GANDHI INSTITUTE OF TECHNOLOGY AND MANAGEMENT
(GITAM)
(Deemed to be University, Estd. u/s 3 of the UGC Act 1956)
*VISAKHAPATNAM * HYDERABAD *BENGALURU*
Accredited by NAAC with ‘A+’ Grade

REGULATIONS & SYLLABUS

Master of Pharmacy
As per the PCI Norm
(w.e.f. 2017-18 admitted batch)

Website: www.gitam.edu
MASTER OF PHARMACY (M. Pharm.)
REGULATIONS as per PCI norms
(w.e.f. 2017-2018 admitted batch)

1.0 ADMISSIONS
1.1 Admissions into M. Pharmacy programme of GITAM University are governed by
GITAM University admission regulations.

2.0 MINIMUM QUALIFICATION FOR ADMISSION
A Pass in the following examinations
2.1 B. Pharm. Degree examination of an Indian University established by law in India
from an institution approved by Pharmacy Council of India (PCI) and has scored not
less than 50 % of the maximum marks (aggregate of 4 years of B. Pharm.)
2.2 Every student, selected for admission to post graduate pharmacy programme 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.
2.3 Admissions into M. Pharm. will be based on All India Entrance Test (GAT - PGP)
conducted by GITAM University and the rule of reservation is followed wherever
applicable.
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 PROGRAMME
The programme of study for M. Pharm. shall extend over a period of four semesters (two
academic years).

4. MEDIUM OF INSTRUCTION AND EXAMINATIONS
Medium of instruction and examination shall be in English.

5. WORKING DAYS IN EACH SEMESTER
Each semester shall consist of not less than 100 working days. The odd semesters shall be
conducted from the month of June/July to November/December and the even semesters shall
be conducted from the month of November/December to April/May 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. PROGRAMME/COURSE CREDIT STRUCTURE
As per the philosophy of Credit Based Semester System, certain quantum of academic work viz. theory classes, practical classes, seminars, assignments, etc. are measured in terms of credits. On satisfactory completion of the courses, a candidate earns credits. The amount of credit associated with a course is dependent upon the number of hours of instruction per week in that course. Similarly the credit associated with any of the other academic, co/extracurricular activities is dependent upon the quantum of work expected to be put in for each of these activities per week/per activity.

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. These credits are divided into theory courses, practical, seminars, assignments, research work, discussions with the supervisor and journal club over the duration of four semesters. The credits are distributed semester-wise as shown in Table 8. 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. programme are given in Table 1.

<table>
<thead>
<tr>
<th>S. No</th>
<th>Specialization</th>
<th>Code</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Pharmaceutics</td>
<td>MPH</td>
</tr>
<tr>
<td>2</td>
<td>Pharmaceutical Chemistry</td>
<td>MPC</td>
</tr>
<tr>
<td>3</td>
<td>Pharmaceutical Analysis</td>
<td>MPA</td>
</tr>
<tr>
<td>4</td>
<td>Pharmacology</td>
<td>MPL</td>
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</table>

The course of study for M. Pharm. specializations shall include semester wise theory & practical as given in Table – 2 to 6. The number of hours to be devoted to each theory and practical course in any semester shall not be less than that shown in Table – 2 to 6.

<table>
<thead>
<tr>
<th>Course Code</th>
<th>Course</th>
<th>Credit Hours</th>
<th>Credit Points</th>
<th>Hrs./wk</th>
<th>Marks</th>
</tr>
</thead>
<tbody>
<tr>
<td>MPH 101T</td>
<td>Modern Pharmaceutical Analytical Techniques</td>
<td>4</td>
<td>4</td>
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<td>100</td>
</tr>
<tr>
<td>MPH 102T</td>
<td>Drug Delivery Systems</td>
<td>4</td>
<td>4</td>
<td>4</td>
<td>100</td>
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<tr>
<td>MPH 103T</td>
<td>Modern Pharmaceutics</td>
<td>4</td>
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<tr>
<td>MPH 104T</td>
<td>Regulatory Affairs</td>
<td>4</td>
<td>4</td>
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<td>100</td>
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<tr>
<td>MPH 105P</td>
<td>Pharmaceutics Practical – I</td>
<td>12</td>
<td>6</td>
<td>12</td>
<td>150</td>
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<tr>
<td>MPH 106P</td>
<td>Seminar/Assignment</td>
<td>7</td>
<td>4</td>
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<th>Semester II</th>
<th>Course Code</th>
<th>Course</th>
<th>Credit Hours</th>
<th>Credit Points</th>
<th>Hrs./wk</th>
<th>Marks</th>
</tr>
</thead>
<tbody>
<tr>
<td>MPH 201T</td>
<td>Molecular Pharmaceutics (Nano Technology and Targeted DDS)</td>
<td>4</td>
<td>4</td>
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<td>100</td>
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<tr>
<td>MPH 202T</td>
<td>Advanced Biopharmaceutics &amp; Pharmacokinetics</td>
<td>4</td>
<td>4</td>
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<tr>
<td>MPH 203T</td>
<td>Computer Aided Drug Delivery System</td>
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<td>4</td>
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<tr>
<td>MPH 204T</td>
<td>Cosmetic and Cosmeceuticals</td>
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<tr>
<td>MPH 206P</td>
<td>Seminar/Assignment</td>
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<td>4</td>
<td>7</td>
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### Table -3: Course of study for M. Pharm. (Pharmaceutical Chemistry)

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<tr>
<th>Course Code</th>
<th>Course</th>
<th>Credit Hours</th>
<th>Credit Points</th>
<th>Hrs./wk</th>
<th>Marks</th>
</tr>
</thead>
<tbody>
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<td>MPC 101T</td>
<td>Modern Pharmaceutical Analytical Techniques</td>
<td>4</td>
<td>4</td>
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<td>100</td>
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<tr>
<td>MPC 102T</td>
<td>Advanced Organic Chemistry – I</td>
<td>4</td>
<td>4</td>
<td>4</td>
<td>100</td>
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<tr>
<td>MPC 103T</td>
<td>Advanced Medicinal Chemistry</td>
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<td>4</td>
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<tr>
<td>MPC 104T</td>
<td>Chemistry of Natural Products</td>
<td>4</td>
<td>4</td>
<td>4</td>
<td>100</td>
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<tr>
<td>MPC 105P</td>
<td>Pharmaceutical Chemistry Practical – I</td>
<td>12</td>
<td>6</td>
<td>12</td>
<td>150</td>
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<tr>
<td>MPC 106P</td>
<td>Seminar/Assignment</td>
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<td>4</td>
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<td>Total</td>
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### Semester II

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<th>Credit Points</th>
<th>Hrs./wk</th>
<th>Marks</th>
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</thead>
<tbody>
<tr>
<td>MPC 201T</td>
<td>Advanced Spectral Analysis</td>
<td>4</td>
<td>4</td>
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<td>100</td>
</tr>
<tr>
<td>MPC 202T</td>
<td>Advanced Organic Chemistry – II</td>
<td>4</td>
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<tr>
<td>MPC 203T</td>
<td>Computer Aided Drug Design</td>
<td>4</td>
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<td>MPC 204T</td>
<td>Pharmaceutical Process Chemistry</td>
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<tr>
<td>MPC 205P</td>
<td>Pharmaceutical Chemistry Practical – II</td>
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<tr>
<td>MPC 206P</td>
<td>Seminar/Assignment</td>
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<td>4</td>
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### Table -4: Course of study for M. Pharm. (Pharmaceutical Analysis)

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<tr>
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<td>MPA 102T</td>
<td>Advanced Pharmaceutical Analysis</td>
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<td>MPA 103T</td>
<td>Pharmaceutical Validation</td>
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<td>4</td>
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<td>MPA 104T</td>
<td>Food Analysis</td>
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<td>MPA 105P</td>
<td>Pharmaceutical Analysis Practical – I</td>
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<td>6</td>
<td>12</td>
<td>150</td>
</tr>
<tr>
<td>MPA 106P</td>
<td>Seminar/Assignment</td>
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<td>4</td>
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<tr>
<td>Total</td>
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### Semester II

<table>
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<tr>
<th>Course Code</th>
<th>Course</th>
<th>Credit Hours</th>
<th>Credit Points</th>
<th>Hrs./wk</th>
<th>Marks</th>
</tr>
</thead>
<tbody>
<tr>
<td>MPA 201T</td>
<td>Advanced Instrumental Analysis</td>
<td>4</td>
<td>4</td>
<td>4</td>
<td>100</td>
</tr>
<tr>
<td>MPA 202T</td>
<td>Modern Bio-Analytical Techniques</td>
<td>4</td>
<td>4</td>
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</tr>
<tr>
<td>MPA 203T</td>
<td>Quality Control and Quality Assurance</td>
<td>4</td>
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<td>MPA 204T</td>
<td>Herbal and Cosmetic Analysis</td>
<td>4</td>
<td>4</td>
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<tr>
<td>MPA 205P</td>
<td>Pharmaceutical Analysis Practical – II</td>
<td>12</td>
<td>6</td>
<td>12</td>
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<tr>
<td>MPA 206P</td>
<td>Seminar/Assignment</td>
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### Table -5: Course of study for M. Pharm. (Pharmacology)

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<th>Credit Points</th>
<th>Hrs./wk</th>
<th>Marks</th>
</tr>
</thead>
<tbody>
<tr>
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<td>Modern Pharmaceutical Analytical Techniques</td>
<td>4</td>
<td>4</td>
<td>4</td>
<td>100</td>
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<tr>
<td>MPL 102T</td>
<td>Advanced Pharmacology – I</td>
<td>4</td>
<td>4</td>
<td>4</td>
<td>100</td>
</tr>
<tr>
<td>MPL 103T</td>
<td>Pharmacological and Toxicological Screening Methods –I</td>
<td>4</td>
<td>4</td>
<td>4</td>
<td>100</td>
</tr>
<tr>
<td>MPL 104T</td>
<td>Cellular and Molecular Pharmacology</td>
<td>4</td>
<td>4</td>
<td>4</td>
<td>100</td>
</tr>
<tr>
<td>MPL 105P</td>
<td>Pharmacological Practical – I</td>
<td>12</td>
<td>6</td>
<td>12</td>
<td>150</td>
</tr>
<tr>
<td>MPL 106P</td>
<td>Seminar/Assignment</td>
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<td>4</td>
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### Semester II

<table>
<thead>
<tr>
<th>Course Code</th>
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<th>Credit Hours</th>
<th>Credit Points</th>
<th>Hrs./wk</th>
<th>Marks</th>
</tr>
</thead>
<tbody>
<tr>
<td>MPL 201T</td>
<td>Advanced Pharmacology – II</td>
<td>4</td>
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<tr>
<td>MPL 202T</td>
<td>Pharmacological and Toxicological Screening Methods – II</td>
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<td>MPL 203T</td>
<td>Principles of Drug Discovery</td>
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<td>MPL 204T</td>
<td>Clinical Research and Pharmacovigilance</td>
<td>4</td>
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<tr>
<td>MPL 205P</td>
<td>Pharmacological Practical – II</td>
<td>12</td>
<td>6</td>
<td>12</td>
<td>150</td>
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<tr>
<td>MPL 206P</td>
<td>Seminar/Assignment</td>
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<td>4</td>
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### Table – 6: Course of study for M. Pharm. III Semester
(Common for All Specializations)

<table>
<thead>
<tr>
<th>Course Code</th>
<th>Course</th>
<th>Credit Hours</th>
<th>Credit points</th>
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<tbody>
<tr>
<td>MRM 301T</td>
<td>Research Methodology and Biostatistics*</td>
<td>4</td>
<td>4</td>
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<td>MPR 301T</td>
<td>Journal club</td>
<td>2</td>
<td>2</td>
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<tr>
<td>MPR 302T</td>
<td>Discussion/Presentation (Proposal presentation)</td>
<td>2</td>
<td>2</td>
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<tr>
<td>MPR 303P</td>
<td>Research Work (Proposed project work, Literature survey, Plan of work, Methodology)</td>
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<td>14</td>
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<td></td>
<td>Total</td>
<td>36</td>
<td>22</td>
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* Non University Exam
### Table – 7: Course of study for M. Pharm. IV Semester
(Common for All Specializations)

<table>
<thead>
<tr>
<th>Course Code</th>
<th>Course</th>
<th>Credit Hours</th>
<th>Credit points</th>
</tr>
</thead>
<tbody>
<tr>
<td>MPR 401T</td>
<td>Discussion/ Final Presentation (Presentation of work, communication skills, question and answers)</td>
<td>3</td>
<td>3</td>
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<tr>
<td>MPR 402P</td>
<td>Research work and colloquium (Objective(s) of the work done, Methodology adopted, Results &amp; Discussions, Conclusions &amp; Outcomes)</td>
<td>36</td>
<td>18</td>
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<td></td>
<td>Total</td>
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<td>21</td>
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### Table – 8: Semester wise credits distribution

<table>
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<th>Semester</th>
<th>Credit points</th>
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<tbody>
<tr>
<td>I</td>
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<td>II</td>
<td>26</td>
</tr>
<tr>
<td>III</td>
<td>22</td>
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<tr>
<td>IV</td>
<td>21</td>
</tr>
<tr>
<td>Total Credit Points</td>
<td>95</td>
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</tbody>
</table>

#### 10. PROGRAMME COMMITTEE

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

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

3. Duties of the Programme Committee:
   i. Periodically reviewing the progress of the classes.
   ii. Discussing the problems concerning curriculum, syllabus and the conduct of classes.
   iii. Discussing with the course teachers on the nature and scope of assessment for the course and the same shall be announced to the students at the beginning of respective semesters.
   iv. Communicating its recommendation to the Head of the institution on academic matters.
   v. The Programme Committee shall meet at least twice in a semester preferably at the end of each sessional exam and before the end semester exam.
11. EXAMINATIONS/ASSESSMENTS
The schemes for internal assessment and end semester examinations are given in Table – 9 to 13.

11.1. End semester examinations
The End Semester Examinations for each theory and practical course through semesters I to IV shall be conducted by the respective University except for the subject with asterix symbol (*) in table 6 for which examinations shall be conducted by the subject experts at college level and the marks/grades shall be submitted to the University.
<table>
<thead>
<tr>
<th>Course code</th>
<th>Course</th>
<th>Internal Assessment</th>
<th>End Semester Exams</th>
<th>Total Marks</th>
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<td>Sessional Exams</td>
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<td>Marks</td>
<td>Duration</td>
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<td>10</td>
<td>15</td>
<td>1 Hr</td>
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<tr>
<td>MPH 102T</td>
<td>Drug Delivery Systems</td>
<td>10</td>
<td>15</td>
<td>1 Hr</td>
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<td>MPH 103T</td>
<td>Modern Pharmaceutics</td>
<td>10</td>
<td>15</td>
<td>1 Hr</td>
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<td>MPH 104T</td>
<td>Regulatory Affairs</td>
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<td></td>
<td><strong>Total</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Semester II</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>MPH 201T</td>
<td>Molecular Pharmaceutics (Nano Technology and Targeted DDS)</td>
<td>10</td>
<td>15</td>
<td>1 Hr</td>
</tr>
<tr>
<td>MPH 202T</td>
<td>Advanced Biopharmaceutics &amp; Pharmacokinetics</td>
<td>10</td>
<td>15</td>
<td>1 Hr</td>
</tr>
<tr>
<td>MPH 203T</td>
<td>Computer Aided Drug Delivery System</td>
<td>10</td>
<td>15</td>
<td>1 Hr</td>
</tr>
<tr>
<td>MPH 204T</td>
<td>Cosmetic and Cosmeceuticals</td>
<td>10</td>
<td>15</td>
<td>1 Hr</td>
</tr>
<tr>
<td>MPH 205P</td>
<td>Pharmaceutics Practical – II</td>
<td>20</td>
<td>30</td>
<td>6 Hr</td>
</tr>
<tr>
<td>MPH 206P</td>
<td>Seminar/Assignment</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td></td>
<td><strong>Total</strong></td>
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<td></td>
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</tr>
<tr>
<td>Course code</td>
<td>Course</td>
<td>Internal Assessment</td>
<td>End Semester Exams</td>
<td>Total Marks</td>
</tr>
<tr>
<td>-------------</td>
<td>--------------------------------------------</td>
<td>---------------------</td>
<td>--------------------</td>
<td>-------------</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Continuous mode</td>
<td>Sessional Exams</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Marks</td>
<td>Duration</td>
<td></td>
</tr>
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<td></td>
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<td>Total</td>
<td>Marks</td>
<td>Duration</td>
</tr>
<tr>
<td>Semester I</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>MPC 101T</td>
<td>Modern Pharmaceutical Analytical Techniques</td>
<td>10</td>
<td>15</td>
<td>25</td>
</tr>
<tr>
<td>MPC 102T</td>
<td>Advanced Organic Chemistry - I</td>
<td>10</td>
<td>15</td>
<td>25</td>
</tr>
<tr>
<td>MPC 103T</td>
<td>Advanced Medicinal Chemistry</td>
<td>10</td>
<td>15</td>
<td>25</td>
</tr>
<tr>
<td>MPC 104T</td>
<td>Chemistry of Natural Products</td>
<td>10</td>
<td>15</td>
<td>25</td>
</tr>
<tr>
<td>MPC 105P</td>
<td>Pharmaceutical Chemistry Practical –</td>
<td>20</td>
<td>30</td>
<td>50</td>
</tr>
<tr>
<td>MPC 106P</td>
<td>Seminar/Assignment</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td></td>
<td>Total</td>
<td></td>
<td></td>
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<tr>
<td>Semester II</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>MPC 201T</td>
<td>Advanced Spectral Analysis</td>
<td>10</td>
<td>15</td>
<td>25</td>
</tr>
<tr>
<td>MPC 202T</td>
<td>Advanced Organic Chemistry – II</td>
<td>10</td>
<td>15</td>
<td>25</td>
</tr>
<tr>
<td>MPC 203T</td>
<td>Computer Aided Drug Design</td>
<td>10</td>
<td>15</td>
<td>25</td>
</tr>
<tr>
<td>MPC 204T</td>
<td>Pharmaceutical Process Chemistry</td>
<td>10</td>
<td>15</td>
<td>25</td>
</tr>
<tr>
<td>MPC 205P</td>
<td>Pharmaceutical Chemistry Practical – II</td>
<td>20</td>
<td>30</td>
<td>50</td>
</tr>
<tr>
<td>MPC 206P</td>
<td>Seminar/Assignment</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td></td>
<td>Total</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Table – 11: Schemes for internal assessments and end semester (Pharmaceutical Analysis – MPA)

<table>
<thead>
<tr>
<th>Course code</th>
<th>Course</th>
<th>Internal Assessment</th>
<th>End Semester Exams</th>
<th>Total Marks</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Continuous mode</td>
<td>Sessional Exams</td>
<td>Total</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Marks</td>
<td>Duration</td>
<td>Marks</td>
</tr>
<tr>
<td>Semester I</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>MPA 101T</td>
<td>Modern Pharmaceutical Analytical Techniques</td>
<td>10</td>
<td>15</td>
<td>1 Hr</td>
</tr>
<tr>
<td>MPA 102T</td>
<td>Advanced Pharmaceutical Analysis</td>
<td>10</td>
<td>15</td>
<td>1 Hr</td>
</tr>
<tr>
<td>MPA 103T</td>
<td>Pharmaceutical Validation</td>
<td>10</td>
<td>15</td>
<td>1 Hr</td>
</tr>
<tr>
<td>MPA 104T</td>
<td>Food Analysis</td>
<td>10</td>
<td>15</td>
<td>1 Hr</td>
</tr>
<tr>
<td>MPA 105P</td>
<td>Pharmaceutical Analysis Practical – I</td>
<td>20</td>
<td>30</td>
<td>6 Hr</td>
</tr>
<tr>
<td>MPA 106P</td>
<td>Seminar/Assignment</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Total</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Semester II</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>MPA 201T</td>
<td>Advanced Instrumental Analysis</td>
<td>10</td>
<td>15</td>
<td>1 Hr</td>
</tr>
<tr>
<td>MPA 202T</td>
<td>Modern Bio-Analytical Techniques</td>
<td>10</td>
<td>15</td>
<td>1 Hr</td>
</tr>
<tr>
<td>MPA 203T</td>
<td>Quality Control and Quality Assurance</td>
<td>10</td>
<td>15</td>
<td>1 Hr</td>
</tr>
<tr>
<td>MPA 204T</td>
<td>Herbal and Cosmetic Analysis</td>
<td>10</td>
<td>15</td>
<td>1 Hr</td>
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<tr>
<td>MPA 205P</td>
<td>Pharmaceutical Analysis Practical – II</td>
<td>20</td>
<td>30</td>
<td>6 Hr</td>
</tr>
<tr>
<td>MPA 206P</td>
<td>Seminar/Assignment</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Total</td>
<td></td>
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Table – 12: Schemes for internal assessments and end semester (Pharmacology – MPL)

<table>
<thead>
<tr>
<th>Course code</th>
<th>Course</th>
<th>Internal Assessment</th>
<th></th>
<th>End Semester Exams</th>
<th></th>
<th>Total Marks</th>
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<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Marks</td>
<td>Duration</td>
<td></td>
<td>Marks</td>
<td>Duration</td>
</tr>
<tr>
<td>Semester I</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>MPL 101T</td>
<td>Modern Pharmaceutical Analytical Techniques</td>
<td>10</td>
<td>15</td>
<td>1 Hr</td>
<td>25</td>
<td>75</td>
</tr>
<tr>
<td>MPL 102T</td>
<td>Advanced Pharmacology – I</td>
<td>10</td>
<td>15</td>
<td>1 Hr</td>
<td>25</td>
<td>75</td>
</tr>
<tr>
<td>MPL 103T</td>
<td>Pharmacological and Toxicological Screening Methods –I</td>
<td>10</td>
<td>15</td>
<td>1 Hr</td>
<td>25</td>
<td>75</td>
</tr>
<tr>
<td>MPL 104T</td>
<td>Cellular and Molecular Pharmacology</td>
<td>10</td>
<td>15</td>
<td>1 Hr</td>
<td>25</td>
<td>75</td>
</tr>
<tr>
<td>MPL 105P</td>
<td>Pharmacological Practical – I</td>
<td>20</td>
<td>30</td>
<td>6 Hr</td>
<td>50</td>
<td>100</td>
</tr>
<tr>
<td>MPL 106P</td>
<td>Seminar/Assignment</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>100</td>
</tr>
<tr>
<td>Total</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>650</td>
</tr>
<tr>
<td>Semester II</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>650</td>
</tr>
<tr>
<td>MPL 201T</td>
<td>Advanced Pharmacology – II</td>
<td>10</td>
<td>15</td>
<td>1 Hr</td>
<td>25</td>
<td>75</td>
</tr>
<tr>
<td>MPL 202T</td>
<td>Pharmacological and Toxicological Screening Methods – II</td>
<td>10</td>
<td>15</td>
<td>1 Hr</td>
<td>25</td>
<td>75</td>
</tr>
<tr>
<td>MPL 203T</td>
<td>Principles of Drug Discovery</td>
<td>10</td>
<td>15</td>
<td>1 Hr</td>
<td>25</td>
<td>75</td>
</tr>
<tr>
<td>MPL 204T</td>
<td>Clinical Research and Pharmacovigilance</td>
<td>10</td>
<td>15</td>
<td>1 Hr</td>
<td>25</td>
<td>75</td>
</tr>
<tr>
<td>MPL 205P</td>
<td>Pharmacological Practical – II</td>
<td>20</td>
<td>30</td>
<td>6 Hr</td>
<td>50</td>
<td>100</td>
</tr>
<tr>
<td>MPL 206P</td>
<td>Seminar/Assignment</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>100</td>
<td>-</td>
</tr>
<tr>
<td>Total</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>650</td>
</tr>
</tbody>
</table>
Table – 13: Schemes for internal assessments and end semester examinations
(Semester III & IV)

<table>
<thead>
<tr>
<th>Course code</th>
<th>Course</th>
<th>Internal Assessment</th>
<th>End Semester Exams</th>
<th>Total Marks</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Continuous mode</td>
<td>Sessional Exams</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Marks</td>
<td>Duration</td>
<td></td>
</tr>
<tr>
<td>Semester III</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>MRM 301T</td>
<td>Research Methodology and Biostatistics*</td>
<td>10</td>
<td>15</td>
<td>1 Hr</td>
</tr>
<tr>
<td>MPR 301T</td>
<td>Journal club</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>MPR 302T</td>
<td>Discussion/Presentation (Proposal presentation)</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>MPR 303P</td>
<td>Research Work (proposed project work, Literature survey, Plan of work, Methodology)</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Total</td>
<td></td>
<td>400</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

|             |                                             |                   |                     |             |
| Semester IV |                                             |                   |                     |             |
| MPR 401T    | Discussion/ Presentation (Presentation of work, communication skills, question and answers) | -    | -        | -      | 100   | -        | -      | 100       |
| MPR 402P    | Research Work and colloquium (Objective(s) of the work done, Methodology adopted, Results & Discussions, Conclusions & Outcomes) | -    | -        | -      | 100   | 1 Hr     |        | 100       |
| Total       |                                             | 200   |          |        |       |          |        |            |

* Non University Examination

11.2. **Internal assessment: Continuous mode**

The marks allocated for Continuous mode of Internal Assessment shall be awarded as follows.

Table – 14: Scheme for awarding internal assessment: Continuous mode

<table>
<thead>
<tr>
<th>Criteria</th>
<th>Maximum Marks</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Theory</strong></td>
<td></td>
</tr>
<tr>
<td>Attendance (Refer Table – 15)</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 – 15)</td>
<td>10</td>
</tr>
<tr>
<td>Based on Practical Records, Regular viva voce, etc.</td>
<td>10</td>
</tr>
<tr>
<td>Total</td>
<td>20</td>
</tr>
</tbody>
</table>
Table – 15: Guidelines for allotment of marks for attendance

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

11.2 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 tables 9 – 13. 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 table 16. The exact dates of examinations shall be notified from time to time.
**Table – 16: Tentative schedule of end semester examinations**

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

**16. ALLOWED TO KEEP TERMS (ATKT):**

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

A student shall be eligible to carry forward all the courses of I and II semesters till the III semester examinations. However, he/she shall not be eligible to attend the courses of IV semester until all the courses of I, II and III semesters are successfully completed. A student shall be eligible to get his/her CGPA upon successful completion of the courses of I to IV semesters within the stipulated time period as per the norms.

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

**17. GRADING OF PERFORMANCES**

17.1. Letter grades and grade points allocations:

Based on the performances, each student shall be awarded a final letter grade at the end of the semester for each course. The letter grades and their corresponding grade points are given in Table – 17.

**Table – 17: 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:

\[ SGPA = \frac{C_1 G_1 + C_2 G_2 + C_3 G_3 + C_4 G_4}{C_1 + C_2 + C_3 + C_4} \]

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 AB grade awarded in that semester. For example if a learner has a F or AB grade in course 4, the SGPA shall then be computed as:

\[ SGPA = \frac{C_1 G_1 + C_2 G_2 + C_3 G_3 + C_4 \times \text{ZERO}}{C_1 + C_2 + C_3 + C_4} \]

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

\[ CGPA = \frac{C_1 S_1 + C_2 S_2 + C_3 S_3 + C_4 S_4}{C_1 + C_2 + C_3 + C_4} \]

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

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

15
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).

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. programme shall not be eligible for award of ranks. Moreover, the candidates should have completed the M. Pharm. programme 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 PROGRAMME OF STUDY
The duration for the completion of the programme shall be fixed as double the actual duration of the programme and the students have to pass within the said period, otherwise they have to get fresh registration.

25. REVALUATION/RETOTALING OF ANSWER PAPERS
There is no provision for revaluation of the answer papers in any examination. However, the candidates can apply for retotaling by paying prescribed fee.

26. RE-ADMISSION AFTER BREAK OF STUDY
Candidate who seeks re-admission to the programme after break of study has to get the approval from the University by paying a condonation fee.
SEMESTER – I

PHARMACEUTICS (MPH)

MPH 101T. MODERN PHARMACEUTICAL ANALYTICAL TECHNIQUES

Hours per week: 4L
Credit: 4
End Examination: 75 Marks
Midsem: 25 Marks

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

UNIT – I

12 Hrs

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 (Characteristics of drugs that can be analyzed by fluorimetry), Quenchers, Instrumentation and Applications of fluorescence spectrophotometer.


UNIT – II

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

UNIT – III

12 Hrs

UNIT – IV

12 Hrs
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

UNIT – V 12 Hrs
a. Principle, instrumentation and applications of Gel electrophoresis and Moving boundary electrophoresis
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
c. Thermal Techniques:
   Differential Scanning Calorimetry (DSC): 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).
   Thermogravimetric Analysis (TGA): Principle, instrumentation, factors affecting results, advantage and disadvantages, pharmaceutical applications.

References

MPH 102T. DRUG DELIVERY SYSTEMS

Hours per week: 4L
Credit: 4
End Examination: 75 Marks
Midsem: 25 Marks

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.

UNIT – I 12 Hrs

UNIT – II 12 Hrs
Polymers: Introduction, definition, classification, properties and application

UNIT – III 12 Hrs

UNIT – IV 12 Hrs
Occular Drug Delivery Systems: Barriers of drug permeation, Methods to overcome barriers.

UNIT – V 12 Hrs
Protein and Peptide Delivery: Barriers for protein delivery.
Formulation and Evaluation of delivery systems of proteins and other macromolecules.
Vaccine delivery systems: Vaccines, uptake of antigens, single shot vaccines, mucosal and transdermal delivery of vaccines.

References
3. Encyclopedia of controlled delivery, Editor - Edith Mathiowitz, Published by Wiley Interscience Publication, John Wiley and Sons, Inc, New York! Chichester/Weinheim
**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

**MPH 103T. MODERN PHARMACEUTICS**

**Hours per week:** 4L  
**Credit:** 4  
**End Examination:** 75 Marks  
**Midsem:** 25 Marks

**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.

**UNIT – I**  
**12 Hrs**
Preformation Concepts – Drug Excipient interactions - different methods, Kinetics of stability, stability testing.
Dissolution: Dissolution mechanisms, kinetic models for drug release - Zero order, First order, Hixson Crowell’s, Higuchi, Peppas, Various compendial dissolution apparatus, Dissolution profiles comparison- difference factor ($f_1$), similarity factor ($f_2$).

**UNIT – II**  
**12 Hrs**
Theories of dispersion and pharmaceutical dispersion (Emulsion and Suspension, SMEDDS) preparation and stability.
Large and small volume parenterals – physiological and formulation consideration, Manufacturing and evaluation.

**UNIT – III**  
**12 Hrs**

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

**UNIT – V**  
**12 Hrs**
Validation: Introduction to Pharmaceutical Validation, Scope & merits of Validation, Validation and calibration of Master plan, ICH & WHO guidelines for calibration and

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

References
1. Theory and Practice of Industrial Pharmacy by Lachmann and Libermann
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.
15. Pharmaceutical Preformulations; by J. J. Wells.
16. Applied production and operations management; by Evans, Anderson, Sweeney and Williams.

MPH 104T. REGULATORY AFFAIRS

Hours per week: 4L  End Examination: 75 Marks
Credit: 4  Midsem: 25 Marks

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
• Pharmacovigilance and process of monitoring in clinical trials.

UNIT – I 12 Hrs
Documentation in pharmaceutical industry: Master formula record, DMF (Drug Master File), distribution records. Generic drugs product development. Introduction, Hatch- Waxman act and amendments, CFR (CODE OF FEDERAL REGULATION), drug product performance, in-vitro, ANDA regulatory approval process, NDA approval process, BE and drug product assessment, in-vivo, scale up process approval changes, post marketing surveillance, outsourcing BA and BE to CRO.

UNIT – II 12 Hrs
Regulatory requirement for product approval: API, biologics, novel, therapies obtaining NDA, ANDA for generic drugs ways and means of US registration for foreign drugs

UNIT – III 12 Hrs
CMC, post approval regulatory affairs. Regulation for combination products and medical devices. CTD and ECTD format, industry and FDA liaison.
ICH - Guidelines of ICH-Q, S, E, M. Regulatory requirements of EU, MHRA, TGA and ROW countries.

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

UNIT – V 12 Hrs

References
7. www.ich.org/
8. www.fda.gov/
9. europa.eu/index_en.htm
MPH 105P. PHARMACEUTICS PRACTICALS – I

Hours per week: 12
Credit: 6
End Examination: 100 Marks
Midsem: 50 Marks

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.

SEMESTER – II

MPH 201T. MOLECULAR PHARMACEUTICS
(NANO TECHNOLOGY & TARGETED DDS) (NTDS)

Hours per week: 4L
Credit: 4
End Examination: 75 Marks
Midsem: 25 Marks

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.

UNIT – I
12 Hrs

UNIT – II
12 Hrs
Targeting Methods: Introduction, preparation and evaluation.
Nano Particles & Liposomes: Types, preparation and evaluation.
UNIT – III 12 Hrs
Micro Capsules/Micro Spheres: Types, preparation and evaluation, Monoclonal Antibodies; preparation and application, preparation and application of Niosomes, Aquasomes, Phytosomes, Electroosmes.

UNIT – IV 12 Hrs
Pulmonary Drug Delivery Systems: Aerosols, propellents, container types, preparation and evaluation
Intra Nasal Route Delivery systems; Types, preparation and evaluation.

UNIT – V 12 Hrs
Biodistribution and Pharmacokinetics. Knowledge of therapeutic antisense molecules and aptamers as drugs of future.

References

MPH 202T. ADVANCED BIOPHARMACEUTICS & PHARMACOKINETICS
Hours per week: 4L
Credit: 4
End Examination: 75 Marks
Midsem: 25 Marks

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 biopharmaceutical 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...
UNIT – I

UNIT – II

UNIT – III

UNIT – IV

UNIT – V
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

MPH 203T. COMPUTER AIDED DRUG DEVELOPMENT

Hours per week: 4L  End Examination: 75 Marks
Credit: 4  Midsem: 25 Marks

Scope: This course is designed to impart knowledge and skills necessary for computer Applications inpharmaceutical 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)
UNIT – I  12 Hrs

UNIT – II  12 Hrs

UNIT – III  12 Hrs

UNIT – IV  12 Hrs
c. Computers in Clinical Development: Clinical Data Collection and Management, Regulation of Computer Systems

UNIT – V  12 Hrs
Artificial Intelligence (AI), Robotics and Computational fluid dynamics: General overview, Pharmaceutical Automation, Pharmaceutical applications, Advantages and Disadvantages. Current Challenges and Future Directions.

References
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.

UNIT – I 12 Hrs
Cosmetics – Regulatory: Definition of cosmetic products as per Indian regulation. Indian regulatory requirements for labeling of cosmetics Regulatory provisions relating to import of cosmetics. Misbranded and spurious cosmetics. Regulatory provisions relating to manufacture of cosmetics – Conditions for obtaining license, prohibition of manufacture and sale of certain cosmetics, loan license, offences and penalties.

UNIT – II 12 Hrs
Cosmetics - Biological aspects: Structure of skin relating to problems like dry skin, acne, pigmentation, prickly heat, wrinkles and body odor. Structure of hair and hair growth cycle. Common problems associated with oral cavity. Cleansing and care needs for face, eye lids, lips, hands, feet, nail, scalp, neck, body and under-arm.

UNIT – III 12 Hrs
Formulation Building blocks: Building blocks for different product formulations of cosmetics/cosmeceuticals.
Surfactants – Classification and application. Emollients, rheological additives: classification and application.
Antimicrobial used as preservatives, their merits and demerits. Factors affecting microbial preservative efficacy.
Building blocks for formulation of a moisturizing cream, vanishing cream, cold cream, shampoo and toothpaste.
Soaps and syndet bars.
Perfumes; Classification of perfumes. Perfume ingredients listed as allergens in EU regulation.
Controversial ingredients: Parabens, formaldehyde liberators, dioxane.

UNIT – IV 12 Hrs
UNIT – V
Herbal Cosmetics: Herbal ingredients used in Hair care, skin care and oral care. Review of guidelines for herbal cosmetics by private bodies like cosmos with respect to preservatives, emollients, foaming agents, emulsifiers and rheology modifiers. Challenges in formulating herbal cosmetics.

References
2. Poucher’s perfume cosmetics and soaps, 10th edition.
4. Handbook of cosmetic science and Technology A. O. Barel, M. Paye and H. I. Maibach. 3rd edition
5. Cosmetic and Toiletries recent suppliers’ catalogue.
6. CTFA directory.

MPH 205P. PHARMACEUTICS PRACTICALS – II

Hours per week: 12
End Examination: 100 Marks
Credit: 6
Midsem: 50 Marks

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® software.
11. In vitro cell studies for permeability and metabolism
12. DoE Using Design Expert® Software
13. Formulation data analysis Using Design Expert® 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
21. To incorporate herbal and chemical actives to develop products.
22. To address Dry skin, acne, blemish, Wrinkles, bleeding gums and dandruff.
SEMESTER – I

PHARMACEUTICAL CHEMISTRY (MPC)

MPC 101T. MODERN PHARMACEUTICAL ANALYTICAL TECHNIQUES

Hours per week: 4L  End Examination: 75 Marks
Credit: 4  Midsem: 25 Marks

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

UNIT – I  12 Hrs
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 (Characteristics of drugs that can be analyzed by fluorimetry), Quenchers, Instrumentation and Applications of fluorescence spectrophotometer.

UNIT – II  12 Hrs
NMR spectroscopy: Quantum numbers and their role in NMR, Principle, Instrumentation, Solvent requirement in NMR, Relaxation process, NMR signals in various compounds, Chemical shift, Factors influencing chemical shift, Spin-Spin coupling, Coupling constant, Nuclear magnetic double resonance, Brief outline of principles of FT-NMR and $^{13}$C NMR. Applications of NMR spectroscopy.

UNIT – III  12 Hrs

UNIT – IV  12 Hrs
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

UNIT – V  12 Hrs
a. Principle, instrumentation and applications of Gel electrophoresis and Moving boundary electrophoresis
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
c. Thermal Techniques:
Differential Scanning Calorimetry (DSC): 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).
Thermogravimetric Analysis (TGA): Principle, instrumentation, factors affecting results, advantage and disadvantages, pharmaceutical applications.

References

MPC 102T. ADVANCED ORGANIC CHEMISTRY – I

Hours per week: 4L  
Credit: 4  
End Examination: 75 Marks  
Midsem: 25 Marks

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 heterosynthesis
- 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

UNIT – I

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
1. Nucleophilic uni- and bimolecular reactions (SN$_1$ and SN$_2$)
2. Elimination reactions (E$_1$ & E$_2$; Hoffman & Saytzeff’s rule)
3. Rearrangement reaction

UNIT – II

12 Hrs
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

UNIT – III

12 Hrs

1. Synthetic Reagents & Applications
Aluminiumisopropoxide, 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).

2. 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: carbamates and amides

UNIT – IV

12 Hrs

Heterocyclic Chemistry:
Organic Name reactions with their respective mechanism and application involved in synthesis of drugs containing five, six membered and fused heterocyclic’s 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, Prochlorperazine, Promazine, Chlorpromazine, Theophylline, Mercaptopurine and Thioguanine.

UNIT – V

12 Hrs

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

MPC 103T. ADVANCED MEDICINAL CHEMISTRY

Hours per week: 4L End Examination: 75 Marks
Credit: 4 Midsem: 25 Marks

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

UNIT – I 12 Hrs
**Drug discovery:** Stages of drug discovery, lead discovery; identification, validation and diversity of drug targets.

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

UNIT – II 12 Hrs
**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,
(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.

UNIT – III 12 Hrs
**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, COX-1 & COX-2 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.

UNIT – IV 12 Hrs
**Rational Design of Enzyme Inhibitors:** Enzyme kinetics & Principles of Enzyme inhibitors, Enzyme inhibitors in medicine, Enzyme in basic research, rational design of non-covalently and covalently binding enzyme inhibitors.

UNIT – V 12 Hrs
**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.
10. An Introduction to Medicinal Chemistry, Graham L. Patrick, 3rd edition, Oxford University Press, USA.

**MPC 104T. CHEMISTRY OF NATURAL PRODUCTS**

Hours per week: 4L  
End Examination: 75 Marks  
Credit: 4  
Midsem: 25 Marks

**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

**UNIT – I**  
12 Hrs  
Study of Natural products as leads for new pharmaceuticals for the following class of drugs
(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)
UNIT – II  
12 Hrs
(a) Alkaloids  
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).

UNIT – III  
(a) Terpenoids: 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.

UNIT – IV  
12 Hrs
(a) Recombinant DNA technology and drug discovery  
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.

UNIT – V  
12 Hrs
Structural Characterization of natural compounds  
Structural characterization of natural compounds using IR, $^1$H NMR, $^{13}$C NMR 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.  
5. Natural Product Chemistry Nakanishi Gg goofy, University Science Books, California.  
8. Introduction to molecular Phytochemistry – CHJ Wells, Chapmannstall.
16. Burger’s Medicinal Chemistry

MPC 105P. PHARMACEUTICAL CHEMISTRY PRACTICAL – I

Hours per week: 12  End Examination: 100 Marks
Credit: 6  Midsem: 50 Marks

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-Schimdt reaction
3. Benzyllic 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
SEMESTER – II

MPC 201T. ADVANCED SPECTRAL ANALYSIS

Hours per week: 4L
Credit: 4
End Examination: 75 Marks
Midsem: 25 Marks

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

UNIT – I

12 Hrs
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.

UNIT – II

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

UNIT – III

12 Hrs
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.

UNIT – IV

12 Hrs
Chromatography:
Principle, Instrumentation and Applications of the following:
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

UNIT – V

12 Hrs
(a) Thermal methods of analysis: Introduction, principle, instrumentation and application of DSC, DTA and TGA.
(c) Radio immuno assay: Biological standardization, bioassay, ELISA, Radioimmuno assay of digitalis and insulin.

References
2. Principles of Instrumental Analysis - Doglas A Skoog, F. James Holler, Timothy A.
MPC 202T. ADVANCED ORGANIC CHEMISTRY – II

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.

UNIT – I

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.

UNIT – II

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.
UNIT – III
12 Hrs
(a) Photochemical reactions
Basic principles of photochemical reactions. Photo-oxidation, photo-addition and photo-fragmentation.
(b) Pericyclic reactions: Mechanism, Types of pericyclic reactions such as cyclo addition, electrocyclic reaction and sigmatropic rearrangement reactions with examples.

UNIT – IV
12 Hrs
Catalysis:
(a) Types of catalysis, heterogeneous and homogenous catalysis, advantages and disadvantages
(b) Heterogeneous catalysis – preparation, characterization, kinetics, supported catalysts, catalyst deactivation and regeneration, some examples of heterogeneous catalysis used in synthesis of drugs.
(c) 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
(d) Transition-metal and Organo-catalysis in organic synthesis: Metal-catalyzed reactions
(e) Biocatalysis: Use of enzymes in organic synthesis, immobilized enzymes/cells in organic reaction.
(f) Phase transfer catalysis - theory and applications

UNIT – V
12 Hrs
Stereochemistry & Asymmetric Synthesis
(a) 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.
(b) 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
MPC 203T. COMPUTER AIDED DRUG DESIGN

Hours per week: 4L
Credit: 4
End Examination: 75 Marks
Midsem: 25 Marks

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

UNIT – I 12 Hrs
Introduction to Computer Aided Drug Design (CADD) - 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.

UNIT – II 12 Hrs
Quantitative Structure Activity Relationships: Applications: 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.

UNIT – III 12 Hrs
Molecular Modeling and Docking
(a) Molecular and Quantum Mechanics in drug design.
(b) Energy Minimization Methods: comparison between global minimum conformation and bioactive conformation.
(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)

UNIT – IV 12 Hrs
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.
UNIT – V 12 Hrs

(a) Pharmacophore Mapping and Virtual Screening
Concept of pharmacophore, pharmacophore mapping, identification of Pharmacophore features and Pharmacophore modeling; Conformational search used in pharmacophore mapping.

(b) In Silico Drug Design and Virtual Screening Techniques
Similarity based methods and Pharmacophore based screening, structure based In-silico virtual screening protocols.

References
1. Computational and structural approaches to drug discovery, Robert M Stroud and Janet. F Moore, RCS Publishers
10. Computational and structural approaches to drug design edited by Robert M Stroud and Janet. F Moore

MPC 204T. PHARMACEUTICAL PROCESS CHEMISTRY

Hours per week: 4L  End Examination: 75 Marks
Credit: 4  Midsem: 25 Marks

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

UNIT – I 12 Hrs

Process chemistry
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.
UNIT – II 12 Hrs
Unit operations
(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.

UNIT – III 12 Hrs
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 H₂O₂, sodium hypochlorite, Oxygen gas, ozonolysis.

UNIT – IV 12 Hrs
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.

UNIT – V 12 Hrs
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)
10. M. Gopal: Dryden’s Outlines of Chemical Technology, WEP East-West Press
12. Lowenheim & M. K. Moran: Industrial Chemicals
17. ICH Guidelines
18. United States Food and Drug Administration official website www.fda.gov

MPC 205P. PHARMACEUTICAL CHEMISTRY PRACTICALS – II

Hours per week: 12
Credit: 6
End Examination: 100 Marks
Midsem: 50 Marks

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 Woodward–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
12. Preparation of 4-iodotolene from p-toluidine.
13. NaBH₄ reduction of vanillin to vanillyl alcohol
14. Preparation of umbelliferone by Pechman 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
SEMESTER – I

PHARMACEUTICAL ANALYSIS (MPA)

MPA 101T. MODERN PHARMACEUTICAL ANALYTICAL TECHNIQUES

Hours per week: 4L  End Examination: 75 Marks
Credit: 4  Midsem: 25 Marks

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

UNIT – I  12 Hrs
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 (Characteristics of drugs that can be analyzed by fluorimetry), Quenchers, Instrumentation and Applications of fluorescence spectrophotometer.

UNIT – II  12 Hrs
NMR spectroscopy: Quantum numbers and their role in NMR, Principle, Instrumentation, Solvent requirement in NMR, Relaxation process, NMR signals in various compounds, Chemical shift, Factors influencing chemical shift, Spin-Spin coupling, Coupling constant, Nuclear magnetic double resonance, Brief outline of principles of FT-NMR and $^{13}$C NMR. Applications of NMR spectroscopy.

UNIT – III  12 Hrs

UNIT – IV  12 Hrs
Chromatography: Principle, apparatus, instrumentation, chromatographic parameters, factors affecting resolution, isolation of drug from excipients, data interpretation and applications of the following:
- Thin Layer chromatography
- High Performance Thin Layer Chromatography
- 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

UNIT – V  
12 Hrs
a. Principle, instrumentation and applications of Gel electrophoresis and Moving boundary electrophoresis
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
c. Thermal Techniques:
   Differential Scanning Calorimetry (DSC): 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).
   Thermogravimetric Analysis (TGA): Principle, instrumentation, factors affecting results, advantage and disadvantages, pharmaceutical applications

References

MPA 102T. ADVANCED PHARMACEUTICAL ANALYSIS

Hours per week: 4L  
End Examination: 75 Marks
Credit: 4  
Midsem: 25 Marks

Scope: This subject deals with the various aspects of Impurity, Impurities in new drug products, in residual solvents, Elemental impurities, Impurity profiling and characterization of degradants, Stability testing of phyto pharmaceuticals and their protocol preparation. It also covers the biological testing of various vaccines and their principle and procedure.
**Objective:** After completion of the course students shall be able to know,

- Appropriate analytical skills required for the analytical method development.
- Principles of various reagents used in functional group analysis that renders necessary support in research methodology and demonstrates its application in the practical related problems.
- Analysis of impurities in drugs, residual solvents and stability studies of drugs and biological products.

**UNIT – I**

**Impurity and stability studies:**
Definition, classification of impurities in drug Substance or Active Pharmaceutical Ingredients and quantification of impurities as per ICH guidelines

Impurities in new drug products:
Rationale for the reporting and control of degradation products, reporting degradation products content of batches, listing of degradation products in specifications, qualification of degradation products

Impurities in residual solvents:
General principles, classification of residual solvents, Analytical procedures, limits of residual solvents, reporting levels of residual solvents

**UNIT – II**

**Elemental impurities:**
Element classification, control of elemental impurities, Potential Sources of elemental Impurities, Identification of Potential Elemental Impurities, analytical procedures, instrumentation & C, H, N and S analysis

**Stability testing protocols:**
Selection of batches, container orientation, test parameters, sampling frequency, specification, storage conditions, recording of results, concept of stability, commitment etc. Important mechanistic and stability related information provided by results of study of factors like temperature, pH, buffering species ionic strength and dielectric constant etc. on the reaction rates with practical considerations.

**UNIT – III**

**Impurity profiling and degradant characterization:** Method development, Stability studies and concepts of validation, accelerated stability testing & shelf life calculation, WHO and ICH stability testing guidelines, Stability zones, steps in development, practical considerations. Basics of impurity profiling and degradant characterization with special emphasis. Photostability testing guidelines, ICH stability guidelines for biological products.

**UNIT – IV**

**a. Stability testing of phytopharmaceuticals:**
Regulatory requirements, protocols, HPTLC/HPLC finger printing, interactions and complexity.

**b. Immunoassays (IA) Basic principles, Separation of bound and unbound drug, Radioimmunoassay, Optical IA, Enzyme IA, Fluoro IA, Luminiscence IA, Quantification and applications of IA.**
UNIT – V  

12 Hrs

Biological tests and assays of the following:
a. Adsorbed Tetanus vaccine  
b. Adsorbed Diphtheria vaccine  
c. Human anti haemophilic vaccine  
d. Rabies vaccine  
e. Tetanus Anti toxin  
g. Oxytocin  
h. Heparin sodium IP  
i. Antivenom  
P. PCR, PCR studies for gene regulation, instrumentation (Principle and Procedures)

References
9. Methods of sampling and microbiological examination of water, first revision, BIS
14. ICH Guidelines for impurity profiles and stability studies.

MPA 103T. PHARMACEUTICAL VALIDATION

Hours per week: 4L  
Credit: 4  
End Examination: 75 Marks  
Midsem: 25 Marks

Scope: The main purpose of the subject is to understand about validation and how it can be applied to industry and thus to improve the quality of the products. The subject covers the complete information about validation, types, methodology and application.

Objectives: Upon completion of the subject student shall be able to

- Explain the aspect of validation
- Carryout validation of manufacturing processes
- Apply the knowledge of validation to instruments and equipments
- Validate the manufacturing facilities
UNIT – I  12 Hrs
Introduction: Definition of Qualification and Validation, Advantage of Validation, Streamlining of Qualification & Validation process and Validation Master Plan.

UNIT – II  12 Hrs

UNIT – III  12 Hrs
Validation of Utility systems: Pharmaceutical Water System & pure steam, HVAC system, Compressed air and nitrogen.
Cleaning Validation: Cleaning Method development, Validation of analytical method used in cleaning. Cleaning of Equipment, Cleaning of Facilities. Cleaning in place (CIP).

UNIT – IV  12 Hrs
Analytical method validation: General principles, Validation of analytical method as per ICH guidelines and USP.
Computerized system validation: Electronic records and digital significance - 21 CFR part 11 and GAMP 5.

UNIT – V  12 Hrs
General Principles of Intellectual Property: Concepts of Intellectual Property (IP), Intellectual Property Protection (IPP), Intellectual Property Rights (IPR); Economic importance, mechanism for protection of Intellectual Property – patents, Copyright, Trademark; Factors affecting choice of IP protection; Penalties for violation; Role of IP in pharmaceutical industry; Global ramification and financial implications. Filing patent applications; patent application forms and guidelines. Types of patent applications-provisional and non-provisional, PCT and convention patent applications; International patenting requirement procedures and costs; Rights and responsibilities of a patentee; Practical aspects regarding maintaining of a Patent file; Patent infringement meaning and scope. Significance of transfer technology (TOT), IP and ethics-positive and negative aspects of IPP; Societal responsibility, avoiding unethical practices.

References
3. Validation Master plan by Terveeks or Deeks, Davis Harwood International publishing.


**MPA 104T. FOOD ANALYSIS**

**Scope**: This course is designed to impart knowledge on analysis of food constituents and finished food products. The course includes application of instrumental analysis in the determination of pesticides in variety of food products

**Objectives**: At completion of this course student shall be able to understand various analytical techniques in the determination of

- Food constituents
- Food additives
- Finished food products
- Pesticides in food
- And also student shall have the knowledge on food regulations and
- Legislations

**UNIT – I**  
12 Hrs
Carbohydrates: classification and properties of food carbohydrates, General methods of analysis of food carbohydrates, Changes in food carbohydrates during processing, Digestion, absorption and metabolism of carbohydrates, Dietary fibre, Crude fibre and application of food carbohydrates

Proteins: Chemistry and classification of amino acids and proteins, Physico-Chemical properties of protein and their structure, general methods of analysis of proteins and amino acids, Digestion, absorption and metabolism of proteins.

**UNIT – II**  
12 Hrs
Lipids: Classification, general methods of analysis, refining of fats and oils; hydrogenation of vegetable oils, Determination of adulteration in fats and oils, various methods used for measurement of spoilage of fats and fatty foods.


**UNIT – III**  
12 Hrs
Food additives: Introduction, analysis of Preservatives, antioxidants, artificial sweeteners, flavors, flavor enhancers, stabilizers, thickening and jelling agents.
Pigments and synthetic dyes: Natural pigments, their occurrence and characteristic properties, permitted synthetic dyes, Non-permitted synthetic dyes used by industries, Method of detection of natural, permitted and non-permitted dyes.

UNIT – IV  12 Hrs
General Analytical methods for milk, milk constituents and milk products like ice cream, milk powder, butter, margarine, cheese including adulterants and contaminants of milk. Analysis of fermentation products like wine, spirits, beer and vinegar.

UNIT – V  12 Hrs
Pesticide analysis: Effects of pest and insects on various food, use of pesticides in agriculture, pesticide cycle, organophosphorus and organochlorine pesticides analysis, determination of pesticide residues in grain, fruits, vegetables, milk and milk products. Legislation regulations of food products with special emphasis on BIS, Agmark, FDA and US-FDA.

References
4. Analysis of Food constituents – Multon, Wiley VCH.

MPA 105P. PHARMACEUTICAL ANALYSIS PRACTICALS – I

End Examination: 100 Marks
Midsem: 50 Marks

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. Assay of official compounds by different titrations
8. Assay of official compounds by instrumental techniques.
9. Quantitative determination of hydroxyl group.
10. Quantitative determination of amino group
11. Colorimetric determination of drugs by using different reagents
12. Impurity profiling of drugs
13. Calibration of glasswares
14. Calibration of pH meter
15. Calibration of UV-Visible spectrophotometer
16. Calibration of FTIR spectrophotometer
17. Calibration of GC instrument
18. Calibration of HPLC instrument
19. Cleaning validation of any one equipment
20. Determination of total reducing sugar
21. Determination of proteins
22. Determination of saponification value, Iodine value, Peroxide value, Acid value in food products
23. Determination of fat content and rancidity in food products
24. Analysis of natural and synthetic colors in food
25. Determination of preservatives in food
26. Determination of pesticide residue in food products
27. Analysis of vitamin content in food products
28. Determination of density and specific gravity of foods
29. Determination of food additives

SEMESTER – II

MPA 201T. ADVANCED INSTRUMENTAL ANALYSIS

Hours per week: 4L End Examination: 75 Marks
Credit: 4 Midsem: 25 Marks

Scope: This subject deals with various hyphenated analytical instrumental techniques for identification, characterization and quantification of drugs. Instruments dealt are LC-MS, GC-MS, and hyphenated techniques.

Objectives: After completion of course student is able to know,
• interpretation of the NMR, Mass and IR spectra of various organic compounds
• theoretical and practical skills of the hyphenated instruments
• identification of organic compounds

UNIT – I
12 Hrs
HPLC: Principle, instrumentation, pharmaceutical applications, peak shapes, capacity factor, selectivity, plate number, plate height, resolution, band broadening, pumps, injector, detectors, columns, column problems, gradient HPLC, HPLC solvents, trouble shooting, sample preparation, method development, New developments in HPLC-role and principles of ultra, nano liquid chromatography in pharmaceutical analysis. Immobilized polysaccharide CSP’s: Advancement in enantiomeric separations, revised phase Chiral method development and HILIC approaches. HPLC in Chiral analysis of pharmaceuticals. Preparative HPLC, practical aspects of preparative HPLC.

UNIT – II
12 Hrs
Biochromatography: Size exclusion chromatography, ion exchange chromatography, ion pair chromatography, affinity chromatography general principles, stationary phases and mobile phases. Gas chromatography: Principles, instrumentation, derivatization, head space sampling, columns for GC, detectors, quantification.
High performance Thin Layer chromatography: Principles, instrumentation, pharmaceutical applications.

UNIT – III 12 Hrs

UNIT – IV 12 Hrs
Mass spectrometry: Principle, theory, instrumentation of mass spectrometry, different types of ionization like electron impact, chemical, field, FAB and MALDI, APCI, ESI, APPI mass fragmentation and its rules, meta stable ions, isotopic peaks and applications of mass spectrometry. LC-MS hyphenation and DART MS analysis. Mass analysers (Quadrpole, Time of flight, FT-ICR, ion trap and Orbitrap) instruments. MS/MS systems (Tandem: QqQ, TOF-TOF;Q-IT, Q-TOF, LTQ-FT, LTQ-Orbitrap).

UNIT – V 12 Hrs
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 with reference to 13C NMR: Spin spin and spin lattice relaxation phenomenon. 13C NMR, 1-D and 2-D NMR, NOESY and COSY techniques, Interpretation and Applications of NMR spectroscopy. LC-NMR hyphenations.

References

MPA 202T. MODERN BIO-ANALYTICAL TECHNIQUES

Hours per week: 4L  End Examination: 75 Marks
Credit: 4       Midsem: 25 Marks

Scope: This subject is designed to provide detailed knowledge about the importance of analysis of drugs in biological matrices.
Objectives: Upon completion of the course, the student shall be able to understand

- Extraction of drugs from biological samples
- Separation of drugs from biological samples using different techniques
- Guidelines for BA/BE studies.

UNIT – I 12 Hrs
Extraction of drugs and metabolites from biological matrices; General need, principle and procedure involved in the Bioanalytical methods such as Protein precipitation, Liquid Liquid extraction and Solid phase extraction and other novel sample preparation approach. Bioanalytical method validation: USFDA and EMEA guidelines.

UNIT – II 12 Hrs

UNIT – III 12 Hrs
Pharmacokinetics and Toxicokinetics: Basic consideration, Drug interaction (PK-PD interactions), The effect of protein-binding interactions, The effect of tissue-binding interactions, Cytochrome P450-based drug interactions, Drug interactions linked to transporters. Microsomal assays
Toxicokinetics - Toxicokinetic evaluation in preclinical studies, Importance and applications of toxicokinetic studies. LC-MS in bioactivity screening and proteomics.

UNIT – IV 12 Hrs
Cell culture techniques: Basic equipments used in cell culture lab. Cell culture media, various types of cell culture, general procedure for cell cultures; isolation of cells, subculture, cryopreservation, characterization of cells and their applications. Principles and applications of cell viability assays (MTT assays), Principles and applications of flow cytometry.

UNIT – V 12 Hrs

References
5. Practical HPLC method Development – Snyder, Kirkland, Glaich, 2nd edition, John Wiley & Sons, New Jersey, USA.
10. ICH, USFDA & CDSCO Guidelines.
11. Palmer

MPA 203T QUALITY CONTROL AND QUALITY ASSURANCE

Hours per week: 4L  
End Examination: 75 Marks
Credit: 4  
Midsem: 25 Marks

Scope: This course deals with the various aspects of quality control and quality assurance aspects of pharmaceutical industries. It covers the important aspects like cGMP, QC tests, documentation, quality certifications, GLP and regulatory affairs.

Objectives: At the completion of this subject it is expected that the student shall be able to know
- the cGMP aspects in a pharmaceutical industry
- to appreciate the importance of documentation
- to understand the scope of quality certifications applicable to Pharmaceutical industries
- to understand the responsibilities of QA & QC departments

UNIT – I  
12 Hrs
Concept and Evolution of Quality Control and Quality Assurance Good Laboratory Practice, GMP, Overview of ICH Guidelines - QSEM, with special emphasis on Q-series guidelines. Good Laboratory Practices: Scope of GLP, Definitions, Quality assurance unit, protocol for conduct of non clinical testing, control on animal house, report preparation and documentation.

UNIT – II  
12 Hrs
cGMP guidelines according to schedule M, USFDA (inclusive of CDER and CBER) Pharmaceutical Inspection Convention (PIC), WHO and EMEA covering: Organization and personnel responsibilities, training, hygiene and personal records, drug industry location, design, construction and plant lay out, maintenance, sanitation, environmental control, utilities and maintenance of sterile areas, control of contamination and Good Warehousing Practice. CPCSEA guidelines.

UNIT – III  
12 Hrs
Analysis of raw materials, finished products, packaging materials, in process quality control (IPQC), Developing specification (ICH Q6 and Q3) Purchase specifications and maintenance of stores for raw materials. In process quality control and finished products quality control for following formulation in Pharma industry according to Indian, US and British pharmacopoeias: tablets, capsules, ointments, suppositories, creams, parenterals, ophthalmic and surgical products, Quality control test for containers, closures and secondary packing materials.

UNIT – IV 12 Hrs
Documentation in pharmaceutical industry: Three tier documentation, Policy, Procedures and Work instructions, and records (Formats), Basic principles- How to maintain, retention and retrieval etc. Standard operating procedures, Master Formula Record, Batch Formula Record, Quality audit plan and reports. Specification and test procedures, Protocols and reports. Distribution records. Electronic data.

UNIT – V 12 Hrs
Manufacturing operations and controls: Sanitation of manufacturing premises, mix-ups and cross contamination, processing of intermediates and bulk products, packaging operations, IPQC, release of finished product, process deviations, charge-in of components, time limitations on production, drug product inspection, expiry date calculation, calculation of yields, production record review, change control, sterile products, aseptic process control, packaging.

References
7. ICH guidelines
8. ISO 9000 and total quality management

MPA 204T. HERBAL AND COSMETIC ANALYSIS

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Scope: This course is designed to impart knowledge on analysis of herbal products. Regulatory requirements, herbal drug interaction with monographs. Performance evaluation of cosmetic products is included for the better understanding of the equipments used in cosmetic industries for the purpose.

Objectives: At completion of this course student shall be able to understand

- Determination of herbal remedies and regulations
- Analysis of natural products and monographs
- Determination of Herbal drug-drug interaction
- Principles of performance evaluation of cosmetic products.

UNIT – I 12 Hrs

UNIT – II 12 Hrs
Adulteration and Deterioration: Introduction, types of adulteration/substitution of herbal drugs, Causes and Measure of adulteration, Sampling Procedures, Determination of Foreign Matter, and DNA Finger printing techniques in identification of drugs of natural origin, heavy metals, pesticide residues, phototoxin and microbial contamination in herbal formulations. Regulatory requirements for setting herbal drug industry: Global marketing management, Indian and international patent law as applicable to herbal drugs and natural products and its protocol.

UNIT – III 12 Hrs

UNIT – IV 12 Hrs
Herbal drug-drug interaction: WHO and AYUSH guidelines for safety monitoring of natural medicine, Spontaneous reporting schemes for bio drug adverse reactions, bio drug-drug and bio drug-food interactions with suitable examples. Challenges in monitoring the safety of herbal medicines.

UNIT – V 12 Hrs
Evaluation of cosmetic products: Determination of acid value, ester value, saponification value, iodine value, peroxide value, rancidity, moisture, ash, volatile matter, heavy metals, fineness of powder, density, viscosity of cosmetic raw materials and finished products. Study of quality of raw materials and general methods of analysis of raw material used in cosmetic manufacture as per BIS.
Indian Standard specification laid down for sampling and testing of various cosmetics in finished forms such as baby care products, skin care products, dental products, personal hygiene preparations, lips sticks. Hair products and skin creams by the Bureau Indian Standards.

References
1. Pharmacognosy by Trease and Evans.
2. Pharmacognosy by Kokate, Purohit and Gokhale.
5. Essential of Pharmacognosy by Dr. S. H. Ansari
10. Suppliers catalogue on specialized cosmetic excipients.

MPA 205P. PHARMACEUTICAL ANALYSIS PRACTICALS – II

Hours per week: 12 End Examination: 100 Marks
Credit: 6 Midsem: 50 Marks

1. Comparison of absorption spectra by UV and Wood ward – Fieser rule
2. Interpretation of organic compounds by FT-IR
3. Interpretation of organic compounds by NMR
4. Interpretation of organic compounds by MS
5. Determination of purity by DSC in pharmaceuticals
6. Identification of organic compounds using FT-IR, NMR, CNMR and Mass spectra
7. Bio molecules separation utilizing various sample preparation techniques and Quantitative analysis of components by gel electrophoresis.
8. Bio molecules separation utilizing various sample preparation techniques and Quantitative analysis of components by HPLC techniques.
9. Isolation of analgesics from biological fluids (Blood serum and urine).
11. Protocol preparation for the conduct of BA/BE studies according to guidelines.
12. In process and finished product quality control tests for tablets, capsules, parenterals and creams
13. Quality control tests for Primary and secondary packing materials
14. Assay of raw materials as per official monographs
15. Testing of related and foreign substances in drugs and raw materials
16. Preparation of Master Formula Record.
17. Preparation of Batch Manufacturing Record.
18. Quantitative analysis of rancidity in lipsticks and hair oil
19. Determination of aryl amine content and Developer in hair dye
20. Determination of foam height and SLS content of Shampoo.
21. Determination of total fatty matter in creams (Soap, skin and hair creams)
22. Determination of acid value and saponification value.
23. Determination of calcium thioglycolate in depilatories

SEMESTER – I

PHARMACOLOGY (MPL)

MPL 101T. MODERN PHARMACEUTICAL ANALYTICAL TECHNIQUES

Hours per week: 4L
Credit: 4
End Examination: 75 Marks
Midsem: 25 Marks

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

UNIT – I 12 Hrs
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 (Characteristics of drugs that can be analyzed by fluorimetry), Quenchers, Instrumentation and Applications of fluorescence spectrophotometer.

UNIT – II 12 Hrs
NMR spectroscopy: Quantum numbers and their role in NMR, Principle, Instrumentation, Solvent requirement in NMR, Relaxation process, NMR signals in various compounds, Chemical shift, Factors influencing chemical shift, Spin-Spin coupling, Coupling constant, Nuclear magnetic double resonance, Brief outline of principles of FT-NMR and $^{13}$C NMR. Applications of NMR spectroscopy.

UNIT – III 12 Hrs
UNIT – IV  
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

UNIT – V  
a. Principle, instrumentation and applications of Gel electrophoresis and Moving boundary electrophoresis  
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  
c. Thermal Techniques:  
Differential Scanning Calorimetry (DSC): 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).  
Thermogravimetric Analysis (TGA): Principle, instrumentation, factors affecting results, advantage and disadvantages, pharmaceutical applications

References

MPL 102T. ADVANCED PHARMACOLOGY – I

Hours per week: 4L  
End Examination: 75 Marks
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
- Explain the mechanism of drug actions at cellular and molecular level
- Discuss the pathophysiology and pharmacotherapy of certain diseases
- Understand the adverse effects, contraindications and clinical uses of drugs used in treatment of diseases

UNIT – I
General Pharmacology a. Pharmacokinetics:
- Pharmacodynamics: Mechanism of drug action and the relationship between drug concentration and effect. Receptors, structural and functional families of receptors, quantitation of drug receptors interaction and elicited effects.

UNIT – II
Neurotransmission
- General aspects and steps involved in neurotransmission.
- Neurohumoral transmission in autonomic nervous system (Detailed study about neurotransmitters- Adrenaline and Acetyl choline).
- Neurohumoral transmission in central nervous system (Detailed study about neurotransmitters- histamine, serotonin, dopamine, GABA, glutamate and glycine).
- Non adrenergic non cholinergic transmission (NANC). Co transmission.
- Systemic Pharmacology: A detailed study on pathophysiology of diseases, mechanism of action, pharmacology and toxicology of existing as well as novel drugs used in the following systems - Autonomic Pharmacology, Parasympathomimetics and lytics, sympathomimetics and lytics, agents affecting neuromuscular junction

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

UNIT – IV
Cardiovascular Pharmacology Diuretics, antihypertensives, antiischemics, anti- arrhythmics, drugs for heart failure and hyperlipidemia. Hematinics, coagulants, anticoagulants, fibrinolytics and anti- platelet drugs

UNIT – V
Autocoid Pharmacology The physiological and pathological role of Histamine, Serotonin, Kinins, Prostaglandins and Opioid autocoids. Pharmacology of antihistamines and 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
9. Green Pathophysiology for Pharmacists

MPL 103T. PHARMACOLOGICAL AND TOXICOLOGICAL SCREENING METHODS – I

Hours per week: 4L
Credit: 4
End Examination: 75 Marks
Midsem: 25 Marks

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

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

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

UNIT – I

Laboratory Animals Common laboratory animals:
Description, handling and applications of different species and strains of animals. Transgenic animals: Production, maintenance and applications Anaesthesia and euthanasia of
experimental animals. Maintenance and breeding of laboratory animals. CPCSEA guidelines to conduct experiments on animals Good laboratory practice. Bioassay - Principle, scope and limitations and methods

UNIT – II  
12 Hrs 

UNIT – III  
12 Hrs 

UNIT – IV  
12 Hrs 

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

MPL 104T. CELLULAR AND MOLECULAR PHARMACOLOGY

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

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

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

UNIT – I 12 Hrs

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

UNIT – III 12 Hrs
Principles and applications of genomic and proteomic tools DNA electrophoresis, PCR (reverse transcription and real time), Gene sequencing, micro array technique, SDS page, ELISA and western blotting, Recombinant DNA technology and gene therapy Basic
principles of recombinant DNA technology—Restriction enzymes, various types of vectors. Applications of recombinant DNA technology. Gene therapy—Various types of gene transfer techniques, clinical applications and recent advances in gene therapy.

UNIT – IV  
12 Hrs

UNIT – V  
12 Hrs
a. Cell culture techniques Basic equipments used in cell culture lab. Cell culture media, various types of cell culture, general procedure for cell cultures; isolation of cells, subculture, cryopreservation, characterization of cells and their application. Principles and applications of cell viability assays, glucose uptake assay, Calcium 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 (2nd 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)

MPL 105P. PHARMACOLOGICAL PRACTICAL – I

Hours per week: 12  
End Examination: 100 Marks  
Credit: 6  
Midsem: 50 Marks

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, anxiogensics 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)

SEMESTER – II

MPL 201T. ADVANCED PHARMACOLOGY – II

Hours per week: 4L
Credit: 4
End Examination: 75 Marks
Midsem: 25 Marks

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

- 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

**UNIT – I**  
12 Hrs
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

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

**UNIT – III**  
12 Hrs
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

**UNIT – IV**  
12 Hrs
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

**UNIT – V**  
12 Hrs
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
MPL 202T. PHARMACOLOGICAL AND TOXICOLOGICAL SCREENING METHODS – II

Hours per week: 4L  End Examination: 75 Marks
Credit: 4  Midsem: 25 Marks

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.

UNIT – I  12 Hrs
Basic definition and types of toxicology (general, mechanistic, regulatory and descriptive)
Regulatory guidelines for conducting toxicity studies OECD, ICH, EPA and Schedule Y
OECD principles of Good laboratory practice (GLP) History, concept and its importance in drug development

UNIT – II  12 Hrs
Acute, sub-acute and chronic- oral, dermal and inhalational studies as per OECD guidelines.
Acute eye irritation, skin sensitization, dermal irritation & dermal toxicity studies. Test item characterization- importance and methods in regulatory toxicology studies

UNIT – III  12 Hrs
Reproductive toxicology studies, Male reproductive toxicity studies, female reproductive studies (segment I and segment III), teratogenecity studies (segment II) Genotoxicity studies (Ames Test, in vitro and in vivo Micronucleus and Chromosomal aberrations studies) In vivo carcinogenicity studies

UNIT – IV  12 Hrs
IND enabling studies (IND studies)- Definition of IND, importance of IND, industry perspective, list of studies needed for IND submission. Safety pharmacology studies- origin, concepts and importance of safety pharmacology. Tier1- CVS, CNS and respiratory safety pharmacology, HERG assay. Tier2- GI, renal and other studies

UNIT – V  12 Hrs
Toxicokinetics – Toxicokinetic evaluation in preclinical studies, saturation kinetics Importance and applications of toxicokinetic studies. Alternative methods to animal toxicity testing. 12 Hrs

References
3. Drugs from discovery to approval by Rick N. G.
4. Animal Models in Toxicology, 3rd edition, Lower and Bryan
5. OECD test guidelines.

MPL 203T. PRINCIPLES OF DRUG DISCOVERY

Hours per week: 4L                  End Examination: 75 Marks
Credit: 4                        Midsem: 25 Marks

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,

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

UNIT – I


UNIT – II

Lead Identification- combinatorial chemistry & high throughput screening, in silico lead discovery techniques, Assay development for hit identification. Protein structure Levels of protein structure, Domains, motifs, and folds in protein structure. Computational prediction of protein structure: Threading and homology modeling methods. Application of NMR and X-ray crystallography in protein structure prediction

UNIT – III

techniques: Drug likeness screening, Concept of pharmacophore mapping and pharmacophore based Screening.

UNIT – IV  
12 Hrs

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

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

MPL 204T. CLINICAL RESEARCH AND PHARMACOVIGILANCE

Hours per week: 4L End Examination: 75 Marks  
Credit: 4 Midsem: 25 Marks

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 marketing surveillance.

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

UNIT – I  12 Hrs

UNIT – II  12 Hrs

UNIT – III  12 Hrs

UNIT – IV  12 Hrs

UNIT – V  12 Hrs

References

MPL 205P. PHARMACOLOGICAL PRACTICAL – II

Hours per week: 12
Credit: 6

End Examination: 100 Marks
Midsem: 50 Marks

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
1. Fundamentals of experimental Pharmacology-by M.N.Ghosh
5. Applied biopharmaceutics and Pharmacokinetics by Leon Shargel and Andrew B. C. Yu. 
6. Handbook of Essential Pharmacokinetics, Pharmacodynamics and Drug Metabolism for Industrial Scientists.

SEMESTER – III

MRM 301T. RESEARCH METHODOLOGY & BIOSTATISTICS

Hours per week: 4L
Credit: 4
Midsem: 25 Marks
End Examination: 75 Marks

UNIT – I

12 Hrs
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

12 Hrs
Biostatistics: Definition, application, sample size, importance of sample size, factors influencing sample size, dropouts.

UNIT – III

12 Hrs
Regression and correlation: Method of least squares, Correlation Coefficient, rank correlation and multiple regressions.
Probability rules: Binomial, Poison and Normal distribution.

UNIT – IV

12 Hrs

UNIT – V

12 Hrs
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.
Declaration of Helsinki: History, introduction, basic principles for all medical research, and additional principles for medical research combined with medical care.

References

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