions
      a) Nucleophilic uni- and bimolecular reactions (SN1 and SN2)
      b) Elimination reactions (E1 & E2; Hoffman & Saytzeff’s rule)
      c) Rearrangement reaction
2. Study of mechanism and synthetic applications of following named Reactions:
   Ugi reaction, Brook rearrangement, Ullmann coupling reactions, Dieckmann Reaction, Doebner–Miller Reaction, Sandmeyer Reaction, Mitsunobu reaction, Mannich reaction, Vilsmeier–Haack Reaction, Sharpless asymmetric epoxidation, Baeyer–Villiger oxidation, Shapiro & Suzuki reaction, Ozonolysis and Michael addition reaction
Synthetic Reagents & Applications:
Aluminium isopropoxide, N-bromosuccinamide, diazomethane, dicyclohexylcarbodiimide, Wilkinson reagent, Witting reagent. Osmium tetroxide, titanium chloride, diazopropane, diethyl azodicarboxylate, Triphenylphosphine, Benzotriazol-1-yloxy) tris (dimethylamino) phosphonium hexafluoro-phosphate (BOP).

Protecting groups
a. Role of protection in organic synthesis
b. Protection for the hydroxyl group, including 1,2-and 1,3-diols: ethers, esters, carbonates, cyclic acetals & ketals
c. Protection for the Carbonyl Group: Acetals and Ketals
d. Protection for the Carboxyl Group: amides and hydrazides, esters
e. Protection for the Amino Group and Amino acids: car bamates and amides

Heterocyclic Chemistry:
Organic Name reactions with their respective mechanism and application involved in synthesis of drugs containing five, six membered and fused heterocyclics such as Debus–Radziszewski imidazole synthesis, Knorr Pyrazole Synthesis Pinner Pyrimidine Synthesis, Combes Quinoline Synthesis, Bernthsen Acridine Synthesis, Smiles rearrangement and Traube purine synthesis.

Synthesis of few representative drugs containing these heterocyclic nucleus such as Ketoconazole, Metronidazole, Miconazole, celecoxib, antipyrin, Metamizole sodium, Terconazole, Alprazolam, Triamterene, Sulfamerazine, Trimethoprim, Hydroxychloroquine, Quinine, Chloroquine, Quinacrine, Amsacrine, Prochlorpherase, Promazine, Chlorpromazine, Theophylline, Mercaptopurine and Thioguanine.

Synthon approach and retrosynthesis applications
i. Basic principles, terminologies and advantages of retrosynthesis; guidelines for dissection of molecules. Functional group interconversion and addition (FGI and FGA)
ii. C-X disconnections; C-C disconnections – alcohols and carbonyl compounds; 1,2-, 1,3-, 1,4-, 1,5-, 1,6-difunctionalized compounds
iii. Strategies for synthesis of three, four, five and six-membered ring.
REFERENCES
ADVANCED MEDICINAL CHEMISTRY  
(MPC 103T)

Scope
The subject is designed to impart knowledge about recent advances in the field of medicinal chemistry at the molecular level including different techniques for the rational drug design.

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

Different stages of drug discovery
  Role of medicinal chemistry in drug research
  Different techniques for drug discovery
  Various strategies to design and develop new drug like molecules for biological targets

Peptidomimetics

THEORY 60 Hrs
1. Drug discovery: Stages of drug discovery, lead discovery; 12 Hrs identification, validation and diversity of drug targets.

Biological drug targets: Receptors, types, binding and activation, theories of drug receptor interaction, drug receptor interactions, agonists vs antagonists, artificial enzymes.

2. Prodrug Design and Analog design:
   a) Prodrug design: Basic concept, Carrier linked prodrugs / Bioprecursors, Prodrugs of functional group, 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.
   b) Combating drug resistance: Causes for drug resistance, strategies to combat drug resistance in antibiotics and anticancer therapy, Genetic principles of drug resistance.
   c) Analog Design: Introduction, Classical & Non classical, Bioisosteric replacement strategies, rigid analogs,
alteration of chain branching, changes in ring size, ring position isomers, design of stereo isomers and geometric isomers, fragments of a lead molecule, variation in inter atomic distance.

3 a) Medicinal chemistry aspects of the following class of drugs

Systematic study, SAR, Mechanism of action and synthesis of new generation molecules of following class of drugs:
a) Anti-hypertensive drugs, Psychoactive drugs, Anticonvulsant drugs, H1 & H2 receptor antagonist, COX1 & COX2 inhibitors, Adrenergic & Cholinergic agents, Antineoplastic and Antiviral agents.

b) Stereochemistry and Drug action: Realization that stereo selectivity is a pre-requisite for evolution. Role of chirality in selective and specific therapeutic agents. Case studies, Enantio selectivity in drug adsorption, metabolism, distribution and elimination.

4 Rational Design of Enzyme Inhibitors

Enzyme kinetics & Principles of Enzyme inhibitors, Enzyme inhibitors in medicine, Enzyme inhibitors in basic research, rational design of non-covalently and covalently binding enzyme inhibitors.

5 Peptidomimetics

Therapeutic values of Peptidomimetics, design of peptidomimetics by manipulation of the amino acids, modification of the peptide backbone, incorporating conformational constraints locally or globally. Chemistry of prostaglandins, leukotrienes and thromboxones.

REFERENCES

1. Medicinal Chemistry by Burger, Vol I –VI.
3. Comprehensive Medicinal Chemistry – Corwin and Hansch.
4. Computational and structural approaches to drug design edited by Robert M Stroud and Janet. F Moore
5. Introduction to Quantitative Drug Design by Y.C. Martin.
CHEMISTRY OF NATURAL PRODUCTS
(MPC 104T)

Scope
The subject is designed to provide detail knowledge about chemistry of medicinal compounds from natural origin and general methods of structural elucidation of such compounds. It also emphasizes on isolation, purification and characterization of medicinal compounds from natural origin.

Objectives
At completion of this course it is expected that students will be able to understand–
- Different types of natural compounds and their chemistry and medicinal importance
- The importance of natural compounds as lead molecules for new drug discovery
- The concept of rDNA technology tool for new drug discovery
- General methods of structural elucidation of compounds of natural origin
- Isolation, purification and characterization of simple chemical constituents from natural source

THEORY 60 Hrs
1. Study of Natural products as leads for new pharmaceuticals for the following class of drugs 12 Hrs
   a) Drugs Affecting the Central Nervous System: Morphine Alkaloids
   b) Anticancer Drugs: Paclitaxel and Docetaxel, Etoposide, and Teniposide
   c) Cardiovascular Drugs: Lovastatin, Teprotide and Dicoumarol
   d) Neuromuscular Blocking Drugs: Curare alkaloids
   e) Anti-malarial drugs and Analogues
   f) Chemistry of macrolid antibiotics (Erythromycin, Azithromycin, Roxithromycin, and Clarithromycin) and β – Lactam antibiotics (Cephalosporins and Carbapenem)

2 a) Alkaloids 12 Hrs
   General introduction, classification, isolation, purification, molecular modification and biological activity of alkaloids, general methods of structural determination of alkaloids, structural elucidation and stereochemistry of ephedrine, morphine, ergot, emetine and reserpine.
b) Flavonoids
Introduction, isolation and purification of flavonoids, General methods of structural determination of flavonoids; Structural elucidation of quercetin.

c) Steroids
General introduction, chemistry of sterols, sapogenin and cardiac glycosides. Stereochemistry and nomenclature of steroids, chemistry of contraceptive agents male & female sex hormones (Testosterone, Estradiol, Progesterone), adrenocorticoids (Cortisone), contraceptive agents and steroids (Vit – D).

3 a) Terpenoids 12 Hrs
Classification, isolation, isoprene rule and general methods of structural elucidation of Terpenoids; Structural elucidation of drugs belonging to mono (citral, menthol, camphor), di(retinol, Phytol, taxol) and tri terpenoids (Squalene,Ginsenoside) carotinoids (β carotene).

b) Vitamins
Chemistry and Physiological significance of Vitamin A, B1, B2, B12, C, E, Folic acid and Niacin.

4 a). Recombinant DNA technology and drug discovery 12 Hrs
rDNA technology, hybridoma technology, New pharmaceuticals derived from biotechnology; Oligonucleotide therapy. Gene therapy: Introduction, Clinical application and recent advances in gene therapy, principles of RNA & DNA estimation

b). Active constituent of certain crude drugs used in Indigenous system
Diabetic therapy – Gymnema sylvestre, Salacia reticulate, Pterocarpus marsupiam, Swertia chirata, Trigonella foenum graccum; Liver dysfunction – Phyllanthus niruri; Antitumor – Curcuma longa Linn.

5 Structural Characterization of natural compounds 12 Hrs
Structural characterization of natural compounds using IR, 1HNMR, 13CNMR and MS Spectroscopy of specific drugs e.g., Penicillin, Morphine, Camphor, Vit–D, Quercetin and Digitalis glycosides.
REFERENCES
4. Chemistry of natural products Vol I onwards IWPAC.
8. Introduction to molecular Phytochemistry – CHJ Wells, Chapmannstall.
16. Burger’s Medicinal Chemistry.
PHARMACEUTICAL CHEMISTRY PRACTICAL - I  
(MPC 105P)

1. Analysis of Pharmacopoeial compounds and their formulations by UV Vis spectrophotometer, RNA & DNA estimation
2. Simultaneous estimation of multi component containing formulations by UV spectrophotometry
3. Experiments based on Column chromatography
4. Experiments based on HPLC
5. Experiments based on Gas Chromatography
6. Estimation of riboflavin/quinine sulphate by fluorimetry
7. Estimation of sodium/potassium by flame photometry

To perform the following reactions of synthetic importance
1. Purification of organic solvents, column chromatography
2. Claisen–schimidt reaction.
3. Benzylic acid rearrangement.
5. Hoffmann rearrangement
6. Mannich reaction
7. Synthesis of medicinally important compounds involving more than one step along with purification and Characterization using TLC, melting point and IR spectroscopy (4 experiments)
8. Estimation of elements and functional groups in organic natural compounds
9. Isolation, characterization like melting point, mixed melting point, molecular weight determination, functional group analysis, co-chromatographic technique for identification of isolated compounds and interpretation of UV and IR data.
10. Some typical degradation reactions to be carried on selected plant constituents
ADVANCED SPECTRAL ANALYSIS  
(MPC 201T)

Scope
This subject deals with various hyphenated analytical instrumental techniques for identification, characterization and quantification of drugs. Instruments dealt are LC–MS, GC–MS, ATR–IR, DSC etc.

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

Interpretation of the NMR, Mass and IR spectra of various organic compounds
Theoretical and practical skills of the hyphenated instruments Identification of organic compounds

THEORY 60Hrs

1. UV and IR spectroscopy:
   Wood ward – Fieser rule for 1,3– butadienes, cyclic dienes and α, β–carbonyl compounds and interpretation compounds of enones.
   ATR–IR, IR Interpretation of organic compounds. 12 Hrs

2 NMR spectroscopy:
   1–D and 2–D NMR, NOESY and COSY, HECTOR, INADEQUATE techniques, Interpretation of organic compounds. 12 Hrs

3 Mass Spectroscopy
   Mass fragmentation and its rules, Fragmentation of important functional groups like alcohols, amines, carbonyl groups and alkanes, Meta stable ions, Mc Lafferty rearrangement, Ring rule, Isotopic peaks, Interpretation of organic compounds. 12 Hrs

4 Chromatography:
   Principle, Instrumentation and Applications of the following : 12 Hrs
   a) GC–MS b) GC–AAS c) LC–MS d) LC–FTIR e) LC–NMR f) CE–MS g) High Performance Thin Layer chromatography h) Super critical fluid chromatography i) Ion Chromatography j) I–EC (Ion–Exclusion Chromatography) k) Flash chromatography
a). Thermal methods of analysis
   Introduction, principle, instrumentation and application of DSC, Hrs
   DTA and TGA.

b). Raman Spectroscopy
   Introduction, Principle, Instrumentation and Applications.

c). Radio immuno assay
   Biological standardization, bioassay, ELISA,
   Radioimmuno assay of digitalis and insulin.

REFERENCES
1. Spectrometric Identification of Organic compounds – Robert M
2. Principles of Instrumental Analysis – Doglas A Skoog, F. James Holler,
5. Quantitative analysis of Pharmaceutical formulations by HPTLC – P
6. Quantitative Analysis of Drugs in Pharmaceutical formulation – P D
7. Pharmaceutical Analysis– Modern methods – Part B – J W Munson,
   Volume 11, Marcel Dekker Series
ADVANCED ORGANIC CHEMISTRY - II
(MPC 202T)

Scope
The subject is designed to provide in-depth knowledge about advances in organic chemistry, different techniques of organic synthesis and their applications to process chemistry as well as drug discovery.

Objectives
Upon completion of course, the student shall able to understand
- The principles and applications of Green chemistry
- The concept of peptide chemistry
- The various catalysts used in organic reactions
- The concept of stereochemistry and asymmetric synthesis.

THEORY
1. Green Chemistry:
   a. Introduction, principles of green chemistry
   b. Microwave assisted reactions: Merit and demerits of its use, increased reaction rates, mechanism, superheating effects of microwave, effects of solvents in microwave assisted synthesis, microwave technology in process optimization, its applications in various organic reactions and heterocycles synthesis
   c. Ultrasound assisted reactions: Types of sonochemical reactions, homogenous, heterogeneous liquid–liquid and liquid–solid reactions, synthetic applications
   d. Continuous flow reactors: Working principle, advantages and synthetic applications.

2. Chemistry of peptides
   a. Coupling reactions in peptide synthesis
   b. Principles of solid phase peptide synthesis, t–BOC and FMOC protocols, various solid supports and linkers: Activation procedures, peptide bond formation, deprotection and cleavage from resin, low and high HF cleavage protocols, formation of free peptides and peptide amides, purification and case studies, site–specific chemical modifications of peptides
   c. Segment and sequential strategies for solution phase peptide synthesis with any two case studies
   d. Side reactions in peptide synthesis: Deletion peptides, side
reactions initiated by proton abstraction, protonation, over-activation and side reactions of individual amino acids.

3 Photochemical Reactions
Basic principles of photochemical reactions. Photo-oxidation, photo-addition and photo-fragmentation.

Pericyclic reactions
Mechanism, Types of pericyclic reactions such as cyclo addition, electrocyclic reaction and sigmatropic rearrangement reactions with examples

4 Catalysis:
- Types of catalysis, heterogeneous and homogenous catalysis, advantages and disadvantages
- Heterogeneous catalysis – preparation, characterization, kinetics, supported catalysts, catalyst deactivation and regeneration, some examples of heterogeneous catalysis used in synthesis of drugs
- Homogenous catalysis, hydrogenation, hydroformylation, hydrocyanation, Wilkinson catalysts, chiral ligands and chiral induction, Ziegler-Natta catalysts, some examples of homogenous catalysis used in synthesis of drugs
- Transition−metal and Organo−catalysis in organic synthesis: Metal−catalyzed reactions
- Biocatalysis: Use of enzymes in organic synthesis, immobilized enzymes/cells in organic reaction
- Phase transfer catalysis - theory and applications

5 Stereochemistry & Asymmetric Synthesis
- Basic concepts in stereochemistry – optical activity, specific rotation, racemates and resolution of racemates, the Cahn, Ingold, Prelog (CIP) sequence rule, meso compounds, pseudo asymmetric centres, axes of symmetry, Fischers D and L notation, cis−trans isomerism, E and Z notation
- Methods of asymmetric synthesis using chiral pool, chiral auxiliaries and catalytic asymmetric synthesis, enantiopure separation and Stereo selective synthesis with examples
REFERENCES
6. Organic synthesis–the disconnection approach, S. Warren, Wily India
7. Principles of organic synthesis, ROCNorman and JMCoxan, Nelson thorns
COMPUTER AIDED DRUG DESIGN
(MPC 203T)

Scope
The subject is designed to impart knowledge on the current state of the art techniques involved in computer assisted drug design.

Objectives
At completion of this course it is expected that students will be able to understand
- Role of CADD in drug discovery
- Different CADD techniques and their applications
- Various strategies to design and develop new drug like molecules.
  - Working with molecular modeling softwares to design new drug molecules
- The in silico virtual screening protocols

Theory 60 Hrs
1. Introduction to Computer Aided Drug Design (CADD) 12 Hrs

   History, different techniques and applications.
   Quantitative Structure Activity Relationships: Basics
   History and development of QSAR: Physicochemical parameters and methods to calculate physicochemical parameters: Hammett equation and electronic parameters (sigma), lipophilicity effects and parameters (log P, pi-substituent constant), steric effects (Taft steric and MR parameters) Experimental and theoretical approaches for the determination of these physicochemical parameters.

2. Quantitative Structure Activity Relationships: Applications 12 Hrs
   Hansch analysis, Free Wilson analysis and relationship between them, Advantages and disadvantages; Deriving 2D-QSAR equations.
   3D-QSAR approaches and contour map analysis.
   Statistical methods used in QSAR analysis and importance of statistical parameters.

3. Molecular Modeling and Docking 12 Hrs
   a) Molecular and Quantum Mechanics in drug design.
   b) Energy Minimization Methods: comparison between global
c) Molecular docking and drug receptor interactions: Rigid docking, flexible docking and extra-precision docking. Agents acting on enzymes such as DHFR, HMG-CoA reductase and HIV protease, choline esterase (AchE & BchE)

4 Molecular Properties and Drug Design

a) Prediction and analysis of ADMET properties of new molecules and its importance in drug design.

b) De novo drug design: Receptor/enzyme interaction and its analysis, Receptor/enzyme cavity size prediction, predicting the functional components of cavities, Fragment based drug design.

c) Homology modeling and generation of 3D-structure of protein.

5 Pharmacophore Mapping and Virtual Screening

Concept of pharmacophore, pharmacophore mapping, identification of Pharmacophore features and Pharmacophore modeling; Conformational search used in pharmacophore mapping.

In Silico Drug Design and Virtual Screening Techniques

Similarity based methods and Pharmacophore based screening, structure based In-silico virtual screening protocols.

REFERENCES


10. Computational and structural approaches to drug design edited by Robert M Stroud and Janet. F Moore
PHARMACEUTICAL PROCESS CHEMISTRY (MPC 204T)

Scope
Process chemistry is often described as scale up reactions, taking them from small quantities created in the research lab to the larger quantities that are needed for further testing and then to even larger quantities required for commercial production. The goal of a process chemist is to develop synthetic routes that are safe, cost-effective, environmentally friendly, and efficient. The subject is designed to impart knowledge on the development and optimization of a synthetic route/s and the pilot plant procedure for the manufacture of Active Pharmaceutical Ingredients (APIs) and new chemical entities (NCEs) for the drug development phase.

Objectives
At completion of this course it is expected that students will be able to understand
- The strategies of scale up process of APIs and intermediates
- The various unit operations and various reactions in process chemistry

THEORY 60 Hrs
1. Process chemistry 12 Hrs
   - Introduction, Synthetic strategy
     Stages of scale up process: Bench, pilot and large scale process.
     In-process control and validation of large scale process.
     Case studies of some scale up process of APIs.
     Impurities in API, types and their sources including genotoxic impurities

2. Unit operations 12 Hrs
   a) Extraction: Liquid equilibria, extraction with reflux, extraction with agitation, counter current extraction.
   b) Filtration: Theory of filtration, pressure and vacuum filtration, centrifugal filtration,
   c) Distillation: azeotropic and steam distillation
   d) Evaporation: Types of evaporators, factors affecting evaporation.
   e) Crystallization: Crystallization from aqueous, non-aqueous solutions factors affecting crystallization, nucleation. Principle and general methods of Preparation of polymorphs, hydrates, solvates and amorphous APIs.
3 Unit Processes - I
   a) Nitration: Nitrating agents, Aromatic nitration, kinetics and mechanism of aromatic nitration, process equipment for technical nitration, mixed acid for nitration,
   b) Halogenation: Kinetics of halogenations, types of halogenations, catalytic halogenations. Case study on industrial halogenation process.
   c) Oxidation: Introduction, types of oxidative reactions, Liquid phase oxidation with oxidizing agents. Nonmetallic Oxidizing agents such as \( \text{H}_2\text{O}_2 \), sodium hypochlorite, Oxygen gas, ozonolysis.

4 Unit Processes - II
   a) Reduction: Catalytic hydrogenation, Heterogeneous and homogeneous catalyst; Hydrogen transfer reactions, Metal hydrides. Case study on industrial reduction process.
   b) Fermentation: Aerobic and anaerobic fermentation. Production of
      i. Antibiotics; Penicillin and Streptomycin,
      ii. Vitamins: B2 and B12
      iii. Statins: Lovastatin, Simvastatin
   c) Reaction progress kinetic analysis
      i. Streamlining reaction steps, route selection,
      ii. Characteristics of expedient routes, characteristics of cost–effective routes, reagent selection, families of reagents useful for scale–up.

5 Industrial Safety
   a) MSDS (Material Safety Data Sheet), hazard labels of chemicals and Personal Protection Equipment (PPE)
   b) Fire hazards, types of fire & fire extinguishers
   c) Occupational Health & Safety Assessment Series 1800 (OHSAS–1800) and ISO–14001 (Environmental Management System), Effluents and its management
REFERENCES

8. P.H. Groggins: Unit processes in organic synthesis (MGH)
9. F.A. Henglein: Chemical Technology (Pergamon)
12. Lowenheim & M.K. Moran: Industrial Chemicals
17. ICH Guidelines
18. United States Food and Drug Administration official website www.fda.gov
1. Synthesis of organic compounds by adapting different approaches involving (3 experiments)
   a) Oxidation
   b) Reduction/hydrogenation
   c) Nitration
2. Comparative study of synthesis of APIs/intermediates by different synthetic routes (2 experiments)
3. Assignments on regulatory requirements in API (2 experiments)
4. Comparison of absorption spectra by UV and Wood ward – Fieser rule
5. Interpretation of organic compounds by FT–IR
6. Interpretation of organic compounds by NMR
7. Interpretation of organic compounds by MS
8. Determination of purity by DSC in pharmaceuticals
9. Identification of organic compounds using FT–IR, NMR, CNMR and Mass spectra
10. To carry out the preparation of following organic compounds
13. NaBH₄ reduction of vanillin to vanillyl alcohol
14. Preparation of umbelliferone by Pechmann reaction
15. Preparation of triphenyl imidazole
16. To perform the Microwave irradiated reactions of synthetic importance (Any two)
17. Determination of log P, MR, hydrogen bond donors and acceptors of selected drugs using softwares
18. Calculation of ADMET properties of drug molecules and its analysis using softwares
   Pharmacophore modeling
19. 2D–QSAR based experiments
20. 3D–QSAR based experiments
21. Docking study based experiment
22. Virtual screening based experiment
PHARMACOLOGY (MPL)

MODERN PHARMACEUTICAL ANALYTICAL TECHNIQUES (MPL 101T)

Scope
This subject deals with various advanced analytical instrumental techniques for identification, characterization and quantification of drugs. Instruments dealt are NMR, Mass spectrometer, IR, HPLC, GC etc.

Objectives
After completion of course student is able to know about,

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

THEORY
60 Hrs


2. NMR spectroscopy: Quantum numbers and their role in NMR, Principle, Instrumentation, Solvent requirement in NMR, Relaxation process, NMR signals in various compounds, Chemical shift, Factors influencing chemical shift, Spin–Spin coupling, Coupling constant, Nuclear magnetic double resonance, Brief outline of principles of FT–NMR and 13C NMR. Applications of NMR spectroscopy.

4 Chromatography: Principle, apparatus, instrumentation, chromatographic parameters, factors affecting resolution, isolation of drug from excipients, data interpretation and applications of the following:
   j) Thin Layer chromatography
   k) High Performance Thin Layer Chromatography
   l) Ion exchange chromatography
   m) Column chromatography
   n) Gas chromatography
   o) High Performance Liquid chromatography
   p) Ultra High Performance Liquid chromatography
   q) Affinity chromatography
   r) Gel 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) 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.


Thermal Techniques: Principle, thermal transitions and Instrumentation (Heat flux and power–compensation and designs), Modulated DSC, Hyper DSC, experimental parameters (sample preparation, experimental conditions, calibration, heating and cooling rates, resolution, source of errors) and their influence, advantage and disadvantages, pharmaceutical applications. Differential Thermal Analysis (DTA): Principle, instrumentation and advantage and disadvantages, pharmaceutical applications, derivative differential thermal analysis (DDTA). TGA: Principle, instrumentation, factors affecting results, advantage and disadvantages, pharmaceutical applications.
REFERENCES

ADVANCED PHARMACOLOGY - I  
(MPL 102T)

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

Objectives
Upon completion of the course the student shall be able to:
- Discuss the pathophysiology and pharmacotherapy of certain diseases
- Explain the mechanism of drug actions at cellular and molecular level
- Understand the adverse effects, contraindications and clinical uses of drugs used in treatment of diseases

THEORY

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

2. Neurotransmission
   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

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

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

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

4 Cardiovascular Pharmacology 12
Diuretics, antihypertensives, antiischemics, anti– arrhythmics, Hrs drugs for heart failure and hyperlipidemia. Hematinics, coagulants , anticoagulants, fibrinolytics and anti–platelet drugs

5 Autocoid Pharmacology 12
The physiological and pathological role of Histamine, Serotonin, Hrs Kinins Prostaglandins Opioid autocoids. Pharmacology of antihistamines, 5HT antagonists.

REFERENCES
1. The Pharmacological Basis of Therapeutics, Goodman and Gillman's
3. Basic and Clinical Pharmacology by B.G Katzung
5. Applied biopharmaceutics and Pharmacokinetics by Leon Shargel and Andrew B.C.Yu.
7. Avery Drug Treatment
10. Robbins & Cortan Pathologic Basis of Disease, 9th Ed. (Robbins Pathology)
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,

1. Appraise the regulations and ethical requirement for the usage of experimental animals.
2. Describe the various animals used in the drug discovery process and good laboratory practices in maintenance and handling of experimental animals.
3. Describe the various newer screening methods involved in the drug discovery process.
4. Appreciate and correlate the preclinical data to humans.

THEORY

1. Laboratory Animals

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

   Transgenic animals: Production, maintenance and applications

   Anaesthesia and euthanasia of experimental animals.

   Maintenance and breeding of laboratory animals.

   CPCSEA guidelines to conduct experiments on animals.

   Good laboratory practice.

   Bioassay–Principle, scope and limitations and methods.

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

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

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


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


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

immunomodulators, Immunosuppressants and immunostimulants

General principles of immunoassay: theoretical basis and optimization of immunoassay, heterogeneous and homogenous immunoassay systems. Immunoassay methods evaluation; protocol outline, objectives and preparation. Immunoassay for digoxin and insulin

Limitations of animal experimentation and alternate animal experiments.

Extrapolation of in vitro data to preclinical and preclinical to humans
REFERENCES

1. Biological standardization by J.H. Burn D.J. Finney and I.G. Goodwin
2. Screening methods in Pharmacology by Robert Turner. A
3. Evaluation of drugs activities by Laurence and Bachrach
5. Fundamentals of experimental Pharmacology by M.N.Ghosh
6. Pharmacological experiment on intact preparations by Churchill Livingstone
7. Drug discovery and Evaluation by Vogel H.G.
9. Preclinical evaluation of new drugs by S.K. Guta
10. Handbook of Experimental Pharmacology, SK.Kulkarni
14. Rodents for Pharmacological Experiments, Dr.Tapan Kumar chatterjee.
15. Practical Manual of Experimental and Clinical Pharmacology by Bikash Medhi (Author), Ajay Prakash (Author)
CELLULAR AND MOLECULAR PHARMACOLOGY
(MPL 104T)

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

Objectives:
Upon completion of the course, the student shall be able to,
- Explain the receptor signal transduction processes.
- Explain the molecular pathways affected by drugs.
- Appreciate the applicability of molecular pharmacology and biomarkers in drug discovery process.
- Demonstrate molecular biology techniques as applicable for pharmacology.

THEORY 60 Hrs
1. Cell biology 12 Hrs
   Structure and functions of cell and its organelles
   Genome organization. Gene expression and its regulation, importance of siRNA and micro RNA, gene mapping and gene sequencing
   Cell cycles and its regulation.
   Cell death– events, regulators, intrinsic and extrinsic pathways of apoptosis.
   Necrosis and autophagy.

2. Cell signaling 12 Hrs
   Intercellular and intracellular signaling pathways.
   Classification of receptor family and molecular structure ligand gated ion channels; G–protein coupled receptors, tyrosine kinase receptors and nuclear receptors.
   Secondary messengers: cyclic AMP, cyclic GMP, calcium ion, inositol 1,4,5–trisphosphate, (IP3), NO, and diacylglycerol.
   Detailed study of following intracellular signaling pathways: cyclic AMP signaling pathway, mitogen–activated protein kinase (MAPK) signaling, Janus kinase (JAK)/signal transducer and activator of transcription (STAT) signaling pathway.
Principles and applications of genomic and proteomic tools

DNA electrophoresis, PCR (reverse transcription and real time), Hrs
Gene sequencing, micro array technique, SDS page, ELISA and western blotting,
Recombinant DNA technology and gene therapy
Basic principles of recombinant DNA technology–Restriction enzymes, various types of vectors. Applications of recombinant DNA technology.
Gene therapy– Various types of gene transfer techniques, clinical applications and recent advances in gene therapy.

Pharmacogenomics
Gene mapping and cloning of disease gene. Hrs
Genetic variation and its role in health/ pharmacology
Polymorphisms affecting drug metabolism
Genetic variation in drug transporters
Genetic variation in G protein coupled receptors
Applications of proteomics science: Genomics, proteomics, metabolomics, functionomics, nutrigenomics
Immunotherapeutics
Types of immunotherapeutics, humanisation antibody therapy,
Immunotherapeutics in clinical practice

a. Cell culture techniques
Basic equipments used in cell culture lab. Cell culture media, Hrs
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

b. 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)
PHARMACOLOGICAL PRACTICAL - I
(MPL 105P)

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

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
(MPL 201T)

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

THEORY

60 Hrs

1. Endocrine Pharmacology
   - Molecular and cellular mechanism of action of hormones such as growth hormone, prolactin, thyroid, insulin and sex hormones
   - Anti-thyroid drugs, Oral hypoglycemic agents, Oral contraceptives, Corticosteroids.
   - Drugs affecting calcium regulation

2. Chemotherapy
   - Cellular and molecular mechanism of actions and resistance of antimicrobial agents such as ß-lactams, aminoglycosides, quinolones, Macrolide antibiotics. Antifungal, antiviral, and anti-TB drugs.

3. Chemotherapy
   - Drugs used in Protozoal Infections
   - Drugs used in the treatment of Helminthiasis Chemotherapy of cancer
   - Immunopharmacology
   - Cellular and biochemical mediators of inflammation and immune response. Allergic or hypersensitivity reactions. Pharmacotherapy of asthma and COPD.
   - Immunosuppressants and Immunostimulants
4 GIT Pharmacology

Antiulcer drugs, Prokinetics, antiemetics, anti-diarrheals and drugs for constipation and irritable bowel syndrome.

Chronopharmacology

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

5 Free radicals Pharmacology

Generation of free radicals, role of free radicals in etiopathology of various diseases such as diabetes, neurodegenerative diseases and cancer.

Protective activity of certain important antioxidant

Recent Advances in Treatment:

Alzheimer’s disease, Parkinson’s disease, Cancer, Diabetes mellitus

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
9. Robbins & Cortan Pathologic Basis of Disease, 9th Ed. (Robbins Pathology)
11. KD.Tripathi. Essentials of Medical Pharmacology
PHARMACOLOGICAL AND TOXICOLOGICAL SCREENING
METHODS-II
(MPL 202T)

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

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

- Explain the various types of toxicity studies.
- Appreciate the importance of ethical and regulatory requirements for toxicity studies.
- Demonstrate the practical skills required to conduct the preclinical toxicity studies.

THEORY

1. Basic definition and types of toxicology (general, mechanistic, regulatory and descriptive)  
   Regulatory guidelines for conducting toxicity studies OECD, ICH, EPA and Schedule Y  
   OECD principles of Good laboratory practice (GLP)  
   History, concept and its importance in drug development  
   Hrs

2. Acute, sub-acute and chronic– oral, dermal and inhalational studies as per OECD guidelines.  
   Acute eye irritation, skin sensitization, dermal irritation & dermal toxicity studies.  
   Test item characterization– importance and methods in regulatory toxicology studies  
   Hrs

3. 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  
   Hrs

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

Hrs
Safety pharmacology studies— origin, concepts and importance of safety pharmacology.
Tier1— CVS, CNS and respiratory safety pharmacology, HERG assay. Tier2— GI, renal and other studies

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

REFERENCES
3. Drugs from discovery to approval by Rick NG.
5. OECD test guidelines.
PRINCIPLES OF DRUG DISCOVERY  
(MPL 203T)

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

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

Explain the various stages of drug discovery.
Appreciate the importance of the role of genomics, proteomics and bioinformatics in drug discovery.
Explain various targets for drug discovery.
Explain various lead seeking method and lead optimization.
Appreciate the importance of the role of computer aided drug design in drug discovery.

THEORY 60 Hrs
Protein structure
3. Rational Drug Design
Virtual Screening techniques: Drug likeness screening, Concept of pharmacophore mapping and pharmacophore based Screening,

**4** Molecular docking: Rigid docking, flexible docking, manual docking; Docking based screening. De novo drug design. Quantitative analysis of Structure Activity Relationship History and development of QSAR, SAR versus QSAR, Physicochemical parameters, Hansch analysis, Fee Wilson analysis and relationship between them.

**5** QSAR Statistical methods – regression analysis, partial least square analysis (PLS) and other multivariate statistical methods. 3D–QSAR approaches like COMFA and COMSIA Prodrug design–Basic concept, Prodrugs to improve patient acceptability, Drug solubility, Drug absorption and distribution, site specific drug delivery and sustained drug action. Rationale of prodrug design and practical consideration of prodrug design.

REFERENCES
2. Darryl León. Scott Markelln. Silico Technologies in Drug Target Identification and Validation. 2006 by Taylor and Francis Group, LLC.
CLINICAL RESEARCH AND PHARMACOVIGILANCE  
(MPL 204T)

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

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

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

THEORY  
60 Hrs

1. Regulatory Perspectives of Clinical Trials:  
   12 Hrs
   Origin and Principles of International Conference on Harmonization – Good Clinical Practice (ICH–GCP) guidelines
   Ethical Committee: Institutional Review Board, Ethical Guidelines for Biomedical Research and Human Participant–Schedule Y, ICMR
   Informed Consent Process: Structure and content of an Informed Consent Process Ethical principles governing informed consent process

2. Clinical Trials: Types and Design  
   12 Hrs
   Experimental Study- RCT and Non RCT,
   Observation Study: Cohort, Case Control, Cross sectional Clinical Trial Study Team
   Roles and responsibilities of Clinical Trial Personnel:
   Investigator, Study Coordinator, Sponsor, Contract Research Organization and its management
Clinical Trial Documentation: Guidelines to the preparation of 12 documents, Preparation of protocol, Investigator Brochure, Case Hrs Report Forms, Clinical Study Report Clinical Trial Monitoring–Safety Monitoring in CT

Basic aspects, terminologies and establishment of 12 pharmacovigilance Hrs
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

Methods, ADR reporting and tools used in 12 Pharmacovigilance Hrs

Pharmacoepidemiology, pharmacoeconomics, safety 12 pharmacology Hrs

REFERENCES
1. To record the DRC of agonist using suitable isolated tissues preparation.
2. To study the effects of antagonist/potentiating agents on DRC of agonist using suitable isolated tissue preparation.
3. To determine to the strength of unknown sample by matching bioassay by using suitable tissue preparation.
4. To determine to the strength of unknown sample by interpolation bioassay by using suitable tissue preparation.
5. To determine to the strength of unknown sample by bracketing bioassay by using suitable tissue preparation.
6. To determine to the strength of unknown sample by multiple point bioassay by using suitable tissue preparation.
7. Estimation of PA2 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.
16. Protocol design for clinical trial.(3 Nos.)
17. Design of ADR monitoring protocol.
18. In-silico docking studies. (2 Nos.)
19. In-silico pharmacophore based screening.
20. In-silico QSAR studies.
21. ADR reporting

REFERENCES
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.
PHARMACOGNOSY (MPG)

MODERN PHARMACEUTICAL ANALYTICAL TECHNIQUES (MPG 101T)

Scope
This subject deals with various advanced analytical instrumental techniques for identification, characterization and quantification of drugs. Instruments dealt are NMR, Mass spectrometer, IR, HPLC, GC etc.

Objectives
After completion of course student is able to know,

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

THEORY


2. 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


Flame emission spectroscopy and Atomic absorption spectroscopy: Principle, Instrumentation, Interferences and Applications.

2. NMR spectroscopy: Quantum numbers and their role in NMR, Principle, Instrumentation, Solvent requirement in NMR, Relaxation process, NMR signals in various compounds, Chemical shift, Factors influencing chemical shift, Spin–Spin coupling, Coupling constant, Nuclear magnetic double resonance, Brief outline of principles of FT–NMR and 13C NMR. Applications of NMR spectroscopy.

4 Chromatography: Principle, apparatus, instrumentation, chromatographic parameters, factors affecting resolution, isolation of drug from excipients, data interpretation and applications of the following:
   a) Thin Layer chromatography
   b) High Performance Thin Layer Chromatography
   c) Ion exchange chromatography
   d) Column chromatography
   e) Gas chromatography
   f) High Performance Liquid chromatography
   g) Ultra High Performance Liquid chromatography
   h) Affinity chromatography
   i) Gel Chromatography

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.


   Thermal Techniques: Principle, thermal transitions and Instrumentation (Heat flux and power-compensation and designs), Modulated DSC, Hyper DSC, experimental parameters (sample preparation, experimental conditions, calibration, heating and
cooling rates, resolution, source of errors) and their influence, advantage and disadvantages, pharmaceutical applications. Differential Thermal Analysis (DTA): Principle, instrumentation and advantage and disadvantages, pharmaceutical applications, derivative differential thermal analysis (DDTA). TGA: Principle, instrumentation, factors affecting results, advantage and disadvantages, pharmaceutical applications.

REFERENCES
SCOPE
To learn and understand the advances in the field of cultivation and isolation of drugs of natural origin, various phytopharmaceuticals, nutraceuticals and their medicinal use and health benefits.

OBJECTIVES
Upon completion of the course, the student shall be able to know the,
advances in the cultivation and production of drugs
various phyto-pharmaceuticals and their source, its utilization and medicinal value.
various nutraceuticals/herbs and their health benefits
Drugs of marine origin
Pharmacovigilance of drugs of natural origin

THEORY


2. Marine natural products: General methods of isolation and purification, Study of Marine toxins, Recent advances in research on marine drugs, Problems faced in research on marine drugs such as taxonomical identification, chemical screening and their solution.

3. Nutraceuticals: Current trends and future scope, Inorganic mineral supplements, Vitamin supplements, Digestive enzymes, Dietary fibres, Cereals and grains, Health drinks of natural origin, Antioxidants, Polyunsaturated fatty acids, Herbs as functional foods, Formulation and standardization of nutraceuticals, Regulatory aspects, FSSAI guidelines, Sources, name of marker compounds and their chemical nature, medicinal uses and health benefits of following
4 Phytopharmaceuticals: Occurrence, isolation and characteristic features (Chemical nature, uses in pharmacy, medicinal and health benefits) of following.
   a) Carotenoids – i) α and β – Carotene ii) Xanthophyll (Lutein)
   b) Limonoids – i) d–Limonene ii) α – Terpineol
   c) Saponins – i) Shatavarins
   d) Flavonoids – i) Resveratrol ii) Rutin iii) Hesperidin iv) Naringin v) Quercetin
   e) Phenolic acids– Ellagic acid
   f) Vitamins
   g) Tocotrienols and Tocopherols
   h) Andrographolide, Glycolipids, Gugulipids, Withanolides, Vascine, Taxol
   i) Miscellaneous

5 Pharmacovigilance of drugs of natural origin: WHO and AYUSH guidelines for safety monitoring of natural medicine, Spontaneous reporting schemes for biodrug adverse reactions, bio drug–drug and bio drug–food interactions with suitable examples.

REFERENCES (Latest Editions of)
2. Pharmacognosy-Tyler, Brady, Robbers
3. Modern Methods of Plant Analysis– Peach & M.V. Tracey, Vol. I&II
4. Text Book of Pharmacognosy by T.E. Wallis
5. Marine Natural Products–Vol.I to IV.
PHYTOCHEMISTRY
(MPG 103T)

SCOPE
Students shall be equipped with the knowledge of natural product drug discovery and will be able to isolate, identify and extract and the phyto-constituents

OBJECTIVES
Upon completion of the course, the student shall be able to know the, different classes of phytoconstituents, their biosynthetic pathways, their properties, extraction and general process of natural product drug discovery phytochemical fingerprinting and structure elucidation of phytoconstituents.

THEORY 60 Hrs
1. Biosynthetic pathways and Radio tracing techniques: 12
Constituents & their Biosynthesis, Isolation, Characterization and Hrs purification with a special reference to their importance in herbal industries of following phyto-pharmaceuticals containing drugs:
   a) Alkaloids: Ephedrine, Quinine, Strychynine, Piperine, Berberine, Taxol, Vinca alkoloids.
   b) Glycosides: Digitoxin, Glycyrrhizin, Sennosides, Bacosides, Quercitin.
   c) Steroids: Hecogenin, guggulostereone and withanolides
   d) Coumarin: Umbelliferone.
   e) Terpenoids: Cucurbitacins

2 Drug discovery and development: History of herbs as source of 12 drugs and drug discovery, the lead structure selection process, Hrs structure development, product discovery process and drug registration, Selection and optimization of lead compounds with suitable examples from the following source : artemesin, andrographolides. Clinical studies emphasising on phases of clinical trials, protocol design for lead molecules.

3 Extraction and Phytochemical studies: Recent advances in 12 extractions with emphasis on selection of method and choice of Hrs solvent for extraction, successive and exhaustive extraction and other methods of extraction commonly used like microwave
assisted extraction, Methods of fractionation. Separation of phytoconstituents by latest CCCET, SCFE techniques including preparative HPLC and Flash column chromatography.

4 Phytochemical finger printing: HPTLC and LCMS/GCMS applications in the characterization of herbal extracts.

5 Structure elucidation of the following compounds by spectroscopic techniques like UV, IR, MS, NMR (1H, 13C) Hrs
   a. Carvone, Citral, Menthol
   b. Luteolin, Kaempferol
   c. Nicotine, Caffeine
   iv) Glycyrrhizin.

REFERENCES (Latest Editions of)
1. Organic chemistry by I.L. Finar Vol.II
2. Pharmacognosy by Trease and Evans, ELBS.
3. Pharmacognosy by Tylor and Brady.
5. Clark’s isolation and Identification of drugs by A.C. Mottal.
9. Natural Products Chemistry Practical Manual by Anees A Siddiqui and Seemi Siddiqui
11. Chemistry of Natural Products– Vol. 1 onwards IWPAC.
12. Modem Methods of Plant Analysis– Peach & M.V. Tracey, Vol. I&II
INDUSTRIAL PHARMACOGNOSTICAL TECHNOLOGY
(MPG 104T)

SCOPE
To understand the Industrial and commercial potential of drugs of natural origin, integrate traditional Indian systems of medicine with modern medicine and also to know regulatory and quality policy for the trade of herbals and drugs of natural origin.

OBJECTIVES
By the end of the course the student shall be able to know,
the requirements for setting up the herbal/natural drug industry.
  the guidelines for quality of herbal/natural medicines and regulatory issues.
  the patenting/IPR of herbals/natural drugs and trade of raw and finished materials.

THEORY
60 Hrs


4 Testing of natural products and drugs: Herbal medicines – 12 clinical laboratory testing. Stability testing of natural products, Hrs protocols.

5 Patents: Indian and international patent laws, proposed 12 amendments as applicable to herbal/natural products and Hrs process. Geographical indication, Copyright, Patentable subject matters, novelty, non obviousness, utility, enablement and best mode, procedure for Indian patent filing, patent processing, grant of patents, rights of patents, cases of patents, opposition and revocation of patents, patent search and literature, Controllers of patents.

REFERENCES (Latest Editions of)
5. Indian Herbal Pharmacopoeia (2002), IDMA, Mumbai.
1. Analysis of Pharmacopoeial compounds of natural origin and their formulations by UV Vis spectrophotometer
2. Analysis of recorded spectra of simple phytoconstituents
3. Experiments based on Gas Chromatography
4. Estimation of sodium/potassium by flame photometry
6. Methods of extraction
7. Phytochemical screening
8. Demonstration of HPLC– estimation of glycerrhizin
9. Monograph analysis of clove oil
10. Monograph analysis of castor oil.
11. Identification of bioactive constituents from plant extracts
12. Formulation of different dosage forms and their standardisation.
MEDICINAL PLANT BIOTECHNOLOGY
(MPG 201T)

SCOPE
To explore the knowledge of Biotechnology and its application in the improvement of quality of medicinal plants

OBJECTIVES
Upon completion of the course, the student shall be able to,
Know the process like genetic engineering in medicinal plants for higher yield of Phytopharmaceuticals.
Use the biotechnological techniques for obtaining and improving the quality of natural products/medicinal plants

THEORY 60 Hrs
1. Introduction to Plant biotechnology: Historical perspectives, 12 prospects for development of plant biotechnology as a source of medicinal agents. Applications in pharmacy and allied fields. Genetic and molecular biology as applied to pharmacognosy, study of DNA, RNA and protein replication, genetic code, regulation of gene expression, structure and complicity of genome, cell signaling, DNA recombinant technology.

2 Different tissue culture techniques: Organogenesis and 15 embryogenesis, synthetic seed and monoclonal variation, Hrs Protoplast fusion, Hairy root multiple shoot cultures and their applications. Micro propagation of medicinal and aromatic plants. Sterilization methods involved in tissue culture, gene transfer in plants and their applications.


4 Biotransformation and Transgenesis: Biotransformation, 13 bioreactors for pilot and large scale cultures of plant cells and Hrs retention of biosynthetic potential in cell culture. Transgenic
plants, methods used in gene identification, localization and sequencing of genes. Application of PCR in plant genome analysis.

5 Fermentation technology: Application of Fermentation technology, Production of ergot alkaloids, single cell proteins, enzymes of pharmaceutical interest.

REFERENCES (Latest Editions of)

9. Plant tissue culture by Street.
12. Biotechnological applications to tissue culture by Shargool, Peter D, Shargoal, CKC Press.
13. Pharmacognosy by Varo E. Tyler, Lynn R. Brady and James E. Robberrt, That Tjen, NGO.
ADVANCED PHARMACOGNOSY  - II  
(MPG 202T)

SCOPE
To know and understand the Adulteration and Deterioration that occurs in herbal/natural drugs and methods of detection of the same. Study of herbal remedies and their validations, including methods of screening

OBJECTIVES
Upon completion of the course, the student shall be able to know the, validation of herbal remedies methods of detection of adulteration and evaluation techniques for the herbal drugs methods of screening of herbals for various biological properties

THEORY 60 Hrs


4. Analytical Profiles of herbal drugs: Andrographis paniculata, 12 Boswellia serata, Coleus forskholii, Curcuma longa, Embelica Hrs officinalis, Psoralea corylifolia.

5. Biological screening of herbal drugs: Introduction and Need for 12 Phyto–Pharmacological Screening, New Strategies for evaluating Hrs
Natural Products, In vitro evaluation techniques for Antioxidants, Antimicrobial and Anticancer drugs. In vivo evaluation techniques for Anti-inflammatory, Antiulcer, Anticancer, Wound healing, Antidiabetic, Hepatoprotective, Cardio protective, Diuretics and Antifertility, Toxicity studies as per OECD guidelines.

REFERENCES (Latest Editions of)
10. Indian Herbal Pharmacopoeia, IDMA, Mumbai.
INDIAN SYSTEMS OF MEDICINE
(MPG 203T)

SCOPE
To make the students understand thoroughly the principles, preparations of medicines of various Indian systems of medicine like Ayurveda, Siddha, Homeopathy and Unani. Also focusing on clinical research of traditional medicines, quality assurance and challenges in monitoring the safety of herbal medicines.

OBJECTIVES
After completion of the course, student is able to

To understand the basic principles of various Indian systems of medicine
To know the clinical research of traditional medicines, Current Good Manufacturing Practice of Indian systems of medicine and their formulations.

THEORY

60 Hrs

1. Fundamental concepts of Ayurveda, Siddha, Unani and Homoeopathy systems of medicine
   Different dosage forms of the ISM.

Ayurveda: Ayurvedic Pharmacopoeia, Analysis of formulations and bio crude drugs with references to: Identity, purity and quality.

Siddha: Gunapadam (Siddha Pharmacology), raw drugs/Dhatu/Jeevam in Siddha system of medicine, Purification process (Suddhi).

2. Naturopathy, Yoga and Aromatherapy practices
   a) Naturopathy – Introduction, basic principles and treatment modalities.
   b) Yoga – Introduction and Streams of Yoga. Asanas, Pranayama, Meditations and Relaxation techniques.
   c) Aromatherapy – Introduction, aroma oils for common problems, carrier oils.

3. Formulation development of various systems of medicine
   Salient features of the techniques of preparation of some of the important class of Formulations as per Ayurveda, Siddha, Homeopathy and Unani Pharmacopoeia and texts. Standardization, Shelf life and Stability studies of ISM formulations.
Schedule T – Good Manufacturing Practice of Indian systems of medicine

Components of GMP (Schedule – T) and its objectives, Infrastructural requirements, working space, storage area, machinery and equipments, standard operating procedures, health and hygiene, documentation and records.

Quality assurance in ISM formulation industry – GAP, GMP and GLP. Preparation of documents for new drug application and export registration.

Challenges in monitoring the safety of herbal medicines: Regulation, quality assurance and control, National/Regional Pharmacopoeias.

REFERENCES (Latest Editions of)

3. Ayurvedic System of Medicine, Kaviraj Nagendranath Sengupata, Sri Satguru Publications, New Delhi.
7. Indian Herbal Pharmacopoeia, IDMA, Mumbai.
8. British Herbal Pharmacopoeia, bRITISH Herbal Medicine Association, UK.
10. Indian System of Medicine and Homeopathy in India, Planning and Evaluation Cell, Govt. of India, New Delhi.
11. Essential of Food and Nutrition, Swaminathan, Bappco, Bangalore.
HERBAL COSMETICS  
(MPG 204T)

SCOPE
This subject deals with the study of preparation and standardization of herbal/natural cosmetics. This subject gives emphasis to various national and international standards prescribed regarding herbal cosmeceuticals.

OBJECTIVES
After completion of the course, student shall be able to,
understand the basic principles of various herbal/natural cosmetic preparations
current Good Manufacturing Practices of herbal/natural cosmetics as per the regulatory authorities

THEORY 60 Hrs
1. Introduction: Herbal/natural cosmetics, Classification & 12 Economic aspects. 

2 Commonly used herbal cosmetics, raw materials, preservatives, 12 surfactants, humectants, oils, colors, and some functional herbs, Hrs preformulation studies, compatibility studies, possible interactions between chemicals and herbs, design of herbal cosmetic formulation.

3 Herbal Cosmetics : Physiology and chemistry of skin and 12 pigmentation, hairs, scalp, lips and nail, Cleansing cream, Hrs Lotions, Face powders, Face packs, Lipsticks, Bath products, soaps and baby product, Preparation and standardisation of the following: Tonic, Bleaches, Dentifrices and Mouth washes & Tooth Pastes, Cosmetics for Nails.

4 Cosmeceuticals of herbal and natural origin: Hair growth 12 formulations, Shampoos, Conditioners, Colorants & hair oils, Hrs Fairness formulations, vanishing & foundation creams, anti-sun burn preparations, moisturizing creams, deodorants.
Analysis of Cosmetics, Toxicity screening and test methods: 12
Quality control and toxicity studies as per Drug and Cosmetics Hrs Act.

REFERENCES (Latest Editions of)
2. Thomson EG. Modern Cosmetics, Universal Publishing Corporation, Mumbai.
7. Chattopadhyay PK. Herbal Cosmetics & Ayurvedic Medicines (EOU), National Institute of Industrial Research, Delhi.
HERBAL COSMETICS PRACTICALS
(MPG 205P)

1. Isolation of nucleic acid from cauliflower heads
2. Isolation of RNA from yeast
3. Quantitative estimation of DNA
4. Immobilization technique
5. Establishment of callus culture
6. Establishment of suspension culture
7. Estimation of aldehyde contents of volatile oils
8. Estimation of total phenolic content in herbal raw materials
9. Estimation of total alkaloid content in herbal raw materials
10. Estimation of total flavonoid content in herbal raw materials
11. Preparation and standardization of various simple dosage forms from Ayurvedic, Siddha, Homoeopathy and Unani formulary
12. Preparation of certain Aromatherapy formulations
13. Preparation of herbal cosmetic formulation such as lip balm, lipstick, facial cream, herbal hair and nail care products
14. Evaluation of herbal tablets and capsules
15. Preparation of sunscreen, UV protection cream, skin care formulations.
16. Formulation & standardization of herbal cough syrup.
Semester III
MRM 301T - Research Methodology & Biostatistics

UNIT – I
General Research Methodology: Research, objective, requirements, practical difficulties, review of literature, study design, types of studies, strategies to eliminate errors/bias, controls, randomization, crossover design, placebo, blinding techniques.

UNIT – II
Biostatistics: Definition, application, sample size, importance of sample size, factors influencing sample size, dropouts, statistical tests of significance, type of significance tests, parametric tests (students “t” test, ANOVA, Correlation coefficient, regression), non-parametric tests (wilcoxon rank tests, analysis of variance, correlation, chi square test), null hypothesis, P values, degree of freedom, interpretation of P values.

UNIT – III
Medical Research: History, values in medical ethics, autonomy, beneficence, non-maleficence, double effect, conflicts between autonomy and beneficence/non-maleficence, euthanasia, informed consent, confidentiality, criticisms of orthodox medical ethics, importance of communication, control resolution, guidelines, ethics committees, cultural concerns, truth telling, online business practices, conflicts of interest, referral, vendor relationships, treatment of family members, sexual relationships, fatality.

UNIT – IV
CPCSEA guidelines for laboratory animal facility: Goals, veterinary care, quarantine, surveillance, diagnosis, treatment and control of disease, personal hygiene, location of animal facilities to laboratories, anesthesia, euthanasia, physical facilities, environment, animal husbandry, record keeping, SOPs, personnel and training, transport of lab animals.

UNIT – V
Declaration of Helsinki: History, introduction, basic principles for all medical research, and additional principles for medical research combined with medical care