ANNAMALAI UNIVERSITY
M.PHARM. DEGREE PROGRAMME
(Choice Based Semester System)
ACADEMIC REGULATIONS - 2019 [M.PHARM-2019]

This document shall be called as M.Pharm. Academic Regulations - 2019 of Annamalai University. These academic regulations shall come into force from the academic year 2019 - 2020.

1. Short title and commencement

These regulations shall be for the Master of Pharmacy (M. Pharm.) Degree Program - Credit Based Semester System (CBSS) of the Annamalai University, Annamalai Nagar and will be called as “M.Pharm. Academic Regulations 2019 of Annamalai University” They shall come into effect from the Academic Year 2019-20. The regulations framed are subject to modifications from time to time by the authorities of the Annamalai University.

2. Minimum qualification for admission

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

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

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

3. Duration of the program

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

4. Medium of instruction and examinations

Medium of instruction and examination shall be in English.

5. Working days in each semester

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

6. Attendance and progress

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

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

7.1. Credit assignment

7.1.1. Theory and Laboratory courses

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

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

7.2. Minimum credit requirements

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

7.3. Registration for courses

A newly admitted student will automatically be registered for all the courses prescribed for first to fourth semester.

8. Academic work

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

The specializations in M.Pharm program is given in Table I.

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

<table>
<thead>
<tr>
<th>S. No.</th>
<th>Specialization</th>
<th>Code</th>
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<tr>
<td>1.</td>
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<td>2.</td>
<td>Industrial Pharmacy</td>
<td>MIP</td>
</tr>
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<td>11.</td>
<td>Pharmaceutical Regulatory Affairs</td>
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The course of study for M.Pharm specializations shall include Semester wise Theory & Practical as given in Table – II to XIII. The number of hours to be devoted to each theory and practical course in any semester shall not be less than that shown in Table – II to XIII.

**Table – 2: Course of study for M. Pharm. (Cosmeceutics)**

<table>
<thead>
<tr>
<th>Course Code</th>
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Semester II

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### Semester II

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### Table – 4: Course of study for M. Pharm. (Pharmaceutical Analysis)

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### Table – 5: Course of study for M. Pharm. (Pharmaceutical Biotechnology)

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### Course Code
- MPA: Modern Pharmaceutical
- MIP: Modern Industrial Pharmacy
- MPA: Modern Pharmaceutical
- MPB: Modern Pharmaceutical Biotechnology
### Table – 6: Course of study for M. Pharm. (Pharmaceutical Chemistry)

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### Table – 9: Course of study for Pharmacology

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<th>Hours</th>
<th>Credit Points</th>
<th>Hrs./wk</th>
<th>Marks</th>
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<tr>
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<td>4</td>
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<tr>
<td>MPL102T</td>
<td>Pharmacological and Toxicological Screening Methods-I</td>
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<td>4</td>
<td>4</td>
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<tr>
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<td>Cellular and Molecular Pharmacology</td>
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### Table – 10: Course of study for M. Pharm. (Pharmacy Practice)

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<th>Hrs./wk</th>
<th>Marks</th>
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<th>Marks</th>
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<td>Clinical Pharmacokinetics and Therapeutic Drug</td>
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### Table – 11: Course of study for M. Pharm. (Pharmaceutical Quality Assurance)

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<td>MQA101T</td>
<td>Quality Management System</td>
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<td>4</td>
<td>4</td>
<td>100</td>
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<td>MQA102T</td>
<td>Quality Control and Quality Assurance</td>
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<td>4</td>
<td>100</td>
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<td>MQA103T</td>
<td>Product Development and Technology Transfer</td>
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<th>Hrs./wk</th>
<th>Marks</th>
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<td>Hazards and Safety Management</td>
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<td>MQA203T</td>
<td>Audits and Regulatory Compliance</td>
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<td>MQA205P</td>
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<td>35</td>
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### Table – 12: Course of study for M. Pharm. (Pharmaceutical Regulatory Affairs)

<table>
<thead>
<tr>
<th>Course Code</th>
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<th>Credit Points</th>
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<th>Marks</th>
</tr>
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<tr>
<td>MRA101T</td>
<td>Good Pharmaceutical Practices</td>
<td>4</td>
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### Table – 13: Course of study for M. Pharm. III Semester (Common for All Specializations)

<table>
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<th>Credit Points</th>
</tr>
</thead>
<tbody>
<tr>
<td>MRM101T</td>
<td>Research Methodology and Biostatistics*</td>
<td>4</td>
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<td>-</td>
<td>Journal Club</td>
<td>1</td>
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<tr>
<td>-</td>
<td>Discussion / Presentation</td>
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<td>2</td>
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<tr>
<td>-</td>
<td>(Proposal Presentation)</td>
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<td>-</td>
<td>Research Work</td>
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Non University Exam

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

<table>
<thead>
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<th>Course</th>
<th>Credit Hours</th>
<th>Credit Points</th>
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<tr>
<td>-</td>
<td>Journal Club</td>
<td>1</td>
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<tr>
<td>-</td>
<td>Research Work</td>
<td>31</td>
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<tr>
<td>-</td>
<td>Discussion/Final Presentation</td>
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<td></td>
<td>Total</td>
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*Credit Points for Co-curricular Activities

### Table – 15: Semester wise credits distribution

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

*Credit Points for Co-curricular Activities

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

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

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

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

10. a. Program Committee

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. 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.

Duties of the Programme Committee:

Periodically reviewing the progress of the classes.

Discussing the problems concerning curriculum, syllabus and the conduct of classes.

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.

Communicating its recommendation to the Head of the institution on academic matters.

The Programme Committee shall meet at least twice in a semester preferably at the end of each sessionalexam and before the end semester exam.

10. b. Student Counsellors (Mentors)

To help the students in planning their course of study and for general advice on the academic programme, the Dean / Head of the Department will attach a certain number of students to a member of the faculty who shall function as student counsellor for those students throughout their period of study. Such student counsellors shall advice the students, give preliminary approval for the courses to be taken by the students during each semester and obtain the final
approval of the Dean/Head of the Department.

Examinations/Assessments

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

### 11.1. End semester examinations

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

### Tables – 17: Schemes for internal assessments and end semester examinations (Cosmeceutics)

<table>
<thead>
<tr>
<th>Course Code</th>
<th>Course</th>
<th>Continuous Mode</th>
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</tr>
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<td>MCC101T</td>
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<tr>
<td>MCC102T</td>
<td>Cosmetics - Formulation Science</td>
<td>10 15 1 Hr 25</td>
<td>75 3 Hrs 100</td>
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<tr>
<td>MCC103T</td>
<td>Quality Assurance</td>
<td>10 15 1 Hr 25</td>
<td>75 3 Hrs 100</td>
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<td>Cellular and Molecular Pharmacology</td>
<td>10 15 1 Hr 25</td>
<td>75 3 Hrs 100</td>
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<td>Cosmeceutics Practical I</td>
<td>20 30 6 Hrs 50</td>
<td>100 6 Hrs 150</td>
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<tr>
<td>MCC201T</td>
<td>Cosmeceuticals</td>
<td>10 15 1 Hr 25</td>
<td>75 3 Hrs 100</td>
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<td>Cosmetic Analysis and Evaluation</td>
<td>10 15 1 Hr 25</td>
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<td>MCC203T</td>
<td>Cosmetics- Industry and Regulatory</td>
<td>10 15 1 Hr 25</td>
<td>75 3 Hrs 100</td>
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<td>MCC204T</td>
<td>Computer Aided Drug Delivery System</td>
<td>10 15 1 Hr 25</td>
<td>75 3 Hrs 100</td>
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<tr>
<td>MCC205T</td>
<td>Cosmeceuticals</td>
<td>20 30 6 Hrs 50</td>
<td>100 6 Hrs 150</td>
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### Tables-18: Schemes for internal assessments and end semester examinations (Industrial Pharmacy)

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<tr>
<td>MPA101T</td>
<td>Modern Pharmaceutical Analytical Techniques</td>
<td>10 15 1 Hr 25</td>
<td>75 3 Hrs 100</td>
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(Pharmaceutical Analysis)

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| **Semester-II** |                         |                  |          |                     |       |
| MPA201T     | Advanced Instrumental Analysis | 10 15 1 Hr | 25 | 75 3 Hrs | 100 |
| MPA202T     | Modern Bio-Analytical Techniques | 10 15 1 Hr | 25 | 75 3 Hrs | 100 |
| MPA203T     | Quality Control and Quality Assurance | 10 15 1 Hr | 25 | 75 3 Hrs | 100 |
| MPA204T     | Cosmetic Analysis and Evaluation | 10 15 1 Hr | 25 | 75 3 Hrs | 100 |
| MPA205P     | Pharmaceutical Analysis-II | 20 30 6 Hrs | 50 | 100 6 Hrs | 150 |
|             | - Seminar /Assignment    |                  |          |                     |       |
| **Total**   |                         |                  |          |                     | 650   |

### Tables – 20: Schemes for internal assessments and end semester examinations
(Pharmaceutical Biotechnology)

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| **Semester-II** |                         |                  |          |                     |       |
| MPA201T     | Proteins and protein Formulation | 10 15 1 Hr | 25 | 75 3 Hrs | 100 |
| MPA202T     | Immunotechnology | 10 15 1 Hr | 25 | 75 3 Hrs | 100 |
| MPA203T     | Bioinformatics and Computer Technology | 10 15 1 Hr | 25 | 75 3 Hrs | 100 |
| MPA204T     | Biological Evaluation of Drug Therapy | 10 15 1 Hr | 25 | 75 3 Hrs | 100 |
| MPA205P     | Pharmaceutical Biotechnology Practical-II | 20 30 6 Hrs | 50 | 100 6 Hrs | 150 |
|             | - Seminar /Assignment    |                  |          |                     |       |
| **Total**   |                         |                  |          |                     | 650   |

### Tables – 21: Schemes for internal assessments and end semester examinations
(Pharmaceutical Chemistry)

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<th>Course Code</th>
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<td>MPA101T</td>
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2511
### Tables – 22: Schemes for internal assessments and end semester examinations (Pharmaceutics)

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### Tables – 23: Schemes for internal assessments and end semester examinations (Pharmacognosy)

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### Tables – 24: Schemes for internal assessments and end semester examinations (Pharmacology)

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### Tables – 25: Schemes for internal assessments and end semester examinations (Pharmacy Practice)

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### Tables – 26: Schemes for internal assessments and end semester examinations (Pharmaceutical Quality Assurance)

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Total 650
### 11.2. Internal assessment: Continuous mode

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

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

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**Practical**

<table>
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Table – 30: Guidelines for the allotment of marks for attendance

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<tbody>
<tr>
<td>95 – 100</td>
<td>8</td>
<td>10</td>
</tr>
<tr>
<td>90 – 94</td>
<td>6</td>
<td>7.5</td>
</tr>
<tr>
<td>85 – 89</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>80 – 84</td>
<td>2</td>
<td>2.5</td>
</tr>
<tr>
<td>Less than 80</td>
<td>0</td>
<td>0</td>
</tr>
</tbody>
</table>

11.2.1. Sessional Exams

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

12. Promotion and award of grades

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

13. Carry forward of marks

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

14. Improvement of internal assessment

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

15. Re-examination of end semester examinations

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

Table – 31: Tentative schedule of end semester examinations

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

16. Allowed to keep terms (ATKT):

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

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

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

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

17. Grading of performances
17.1. Letter grades and grade points allocations:

Based on the performances, each student shall be awarded a final letter grade at the end of the semester for each course. The letter grades and their corresponding grade points are given in Table – 32:

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

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

18. The Semester grade point average (SGPA)

The performance of a student in a semester is indicated by a number called ‘Semester Grade Point Average’ (SGPA). The SGPA is the weighted average of the grade points obtained in all the courses by the student during the semester. For example, if a student takes five courses (Theory/Practical) in a semester with credits C1, C2, C3 and C4 and the student’s grade points in these courses are G1, G2, G3 and G4, respectively, and then students’ SGPA is equal to:

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

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

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

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

21. Project work

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

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

<table>
<thead>
<tr>
<th>Evaluation of Dissertation Book:</th>
<th></th>
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</thead>
<tbody>
<tr>
<td>Objective(s) of the work done</td>
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<tr>
<td>Methodology adopted</td>
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<tr>
<td>Results and Discussions</td>
<td>250</td>
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<tr>
<td>Conclusions and Outcomes</td>
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<tr>
<td>Total</td>
<td>500</td>
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</tbody>
</table>

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

22. Award of Ranks

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

23. Award of degree

Candidates who fulfill the requirements mentioned above shall be eligible for award of degree during the ensuing convocation.
24. Duration for completion of the program of study

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

25. Revaluation I Retotaling of answer papers

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

26. Re-admission after break of study

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

27. Transitory Regulations

The University shall have powers to revise or change or amend the regulations, the scheme of examinations, the course of study and syllabus as and when the statutory authorities recommend.
Program Outcomes
The post graduate in M. Pharmacy Degree Programme (Pharmacology) shall be able to:

PO1. Domain Knowledge: Demonstrate comprehension of basic principles of pharmaceutical and allied sciences in all pertinent scenarios. Exhibit skills associated with the profession of pharmacy, pharmaceutical manufacturing practices and quality control.

PO2. Problem analysis: Use domain knowledge, analytical and critical thinking for solving problems and taking decisions during everyday practice in profession, industry and all work environment.

PO3. Research and Development: Exhibit knowledge from his major domain in problem identification, critical thinking, analysis, usage of statistical tools, and providing solutions to pharmaceutical and allied technology disciplines.

PO4. Modern tools usage: Demonstrate an ability to handle/use various tools, apparatus, instrument, ethical animal studies, equipment or machinery pertinent to the pharmaceutical domain with practical knowledge on standard operating procedures and safety aspects.

PO5. The Pharmacist and Society: Use contextual knowledge – informed reasoning to understand medical prescription, perform patient counselling. Recognize the necessity to engage in independent and life-long learning.

PO6. Environment and sustainability: Demonstrate knowledge and responsibility while handling pharmaceutical techniques/ processes that have social and environmental impacts and promote sustainable development.

PO7. Ethics: Demonstrate exemplary professional, ethical, and legal behaviours in accordance with all drug, pharmaceutical, and pharmacy-related central, state laws and regulations.

PO8. Individual and Team skills: Function effectively as an individual member or leader in different teams and multidisciplinary settings. Assume participatory or lead role in an organization's planning and execution of transformational projects to enhance its prospects.

PO9. Communication: Communicate effectively with the pharmaceutical scientific community, work-force and with society at large, with abilities to comprehend and write effective reports, make effective presentations and documentation.
PO10. Project management abilities: Demonstrate effective delegation and organizational skills. Organize work with necessary planning and execution to meet deadlines. Demonstrate knowledge and understanding of pharmaceutical, legal processes and apply them in project management.

Program Specific Outcomes (PSOs)

The post graduate in M. Pharmacy Degree Programme (Pharmacology) shall be able to:

PSO1. Understand, apply pharmaceutical analysis principles and techniques towards identification, structural elucidation, and quantification of drugs using modern analytical instruments.

PSO2. Understand, apply, cellular and molecular pharmacology, pathophysiology and pharmacotherapy of certain diseases and mechanism of drug actions.

PSO3. Understand, appreciate and apply concepts about various aspects of regulations and ethical requirement for the usage of experimental animals, CPCSEA guidelines for laboratory animal facilities, and toxicity studies.

PSO4. Understand, appreciate and apply concepts of principles of drug discovery, clinical research and pharmacovigilance, Research Methodology & Biostatistics systematically in research.

PSO5. Act responsibly towards environment, follow ethical principles, be able to comprehend, interpret and apply laws pertinent to all spheres of pharmaceutical and allied domains. Imbibe the spirit of being an entrepreneur.
PHARMACOLOGY (MPC)

SEMESTER I

Semester-I
1. Modern Pharmaceutical Analysis
2. Advanced Pharmacology-I
3. Pharmacological and Toxicological Screening Methods-I
4. Cellular and Molecular Pharmacology Practicals

Semester-I
Advanced Pharmacology-II
Toxicological Screening Methods
Principles of Drug Discovery
Clinical Research and Pharmaco vigilance
Experimental Pharmacology-II

Practicals
1. *Soft skills should be added in research methodology and biostatistics paper in semester-III
2. *Practical in Modern pharmaceutical with emphasis on analysis case study

MODERN PHARMACEUTICAL ANALYSIS (MPA101T)

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

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

Theory 60 Hrs.

1. UV-Visible spectroscopy
Introduction, Theory, Laws, Instrumentation 12 Hrs associated with UV-Visible spectroscopy, Choice of solvents and solvent effect and Applications of UV-Visible spectroscopy.

IR spectroscopy: Theory, Modes of Molecular vibrations, Sample handling, Instrumentation of Dispersive and Fourier - Transform IR Spectrometer, Factors affecting vibrational frequencies and Applications of IR spectroscopy
Spectrofluorimetry: Theory of Fluorescence, Factors affecting fluorescence, Quenchers, Instrumentation and Applications of fluorescence spectrophotometer.
Flame emission spectroscopy and Atomic absorption spectroscopy: Principle, Instrumentation, Interferences and Applications.

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

3. **Mass Spectroscopy**
   **12Hrs**
   Principle, Theory, Instrumentation of Mass Spectroscopy, Different types of ionization like electron impact, chemical, field, FAB and MALDI, APCI, ESI, APPI Analyzers of Quadrupole and Time of Flight, Mass fragmentation and its rules, Meta stable ions, Isotopic peaks and Applications of Mass spectroscopy

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

5. **Electrophoresis**
   Principle, Instrumentation, Working conditions, factors 12 Hrs affecting separation and applications of the following:
   Paper electrophoresis b) Gel electrophoresis c) Capillary electrophoresis d) Zone electrophoresis e) Moving boundary electrophoresis f) Iso electric focusing

6. **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.

**MPA101T Modern Pharmaceutical Analytical Techniques Course Outcomes:**

**The Student:**
1] Describes the principles & applications of instruments Involved in drug analysis.
2] Discusses analysis of various drugs in single and combination dosage forms using various analytical Instruments.

<table>
<thead>
<tr>
<th>MPA101T Modern Pharmaceutical Analytical Techniques</th>
</tr>
</thead>
<tbody>
<tr>
<td>MappingPOs&amp;PSOsX Course Outcomes</td>
</tr>
<tr>
<td>PO1  PO2  PO3  PO4  PO5  PO6  PO7  PO8  PO9  PO10</td>
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<tr>
<td>PSO1  PSO2  PSO3  PSO4  PSO5</td>
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<td>X</td>
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<td>X</td>
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<td>X</td>
<td>X</td>
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<td>X</td>
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</tbody>
</table>

References

ADVANCED PHARMACOLOGY-I (MPL101T)

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

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

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

Theory 60 Hours
Unit-I: General Pharmacology
Pharmacokinetics: The dynamics of drug absorption, distribution, biotransformation and elimination. Concepts of linear and non-linear compartment models. Significance of Protein binding. 06 hrs b. Pharmacodynamics: Mechanism of drug action and the relationship between drug concentration and effect. Receptors, structural and functional families of receptors, quantitation of drug receptors interaction and elicited effects. 06 hrs

Unit-II: 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).

d. Non adrenergic non cholinergic transmission (NANC). Co-transmission

**Systemic Pharmacology**

06 Hrs

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

a. Autonomic Pharmacology

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

**Unit-III: Central nervous system Pharmacology**

12 Hrs

General and local anesthetics

02 hrs

Sedatives and hypnotics, drugs used to treat anxiety.

02 hrs

Depression, psychosis, mania, epilepsy, neurodegenerative diseases. 02 hrs

Narcotic and non-narcotic analgesics.

02 hrs

**Unit-IV: Cardiovascular Pharmacology**

12 Hrs

Diuretics, antihypertensives, antiischemics, anti- arrhythmics, drugs for heart failure and hyperlipidemia. 07 hrs Hematinics, coagulants, anticoagulants, fibrinolytics and anti-platelet drugs 05 hrs

**Unit-V: Autocoid Pharmacology**

12 Hrs

The physiological and pathological role of Histamine, Serotonin, Kinins Prostaglandins

Opioid autocoids.

08 hrs

Pharmacology of antihistamines, 5HT antagonists.

04 hrs

**MPL101T-Advanced Pharmacology I: Course Outcomes**

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

**MPL101T-Advanced Pharmacology I Theory**

MappingPOs&PSOsX Course Outcomes:
null
Transgenic animals: Production, maintenance and applications 02 hrs
Anaesthesia and euthanasia of experimental animals. 03 hrs
Maintenance and breeding of laboratory animals. 02 hrs
CPCSEA guidelines to conduct experiments on animals 02 hrs
Good laboratory practice. 01 hrs

Unit-II: Preclinical screening of new substances for the pharmacological activity using in vivo, in vitro, and other possible animal alternative models. 12 Hrs


Unit-III: Preclinical screening of new substances for the pharmacological activity using in vivo, in vitro, and other possible animal alternative models. 12 Hrs

Respiratory Pharmacology: anti-asthmatics, drugs for COPD and anti allergies.

Unit-IV: Preclinical screening of new substances for the pharmacological activity using in vivo, in vitro, and other possible animal alternative models. 12 hrs

Cardiovascular Pharmacology: antihypertensives, antiarrythmics, antianginal, antiatherosclerotic agents and diuretics. Drugs for metabolic disorders like anti-diabetic, antihyperlipidemic, and agents. Anti cancer agents

Unit-V: Preclinical screening of new substances for the pharmacological activity using in vivo, in vitro, and other possible animal alternative models. 12 hrs

Immunosuppressants and immunomodulators 02 hrs General principles of immunoassay: theoretical basis and optimization of immunoassay, heterogeneous and homogenous immunoassay systems. Immunoassay methods evaluation; protocol outline, objectives and preparation. Immunoassay for digoxin and insulin 08 hrs

Limitations of animal experimentation and alternate animal experiments. 01hr
Extrapolation of in vitro data to preclinical and preclinical to humans. 01 hr

MPL102T-Pharmacological and Toxicological Screening MethodsI: Course Outcomes
Upon completion of the course the student shall be able to:
➢ Describe the regulations and ethical requirement for the usage of experimental animals..
➢ Describe the various animal models used in the drug discovery process and good laboratory practices in maintenance and handling of experimental animals
➢ Describe the various newer screening methods involved in the drug discovery process and correlate the preclinical data to humans.
### References

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

### CELULAR AND MOLECULAR PHARMACOLOGY (MPL103T)

**Scope:**

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

**Objectives**

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

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

**Unit-I: Cell biology**

<table>
<thead>
<tr>
<th>Hrs</th>
<th>Structure and functions of cell and its organelles</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Genome organization. Gene expression and its regulation, importance of siRNA and micro RNA, gene mapping and gene sequencing</td>
</tr>
<tr>
<td></td>
<td>Cell cycles and its regulation.</td>
</tr>
</tbody>
</table>

Unit-II: Cell signalling

12Hrs

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: Principles and applications of genomic and proteomic tools

12Hrs

06 hrs

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

06 hrs

Basic principles of recombinant DNA technology- Restriction enzymes, various types of vectors. Applications of recombinant DNA technology.

Gene therapy- Various types of gene transfer techniques, clinical applications and recent advances in gene therapy

Unit IV: Pharmacogenomics

12Hrs

08 hrs

Gene mapping and cloning of disease gene.

Genetic variation and its role in health/ pharmacology

Polymorphisms affecting drug metabolism

Genetic variation in drug transporters

Genetic variation in G protein coupled receptors

Applications of proteomics science: Genomics, proteomics, metabolomics, functionomics, nutrigenomics

Immunotherapeutics

04 hrs

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

Unit-V: Cell culture techniques

12Hrs

Basic equipments used in cell culture lab. Cell culture media, various types of cell culture, general procedure for cell cultures; isolation of cells, subculture, cryopreservation, characterization of cells and their application.

Principles and applications of cell viability assays, glucose uptake assay, Calcium influx assays
Principles and applications of flow cytometry

**Unit-VI: Biosimilars**

**References**

2. Pharmacogenomics: The Search for Individualized Therapies. Edited by J. Licinio and M -L. Wong
3. Handbook of Cell Signaling (Second Edition) Edited by Ralph A. et.al
4. Molecular Pharmacology: From DNA to Drug Discovery. John Dickenson et.al
5. Basic Cell Culture protocols by Cheril D.Helgason and Cindy L.Miller
6. Basic Cell Culture (Practical Approach ) by J. M. Davis (Editor)
7. Animal Cell Culture: A Practical Approach by John R. Masters (Editor)

**Experimental Pharmacology- I (MPL104P)**

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

**Handling of laboratory animals.**

1. Various routes of drug administration.
2. Techniques of blood sampling, anesthesia and euthanasia of experimental animals.
3. Functional observation battery tests (modified Irwin test)
4. Evaluation of CNS stimulant, depressant, anxiogenics and anxiolytic, anticonvulsant activity.
5. Evaluation of analgesic, anti-inflammatory, local anesthetic, mydriatic and miotic activity.
8. Oral glucose tolerance test.
9. Isolation and identification of DNA from various sources (Bacteria, Cauliflower, onion, Goat liver).
10. Isolation of RNA from yeast
11. Estimation of proteins by Braford/Lowry’s in biological samples.
12. Estimation of RNA/DNA by UV Spectroscopy
13. Gene amplification by PCR.
14. Protein quantification Western Blotting.
15. Enzyme based in-vitro assays (MPO, AChEs, a amylase, a 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.
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).

(MPL103T) CELLULAR AND MOLECULAR PHARMACOLOGY: Course Outcomes
The Student:
1] Able to describe receptor signal transduction processes (Cell biology, Cell signalling)
2] Able to describe molecular pathways affected by drugs.
3] Able to describe molecular pharmacology and biomarkers in drug discovery process, molecular biology techniques as applicable for pharmacology (Genomic and proteomic tools, Pharmacogenomics, Cell culture techniques).

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<thead>
<tr>
<th>PO1</th>
<th>PO2</th>
<th>PO3</th>
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</tbody>
</table>

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,
SEMESTER II

ADVANCED PHARMACOLOGY-II (MPL201T)

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

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

- Explain the mechanism of drug actions at cellular and molecular level
- Discuss the Pathophysiology and pharmacotherapy of certain diseases
- Understand the adverse effects, contraindications and clinical uses of drugs used in treatment of diseases

Unit-I: Endocrine Pharmacology 12 Hrs
Molecular and cellular mechanism of action of hormones such as growth hormone, prolactin, thyroid, insulin and sex hormones
Anti-thyroid drugs, Oral hypoglycemic agents, Oral contraceptives, Corticosteroids. Drugs affecting calcium regulation

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

Unit-III: Chemotherapy 12 Hrs

06 Hrs
Drugs used in Protozoal Infections
Drugs used in the treatment of Helminthiasis
Chemotherapy of cancer
Immunopharmacology

06 Hrs
Cellular and biochemical mediators of inflammation and immune response. Allergic or hypersensitivity reactions. Pharmacotherapy of asthma and COPD.

Unit-IV: GIT Pharmacology 08 Hrs
Antiulcer drugs, Prokinetics, antiemetics, anti-diarrheals and drugs for constipation and irritable bowel syndrome.

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

**Unit-V: Free radicals Pharmacology** 04 Hrs

Generation of free radicals, role of free radicals in etiopathology of various diseases such as diabetes, neurodegenerative diseases and cancer. Protective activity of certain important antioxidant

**Recent Advances in Treatment** 08 Hrs

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

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(MPL201T) ADVANCED PHARMACOLOGY-II: Course Outcomes

The Student:
- Able to describe the mechanism of drug actions at cellular and molecular level
- Able to describe the Pathophysiology and pharmacotherapy of certain diseases.
- Able to describe the adverse effects, contraindications and clinical uses of drugs used in treatment of diseases

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(MPL201T) ADVANCED PHARMACOLOGY-II
Mapping POs & PSOs

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References
1. The Pharmacological basis of therapeutics- Goodman and Gill man's
3. Basic and Clinical Pharmacology by B.G -Katzung
7. Applied biopharmaceutics and Pharmacokinetics by Leon Shargel and Andrew B.C.Yu.
8. Handbook of Essential Pharmacokinetics, Pharmacodynamics and Drug Metabolism for Industrial Scientists
TOXICOLOGICAL SCREENING METHODS (MPL202T)

Scope

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

Objectives

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

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

Unit-I: 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), teratogenicity 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.

**MPL202T) TOXICOLOGICAL SCREENING METHODS: COURSE OUTCOMES**

The Student:

1] Demonstrates the practical skills required to conduct the preclinical toxicity studies in the drug discovery process and good laboratory practices in maintenance and handling of experimental animals (CPCSEA guidelines, Bioassay)

2] Able to apply newer screening methods involved in the drug discovery process (Preclinical screening – In Vivo, In Vitro, animal alternative models), Correlate the preclinical data to humans.

3] Able to do Toxicity studies, ethical and regulatory requirements for toxicity studies (IND studies, Reproductive toxicology studies), skills required to conduct the preclinical toxicity studies (Toxicokinetic).

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<th>(MPL103T) CELLULAR AND MOLECULAR PHARMACOLOGY</th>
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<td>3. Drugs from discovery to approval by Rick NG.</td>
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<td>5. OECD test guidelines.</td>
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**PRINCIPLES OF DRUG DISCOVERY (MPL203T)**

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

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

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

**Unit-I:** 12 Hrs


Target Discovery and validation-Role of Genomics, Proteomics and Bioinformatics. Role of Nucleic acid microarrays, Protein microarrays, Antisense technologies, siRNAs, antisense oligonucleotides, Zinc finger proteins. Role of transgenic animals in target validation.

**Unit-II:** 12 Hrs

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

**Protein structure**
Levels of protein structure, Domains, motifs, and folds in protein structure. Computational prediction of protein structure: Threading and homology modeling methods. Application of NMR and X-ray crystallography in protein structure prediction.

**Unit-III:** 12 Hrs

Rational Drug Design


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

**Unit-IV:** 12 Hrs

Molecular docking: Rigid docking, flexible docking, manual docking; Docking based screening. De novo drug design.

Quantitative analysis of Structure Activity Relationship

History and development of QSAR, SAR versus QSAR, Physicochemical parameters, Hansch analysis, Fee Wilson analysis and relationship between them.

**Unit-V:** 12 Hrs
QSAR Statistical methods – regression analysis, partial least square analysis (PLS) and other multivariate statistical methods. 3D-QSAR approaches like COMFA and COMSIA

Prodrug design-Basic concept, Prodrugs to improve patient acceptability, Drug solubility,

Drug absorption and distribution, site specific drug delivery and sustained drug action.

Rationale of prodrug design and practical consideration of prodrug design

(MPL203T) PRINCIPLES OF DRUG DISCOVERY: COURSE OUTCOMES

The Student:
2] Able to describe the targets for drug discovery, lead seeking method and lead optimization,
3] Able to describe the role of computer aided drug design in drug discovery.

|MPL203T) PRINCIPLES OF DRUG DISCOVERY MappingPOs&PSOsX Course Outcomes:|
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|CO2|X|X|X|X|X|
|CO3|X|X|X|X|X|

References
2. Darryl León. Scott MarkellIn. Silico Technologies in Drug Target Identification and Validation. 2006 by Taylor and Francis Group, LLC.
CLINICAL RESEARCH AND PHARMACOVIGILANCE (MPL204T)

Scope
This subject will provide a value addition and current requirement for the students in clinical research and pharmacovigilance. It will teach the students on conceptualizing, designing, conducting, managing and reporting of clinical trials.

This subject also focuses on global scenario of Pharmacovigilance in different methods that can be used to generate safety data. It will teach the students in developing drug safety data in Pre-clinical, Clinical phases of Drug development and post market surveillance.

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

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

Unit-I: Regulatory Perspectives of Clinical Trials 12 hours
Origin and Principles of International Conference on Harmonization - Good Clinical Practice (ICH-GCP) guidelines

Ethical Committee- Institutional Review Board, Ethical Guidelines for Biomedical Research and Human Participant-Schedule Y, ICMR

Informed Consent Process: Structure and content of an Informed Consent Process
Ethical principles governing informed consent process

Unit- II: Clinical Trials: Types and Design 12 hours
Experimental Study- RCT and Non RCT,

Observation Study: Cohort, Case Control, Cross sectional

Clinical Trial Study Team: Roles and responsibilities of Clinical Trial Personnel: Investigator, Study Coordinator, Sponsor, Contract Research Organization and its management

Unit- III: Clinical Trial Documentation 12 hours
Clinical Trial Documentation- Guidelines to the preparation of documents, Preparation of protocol, Investigator Brochure, Case Report Forms, Clinical Study Report Clinical Trial Monitoring-Safety Monitoring in CT


Unit-IV: Basic aspects, terminologies and establishment of pharmacovigilance  12 hours

History and progress of pharmacovigilance, Significance of safety monitoring, Pharmacovigilance in India and international aspects, WHO international drug monitoring programme, WHO and Regulatory terminologies of ADR, evaluation of medication safety, Establishing pharmacovigilance centres in Hospitals, Industry and National programmes related to pharmacovigilance. Roles and responsibilities in Pharmacovigilance

Unit-V: Methods, ADR reporting and tools used in Pharmacovigilance  12 hours


Unit-VI:
1. Pharmacoepi Dermatology , pharmacoeconomics , safety pharmacology

(MPL204T) CLINICAL RESEARCH AND PHARMACOVIGILANCE : COURSE OUTCOMES

The Student is able to:
1] Describe regulatory requirements for conducting clinical trial, Clinical trial designs.
2] Describe the responsibilities of key players involved in clinical trials, Safety monitoring, reporting and close-out activities.
3] Describe the principles of pharmacovigilance, new adverse drug reactions and their assessment, adverse drug reaction reporting systems and communication in pharmacovigilance.

(MPL204T) CLINICAL RESEARCH AND PHARMACOVIGILANCE

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References


Experimental Pharmacology-II (MPL205P)

1. To record the DRC of agonist using suitable isolated tissues preparation.

2. To study the effects of antagonist/potentiating agents on DRC of agonist using suitable isolated tissue preparation.

3. To determine 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.
17. Protocol design for clinical trial.
18. Protocol design for clinical trial.
20. In silico docking studies.
21. In silico pharmacophore-based screening.
22. In silico QSAR studies.
23. ADR reporting
24. In silico docking studies.

References
1. Fundamentals of experimental Pharmacology-by M.N.Ghosh
5. Applied biopharmaceutics and Pharmacokinetics by Leon Shargel and Andrew B.C.Yu.
6. Handbook of Essential Pharmacokinetics, Pharmacodynamics and Drug etabolism for Industrial Scientists.
M. Pharmacy Degree Programme (Industrial Pharmacy)

**Program Outcomes**
The Post Graduate in M. Pharmacy Degree Programme (Industrial Pharmacy) shall be able to:

**PO1. Domain Knowledge:** Demonstrate comprehension of basic principles of pharmaceutical and allied sciences in all pertinent scenarios. Exhibit skills associated with the profession of pharmacy, pharmaceutical manufacturing practices and quality control.

**PO2. Problem analysis:** Use domain knowledge, analytical and critical thinking for solving problems and taking decisions during everyday practice in profession, industry and all work environment.

**PO3. Research and Development:** Exhibit knowledge from his major domain in problem identification, critical thinking, analysis, usage of statistical tools, and providing solutions to pharmaceutical and allied technology disciplines.

**PO4. Modern tools usage:** Demonstrate an ability to handle/use various tools, apparatus, instrument, ethical animal studies, equipment or machinery pertinent to the pharmaceutical domain with practical knowledge on standard operating procedures and safety aspects.

**PO5. The Pharmacist and Society:** Use contextual knowledge – informed reasoning to understand medical prescription, perform patient counselling. Recognize the necessity to engage in independent and life-long learning.

**PO6. Environment and sustainability:** Demonstrate knowledge and responsibility while handling pharmaceutical techniques/processes that have social and environmental impacts and promote sustainable development.

**PO7. Ethics:** Demonstrate exemplary professional, ethical, and legal behaviours in accordance with all drug, pharmaceutical, and pharmacy-related central, state laws and regulations.

**PO8. Individual and Team skills:** Function effectively as an individual member or leader in different teams and multidisciplinary settings. Assume a participatory or lead role in an organization's planning and execution of transformational projects to enhance its prospects.

**PO9. Communication:** Communicate effectively with the pharmaceutical scientific community, work-force and with society at large, with abilities to
comprehend and write effective reports, make effective presentations and documentation.

**PO10. Project management abilities:** Demonstrate effective delegation and organizational skills. Organize work with necessary planning and execution to meet deadlines. Demonstrate knowledge and understanding of pharmaceutical, legal processes and apply them in project management.

**Program Specific Outcomes (PSOs)**

The post graduate in M. Pharmacy Degree Programme (Industrial Pharmacy) shall be able to:

**PSO1.** Understand, apply pharmaceutical analysis principles and techniques towards identification, structural elucidation, and quantification of drugs using modern analytical instruments.

**PSO2.** Understand and apply concepts for routine Industrial activities, formulation, research & development: Pharmaceutical products, Novel Drug Delivery Systems, Biopharmaceutics & Pharmacokinetics.

**PSO3.** Understand Concepts involved in scale up and technology transfer, large-scale pharmaceutical production technology, Intellectual Property Rights.

**PSO4.** Understand and apply concepts of research methodology & biostatistics systematically in research, and CPCSEA guidelines for laboratory animal facilities.

**PSO5.** Understand and apply Industrial Hazards-Safety Management Protocols, and act responsibly towards environment, follow ethical principles, be able to comprehend, interpret and apply laws pertinent to all spheres of pharmaceutical and allied domains, imbibe the spirit of being an entrepreneur.
M. PHARM. INDUSTRIAL PHARMACY (MIP)  
SEMESTER I  

MODERN PHARMACEUTICAL ANALYSIS (MPA101T)  

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

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

Theory 60 Hours  

1. UV-Visible spectroscopy 11 Hrs  

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

Spectrofluorimetry  
Theory of Fluorescence, Factors affecting fluorescence, Quenchers, Instrumentation and Applications of fluorescence spectrophotometer.

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

2. NMR spectroscopy 11 Hrs  
Quantum numbers and their role in NMR, Principle, Instrumentation, Solvent requirement in NMR, Relaxation process, NMR signals in various compounds, Chemical shift, Factors influencing chemical shift, Spin-Spin coupling, Coupling constant, Nuclear magnetic double resonance, Brief outline of principles of FT-NMR and 13C NMR. Applications of NMR spectroscopy.

Mass Spectroscopy  

4. Chromatography 11 Hrs  
Principle, apparatus, instrumentation, chromatographic parameters, factors affecting resolution and applications of the following:
a) Paper chromatography  b) Thin Layer chromatography  
c) Ion exchange chromatography  d) Column chromatography  
e) Gas chromatography  f) High Performance Liquid chromatography  
g) Affinity chromatography  

5. **Electrophoresis**  **11 Hrs**  
Principle, Instrumentation, Working conditions, factors affecting separation and applications of the following:  
a) Paper electrophoresis  b) Gel electrophoresis  c) Capillary electrophoresis  
d) Zone electrophoresis  e) Moving boundary electrophoresis  f) Iso electric focusing  

**X ray Crystallography**  
Production of X rays, Different X ray methods, Bragg's law, Rotating crystal technique, X ray powder technique, Types of crystals and applications of X-ray diffraction.  

6. **Immunological Assays**  **5 Hrs**  
Radioimmunoassay (RIA), ELISA (Theory & practical) and knowledge on Bioluminescence assays.  

**MPA101T Modern Pharmaceutical Analytical Techniques Course Outcomes:**  
**The Student:**  
1] Describes the principles & applications of instruments involved in drug analysis.  
2] Discusses analysis of various drugs in single and combination dosage forms using various analytical Instruments.  

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**References**  
PHARMACEUTICAL FORMULATION DEVELOPMENT (MIP101T)

Scope
This course is designed to impart knowledge and skills necessary to train the students on par with the routine of Industrial activities in R&D and F&D

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

- The scheduled activities in a Pharmaceutical firm.
- The pre formulation studies of pilot batches of pharmaceutical industry.
- The significance of dissolution and product stability

Theory 60Hrs

12 Hrs

Preformulation Studies: Molecular optimization of APIs (drug substances), crystal morphology and variations, powder flow, structure modification, drug-excipient compatibility studies, methods of determination.

12 Hrs

Formulation Additives: Study of different formulation additives, factors influencing their incorporation, role of formulation development and processing, new developments in excipient science, determination methods, drug excipient interactions. Design of experiments – factorial design for product and process development.

12 Hrs

Solubility: Importance, experimental determination, phase-solubility analysis, pH-solubility profile, solubility techniques to improve solubility and utilization of analytical methods – cosolvency, salt formation, complexation, solid dispersion, micellar solubilization and hydrotropy.

12 Hrs


12 Hrs

Product Stability: Degradation kinetics, mechanisms, stability testing of drugs and pharmaceuticals, factors influencing-media effects and pH effects, accelerated stability studies, interpretation of kinetic data (API & tablets). Solid
state stability and shelf life assignment. Stability protocols, reports and ICH guidelines.

MIP101TPHARMACEUTICAL FORMULATION DEVELOPMENT COURSE OUTCOMES:

**The Student:**

1] Describes and protocol for the Pre-formulation Studies.
2] Describes, explores the use of Formulation Additives.
3] Able to describe, analyse, evaluates solubility, dissolution and product stability studies.

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**References**


CUSTOMIZED DRUG DELIVERY SYSTEMS (MIP102T)

Scope
This course is designed to impart knowledge and skills necessary to train the students in the area of customized drug delivery systems.

Objective
At completion of this course it is expected that students will be able to understand-
- The need, concept, design and evaluation of various customized, sustained and controlled release dosage forms.
- To formulate and evaluate various customized/novel drug delivery systems

Theory 60Hrs

12 Hrs
Concept & Models for NDDS: Classification of rate controlled drug delivery systems (DDS), rate programmed release, activation modulated & feedback regulated DDS, effect of system parameters in controlled drug delivery, computation of desired release rate and dose for controlled release DDS, pharmacokinetic design for DDS – intermittent, zero order & first order release.


Study of Various DDS: Concepts, design, formulation & evaluation of controlled release oral DDS, Mucoadhesive DDS (buccal, nasal, pulmonary) Pulsatile, colon specific, liquid sustained release systems.

Marcel Dekker Inc, New Theory, design, formulation & evaluation including iontophoresis and other latest developments in skin delivery systems. Sub Micron Cosmeceuticals: Biology, formulation science and evaluation of various cosmetics for skin, hair, nail, oral cavity, eye etc and it’s regulatory aspects.

Targeted Drug Delivery Systems: Importance, concept, biological process and events involved in drug targeting, design, formulation & evaluation, methods in drug targeting – nanoparticles, liposomes, niosomes, pharmacosomes, resealed

Biotechnology in Drug Delivery Systems: Brief review of major areas-recombinant DNA technology, monoclonal antibodies, gene therapy.

**12 Hrs**

Dosage Forms for Personalized Medicine: Introduction, Definition, Pharmacogenetics, Categories of Patients for Personalized Medicines: Customized drug delivery systems, Bioelectronic Medicines, 3D printing of pharmaceuticals, Telepharmacy.

**MIP102T-Customised Drug Delivery Systems Theory: Course Outcomes**

The student:

- Able to describe the need, concept, design and evaluate various customized, sustained and controlled release dosage forms.
- Able to describe, formulate, evaluate various customized/novel drug delivery systems and trends in personalized medicines.

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<th>MIP102T-Customised Drug Delivery Systems Theory</th>
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**References**

- Controlled Drug Delivery Systems, Robinson, Vol 29, Marcel Dekker, NY.
- Transdermal Controlled Systemic Medications, YW Chein, Vol 31, Marcel Dekker, NY.
- Bioadhesive DDS, E. Mathiowitz, Vol 98, Marcel Dekker, NY.
- Polymers for Controlled Drug Delivery, P.J. Tarcha, CRC Press.
- Pharmaceutical Biotechnology, Vyas, CBS, Delhi.
- Biotechnology of Industrial Antibiotics, E.J. Vandamme, Marcel Dekker, NY.
- Formulation & Delivery, E.J. McNally, Vol 99, Marcel Dekker, NY.
- Drug Targeting, M.H. Rubinstein, John Wiley, NY.
INTELECTUAL PROPERTY RIGHTS (MIP103T)

Scope
This course is designed to impart knowledge and skills necessary to train the students to be on par with the routine of Industrial activities in drug regulatory affairs.

Objectives
At completion of this course it is expected that students will be able to understand:
- Assist in Regulatory Audit process.
- Establish regulatory guidelines for drug and drug products.
- The Regulatory requirements for contract research organization.

Theory 60Hrs

12 Hrs
Definition, Need for patenting, Types of Patents, Conditions to be satisfied by an invention to be patentable, Introduction to patent search. Parts of patents. Filling of patents. The essential elements of patent; Guidelines for preparation of laboratory note book, Non-obviousness in Patent.

12 Hrs
Role of GATT, TRIPS, and WIPO.

12 Hrs
Brief introduction to Trademark protection and WHO Patents. IPR’s and its types, Major bodies regulating Indian Pharmaceutical sector,

12 Hrs
Brief introduction to CDSCO. WHO, USFDA, EMEA, TGA, MHRA, MCC,ANVISA

12 Hrs
Regulatory requirements for contract research organization. Regulations for Biosimilars.

MIP103T-Drug Regulations and Intellectual Property Rights: Course Outcomes
The Student:
- Able to describe, assist in regulatory audit process.
- Able to describe regulatory guidelines for drug and drug products.
- Able to describe the regulatory requirements for contract research organization.

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<th>MIP103T-Drug Regulations and Intellectual Property Rights</th>
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CO1
References
2. Applied Production and Operation Management By Evans, Anderson and Williams
3. GMP for pharmaceuticals Material Management by K.K. Ahuja Published by CBS publishers
4. ISO 9000-Norms and explanations
5. GMP for pharmaceuticals- Willing S.H. Marcel and Dekker

Practicals
IndustrialPharmacyPractical I
Semester-1(MIP104P)
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. Effect of surfactants on the solubility of drugs.
8. Effect of pH on the solubility of drugs.
10. Stability testing of solution and solid dosage forms for photo degradation..
11. Stability studies of drugs in dosage forms at 25 C, 60% RH and 40 C, 75% RH.
12. Compatibility evaluation of drugs and excipients.
13. Preparation and evaluation of different polymeric membranes.
14. Formulation and evaluation of sustained release oral matrix tablet.
15. Formulation and evaluation of sustained release oral reservoir system.
16. Formulation and evaluation of microspheres / microcapsules.
17. Formulation and evaluation of transdermal films.
18. Design and evaluation of face wash, body- wash, creams, lotions, shampoo, toothpaste, lipstick.
MIP104P-IndustrialPharmacyPractical I: Course Outcomes

The Student:
- Able to describe, demonstrate the principles and evaluation procedures for pure drugs and their formulations by spectrometry, fluorimetry, flame photometry and HPLC/GC.
- Able to describe, demonstrate the effect of pH, stability and compatibility on formulations.
- Able to describe, demonstrate the different designing methods and evaluating procedures of body wash, creams, lotions, shampoo, tooth paste and lipstick.
- Able to describe the concept of targeted drug delivery system.

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SEMESTER II

ADVANCED BIOPHARMACEUTICS & PHARMACOKINETICS (MIP201T)

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.

Objectives
At completion of this course it is expected that students will be able to understand:
- The basic concepts in Biopharmaceutics and pharmacokinetics.
- The use of raw data and derive the pharmacokinetic models and parameters the best describe the process of drug absorption, distribution, metabolism and elimination.
- To critically evaluate Biopharmaceutics studies involving drug product equivalency.
- To design and evaluate dosage regimens of the drugs using pharmacokinetic and biopharmaceutic parameters.

Theory 60Hrs
12Hrs

12Hrs


12Hrs


12Hrs


MIP201T-Advanced Biopharmaceutics and Pharmacokinetics: Course Outcomes

- Describe the basic concept of biopharmaceutics & pharmacokinetics and concept of ADME in human body
- Use plasma data and derive the pharmacokinetic parameters to describe the process of drug absorption, distribution, metabolism and elimination
- Determine the various pharmacokinetic parameters from plasma concentration or urinary excretion data for a drug
- Describe the concepts of bioavailability and bioequivalence, and Apply these concepts related to developing BE study protocol for generic products.
- Design novel drug delivery products based on pharmacokinetics data consideration

| MIP201T-Advanced Biopharmaceutics and Pharmacokinetics MappingPOs&PSOsX Course Outcomes: |
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| CO1 | X | X | X | | X | | | | | X | | | |
| CO2 | X | X | X | | | X | | | | | | | |
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| CO4 | X | X | X | | | | | X | | | | | |
| CO5 | | | | | X | | | | | | X | | |

References

2. Biopharmaceutics and Pharmacokinetics, A. Treatise, D .M. Brahmankar and Sunil B.J aiswal., Vallab Prakashan, Pitampura, Delhi
4. Textbook of Biopharmaceutics and Pharmacokinetics, Dr. Shobha Rani R. Hiremath, Prism Book

SCALE UP AND TECHNOLOGY TRANSFER (MIP202T)

Scope
This course is designed to impart knowledge and skills necessary to train the students to be on scale up, technology transfer process and industrial safety issues.

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

- Manage the scale up process in pharmaceutical industry. Assist in technology transfer.
- To establish safety guidelines, which prevent industrial hazards.

Theory 60Hrs

Pilot plant design: Basic requirements for design, facility, equipment selection, for tablets, capsules, liquid orals, parenterals and semisolid preparations.

Scale up: Importance, Technology transfer from R & D to pilot plant to plant scale, process scale up for tablets, capsules, liquid orals, semisolids, parenterals, NDDS products – stress on formula, equipments, product uniformity, stability, raw materials, physical layout, input, in-process and finished product specifications, problems encountered during transfer of technology.

Validation: General concepts, types, procedures & protocols, documentation, VMF. Analytical method validation, cleaning validation and vendor qualification.
Equipment Qualification: Importance, IQ, OQ, PQ for equipments – autoclave, DHS, membrane filter, rapid mixer granulator, cone blender, FBD, tablet compression machine, liquid filling and sealing machine.

4. Process validation

Importance, validation of mixing, granulation, drying, compression, tablet coating, liquid filling and sealing, sterilization, water process systems, environmental control.


MIP202T-Scale Up and Technology Transfer: Course Outcomes

- Students should be able to identify the variables in the process and parameters are controlled and sufficient in the face of the rigors of a commercial production environment.
- Students should be able to validate parameters established during development are still within the determined design space and/or adjusted at scale-up.
- Students should be able to prevent accidents in the plant by reducing the hazard to minimum.
- Students should be able to eliminate accident caused work stoppage and lost production.
- Students should be able to achieve lower workmen’s compensation, insurance rates and reduce all other direct and indirect costs of accidents.

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1. Pharmaceutical process validation, JR Berry, Nash, Vol 57, Marcel Dekker, NY.
3. Pharmaceutical project management, T.Kennedy, Vol 86, Marcel Dekker, NY.
5. Tablet machine instruments in pharmaceuticals, PR Watt, John Wiloy.
6. Pharmaceutical dosage forms, Tablets, Vol 1, 2, 3 by Lachman, Lieberman, Marcel Dekker, NY.
7. Pharmaceutical dosage forms, Parentral medications, Vol 1, 2 by K.E. Avis, Marcel Dekker, NY.
8. Dispersed system Vol 1, 2, 3 by Lachman, Lieberman, Marcel Dekker, NY.

PHARMACEUTICAL PRODUCTION TECHNOLOGY (MIP203T)

Scope
This course is designed to impart knowledge and skills necessary to train the students to be on par with the routine of Industrial activities in Production

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

- Handle the scheduled activities in a Pharmaceutical firm.
- Manage the production of large batches of pharmaceutical formulations.

Theory 60Hrs

12Hrs

Improved Tablet Production: Tablet production process, unit operation improvements, granulation and pelletization equipments, continuous and batch mixing, rapid mixing granulators, rota granulators, speronizers and marumerisers, and other specialized granulation and drying equipments. Problems encountered.


12Hrs

Parenteral Production: Area planning & environmental control, wall and floor treatment, fixtures and machineries, change rooms, personnel flow, utilities & utilities equipment location, engineering and maintenance.

12Hrs


12Hrs

Capsule Production: Production process, improved capsule manufacturing and filling machines for hard and soft gelatin capsules. Layout and problems encountered.
Disperse Systems Production: Production processes, applications of mixers, mills, disperse equipments including fine solids dispersion, problems encountered.

Packaging Technology: Types of packaging materials, machinery, labeling, package printin for different dosage forms.


MIP203T-Pharmaceutical Production Technology: Course Outcomes

- This course is designed to impart knowledge and skills necessary to train the students to be on par with the routine of Industrial activities in Production
- At completion of this course it is expected that students will be able to understand:
- Handle the scheduled activities in a Pharmaceutical firm.
- Manage the production of large batches of pharmaceutical formulations.

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References
1. The theory & Practice of Industrial Pharmacy, L. Lachman, Varghese Publ, Bombay.
2. Modern Pharmaceutics by Banker, Vol 72, Marcel Dekker, NY.
3. Pharmaceutical Dosage Forms, Vol 1, 2, 3 by Lachman, Lieberman, Marcel Dekker, NY.
4. Pharmaceutical Dosage Forms, Parentral medications, Vol 1, 2 by K.E. Avis, Marcel Dekker, NY.
6. Dispersed System Vol 1, 2, 3 by Lachman, Lieberman, Marcel Dekker, NY.
7. Product design and testing of polymeric materials by N.P. Chezerisionoff.
12. Tablet Machine instrumentation in pharmaceuticals, PR Watt, Ellis Horwoods, UK.

ENTREPRENEURSHIP MANAGEMENT (MIP204T)

Scope
This course is designed to impart knowledge and skills necessary to train the students on entrepreneurship management.

Objectives
At completion of this course it is expected that students will be able to understand:
- The Role of enterprise in national and global economy
- Dynamics of motivation and concepts of entrepreneurship
- Demands and challenges of Growth Strategies and Networking

Theory 60Hrs
12Hrs

1. Conceptual Frame Work
Concept need and process in entrepreneurship development. Role of enterprise in national and global economy. Types of enterprise – Merits and Demerits. Government policies and schemes for enterprise development. Institutional support in enterprise development and management

12Hrs

2. Entrepreneur

Developing Entrepreneurial competencies – requirements and understanding the process of entrepreneurship development, self awareness, interpersonal skills, creativity, assertiveness, achievement, factors affecting entrepreneur role.

12Hrs

Launching And Organising An Enterprise

12Hrs

Growth Strategies And Networking

12Hrs

Preparing Project Proposal To Start On New Enterprise

Project work – Feasibility report; Planning, resource mobilisation and implementation.

MIP204T-Entrepreneurship Management: Course Outcomes

The Student:

- Able to describe the role of enterprise in national and global economy.
- Able to describe the dynamics of motivation, concepts of entrepreneurship and imbibe the spirit of entrepreneurship.
- Able to describe the demands and challenges of Growth Strategies and networking.

| MIP204T-Entrepreneurship Management MappingPOs&PSOsX Course Outcomes: |
|-----------------|-----------------|-----------------|-----------------|-----------------|-----------------|-----------------|-----------------|-----------------|-----------------|-----------------|-----------------|-----------------|
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| CO1             | X   |     |     |     |     |     |     |     |     |     |     |     |     |     |     |
| CO2             |     | X   |     |     |     |     |     |     |     |     |     |     | X   |     |     |
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| CO4             |     |     |     | X   |     |     |     |     |     |     |     |     |     |     | X   |
| CO5             |     |     |     |     | X   |     |     |     |     |     |     |     | X   |     |     |

References


Practicals

Semester-2(MIP205P): INDUSTRIAL PHARMACY PRACTICALS-II

1. Improvement of dissolution characteristics of slightly soluble drug by Solid dispersion technique.
2. Comparison of dissolution of two different marketed products /brands
3. Protein binding studies of a highly protein bound drug & poorly protein bound drug
4. Bioavailability studies of Paracetamol.
5. Pharmacokinetic and IVIVC data analysis by WinnolineR software
6. In vitro cell studies for permeability and metabolism
7. Formulation and evaluation of tablets
8. Formulation and evaluation of capsules
9. Formulation and evaluation of injections
10. Formulation and evaluation of emulsion
11. Formulation and evaluation of suspension.
12. Formulation and evaluation of enteric coating tablets.

**MIP205P-Industrial Pharmacy Practicals: Course Outcomes**

**The student:**
- Able to describe and apply concepts involved in Pharmaceutical Formulation Development for routine Industrial activities.
- Able to describe and apply Novel Drug Delivery Systems, Biopharmaceutics & Pharmacokinetics in R&D and F&D.

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M. Pharmacy Degree Programme (Pharmaceutical Quality Assurance)

Program Outcomes
The Post Graduate in M. Pharmacy Degree Programme (Pharmaceutical Quality Assurance) shall be able to:

PO1. Domain Knowledge: Demonstrate comprehension of basic principles of pharmaceutical and allied sciences in all pertinent scenarios. Exhibit skills associated with the profession of pharmacy, pharmaceutical manufacturing practices and quality control.

PO2. Problem analysis: Use domain knowledge, analytical and critical thinking for solving problems and taking decisions during everyday practice in profession, industry and all work environment.

PO3. Research and Development: Exhibit knowledge from his major domain in problem identification, critical thinking, analysis, usage of statistical tools, and providing solutions to pharmaceutical and allied technology disciplines.

PO4. Modern tools usage: Demonstrate an ability to handle/use various tools, apparatus, instrument, ethical animal studies, equipment or machinery pertinent to the pharmaceutical domain with practical knowledge on standard operating procedures and safety aspects.

PO5. The Pharmacist and Society: Use contextual knowledge – informed reasoning to understand medical prescription, perform patient counselling. Recognize the necessity to engage in independent and life-long learning.

PO6. Environment and sustainability: Demonstrate knowledge and responsibility while handling pharmaceutical techniques/ processes that have social and environmental impacts and promote sustainable development.

PO7. Ethics: Demonstrate exemplary professional, ethical, and legal behaviours in accordance with all drug, pharmaceutical, and pharmacy-related central, state laws and regulations.

PO8. Individual and Team skills: Function effectively as an individual member or leader in different teams and multidisciplinary settings. Assume a participatory or lead role in an organization’s planning and execution of transformational projects to enhance its prospects.

PO9. Communication: Communicate effectively with the pharmaceutical scientific community, work-force and with society at large, with abilities to
comprehend and write effective reports, make effective presentations and documentation.

**PO10. Project management abilities:** Demonstrate effective delegation and organizational skills. Organize work with necessary planning and execution to meet deadlines. Demonstrate knowledge and understanding of pharmaceutical, legal processes and apply them in project management.

**Program Specific Outcomes (PSOs)**

The Post Graduate in M. Pharmacy Degree Programme (Pharmaceutical Quality Assurance) shall be able to:

**PSO1.** Understand and apply in the pharmaceutical industries: Pharmaceutical analysis principles and techniques, quality control and quality assurance concepts, Pharmaceutical validation.

**PSO2.** Understand and apply concepts in the pharmaceutical industries: Quality management principles and systems, quality evaluation, overview of pharmaceutical manufacturing technology and develop quality assurance protocols.

**PSO3.** Understand and apply concepts in the pharmaceutical industries: Product development and technology transfer protocols, intellectual property rights, audits and regulatory compliance.

**PSO4.** Understand and apply concepts of research methodology & biostatistics systematically in research, and CPCSEA guidelines for Laboratory animal facilities.

**PSO5.** Understand and apply Industrial hazards - safety management protocols, act responsibly towards environment, follow ethical principles, be able to comprehend, interpret and apply laws pertinent to all spheres of pharmaceutical and allied domains and imbibe the spirit of being an entrepreneur.
Scope
This subject deals with various advanced analytical instrumental techniques for identification, characterization and quantification of drugs. Instruments dealt are NMR, Mass spectrometer, IR, HPLC, GC etc.

Objectives
After completion of course student is able to know about chemicals and excipients Ø The analysis of various drugs in single and combination dosage forms Ø Theoretical and practical skills of the instruments

Theory Hours 60

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.

Spectrofluorimetry: Theory of Fluorescence, Factors affecting fluorescence (Characteristics of drugs that can be analysed by flourimetry), Quenchers, Instrumentation and Applications of fluorescence spectrophotometer.

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

NMR spectroscopy: Quantum numbers and their role in NMR, Principle, 10 Hrs Instrumentation, Solvent requirement in NMR, Relaxation process, NMR signals in various compounds, Chemical shift, Factors influencing chemical shift, Spin-Spin coupling, Coupling constant, Nuclear magnetic double resonance, Brief outline of principles of FT-NMR and 13C NMR. Applications of NMR spectroscopy.

Mass Spectroscopy: Principle, Theory, Instrumentation of Mass Spectroscopy 10 Hrs
Different types of ionization like electron impact, chemical, field, FAB and MALDI, APCI, ESI, APPI Analyzers of Quadrupole and Time of Flight, Mass fragmentation and its rules, Meta stable ions, Isotopic peaks and Applications of Mass spectroscopy

Chromatography: Principle, apparatus, instrumentation, chromatographic 12 Hrs
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
- Column chromatography
- Gas chromatography
- High Performance Liquid chromatography
- Ultra High Performance Liquid chromatography
- Affinity chromatography
- Gel Chromatography

Electrophoresis: Principle, Instrumentation, Working conditions, factors affecting 8 Hrs separation and applications of the following:
  - Paper electrophoresis
  - Gel electrophoresis
  - Capillary electrophoresis
  - Zone electrophoresis
  - Moving boundary electrophoresis
  - Iso electric focusing

X ray Crystallography: Production of X rays, Different X ray methods, Bragg’s law, Rotating crystal technique, X ray powder technique, Types of crystals and applications of X-ray diffraction.

Potentiometry: Principle, working, Ion selective Electrodes and Application of 4 Hrs potentiometry.

Thermal Analysis: Polymer behavior, factors affecting and instrumentation, and working, application of TGA

MODERN PHARMACEUTICAL ANALYSIS (MPA101T) Course Outcomes:

**The Student:**
1. Describes the principles & applications of instruments involved in drug analysis.
2. Discusses analysis of various drugs in single and combination dosage forms using various analytical Instruments.
3. Able to interpret spectra and solve analytical problems.

MODERN PHARMACEUTICAL ANALYSIS (MPA101T)
Mapping POs & PSOs X Course Outcomes

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**References (Latest edition to be recommended)**
QUALITY MANAGEMENT SYSTEMS (MQA101T)

Scope
This course is designed to impart fundamental knowledge and concepts about various quality management principles and systems utilized in the manufacturing industry. It also aids in understanding the quality evaluation in the pharmaceutical industries.

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

- The importance of quality ISO management systems
- Tools for quality improvement Analysis of issues in quality
- Quality evaluation of pharmaceuticals
- Stability testing of drug and drug substances Statistical approaches for quality

Theory 60 Hrs
Introduction to Quality: Evolution of Quality, Definition of Quality, Dimensions of Quality

Quality as a Strategic Decision: Meaning of strategy and strategic quality management, mission and vision statements, quality policy, Quality objectives, strategic planning and implementation, McKinsey 7s model, Competitive analysis, Management commitment to quality

Customer Focus: Meaning of customer and customer focus, Classification of customers, Customer focus, Customer perception of quality, Factors affecting customer perception, Customer requirements, Meeting customer needs and expectations, Customer satisfaction and Customer delight, Handling customer complaints, Understanding customer behavior, concept of internal and external customers. Case studies.

Cost of Quality: Cost of quality, Categories of cost of Quality, Models of cost of quality, Optimising costs, Preventing cost of quality

12 Hrs

Review. OSHAS guidelines, NABL certification and accreditation, CFR-21 part 11, WHO-GMP requirements.

12 Hrs

Six System Inspection model: Quality Management system, Production system, Facility and Equipment system, Laboratory control system, Materials system, Packaging and labeling system. Concept of self inspection.


12 Hrs


Study of ICH Q8, Quality by Design and Process development report
Quality risk management: Introduction, risk assessment, risk control, risk review, risk management tools, HACCP, risk ranking and filtering according to ICH Q9 guidelines

12 Hrs

Statistical Process control (SPC): Definition and Importance of SPC, Quality measurement in manufacturing, Statistical control charts - concepts and general aspects, Advantages of statistical control, Process capability, Estimating Inherent or potential capability from a control chart analysis, Measuring process control and quality improvement, Pursuit of decreased process variability.

8Hrs

Regulatory Compliance through Quality Management and development of Quality Culture
Benchmarking: Definition of benchmarking, Reasons for benchmarking, Types of Benchmarking, Benchmarking process, Advantages of benchmarking, Limitations of benchmarking 4 Hrs

QUALITY MANAGEMENT SYSTEMS (MQA101T) COURSE OUTCOMES:

The Student:
1] Able to describe the importance of quality management systems.
2] Able to describe the tools for quality improvement studies.
3] Able to describe and implement quality evaluation protocols of pharmaceuticals.
4] Able to describe stability testing of drug and drug substances and statistical approaches for quality.
References
1. Implementing Juran's Road Map for Quality Leadership: Benchmarks and Results, By Al Endres, Wiley, 2000
2. Understanding, Managing and Implementing Quality: Frameworks, Techniques and Cases, By Jiju Antony; David Preece, Routledge, 2002
3. Organizing for High Performance: Employee Involvement, TQM, Reengineering, and
5. Corporate Culture and the Quality Organization By James W. Fairfield-Sonn, Quorum Books, 2001

QUALITY CONTROL AND QUALITY ASSURANCE (MQA102T)

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
Upon completion of this course the student should be able to:
- Understand 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.
Theory

Introduction: Concept and evolution and scopes 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. CPCSEA guidelines.

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.

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 dosage forms in Pharma industry according to Indian, US and British pharmacopoeias: tablets, capsules, ointments, suppositories, creams, parenterals, ophthalmic and surgical products (How to refer pharmacopoeias).

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 (How to write), Master Batch Record, Batch Manufacturing Record, Quality audit plan and reports. Specification and test procedures, Protocols and reports. Distribution records. Electronic data handling. Concepts of controlled and uncontrolled documents.


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, reprocessing, salvaging, handling of waste and scrap disposal.
Introduction, scope and importance of intellectual property rights. Concept of trade mark, copyright and patents.

12 Hrs

QUALITY CONTROL AND QUALITY ASSURANCE (MQA102T) COURSE OUTCOMES:

The Student:
1) Able to describe & appreciate the importance of GMP aspects, documentation & implement in pharmaceutical industry.
2) Able to describe & appreciate the scope of quality certifications applicable to Pharmaceutical industries
3) Able to describe the responsibilities of QA & QC departments.

QUALITY MANAGEMENT SYSTEMS (MQA101T)
Mapping POs & PSOs X Course Outcomes

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References
7. ICH guidelines
8. ISO 9000 and total quality management
14. Packaging of Pharmaceuticals.
15. Schedule M and Schedule N.

PRODUCT DEVELOPMENT AND TECHNOLOGY TRANSFER (MQA103T)

Scope

This deal with technology transfer covers the activities associated with Drug Substance, Drug Product and analytical tests and methods, required following candidate drug selection to completion of technology transfer from R&D to the first receiving site and technology transfer related to post-marketing changes in manufacturing places.

Objectives

Upon completion of this course the student should be able to:

- To understand the new product development process
- To understand the necessary information to transfer technology from R&D to actual manufacturing by sorting out various information obtained during R&D
- To elucidate necessary information to transfer technology of existing products between various manufacturing places

Theory 60 Hrs

Principles of Drug discovery and development: Introduction, Clinical research process. Development and informational content for Investigational New Drugs Application (IND), New Drug Application (NDA), Abbreviated New Drug Application (ANDA), Supplemental New Drug Application (SNDA), Scale Up Post Approval Changes (SUPAC) and Bulk active chemical Post approval changes (BACPAC), Post marketing surveillance, Product registration guidelines – CDSCO, USFDA.

12 Hrs


Hrs

Pilot plant scale up: Concept, Significance, design, layout of pilot plant scale up study, operations, large scale manufacturing techniques (formula, equipment, process, stability and quality control) of solids, liquids, semisolid and parenteral dosage forms. New era of drug products: opportunities and challenges.
12 Hrs


Quality control test: Containers, closures and secondary packing materials.

Technology transfer:

Development of technology by R & D, Technology transfer from R & D to production, Optimization and Production, Qualitative and quantitative technology models.

Documentation in technology transfer: Development report, technology transfer plan and Exhibit.

12 Hrs

PRODUCT DEVELOPMENT AND TECHNOLOGY TRANSFER (MQA103T) COURSE OUTCOMES:

The Student:

1] Able to describe the new product development process.
2] Able to describe the protocol to transfer technology from R&D to actual manufacturing by sorting out various information obtained during R&D
3] Able to describe the procedures involved in technology transfer - R & D to production.

PRODUCT DEVELOPMENT AND TECHNOLOGY TRANSFER (MQA103T)
Mapping POs & PSOs X Course Outcomes

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QUALITY ASSURANCE PRACTICAL-I (MQA104P)

Practicals

Analysis of pharmacopoeial compounds in bulk and in their formulations (tablet/ capsules/ semisolids) by UV Vis spectrophotometer

- Simultaneous estimation of multi-drug component containing formulations by UV spectrophotometry
- Experiments based on HPLC
- Experiments based on Gas Chromatography
- Estimation of riboflavin/quinine sulphate by fluorimetry
- Estimation of sodium/potassium by flame photometry or AAS

Case studies on

- Total Quality Management
- Six Sigma
- Change Management/ Change control. Deviations,
- Out of Specifications (OOS)
- Out of Trend (OOT)
- Corrective & Preventive Actions (CAPA)
- Deviations
- Development of Stability study protocol
- Estimation of process capability
- In process and finished product quality control tests for tablets, capsules, parenterals and semisolid dosage forms.
- Assay of raw materials as per official monographs
• Testing of related and foreign substances in drugs and raw materials
• To carry out pre formulation study for tablets, parenterals (2 experiment).
• To study the effect of pH on the solubility of drugs, (1 experiment)
• Quality control tests for Primary and secondary packaging materials
• Accelerated stability studies (1 experiment)
• Improved solubility of drugs using surfactant systems (1 experiment)
• Improved solubility of drugs using co-solvency method (1 experiment)
• Determination of Pka and Log p of drugs.

QUALITY ASSURANCE PRACTICAL-I (MQA104P) COURSE OUTCOMES:

The Student:
1] Able to analyse drugs, excipients, finished products by both classical and modern analytical techniques and instruments.
2] Able to describe, perform, apply statistical protocols in manufacturing process.
3] Able to do preformulation studies, stability testing of drug and improve solubility of drug.
4] Able to perform quality control tests on packaging.

QUALITY ASSURANCE PRACTICAL-I (MQA104P) MAPPING POS & PSOS X COURSE OUTCOMES:

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SEMINETER II

HAZARDS AND SAFETY MANAGEMENT (MPA201T)

Scope
This course is designed to convey the knowledge necessary to understand issues related to different kinds of hazard and their management. Basic theoretical and practical discussions integrate the proficiency to handle the emergency situation in the pharmaceutical product development process and provides the principle-based approach to solve the complex tribulations.

Objectives
At completion of this course it is expected that students will be able to:
Understand about environmental problems among learners.

Impart basic knowledge about the environment and its allied problems. Develop an attitude of concern for the industry environment.

Ensure safety standards in pharmaceutical industry

Provide comprehensive knowledge on the safety management

Empower an ideas to clear mechanism and management in different kinds of hazard management system

Teach the method of Hazard assessment, procedure, methodology for provide safe industrial atmosphere.

**Theory 60Hrs**

Multidisciplinary nature of environmental studies: Natural Resources, Renewable and non-renewable resources, Natural resources and associated problems, a) Forest resources; b) Water resources; c) Mineral resources; d) Energy resources; e) Land resources

Ecosystems: Concept of an ecosystem and Structure and function of an ecosystem. Environmental hazards: Hazards based on Air, Water, Soil and Radioisotopes.

12 Hrs

Air based hazards: Sources, Types of Hazards, Air circulation maintenance industry for sterile area and non sterile area, Preliminary Hazard Analysis (PHA)

Fire protection system: Fire prevention, types of fire extinguishers and critical Hazard management system.

12 Hrs

Chemical based hazards: Sources of chemical hazards, Hazards of Organic synthesis, sulphonating hazard, Organic solvent hazard, Control measures for chemical hazards, Management of combustible gases, Toxic gases and Oxygen displacing gases management, Regulations for chemical hazard, Management of over-Exposure to chemicals and TLV concept.

12 Hrs

Fire and Explosion: Introduction, Industrial processes and hazards potential, mechanical electrical, thermal and process hazards. Safety and hazards regulations, Fire protection system: Fire prevention, types of fire extinguishers and critical Hazard management system mechanical and chemical explosion, multiphase reactions, transport effects and global rates. Preventive and protective management from fires and explosion- electricity passivation, ventilation, and sprinkling, proofing, relief systems -relief valves, flares, scrubbers. 12 Hrs

Determination of some contaminants, Effluent treatment procedure, Role of emergency services

HAZARDS AND SAFETY MANAGEMENT (MPA201T) COURSE OUTCOMES:

**The Student:**

1. Is able to describe, with involvement (concern) environment and its allied hazard problems specific to the industry and universal environment at large.
2. Able to describe and ensure safety standards in pharmaceutical industry.
3. Able to describe and impart the method of Hazard assessment, procedure, methodology for providing safe industrial atmosphere.

**HAZARDS AND SAFETY MANAGEMENT (MPA201T) Mapping POs & PSOs X Course Outcomes**

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1. Y.K. Sing, Environmental Science, New Age International Pvt, Publishers, Bangalore

**PHARMACEUTICAL VALIDATION (MQA202T)**

**Scope**

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

**Objectives**

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

- The concepts of calibration, qualification and validation The qualification of various equipments and instruments Process validation of different dosage forms
Validation of analytical method for estimation of drugs
Cleaning validation of equipments employed in the manufacture of pharmaceuticals

Theory

Introduction to validation: Definition of Calibration, Qualification and Validation, Scope, frequency and importance. Difference between calibration and validation. Calibration of weights and measures. Advantages of Validation, scope of Validation, Organization for Validation, Validation Master plan, Types of Validation, Streamlining of qualification & Validation process and Validation Master Plan.

Qualification: User requirement specification, Design qualification, Factory Acceptance Test (FAT)/Site Acceptance Test (SAT), Installation qualification, Operational qualification, Performance qualification, Re-Qualification (Maintaining status- Calibration Preventive Maintenance, Change management).


Qualification of analytical instruments: UV-Visible spectrophotometer, FTIR, DSC, GC, HPLC, HPTLC, LC-MS.

Qualification of laboratory equipments: Hardness tester, Friability test apparatus, tap density tester, Disintegration tester, Dissolution test apparatus

Validation of Utility systems: Pharmaceutical water system & pure steam, HVAC system, Compressed air and nitrogen.

Process Validation: Concept, Process and documentation of Process Validation. Prospective, Concurrent & Retrospective Validation, Re validation criteria, Process Validation of various formulations (Coated tablets, Capsules, Ointment/Creams, Liquid Orals and aerosols.), Aseptic filling: Media fill validation, USFDA guidelines on Process Validation- A life cycle approach.

Analytical method validation: General principles, Validation of analytical method as per ICH guidelines (Q2) and USP.

Cleaning Validation: Cleaning Method development, Validation of analytical method used in cleaning, Cleaning of Equipment, Cleaning of Facilities. Cleaning in place (CIP).

Validation of facilities in sterile and non-sterile plant

Computerized system validation: Electronic records and digital signature - 21 CFR Part 11 and GAMP 5.
PHARMACEUTICAL VALIDATION (MQA202T) COURSE OUTCOMES:

The Student:
1] Is able to describe the concepts of calibration, qualification and validation of various equipments and instruments, process validation protocol of different dosage forms
2] Able to describe and implement analytical validation protocol.
3] Able to describe and implement the cleaning validation protocol of equipments employed in the manufacture of pharmaceuticals

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References
3. Validation Master plan by Terveeks or Deeks, Davis Harwood International publishing.
6. 157,2nd Ed., Marcel Dekker Inc., N.Y.
AUDITS AND REGULATORY COMPLIANCE (MPA203T)

Scope
This course deals with the understanding and process for auditing in pharmaceutical industries. This subject covers the methodology involved in the auditing process of different in pharmaceutical industries.

Objectives
Upon completion of this course the student should be able to:

- To understand the importance of auditing
- To understand the methodology of auditing
- To carry out the audit process
- To prepare the auditing report
- To prepare the check list for auditing

Theory

- Introduction: Objectives, Management of audit, Responsibilities, Planning process, information gathering, administration, Classifications of deficiencies
- Role of quality systems and audits in pharmaceutical manufacturing environment: cGMP Regulations, Quality assurance functions, Quality systems approach, Management responsibilities, Resource, Manufacturing operations, Evaluation activities, Transitioning to quality system approach, Audit checklist for drug industries

12 Hrs

Auditing of vendors and production department: Bulk Pharmaceutical Chemicals and packaging material Vendor audit, Warehouse and weighing, Dry Production: Granulation, tableting, coating, capsules, sterile production and packaging

12 Hrs

Auditing of Microbiological laboratory: Auditing the manufacturing process, Product and process information, General areas of interest in the building raw materials, Water, Packaging materials

Hrs

Auditing of Quality Assurance and engineering department: Quality Assurance

Maintenance, Critical systems: HVAC, Water, Water for Injection systems, ETP.
AUDITS AND REGULATORY COMPLIANCE (MPA203T) COURSE OUTCOMES:

The Student:
1] Able to describe the concepts of auditing, methodology of auditing, implementing audit process in production, analytical quality control.
2] Able to prepare audit report.
3] Able to describe auditing protocols applied in different sections of pharmaceutical industry.

AUDITS AND REGULATORY COMPLIANCE (MPA203T)
Mapping POs & PSOs X Course Outcomes

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PHARMACEUTICAL MANUFACTURING TECHNOLOGY (MPA204T)
Scope
This course is designed to impart knowledge and skills necessary to train the students with the industrial activities during Pharmaceutical Manufacturing.

Objectives
At completion of this course it is expected that students will be able to understand:
- The common practice in the pharmaceutical industry developments, plant layout and production planning
- Will be familiar with the principles and practices of aseptic process technology, non sterile manufacturing technology and packaging technology.
• Have a better understanding of principles and implementation of Quality by design (QbD) and process analytical technology (PAT) in pharmaceutical manufacturing

**Theory**  
60Hrs

Pharmaceutical industry developments: Legal requirements and Licenses for API and formulation industry, Plant location-Factors influencing.

Plant layout: Factors influencing, Special provisions, Storage space requirements, sterile and aseptic area layout.

Production planning: General principles, production systems, calculation of standard cost, process planning, routing, loading, scheduling, dispatching of records, production control.

12Hrs

Aseptic process technology: Manufacturing, manufacturing flowcharts, in process- quality control tests for following sterile dosage forms: Ointment, Suspension and Emulsion, Dry powder, Solution (Small Volume & large Volume).

Advanced sterile product manufacturing technology : Area planning & environmental control, wall and floor treatment, fixtures and machineries, change rooms, personnel flow, utilities & utilities equipment location, engineering and maintenance.


12Hrs

Non sterile manufacturing process technology: Manufacturing, manufacturing flowcharts, in process-quality control tests for following Non-Sterile solid dosage forms: Tablets (compressed & coated), Capsules (Hard & Soft).


Coating technology: Process, equipments, particle coating, fluidized bed coating, application techniques. Problems encountered.

12Hrs

Containers and closures for pharmaceuticals: Types, performance, assuring quality of glass; types of plastics used, Drug plastic interactions, biological tests, modification of plastics by drugs; different types of closures and closure liners; film
wrapper; blister packs; bubble packs; shrink packaging; foil / plastic pouches, bottle seals, tape seals, breakable seals and sealed tubes; quality control of packaging material and filling equipment, flexible packaging, product package compatibility, transit worthiness of package, Stability aspects of packaging. Evaluation of stability of packaging material.

Quality by design (QbD) and process analytical technology (PAT): Current approach and its limitations. Why QbD is required, Advantages, Elements of QbD, Terminology: QTPP. CMA, CQA, CPP, RLD, Design space, Design of Experiments, Risk Assessment and mitigation/minimization. Quality by Design, Formulations by Design, QbD for drug products, QbD for Drug Substances, QbD for Excipients, Analytical QbD. FDA initiative on process analytical technology. PAT as a driver for improving quality and reducing costs: quality by design (QbD), QA, QC and GAMP. PAT guidance, standards and regulatory requirements.

PHARMACEUTICAL MANUFACTURING TECHNOLOGY (MPA204T COURSE OUTCOMES:

**The Student:**

1] Able to describe the Common practices in pharmaceutical industry, plant layout and production planning, principles and practices of aseptic process technology, non-sterile manufacturing technology and packaging technology.
2] Able to describe Implementation of Quality by design (QbD - QTPP. CMA, CQA, CPP, RLD, Design space, Design of Experiments).
3] Able to describe process analytical technology (PAT) in pharmaceutical manufacturing.

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References
Practicals
1. Organic contaminants residue analysis by HPLC
2. Estimation of Metallic contaminants by Flame photometer
3. Identification of antibiotic residue by TLC
4. Estimation of Hydrogen Sulphide in Air.
6. Sampling and analysis of SO2 using Colorimetric method
7. Qualification of following Pharma equipment
8. a) Autoclave b. Hot air oven c. Powder Mixer (Dry) d. Tablet Compression Machine
9. Validation of an analytical method for a drug
10. Validation of a processing area
11. Qualification of at least two analytical instruments
12. Cleaning validation of one equipment
13. Qualification of Pharmaceutical Testing Equipment (Dissolution testing apparatus, Friability Apparatus, Disintegration Tester)
14. Check list for Bulk Pharmaceutical Chemicals vendors
15. Check list for tableting production.
16. Check list for sterile production area
17. Check list for Water for injection.
18. Design of plant layout: Sterile and non-sterile
19. Case study on application of QbD
20. Case study on application of PAT
QUALITY ASSURANCE PRACTICAL-II (MQA204P) COURSE OUTCOMES:

**The Student:**
1. Able to analyse drug by classical and modern analytical techniques and instruments.
2. Able to perform, apply validation protocols on method of drug analysis, cleaning, processing areas etc.
3. Able to create check lists for processes, vendors etc.
4. Able to create Design of plant layout for sterile and non-sterile products.
5. Able to go through case studies on applications of QbD, PAT.

QUALITY ASSURANCE PRACTICAL-II (MQA204P)

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

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

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

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

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

MRM 301T Research Methodology & Biostatistics Course Outcomes:

The Student:
1) Able to describe research problem, methodology, literature study, design of experiments.
2) Able to apply appropriate statistical parametric and non parametric tools.
3) Able to describe ethical research and its significance.
4) Able to describe CPCSEA guidelines for laboratory animal facility.
5) Able to describe the significance of Helsinki declaration.

**MRM 301T Research Methodology & Biostatistics**

**MAPPING POS & PSOS X COURSE OUTCOMES:**

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SEMESTER IV
Project Work

[Common for ALL Branches]

All the students shall undertake a project under the supervision of a teacher in Semester III to IV and submit a report.

The Studentable to:

1] Identify, formulate, research literature, and analyse complex pharmaceutical problems relevant to industry reaching substantiated conclusions using first principles of physical, natural sciences, and applied sciences.
2) Apply appropriate statistical parametric and non parametric tools and experimental design.
3] Express with clarity and sound reasoning student’s work by the way of speech and writing.

PW401 Project Work

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M. PHARM. PHARMACEUTICS (MPH)
MODERN PHARMACEUTICAL ANALYSIS (MPA101T)

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

Objectives
After completion of course student is able to know,

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

THEORY 60 Hours


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


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

2. NMR spectroscopy 11 Hrs.
Quantum numbers and their role in NMR, Principle, Instrumentation, Solvent requirement in NMR, Relaxation process, NMR signals in various compounds, Chemical shift, Factors influencing chemical shift, Spin-Spin coupling, Coupling constant, Nuclear magnetic double resonance, Brief outline of principles of FT-NMR and 13C NMR. Applications of NMR spectroscopy.

Principle, Theory, Instrumentation of Mass 11 Hrs Spectroscopy, Different types of ionization like electron impact, chemical, field, FAB and MALDI, APCI, ESI, APPI Analyzers of Quadrupole and Time of Flight, Mass fragmentation and its rules, Meta stable ions, Isotopic peaks and Applications of Mass spectroscopy

4. Chromatography 11Hrs.
Principle, apparatus, instrumentation, chromatographic 11Hrs parameters, factors affecting resolution and applications of the following: a) Paper chromatography b) Thin Layer chromatography c) Ion exchange chromatography d) Column chromatography

Gas chromatography f) High Performance Liquid chromatography
Affinity chromatography

5. Electrophoresis 11Hrs.
Principle, Instrumentation, Working conditions, factors 11 Hrs affecting separation and applications of the following:
   - Paper electrophoresis
   - Gel electrophoresis
   - Capillary electrophoresis
   - Zone electrophoresis
   - Moving boundary electrophoresis
   - Iso electric focusing

X ray Crystallography
Production of X rays, Different X ray methods, Bragg’s law, Rotating crystal technique, X ray powder technique, Types of crystals and applications of X-ray diffraction.

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

References

DRUG DELIVERY SYSTEM (MPH101T)

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

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

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

THEORY 60 Hrs 10 Hrs
Categories of Patients for Personalized Medicines: Customized drug delivery systems, Bioelectronic Medicines, 3D printing of pharmaceuticals, Telepharmacy.

10 Hrs


10 Hrs

Occular Drug Delivery Systems: Barriers of drug permeation, Methods to overcome barriers.

6 Hrs

Trans Dermal Drug Delivery Systems: Structure of skin and barriers, Penetration enhancers, Transdermal Drug Delivery Systems, Formulation and evaluation

10 Hrs

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

8 Hrs

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

6 Hrs

References
3. Encyclopedia of controlled delivery, Editor- Edith Mathiowitz, Published by WileyInterscience Publication, John Wiley and Sons, Inc, New York! Chichester/Weinheim
5. S.P.Vyas and R.K.Khar, Controlled Drug Delivery - concepts and advances, Vallabh Prakashan, New Delhi, First edition 2002

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

MODERN PHARMACEUTICS (MPH102T)

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

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

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

THEORY

60 HRS


   Theories of dispersion and pharmaceutical Dispersion (Emulsion and Suspension, SMEDDS) preparation and stability

   Large and small volume parental – physiological and formulation consideration, Manufacturing and evaluation

10 Hrs

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

10 Hrs

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

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

10 Hrs
Compression and compaction: Physics of tablet compression, compression, consolidation, effect of friction, distribution of forces, compaction profiles. Solubility enhancement techniques.

10 Hrs

Study of consolidation parameters; Diffusion parameters, Dissolution parameters and Pharmacokinetic parameters, Heckal plats, Similarity factors – f2 and f1, Higuchi and peppas plot, Linearity Concept of significance, Standard deviation, chi square test, student T-test, Anova test.

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

Regulatory Affairs (MPH103T)

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

- To know the approval process of
- To know the chemistry, manufacturing controls and their regulatory importance To learn the documentation requirements for
- To learn the importance and
Objectives
Upon completion of the course, it is expected that the students will be able to understand

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

Theory 60 Hr

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

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

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.

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

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

References
1.


8. www.ich.org/

9. www.fda.gov/

10. europa.eu/index_en.htm

Practicals (MPH104P)
1. Analysis of pharmacopoeial compounds and their formulations by UV Vis spectrophotometer
2. Simultaneous estimation of multi component containing formulations by UV spectrophotometry
3. Experiments based on HPLC
4. Experiments based on Gas Chromatography
5. Estimation of riboflavin/quinine sulphate by fluorimetry
6. Estimation of sodium/potassium by flame photometry
   a. To perform In-vitro dissolution profile of CR/ SR marketed formulation
7. Formulation and evaluation of sustained release matrix tablets
8. Formulation and evaluation osmotically controlled DDS
9. Preparation and evaluation of Floating DDS- hydro dynamically balanced DDS
10. Formulation and evaluation of Muco adhesive tablets.
11. Formulation and evaluation of trans dermal patches.
12. To carry out preformulation studies of tablets.
13. To study the effect of compressional force on tablets disintegration time.
14. To study Micromeritic properties of powders and granulation.
15. To study the effect of particle size on dissolution of a tablet.
16. To study the effect of binders on dissolution of a tablet.
17. To plot Heckal plot, Higuchi and peppas plot and determine similarity factors.

MOLECULAR PHARMACEUTICS (NANO TECHNOLOGY & TARGETED DDS) (NTDS)(MPH201T)

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

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

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

Theory 60 Hrs
Targeted Drug Delivery Systems: Concepts, Events and biological process involved in drug targeting. Tumor targeting and Brain specific delivery. 12hrs


Micro Capsules/Micro Spheres: Types, preparation and evaluation , Monoclonal Antibodies ; preparation and application, preparation and application of Niosomes, Aquasomes, Phytosomes, Electrosomes.
Pulmonary Drug Delivery Systems: Aerosols, propellents, Containers,Types, preparation and evaluation, Intra Nasal Route Delivery systems; Types, preparation and evaluation

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

References

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

ADVANCED BIOPHARMACEUTICS & PHARMACOKINETICS (MPH202T)

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

Objectives
At completion of this course it is expected that students will be able understand – The basic concepts in biopharmaceutics and pharmacokinetics.

The use raw data and derive the pharmacokinetic models and parameters the best describe the process of drug absorption, distribution, metabolism and elimination.

The critical evaluation of biopharmaceutic studies involving drug product equivalency.

The design and evaluate dosage regimens of the drugs using pharmacokinetic and biopharmaceutic parameters.

The potential clinical pharmacokinetic problems and apply basic pharmacokinetic The principles to solve them

Theory 60 Hrs 12hrs

12Hrs


12Hrs


12Hrs


12Hrs

References
2. Biopharmaceutics and Pharmacokinetics, A. Treatise, D. M. Brahmankar and Sunil B. Jaiswal, Vallab Prakashan, Pitampura, Delhi
4. Textbook of Biopharmaceutics and Pharmacokinetics, Dr. Shobha Rani R. Hiremath, Prism Book

COMPUTER AIDED DRUG DEVELOPMENT (MPH203T)

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

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

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

**THEORY 60Hrs**

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

**12Hrs**


**12Hrs**


**12Hrs**

- Computer-aided biopharmaceutical characterization: Gastrointestinal absorption simulation Introduction, Theoretical background, Model construction, Parameter sensitivity analysis, Virtual trial, Fed vs. fasted state, In vitro dissolution and in vitro in vivo correlation, Bioequivalence considerations
Computers in Clinical Development: Clinical Data Collection and Management, Regulation of Computer Systems

12Hrs

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

12Hrs

References


COSMETICS AND COSMECEUTICALS (MPH204T)

Scope

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

Objectives

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

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

Theory 60Hrs

1. Formulations approaches and Requirements 12Hrs

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

2. Plant Lay out, factory requirements and commonly used cosmetics raw materials 12Hrs

Building blocks for different product formulations of cosmetics/cosmeceuticals. Surfactants classification and application. Emollients rheological additives: classification and application. Antimicrobials used as
preservatives, their merits and demerits. Factors affecting microbial preservative efficacy. Building blocks for formulation of a cream, shampoo and toothpaste.

Perfumes; Classification of perfumes. Perfume ingredients listed as allergens in EU regulation.

Controversial ingredients: Parabens, formaldehyde liberators, dioxane.

3. Design of special purpose cosmeceutical products

Sun protection, sunscreens classification and regulatory aspects. Addressing dry skin, acne, sun-protection, pigmentation, prickly heat, wrinkles, body odor. Dandruff, dental cavities, bleeding gums, mouth odor and sensitive teeth.

12Hrs

Herbal Cosmetics

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

12Hrs

4. Formulation of Lip care products and Cosmetic Safety

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

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

Practical (MPH205P)

To study the effect of temperature change, non solvent addition, incompatible polymer addition in microcapsules preparation

1. Preparation and evaluation of Alginate beads
2. Formulation and evaluation of gelatin /albumin microspheres
3. Formulation and evaluation of liposomes
4. Formulation and evaluation of niosomes
5. Formulation and evaluation of spheruls
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
10. Pharmacokinetic and IVIVC data analysis by WinnolineR 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
16. Computer Simulations Pharmacodynamics
17. Computational Modeling Of Drug Disposition
18. To develop Clinical Data Collection manual
20. Development and evaluation of Creams
21. Development and evaluation of Shampoo and Toothpaste base
22. To Incorporate herbal and chemical actives to develop products
23. To address Dry skin, acne, blemish, Wrinkles, bleeding gums and dandruff

PHARM. PHARMACEUTICAL CHEMISTRY
(MPC)
MODERN PHARMACEUTICAL ANALYSIS (MPA101T)

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

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

Theory 60Hours

IR spectroscopy: Theory, Modes of Molecular vibrations, Sample handling, Instrumentation of Dispersive and Fourier - Transform IR Spectrometer, Factors affecting vibrational frequencies and Applications of IR spectroscopy
Flame emission spectroscopy and Atomic absorption spectroscopy: Principle, Instrumentation, Interferences and Applications.

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

3. Mass Spectroscopy
Principle, Theory, Instrumentation of Mass Spectroscopy, 12 Hrs Different types of ionization like electron impact, chemical, field, FAB and MALDI, APCI, ESI, APPI Analyzers of Quadrupole and Time of Flight, Mass fragmentation and its rules, Meta stable ions, Isotopic peaks and Applications of Mass spectroscopy

4. Chromatography
Principle, apparatus, instrumentation, chromatographic 12 Hrs parameters, factors affecting resolution and applications of the following:

a) Paper chromatography
b) Thin Layer chromatography
c) Ion exchange chromatography
d) Column chromatography

g) Gas chromatography
f) High Performance Liquid chromatography

Affinity chromatography

5. Electrophoresis
Principle, Instrumentation, Working conditions, factors affecting 12 Hrs separation and applications of the following:

Paper electrophoresis
b) Gel electrophoresis
c) Capillary electrophoresis
d) Zone electrophoresis
e) Moving boundary electrophoresis
f) Iso electric focusing

X ray Crystallography: Production of X rays, Different X ray methods, Bragg’s law, Rotating crystal technique, X ray powder technique, Types of crystals and applications of X-ray diffraction.

Medical device and applications: Introduction, Historical and current prospectus( specific division to be included)

References
ADVANCED ORGANIC CHEMISTRY-1 (MPC101T)

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

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

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

Theory 60 Hrs

Basic Aspects of Organic Chemistry
Organic intermediates: Carbocations, carbanions, free radicals, carbenes and nitrenes. Their method of formation, stability and synthetic applications.

Types of reaction mechanisms and methods of determining them,

Detailed knowledge regarding the reactions, mechanisms and their relative reactivity and orientations.

- Aliphatic and aromatic compounds,
- Nucleophilic uni- and bimolecular reactions (SN1 and SN2)
- Elimination reactions (E1 & E2; Hoffman & Saytzeff's rule)
- Rearrangement reaction

12 Hrs

Study of mechanism 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

12 Hrs

Synthetic Reagents & Applications
Aluminiumisopropoxide, N-bromosuccinamide, diazomethane, dicyclohexylcarbodimide, Wilkinson reagent, Witting reagent. Osmium tetroxide, titanium chloride, diazopropane, diethyl azodicarboxylate, Triphenylphosphine, Benzotriazol-1-yloxy) tris (dimethylamino) phosphonium hexafluoro-phosphate (BOP).
Protecting groups

Role of protection in organic synthesis

Protection for the hydroxyl group, including 1,2-and 1,3-diols: ethers, esters, carbonates, cyclic acetals & ketals

Protection for the Carbonyl Group: Acetals and Ketals

Protection for the Carboxyl Group: amides and hydrazides, esters

Protection for the Amino Group and Amino acids: carbamates and amides

Heterocyclic Chemistry

General methods of synthesis and applications of drugs of five, six membered and fused heterocycles such as imidazole, pyrazole, triazole, pyrimidine, quinoline, acridine, phenothiazine and purine. Synthesis of few representative drugs containing these heterocyclic nucleus

Synthon approach and retrosynthesis applications

Basic principles, terminologies and advantages of retrosynthesis; guidelines for dissection of molecules. Functional group interconversion and addition (FGI and FGA)

C–X disconnections; C–C disconnections – alcohols and carbonyl compounds; 1,2–, 1,3–, 1,4–, 1,5–, 1,6–difunctionalized compounds

Strategies for synthesis of three, four, five and six–membered ring

References

9. Organic synthesis-The disconnection approach, S. Warren, Wily India
11. Organic synthesis- Special techniques VK Ahluwalia and R Agarwal, Narosa Publishers
12. Organic reaction mechanisms IV edtn, VK Ahluwalia and RK Parashar, Narosa Publishers

**ADVANCED MEDICINAL CHEMISTRY (MPC102T)**

**Scope**

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

**Objectives**

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

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

Peptidomimetics

**Theory 60 Hrs**

Drug discovery: Stages of drug discovery, lead discovery; identification, validation and diversity of drug targets. Chemistry of prostaglandins, leukotrienes and thromboxones.

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

**12 Hrs**

**Prodrug Design and Analog design:**

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.

Combating drug resistance: Causes for drug resistance, strategies to combat drug resistance in antibiotics and anticancer therapy, Genetic principles of drug resistance.

**12 Hrs**

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 geometricisomers, fragments of a lead molecule, variation in inter atomic distance.

Chemistry of Synthetic drugs: Systematic study, SAR, Mechanism of action and synthesis of new generation molecules of following class of drugs: Anti-hypertensive drugs, Psychoactive drugs, Anticonvulsant drugs, H1 & H2 receptor antagonist, COX1 & COX2 inhibitors, Adrenergic & Cholinergic agents, Antineoplastic and Antiviral agents.
Stereochemistry and Drug action: Realization that stereo selectivity is a prerequisite for evolution. Role of chirality in selective and specific therapeutic agents. Case studies, Enantio selectivity in drug adsorption, metabolism, distribution and elimination.

12 Hrs

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

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.

Combinatorial chemistry and High throughput screening: Different techniques, Solid phase synthesis, Solution phase synthesis, Parallel synthesis, applications of combinatorial chemistry. High Throughput Screening- general outline, importance and application.

12Hrs

References:
1. Medicinal Chemistry by Burger.
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, (III Edition.)

CHEMISTRY OF NATURAL PRODUCTS (MPC103T)

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

**Objectives**

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

- Different types of natural compounds and their chemistry and medicinal importance
- The importance of natural compounds as lead molecules for new drug discovery
  - The concept of rDNA technology tool for new drug discovery
  - General methods of structural elucidation of compounds of natural origin
  - Isolation, purification and characterization of simple chemical constituents from natural source

**Theory 60 Hrs**

**Study of Natural products as leads for new pharmaceuticals for the following class of drugs:**

- Drugs Affecting the Central Nervous System: Morphine Alkaloids
- Anticancer Drugs: Paclitaxel and Docetaxel, Etoposide, and Teniposide
- Cardiovascular Drugs: Lovastatin, Teprotide and Dicoumarol
- Neuromuscular Blocking Drugs: Curare alkaloids
- Chemistry of macrolid antibiotics: Erythromycine, Azithromycine, Cephalosporins (New generation)

**12 Hrs**

Alkaloids- General introduction, classification, isolation, purification, stereochemistry, molecular modification and biological activity of alkaloids, general methods of structural determination of alkaloids, structural elucidation of ephedrine, morphine, ergot, emetine and reserpine.

Flavonoids. Introduction, isolation and purification of flavonoids, General methods of structural determination of flavonoids; Structural elucidation of quercetin.

**12 Hrs**

Steroids- General introduction, chemistry of sterols, sapogenin and cardiac glycosides. Stereochemistry and nomenclature of steroids, Structure elucidation of female & female sex hormones( testosterone, Estradiol, progesterone), Adrenocortcoids (carisone) and contraceptive agents.

Terpenoids – Classification, isolation, isoprene rule and general methods of structural elucidation of Terpenoids; Structural elucidation of drugs belonging to mono, di and tri terpenoids, carotinoids.

**12 Hrs**

**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

**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.

**Structural Characterization of natural Products**

  Structural characterization of natural compounds using IR, 1HNMR, 13CNMR and MS Spectroscopy

**References**

4. Chemistry of natural products Vol I onwards IWPAC.
5. Natural Product Chemistry Nakanishi Gggolo.
7. The Alkaloid Chemistry and Physiology by THF Manske.
8. Introduction to molecular Phytochemistry – CHJ Wells, Chapmannstall.
14. Biotechnology by Purohit and Mathoor.
15. Phytochemical methods of Harborne.
16. Burger’s Medicinal Chemistry.

**Practicals (MPC104P)**

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 HPLC
4. Experiments based on Gas Chromatography
5. Estimation of riboflavin/quinine sulphate by fluorimetry
6. Estimation of sodium/potassium by flame photometry

**To perform the following reactions of synthetic importance**

1. Purification of organic solvents, column chromatography
2. Claisen-schmidt reaction.
3. Benzyllic acid rearrangement.
5. Hoffmann rearrangement
6. Mannich reaction

Synthesis of medicinally important compounds involving more than one step along with purification and Characterization using TLC, melting point and IR spectroscopy (4 experiments)

Estimation of elements and functional groups in organic natural compounds

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.

Some typical degradation reactions to be carried on selected plant constituents

**ADVANCED SPECTRAL ANALYSIS (MPC201T)**

**Scope**

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

**Objectives**

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

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

**Theory**

60Hrs

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

12Hrs

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

12Hrs


12Hrs

4. 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.

Thermal methods of analysis – Introduction, principle, instrumentation and application of DSC, DTA and TGA.


Radio immuno assay: Biological standardization, bioassay, ELISA, Radioimmuno assay of digitalis and insulin

References

ADVANCED ORGANIC CHEMISTRY -II(MPC202T)

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

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

The principles and applications of Green chemistry The concept of peptide chemistry.

The various catalysts used in organic reactions

The concept of stereochemistry and asymmetric synthesis.

Theory

Green Chemistry

Introduction, principles of green chemistry

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
Ultrasound assisted reactions: Types of sonochemical reactions, homogenous, heterogeneous liquid-liquid and liquid-solid reactions, synthetic applications

Continuous flow reactors: Working principle, advantages and synthetic applications.

Chemistry of peptides

Coupling reactions in peptide synthesis

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

Segment and sequential strategies for solution phase peptide synthesis with any two case studies

Side reactions in peptide synthesis: Deletion peptides, side reactions initiated by proton abstraction, protonation, over-activation and side reactions of individual amino acids.

Photochemical Reactions

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

Pericyclic reactions

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

Catalysis

Types of catalysis, heterogeneous and homogenous catalysis, advantages and disadvantages

Heterogeneous catalysis – preparation, characterization, kinetics, supported catalysts, catalyst deactivation and regeneration, some examples of heterogeneous catalysis used in synthesis of drugs.

Homogenous catalysis, hydrogenation, hydroformylation, hydrocyanation, Wilkinson catalysts, chiral ligands and chiral induction, Ziegler-Natta catalysts, some examples of homogenous catalysis used in synthesis of drugs

Transition-metal and Organo-catalysis in organic synthesis: Metal-catalyzed reactions

Biocatalysis: Use of enzymes in organic synthesis, immobilized enzymes/cells in organic reaction.

Phase transfer catalysis theory and applications
5. Stereochemistry & Asymmetric Synthesis

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.

Methods of asymmetric synthesis using chiral pool, chiral auxiliaries and catalytic asymmetric synthesis, enantiopure separation and Stereo selective synthesis with examples.

References

6. Organic synthesis-the disconnection approach, S. Warren, Wily India
7. Principles of organic synthesis, ROCNorman and JM Coxan, Nelson thorns
8. Organic synthesis- Special techniques VK Ahluwalia and R Aggarwal, Narosa Publishers

COMPUTER AIDED DRUG DESIGN (MPC203T)

Scope

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

Objectives

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

- Role of CADD in drug discovery
- Different CADD techniques and their applications
- Various strategies to design and develop new drug like molecules.
- Working with molecular modeling softwares to design new drug molecules
- The in silico virtual screening protocols

Theory 60 Hrs

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.

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.

12 Hrs

Molecular Modeling and Docking
Molecular and Quantum Mechanics in drug design

Energy Minimization Methods: comparison between global minimum
conformation and bioactive conformation

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)

12 Hrs

Molecular Properties and Drug Design
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.

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

12 Hrs

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

In Silico Drug Design and Virtual Screening Techniques

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

12 Hrs

References
1. Computational and structural approaches to drug design edited by Robert M
   Stroud and Janet. F Moore
2. Introduction to Quantitative Drug Design by Y.C. Martin.
10. Computational and structural approaches to drug design edited by Robert M Stroud and Janet. F Moore

**PHARMACEUTICAL PROCESS CHEMISTRY (MPC204T)**

**Scope**

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

**Objectives**

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

- The strategies of scale up process of apis and intermediates
- The various unit operations and various reactions in process chemistry

**Theory**

**60 Hrs**

**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

**12 Hrs**

**Unit operations**

Extraction: Liquid equilibria, extraction with reflux, extraction with agitation, counter current extraction.

Filtration: Theory of filtration, pressure and vacuum filtration, centrifugal filtration,

Distillation: azeotropic and steam distillation

Evaporation: Types of evaporators, factors affecting evaporation.
Crystallization: Crystallization from aqueous, non-aqueous solutions factors affecting crystallization, nucleation. Principle and general methods of Preparation of polymorphs, hydrates, solvates and amorphous APIs.

12 Hrs

Unit Processes

Nitration: Nitrating agents, Aromatic nitration, kinetics and mechanism of aromatic nitration, process equipment for technical nitration, mixed acid for nitration,

Halogenation: Kinetics of halogenations, types of halogenations, catalytic halogenations. Case study on industrial halogenation process.

Oxidation: Introduction, types of oxidative reactions, Liquid phase oxidation with oxidizing agents. Nonmetallic Oxidizing agents such as H2O2, sodium hypochlorite, Oxygen gas, ozonolysis.

12 Hrs

Unit Processes

Reduction: Catalytic hydrogenation, Heterogeneous and homogeneous catalyst; Hydrogen transfer reactions, Metal hydrides. Case study on industrial reduction process.

Fermentation: Aerobic and anaerobic fermentation. Production of Antibiotics; Penicillin and Streptomycin,

Vitamins: B2 and B12

Statins: lovastatin, simvastatin

Reaction progress kinetic analysis

Streamlining reaction steps, route selection,

Characteristics of expedient routes, characteristics of cost-effective routes, reagent selection, families of reagents useful for scale-up.

12 Hrs

Industrial Safety

MSDS (Material Safety Data Sheet), hazard labels of chemicals and Personal Protection Equipment (PPE)

Fire hazards, types of fire & fire extinguishers

Occupational Health & Safety Assessment Series 1800 (OHSAS-1800) and ISO-14001(Environmental Management System), Effluents and its management

12 Hrs

References

Practicals (MPC205P)
Synthesis of organic compounds by adapting different approaches involving (3 experiments)
- Oxidation
- Reduction/hydrogenation
- Nitration

Comparative study of synthesis of APIs/intermediates by different synthetic routes (2 experiments)
1. Assignments on regulatory requirements in API (2 experiments)
2. Comparison of absorption spectra by UV and Woodward – Fieser rule
3. Interpretation of organic compounds by FT-IR
4. Interpretation of organic compounds by NMR
5. Interpretation of organic compounds by MS
6. Determination of purity by DSC in pharmaceuticals
7. Identification of organic compounds using FT-IR, NMR, CNMR and Mass spectra
8. To carry out the preparation of following organic compounds
10. Preparation of 4-iodotolene from p-toluidine.
11. NaBH4 reduction of vanillin to vanillyl alcohol
12. Preparation of umbelliferone by Pechman reaction
13. Preparation of triphenyl imidazole
14. To perform the Microwave irradiated reactions of synthetic importance (Any two)
15. Determination of log P, MR, hydrogen bond donors and acceptors of selected drugs using softwares
16. Calculation of ADMET properties of drug molecules and its analysis using softwares
17. Pharmacophore modeling
18. 2D-QSAR based experiments
19. 3D-QSAR based experiments
20. Docking study
21. Virtual screening based experiment

**M. PHARM. PHARMACOGNOSY (MPG)**

**ADVANCED PHARMACOGNOSY-1 (MPG101 T)**

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

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

- Know the advances in the cultivation and production of drugs
- Know the various phyto-pharmaceuticals and their source & utilization and medicinal value.
- Know the various nutraceuticals/herbs and their health benefits

**Course Description**

**Theory**  

**60Hours**

Plant drug cultivation: General introduction to the importance of Pharmacognosy in herbal drug industry, Indian Council of Agricultural Research, Current good agricultural practices, Current good cultivation practices, Current good collection practices, Conservation of medicinal plants- Ex-situ and In-situ conservation of medicinal plants.

**Hrs**

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

**Hrs**

Nutraceuticals: Current trends and future scope, Inorganic mineral supplements, Vitamin supplements, Digestive enzymes, Dietary fibres, Cereals and grains, Health drinks from natural origin, Antioxidants, Polyunsaturated fatty acids, Herbs as functional foods, Formulation and standardization of
neutraceuticals, Regulatory aspects, FSSAI guidelines, Sources, name of marker compounds and their chemical nature, medicinal uses and health benefits of following


Hrs

Phytopharmaceuticals: Occurrence, isolation and characteristic features (Chemical nature, uses in pharmacy, medicinal and health benefits) of following.

   Carotenoids – i) α and β - Carotene ii) Xanthophyll (Lutein)
   Limonoids – i) d-Limonene ii) α – Terpineol
   Saponins – i) Shatavarins
   Flavonoids – i) Resveratrol ii) Rutin iii) Hesperidin iv) Naringin v) Quercetin
   Phenolic acids- Ellagic acid
   Tocotrienols and Tocopherols

   g) Andrographolide, glycolipids, gugulipids, withanolides, vascine, taxol

12Hrs

Pharmacovigilance of drugs of natural origin: WHO and AYUSH guidelines for safety monitoring of natural medicine, Spontaneous reporting schemes for biodrug adversereactions, bio drug-drug and bio drug-food interactions with suitable examples. 12Hrs

References
   7. Pharmacognosy-Tyler, Brady, Robbers
   8. Modern Methods of Plant Analysis- Peach & M.V. Tracey, Vol. I&II
   11. Marine Natural Products-Vol.I to IV.
   13. Cultivation and Utilization of Aromatic Plants By C.K. Atal & B.M. Kapoor
PHYTOCHEMISTRY (MPG102T)

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

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

- know the different classes of phytoconstituents and their properties and general process of natural product drug discovery
- know the process isolation, purification and identification of phytoconstituents

Theory

Biosynthetic pathways and Radio tracing techniques: Constituents & their Biosynthesis, Isolation, Characterization and purification with a special reference to their importance in herbal industries of following phyto-pharmaceuticals containing drugs:

- Alkaloids: Ephedrine, Quinine, Strychnine, Piperine, Berberine, Taxol, Vincaalkoloids.
- Glycosides: Digitoxin, Glycyrrhizin, Sennosides, Bacosides, Ginsenosides, Quercitin, Rutin.
- Steroids: Hecogenin, guggulosterone and withanolides
- Coumarin: Umbelliferone.
- Terpenoids: Cucurbitacins
- Carotenoids: Lycopene, β-carotene.
- Camphor, Menthol, Eugenol.

Drug discovery and development: History of herbs as source of drugs and drug discovery, the lead structure selection process, structure development, product discovery process and drug registration, Selection and optimization of lead compounds with suitable examples from anticancer, CNS cardiovascular drugs, antitubercular drugs and immunomodulators, Clinical studies emphasis on phase of clinical trials, protocol design for lead molecules.

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

Phytochemical finger printing: HPTLC and LCMS/GCMS characterization of extracts containing alkaloids, saponins, glycosides and flavanoids.

Pharmacological screening: In vitro, In vivo screening techniques with reference to antiglycomerate, analgesics, antidiabetic, antilipidemic, anticancer, antiulcer, antiviral, antipsychotic, antilithiatic, Toxicity studies as per OECD guidelines, acute, chronic and clinical toxicity.

References

1. Organic chemistry by I.L. Finar Vol.II
2. Pharmacognosy by Trease and Evans, ELBS.
3. Pharmacognosy by Tylor and Brady.
5. Clark’s isolation and Identification of drugs by A.C. Mottal.
9. Natural Products Chemistry Practical Manual by Anees A Siddiqui and SeemiSiddiqui
11. Chemistry of Natural Products- Vol. 1 onwards IWPAC.
12. Modem Methods of Plant Analysis- Peach & M.V. Tracey, Vol. I&II

INDUSTRIAL PHARMACOGNOSTICAL TECHNOLOGY (MPG103T)

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

Objective
By the end of the course the student shall be able to:

- Know the requirements for setting up the herbal/natural drug industry.
- To know and understand the guidelines for quality of herbal/natural medicines and regulatory issues.
- To know patenting/IPR of herbals/natural drugs and trade of raw and finished materials.

12 Hrs

Regulatory requirements for setting herbal drug industry: Global marketing management. Indian and international patent law as applicable herbal drugs and natural products.

- Export-import (EXIM) policy, TRIPS, IPR.
- Quality assurance in herbal/natural drug products.
- Concepts of TDM, GMP, GLP, ISO-9000.

12 Hrs


12 Hrs

Testing of natural products and drugs: Effect of herbal medicines on clinical laboratory testing. Regulation and dispensing of herbal drugs. Stability testing of natural products, protocols.

12 Hrs

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

12 Hrs

References

4. The complete technology book on herbal perfumes and cosmetics, by H.Pande, National Institute of Industrial Research, Delhi.
Practicals (MPGI04P)
1. Analysis of pharmacopoeial compounds of natural origin and their formulations by UV Vis spectrophotometer
2. Simultaneous estimation of multi component containing formulations by UV spectrophotometry
3. Analysis of recorded spectra of simple phytoconstituents
4. Experiments based on Gas Chromatography
5. Estimation of sodium/potassium by flame photometry
6. Development of fingerprint of selected medicinal plant extracts commonly used in herbal drug industry viz. ashwagandha, tulsi, bael, amla, ginger, aloe, vidang, senna, lawronia by HPTLC method
7. Method of extraction
8. Phytochemical screening
9. Thin layer chromatography
10. Demonstration of HPLC- estimation of glycyerizin
11. Monograph analysis of clove oil
13. Identification of bioactive constituents from plant extracts
14. Formulation using qualitative and quantitative methods.

MEDICINAL PLANT BIOTECHNOLOGY (MPG201T)

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

Objectives
Upon completion of the course, the student shall be able to:
Know the process like genetic engineering in medicinal plants for higher yield of Phytopharmaceuticals.

Use the biotechnological techniques for obtaining and improving the quality of natural products/medicinal plants.

**Theory 60 Hrs**

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

12 Hrs

2. Different tissue culture techniques: Organogenesis and embryogenesis, synthetic seed and monoclonal variation, Protoplast fusion, Hairy root multiple shoot cultures and their applications. Micro propagation of medicinal and aromatic plants. Sterilization methods involved in tissue culture, gene transfer in plants and their applications. 12 Hrs


12 Hrs

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

12 Hrs

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

12 Hrs

**References**

1. Plant tissue culture – Bhagwani, Vol 5. (Elsevier)
5. Experiments in Plant Tissue Culture by John H. D and Lorin W. R.
9. Plant tissue culture by Street.
11. Biotechnology by Purohit and Mathur.
12. Biotechnological applications to tissue culture by Shargool.

**ADVANCED PHARMACOGNOSY-II (MPG202T)**

**Scope**

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

**Objectives**

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

- Know the validation of herbal remedies
- Know the methods of detection of adulteration and evaluation techniques for the herbal drugs
- To know the methods of screening of herbals for various biological properties

**Theory**  
60Hrs


12 Hrs


12 Hrs


12 Hrs

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

12 Hrs

Biological screening of herbal drugs: Introduction and Need for Phyto-Pharmacological Screening, New Strategies for evaluating Natural Products, In vitro evaluation techniques for Antioxidants, Antimicrobial and Anticancer drugs. In vivo evaluation techniques for Anti-inflammatory, Antiulcer, Anticancer, Wound healing, Antidiabetic, Hepatoprotective, Cardio protective, Diuretics and Antifertility. 12 Hrs
References
4. Pharmacognosy-Tyler, Brady, Robbers
5. Modern Methods of Plant Analysis- Peach & M.V. Tracey, Vol. I&II
8. Text Book of Pharmacognosy by T.E. Wallis

INdIAN SYSTEmS OF MEdicINE (MPG203T)

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

Objective
After completion of the course, student is able to:
- To understand the basic principles of various Indian systems of medicine
- To know the clinical research of traditional medicines, Current Good Manufacturing Practice of Indian systems of medicine and formulation.

Theory 60Hrs
Fundamental concepts of Ayurveda, Siddha, Unani, and Homoeopathy systems of medicine:
Different dosage forms of the ISM-
Ayurveda: Chronological development of Charak Samhita, Sushrut Samhita and Kashyapa Samhita. Ayurvedic Pharmacopoeia Analysis of Ayurvedic
Formulations and crude drugs with references to: Identity, purity and quality of crude drugs.

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

12 Hrs


12 Hrs

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

12 Hrs

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

Quality assurance in herbal drug industry of GAP, GMP and GLP in traditional system of medicine. Preparation of documents for new drug application and export registration.

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

Hrs

TKDL, Geographical indication skill, Government skills in AYUSH, ISM, CCRAS, CCS, CCRH, CCRU.

References

8. British Herbal Pharmacopoeia British (1990), Herbal Medicine Association, UK.
10. Indian System of Medicine and Homeopathy in India (2001), Planning and Evaluation Cell, Govt. of India, New Delhi.
11. Essential of Food and Nutrition by Swaminathan (1999), Bappco, Bangalore.

HERBAL COSMETICS (MPG204T)

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

Objective
After completion of the course, student is able to:

- Understand the basic principles of various herbal/natural cosmetic preparations
- Current Good Manufacturing Practices of herbal/natural cosmetics as per the regulatory authorities

Theory 60Hrs

Introduction: Herbal/natural cosmetics, Classification & Economic aspects.

Hrs

Herbal Cosmetics for the skin: Physiology and chemistry of skin and pigmentation, hairs, scalp, oral and nail, Cleansing cream, Lotions, Vanishing and Foundation creams, Anti- sun burn preparations, Moisturizing cream, deodorants, Face powders, Face packs, Lipsticks, Bath products, soaps and baby product, Preparation and standardisation of the following:

- Shampoos, Conditioners, Tonic, Bleaches, Colorants, Depilatories and Hair oils, Dentifrices and Mouth washes & Tooth Pastes, Cosmetics for Nails.

12 Hrs

Cosmeceuticals of herbal and natural origin: Hair growth formulations, Fairness formulations.

Hrs

Commonly used herbal cosmetics, raw materials, preservatives, surfactants, humectants, oils, colours, and some functional herbs, preformulation studies, compatibility studies, possible interactions between chemicals and herbs, design of herbal cosmetic formulation.
Analysis of Cosmetics, Toxicity screening and test methods: Quality control and toxicity studies as per Drug and Cosmetics acts.

References


Practicals (MPG205P)

1. Isolation of nucleic acid from cauliflower heads
2. Isolation of RNA from yeast
3. Quantitative estimation of DNA
4. Immobilization of whole cell
5. Establishment of callus culture
6. Establishment of suspension culture
7. Estimation of aldehyde
8. Estimation of phenolic content in herbal raw materials
9. Estimation of alkaloid content in herbal raw materials
10. Estimation of flavonoid content in herbal raw materials
11. Preparation and standardization of various simple dosage forms from Ayurvedic, siddha, homoeopathy and Unani formulary
12. Preparation of certain Aromatherapy formulations
13. Herbal cosmetic formulation such as lip balm, lipstick, facial cream, herbal hair and nail care products
14. Evaluation of herbal tablets and capsules
15. Dermatological preparation like sunscreen, UV protection cream, skin care formulations for fungal and dermato reaction
16. Formulation of cough syrup

M. PHARM. COSMECEUTICS (MCC)
COSMECEUTICALS-BIOLOGY (MCC101T)

Scope
To impart knowledge on the biological aspects of – skin and hair, nails, eyes.
To understand basic problems associated with skin and hair.
To understand the mechanism of Skin irritation, allergy and allergic reactions that are major causes for skin problems.

Objectives
To have stronger scientific basis in developing cosmeceutical products:

Theory 60 Hours

1. Skin
   Structure and functions of skin, baby’s skin and problems unique to baby’s skin, Age-associated morphological and histological changes in human skin. Difference between baby’s skin and adult skin, Ethnic and gender differences in skin properties. Etiology and current treatment for psoriasis and wound healing process.
   12Hrs

2. Immunology
   Types of skin allergic reaction, immunological mechanism of skin allergy. Terminologies used: Contact dermatitis, Irritant Contact Dermatitis, allergic Contact dermatitis, photo-irritant contact dermatitis, phototoxicity, contact urticaria syndrome. General concepts of skin irritancy: Principles and molecular mechanisms of skin irritation, evaluation, factors predisposing to cutaneous irritation. Cosmetic and occupational Irritants.
   12Hrs

3. Irritation study models
   Artificial skin modeling – Human reconstituted epidermis and skin, Skin organ culture models and other new types of skin equivalents. Cosmetic safety testing as per BIS (Bureau of Indian Standards), alternate safety testing methods: Cell line techniques for safety studies (including mutagenecity studies) and toxicity studies, toxicity studies models.
   12Hrs

4. Nail
   12Hrs

5. Hair

Microbiology
Pharmacopeial methods of evaluation of preservative efficacy.

  12Hrs
References
1. Harry’s Cosmeticology. 8th edition
2. Poucher’s perfume cosmetics and Soaps, 10th edition
3. Cosmetics - Formulation, manufacture and quality control PP.Sharma, 4th edition
4. Handbook of cosmetic science and Technology A.O.Barel, M.Paye and H.I.Maibach. 3rd edition
5. Cosmetic and Toiletries recent suppliers catalogue.
6. CTFA directory.
7. British Pharmacopoeia

COSMETICS – FORMULATION SCIENCE (MCC102T)

Scope
- To impart knowledge on the fundamental principles of cosmetic product development.
- To understand key ingredients used in cosmetics and cosmeceuticals
- To understand the building blocks in the formulation of cosmetic products.

Objectives:
Upon completion of the course, the students will be able to: Know various key ingredients used to develop cosmetics. Combine the ingredients together to develop cosmetics with desired sensory.

Theory 60 Hours

1. Formulation Principles
   - Definition of Cosmetics as per EU and Indian Guidelines
   - Cleansing and care needs for face, eye lids, lips, hands, feet, nail, scalp, neck, body and underarms. Examples of marketed product.
   - Formulation requirements for ethnic needs.
   - Cosmetic product development process

2. Formulation Building blocks
   - Building blocks for different product formulations of cosmetics/cosmeceuticals:
   - Surfactants- Classification and application.
   - Emollients and rheological additives: classification and application.
   - Antimicrobial used as preservatives, their merits and demerits. Factors affecting microbial preservative efficacy.
   - Perfumes; Classification of perfumes. Perfume ingredients listed as allergens.
   - Application of various product forms in cosmetics: Solution, creams, lotion, ointment, paste, gels, stick, tablets, capsules, powders and aerosol. Examples from marketed product.
Skin cleansing and care

Dry skin, skin moisturisation,

Skin Cleansing: Building blocks and formulation of Soap, syndet bars, face wash, body wash, face mask. Their relative advantages and disadvantages Skin Care: Classification, requirement of an Ideal skin cream.

Building blocks and formulation of cold cream, vanishing cream, moisturizing cream, moisturizing gel, body lotion, petroleum Jelly. 12 Hrs

4. Hair

Hair Care: Ideal requirements of a shampoo. Formulation of shampoos, Hair conditioners, Hair oil, hair cream, and hair styling gels. Chemistry and formulation of Paraphenylen diamine based Hair dyes.

12 Hrs

5. Oral care, color cosmetics, deodorants and baby care

Oral Care: Ideal requirements of a toothpaste. Building blocks and formulation of tooth paste and mouth wash. Color Cosmetics: Building blocks and formulation of Lipstick, Mascara, nail polish and Face Powder.


12 Hrs

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

PRODUCTION TECHNOLOGY & QUALITY ASSURANCE (MCC103T)

Scope
This course deals with the various quality assurance aspects of pharmaceutical industries. It covers the important aspects like cGMP, documentation, to understand about validation types, methodology application and how it can be applied to industry and thus to improve the quality of the products. Impart fundamental knowledge about quality management System. This knowledge can be applied in QA of cosmetics.

Objectives
At the completion of this subject it is expected that the student will be able to know:

The cGMP aspects in a pharmaceutical industry To appreciate the importance of documentation. Explain the aspect of validation.
Apply the knowledge of validation to manufacturing, instruments and equipments To understand the quality evaluation of products

Need of Quality management system in Industry

This knowledge can be used to evolve stringent QA systems for cosmeceuticals

**Theory 60 Hours**

**Introduction to Quality**

Definition - Quality assurance and Quality control, concept of TQM, GMP, ICH, Brief study of ICH common technical documents – Q1-Q11, Quality by design, six sigma concept, ISO 9000 & 14000.

Document maintenance in pharmaceutical industry: Batch Formula Record, Master Formula Record, Quality audit reports and documents, quality reports, distribution records, Common Technical Document and Drug Master Files, Medical Devices, Electronic Common Technical Documentation, complaints and evaluation of complaints, Handling of return goods, recalling and waste disposal.

**12Hrs**


**12Hrs**

Introduction to Pharmaceutical Validation:Definition, Manufacturing Process Model, scope of Validation, Advantage of Validation, Organization for Validation, Validation Master plan, Types of validation, Design Qualification, Installation Qualification, Operational Qualification & Performance Qualification of facilities. A Review of Prospective, Concurrent, Retrospective Validation & Revalidation including the use of Statistical Process Control (SPC).

**12Hrs**


**12Hrs**


**12Hrs**

References


4. ICH guidelines

5. ISO 9000 and total quality management


12. Lachman L Liberman Theory and practice of industrial pharmacy by 3 rd edition


**CELLULAR AND MOLECULAR PHARMACOLOGY (MCC104T)**

**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.

This subject is important since animal experimentation is restricted and cell biology knowledge is critical for alternate preclinical studies on safety and efficacy.

**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
  Apply the knowledge in developing cell line safety studies.

Theory  
60 Hours
1. Cell biology  
12 Hrs

2. 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.  
12 Hrs

3. 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.  
12 Hrs

4. 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  
12 Hrs

5. Chapter to be identified  
12 Hrs

References  
Pharmacogenomics: The Search for Individualized Therapies. Edited by J. Licinio and M -L. Wong  
Handbook of Cell Signaling (Second Edition) Edited by Ralph A. et.al  
Molecular Pharmacology: From DNA to Drug Discovery. John Dickenson et.al  
Basic Cell Culture protocols by Cheril D.Helgason and Cindy L.Miller  
Basic Cell Culture (Practical Approach ) by J. M. Davis (Editor)  
Animal Cell Culture: A Practical Approach by John R. Masters (Editor)
Current protocols in molecular biology Vol I to VI edited by Frederick M. Ausuvel et al.

Practicals (MCC105P)

A) Visit to dermatology and dental wards. Submitting case report on common skin and oral cavity problems observed.

1. Analysis in detail selecting a specific skin or oral cavity problem.

Lab Practicals

1. Cytotoxicity studies using cell lines,
2. Preservative efficacy test

Design and Development of following products:

1. Moisturizing cream
2. Tooth Paste
3. Shampoo
4. Hair oil
5. Lip Balm
6. Petroleum jelly
7. Isolation and identification of DNA from various sources (Bacteria, Cauliflower, onion, Goat liver).
8. Isolation of RNA from yeast
9. Estimation of RNA/DNA by UV Spectroscopy
10. Gene amplification by PCR.
11. Enzyme based in-vitro assays (MPO, AChEs, \( \alpha \) amylase, \( \alpha \) glucosidase).
13. DNA damage study by Comet assay.

COSMECEUTICALS (MCC201T)

Scope

- To impart knowledge on the fundamental principles of cosmeceuticals product development.
- To understand the building blocks in the formulation of cosmeceutical products.
- To develop knowledge in design and development of cosmeceuticals focusing on safety, stability, sensory and delivery of actives.

Objectives

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

- Various key ingredients used to develop cosmeceuticals.
- Combine the ingredients together to develop cosmeceuticals with desired sensory and efficacy.

Theory 60 Hours

1. Sun protection, pigmentation and wrinkles

   Sun Protection: Solar spectrum, UV A and UV B rays of the sun. Skin damages caused by over exposure to sunlight, organic and in-organic sunscreens, SPF and


Skin wrinkles: Factors that leads to skin wrinkles. Role of anti-oxidants in reducing skin wrinkles. Building block and formulation of an anti-wrinkle product. Case study on anti-aging/antiwrinkle product in the market.

2. Acne, Prickly heat, Dandruff and oral care
Causes for acne, prickly heat and dandruff and current treatment.

Building blocks and formulation of products for treatment of acne, prickly heat and dandruff.

Case study of marketed products.

Oral care:
Basic understating of the cause of Bleeding gums, sensitive teeth, plague, halitosis.

Role of antimicrobial agents, anti oxidants and astringents for oral care.

Denture cleansers. Building blocks and formulation of anti-cavity, tooth sensitivity relief and teeth-whitening tooth paste. Case study on the marketed products

3. Herbal Cosmetics
Herbal ingredients used in Hair care, skin care and oral care and nail.

Guidelines for herbal cosmetics by private bodies like cosmos with respect to preservatives, emollients, foaming agents, emulsifiers and rheology modifiers. Formulation and development of herbal cosmetics.

4. Dermal Drug Delivery

5. To be identified

References
2. Poucher’s perfume cosmetics and Soaps, 10th edition
3. Cosmetics - Formulation, manufacture and quality control PP.Sharma, 4th edition
4. Handbook of cosmetic science and Technology A.O.Barel, M.Paye and H.I.Maibach. 3rd edition
5. S.P.Vyas and Roop K.Khar Controlled Drug Delivery system, Concepts and Advances
6. Cosmetic and Toiletries recent suppliers catalogue.
7. CTFA directory.

**COSMETIC ANALYSIS & EVALUATION (MCC202T)**

**Scope**

This course is designed to impart knowledge on analysis of cosmetic raw materials and finished products. 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 physical constants of cosmetic raw materials
- Cosmetic raw materials, additives and their analysis
- Analysis of finished cosmetic products
- Principles of performance evaluation of cosmetic products.

**Theory 60Hrs**

- Determination of acid value, ester value, Saponification value, iodine value, peroxide value, rancidity, moisture, ash, volatile matter, heavy metals, fineness of powders, density, viscosity of cosmetics raw materials. 12 hrs

- Study on the quality of raw materials and general methods of analysis of raw material used in cosmetic manufacture as per BIS. 12 hrs

- Indian standard specifications laid down for sampling and testing of various cosmetics in finished forms such as baby care powders, skin care products, dental products, personal hygiene preparations, lips sticks, hair products and skin creams by the Bureau Indian Standards. 12 hrs

- Principles of equipment used to measure product performance of skin and hair care products - Sebumeter, corneometer, trans-epidermal water loss, Skin color, hair tensile properties, hair combing properties.

- Performance evaluation of shampoos, antiperspirants, deodorants, sunscreens, foam baths and abrasiveness of dentifrices. 12 hrs

- Study of specialized additives- quality parameters and analysis of rheology modifiers, preservatives, emollients, hair conditioners and fragrances 12 hrs

**References**

2. Indian Standard specification, for raw materials, BIS, New Delhi.
3. Indian Standard specification for 28 finished cosmetics BIS, New Delhi
4. Harry’s Cosmeticology 8th edition
5. Suppliers catalogue on specialized cosmetic excipients

COSMETICS- INDUSTRY AND REGULATORY (MCC203T)

Scope
- To impart knowledge on the basic regulatory aspects relating to cosmetics
- To understand the manufacturing equipments and GMP as per regulatory guidelines
- To understand the aspects of technology transfer from R&D to manufacturing.

Objectives
Upon completion of the course, the students will be able to:
1. Effectively design products and documentation that meets regulatory requirements
2. Implement smooth transfer of technology from design stage to factory production.

Theory 60Hours

1. Indian Regulations

Indian Regulation for cosmetics:
   Regulatory provisions relating to import and manufacturing of cosmetics – conditions for obtaining license, prohibition of manufacture and sale of certain cosmetics, loan license, offences and penalties.

MISBRANDED and spurious cosmetics.
   Indian regulatory requirement for factory premises, location and surrounding, designing of plant layout, building, light, ventilation, water supply, disposal of waste, first aid, packaging facilities, sanitation in manufacturing premises and health clothing and sanitary requirement of staff.

2. Manufacturing & ASEAN standards
   Equipments used in the manufacturing of creams, shampoo and toothpaste. GMP guidelines as per ASEAN standards for cosmetics

3. European Union Guidelines
   Summary of features of EU guidelines for cosmetics: Ingredients, safety assessment, labeling, the product information package, GMP, animal testing and efficacy testing. Cosmeceuticals as OTC and quasi drugs.
4. Technology transfer

Significance of pilot plant scale up studies.

Stability studies: Change in parameter to be observed, Photostability, accelerated stability testing- Temperature humidity, freest thaw and stress test. Aerosol product stability studies. Technology transfer of formulations from R&D to factory- Documentations.

5. Private Regulatory bodies:

a) Environmental and safety concerns of certain cosmetic ingredients that are debated and discussed. – Nano sized sunscreens, triclosan, formaldehyde liberators, Polythene beads, Sodium and ammonium laureth sulfates, phthalates.

Study of salient features of cosmetic safety data base developed by private body, and International Nomenclature of Cosmetic Ingredients (INCI).

c) Principles of cosmetovigilance.

d) Product claim development and advertisement; Role of ASCI.

References

1. Harry’s Cosmeticology. 8th edition
2. Cosmetics - Formulation, manufacture and quality control PP.Sharma, 4th edition
3. ASEAN definition of Cosmetics and illustrative list by category of Cosmetic products.
5. Theory and Practice of Industrial Pharmacy by Lachmann and Libermann

COMPUTER AIDED DRUG DELIVERY SYSTEM (MCC204T)
(This should be an Elective)

Scope

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

Objectives

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

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

Theory 60Hrs


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


Computer-aided biopharmaceutical characterization: Gastrointestinal absorption simulation. Introduction, Theoretical background, Model construction, Parameter sensitivity analysis, Virtual trial, Fed vs. fasted state, In vitro dissolution and in vitro-in vivo correlation, Biowaiver considerations


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

References

4. Practicals (MCC205P):
5. Design and formulate unique Cream, shampoo, toothpaste, moisturizing gel, and lip balm. Study private body guidelines for green/premium cosmetics of Ecocert/Cosmos, an suggest changes in the formulations.
7. Case study report of products in the market- Sun-protection, aging, acne, pigmentation, prickly heat, dandruff, hair-fall, teeth cavities, bleeding gums, teeth whitening, Comparing labeled formulation ingredients.
8. Quantitative analysis of rancidity in hair oils and Lipsticks
9. Determination of aryl amine content and Developer in hair dye
10. Determination of foam height and SLS content of Shampoo.
11. Determination of total fatty matter in creams (Soap, Skin and hair Creams)
12. Comparative Study of marketed cosmetic product claims
14. Formulation data analysis Using Design Expert® Software
15. Quality-by-Design in Pharmaceutical Development

M. PHARM. PHARMACEUTICAL ANALYSIS (MPA)
MODERN PHARMACEUTICAL ANALYSIS (MPA101T)

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

Objectives
After completion of course student is able to know,

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

Theory 60 Hours
1. UV-Visible spectroscopy 11 Hrs

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

Spectrofluorimetry
Theory of Fluorescence, Factors affecting fluorescence, Quenchers, Instrumentation and Applications of fluorescence spectrophotometer.

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

2. **NMR spectroscopy** 11 Hrs
Quantum numbers and their role in NMR, Principle, Instrumentation, Solvent requirement in NMR, Relaxation process, NMR signals in various compounds, Chemical shift, Factors influencing chemical shift, Spin-Spin coupling, Coupling constant, Nuclear magnetic double resonance, Brief outline of principles of FT-NMR and 13C NMR. Applications of NMR spectroscopy.

**Mass Spectroscopy** 11 Hrs

4. **Chromatography** 11 Hrs
Principle, apparatus, instrumentation, chromatographic parameters, factors affecting resolution and applications of the following:
- a) Paper chromatography
- b) Thin Layer chromatography
- c) Ion exchange chromatography
- d) Column chromatography
- e) Gas chromatography
- f) High Performance Liquid chromatography
- g) Affinity chromatography

5. **Electrophoresis** 11 Hrs
Principle, Instrumentation, Working conditions, factors affecting separation and applications of the following:
- a) Paper electrophoresis
- b) Gel electrophoresis
- c) Capillary electrophoresis
- d) Zone electrophoresis
- e) Moving boundary electrophoresis
- f) Iso electric focusing

**X ray Crystallography**
Production of X rays, Different X ray methods, Bragg's law, Rotating crystal technique, X ray powder technique, Types of crystals and applications of X-ray diffraction.

6. **Immunological Assays** 5 Hrs
Radioimmunology assay (RIA), ELISA (Theory & practical) and knowledge on Bioluminescence assays.

**References**
Scope

This subject deals with the various aspects of reagents, quantitative analysis of functional group used in the analytical method development. It also covers the biological testing of various vaccines and impurities.

Objectives

After the completion of the course, it is expected that the student 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 sability studies of drugs and biological products.

Theory 60 Hours

1. Analytical principle and procedure involved in the assay of following methods with special emphasize on official drugs in IP 12 Hrs
   a) Complexometric titration b) Non aqueous titration c) Redox titration
   Diazotization titration e) UV – Visible method f) HPLC g) Potentiometric titrations h) pKa and log p determination

2. Analytical principle, procedure and applications of the following reagents: 12 Hrs
   Ninhydrin b) 3-Methyl-2-benzthiazolinone hydrazone [MBTH] c) Folin – Ciocaltau [FC] d) Para-dimethyl-amino benzaldehyde [PDAB] e) Para-dimethyl-amino cinnamaldehyde [PDAC] f) 2, 6- Dichloroquinone chlorimide1,2-napthaquinone-4-sulfonate h) 2,3,5-Triphenyltetrazolium i) 2,4-Dinitro Phenyl hydrazine [DNPH] j) Bratton – Marshall reagent k) 3,5- Dinitro salicylic acid [DNSA]

Principles and procedure involved in quantitative estimation of following 12 Hrs functional groups in drugs and elements:
   Hydroxyl b) Amine c) Carboxyl d) Carbonyl f) Ester g) Methoxyl
   a) Sodium b) Potassium c) Calcium d) Halogens e) Phosphorus e) Sulphur

4. Biological tests and assays of the following 12 Hrs
   a. Adsorbed Tetanus vaccine b. Adsorbed Diphtheria vaccine
   c. Human anti haemophilic vaccine d. Rabies vaccine e. Tetanus Antitoxin
   f. Tetanus Anti serum g. Oxytocin h. Heparin sodium IP i. Antivenom.
PCR, PCR studies for gene regulation, instrumentation (Principles and procedures).

5. Impurities and stability studies

12 Hrs

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

Elemental Impurities


Method development, Stability studies and concepts of validation

Accelerated stability testing & shelf life calculation, WHO and ICH stability testing guideline, Stability zones, Photostability testing guidelines, ICH stability guidelines for biological products

References

9. Methods of sampling and microbiological examination of water, first revision, BIS
PHARMACEUTICAL VALIDATION (MPA103T)

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

<table>
<thead>
<tr>
<th>Theory</th>
<th>60 Hours</th>
</tr>
</thead>
<tbody>
<tr>
<td>Introduction</td>
<td>Hrs</td>
</tr>
<tr>
<td>Qualification</td>
<td>12 Hrs.</td>
</tr>
<tr>
<td>User Requirement Specification, Design Qualification, Factory Acceptance Test (FAT)/ Site Acceptance Test (SAT), Installation Qualification, Operational Qualification, Performance Qualification, Re- Qualification (Maintaining status- Calibration Preventive Maintenance, Change management), Qualification of Manufacturing Equipments, Qualification of Analytical Instruments and Laboratory equipments.</td>
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<tr>
<td>Qualification of analytical instruments</td>
<td>Hrs.</td>
</tr>
<tr>
<td>Electronic balance, pH meter, UV-Visible spectrophotometer, FTIR, GC, HPLC, HPTLC, Disintegration and Dissolution Qualification of Glassware: Volumetric flask, pipette, beakers and burette</td>
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<tr>
<td>Validation of Utility systems - Pharmaceutical Water System &amp; pure steam, HVAC system, Compressed air and nitrogen.</td>
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<tr>
<td>Cleaning Validation</td>
<td>Hrs.</td>
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<tr>
<td>Cleaning Validation - Cleaning Method development, Validation and validation of analytical method used in cleaning. Cleaning of Equipment, Cleaning of Facilities. Cleaning in place (CIP).</td>
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<tr>
<td>History of various phases of drug development and drug approval, IND, NDA (Phase I - IV), Content and Formal ANDA</td>
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</tr>
<tr>
<td>Analytical method validation</td>
<td>Hrs</td>
</tr>
<tr>
<td>General principles, Validation of analytical method as per ICH guidelines</td>
<td></td>
</tr>
</tbody>
</table>
5. Regulatory scenario in India

Regulatory aspects of pharmaceutical and bulk drug manufacture and drug analysis, loan license (contract manufacture) auditing, recent amendments to drugs and cosmetics act, provisions of consumer protection act, environment protection act.

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

FOOD ANALYSIS (MPA104T)

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
Student shall have the knowledge on food regulations and legislations.

Theory 60Hrs

a. Carbohydrates – Chemistry & 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

b. 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

12Hrs

a. 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.

b. Vitamins – classification of vitamins, methods of analysis of vitamins, Principles of microbial assay and physiological significance of vitamins of B-series

12Hrs

a. Food additives – Introduction, analysis of Preservatives, antioxidants, artificial sweeteners, flavors, flavor enhancers, stabilizers, thickening and jelling agents

b. 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

12Hrs

a. General Analytical methods for milk, milk constituents and milk products like ice cream, milk powder, butter, margarine, cheese including adulterants and contaminants of milk.

b. Analysis of fermentation products like wine, spirits, beer and vinegar.

12Hrs

a. Pesticide analysis - Effects of pest and insects on various food, use of pesticides in agriculture, pesticide cycle, organophosphorous and organo chlorine pesticides analysis, determination of pesticide residues in grain, fruits, vegetables, milk and milk products.

b. Legislation regulations of food products with special emphasis on BIS, Agmark and US-FDA.

12Hrs

References

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

Practical (MPL101P)
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 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

ADVANCED INSTRUMENTAL ANALYSIS (MPA201T)
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

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

Theory 60 Hrs

1. UV and IR spectroscopy 12 Hrs

   Woodward – Fiesure rule for 1,3- butadienes, cyclicdienes and α, β-carbonyl compounds and interpretation compounds of enones. ATR-IR, IR Interpretation of organic compounds

2. NMR spectroscopy 12 Hrs

   1-D and 2-D NMR, NOESY and COSY, HECTOR, INADEQUATE techniques, Interpretation of organic compounds

3. Mass Spectroscopy 12 Hrs

   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

4. Hyphenated analytical techniques 12 Hrs

   Principle, Instrumentation and Applications of the following:

   GC-MS b) LC-MS c) ICP-MS d) LC-NMR e) EC-MS f) High Performance Thin Layer chromatography h) Super critical fluid chromatography i) Ion Chromatography j) I-EC (Ion-Exclusion Chromatography) k) Flash chromatography

5. Thermal methods of analysis 12 Hrs

   Thermal methods of analysis – Introduction, principle, instrumentation and application of DSC, DTA and TGA.

   Radio Immuno Assay: Importance, various components, Principle, Different methods, Limitation & Applications of RIA.

   Optical Rotatory Dispersion: Principle, Plain curves, Cotton effect, Circular Dichroism, Measurement of rotation angle in ORD and applications

References

MODERN BIO-ANALYTICAL TECHNIQUES (MPA202T)

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
- Bioanalytical method validation
- Guidelines for BA/BE studies.
- GCP

Theory

1. **Analysis of drugs in biological matrices**

   Analysis of drugs in use and drugs in Research and Development

   **Biological matrix and Problems with analysis of biological matrices**

   Properties of the biological media, small organic molecules, peptides and protein drugs, prodrugs, formulations, drug metabolites, other drugs, safety considerations.

2. **Good Clinical Practice (GCP):**

   Origin of GCP, Requirements of GCP compliance, Guidelines for GCP, guidelines of ICH, guidelines of ICMR, Ensuring GCP, Documentation of GCP practice, Audit of GCP compliance

3. **USFDA & UDSCO Guidelines for BA/BE studies for orally administered drug products:**

   Introduction, Design and conduct of studies, Facilities to conduct BA/BE studies, SPE sorbents, Retention of BA/BE samples, Maintenance of records of BA/BE studies

4. **Extraction of drugs and metabolites from biological matrices:**

   General principle and procedure involved in the bio-analytical methods such as Protein precipitation, Liquid - Liquid extraction and Solid phase extraction and membrane filtration.

5. **Separation techniques**

   Bio molecules separation by HPLC, LC MS/MS and Gelelectrophoresis
References
10. ICH guidelines

QUALITY CONTROL AND QUALITY ASSURANCE (MPA203T)

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 will 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

Theory 60 Hours
1. Concept and evolution of Quality Control and Quality Assurance 12 Hrs
   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.

cGMP guidelines according to schedule M, USFDA (inclusive of CDER and 12 Hrs 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.

3. Analysis of raw materials, finished products, packaging materials, in process quality control (IPQC), Developing specification (ICH Q6 and Q3) 12 Hrs

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 (How to refer pharmacopoeias), Quality control test for containers, closures and secondary packing materials.

4. Documentation in pharmaceutical industry

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

5. Manufacturing operations and controls

Sanitation of manufacturing premises, 12 Hrs 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.

b. NABL certification & accreditation procedure  c. Patent Regime and IPR

References

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

COSMETIC ANALYSIS & EVALUATION (MPA204T)

Scope
This course is designed to impart knowledge on analysis of cosmetic raw materials and finished products. Performance analysis 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 Food constituents:

- Determination of physical constants of cosmetic raw materials Cosmetic raw materials, additives and their analysis
- Analysis of finished cosmetic products
- Principles of performance evaluation of cosmetic products.

Theory 60Hrs
Determination of acid value, ester value, Saponification value, iodine value, peroxide value, rancidity, moisture, ash, volatile matter, heavy metals, fineness of powders, density, viscosity of cosmetics raw materials and finished products

12 Hrs
Study on the quality of raw materials and general methods of analysis of raw material used in cosmetic manufacture as per BIS.

12 Hrs
Indian standard specifications laid down for sampling and testing of various cosmetics in finished forms such as baby care powders, skin care products, dental products, personal hygiene preparations, lips sticks, hair products and skin creams by the Bureau Indian Standards.

12 Hrs
Principles of equipment used to measure product performance of skin and hair care products - Sebumeter, corneometer, trans-epidermal water loss, Skin color, hair tensile properties, hair combing properties.

Performance evaluation of shampoos, antiperspirants, deodorants, sunscreens, foam baths and abrasiveness of dentifrices.
Study of specialized additives- quality parameters and analysis of rheology modifiers, preservatives, emollients, hair conditioners and fragrances

References
2. Indian Standard specification, for raw materials, BIS, New Delhi.
3. Indian Standard specification for 28 finished cosmetics BIS, New Delhi
4. Harry’s Cosmeticology
5. Wilkinson, Moore, seventh edition, George Godwin. Poucher’s Perfumes, Cosmetics and Soaps

Practical (MPL205P)
1. Comparison of absorption spectra by UV and Wood ward – Fiesure 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
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

M.PHARM. PHARMACEUTICAL REGULATORY AFFAIRS
(MRA)
GOOD REGULATORY PRACTICES (MRA 101T)

Scope
This course is designed to impart fundamental knowledge biological and medical devices on various Good Regulatory Practices viz., cGMP, GLP, GALP and GDP pharmaceutical industries and understand the rationale behind these requirements and will propose ways and means of complying them.

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

- The key elements of current Good Manufacturing Practices, Good Laboratory Practices, Good Automated Laboratory Practices, Good Documentation Practices
- The check lists for various Good Regulatory Practices and Prepare SOPs for Good Pharmaceutical Practices
- Implement Good Regulatory Practices in the Health care Industries and Prepare for the Audit of the Pharmaceutical Industries.
- Prepare for the rediness and conduct of the audit/inspections

Theory 60Hrs


Good Laboratory Practices: Introduction,USFDA GLP Regulations (Subpart A to SubpartK),Controlling the GLP inspection process,GLP Documentation,Audit, goals of LaboratoryQuality Audit, Audit tools, Future of GLP regulations, ISO 12Hrs


Good Distribution Practices: Introduction to GDP, Legal GDP requirements put worldwide, Principles, Personnel, Documentation, Premises and Equipment, Deliveries to Customers, Returns, Self Inspection, Provision of information, Stability testing principles, WHO GDP, USP GDP( Supply chain integrity), GHTF guidance/IMDRF/CDSCO 12Hrs

Quality management systems: Concept of Quality, Total Quality Management, Quality bydesign, Six Sigma concept, Out of Specifications (OOS), Change control. Validation: Types of Validation, Types of Qualification, Validation 12Hrs
master plan (VMP), Analytical Method Validation. Validation of utilities, [Compressed air, steam, water systems, Heat Ventilation and Air conditioning (HVAC)] and Cleaning Validation. The International Conference on Harmonization (ICH) process, ICH guidelines to establish quality, safety and efficacy of drug substances and products, ISO 13485, Schedule M III

12Hrs

References

2. Good Pharmaceutical Manufacturing practice, Rational and compliance by John Sharp, CRC Press


4. How to practice GLP by PP Sharma, Vandana Publications.

5. Laboratory Auditing for Quality and Regulatory compliance by Donald C. Singer, Drugs and the Pharmaceutical Sciences, Vol.150.

REGULATIONS LEGISLATIONS FOR FOOD PMBC IN INDIA (MRA 102T)

Scope
This course is designed to impart fundamental knowledge on regulations and legislations in India with respect to PMBC. It prepares the students for basic regulatory requirements in India of PMB for manufacture, import, registration, export, sale, marketing authorization, clinical trials and intellectual property rights.

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

- Know different Acts and guidelines that regulate PMBC industry in India.
- Understand the approval process and regulatory requirements for drugs and medical devices

Theory 60 Hours

Unit-I

Study of Relevant provisions of FPMBC

Acts and Rules (with latest amendments):

Drugs and Cosmetics Act 1940 and other Relevant provisions (Rules, Schedules and Guidelines) for approval of FPMBC, Rules 1945: DPCO and NPPA

Legal definitions of schedules to the Act and Rules, Import of drugs, Manufacture of drugs, Sale of Drugs & Packing of drugs & other related Acts-Narcotic etc

Central Drug Standard Control Organization and State Licensing Authority:

- Rules, Regulations, Guidelines For Regulatory filling of FPMB to Relevant Regulations
- Format and contents of Regulatory dossier filling
- Clinical trials / Investigations
• Clinical Trials
• New Drugs
• Medical Devices
• Fixed Dose Combinations

Unit-II: Regulatory requirements FNPCMB and approval procedures for: 12 Hrs
Unit-III: Indian Pharmacopoeial standards
   BIS Standards & ISO and other relevant standards

Unit-IV:
• BA/BE: Bioavailability and Bioequivalence data, BCS Classification of Drugs, Regulatory
• Requirements for Bioequivalence study
• Stability requirements: ICH and WHO

Guidelines for drug testing in animals/Preclinical studies
• Animal testing: Rationale for conducting studies, CPCSEA Guidelines
• ethical guidelines for human participants
• ICMR-DBT Guidelines for Stem Cell Research 12 Hrs

Unit-V

References
3. Principles and Practice of Clinical Trial Medicine by Richard Chin and Bruce Y. Lee
4. Ethical Guidelines for Biomedical Research on Human Participants by Indian Council of Medical Research New Delhi 2006.
5. CPCSEA Guidelines for Laboratory Animal Facility by Committee for the purpose of control and supervision on experiments on animals (CPCSEA)
6. ICH E6 Guideline — Good Clinical Practice by ICH Harmonised Tripartite
7. Guidance for Industry on Submission of Clinical Trial Application for Evaluating Safety and Efficacy by CDSCO (Central Drug Standard Control Organisation)
8. Guidance for Industry on Requirement of Chemical & Pharmaceutical Information including Stability Study Data before approval of clinical trials / BE studies by CDSCO
9. Guidelines for Import and Manufacture of Medical Devices by CDSCO
10. Guidelines from official website of CDSCO

INTERNATIONAL REGULATORY ASPECTS OF FNPCMB (MRA103T)

Scope
This course is designed to impart the fundamental knowledge on the drug development general regulatory requirements for approval of FNPCMB Japan. It prepares the students to have elementary knowledge on the regulatory requirements, documentation requirements, and registration procedures for marketing the products in above countries.

Objectives
Upon completion of the course, the student shall be able to understand the Regulatory registration and landscape

Theory 60 Hours
Unit-I: 12 Hours

Unit-II: 12 Hours
EUROPEAN UNION and AUSTRALIA: Organization and structure of EMA & EDQM, General guidelines, Active Substance Master Files (ASMF) system in EU, Content and approval process of IMPD, Marketing Authorization procedures in EU (Centralized procedure, Decentralized procedure, Mutual recognition procedure and National Procedure). Regulatory considerations for manufacturing, packaging and labeling of pharmaceuticals in EU, Eudralex directives for human medicines, Variations & extensions, Compliance of European Pharmacopoeia (CEP)/ Certificate of Suitability (CoS), Marketing Authorization (MA) transfers, Qualified Person (QP) in EU

Unit-III 12Hours
Japan: Organization of the PMDA, Pharmaceutical Laws and regulations, types of registration applications, DMF system in Japan, drug regulatory approval process, Regulatory considerations for manufacturing, packaging and labeling of pharmaceuticals in Japan, Post marketing surveillance in Japan

Unit-IV
Brazil and China

Unit-V
Asean and South Asia

References
2. Pharmaceutical Regulatory Process, Edited by Ira R. Berry, Marcel Dekker Series, Vol.144
7. Drugs: From Discovery to Approval, Second Edition By Rick Ng
10. Preparation and Maintenance of the IND Application in eCTD Format By William K. Sietsema

CLINICAL RESEARCH REGULATIONS (MRA 104T)

Scope
This course is designed to impart the fundamental knowledge on the clinical development process of FNPCMB, phases and conduct of clinical trials and research, regulations and guidance governing the conduct of clinical research in INDIA. It prepares the students to learn in detail on various laws, legislations and guidance related to safety, efficacy, ethical conduct and regulatory approval of clinical trials and investigations.

Objectives
- Upon completion of the course, the student shall be able to (know, do and appreciate)
  - Clinical drug development process and different phases of clinical trials, investigations History, origin and ethics of clinical research
  - regulatory requirements for conducting clinical trials investigations and research regulations and guidance governing the conduct of clinical research,

Theory 60 Hours
Unit-I: Basics for Clinical trials for drug development process 12 Hours
Phases of clinical trials, Clinical Trial protocol Phase 0 studies
Phase-I: and subtype studies (single ascending, multiple ascending, dose escalation, methods, food effect studies, drug – drug interaction, PK end points
Phase-II: studies (proof of concept or principle studies to establish efficacy)

Phase-III: studies (Multi ethnicity, global clinical trial, registration studies)

Phase-IV: studies (Post marketing authorization studies; pits and practices)

   Ethical principles governing informed consent process
   Information Sheet and Informed Consent Form
   The informed consent process and documentation

Unit-II Basic CT for MD Ethics in Clinical Research 12 Hours

   - Origin of International Conference on Harmonization - Good Clinical Practice (ICH-GCP) guidelines.
   - The ethics of randomized clinical trials
   - The role of placebo in clinical trials

Ethics of clinical research in special population

   - Institutional Review Board/Independent Ethics Committee/Ethics Committee – composition, roles, responsibilities, review and approval process and ongoing monitoring of safety data
   - Data safety monitoring boards.
   - Responsibilities of sponsor, CRO, and investigator in ethical conduct of clinical research

Unit-III: Regulations governing Clinical Trials 12 Hours

   - USA: Regulations to conduct drug studies in USA (FDA)
   - NDA 505(b)(1) of the FD&C Act (Application for approval of a new drug)
   - NDA 505(b)(2) of the FD&C Act (Application for approval of a new drug that relies, at least in part, on data not developed by the applicant)
   - ANDA 505(j) of the FD&C Act (Application for approval of a generic drug product) FDA Guidance for Industry - Acceptance of Foreign Clinical Studies
   - FDA Clinical Trials Guidance Document: Good Clinical Practice
   - EU: Clinical Research regulations in European Union (EMA)
   - India: Clinical Research regulations in India – Schedule Y

Unit-IV: Clinical Research Related Guidelines 12 Hours

   - Good Clinical Practice Guidelines (ICH GCP E6) Indian GCP Guidelines
   - ICMR Ethical Guidelines for Biomedical Research
   - CDSCO guidelines

Regulatory Guidance on Efficacy and Safety ICH Guidance’s

   - E4 – Dose Response Information to support Drug Registration
   - E7 – Studies in support of General Population: Geriatrics
   - E8 – General Considerations of Clinical Trials
   - E10 – Choice of Control Groups and Related Issues in Clinical Trials,
   - E 11 – Clinical Investigation of Medicinal Products in the Pediatric Population

Unit-V: USA & EU Guidance 12 Hours

   - USA: FDA Guidance
• CFR 21Part 50: Protection of Human Subjects
• CFR 21Part 54: Financial Disclosure by Clinical Investigators
• CFR 21Part 312: IND Application
• CFR 21Part 314: Application for FDA Approval to Market a New Drug
• CFR 21Part 320: Bioavailability and bioequivalence requirements
• CFR 21Part 812: Investigational Device Exemptions
• CFR 21Part 822: Post-market surveillance
• FDA Safety Reporting Requirements for INDs and BA/BE Studies FDA Med Watch
• Guidance for Industry: Good Pharmacovigilance Practices and Pharmacoepidemiologic Assessment
• European Union: EMA Guidance
• EU Directives 2001
• EudraLex (EMEA) Volume 3 – Scientific guidelines for medicinal products for human use EU Annual Safety Report (ASR)
• Volume 9A – Pharmacovigilance for Medicinal Products for Human Use

References:
2. HIPAA and Human Subjects Research: A Question and Answer Reference Guide By Mark Barnes, JD, LLM and Jennifer Kulynych, JD, PhD
4. Reviewing Clinical Trials: A Guide for the Ethics Committee; Johan PE Karlberg and Marjorie A Speers; Karlberg, Johan Petter Einar, Hong Kong.
5. International Pharmaceutical Product Registration: Aspects of Quality, Safety and Efficacy; Anthony C. Cartwright; Taylor & Francis Inc., USA.
7. FDA regulatory affairs: a guide for prescription drugs, medical devices, and biologics; Douglas J. Pisano, David Mantus; CRC Press, USA

Recommended Websites
5. FDA New Drug Application:
Practicals (MRA105P)

1. Case studies (4 Nos.) of each of Good Pharmaceutical Practices.
2. Documentation for in process and finished products Quality control tests for Solid, liquid, Semisolid and Sterile preparations.
3. Preparation of SOPs, Analytical reports (Stability and validation)
4. Protocol preparation for documentation of various types of records (BMR, MFR, DR)
5. Labeling comparison between brand & generics.
6. Preparation of clinical trial protocol for registering trial in India
7. Registration for conducting BA/ BE studies in India
8. Import of drugs for research and developmental activities
9. Preparation of regulatory dossier as per Indian CTD format
10. Registering for different Intellectual Property Rights in India
11. GMP Audit Requirements as per CDSCO
12. Preparation and documentation for Indian Patent application.
13. Preparation of checklist for registration of IND as per ICH CTD format.
14. Preparation of checklist for registration of NDA as per ICH CTD format.
15. Preparation of checklist for registration of ANDA as per ICH CTD format.
16. Case studies on response with scientific rationale to USFDA Warning Letter
17. Preparation of submission checklist of IMPD for EU submission.
18. Comparison study of marketing authorization procedures in EU.
19. Comparative study of DMF system in US, EU and Japan
20. Preparation of regulatory submission using eCTD software
21. Preparation of Clinical Trial Application (CTA) for US submission
22. Preparation of Clinical Trial Application (CTA) for EU submission
23. Comparison of Clinical Trial Application requirements of US, EU and Japan of a dosage form.
24. Regulatory requirements checklist for conducting clinical trials in India.
25. Regulatory requirements checklist for conducting clinical trials in Europe.
26. Regulatory requirements checklist for conducting clinical trials in USA

Scope
This course is designed to impart fundamental knowledge on documentation and general principles involved in regulatory writing and submission to agencies.

**Objectives**

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

- Know the various documents pertaining to drugs in pharmaceutical industry
- Understand the basics of regulatory compilation
- Create and assemble the regulation submission as per the requirements of agencies

Follow up the submissions and post approval document requirements

Documentation in pharmaceutical industry: Exploratory Product Development Brief (EPDB) for Drug substance and Drug product, Product Development Plan (PDP), Product Development Report (PDR), Master Formula Record, Batch Manufacturing Record and its calculations, Batch Reconciliation, Batch Packaging Records, Print pack specifications, Distribution records, Certificate of Analysis (CoA), Site Master File and Drug Master Files (DMF).


Electronic submission: Planning electronic submission, requirements for submission, regulatory bindings and requirements, Tool and Technologies, electronic dossier submission process and validating the submission, Electronic Submission Gateway (ESG). Non eCTD electronic submissions (NeeS), Asian CTD formats (ACTD) submission. Organizing, process and validation of submission


Inspections: Pre-approval inspections, Inspection of pharmaceutical manufacturers, Inspection of drug distribution channels, Quality systems requirements for national good manufacturing practice inspectorates, inspection report, model certificate of good manufacturing practices, Root cause analysis, Corrective and Preventive action (CAPA)

Product life cycle management: Prior Approval Supplement (PAS), Post Approval Changes [SUPAC], Changes Being Effected in 30 Days (CBE-30), Annual Report, Post marketing

Reporting Requirements, Post approval Labeling Changes, Lifecycle Management, FDA Inspection and Enforcement, Establishment Inspection Report (EIR), Warning Letters, Recalls, Seizure and Injunctions

**References**


5. Implementing Juran’s Road Map for Quality Leadership: Benchmarks and Results, By Al Endres, Wiley, 2000

6. Understanding, Managing and Implementing Quality: Frameworks, Techniques and Cases, By Jiju Antony; David Preece, Routledge, 2002

7. Organizing for High Performance: Employee Involvement, TQM, Reengineering, and Knowledge


9. Corporate Culture and the Quality Organization By James W. Fairfield-Sonn, Quorum Books, 2001


**BIOLOGICS REGULATIONS (MRA 203T)**

**Scope**

This course is designed to impart fundamental knowledge on Regulatory Requirements, Licensing and Registration, Regulation on Labelling of Biologics in India, USA and Europe

It prepares the students to learn in detail on Regulatory Requirements for biologics, Vaccines and Blood Products

**Objectives**

- Upon the completion of the course the student shall be able to:
  - Know the regulatory Requirements for Biologics and Vaccines
  - Understand the regulation for newly developed biologics and biosimilars
  - Know the pre-clinical and clinical development considerations of biologics
  - Understand the Regulatory Requirements of Blood and/or Its Components Including Blood Products and label requirements

**Theory** 60 Hrs
Unit I: 1. India

Introduction, Applicable Regulations and Guidelines, Principles for Development of Similar Biologics, Data Requirements for Preclinical Studies, Data Requirements for Clinical Trial Application, Data Requirements for Market Authorization Application, Post-Market Data for Similar Biologics, Pharmacovigilance, GMP and GDP.

12 Hrs

Unit II: 2. USA

Introduction to Biologics; biologics, biological and biosimilars, different biological products, difference between generic drug and biosimilars, laws, regulations and guidance on biologics/biosimilars, development and approval of biologics and biosimilars (IND, PMA, BLA, NDA, 510(k)), pre-clinical and clinical development considerations, advertising, labelling and packing of biologics.

12 Hrs

Unit III: European Union

Introduction to Biologics; directives, scientific guidelines and guidance related to biologics in EU, comparability/biosimilarity assessment, Plasma master file, TSE/BSE evaluation, development and regulatory approval of biologics (Investigational medicinal products and biosimilars), pre-clinical and clinical development considerations; stability, safety, advertising, labelling and packing of biologics in EU.

12 Hrs

Unit IV: Vaccine regulations in India, US and European Union:

Clinical evaluation, Marketing authorisation, Registration or licensing, Quality assessment, Pharmacovigilance, Additional requirements

12 Hrs

Unit V: Blood and Blood Products Regulations in India, US and European Union:

Regulatory Requirements of Blood and/or Its Components Including Blood Products, Label Requirements, ISBT (International Society of Blood Transfusion) and IHN (International Haemovigilence Network)

12 Hrs

References

2. Biological Drug Products: Development and Strategies; Wei Wang, Manmohan Singh; Wiley, 2013
4. www.who.int/biologicals/en
5. www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/
6. www.ihn-org.com
7. www.isbtweb.org
8. Guidelines on Similar Biologics: Regulatory Requirements for Marketing Authorization in India
9. www.cdsco.nic.in
10. www.ema.europa.eu › scientific guidelines › Biologicals
11. www.fda.gov/biologicsbloodVaccines/GuidanceComplianceRegulatoryInformation(Biologics)

INTERNATIONAL PHARMACEUTICAL REGULATIONS – II (MRA 203T)

Scope
This course is designed to impart fundamental knowledge on Regulatory Requirements for registration of drugs, medical devices and post approval requirements in WHO and emerging market (rest of world countries) like CIS, GCC, LATAM, ASIAN and African region.

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

- Know the regulatory Requirements for drug and medical device registration in emerging market; Understand the registration requirements of emerging market by comparison; and
- Prepare dossiers for the registration of the products in emerging market.

Theory 60 Hours
Emerging Market: Introduction, Countries covered, Study of the world map, study of various committees across the globe (ASEAN, APEC, EAC, GCC, PANDRH, SADC)

12 Hrs

WHO: WHO GMP, Regulatory Requirements for registration of drugs and post approval requirements in WHO through prequalification programme, Certificate of Pharmaceutical Product (CoPP) - General and Country Specific (South Africa, Egypt, Algeria and Morocco, Nigeria, Kenya and Botswana)

12 Hrs

ASIAN Countries: Introduction to ACTD, Regulatory Requirements for registration of drugs and post approval requirements in China and South Korea & Association of Southeast Asian Nations (ASEAN) Region i.e. Vietnam, Malaysia, Philippines, Singapore and Thailand.

12 Hrs

CIS (Commonwealth Independent States): Regulatory pre-requisites related to Marketing authorization requirements for drugs and post approval requirements in CIS countries i.e. Russia, Kazakhstan and Ukraine

12 Hrs

GCC (Gulf Cooperation Council) for Arab states: Regulatory pre-requisites related to Marketing authorization requirements for drugs and post approval requirements in Saudi Arabia and UAE

12 Hrs

References
5. Outsourcing to India: The Offshore Advantage, Mark Kobayashi-Hillary, Springer Trade performance and Regional Integration of the CIS Countries, Lev Freinkman,
8. The Gulf Cooperation Council: A Rising Power and Lessons for ASEAN by Linda
10. Realizing the ASEAN Economic Community: A Comprehensive Assessment, Michael G Plummer (Editor), Chia Siow Yue (Editor), Institute of South east asian studies, Singapore

**INDIA MEDICAL DEVICE REGULATIONS (MRA 204T)**

**Scope**

This course is designed to impart the fundamental knowledge on the medical devices and in vitro diagnostics, basis of classification and product life cycle of medical devices, regulatory requirements for approval of medical devices in regulated countries like US, EU and ASEAN countries along with WHO regulations. It prepares the students to learn in detail on the harmonization initiatives, quality and ethical considerations, regulatory and documentation requirements for marketing medical devices in regulated countries.

**Objectives**

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

- basics of medical devices, process of development, ethical and quality considerations harmonization initiatives for approval and marketing medical devices
- regulatory approval process for medical devices in US, EU and Asia clinical aspects of medical devices

**Theory**

| Unit-I: Medical Devices | 12 Hours |

Medical Devices: Introduction, differentiating medical devices from IVDs and Combination Products, History of Medical Device Regulation, Product Lifecycle of Medical Devices, Classification of Medical Devices.

**Unit-II: Ethics 12 Hours**

Clinical Investigation of Medical Devices, Clinical Investigation Plan for Medical Devices, Good Clinical Practice for Clinical Investigation of medical devices (ISO 14155:2011)

Quality: Quality System Regulations of Medical Devices: ISO 13485, Quality Risk

Management of Medical Devices: ISO 14971, Validation and Verification of Medical device, Adverse Event Reporting of Medical device

**Unit-III 12 Hours**

USA: Introduction, Classification, Regulatory approval process for Medical Devices (510k) Premarket Notification, Pre-Market Approval (PMA), Investigational Device Exemption (IDE) and In vitro Diagnostics, Quality System Requirements 21 CFR Part 820, Labeling requirements 21 CFR Part 801, Post marketing surveillance of MD and Unique Device Identification (UDI). Basics of In vitro diagnostics, classification and approval process.

**Unit-IV 12 Hours**


**Unit-V 12 Hours**

Medical Device Regulations in World Health Organization (WHO): Registration Procedures, Quality System requirements and Regulatory requirements

Asia: Clinical Trial Regulations specific for Medical Devices, Registration Procedures, Quality System requirements and Regulatory requirements for Japan, India and China

**References**

2. Medical Device Development: A Regulatory Overview by Jonathan S. Kahan
3. Medical Product Regulatory Affairs: Pharmaceuticals, Diagnostics, Medical Devices by John J. Tobin and Gary Walsh
4. Compliance Handbook for Pharmaceuticals, Medical Devices and Biologics by Carmen Medina

**Practical (MRA205P)**

1. Case studies on
2. Change Management/ Change control. Deviations
3. Corrective & Preventive Actions (CAPA)
4. Documentation of raw materials analysis as per official monographs
5. Preparation of audit checklist for various agencies
6. Preparation of submission to FDA using eCTD software
7. Preparation of submission to EMA using eCTD software
8. Preparation of submission to MHRA using eCTD software
9. Preparation of Biologics License Applications (BLA)
10. Preparation of documents required for Vaccine Product Approval
11. Comparison of clinical trial application requirements of US, EU and India of Biologics
12. Preparation of Checklist for Registration of Blood and Blood Products
13. Registration requirement comparison study in 5 emerging markets (WHO) and preparing check list for market authorization
14. Registration requirement comparison study in emerging markets (BRICS) and preparing check list for market authorization
15. Registration requirement comparison study in emerging markets (China and South Korea) and preparing check list for market authorization
16. Registration requirement comparison study in emerging markets (ASEAN) and preparing check list for market authorization
17. Registration requirement comparison study in emerging markets (GCC) and preparing check list for market authorization
18. Checklists for 510k and PMA for US market
19. Checklist for CE marking for various classes of devices for EU
20. STED Application for Class III Devices
21. Audit Checklist for Medical Device Facility
22. Clinical Investigation Plan for Medical Devices

M. PHARM. PHARMACEUTICAL BIOTECHNOLOGY (MPB)
MODERN PHARMACEUTICAL ANALYSIS (MPA101T)

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

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

Theory

1. UV-Visible spectroscopy  
60 Hours
2. IR spectroscopy  
12 Hrs

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

Spectrofluorimetry: Theory of Fluorescence, Factors affecting fluorescence, Quenchers, Instrumentation and Applications of fluorescence spectrophotometer.

**Flame emission spectroscopy and Atomic absorption spectroscopy:**

Principle, Instrumentation, Interferences and Applications.

2. **NMR spectroscopy**  12 Hrs

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


4. **Chromatography**  12 Hrs

Principle, apparatus, instrumentation, chromatographic parameters, factors affecting resolution and applications of the following:

- Paper chromatography
- Thin Layer chromatography
- Ion exchange chromatography
- Column chromatography
- Gas chromatography
- High Performance Liquid chromatography
- Affinity chromatography

5. **Electrophoresis**  12 Hrs

Principle, Instrumentation, Working conditions, factors affecting separation and applications of the following:

- Paper electrophoresis
- Gel electrophoresis
- Capillary electrophoresis
- Zone electrophoresis
- Moving boundary electrophoresis
- Isoelectric focusing

X-ray Crystallography: Production of X rays, Different X-ray methods, Bragg's law, Rotating crystal technique, X-ray powder technique, Types of crystals and applications of X-ray diffraction.

**References**

MICROBIAL AND CELLULAR BIOLOGY (MPB101T)

Scope
This subject is designed to provide the advanced knowledge to the biotechnology students in invaluable areas of advanced microbiology which plays a crucial role in determining its future use and applications in medicine, drug discovery and in pharmaceutical industry.

Objective
At the completion of this course it is expected that the students will get an understanding about the following aspects;

- Importance of Microorganisms in Industry Central dogma of molecular biology
- Structure and function of cell and cell communication
- Cell culture technology and its applications in pharmaceutical industries. Microbial pathogenesis

Theory 60Hrs

Unit-I: Microbiology 12Hrs

Introduction – Prokaryotes and Eukaryotes. Bacteria, fungi, actionomyocytes and virus - structure, chemistry and morphology, cultural, physiological and reproductive features. Methods of isolation, cultivation and maintenance of pure cultures. Industrially important microorganisms - examples and applications.

Unit-II: Molecular Biology 12 Hrs

Structure of nucleus and chromosome, Nucleic acids and composition, structure and types of DNA and RNA. Central dogma of molecular biology: Replication, Transcription and transcription.

Gene regulation 02 Hrs

Gene copy number, transcriptional control and translational control.

RNA Processing 05 Hrs

Modification and Maturation, RNA splicing, RNA editing, RNA amplification. Mutagenesis and repair mechanisms, types of mutants, application of
mutagenesis in stain improvement, gene mapping of plasmids- types purification and application. Phage genetics, genetic organization, phage mutation and lysogeny.

**Unit-III**

**Cell structure and function**

Cell organelles, cytoskeleton & cell movements, basic aspects of cell regulation, bioenergetics and fuelling reactions of aerobics and anaerobics, secondary metabolism & its applications. Cell communication, cell cycle and apoptosis, mechanism of cell division. Cell junctions/adhesion and extra cellular matrix, germ cells and fertilization, histology – the life and death of cells in tissues.

**Cell Cycle and Cytoskeleton**

Cell Division and its Regulation, G-Protein Coupled Receptors, Kinases, Nuclear receptors, Cytoskeleton & cell movements, Intermediate Filaments.

**Apoptosis and Oncogenes**

Programmed Cell Death, Tumor cells, carcinogens & repair.

**Differentiation and Developmental Biology**


**Unit-IV**

**Principles of microbial nutrition**

Physical and chemical environment for microbial growth, Stability and degeneration of microbial cultures.

**Growth of animal cells in culture**

General procedure for cell culture, Nutrient composition, Primary, established and transformed cell cultures, applications of cell cultures in pharmaceutical industry and research. Growth of viruses in cell culture propagation and enumeration. In vitro screening techniques- cytotoxicity, anti-tumor, anti-viral assays.

**Unit-V**

**Microbial pathology**

Identifying the features of pathogenic bacteria, fungi and viruses. Mechanism of microbial pathogenicity, etiology and pathology of common microbial diseases and currently recommended therapies for common bacterial, fungal & viral infections. Mechanism of action of antimicrobial agents and possible sites of chemotherapy.

**References**


(MPB102T)

Scope
This paper has been designed to provide the knowledge to the biotechnology students in invaluable areas of bioprocess technology to develop skills to modify, design and operate different types of fermenters, to understand and implement various fermentation procedures, to train students in scale up fermentation operations.

Objective
At the completion of this subject it is expected that students will be able to:
- Understand basics and design of fermentation technology
- Scale up and scale down processing of fermentation technology
- Bioprocessing of the industrially important microbial metabolites for the growth of microorganisms in industries and R & D organizations.
- Regulation governing the manufacturing of biological products

Understand and conduct fermentation process kinetics.

THEORY 60 Hrs
Unit-I 12 Hrs
Introduction to fermentation technology 02 Hrs
Basic principles of fermentation

Study of the design and operation of bioreactor 04 Hrs
Ancillary parts and function, impeller design and agitation, power requirements on measurements and control of dissolved oxygen, carbon dioxide, temperature, pH and foam.

Types of bioreactor 04 Hrs
CSTR, tower, airlift, bubble column, packed glass bead, hollow fiber, configuration and application

Computer control of fermentation process 02 Hrs
System configuration and application

Unit II 12 Hrs
Mass transfer and Rheology
Mass transfer 07 Hrs
Theory, diffusional resistance to oxygen requirements of microorganisms, measurements of mass transfer co-efficient and factor affecting them, effects of aeration and agitation on mass transfer, supply of air, air compressing, cleaning and sterilization of air and plenum ventilation, air sampling and testing standards for air purity.
### Rheology (05 Hrs)
Rheological properties of fermentation system and their importance in bioprocessing.

### Unit-III (12 Hrs)
#### Scale up of fermentation process (04 Hrs)
Principles, theoretical considerations, techniques used, media for fermentation, HTST sterilization, advantage and disadvantage, liquid sterilization.

#### Cultivation and immobilized culture system (04 Hrs)
Cultivation system - batch culture, continuous culture, synchronous cultures, fed batch culture. Graphical plot representing the above systems.

#### Introduction to immobilization (04 Hrs)
Techniques, immobilization of whole cell, immobilized culture system to prepare fine chemicals. Immobilization of enzymes and their applications in the industry. Reactors for immobilized systems and perspective of enzyme engineering.

### Unit-IV (12 Hrs)
#### Scale down of fermentation process (08 Hrs)
Theory, equipment design and operation, methods of filtration, solvent extraction, chromatographic separation, crystallization turbidity analysis, and plant yield determination, metabolic response assay, enzymatic assay, bioautographic techniques and disruption of cells for product recovery.

#### Isolation, screening (04 Hrs)
Primary and secondary, maintenance of stock culture, strain improvement for increased yield.

### Unit-V (12 Hrs)
#### Bioprocessing of the industrially important microbial metabolites (08 Hrs)
- Organic solvents – Alcohol and Glycerol
- Organic acids - Citric acids, Lactic acids
- Antibiotics - Penicillin, Streptomycin, Griseofulvin
- Vitamins - B12, Riboflavin and Vitamin C
- Amino acids - Glutamic acids, Lysine, Cyclic AMP and GMP

#### Biosynthetic pathways for some secondary metabolites, microbial transformation of steroids and alkaloids (02 Hrs)

#### Regulation governing the manufacturing of biological products (02 Hrs)

### References
4. Biotol Board, Bioreactor design and product yield, Butterworth and Helhemann publishers.
ADVANCED PHARMACEUTICAL BIOTECHNOLOGY (MPB103T)

Scope
This paper has been designed to provide the knowledge to the students to develop skills of advanced techniques of isolation and purification of enzymes, to enrich students with current status of development of vaccines and economic importance of biotechnology products.

Objective
At the completion of this subject it is expected that students will be able to:

1. Understand about the latest technology development in biotechnology technique, tools and their uses in drug and vaccine development.
2. Identify appropriate sources of enzymes:
   - Understand and perform genetic engineering techniques in gene manipulation, r-DNA technology and gene amplification.
3. Understand the overview of pharmacogenomics:
   - Learn the regulatory approval process and key regulatory agencies for new drugs, biologics, devices, and drug-device combinations.

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<tr>
<th>Theory</th>
<th>60 Hrs</th>
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<tr>
<td>Unit-I</td>
<td>12 Hrs</td>
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**Enzyme Technology**
Classification, general properties of enzymes, dynamics of enzymatic activity, sources of enzymes, extraction and purification, Applications pharmaceutical, therapeutic and clinical. Production of amyloglucosidase, glucose isomerase, amylase and trypsin.

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<tr>
<th>Unit-II</th>
<th>12 Hrs</th>
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<tr>
<td>Genetic Engineering</td>
<td>06 Hrs</td>
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Techniques of gene manipulation, cloning strategies, procedures, cloning vectors, expression vectors, recombinant selection and screening, expression in E.coli and yeast.

<table>
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<tr>
<th>Site directed mutagenesis, polymerase chain reaction, and analysis of DNA sequences</th>
<th>02 Hrs</th>
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<tbody>
<tr>
<td>Gene library and cDNA0</td>
<td>1 Hrs</td>
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**Applications of the above technique in the production of:**

- Regulatory proteins - Interferon, Interleukins
- Blood products - Erythropoietin
- Vaccines - Hepatitis-B
- Hormones - Insulin

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<tr>
<th>Unit-III</th>
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<tr>
<td>Therapeutic peptides</td>
<td>05 Hrs</td>
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Study on controlled and site specified delivery of therapeutic peptides and proteins through various routes of administration.

**Transgenic animals**
- Production of useful proteins in transgenic animals and gene therapy. 02 Hrs

**Human Genome**
- The human genome project-a brief study, Human chromosome – Structure and classification, chromosomal abnormalities – Syndromes 05 Hrs

**Unit-IV**
**Signal transduction**
- Introduction, cell signaling pathways, Ion channels, Sensors and effectors, ON and OFF mechanisms, Spatial and temporal aspects of signaling, cellular process, development, cell cycle and proliferation, neuronal signaling, cell stress, inflammatory responses and cell death, signaling defects and diseases. 08 Hrs

**Oncogenes**
- Introduction, definition, various oncogenes and their proteins. 04 Hrs

**Unit-V**
**Microbial Biotransformation**
- Biotransformation for the synthesis of chiral drugs and steroids. 04 Hrs

**Microbial Biodegradation**
- Biodegradation of xenobiotics, chemical and industrial wastes, production of single-cell protein, applications of microbes in environmental monitoring. 04 Hrs

**Biosensors**
- Definition, characteristics of ideal biosensors, types of biosensors, biological recognition elements, transducers, application of biosensors. 04 Hrs

**References**
2. Immobilization of cells and enzymes: HosevearKennadycabral& Bicker staff
5. Modern Biotechnology: S.B Primrose
7. Current protocols in Molecular Biology, Vo1.I & II:F.M. Asubel, John wiley Publishers

**SEMESTER – I**
Practicals (MPB104P)
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. Isolation and Purification of microorganism from the soil
8. Microbial contamination of Water and biochemical parameters.
9. Determination of Minimum Inhibitory concentration by gradient plate technique and serial dilution method.
10. UV- survival curve and Dark repair
11. Sterility test for pharmaceutical preparations
12. Sub culturing of cells and cytotoxicity assays.
13. Construction of growth curve and determination of specific growth rate and doubling time
14. Fermentation process of alcohol and wine production
15. Fermentation of vitamins and antibiotics
16. Whole cell immobilization engineering
17. Thermal death kinetics of bacteria
18. Replica plating
20. Isolation and estimation of DNA
21. Isolation and estimation of RNA
22. Isolation of plasmids
23. Agarose gel electrophoresis.
24. Transformation techniques
25. SDS – polyacrylamide gel electrophoresis for proteins
26. Polymerase chain reaction technique.

PROTEINS AND PROTEIN FORMULATIONS (MPB201T)

Scope
This course is designed to impart knowledge and skills necessary for knowing fundamental aspects of proteins and their formulations is a part of drug research and development process. Basic theoretical discussions of the principles of more integrated and coherent use of information for protein formulation and design are provided to help the students to clarify the various biological concepts of protein.

Objective
At the completion of this course it is expected that students will be able to understand:
• Various methods of purification of proteins Peptides in drug development
• Protein identification and characterization Protein based formulations
• Sequencing proteins

**Theory** 60 Hrs

**Unit-I: Protein engineering** 12 Hrs

Concepts for protein engineering. Isolation and purification of proteins, Stability and activity based approaches of protein engineering, Chemical and Physical Considerations in Protein and Peptide Stability, Different methods for protein engineering, gene shuffling, and direct evolution

**Unit-II Peptidomimetics** 12 Hrs

Introduction, classification; Conformationally restricted peptides, design, pseudopeptides, peptidomimetics and transition state analogs; Biologically active template; Amino acid replacements; Peptidomimetics and rational drug design; CADD techniques in peptidomimetics; Development of non peptide peptidomimetics.

**Unit-III: Proteomics** 12 Hrs

Proteomics 08 Hrs


**2-Dimensional gel electrophoresis** 04 Hrs

Methods (including IPGs), resolution, reproducibility and image analysis, future developments

**Unit-IV: Protein formulation** 12 Hrs

Different strategies used in the formulation of DNA and proteins, Analytical and biophysical parameters of proteins and DNA in pre-formulation, Liposomes, Neon-spears, Neon-particulate system, Pegilation, Biological Activity, Biophysical Characterization Techniques, Forced degradation studies of protein.

**Unit-V: Methods of protein sequencing** 12 Hrs

Various methods of protein sequencing, characterisation, Edman degradation, Tryptic and/or Chymotryptic Peptide Mapping.

**Reference**

2. Protein Purification – Hand Book – 1998 Amersham pharmacia biotech
This course is designed to impart knowledge on product ion and engineering of antibodies, the application of antigens, the design of (recombinant) vaccines, strategies for immune intervention, etc. The Immunotechnology - based techniques will be used in the medicine for therapeutics and diagnostics, industries in the production, quality control and quality assurance, and in R&D.

**Objective**

After this course, the students will be able to:-

- Understand the techniques like immunodiagnostic tests,
- Characterization of lymphocytes, purification of antigens and antibody, etc.
- Access health problems with immunological background;
- Develop approaches for the immune intervention of diseases

**Theory**

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<thead>
<tr>
<th>Unit-I</th>
<th>12 Hrs</th>
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<tr>
<td><strong>Fundamental aspects of immunology</strong></td>
<td>06 Hrs</td>
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- Introduction, cells and organs of the immune system, cellular basis of Immune response, primary and secondary lymphoid organs, antigen antibody and their structure. Types of immune responses, anatomy of immune response.
- Overview of innate and adaptive Immunity.

**Humoral Immunity**

- B–Lymphocytes and their activation. Structure and function of immunoglobulins, idiotypes and anti idiotypic antibodies.

**Cell mediated Immunity**

- Thymus derived lymphocytes (T cells) – their ontogeny and types, MHC complex, antigen presenting cells (APC), mechanisms of T cell activation, macrophages, dendritic cells, langerhans cells, mechanism of phagocytosis

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<th>Unit-II</th>
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<tr>
<td><strong>Immune Regulation and Tolerance</strong></td>
<td>08 Hrs</td>
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- Complement activation and types and their biological functions, cytokines and their role in immune response.

**Hypersensitivity**

- Hypersensitivity Types I-IV, Hypersensitivity reactions and treatment

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<tr>
<th>Unit-III</th>
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<tr>
<td><strong>Vaccine technology</strong></td>
<td>06 Hrs</td>
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Vaccine and their types, conventional vaccines, novel methods for vaccine production, antiidiotype vaccine, DNA vaccine, genetically engineered vaccine, iscoms, synthetic peptides, and immunodiagnostics.

**Stem cell technology** 06 Hrs
- Stem cell technology and applications to immunology

**Unit-IV: Hybridoma Technology** Hrs

**Unit-V** 12 Hrs
**Immunological Disorder** 06 Hrs
- Autoimmune disorders and types, pathogenic mechanisms, treatment, experimental models of auto immune diseases, primary and secondary immunodeficiency disorders.

**Immunodiagnosis** 06 Hrs
- Antigen antibody interaction – Precipitation reaction, Agglutination reactions, Principles and applications of ELISA, Radio Immuno Assay, Western blot analysis, immune-electrophoresis, immune florescence, chemiluminescence assay.

**References**
4. E. Benjamini, Molecular Immunology, 2002.

**BIOINFORMATICS AND COMPUTATIONAL BIOTECHNOLOGY (MPB203T)**

**Scope**
This paper has been designed to provide the advanced knowledge to the biotechnology students in invaluable areas of advanced bioinformatics which plays a crucial role in determining its future use and applications in medicine, drug discovery and in pharmaceutical industry.

**Objectives**
At completion of this course it is expected that the students will be able to understand:
- Usage of computers in developing a new drugs Biological concepts for bioinformatics
- Proteins and their diversity
- Various gene finding methods
- Searching the biological databases Target searching
- Various methods of drug designing

**Theory** 60 Hrs
**Unit-I** 12 Hrs
**Introduction to Bioinformatics** 04 Hrs
Definition and History of Bioinformatics, Internet and Bioinformatics, Introduction to Data Mining, Applications of Data Mining to Bioinformatics,

### Biological Database 08 Hrs

Protein and nucleic acid databases. Structural data bases. Collecting and storing the sequence and Applications of Bioinformatics.

### Unit II: Sequence analysis Hrs

Sequence alignment, pair wise alignment techniques, multiple sequence analysis, multiple sequence alignment; Flexible sequence similarity searching with the FAST3 program package, the use of CLUSTAL W and CLUSTAL X for the multiple sequence alignment. Tools used for sequence analysis.

### Unit-III Protein informatics Hrs

Introduction; Force field methods; Energ, buried and exposed residues, side chains and neighbours; Fixed regions, hydrogen bonds, mapping properties onto surfaces; Fitting monomers, rms fit of conformers, assigning secondary structures; Sequence alignment-methods, evaluation, scoring; Protein completion, backbone construction and side chain addition; Small peptide methodology, software accessibility, building peptides; Protein displays; Substructure manipulations, annealing.

### Protein structure prediction 05 Hrs

Protein folding and model generation; Secondary structure prediction, analyzing secondary structures; Protein loop searching, loop generating methods, loop analysis; Homology modeling, concepts of homology modeling, potential applications, description, methodology, homologous sequence identification; Align structures, align model sequence; Construction of variable and conserved regions, threading techniques, Topology fingerprint approach for prediction, evaluation of alternate models; Structure prediction on a mystery sequence, structure aided sequence techniques of structure prediction, structural profiles, alignment algorithms, mutation tables, prediction, validation, sequence based methods of structure prediction, prediction using inverse folding, fold prediction; Significance analysis,scoring techniques, sequence- sequence scoring.

### Docking 02 Hrs

Docking problems, methods for protein- ligand docking, validation studies and applications; Screening small molecule databases, docking of combinatorial libraries, input data, analyzing docking results.

### Unit-IV Diversity of Genomes 12 Hrs


### Completed Genomes 02 Hrs
Bacterium, Nematode, Plant and Human

**Evolution of Genomes** 04 Hrs
Lateral or Horizontal Transfer among Genomes, Transcriptome and Proteome-General Account

**Phylogenetic analysis** 02 Hrs
Evolutionary Change in Nucleotide Sequences, Rates and Patterns of Nucleotide Substitution, Models for Nucleotide Substitution, Construction of Phylogenetic Tree, Genome Annotation technique.

**Unit-V: Target searching and Drug Designing** 12Hrs
Target and lead, timeline for drug development, target discovery, target modulators, insilico gene expression, microarray, and lead discovery, libraries of ligands, active site analysis, and prediction of drug quality.

**Reference**
7. David Posada, Bioinformatics for DNA Sequence Analysis (2008), Humana press.

**BIOLOGICAL EVALUATION OF DRUG THERAPY (MPB204T)**

**Scope**
This paper has been designed to provide the knowledge to the biotechnology students to understand the importance of biological and evaluation of drug therapy of biological medicines.

**Objective**
At the completion of this subject it is expected that students will be able to:
- Understand about the general concept of standardization of biological.
- Understand the importance of transgenic animals and knockout animals.
- Understand the biological medicines in development of various diseases.
- Learn the biological evaluation of drugs in vitro and in vivo.
<table>
<thead>
<tr>
<th>Theory</th>
<th>60 Hrs</th>
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<tr>
<td>Unit-I</td>
<td>12 Hrs</td>
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<tr>
<td><strong>Biological Standardization</strong></td>
<td>04 Hrs</td>
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<tr>
<td>General principles, Scope and limitation of bio-assay, bioassay of some official drugs.</td>
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<tr>
<td><strong>Preclinical drug evaluation</strong></td>
<td>06 Hrs</td>
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<td>Preclinical drug evaluation of its biological activity, potency and toxicity. Toxicity test in animals including acute, sub-acute and chronic toxicity, ED50 and LD50 determination, special toxicity test like teratogenicity and mutagenecity.</td>
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<tr>
<td><strong>Guidelines for toxicity studies</strong></td>
<td>02 Hrs</td>
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<tr>
<td>Various guidelines for toxicity studies. Animal experiments assessing safety of packaging materials.</td>
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<td>Unit-II</td>
<td>12 Hrs</td>
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<tr>
<td><strong>Pyrogens</strong></td>
<td>04 Hrs</td>
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<tr>
<td>Pyrogens: Sources, Chemistry and properties of bacterial pyrogens and endotoxins, Official pyrogen tests.</td>
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<td><strong>Microbiological assay</strong></td>
<td>04 Hrs</td>
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<td>Assay of antibiotics and vitamins.</td>
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<td><strong>Biological evaluation of drugs</strong></td>
<td>04 Hrs</td>
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<tr>
<td>Screening and evaluation (including principles of screening, development of models for diseases: In vivo models / In vitro models / cell line study).</td>
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<tr>
<td>Unit-III</td>
<td>12 Hrs</td>
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<tr>
<td><strong>Biologic Medicines in Development for various diseases</strong></td>
<td>06 Hrs</td>
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<td><strong>By Therapeutic Category</strong></td>
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<tr>
<td>• Genetic Disorders Eye Conditions</td>
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<td>• Digestive Disorders</td>
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<td>• Diabetes/Related Conditions Cardiovascular Disease</td>
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<td>• Cancer/Related Conditions Blood Disorders</td>
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<td>• Autoimmune Disorders Infectious Diseases</td>
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<td>• Neurologic Disorders Skin Diseases</td>
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<td>• Transplantation</td>
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<tr>
<td>• Biologic Medicines in Development for various diseases — 06 Hrs</td>
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<td>• by Product Category</td>
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<td>• Antisense Vaccines</td>
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<td>• Recombinant Hormones/Proteins Monoclonal Antibodies (mAb) Interferons</td>
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<td>• Growth Factors Gene Therapy</td>
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<td>• RNA Interference</td>
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<td>Unit-IV</td>
<td>12 Hrs</td>
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<tr>
<td><strong>Regulatory aspects : drugs, biologics and medical devices</strong></td>
<td>04 Hrs</td>
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<tr>
<td>An introduction to the regulations and documents necessary for approval of a medical product.</td>
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Regulatory consideration 04 Hrs
Regulatory consideration for pre-clinical testing and clinical testing of drugs, biologics and medical devices.

New Drug Applications for Global Pharmaceutical Product Approvals 04 Hrs

Unit-V 12 Hrs

Bioavailability 06 Hrs
Objectives and consideration in bio-availability studies, Concept of equivalents, Measurements of bio-availability.

Determination of the rate of absorption, Bioequivalence and its importance, Regulatory aspects of bio-availability and bioequivalence studies for conventional dosage forms and controlled drug delivery systems.

Pharmacokinetics 06 Hrs
Pharmacokinetics:- Basic consideration, Pharmacokinetic models, Application of Pharmacokinetics in new drug development and designing of dosage forms and Novel drug delivery systems.

References
1. Perkins F.T., Hennessen W. Standardization and Control of Biologicals Produced by Recombinant DNA Technology, International Association of Biological Standardization
2. J.H. Burn., Biological Standardization, Oxford University Press
3. Drug Discovery and Evaluation in Pharmacology assay: Vogel
4. Chow, Shein, Ching, Design and analysis of animal studies in pharmaceutical development,
5. Nodine and Siegler, Animal and Clinical pharmacologic Techniques in Drug Evaluation-
6. Screening methods in pharmacology (vol I & II)–R.A. Turner

Semester – II
PRACTICALS (MPB205P)

1. Protein identification
2. Protein characterization
3. Protein biochemistry
4. Recombinant DNA Technology
5. Protein expression
6. Protein formulations
7. Database searching
8. Sequence analysis methods
9. Protein structure prediction
10. Gene annotation methods
11. Phylogenetic analysis
12. Protein, DNA binding studies
13. Preparation of DNA for PCR applications – Isolation, Purity and Quantification
15. Introduction to RT-PCR – working, programming.
16. Primer design using softwares.
17. Gene DNA amplification by random / specific primers.
18. Southern Hybridization
19. Western Blotting
20. Gene transformation

PHARMACY PRACTICE
(MPP)

CLINICAL PHARMACY PRACTICE (MPP101T)

Scope

This course is designed to impart the basic knowledge and skills that are required to practice pharmacy including the provision of pharmaceutical care services to both healthcare professionals and patients in clinical settings.

Objectives

Upon completion of this course it is expected that students shall be able to:

- Understand the elements of pharmaceutical care and provide comprehensive patient care services
- Interpret the laboratory results to aid the clinical diagnosis of various disorders
- Provide integrated, critically analyzed medicine and poison information to enable healthcare professionals in the efficient patient management

Theory 60 Hrs

Introduction to Clinical Pharmacy: Definition, evolution and scope of clinical pharmacy, International and national scenario of clinical pharmacy practice, Pharmaceutical care

Clinical Pharmacy Services: Ward round participation, Drug therapy review (Drug therapy monitoring including medication order review, chart endorsement, clinical review and pharmacist interventions)

12 Hrs

Clinical Pharmacy Services: Patient medication history interview, Basic concept of medicine and poison information services, Basic concept of pharmacovigilance, Hemovigilance, Materiovigilance and AEFI, Patient medication counselling, Drug utilisation evaluation, Documentation of clinical pharmacy services, Quality assurance of clinical pharmacy services

12 Hrs

Patient Data Analysis:

Patient Data & Practice Skills: Patient’s case history - its structure and significances in drug therapy management, Common medical abbreviations and
terminologies used in clinical practice, Communication skills: verbal and non-verbal communications, its applications in patient care services.

Lab Data Interpretation: Haematological tests, Renal function tests, Liver function tests

Lab Data Interpretation: Tests associated with cardiac disorders, Pulmonary function tests, Thyroid function tests, Fluid and electrolyte balance, Microbiological culture sensitivity tests

12 Hrs

Medicines & Poison Information Services

Medicine Information Service: Definition and need for medicine information service, Medicine information resources, Systematic approach in answering medicine information queries, Preparation of verbal and written response, Establishing a drug information centre

Poison Information Service: Definition, need, organization and functions of poison information centre

12 Hrs

References
2. Practice Standards and Definitions - The Society of Hospital Pharmacists of Australia (latest edition)
3. Basic skills in interpreting laboratory data - Scott LT, American Society of Health System Pharmacists Inc (latest edition)
4. Relevant review articles from recent medical and pharmaceutical literature.

PHARMACOTHERAPEUTICS-I (MPP102T)

Scope
This course aims to enable the students to understand the different treatment approaches in managing various disease conditions. Also, it imparts knowledge and skills in optimizing drug therapy of a patient by individualising the treatment plan through evidence-based medicines.

Objectives
Upon completion of this course it is expected that students shall be able to:

• Describe and explain the rationale for drug therapy
• Summarize the therapeutic approach for management of various disease conditions including reference to the latest available evidence
• Discuss the clinical controversies in drug therapy and evidence based medicine
• Prepare individualized therapeutic plans based on diagnosis
• Identify the patient specific parameters relevant in initiating drug therapy, and monitoring therapy (including alternatives, time-course of clinical and laboratory indices of therapeutic response and adverse effect/s)

Theory 60 Hrs
Etiopathogenesis and pharmacotherapy of diseases associated with following systems:

Cardiovascular system: Hypertension, Congestive cardiac failure, Acute coronary syndrome, Arrhythmias, Hyperlipidemias  

12 Hrs

Respiratory system: Asthma, Chronic obstructive airways disease, Drug induced pulmonary diseases

Endocrine system: Diabetes, Thyroid diseases  

12 Hrs

Gastrointestinal system: Peptic ulcer diseases, Reflux esophagitis, Inflammatory bowel diseases, Jaundice & hepatitis  

12 Hrs

Gastrointestinal system: Cirrhosis, Diarrhea and Constipation, Drug-induced liver disease

Hematological diseases: Anemia, Deep vein thrombosis, Drug induced hematological disorders

Bone and joint disorders: Rheumatoid arthritis, Osteoarthritis, Gout, Osteoporosis

Dermatological Diseases: Psoriasis, Eczema and scabies, impetigo, drug induced skin disorders

Ophthalmology: Conjunctivitis, Glaucoma  

12 Hrs

References

1. Roger and Walker. Clinical Pharmacy and Therapeutics - Churchill Livingstone publication
3. Robins SL. Pathologic basis of disease - W.B. Saunders publication
4. Eric T. Herfindal. Clinical Pharmacy and Therapeutics- Williams and Wilkins Publication
5. Lloyd Young and Koda-Kimble MA Applied Therapeutics: The clinical Use of Drugs- Lippincott Williams and Wilkins
7. Carol Mattson Porth. Principles of Pathophysiology- Lippincott Williams and Wilkins
9. Relevant review articles from recent medical and pharmaceutical literature

Scope

This course is designed to impart basic knowledge and skills that are required to practice pharmacy in both hospital and community settings.

Objectives
Upon completion of this course it is expected that students shall be able to:

- Understand the organizational structure of hospital pharmacy and drug policy and drug committees
- Know about procurement & drug distribution practices and know the admixtures of radiopharmaceuticals
- Understand the community pharmacy management
- Know about value added services in community pharmacies

**Theory 60 Hrs**

Introduction to Hospitals – Definition, classification, organizational structure Hospital Pharmacy: Definition, Relationship of hospital pharmacy department with other departments, Organizational structure, legal requirements, work load statistics, infrastructural requirements, Hospital Pharmacy budget and Hospital Pharmacy management

Hospital Drug Policy: Pharmacy & Therapeutics Committee, Infection Control committee, Research & Ethics Committee

12 Hrs

Hospital Formulary Guidelines and its development, Developing Therapeutic guidelines, Drug procurement process, and methods of Inventory control, Methods of Drug distribution, Intravenous admixtures, Hospital Waste Management

Education and training: Training of technical staff, Training and continuing education for pharmacists, Pharmacy students, Medical staff and students, Nursing staff and students, Formal and informal meetings and lectures, Drug and therapeutics newsletter.

Community Pharmacy Practice: Definition, roles & responsibilities of community pharmacists, relationship of community pharmacists with other health care providers

Community Pharmacy management: Legal requirements to start community pharmacy, site selection, lay out & design, drug display, super drug store model, accounts

Prescription – Legal requirements & interpretation, prescription related problems Responding to symptoms of minor ailments: Head ache, pyrexia, menstrual pains, food and drug allergy,

OTC medication: Rational use of over the counter medications Medication adherence and Patient referrals to the doctors ADR monitoring in community pharmacies.

Health Promotion – Definition and health promotion activities, family planning, Health screening services, first aid, prevention of communicable and non-communicable diseases, smoking cessation, Child & mother care

Home Medicines review program – Definition, objectives, Guidelines, method and outcomes

*Research in community pharmacy*  Hrs
References
1. Hospital Pharmacy - Hassan WE. Lec and Febiger publication.
5. Relevant review articles from recent medical and pharmaceutical literature

CLINICAL RESEARCH (MPP104T)

Scope
This course aims to provide the students an opportunity to learn drug development process especially the phases of clinical trials and also the ethical issues involved in the conduct of clinical research. Also, it aims to impart knowledge and develop skills on conceptualizing, designing, conducting and managing clinical trials.

Objectives
Upon completion of this course it is expected that students shall be able to:

- Know the new drug development process.
- Understand the regulatory and ethical requirements. Appreciate and conduct the clinical trials activities
- Know safety monitoring and reporting in clinical trials
- Manage the trial coordination process

Theory

Drug development process: Introduction, various approaches to drug discovery, Investigational new drug application submission

Ethics in Biomedical Research: Ethical Issues in Biomedical Research – Principles of ethics in biomedical research, Ethical committee [institutional review board] - its constitution and functions, Challenges in implementation of ethical guidelines

Types and Designs used in Clinical Research: Planning and execution of clinical trials, Various Phases of clinical trials, Bioavailability and Bioequivalence studies, Randomization techniques (Simple randomization, restricted randomization, blocking method and stratification), Types of research designs based on Controlling Method (Experimental, Quasi experimental, and Observational methods) Time Sequences (Prospective and Retrospective), Sampling methods (Cohort study, case Control study and cross sectional study), Health outcome measures (Clinical & Physiological, Humanistic and economic)

Clinical Trial Study team: Roles and responsibilities of: Investigator, Study Coordinator, Sponsor, Monitor, Contract Research Organization.

Clinical trial Documents: Guidelines to the preparation of following documents: Protocols, Investigator’s Brochure, Informed Consent Form, Case report forms, Contracts and agreements, Dairy Cards

Clinical Trial Start up activities: Site Feasibility Studies, Site/Investigator selection, Pre-study visit, Investigator meeting, Clinical trial agreement execution, Ethics committee document preparation and submission
Investigational Product: Procurement and Storage of investigation product

Filing procedures: Essential documents for clinical trial, Trial Master File preparation and maintenance, Investigator Site File, Pharmacy File, Site initiation visit, Conduct, Report and Follow up

Clinical Trial Monitoring and Close out:

Preparation and conduct of monitoring visit: Review of source documents, CRF, ICF, IP storage, accountability and reconciliation, Study Procedure, EC communications, Safety reporting, Monitoring visit reporting and follow-up

Close-Out visit: Study related documents collection, Archival requirement, Investigational Product reconciliation and destruction, Close-Out visit report

Quality Assurance and Quality Control in Clinical Trials: Types of audits, Audit criteria, Audit process, Responsibilities of stakeholders in audit process, Audit follow-up and documentation, Audit resolution and Preparing for FDA inspections, Fraud and misconduct management

Data Management

Infrastructure and System Requirement for Data Management: Electronic data capture systems, Selection and implementation of new systems, System validation and test procedures, Coding dictionaries, Data migration and archival

Clinical Trial Data Management: Standard Operating Procedures, Data management plan, CRF & Data base design considerations, Study set-up, Data entry, CRF tracking and corrections, Data cleaning, Managing laboratory and ADR data, Data transfer and database lock, Quality Control and Quality Assurance in CDM, Data mining and warehousing

References

11. Relevant review articles from recent medical and pharmaceutical literature.

**PHARMACY PRACTICE PRACTICAL – I (MPP105P)**

Pharmacy Practice practical component includes experiments covering important topics of the courses Clinical Pharmacy Practice, Pharmacotherapeutics-I, Hospital & Community Pharmacy and Clinical Research.
List of Experiments (24)
1. Treatment Chart Review (one)
2. Medication History Interview (one)
3. Patient Medication Counseling (two)
4. Drug Information Query (two)
5. Poison Information Query (one)
6. Lab Data Interpretation (two)
7. Presentation of clinical cases of various disease conditions adopting Pharmaceutical Care Plan Model (eight)
8. ABC Analysis of a given list of medications (one)
9. Preparation of content of a medicine, with proper justification, for the inclusion in the hospital formulary (one)
10. Formulation and dispensing of a given IV admixtures (one)
11. Preparation of a patient information leaflet (two)
12. Preparation of Study Protocol (one)
13. Preparation of Informed Consent Form (one)

**PRINCIPLES OF QUALITY USE OF MEDICINES (MPP201T)**

**Scope:**
This course is designed to impart basic knowledge and skills that are required to practice quality use of medicines (QUM) in different healthcare settings and also to promote quality use of medicines, in clinical practice, through evidence-based medicine approach.

**Objectives**
Upon completion of this course it is expected that students shall be able to:
- Understand the principles of quality use of medicines
- Know the benefits and risks associated with use of medicines
- Understand regulatory aspects of quality use of medicines
- Identify and resolve medication related problems
- Promote quality use of medicines
- Practice evidence-based medicines

**Theory**

- Introduction to Quality use of medicines (QUM): Definition and Principles of QUM, Key partners and responsibilities of the partners, Building blocks in QMC, Evaluation process in QMC, Communication in QUM, Cost effective prescribing

**Concepts in QUM**

- Evidence based medicine: Definition, concept of evidence based medicine, Approach and practice of evidence based medicine in clinical settings
- Essential drugs: Definition, need, concept of essential drug, National essential drug policy and list
- Rational drug use: Definition, concept and need for rational drug use, Rational drug prescribing, Role of pharmacist in rational drug use

- QUM in various settings: Hospital settings, Ambulatory care/Residential care, Role of health care professionals in promoting the QUM, Strategies to promote
the QUM, Impact of QUM on E-health, integrative medicine and multidisciplinary care.

QUM in special population: Pediatric prescribing, Geriatric prescribing, Prescribing in pregnancy and lactation, Prescribing in immune compromised and organ failure patients

Hrs

Regulatory aspects of QUM in India: Regulation including scheduling, Regulation of complementary medicines, Regulation of OTC medicines, Professional responsibility of pharmacist, Role of industry in QUM in medicine development

Hrs

Medication errors: Definition, categorization and causes of medication errors, Detection and prevention of medication errors, Role of pharmacist in monitoring and management of medication errors

Pharmacovigilance: Definition, aims and need for pharmacovigilance, Types, predisposing factors and mechanism of adverse drug reactions (ADRs), Detection, reporting and monitoring of ADRs, Causality assessment of ADRs, Management of ADRs, Role of pharmacist in pharmacovigilance

12 Hrs

References
6. Online:
http://www.rug.nl/research/portal/files/14051541/Chapter_2.pdf
9. Relevant review articles from recent medical and pharmaceutical literature.

PHARMACOTHERAPEUTICS II (MPP202T)

Scope

This course aims to enable the students to understand the different treatment approaches in managing various disease conditions. Also, it imparts knowledge and skills in optimizing drug therapy of a patient by individualising the treatment plan through evidence-based medicines.

Objectives

Upon completion of this course it is expected that students shall be able to:

- Describe and explain the rationale for drug therapy
- Summarize the therapeutic approach for management of various disease conditions including reference to the latest available evidence
• Discuss the clinical controversies in drug therapy and evidence based medicine
  Prepare individualized therapeutic plans based on diagnosis
• Identify the patient specific parameters relevant in initiating drug therapy, and
  monitoring therapy (including alternatives, time- course of clinical and
  laboratory indices of therapeutic response and adverse effect/s)

**Theory**  
60 Hrs

Nervous system: Epilepsy, Parkinson’s disease, Stroke, Headache, Alzheimer’s disease, Neuralgias and Pain pathways and Pain management

12 Hrs

Psychiatric disorders: Schizophrenia, Depression, Anxiety disorders, Sleep disorders, Drug induced psychiatric disorders
  Renal system: Acute renal failure, Chronic renal failure, Renal dialysis, Drug induced renal disease

12 Hrs

Infectious diseases: General guidelines for the rational use of antibiotics and surgical prophylaxis, Urinary tract infections, Respiratory tract infections, Gastroenteritis, Tuberculosis, Malaria, Bacterial endocarditis, Septicemia

12 Hrs

Infectious diseases: Meningitis, HIV and opportunistic infections, Rheumatic fever, Dengue fever, H1N1, Helmenthiasis, Fungal infections
  Gynecological disorders: Dysmenorrhea, Hormone replacement therapy

12 Hrs

Oncology: General principles of cancer chemotherapy, pharmacotherapy of breast cancer, lung cancer, head & neck cancer, hematological malignancies, Management of nausea and vomiting, Palliative care

12 Hrs

**References**

1. Roger and Walker. Clinical Pharmacy and Therapeutics - Churchill Livingstone publication
3. Robins SL. Pathologic basis of disease -W.B. Saunders publication
4. Eric T. Herfindal. Clinical Pharmacy and Therapeutics- Williams and Wilkins Publication
5. Lloyd Young and Koda-Kimble MA Applied Therapeutics: The clinical Use of Drugs- Lippincott Williams and Wilkins
7. Carol Mattson Porth. Principles of Pathophysiology- Lippincott Williams and Wilkins
9. Relevant review articles from recent medical and pharmaceutical literature
CLINICAL PHARMACOKINETICS AND THERAPEUTIC DRUG MONITORING (MPP203T)

Scope

This course is designed to enable students to understand the basics principles and applications of pharmacokinetics in designing the individualized dosage regimen, to interpret the plasma drug concentration profile in altered pharmacokinetics, drug interactions and in therapeutic drug monitoring processes to optimize the drug dosage regimen. Also, it enable students to understand the basic concepts of pharmacogenetics, pharmametrics for modeling and simulation of pharmacokinetic data.

Objectives

Upon completion of this course it is expected that students shall be able to:

- Design the drug dosage regimen for individual patients
- Interpret and correlate the plasma drug concentrations with patients' therapeutic outcomes
- Recommend dosage adjustment for patients with renal/ hepatic impairment
- Recommend dosage adjustment for paediatrics and geriatrics
- Manage pharmacokinetic drug interactions
- Apply pharmacokinetic parameters in clinical settings
- Interpret the impact of genetic polymorphisms of individuals on pharmacokinetics and or pharmacodynamics of drugs
- Do pharmacokinetic modeling for the given data using the principles of pharmametrics

Theory

Introduction to Clinical pharmacokinetics: Compartmental and Non compartmental models, Renal and non-renal clearance, Organ extraction and models of hepatic clearance, Estimation and determinants of bioavailability, Multiple dosing, Calculation of loading and maintenance doses

Designing of dosage regimens: Determination of dose and dosing intervals, Conversion from intravenous to oral dosing, Nomograms and Tabulations in designing dosage regimen

Pharmacokinetics of Drug Interaction: Pharmacokinetic drug interactions, Inhibition and Induction of Drug metabolism, Inhibition of Biliary Excretion

Pharmacogenetics: Genetic polymorphism in Drug metabolism: Cytochrome P-450 Isoenzymes, Genetic Polymorphism in Drug Transport and Drug Targets, Pharmacogenetics and Pharmacokinetic / Pharmacodynamic considerations

Introduction to Pharmametrics: Introduction to Bayesian Theory, Adaptive method or Dosing with feedback, Analysis of Population pharmacokinetic Data

Non Linier Mixed Effects Modelling: The Structural or Base Model, Modeling Random Effects, Modeling Covariate Relationships, Mixture Model, Estimation Methods, Model Building Techniques, Covariate Screening Methods, Testing the model assumptions, Precision of the parameter estimates and confidence intervals, Model misspecification and violation of the model assumptions, Model Validation, Simulation of dosing regimens and dosing recommendations, Pharmametrics software
Altered Pharmacokinetics: Drug dosing in the elderly, Drug dosing in the paediatrics, Drug dosing in the obese patients, Drug dosing in the pregnancy and lactation, Drug dosing in the renal failure and extracorporeal removal of drugs, Drug dosing in the hepatic failure

Therapeutic Drug monitoring: Introduction, Individualization of drug dosage regimen (Variability – Genetic, age, weight, disease and Interacting drugs), Indications for TDM, Protocol for TDM, Pharmacokinetic/Pharmacodynamic Correlation in drug therapy, TDM of drugs used in the following conditions: Cardiovascular disease: Digoxin, Lidocaine, Amiodarone; Seizure disorders: Phenytoin, Carbamazepine, Sodium Valproate; Psychiatric conditions: Lithium, Fluoxetine, Amitriptyline; Organ transplantations: Cyclosporine; Cytotoxic Agents: Methotrexate, 5-FU, Cisplatin; Antibiotics: Vancomycin, Gentamicin, Meropenem

12 Hrs

References
13. Relevant review articles from recent medical and pharmaceutical literature
PHARMACOEPIDEMIOLOGY & PHARMACOECONOMICS (MPP204T) SCOPE

Scope
This course enable students to understand various pharmacoepidemiological methods and their clinical applications. Also, it aims to impart knowledge on basic concepts, assumptions, terminology, and methods associated with pharmacoeconomics and health related outcomes, and when should be appropriate pharmacoeconomic model should be applied for a health care regimen.

Objectives
Upon completion of this course it is expected that students shall be able to:
- Understand the various epidemiological methods and their applications
- Understand the fundamental principles of pharmacoeconomics.
- Identify and determine relevant cost and consequences associated with pharmacy products and services.
- Perform the key pharmacoeconomics analysis methods
- Understand the pharmacoeconomic decision analysis methods and its applications. Describe current pharmacoeconomic methods and issues.
- Understand the applications of pharmacoeconomics to various pharmacy settings.

Theory  60 Hrs

Introduction to Pharmacoepidemiology: Definition, Scope, Need, Aims & Applications; Outcome measurement: Outcome measures, Drug use measures: Monetary units, Number of prescriptions, units of drug dispensed, defined daily doses, prescribed daily doses, Diagnosis and Therapy surveys, Prevalence, Incidence rate, Monetary units, number of prescriptions, unit of drugs dispensed, defined daily doses and prescribed daily doses, medications adherence measurements.

Concept of risk: Measurement of risk, Attributable risk and relative risk, Time- risk relationship and odds ratio

Pharmacoepidemiological Methods: Qualitative models: Drug Utilization Review;
Quantitative models: case reports, case series, Cross sectional studies, Cohort and case control studies, Calculation of Oddss ratio, Meta analysis models, Drug effects study in populations: Spontaneous reporting, Prescription event monitoring, Post marketing surveillance, Record linkage systems, Applications of pharmacoepidemiology

Introduction to Pharmacoeconomics: Definition, history of pharmacoeconomics, Need of Pharmacoeconomic studies in Indian healthcare system.Cost categorization and resources for cost estimation: Direct costs. Indirect costs. Intangible costs.

Outcomes and Measurements of Pharmacoeconomics: Types of outcomes: Clinical outcome, Economic outcomes, Humanistic outcomes; Quality Adjusted Life Years, Disability Adjusted Life Years Incremental Cost Effective Ratio, Average Cost Effective Ratio. Person Time, Willingness To Pay, Time Trade Off and Discounting.
Pharmacoeconomic evaluations: Definition, Steps involved, Applications, Advantages and disadvantages of the following Pharmacoeconomic models: Cost Minimization Analysis (CMA), Cost Benefit Analysis (CBA), Cost Effective Analysis (CEA), Cost Utility Analysis (CUA), Cost of Illness (COI), Cost Consequences Analysis (COA).

Definition, Steps involved, Applications, Advantages and disadvantages of the following:

Health related quality of life (HRQOL): Definition, Need for measurement of HRQOL, Common HRQOL measures.

Definition, Steps involved, Applications of the following: Decision Analysis and Decision tree, Sensitivity analysis, Markov Modeling, Software used in pharmacoeconomic analysis, Applications of Pharmacoeconomics 12 Hrs

References
5. George E Mackinnon III. Understanding health outcomes and pharmacoeconomics, 2013.
9. Relevant review articles from recent medical and pharmaceutical literature

PHARMACY PRACTICE PRACTICAL - II (MPP205T)
Pharmacy Practice practical component includes experiments covering important topics of the courses Principles of Quality Use of Medicines, Pharmacotherapeutics-II, Clinical Pharmacokinetics & Therapeutic Drug Monitoring and Pharmaepidemiology and Pharmacoeconomics.

List of Experiments (24)
1. Causality assessment of adverse drug reactions (three)
2. Detection and management of medication errors (three)
3. Rational use of medicines in special population (three)
4. Presentation of clinical cases of various disease conditions adopting Pharmaceutical Care Plan Model (eight)
5. Calculation of Bioavailability and Bioequivalence from the given data (two)
6. Interpretation of Therapeutic Drug Monitoring reports of a given patient (three)
7. Calculation of various Pharmacoeconomic outcome analysis for the given data (two)