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

Credit Based Semester System

JSS UNIVERSITY
SRI SHIVARATHREESHWARA NAGAR
MYSURU – 570 015, KARNATAKA
CHAPTER – I: REGULATIONS

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

2. Minimum qualification for admission
   A Pass in the following examination
   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.)
   Provided that,
   Every student, selected for admission to M. Pharm. program in JSS University, Mysuru 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: If the candidate had passed his/her qualifying degree (B.Pharm.) from universities other than JSS University, Mysuru, it is mandatory to submit a migration certificate obtained from the respective university.

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 JSS University, Mysuru.

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 course consists of lecture (L) and Practical (P) course consists of hours spent in the laboratory/hospital. 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/hospital) 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/hospital 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 by JSS University, Mysuru 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, Practicals, Seminars, Assignments, Research work, Discussions with the supervisor, Research Audits, Journal club and Co-Curricular activities over the duration of four semesters. The credits are distributed semester-wise as shown in Table-15.
Courses generally progress in sequence, building competencies and their positioning indicates certain academic maturity on the part of the learners. Learners are expected to follow the semester-wise schedule of courses given in the syllabus.

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

9. Course of study
The specializations offered in M.Pharm. Program are given in Table – 1.

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

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<tr>
<th>S. No.</th>
<th>Specialization</th>
<th>Code</th>
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<td>Industrial Pharmacy</td>
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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 – 2 to 14. The number of hours to be devoted to each theory and practical course in any semester shall not be less than that shown in Table – 2 to 14.
Table – 2: Course of study for M. Pharm. (Cosmeceutics)

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<th>Hrs./wk</th>
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**Semester II**

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Table – 9: Course of study for (Pharmacology)

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<th>Hrs./wk</th>
<th>Marks</th>
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Table – 10: Course of study for M. Pharm. (Pharmacy Practice)

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<th>Marks</th>
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**Semester II**

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<td>Pharmacoepidemiology &amp; Pharmacoeconomics</td>
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Table – 11: Course of study for M. Pharm. (Pharmaceutical Quality Assurance)

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<th>Marks</th>
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Table – 12: Course of study for M. Pharm. (Pharmaceutical Regulatory Affairs)

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Table – 13: Course of study for M. Pharm. III Semester
(Common for All Specializations)

<table>
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<td>Discussion / Presentation</td>
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* Non University Exam

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

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<td>Research Work</td>
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<td>Discussion/Final Presentation</td>
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Table – 15: Semester wise credits distribution

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<td>II</td>
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<td>III</td>
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<tr>
<td>IV</td>
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</table>

Co-curricular Activities
(Attending Conference, Scientific Presentations and Other Scholarly Activities)

| Minimum=02 | Maximum=07* |

| Total Credit Points | Minimum=95 | Maximum=100* |

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

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

Note: International Conference: Held Outside India
       International Journal: The Editorial Office 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 these credit points shall be defined by the colleges from time to time.

10. Program Committee

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

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

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

3. Duties of the Programme Committee:

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

11. Examinations/Assessments
The schemes for internal assessment and end semester examinations are given in Table – 17 – 28.

11.1. End semester examinations
The End Semester Examinations for each theory and practical course through semesters I to IV shall be conducted by the University except for the subject with asterix symbol (*) in table 28 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)

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**Tables – 18: Schemes for internal assessments and end semester examinations (Industrial Pharmacy)**

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| **SEMESTER II** |                                 |                     |                    |             |          |         |          |
| MPH201T      | Advanced Biopharmaceutics and Pharmacokinetics  | 10                  | 15                 | 25          | 75       | 3 Hrs   | 100     |
| MIP201T      | Scale up and Technology Transfer                | 10                  | 15                 | 25          | 75       | 3 Hrs   | 100     |
| MIP202T      | Pharmaceutical Production Technology             | 10                  | 15                 | 25          | 75       | 3 Hrs   | 100     |
| MIP203T      | Entrepreneurship Management                     | 10                  | 15                 | 25          | 75       | 3 Hrs   | 100     |
| MIP204P      | Industrial Pharmacy Practical II                | 20                  | 30                 | 50          | 100      | 12 Hrs  | 150     |
| -            | Seminar /Assignment                             | -                   | -                  | -           | -        | -       | 100     |

**Total 650**
### Tables – 19: Schemes for internal assessments and end semester examinations (Pharmaceutical Analysis)

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#### SEMESTER II

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

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|             |                                             | Continuous Mode     | Sessional Exams    | Total Marks |
|             |                                             | Marks | Duration | Marks | Duration | Marks | Duration |
| MPB201T     | Proteins and protein Formulation           | 10     | 15       | 1 Hr   | 25       | 75       | 3 Hrs   | 100      |
| MPB202T     | Immunotechnology                           | 10     | 15       | 1 Hr   | 25       | 75       | 3 Hrs   | 100      |
| MPB203T     | Bioinformatics and Computer Technology      | 10     | 15       | 1 Hr   | 25       | 75       | 3 Hrs   | 100      |
| MPB204T     | Biological Evaluation of Drug Therapy      | 10     | 15       | 1 Hr   | 25       | 75       | 3 Hrs   | 100      |
| MPB205P     | Pharmaceutical Biotechnology Practical II  | 20     | 30       | 6 Hrs  | 50       | 100      | 12 Hrs  | 150      |
|             | Seminar /Assignment                        | -      | -        | -      | -        | -        | -       | 100      |
| **Total**   | **650**                                    |         |          |        |          |          |         | **650**  |
Tables – 21: Schemes for internal assessments and end semester examinations (Pharmaceutical Chemistry)

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### 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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| **SEMESTER II** |                                             |                 |                 |       |                    |             |
| MPG201T      | Medicinal Plant biotechnology               | 10              | 1 Hr            | 25    | 75                 | 100         |
| MPG202T      | Advanced Pharmacognosy-II                  | 10              | 1 Hr            | 25    | 75                 | 100         |
| MPG203T      | Indian system of medicine                   | 10              | 1 Hr            | 25    | 75                 | 100         |
| MPG204T      | Herbal cosmetics                            | 10              | 1 Hr            | 25    | 75                 | 100         |
| MPG205P      | Pharmacognosy Practical II                  | 20              | 6 Hrs           | 50    | 100                | 150         |
| -           | Seminar /Assignment                         | -               | -               |       | -                  | 100         |
|             | **Total**                                   |                 |                 |       |                    | **650**     |
## 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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**SEMESTER II**

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Tables – 27: Schemes for internal assessments and end semester examinations (Pharmaceutical Regulatory Affairs)

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SEMESTER II

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Note: The 12 Hours duration of end semester practical examination shall equally be distributed to two examination days.
Tables – 28: Schemes for internal assessments and end semester examinations (Semester III& IV)

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*Non University Examination
11.2. Internal assessment: Continuous mode

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

| Table – 29: Scheme for awarding internal assessment: Continuous mode |
|---|---|---|
| **Criteria** | **Theory** | **Maximum Marks** |
| Attendance (Refer Table – 30) | 8 |
| Student – Teacher interaction | 2 |
| **Total** | **10** |

| **Practical** |
|---|---|
| Attendance (Refer Table – 30) | 10 |
| Practical Record | 05 |
| Viva voce | 05 |
| **Total** | **20** |

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

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

11.2.1. Sessional Exams

Two sessional exams shall be conducted for each theory / practical course as per the schedule fixed by the college(s). The scheme of question paper for theory and practical sessional examinations is given below. The average marks of two sessional exams shall be computed for internal assessment as per the requirements given in tables 17 – 28.

Question paper pattern for sessional theory examinations

I. Long Answers (Answer 1 out of 2) = 1 x 10 = 10
II. Short Answers (Answer 4 out of 5) = 4 x 5 = 20

------------------
Total = 30 marks
------------------
Question paper pattern for sessional practical examinations

I. Synopsis = 10
II. Experiment - I = 25
III. Experiment – II = 15
IV. Viva voce = 10

------------------
Total = 60 marks
------------------

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 a minimum of 50% of marks 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. Schedule for end semester examinations
The end semester examinations shall be conducted as per the schedule given in Table – 31. The exact dates of examinations shall be notified from time to time.

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

32
Question paper pattern for end semester theory examinations

I. Long Answers (Answer 3 out of 4) = 3 x 10 = 30
II. Short Answers (Answer 9 out of 11) = 9 x 5 = 45
------------------
Total = 75 marks
------------------

Question paper pattern for end semester practical examinations

I. Synopsis = 15
II. Experiment - I = 40
III. Experiment – II = 30
IV. Viva voce = 15
------------------
Total = 100 marks
------------------

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 IV semester examination until all the courses of I, II and III semesters are successfully completed.

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

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

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

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

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

18. The Semester grade point average (SGPA)

The performance of a student in a semester is indicated by a number called ‘Semester Grade Point Average’ (SGPA). The SGPA is the weighted average of the grade points obtained in all the courses by the student during the semester. For example, if a student takes five courses (Theory/Practical) in a semester with credits C1, C2, C3, C4 and C5 and the student’s grade points in these courses are G1, G2, G3, G4 and G5, respectively, and then students’ SGPA is equal to:

\[
\text{SGPA} = \frac{C_1G_1 + C_2G_2 + C_3G_3 + C_4G_4 + C_5G_5}{C_1 + C_2 + C_3 + C_4 + C_5}
\]

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

\[
\text{SGPA} = \frac{C_1G_1 + C_2G_2 + C_3G_3 + C_4 \times \text{ZERO} + C_5G_5}{C_1 + C_2 + C_3 + C_4 + C_5}
\]

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

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

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

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

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

21.1. Discussion / Presentation:
21.1.1. Discussion: Every student shall spend a minimum of 1 hour per week with his/her supervisor to discuss about the research work. A Log book shall be maintained by the students that shall be endorsed by the supervisor regularly. The supervisor shall award a maximum of 15 marks for the discussions held during III and IV semesters.

21.1.2 Proposal Presentation / Research Audit: Every student shall be evaluated for the proposal presentation in the III semester and research audit (prior to the submission of dissertation) in the IV semester by the department faculty members for 35 marks and 60 marks for Proposal Presentation and Research Audit respectively.

21.2. Evaluation of Research Work in III Semester
The progress of the research work done by the student shall be assessed by the project supervisor for a total of 350 marks based on the regularity, student work log book, and extent of literature review.
21.3. Evaluation of Research Work in IV Semester

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

**Evaluation of Dissertation Book:**

<table>
<thead>
<tr>
<th>Objective(s) of the work done</th>
<th>25 Marks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Methodology adopted</td>
<td>75 Marks</td>
</tr>
<tr>
<td>Results and Discussions</td>
<td>100 Marks</td>
</tr>
<tr>
<td>Conclusions and Outcomes</td>
<td>50 Marks</td>
</tr>
</tbody>
</table>

**Total** 250 Marks

**Evaluation of Presentation:**

<table>
<thead>
<tr>
<th>Presentation of work</th>
<th>75 Marks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Question and answer skills</td>
<td>50 Marks</td>
</tr>
<tr>
<td>Communication skills</td>
<td>25 Marks</td>
</tr>
</tbody>
</table>

**Total** 150 Marks

22. Seminar / Assignment

**122.1. Seminar:** Each student shall be given a seminar topic by the department relevant to the field of specialization and the same shall be presented (for a minimum of 30 minutes per student) by the students as per the schedule given by the department. The seminar shall be evaluated for 50 marks by the department faculty members against each criterion given below. The average of the marks awarded by individual faculty members shall be submitted to the University.

**Criteria for evaluation of seminar:** The seminars shall be evaluated based on but not limited to the following criteria.

1. Format of the presentation
2. Clarity of the presentation
3. Communication skill
4. Effective use of audio visual aids
5. Extent of subject understanding
6. Relevance of references
7. Ability to defend/answer questions
8. Time management
22.2. **Assignment**: Each student shall be given an assignment topic (different from the seminar topic) by the department relevant to the field of specialization and the same shall be submitted (a minimum of 25 pages) as a typed and spiral bound book on or before the date given by the department. The assignment shall be evaluated for 50 marks by the concerned subject teacher pertaining to topic of the assignment.

**Criteria for evaluation of assignment**: The assignments shall be evaluated based on but not limited to the following criteria.

1. Relevance with the content
2. Use of source material
3. Organization and mechanical accuracy
4. Cohesion & coherence
5. Command on Language
6. Timely submission

23. **Journal Club**
Each student shall deliver a journal club presentation during his/her III and IV semester. The published research articles relevant to the field of specialization shall be selected for journal club discussion in consultation with the department faculty members and the same shall be presented (for a minimum of 30 minutes per student) by the students as per the schedule given by the department. The journal club presentation shall be evaluated for 25 marks by the department faculty members against each criterion given below. The average of the marks awarded by individual faculty members shall be submitted to the University.

**Criteria for evaluation of journal club presentation**: The journal club presentations shall be evaluated based on but not limited to the following criteria.

1. Format of presentation
2. Communication skills
3. Appropriate interventions made by the students (about methodology, sample size, statistical tools, etc.)
4. Discussions on the topic

24. **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.
25. Award of degree
Candidates who fulfill the requirements mentioned above shall be eligible for award of degree during the ensuing convocation.

26. 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.

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

28. 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.
COSMECEUTICS

(MCC)
COSMECEUTICALS-BIOLOGY (MCC101T)

Scope:

- To impart knowledge on the biological aspects of – skin and hair
- 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
- To equip students with the knowledge of alternate methods to animal testing.

Objectives:

- To have stronger scientific basis in developing cosmeceutical products.
- To appreciate and contribute to areas of alternate to animal testing.

Theory 60 Hours

1. Skin 12 Hrs
   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. Wound healing process

2. Immunology 12Hrs
   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.

3. Irritation study models 12Hrs
   Artificial skin modeling – Human reconstituted epidermis and skin, Skin organ culture models and other new types of skin equivalents
   Skin sensizitization and sensitivity testing, patch test, open patch test, prophetic patch test, repeated insult test, photo-patch test, Skin sensitivity testing for creams, deodorants and antiperspirants, depilatories, hair dyes, lipsticks and nail polish.
4. **Nail and eye:**  

5. **Hair:**  

**Microbiology:**  
Pharmacopeial methods of evaluation of preservative efficacy.

**REFERENCES**
1. Harry’s Cosmetology.  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. United states Pharmacopedia
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

Formulation Principles: 12Hrs

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

Formulation Building blocks: 12Hrs

a) Building blocks for different product formulations of cosmetics/cosmeceuticals:
b) Surfactants- Classification and application.
c) Emollients and rheological additives: classification and application.
d) Antimicrobial used as preservatives, their merits and demerits. Factors affecting microbial preservative efficacy.
e) Perfumes; Classification of perfumes. Perfume ingredients listed as allergens.
f) Application of various product forms in cosmetics: Solution, creams, lotion, ointment, paste, gels, stick, tablets, capsules, powders and aerosol. Examples from marketed product.
3. 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.

4. Hair

**Hair Care:** Ideal requirement of a shampoo.
Building blocks and formulation of shampoos, Hair conditioners, Hair oil, hair cream, and hair styling gels
Chemistry and formulation of Parapheylene diamine based Hair dyes.

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

**Oral Care:** Ideal requirement 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.
**Deodorants and antiperspirants:** Ingredients and mechanism of action
**Baby Care:** Approach to baby care formulations.

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.
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

12Hrs

1. 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

2. cGMP of Pharmaceutical manufacturing:
   Evolution and Principles of cGMP, Schedule-M, WHO-GMP requirements, European Union (EU) and United States Food and Drug Administration (USFDA) guidelines on Pharmaceutical manufacturing. URS, FAT, DQ, SAT, IQ, OQ, PQ of machines and equipment. Clean room standards for different countries and names.
3. **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).

4. **Quality Management System:**
Quality risk management: Introduction, risk assessment, risk control, risk review, risk Management tools, HACCP, risk ranking and filtering.
Change Control, Deviation-(planned and unplanned), Corrective Action and Preventive Action (CAPA), Handling of nonconformance, Vendor evaluation process, Out of specification (OOS), Annual Product Review, batch reconciliation and finished goods release, Market recalls & Market complaints.

5. **Quality Control Process**
In process quality control and finished products quality control for following formulation in pharma industry: Liquids – Suspension, Emulsion, solutions, Ointments, creams, Jelly’s, Parenterals, ophthalmic.
Quality control test for containers, closures and secondary packing materials.
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

SAFETY AND EFFICACY EVALUATION (MCC 104T)

SCOPE
Have basic knowledge on the cell line safety studies, principles of animal testing and human clinical trials for application in cosmeceuticals and dermatological products.

OBJECTIVES:
Upon completion of the course, the student shall be able to have basic understanding of
- cell line studies
- Procedure and method of conducting safety and efficacy study using animals
- Procedure and stages of human clinical trials.

THEORY

60 HOURS

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

2. Cell culture techniques
12 Hrs
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.

3. Principles of cell line studies
12 Hrs
Principles and applications of cell viability assays, glucose uptake assay, Calcium influx assays.
Principles and applications of flow cytometry
Principles of cell line studies -- Skin irritation, phototoxicity, mutagenicity genotoxicity.
Melanocyte-keratinocyte coculture model to assess \textit{in vitro} regulators of pigmentation.

4. Principles of preclinical Animal testing
12Hrs
CPCSEA guidelines to conduct experiments on animals, Regulatory guidelines for conducting toxicity studies OECD.
General principles of preclinical screening, screening methods for Immunosuppressant and immunomodulators, antioxidants, and wound healing activity.

5. Human clinical studies: 12Hr

Various Phases of clinical trials
Designing of methods of clinical trials (randomization and blinding)
Ethics in research:
Historical aspects - Helsinki declaration, Nuremberg code, Belmont report
Ethical guidelines for biomedical research on human participants-ICMR
Ethical committee constitution, responsibilities and procedure
Informed consent process
Roles and responsibilities of clinical trial personnel as per ICH GCP (sponsor, investigator, clinical research associate, clinical research coordinators, auditors and regulatory authority)
Designing of clinical study documents (case report form, protocol and informed consent)

6. 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

References:
11. Shargel, L., & Swanson, L. N. Comprehensive pharmacy review. Lippincott Williams & Wilkins.
PRACTICALS (MCC105P):

Dermatology ward visits:

A) Visit to dermatology ward and submitting case report on common skin problems
   Specific examples: Acne, Lichen planus, Psoriasis, Rosacea, Sebhhoric dermatitis,
   Vitiligo, warts, Corns and calluses, eczema, Ichthyosis, dandruff, hair-fall, nail
   infections.

B) Analysis in detail selecting a specific skin problem.

Lab Practicals

1) Cytotoxicity studies using cell lines,
2) Preservative efficacy test
3) In vitro assay for antibacterial efficacy.
4) Isolation and identification of DNA from various sources (Bacteria)
5) Isolation of RNA from yeast
6) Estimation of RNA/DNA by UV Spectroscopy
7) Gene amplification by PCR.
8) Cell viability assays (MTT/Trypan blue/SRB).
9) DNA damage study by Comet assay.
10) Development of skin cream cream, shampoo and toothpaste base
COSMECEUTICALS (MCC201T)

SCOPE:
- To impart knowledge on the fundamental principles of cosmeceuticals product development.
- To understand the building blocks in the formulation of cosmeceuticals 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

1. Sun protection, pigmentation and wrinkles
   12Hrs


   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
   12Hrs
Case study of marketed products.

**Oral care:**
Basic understanding of the cause of Bleeding gums, sensitive teeth, plaque, 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 12Hrs

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

4. **Dermal Drug Delivery**
Factors affecting dermal drug delivery. Role of penetration enhancers in dermal delivery.
Dermal drug delivery systems: Nano particles, Liposomes, patches, Ionophoresis, sonophoresis, electroporation, micro-needles. 12Hrs

5. **Packaging**
Functions and principles of pack design. Plastics: Type of plastics and application
Metal, glass, laminates and paper boards. Basic principles in testing quality of packaging materials Relative merits and demerits of various packaging materials.

**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 (MPA204T)

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

12 hrs

1. 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

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

12 hrs

3. 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

4. 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

5. 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 8th edition
5. Suppliers catalogue on specialized cosmetic excipients
COSMETICS- INDUSTRY AND REGULATORY (MCC202T)

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:
- Effectively design products and documentation that meets regulatory requirements
- Implement smooth transfer of technology from design stage to factory production.

Theory 60 Hours

1. Indian Regulations 12Hrs
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 12Hrs
Equipments used in the manufacturing of creams, shampoo and toothpaste. GMP guidelines as per ASEAN standards for cosmetics

3. European Union Guidelines 12Hrs
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.
b) 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 Cosmetics. 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 DEVELOPMENT SYSTEM (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


12 Hrs

12 Hrs

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

**Computer Simulations in Pharmacokinetics and Pharmacodynamics**: Introduction, Computer Simulation: Whole Organism, Isolated Tissues, Organs, Cell, Proteins and Genes.

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

12 Hrs


12 Hrs

**REFERENCES**

PRACTICALS (MCC203P):

1. Design and formulate unique Cream, shampoo, face wash, toothpaste, moisturizing gel, lip balm, hair oil.
2. Study private body guidelines for green/premium cosmetics of Ecocert/Cosmos, and suggest changes in the formulations.
3. Design and Development of cosmeceutical product for the treatment of dry skin, wrinkles, acne, blemishes, dandruff, and bleeding gums.
5. Quantitative analysis of rancidity in hair oils and Lipsticks
6. Determination of aryl amine content and Developer in hair dye
7. Determination of foam height and SLS content of Shampoo.
8. Determination of total fatty matter in creams (Soap, Skin and hair Creams)
10. Formulation data analysis Using Design Expert® Software
11. Quality-by-Design in Pharmaceutical Development
INDUSTRIAL PHARMACY
(MIP)
MODERN PHARMACEUTICAL ANALYTICAL TECHNIQUE (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 spectroscopic analysis of various drugs in single and combination dosage forms
- Theoretical and practical skills of the spectroscopic and chromatographic instruments

THEORY 60 HOURS

UNIT I 12 Hrs

UV-Visible spectroscopy: Introduction, Theory, Laws, Instrumentation associated with UV-Visible spectroscopy, choice of solvents and solvent effect and applications of UV-Visible spectroscopy. 04 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 04 Hrs

Spectrofluorimetry: Theory of Fluorescence, Factors affecting fluorescence, Quenchers, Instrumentation and Applications of fluorescence spectroscopy. 02 Hrs

Flame emission spectroscopy and Atomic absorption spectroscopy: Principle, Instrumentation, Interferences and Applications. 02 Hrs

UNIT II 12 Hrs

NMR spectroscopy: Quantum numbers and their role in NMR, Principle, Instrumentation, Solvent requirement in NMR, Relaxation process, NMR signals in various compounds, Chemical shift, Factors influencing chemical shift, Spin-Spin coupling, Coupling constant, Nuclear magnetic double resonance 08 Hrs

Brief outline of principles of FT-NMR and 13C NMR. Applications of NMR spectroscopy. 04 Hrs
UNIT III  
12 Hrs

**Mass Spectroscopy:** Principle, Theory, Instrumentation of Mass Spectroscopy, Different types of ionization techniques like electron impact, chemical, field desorption, FAB and MALDI, APCI, ESI, APPI Analyzers and detectors. Meta stable ions, Isotopic peaks and Applications of Mass spectroscopy

UNIT IV  
12 Hrs

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

UNIT V  
12 Hrs

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

**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.  
4 Hrs

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

1. 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

2. 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


12 Hrs


REFERENCES:

ADVANCED 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

1. 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.


3. Transdermal Drug Delivery Systems: 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.

4. 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 erythorocytes, microspheres, magnetic microspheres. Specialized pharmaceutical emulsions – multiple emulsions, micro-emulsions.

**Protein / Peptide Drug Delivery Systems:** Concepts, delivery techniques, formulation, stability testing, causes of protein destabilization, stability and destabilization.

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

12 Hrs

5. **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.

**REFERENCES:**

2. Robinson, Marcel Dekker, NY, Controlled Drug Delivery Systems.
3. YW Chein, Marcel Dekker, NY, Transdermal Controlled Systemic Medications.
4. E. Mathiowitz, Marcel Dekker, NY, Bioadhesive DDS.
8. Vyas, CBS, Delhi, Pharmaceutical Biotechnology.
10. E.J. McNally, Marcel Dekker, NY, Protein Formulation & Delivery.
DRUG REGULATIONS AND INTELECTUAL PROPRTY 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

1. 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

2. Role of GATT, TRIPS, and WIPO.

12 Hrs

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

12 Hrs

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

12 Hrs

5. Regulatory requirements for contract research organization. Regulations for Biosimilars.
REFERENCE:

2. Evans, Anderson and Williams, Applied Production and Operation Management.
4. ISO 9000-Norms and explanations.
5. Willing S.H. Marcel and Dekker, GMP for pharmaceutical.
PRACTICALS (MIP104P)

Industrial pharmacy practical component includes experiments covering important topics of the courses Modern Pharmaceutical Analytical Techniques, Pharmaceutical Formulation Development, Customized drug Delivery System and Drug Regulations and Intellectual Property Rights.

List of Experiments (20)

1. Analysis of pharmacopoeial compounds and their formulations by UV Vis spectrophotometer (one)
2. Simultaneous estimation of multi component containing formulations by UV spectrophotometry (one)
3. Experiments based on HPLC (one)
4. Experiments based on Gas Chromatography (one)
5. Estimation of riboflavin/quinine sulphate by fluorimetry (one)
6. Estimation of sodium/potassium by flame photometry (one)
7. Effect of surfactants on the solubility of drugs. (one)
8. Effect of pH on the solubility of drugs. (one)
9. Dissolution methods of transdermal drug delivery systems. (one)
10. Stability testing of solution and solid dosage forms for photo degradation. (one)
11. Stability studies of drugs in dosage forms at 25°C, 60% RH and 40°C, 75% RH (one)
12. Compatibility evaluation of drugs and excipients (one)
13. Preparation and evaluation of different polymeric membranes. (one)
14. Formulation and evaluation of sustained release oral matrix tablet. (one)
15. Formulation and evaluation of sustained release oral reservoir system. (one)
16. Formulation and evaluation of microspheres / microcapsules. (one)
17. Formulation and evaluation of transdermal films. (one)
18. Design and evaluation of face wash, body- wash, creams, lotions, shampoo, toothpaste, lipstick. (one)
19. Registering for different Intellectual Property Rights in India(one)
20. Comparative study of DMF system in US, EU and Japan(one)
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.

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


drugs: Introduction, Proteins and peptides, Monoclonal antibodies, Oligonucleotides, Vaccines (immunotherapy), Gene therapies.

REFERENCES:
1. Milo Gibaldi, Philadelphia, Lea and Febiger, Biopharmaceutics and Clinical Pharmacokinetics
4. Dr. Shobha Rani R. Hiremath, Textbook of Biopharmaceutics and Pharmacokinetics, 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

1. 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.

2. Validation: General concepts, types, procedures & protocols, documentation, VMF. Analytical method validation, cleaning validation and vendor qualification.


REFERENCES:
1. JR Berry, Nash. Pharmaceutical process validation, Marcel Dekker, NY.
2. GC Cole, Taylor and Francis. Pharmaceutical Production facilities, design and applications.
3. T.Kennedy, Marcel Dekker. Pharmaceutical project management, NY.
5. PR Watt, John Wiloy. Tablet machine instruments in pharmaceuticals.
7. K.E. Avis, Marcel Dekker. Pharmaceutical dosage forms, Parentral medications, NY.
8. Lachman, Lieberman, Marcel Dekker. Dispersed system, 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

1. 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

2. 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


Disperse Systems Production: Production processes, applications of mixers, mills, disperse equipments including fine solids dispersion, problems encountered.

Packaging Technology: Types of packaging materials, machinery, labelling, package print in for different dosage forms.
5. **Air Handling Systems:** Study of AHUs, humidity & temperature control, air filtration systems, dust collectors. **Water Treatment Process:** Techniques and maintenance – RO, DM, ultra – filtration, WFI.

**REFERENCES:**

7. N.P. Chezerisionoff. *Product design and testing of polymeric materials*.
11. L. Ray, Marcel Dekker. *Freeze drying / Lyophilization of Pharmaceuticals & Biological Products*, NY.
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

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

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

3. Launching And Organising An Enterprise

4. Growth Strategies And Networking
   Performance appraisal and assessment. Profitability and control measures, demands and challenges. Need for diversification. Future Growth – Techniques of
expansion and diversification, vision strategies. Concept and dynamics. Methods, Joint venture, co-ordination and feasibility study.

5. Preparing Project Proposal To Start On New Enterprise

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

REFERENCES:

5. Patel, V.C. Women Entrepreneurship – Developing New Entrepreneurs, Ahmedabad EDII.
PRACTICALS (MIP205P)

Industrial pharmacy practical component includes experiments covering important topics of the courses Advanced Biopharmaceutics and Pharmacokinetics, Scale up and Technology Transfer, Pharmaceutical Production Technology and Entrepreneurship Management.

List of Experiments (20)

1. Improvement of dissolution characteristics of slightly soluble drug by Solid dispersion technique.(one)
2. Comparison of dissolution of two different marketed products /brands(one)
3. Protein binding studies of a highly protein bound drug & poorly protein bound drug. (one)
4. Bioavailability studies of Paracetamol. (one)
5. Pharmacokinetic and IVIVC data analysis by Winnoline® software(one)
6. *In vitro* cell studies for permeability and metabolism (one)
7. Formulation and evaluation of tablets (two)
8. Formulation and evaluation of capsules (one)
9. Formulation and evaluation of injections (two)
10. Formulation and evaluation of emulsion .(two)
11. Formulation and evaluation of suspension.(two)
12. Formulation and evaluation of enteric coating tablets. (one)
13. Review essential elements of Scale-up/Technology Transfer(one)
14. Process validation(one)
15. Presentation and defense of Business identification report(one)
16. Presentation and defense of mini business plan on business to be commenced(one)
PHARMACEUTICAL ANALYSIS
(MPA)
MODERN PHARMACEUTICAL ANALYTICAL TECHNIQUE (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 spectroscopic analysis of various drugs in single and combination dosage forms
- Theoretical and practical skills of the spectroscopic and chromatographic instruments

THEORY 60 HOURS

UNIT I 12 Hrs

UV-Visible spectroscopy: Introduction, Theory, Laws, Instrumentation associated with UV-Visible spectroscopy, choice of solvents and solvent effect and applications of UV-Visible spectroscopy. 04 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 04 Hrs

Spectroflourimetry: Theory of Fluorescence, Factors affecting fluorescence, Quenchers, Instrumentation and Applications of fluorescence spectroscopy. 02 Hrs

Flame emission spectroscopy and Atomic absorption spectroscopy: Principle, Instrumentation, Interferences and Applications. 02 Hrs

UNIT II 12 Hrs

NMR spectroscopy: Quantum numbers and their role in NMR, Principle, Instrumentation, Solvent requirement in NMR, Relaxation process, NMR signals in various compounds, Chemical shift, Factors influencing chemical shift, Spin-Spin coupling, Coupling constant, Nuclear magnetic double resonance 08 Hrs

Brief outline of principles of FT-NMR and 13C NMR. Applications of NMR spectroscopy. 04 Hrs
UNIT III 12 Hrs

**Mass Spectroscopy:** Principle, Theory, Instrumentation of Mass Spectroscopy, Different types of ionization techniques like electron impact, chemical, field desorption, FAB and MALDI, APCI, ESI, APPI Analyzers and detectors. Meta stable ions, Isotopic peaks and Applications of Mass spectroscopy

UNIT IV 12 Hrs

**Chromatography:** Principle, apparatus, instrumentation, chromatographic parameters, factors affecting resolution and applications of the following:
1. Paper chromatography
2. Thin Layer chromatography
3. Ion exchange chromatography
4. Column chromatography
5. Gas chromatography
6. High Performance Liquid chromatography
7. Affinity chromatography

UNIT V 12 Hrs

**Electrophoresis:** Principle, Instrumentation, Working conditions, factors affecting separation and applications of the following:
1. Paper electrophoresis
2. Gel electrophoresis
3. Capillary electrophoresis
4. Zone electrophoresis
5. Moving boundary electrophoresis
6. 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 8 Hrs

REFERENCES

ADVANCED PHARMACEUTICAL ANALYSIS (MPA102T)

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 stability studies of drugs and biological products.

THEORY

60 HOURS

UNIT I

Analytical principle and procedure involved in the assay of following methods with special emphasize on official drugs in IP:
- a) Complexometric titration
- b) Non aqueous titration
- c) Redox titration
- d) Diazotization titration
- e) UV – Visible method
- f) HPLC

UNIT II

Analytical principle, procedure and applications of the following reagents:
- a) 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 chlorimide
- g) 1,2- 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]

UNIT III

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

UNIT IV

12 Hrs
Biological tests and assays of the following:
a. Adsorbed Tetanus vaccine b. Adsorbed Diphtheria vaccine
c. Human anti haemophilic vaccine d. Rabies vaccine e. Tetanus Anti toxin
f. Tetanus Anti serum g. Oxytocin h. Heparin sodium IP i. Antivenom

UNIT V 12 Hrs

Impurity and stability studies
Definition, classification of impurities in drug Substance or Active Pharmaceutical Ingredients and quantification of impurities as per ICH guidelines 02 Hrs

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 03 Hrs

Impurities in residual solvents
General principles, classification of residual solvents, Analytical procedures, limits of residual solvents, Reporting levels of residual solvents 02 Hrs

Elemental impurities
Element classification, control of elemental impurities, Potential Sources of elemental Impurities, Identification of Potential Elemental Impurities, analytical procedures 02 Hrs

Stability studies
Accelerated stability testing & shelf life calculation, WHO and ICH stability testing guideline, Stability zones, photostability testing guidelines, ICH stability guidelines for biological products 03 Hrs

REFERENCES

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

- 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 Hrs

UNIT- I 12 Hrs

Concept and evolution of Quality Control and Quality Assurance,

Good Laboratory Practice, GMP, Overview of ICH Guidelines - QSEM, with special emphasis on Q-series guidelines.

Good Laboratory Practices: Scope of GLP, Definitions, Quality assurance unit, protocol for conduct of non clinical testing, control on animal house, report preparation and documentation. CPCSEA guidelines.

UNIT- II 12 Hrs

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

UNIT-III 12 Hrs

Analysis of raw materials, finished products, packaging materials, in process quality control (IPQC), Developing specification (ICH Q6 and Q3), purchase specifications and maintenance of stores for raw materials.

In process quality control and finished products quality control for following formulation in Pharma industry according to Indian, US and British pharmacopoeias: tablets, capsules, ointments, suppositories, creams, parenterals, ophthalmic and surgical products. Quality control test for containers, closures and secondary packing materials.
UNIT-IV

**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 Formula Record, Batch Formula Record, Quality audit plan and reports. Specification and test procedures, Protocols and reports. Distribution records. Electronic data.

Submission documents for regulators DMFs, as Common Technical Document and Electronic Common Technical Documentation (CTD, eCTD)

UNIT-V

**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.

Introduction, scope and importance of intellectual property rights. Concept of trade mark, copyright and patents.

REFERENCES

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


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 60 Hrs

UNIT-I 12 Hrs

a. Carbohydrates – classification and properties of food carbohydrates, General methods of analysis of food carbohydrates, Changes in food carbohydrates during processing, Digestion, absorption and metabolism of carbohydrates, Dietary fibre, crude fibre and application of food carbohydrates 06 Hrs

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 06 Hrs
UNIT-II

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. \textbf{08 Hrs}
b. Vitamins – classification of vitamins, methods of analysis of vitamins, Principles of microbial assay of vitamins of B-series. \textbf{04 Hrs}

UNIT-III

a. Food additives – Introduction, analysis of Preservatives, antioxidants, artificial sweeteners, flavors, flavor enhancers, stabilizers, thickening and jelling agent \textbf{06 Hrs}
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 \textbf{06 Hrs}

UNIT IV

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. \textbf{06 Hrs}
b. Analysis of fermentation products like wine, spirits, beer and vinegar. \textbf{06 Hrs}

UNIT V

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. \textbf{07 Hrs}
b. Legislation regulations of food products with special emphasis on BIS, Agmark and US-FDA \textbf{05 Hrs}
REFERENCES

4. Analysis of Food constituents – Multon, Wiley VCH.
PRACTICALS (MPA105P)

1. Assay of Pharmaceopoeial compounds/formulations by instrumental techniques. – UV/Visible/Fluorimetry/simultaneous estimation by UV/HPLC. (Min 5 expts)
2. Estimation of sodium/potassium/calcium by AAS/FES. (2 expts)
3. Assay of official compounds by titrimetric methods – Diazotisation/complexometry/redox titrations. (2 Expts)
4. Quantitative determination of hydroxyl/amino/carbonyl/carboxyl group. (3 Expts)
5. Colorimetric determination of drugs by using different reagents. (2 Expts)
6. IPQC and FPQC tests for pharmaceutical formulations. (3 Expts)
7. Test for related substances in pharmaceutical formulations. (2 Expts)
8. Monograph analysis of pharmacopoeial formulations. (2 Expts)
9. Determination of total reducing sugar
10. Determination of proteins
11. Determination of saponification value, Iodine value and Acid value in food products
12. Determination of fat content and peroxide value in food products
13. Analysis of natural and synthetic colors in food
14. Determination of preservatives in food
   (Minimum 24 experiments to be carried out)
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

UNIT I 12 Hrs

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

UNIT II 12 Hrs

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

UNIT III 12 Hrs

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

UNIT IV 12 Hrs

Hyphenated analytical techniques: Principle, Instrumentation and Applications of the following:

a) GC-MS  b) LC-MS  c) ICP-MS  d) LC-NMR  e) CE-MS  f) High Performance Thin Layer chromatography  g) Super critical fluid chromatography  h) Ion Chromatography  i) I-EC (Ion-Exclusion Chromatography)  j) Flash chromatography
UNIT V 12 Hrs

**Thermal methods of analysis:** Introduction, principle, instrumentation and application of DSC, DTA and TGA. 04 Hrs

**Radio Immuno Assay:** Importance, various components, Principle, Different methods, Limitation & Applications of RIA. 04 Hrs

**Optical Rotatory Dispersion:** Principle, Plain curves, Cotton effect, Circular Dichroism, Measurement of rotation angle in ORD and applications 04 Hrs

**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 60 HOURS

UNIT I 12 Hrs
Analysis of drugs in biological matrices
Analysis of drugs in use and drugs in Research and Development 03 Hrs

Biological matrix and Problems with analysis of biological matrices:
Types and Properties of the biological media, small organic molecules, peptides and protein drugs, prodrugs, formulations, drug metabolites, safety considerations. 09 Hrs

UNIT II 12 Hrs
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

UNIT III 12 Hrs
USFDA & CDSCO 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
UNIT IV

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

UNIT V

Separation techniques
Bio molecules separation and quantification by HPLC, LC MS/MS, GC/MS and Gel electrophoresis

REFERENCES:

10. ICH, USFDA & CDSCO Guidelines.
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 60 Hrs

UNIT-1 12 Hrs

Introduction to validation: Definition of Qualification and Validation, Advantages of Validation, scope of Validation, Organization for Validation, Validation Master plan, Types of Validation, Streamlining of qualification & Validation process and Validation Master Plan. 06 Hrs

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). 06 Hrs
UNIT-II 12 Hrs


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

UNIT-III 12 Hrs

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.

UNIT-IV 12 Hrs


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

UNIT V 12 Hrs

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.

REFERENCES:


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


8. Validation of Pharmaceutical Processes: Sterile Products, Frederick J. Carlton (Ed.) and James Agalloco (Ed.), Marcel Dekker


10. Huber L. Validation and Qualification in Analytical Laboratories. Informa Healthcare


COSMETIC ANALYSIS & EVALUATION (MPA204T)

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

UNIT I

12 Hrs
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.

UNIT II

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

UNIT III

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.

UNIT IV

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.
UNIT V

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 8th edition
5. Suppliers catalogue on specialized cosmetic excipients
PRACTICALS (MPA205P):

1. Comparison of absorption spectra by UV and Wood ward – Fiesure rule.
2. Interpretation of organic compounds by FT-IR. (2 Expts)
3. Interpretation of organic compounds by NMR and Mass spectra. (3 Expts)
4. Determination of purity for API by DSC. (1 Expts)

5. Bio molecules separation utilizing various sample preparation techniques and 
   Quantitative analysis of components by HPLC/LC MS. (2 Expts)
6. Protocol preparation and performance of analytical/Bioanalytical method 
   validation. (1 Expt)
7. Protocol preparation for the conduct of BA/BE studies according to guidelines (1 
   Expt)
8. Qualification of analytical instruments – UV VIS Spectrophotometer/FT 
   IR/HPLC/LCMS. (3 Expts)
9. Qualification of equipments – Dissolution apparatus/Disintegration/(2 Expts)
10. Protocol preparation for validation of stream sterilizer/autoclave unit/fluid bed 
    drier. (2 Expts)
11. Quantitative analysis of rancidity (peroxide value) in hair oils and Lipsticks
12. Determination of aryl amine content and Developer in hair dye
14. Determination of total fatty matter in creams (Soap, Skin and hair Creams)
15. Determination of acid value and saponification value.
16. Determination of calcium thioglycolate in depilatories
PHARMACEUTICAL BIOTECHNOLOGY

(MPB)
MODERN PHARMACEUTICAL ANALYTICAL TECHNIQUE (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 spectroscopic analysis of various drugs in single and combination dosage forms
- Theoretical and practical skills of the spectroscopic and chromatographic instruments

THEORY 60 HOURS

UNIT I 12 Hrs

**UV-Visible spectroscopy**: Introduction, Theory, Laws, Instrumentation associated with UV-Visible spectroscopy, choice of solvents and solvent effect and applications of UV-Visible spectroscopy. **04 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 **04 Hrs**

**Spectrofluorimetry**: Theory of Fluorescence, Factors affecting fluorescence, Quenchers, Instrumentation and Applications of fluorescence spectroscopy. **02 Hrs**

**Flame emission spectroscopy and Atomic absorption spectroscopy**: Principle, Instrumentation, Interferences and Applications. **02 Hrs**

UNIT II 12 Hrs

**NMR spectroscopy**: Quantum numbers and their role in NMR, Principle, Instrumentation, Solvent requirement in NMR, Relaxation process, NMR signals in various compounds, Chemical shift, Factors influencing chemical shift, Spin- Spin coupling, Coupling constant, Nuclear magnetic double resonance **08 Hrs**
Brief outline of principles of FT-NMR and 13C NMR. Applications of NMR spectroscopy.  

04 Hrs

UNIT III

Mass Spectroscopy: Principle, Theory, Instrumentation of Mass Spectroscopy, Different types of ionization techniques like electron impact, chemical, field desorption, FAB and MALDI, APCI, ESI, APPI Analyzers and detectors. Meta stable ions, Isotopic peaks and Applications of Mass spectroscopy

12 Hrs

UNIT IV

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

a) Paper chromatography  
b) Thin Layer chromatography  
c) Ion exchange chromatography  
d) Column chromatography  
e) Gas chromatography  
f) High Performance Liquid chromatography  
g) Affinity chromatography

12 Hrs

UNIT V

Electrophoresis: Principle, Instrumentation, Working conditions, factors affecting separation and applications of the following:

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

8 Hrs

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.

4 Hrs

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 12 Hrs

Microbiology
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 12 Hrs

Molecular Biology 05 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 12 Hrs

Cell structure and function 05 Hrs
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 03 Hrs
Cell Division and its Regulation, G-Protein Coupled Receptors, Kinases, Nuclear receptors, Cytoskeleton & cell movements, Intermediate Filaments.

Apoptosis and Oncogenes 02 Hrs
Programmed Cell Death, Tumor cells, carcinogens & repair.

Differentiation and Developmental Biology 02 Hrs

UNIT IV 12 Hrs

Principles of microbial nutrition 05 Hrs
Physical and chemical environment for microbial growth, Stability and degeneration of microbial cultures.

Growth of animal cells in culture 07 Hrs
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 12 Hrs

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

2. Prescott and Dunn, Industrial Microbiology, CBS Publishers & Distributors, Delhi.
5. R. Ian Freshney, Culture of animal cells – A manual of Basic techniques, Wileys publication house.
BIOPROCESS ENGINEERING AND TECHNOLOGY (MPB102T)

Scope
This paper has been designed to provide the knowledge to the biotechnologist 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
Basic principles of fermentation 02 Hrs

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 forfermentation, 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 cell 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

a. Organic solvents – Alcohol and Glycerol
b. Organic acids - Citric acids, Lactic acids,
c. Antibiotics - Penicillin, Streptomycin, Griseofulvin,
d. Vitamins - B12, Riboflavin and Vitamin C

e. 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

2. L.E. Casida, Industrial Microbiology, John Wiley & sons Inc.
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 –
- Understand about the latest technology development in biotechnology technique, tools and their uses in drug and vaccine development.
- Identify appropriate sources of enzymes.
- Understand and perform genetic engineering techniques in gene manipulation, r-DNA technology and gene amplification.
- Understand the overview of pharmacogenomics.
- Learn the regulatory approval process and key regulatory agencies for new drugs, biologics, devices, and drug-device combinations.

THEORY 60 Hrs

UNIT I 12 Hrs

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.

UNIT II 12 Hrs

Genetic Engineering 06 Hrs
Techniques of gene manipulation, cloning strategies, procedures, cloning vectors, expression vectors, recombinant selection and screening, expression in E.coli and yeast. Site directed mutagenesis, polymerase chain reaction, and analysis of DNA sequences.

02 Hrs
Gene library and cDNA 01 Hrs
Applications of the above technique in the production of,
- Regulatory proteins - Interferon, Interleukins 03 Hrs
- Blood products - Erythropoietin
- Vaccines - Hepatitis-B
- Hormones - Insulin

UNIT III 12 Hrs

Therapeutic peptides 05 Hrs
Study on controlled and site specified delivery of therapeutic peptides and proteins through various routes of administration.

Transgenic animals 02 Hrs
Production of useful proteins in transgenic animals and gene therapy.

Human Genome 05 Hrs
The human genome project-a brief study, Human chromosome – Structure and classification, chromosomal abnormalities – Syndromes

UNIT IV 12 Hrs

Signal transduction 08 Hrs
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.

Oncogenes 04 Hrs
Introduction, definition, various oncogenes and their proteins.

UNIT V 12 Hrs

Microbial Biotransformation 04 Hrs
Biotransformation for the synthesis of chiral drugs and steroids.

Microbial Biodegradation 04 Hrs
Biodegradation of xenobiotics, chemical and industrial wastes, Production of single-cell protein, Applications of microbes in environmental monitoring.

Biosensors 04 Hrs
Definition, characteristics of ideal biosensors, types of biosensors, biological recognition elements, transducers, application of biosensors.
REFERENCES

2. Immobilization of cells and enzymes: HosevearKennadycabral& Bicker staff
5. Modern Biotechnology: S.B Primrose
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 and Bio-autography.
19. Isolation and estimation of DNA and RNA
20. Agarose gel electrophoresis.
21. SDS – polyacrylamide gel electrophoresis for proteins
22. 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 12 Hrs

Protein engineering
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 12 Hrs

Peptidomimetics
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

2-DIMENSIONAL GEL ELECTROPHORESIS
Methods (including IPGs), resolution, reproducibility and image analysis, future developments

UNIT IV

PROTEIN FORMULATION
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
Various methods of protein sequencing, characterisation, Edman degradation, Tryptic and/or Chymotryptic Peptide Mapping.

REFERENCE
2. Protein Purification – Hand Book – 1998 Amersham pharmacia biotech
6. David Whitford, Proteins-Structure and Function, John Wiley & Sons Ltd.
7. James Swarbrick, Protein Formulation and Delivery, Informa Healthcare USA, Inc.
IMMUNOTECHNOLOGY (MPB202T)

Scope

This course is designed to impart knowledge on production 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 60 Hrs

UNIT I 12 Hrs

Fundamental aspects of immunology 06 Hrs
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 03 Hrs
B – Lymphocytes and their activation. Structure and function of immunoglobulins, idiotypes and anti idiotypic antibodies.

Cell mediated Immunity 03 Hrs
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

UNIT II 12 Hrs
Immune Regulation and Tolerance 08 Hrs
Complement activation and types and their biological functions, cytokines and their role in immune response.

Hypersensitivity 02 Hrs
Hypersensitivity Types I-IV, Hypersensitivity reactions and treatment
Autoimmune diseases 02 Hrs

UNIT III 12 Hrs

Vaccine technology 06 Hrs
Vaccine and their types, conventional vaccines, novel methods for vaccine production, antidiotype 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 12 Hrs

Hybridoma Technology

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, immuneflorescence, chemiluminescence assay.

References
1. J. Kubey, Immunology – an Introduction.
3. Ashim Chakravarthy, Immunology and Immunotechnology, Oxford University Press.
4. E. Benjamini, Molecular Immunology.
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 12 Hrs

Sequence analysis
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
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
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
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

Completed Genomes
Bacterium, Nematode, Plant and Human

Evolution of Genomes
Lateral or Horizontal Transfer among Genomes, Transcriptome and Proteome-General Account

Phylogenetic analysis

122
Evolutionary Change in Nucleotide Sequences, Rates and Patterns of Nucleotide Substitution, Models for Nucleotide Substitution, Construction of Phylogenetic Tree, Genome Annotation technique.

UNIT V 

12Hrs

Target searching and Drug Designing
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
1. David W. Mount, Bioinformatics Sequence and Genome Analysis, CBS Publishers and Distributors
7. David Posada, Bioinformatics for DNA Sequence Analysis, 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

THEORY

UNIT I

12 Hrs

Biological Standardization

04 Hrs

General principles, Scope and limitation of bio-assay, bioassay of some official drugs.

Preclinical drug evaluation

06 Hrs

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 teratogenecity and mutagenecity.

Guidelines for toxicity studies

02 Hrs

Various guidelines for toxicity studies. Animal experiments assessing safety of packaging materials.

UNIT II

12 Hrs

Pyrogens

04 Hrs

Pyrogens: Sources, Chemistry and properties of bacterial pyrogens and endotoxins, Official pyrogen tests.

Microbiological assay

04 Hrs

Assay of antibiotics and vitamins.

Biological evaluation of drugs

04 Hrs

Screening and evaluation (including principles of screening, development of models for diseases: In vivo models / In vitro models / cell line study).
UNIT III

Biologic Medicines in Development for various diseases — 06 Hrs
By Therapeutic Category
- Genetic Disorders
- Eye Conditions
- Digestive Disorders
- Diabetes/Related Conditions
- Cardiovascular Disease
- Cancer/Related Conditions
- Blood Disorders
- Autoimmune Disorders
- Infectious Diseases
- Neurologic Disorders
- Skin Diseases
- Transplantation

Biologic Medicines in Development for various diseases — 06 Hrs
by Product Category
- Antisense
- Vaccines
- Recombinant Hormones/Proteins
- Monoclonal Antibodies (mAb)
- Interferons
- Growth Factors
- Gene Therapy
- RNA Interference

UNIT IV

Regulatory aspects : Biologics and biosimilars 04 Hrs
An introduction to the regulations and documents necessary for approval of a biological product.

Regulatory consideration 04 Hrs
Regulatory consideration for pre-clinical testing and clinical testing of biologics and biosimilars.

New Drug Applications for Global Pharmaceutical Product Approvals 04 Hrs
UNIT V

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 and characterization
2. Protein biochemistry
3. Recombinant DNA Technology
4. Protein expression
5. Protein formulations
6. Database searching
7. Sequence analysis methods
8. Protein structure prediction
9. Phylogenetic analysis
10. Protein, DNA binding studies
11. Preparation of DNA for PCR applications – Isolation, Purity and Quantification
12. Introduction to PCR – working of PCR, Programming.
13. Introduction to RT-PCR – working, programming.
14. Primer design using softwares.
15. Gene DNA amplification by random / specific primers.
16. Western Blotting and Southern Hybridization
PHARMACEUTICAL CHEMISTRY
(MPC)
MODERN PHARMACEUTICAL ANALYTICAL TECHNIQUE (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 spectroscopic analysis of various drugs in single and combination dosage forms
- Theoretical and practical skills of the spectroscopic and chromatographic instruments

THEORY 60 HOURS

UNIT I

UV-Visible spectroscopy: Introduction, Theory, Laws, Instrumentation associated with UV-Visible spectroscopy, choice of solvents and solvent effect and applications of UV-Visible spectroscopy. 04 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 04 Hrs

Spectrofluorimetry: Theory of Fluorescence, Factors affecting fluorescence, Quenchers, Instrumentation and Applications of fluorescence spectroscopy. 02 Hrs

Flame emission spectroscopy and Atomic absorption spectroscopy: Principle, Instrumentation, Interferences and Applications. 02 Hrs

UNIT II

NMR spectroscopy: Quantum numbers and their role in NMR, Principle, Instrumentation, Solvent requirement in NMR, Relaxation process, NMR signals in various compounds, Chemical shift, Factors influencing chemical shift, Spin-Spin coupling, Coupling constant, Nuclear magnetic double resonance 08 Hrs

Brief outline of principles of FT-NMR and 13C NMR. Applications of NMR spectroscopy. 04 Hrs
UNIT III 12 Hrs

Mass Spectroscopy: Principle, Theory, Instrumentation of Mass Spectroscopy, Different types of ionization techniques like electron impact, chemical, field desorption, FAB and MALDI, APCI, ESI, APPI Analyzers and detectors. Meta stable ions, Isotopic peaks and Applications of Mass spectrometry

UNIT IV 12 Hrs

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

UNIT V 12 Hrs

Electrophoresis: Principle, Instrumentation, Working conditions, factors affecting separation and applications of the following: a) Paper electrophoresis b) Gel electrophoresis c) Capillary electrophoresis d) Zone electrophoresis e) Moving boundary electrophoresis f) Iso electric focusing 8 Hrs

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. 4 Hrs

REFERENCES

ADVANCED ORGANIC CHEMISTRY-1 (MPC102T)

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

Unit 1 12Hrs
Basic Aspects of Organic Chemistry
b. Types of reaction mechanisms and methods of determining them,
c. Detailed knowledge regarding the reactions, mechanisms and their relative reactivity and orientations.
   i. Nucleophilic uni- and bimolecular reactions (SN$_1$ and SN$_2$)
   ii. Elimination reactions (E$_1$ & E$_2$; Hoffman and Saytzeff’s rule)

Unit 2 12Hrs
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

Unit 3 12Hrs
Synthetic Reagents & Applications
Aluminium isopropoxide, N-Bromosuccinamide, Diazomethane, N,N’-dicyclohexylcarbodimide, Wilkinson’s reagent, Wittig reagent. Osmium tetroxide, Titanium chloride, Diazopropane, Diethyl azodicarboxylate, Triphenylphosphine,
Protecting groups
a. Role of protection in organic synthesis
b. Protection for the hydroxyl group, including 1,2-and 1,3-diols: ethers, esters, carbonates, cyclic acetals & ketals
c. Protection for the Carbonyl Group: Acetals and Ketals
d. Protection for the Carboxyl Group: amides and hydrazides, esters
e. Protection for the Amino Group and Amino acids: carbamates and amides

Unit 4

Heterocyclic Chemistry
General methods of synthesis of five, six membered and fused heterocycles such as triazole, pyrimidine, quinoline, acridine, phenothiazine and purine. Synthesis of any one representative drug from each heterocyclic nucleus.

Unit 4

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

REFERENCES

9. Organic synthesis-the disconnection approach, S. Warren, Wily India
11. Organic reaction mechanisms IV edtn, VK Ahluwalia and RK Parashar, Narosa Publishers
ADVANCED MEDICINAL CHEMISTRY (MPC103T)

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

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

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

Unit 2  12 Hrs

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

Unit 3  12 Hrs
Analog Design: Introduction, Bioisosteric replacement, rigid analogs, alteration of chain branching, changes in ring size, ring position isomers, design of stereo isomers and geometric isomers, fragments of a lead molecule, variation in inter atomic distance.
Stereochemistry and Drug action: Realization that stereo selectivity is a pre-requisite for evolution. Role of chirality in selective and specific therapeutic agents. Case studies, Enantio selectivity in drug adsorption, metabolism, distribution and elimination.

Unit 4  
Rational Design of Enzyme Inhibitors: Enzyme inhibitors in medicine, Enzyme inhibitors in basic research, rational design of non-covalently and covalently binding enzyme inhibitors.

Unit 5  
Peptidomimetics: Therapeutic values of Peptidomimetics, design of peptidomimetics by manipulation of the amino acids, modification of the peptide backbone, incorporating conformational constraints locally or globally.

REFERENCES:
CHEMISTRY OF NATURAL PRODUCTS (MPC104T)

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

Unit 1 12 Hrs
Study of Natural products as leads for new pharmaceuticals for the following class of drugs:
- a. Drugs Affecting the Central Nervous System: Morphine Alkaloids
- b. Anticancer Drugs: Paclitaxel and Docetaxel, Etoposide, and Teniposide
- c. Cardiovascular Drugs: Lovastatin, Teprotide and Dicoumarol
- d. Neuromuscular Blocking Drugs: Curare alkaloids

Unit 2 12 Hrs
Alkaloids- General introduction, classification, isolation and purification of alkaloids, general methods of structural determination of alkaloids, structural elucidation of ephedrine
Flavonoids. Introduction, isolation and purification of flavonoids, General methods of structural determination of flavonoids; Structural elucidation of quercetin

Unit 3 12Hrs
Steroids- General introduction, chemistry of sterols, sapogenin and cardiac glycosides Stereochemistry and nomenclature of steroids; Structure elucidation of cholesterol
Terpenoids – Classification, isolation, isoprene rule and general methods of structural elucidation of Terpenoids; Structural elucidation of Menthol.
Unit 4 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

Unit 5 12 Hrs
Awareness of the 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.

REFERENCES
7. O.P. Agarwal. Organic Chemistry of Natural Products Volume I and II, Krishan Prakashan
8. K. Peech and M.V.Tracey. Modern methods of plant analysis
10. P.K. Gupta .Elements of Biotechnology
15. Scikel and V. C Runeckles. Recent advances in Phytochemistry. Volume I to IV
Pharmaceutical Chemistry I (MPC101P)

A. Modern pharmaceutical analysis (5 experiments)
   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

B. To perform the following reactions of synthetic importance (5 experiments)
   1. Purification of organic solvents
   2. Claisen-Schmidt reaction.
   3. Benzylic acid rearrangement.
   5. Hoffmann rearrangement
   6. Mannich reaction

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

D. Chemistry of Natural Products (5 experiments)
   1. Estimation of elements and functional groups in organic natural compounds
   2. 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.
   3. Some typical degradation reactions to be carried on selected plant constituents
ADVANCED SPECTRAL 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

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.

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

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

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.

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

REFERENCES


ADVANCED ORGANIC CHEMISTRY (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

Unit 1 12Hrs
Green Chemistry
a. Introduction, principles of green chemistry
b. Microwave assisted reactions: Merit and demerits of its use, increased reaction rates, mechanism, superheating effects of microwave, effects of solvents in microwave assisted synthesis, microwave technology in process optimization, its applications in synthesis of organic compounds.
c. Ultrasound assisted reactions: Types of sonochemical reactions, homogenous, heterogeneous liquid-liquid and liquid-solid reactions, synthetic applications
d. Continuous flow reactors: Working principle, advantages and synthetic applications.

Unit 2 12Hrs
Chemistry of peptides
a. Coupling reactions in peptide synthesis
b. Principles of solid phase peptide synthesis, t-BOC and FMOC protocols, various solid supports and linkers: Activation procedures, peptide bond formation, deprotection and cleavage from resin, low and high HF cleavage protocols, formation of free peptides and peptide amides, purification and case studies, site-specific chemical modifications of peptides
c. Segment and sequential strategies for solution phase peptide synthesis with any two case studies
Unit 3  12Hrs

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

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

Unit 4  12Hrs

Catalysis
a. Types of catalysis, heterogeneous and homogenous catalysis, advantages and disadvantages
b. Heterogeneous catalysis – preparation, characterization, kinetics, supported catalysts, catalyst deactivation and regeneration, some examples of heterogeneous catalysis used in synthesis of drugs.
c. Homogenous catalysis, hydrogenation, hydroformylation, hydrocyanation, Wilkinson catalysts, chiral ligands and chiral induction, Ziegler-Natta catalysts, some examples of homogenous catalysis used in synthesis of drugs
d. Transition-metal and Organo-catalysis in organic synthesis: Metal-catalyzed reactions
f. Phase transfer catalysis - theory and applications

Unit 4  12Hrs

Stereochemistry & Asymmetric Synthesis
a. Basic concepts in stereochemistry – optical activity, specific rotation, racemates and resolution of racemates, the Cahn-Ingold-Prelog (CIP) sequence rule, meso compounds, pseudo asymmetric centres, axes of symmetry, Fischers D and L-notation, cis-trans isomerism, E and Z-notation.
b. Methods of asymmetric synthesis using chiral pool, chiral auxiliaries and catalytic asymmetric synthesis, enantiopure separation and Stereo selective synthesis with examples.
REFERENCES

6. Organic synthesis-the disconnection approach, S. Warren, Wily India
7. Principles of organic synthesis, ROC Norman and JMCoxan, 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 aided 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

Unit 1 12Hrs
Introduction to Computer Aided Drug Design (CADD): History, different techniques and applications.

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

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

Unit 3 12Hrs
Molecular Modeling and Docking
a. Molecular and Quantum Mechanics in drug design
c. Molecular docking and drug receptor interactions: Rigid docking, flexible docking and extra-precision docking. Agents acting on enzymes such as HMG-CoA reductase and HIV protease. Agents acting on PPAR receptors.
Unit 4  
Molecular Properties and Drug Design  
a. Prediction and analysis of ADMET properties of new molecules and its importance in drug design.  
b. *De novo* drug design: Receptor/ enzyme - interaction and its analysis, Receptor/ enzyme cavity size prediction, predicting the functional components of cavities, Fragment based drug design.  

Unit 5  
Pharmacophore Mapping and Virtual Screening  
Concept of pharmacophore, pharmacophore mapping, identification of pharmacophore features and pharmacophore modeling; conformational search used in pharmacophore mapping. Similarity based methods and pharmacophore based screening, pharmacophore and structure based *in silico* virtual screening protocols.

REFERENCES:  
11. The Practice of Medicinal Chemistry, by Wermuth C.G. (Author), Publisher: Elsevier Exclusive.
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 reactions in process chemistry
- Industrial hazards and safety aspects

THEORY 60 Hrs

Unit 1 12 Hrs
Process chemistry
a. Introduction, Synthetic strategy
b. Stages of scale up process: Bench, pilot and large scale process.
c. In-process control and validation of large scale process.
d. Impurities in API, types and their sources including genotoxic impurities

Unit 2 12 Hrs
Unit operations
a. Extraction: Liquid equilibria, extraction with reflux, extraction with agitation, counter current extraction.
b. Filtration: Theory of filtration, pressure and vacuum filtration, centrifugal filtration,
c. Distillation: Azeotropic and steam distillation
d. Evaporation: Types of evaporators, factors affecting evaporation.
e. Crystallization: Crystallization from aqueous, non-aqueous solutions factors affecting crystallization, nucleation. Principle and general methods of Preparation of polymorphs, hydrates, solvates and amorphous APIs.
Unit 3 12 Hrs
Unit Processes

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

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

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

Unit 4 12 Hrs
Unit Processes

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

b. **Fermentation:** Aerobic and anaerobic fermentation. Production of
   i. Antibiotics; Penicillin and Streptomycin,
   ii. Vitamins: B2 and B12
   iii. Statins: lovastatin, simvastatin

**Reaction progress kinetic analysis**

a. Streamlining reaction steps, route selection,

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

Unit 5 12 Hrs
Industrial Safety

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

b. Fire hazards, types of fire & fire extinguishers

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

8. P.H.Groggins. Unit processes in organic synthesis, 3rd edition, Mcgraw Hill;
9. M. Gopal: Dryden’s Outlines of Chemical Technology
10. Clausen, Mattson: Principle of Industrial Chemistry
11. Lowenheim and M.K. Moran: Industrial Chemicals
13. J.K. Stille: Industrial Organic Chemistry (PH)
14. B.K.Sharma: Industrial Chemistry
15. Occupational Health & Safety Assessment Series 1800 (OHSAS-1800) guidelines
16. ISO-14001standard/ guidelines
Pharmaceutical Chemistry II Practical (MPC201P)

A. Advanced Spectral Analysis (5 experiments)
   1. Comparison of absorption spectra by UV and Wood ward – Fieser rule
   2. Interpretation of organic compounds by FT-IR
   3. Interpretation of organic compounds by $^1$H and $^{13}$C-NMR
   4. Interpretation of organic compounds by Mass spectroscopy
   5. Determination of purity by DSC in pharmaceuticals
   6. Identification of organic compounds using FT-IR, $^1$H-NMR, $^{13}$C-NMR and Mass spectra

B. To carry out the preparation of following organic compounds (4 experiments)
   1. Preparation of 4-chlorobenzhydrylpiperazine (An intermediate for cetrizine HCl).
   2. Preparation of 4-iodotolene from p-toluidine.
   3. NaBH$_4$ reduction of vanillin to vanillyl alcohol
   4. Preparation of umbelliferone by Pechhman reaction
   5. Preparation of triphenyl imidazole
   6. To perform the Microwave irradiated reactions of synthetic importance

C. Computer Aided Drug Design (6 Experiments)
   1. Determination of log P, MR, hydrogen bond donors and acceptors of selected drugs
   2. Calculation of ADMET properties of drug molecules and its analysis
   3. Pharmacophore modeling
   4. 2D-QSAR based experiments
   5. 3D-QSAR based experiments
   6. Docking study
   7. 3D-structure of protein by Homology modeling using Fasta sequences.
   8. Electronic parameters of molecules by NMDO/DFT method and correlation with the biological activity.

D. Pharmaceutical Process Chemistry (4 experiments)
   1. Comparative study of synthesis of APIs/intermediates by different synthetic routes
   2. Synthesis of organic compounds by adapting different approaches involving
      a. Oxidation
      b. Reduction/hydrogenation
      c. Nitration
   3. Assignments on regulatory requirements in API
MODERN PHARMACEUTICAL ANALYTICAL TECHNIQUE (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 spectroscopic analysis of various drugs in single and combination dosage forms
- Theoretical and practical skills of the spectroscopic and chromatographic instruments

THEORY 60 HOURS

UNIT I 12 Hrs

UV-Visible spectroscopy: Introduction, Theory, Laws, Instrumentation associated with UV-Visible spectroscopy, choice of solvents and solvent effect and applications of UV-Visible spectroscopy. 04 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 04 Hrs

Spectrofluorimetry: Theory of Fluorescence, Factors affecting fluorescence, Quenchers, Instrumentation and Applications of fluorescence spectroscopy. 02 Hrs

Flame emission spectroscopy and Atomic absorption spectroscopy: Principle, Instrumentation, Interferences and Applications. 02 Hrs

UNIT II 12 Hrs

NMR spectroscopy: Quantum numbers and their role in NMR, Principle, Instrumentation, Solvent requirement in NMR, Relaxation process, NMR signals in various compounds, Chemical shift, Factors influencing chemical shift, Spin-Spin coupling, Coupling constant, Nuclear magnetic double resonance 08 Hrs

Brief outline of principles of FT-NMR and 13C NMR. Applications of NMR.
spectroscopy. 04 Hrs

UNIT III 12 Hrs

Mass Spectroscopy: Principle, Theory, Instrumentation of Mass Spectroscopy, Different types of ionization techniques like electron impact, chemical, field desorption, FAB and MALDI, APCI, ESI, APPI Analyzers and detectors. Meta stable ions, Isotopic peaks and Applications of Mass spectroscopy

UNIT IV 12 Hrs

Chromatography: 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

UNIT V 12 Hrs

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

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. 4 Hrs

REFERENCES

MODIFIED RELEASE 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


2. **Rate Controlled Drug Delivery Systems:** Principles & Fundamentals, Types, Activation; Modulated Drug Delivery Systems;Mechanically activated, PH activated, Enzyme activated, and Osmotic activated Drug Delivery Systems Feedback regulated Drug Delivery Systems; Principles & Fundamentals


4. **Ocular Drug Delivery Systems:** Barriers of drug permeation, Methods to overcome barriers, approachess involed in occular drug delivery system, new ophthalmic drug delivery system(NODS), bioadhesive ophthalmic drug inserts(BODI)

5. **Trans Dermal Drug Delivery Systems:** Structure of skin and barriers, Penetration enhancers, advantages and disadvantages of TDDS , formulation and evaluation of transdermal drug delivery system
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

1. **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.

12 Hrs

2. **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

12 Hrs

3. **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

12 Hrs

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

12 Hrs

5. **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 Alfred martin
11. Quality Assurance Guide; By Organization of Pharmaceutical producers of India.
13. How to practice GMPs; By P.P.Sharma. Vandhana Publications, Agra.
15. Pharmaceutical Preformulations; By J.J. Wells.
16. Applied production and operations management; By Evans, Anderson, Sweeney and Williams.
PHARMACEUTICAL REGULATORY AFFAIRS (MPH103T)

Scope

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

- To know the approval process 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

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<th>60 Hr</th>
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<td>12 hrs</td>
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</table>

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

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

3. CMC, post approval regulatory affairs. Regulation for combination products and medical devices. CTD and ECTD format, industry and FDA liaison

12 hrs

159
4. **Non clinical drug development**: Global submission of IND, NDA, ANDA. Investigation medicinal products dossier, dossier (IMPD) and investigator brochure (IB) **12 hrs**

5. **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**

PRACTICALS (MPH104P)

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

<table>
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<tr>
<th>Theory Title</th>
<th>Hrs</th>
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<tbody>
<tr>
<td>2. Targeting Methods: Introduction and Biological processes involved in targeting drug delivery system, nano particles and its types, Niosomes, Liposomes, Aquasomes, Phytosomes, Electrosomes. preparation and evaluation process of nano particles formulation</td>
<td>12</td>
</tr>
<tr>
<td>5. Veterinary Drug Delivery Systems: Tablets and bolus, Feed additives, Drinking water medication, Oral paste and gels, Drenchers and Tubing product</td>
<td>12</td>
</tr>
</tbody>
</table>

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.

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


   **Biopharmaceutics Classification System**. Solubility: Experimental methods. Permeability: In-vitro, in-situ and In-vivo methods.

2. **Biopharmaceutic Considerations in Drug Product Design and In Vitro Drug Product Performance**: Introduction, Biopharmaceutic Factors Affecting Drug...

**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

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

**Computer Simulations in Pharmacokinetics and Pharmacodynamics**: Introduction, Computer Simulation: Whole Organism, Isolated Tissues, Organs, Cell, Proteins and Genes.

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

12Hrs


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.
- Basic science to develop cosmetics and cosmeceuticals

THEORY

1. Cosmetics – Regulatory

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

2. Cosmetics – Biological aspects

Structure of skin relating to problems like dry skin, acne, pigmentation, prickle heat, wrinkles and body odor. Structure of hair and hair growth cycle. Common problems associated with oral cavity. Cleansing and care needs for face, eye lids, lips, hands, feet, nail, scalp, neck, body and under-arm.

3. Formulation Building blocks


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

Controversial ingredients: Parabens, formaldehyde liberators, dioxane.
4. Design of cosmeceutical products  
12Hrs

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 through cosmeceutical formulations.

5. Herbal Cosmetics  
12Hrs

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.

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

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

THEORY  

<table>
<thead>
<tr>
<th>UNIT I</th>
<th>12 Hrs</th>
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<tbody>
<tr>
<td><strong>UV-Visible spectroscopy</strong>: Introduction, Theory, Laws, Instrumentation associated with UV-Visible spectroscopy, choice of solvents and solvent effect and applications of UV-Visible spectroscopy.</td>
<td>04 Hrs</td>
</tr>
<tr>
<td><strong>IR spectroscopy</strong>: Theory, Modes of Molecular vibrations, Sample handling, Instrumentation of Dispersive and Fourier - Transform IR Spectrometer, factors affecting vibrational frequencies and applications of IR spectroscopy</td>
<td>04 Hrs</td>
</tr>
<tr>
<td><strong>Spectrofluorimetry</strong>: Theory of Fluorescence, Factors affecting fluorescence, Quenchers, Instrumentation and Applications of fluorescence spectroscopy.</td>
<td>02 Hrs</td>
</tr>
<tr>
<td><strong>Flame emission spectroscopy and Atomic absorption spectroscopy</strong>: Principle, Instrumentation, Interferences and Applications.</td>
<td>02 Hrs</td>
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<tr>
<th>UNIT II</th>
<th>12 Hrs</th>
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<tbody>
<tr>
<td><strong>NMR spectroscopy</strong>: 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</td>
<td>08 Hrs</td>
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<tr>
<td>Brief outline of principles of FT-NMR and 13C NMR. Applications of NMR spectroscopy.</td>
<td>04 Hrs</td>
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UNIT III 12 Hrs

**Mass Spectroscopy:** Principle, Theory, Instrumentation of Mass Spectroscopy, Different types of ionization techniques like electron impact, chemical, field desorption, FAB and MALDI, APCI, ESI, APPI Analyzers and detectors. Metastable ions, Isotopic peaks and Applications of Mass spectroscopy

UNIT IV 12 Hrs

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

UNIT V 12 Hrs

**Electrophoresis:** Principle, Instrumentation, Working conditions, factors affecting separation and applications of the following: a) Paper electrophoresis b) Gel electrophoresis c) Capillary electrophoresis d) Zone electrophoresis e) Moving boundary electrophoresis f) Iso electric focusing 8 Hrs

**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 4 Hrs

REFERENCES

ADVANCED PHARMACOGNOSY-1 (MPG102 T)

SCOPE:
To learn and understand the advances in the field of cultivation and production of plant drugs, 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

THEORY 60 Hour

UNIT 1 12 Hrs


UNIT II 12 Hrs

Marine natural products: Definition, Present status, Classification of important bioactive agents from marine sources. General methods of isolation and purification. Study of Marine toxins, Marine bio medicinals falling under the class of Cardiovascular, Anticancer, Antimicrobial, Anti-inflammatory and Antibiotic drugs.

UNIT III 12 Hrs

Nutraceuticals: General introduction, Definition, Classification, Inorganic mineral supplements, Vitamin supplements, Digestive enzymes, Probiotics, Prebiotics, Dietary fibres, Cereals and grains, Health drinks, Antioxidants, Polyunsaturated fatty acids, Herbs as functional foods. Sources, name of marker compounds and their chemical nature, medicinal uses and health benefits of following:
- Spirulina
- Soya bean
- Ginseng
- Garlic
- Broccoli
- Tea
- Flax seeds
- Black cohosh
- Turmeric.
UNIT IV  12 Hrs

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

a) Carotenoids – i) α and β - Carotene ii) Lycopene iii) Xanthophyll (Lutein)
b) Limonoids – i) d-Limonene ii) α - Terpineol
c) Saponins – i) Glycyrrhizin ii) Shatavars

d) Flavonoids – i) Resveratrol ii) Rutin iii) Hesperidin iv) Naringin v) Quercetin
e) Phenolic acids:- Ellagic acid
f) Tocotrienols and Tocopherols

UNIT V  12 Hrs

**Vegetable Bitters:**  6Hrs

Definition; Biological source, chemical structural description of the bitter principles, actions and therapeutics of following.


**Vegetable Laxatives:**  6Hrs

Biological source, chemical structural description of active principles, tests for identification/evaluation, action and therapeutics of following.


**REFERENCES:**


7) Tyler, Brady, Robbers, Pharmacognosy-

8) Peach & M.V. Tracey, Modern Methods of Plant Analysis-, Vol. I&II
11) Marine Natural Products-Vol.I to IV.
12) C.K. Atal & B.M. Kapoor, Cultivation of Medicinal Plants.
14) RD. Choudhary, Herbal Drug Industryy, 1st edition, Eastern Publisher, New Delhi, 1996.
17) T.E. Wallis, Text Book of Pharmacognosy.
PHYTOCHEMISTRY (MPG103T)

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 60 Hrs

UNIT I 12 Hrs

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. Natural products as a lead source for newer drugs. Optimization of lead compounds with suitable examples from anticancer, CNS, cardiovascular drugs, antitubercular drugs and immunomodulators.

UNIT II 12 Hrs

Extraction and Phytochemical studies: Method of extractions with emphasis on selection of method and choice of solvent for extraction, successive and exhaustive extraction and other methods of extraction commonly used and method of Fractionation. Detection of different classes of Phytoconstituents by test tube and TLC methods, latest techniques including preparative HPLC and Flash column chromatography.

UNIT III 12 Hrs


UNIT IV 12 Hrs
**Phytochemical finger printing:** HPTLC and LCMS/GCMS characterization of extracts containing alkaloids, saponins, glycosides and flavanoids.

**UNIT V**

**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:

a) Alkaloids: Ephedrine, Quinine, Strychnine, Piperine, Berberine, Taxol.

b) Glycosides: Digitoxin, Glycyrrhizin, Sennosides, Bacosides

c) Steroids: Hecogenin, guggulsterone and withanolides

d) Coumarin: Umbelliferone.

e) Flavones: Hesperidin, Myrecetin.

f) Volatile oils: Lemongrass oil, Camphor, Menthol, Eugenol.

**REFERENCES:**

1) I.L. Finar, Organic chemistry Vol.II

2) Trease and Evans, Pharmacognosy by, ELBS.

3) Tylor and Brady, Pharmacognosy.


5) A.C. Mottal, Clark’s isolation and Identification of drugs.


11) Chemistry of Natural Products- Vol. 1 onwards IWPAC.

12) Peach & M.V. Tracey, Modern Methods of Plant Analysis- Vol. I&II
INDUSTRIAL HERBAL DRUG TECHNOLOGY (MPG104T)

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

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

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

THEORY 60Hrs

UNIT 1 12 Hrs


UNIT II 12 Hrs

Institution and industries involved in herbal drug research: Indian research institution and industries involved in herbal drug research and commerce. World trade and market of herbal drugs, 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 drug industry. Concepts of TDM, GMP, GLP, ISO-9000.

UNIT III 12 Hrs

UNIT IV

Regulatory affairs in herbal drugs:  Basic principles of clinical studies, Safety and toxicology of herbal drugs. Adverse drug reaction in herbal drugs. Effect of herbal medicines on clinical laboratory testing. Regulation and dispensing of herbal drugs.

UNIT V

Patents:  5Hrs
Indian and international patent laws, proposed amendments as applicable to herbal / natural products and process.

Safety monitoring of herbal medicines:  7Hrs

REFERENCES:


PHARMACOGNOSY-1 (MPG105 P)

List of practical (25)

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. Determination of extractive value
8. Determination of volatile oil content of a drug
9. Determination of moisture content
10. Determination of haemolytic activity
11. Determination of bitterness value
12. Determination of foaming index
13. Method of extraction
14. Preliminary Phytochemical screening
15. Thin layer chromatography studies of phyto extracts
16. Demonstration of HPTLC
17. Demonstration of HPLC
18. Demonstration of GC-MS
19. Study of crude drugs under UV light
20. Determination of total solids
21. Determination of ash value
22. Determination of stomatal number and index
23. Determination of vein islet and vein termination number
24. Determination of foreign organic matter by lycopodium spore method
25. Crude fibre in vegetative crude drugs
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 60Hrs

UNIT I 12 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.

UNIT II 12 Hrs


UNIT III 12 Hrs

UNIT IV

**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.

UNIT V

**Fermentation technology:** Application of Fermentation technology, Production of Vit. B12, Vit. C, Dextrose from starch and cellulose, Streptomycin and single cell proteins

REFERENCES:

1. Bhagwani, Plant tissue culture – Vol 5. (Elsevier)
7. Jeffrey W. Pollard and John M Walker, Plant cell and tissue culture.
9. Street, Plant tissue culture by.
11. Purohit and Mathur, Biotechnology.
12. Shargool, Biotechnological applications to tissue culture.
ADVANCED PHARMACOGNOSY-II (MPG202T)

Scope:
To know and understand the Adulteration and Deterioration that occurs in herbal 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

UNIT I 12 Hrs
Herbal remedies – Toxicity and Regulations: Herbals vs Conventional drugs, Efficacy of Herbal medicine products, Validation of herbal therapies, Pharmacodynamic and Pharmacokinetic issues, Herbal drug regulations in India.

UNIT II 12 Hrs

UNIT III 12 Hrs

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


REFERENCES:

4. Tyler, Brady, Robbers, Pharmacognosy-Pharmacopoeia.
5. Peach & M.V. Tracey, Modern Methods of Plant Analysis-, Vol. I&II
8. T.E. Wallis, Text Book of Pharmacognosy by
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

- Understand the basic principles of various Indian systems of medicine
- know the clinical research of traditional medicines, Good Manufacturing Practice of Indian systems of medicine

THEORY 60Hrs

UNIT I 12 Hrs

Introduction Ayurveda, Siddha, Unani and Homoeopathy systems of medicine

Historical development Fundamental Principles, Merits and demerits, Different dosage forms,

UNIT II 12 Hrs

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.

UNIT III 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.  

UNIT IV  

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

UNIT V  

Nutrition and Balanced diet: Introduction, Nutrients – functions and deficiencies, Food and toxins, Clinical adverse reactions of herbal medicine, Indian Tribal medicine and Ethnomedicine.  

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. Swaminathan, Essential of Food and Nutrition (1999), Bappco, Bangalore.
HERBAL COSMETICS (MPG204T)

Scope
This subject deals with the study of preparation and standardization of herbal 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 cosmetic preparations
- Good Manufacturing Practices of herbal cosmetics as per the regulatory authorities

THEORY 60Hrs

UNIT I 12 Hrs
Introduction: Herbal cosmetics, Classification & Economic aspects.

UNIT II 12 Hrs

Herbal Cosmetics for the skin: Physiology and chemistry of skin and pigmentation, Cleansing cream, Lotions, Vanishing and Foundation creams, Anti- sun burn preparations, Moisturizing cream, deodorants, Face powders, Face packs, Lipsticks, Bath products, soaps and baby products.

UNIT III 12 Hrs

Herbal cosmetics for Hair & Scalp: Preparation and standardisation of the following: Shampoos, Conditioners, Tonic, Bleaches, Colorants, Depilatories and Hair oils.

UNIT IV 12 Hrs

Cosmetics for oral and Nail preparations: Preparation and standardisation of the following Dentifrices and Mouth washes & Tooth Pastes, Cosmetics for Nails.
UNIT V

Analysis of Cosmetics, Toxicity screening and test methods: Quality control and toxicity studies as per Drug and Cosmetics acts.

REFERENCES:


PHARMACOGNOSY-II (MPG205 P)

List of practical (25)

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. Determination of moisture content
8. Determination of swelling index
9. Estimation of aldehyde content
10. Estimation of phenolic content
11. Estimation of total alkaloid from vasaka leaves
12. Estimation of flavonoid content
13. Isolation of aloin from aloe
14. Resin from Indian podophyllum
15. Solanine form potatoes
16. Piperine from black pepper
17. Lawsonite from henna
18. Caffeine from tea
19. Preparation and standardization of various simple dosage forms from Ayurvedic, siddha, homoeopathy and Unani formulary.(two experiments)
20. Preparation of certain Aromatherapy formulations (two experiments)

21. Herbal formulation for skin
22. Dermatological preparation
23. Formulation of cough syrup
PHARMACOLOGY (MPL)
MODERN PHARMACEUTICAL ANALYTICAL TECHNIQUE (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 spectroscopic analysis of various drugs in single and combination dosage forms
- Theoretical and practical skills of the spectroscopic and chromatographic instruments

THEORY 60 HOURS

UNIT I 12 Hrs

UV-Visible spectroscopy: Introduction, Theory, Laws, Instrumentation associated with UV-Visible spectroscopy, choice of solvents and solvent effect and applications of UV-Visible spectroscopy. 04 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 04 Hrs

Spectrofluorimetry: Theory of Fluorescence, Factors affecting fluorescence, Quenchers, Instrumentation and Applications of fluorescence spectroscopy. 02 Hrs

Flame emission spectroscopy and Atomic absorption spectroscopy: Principle, Instrumentation, Interferences and Applications. 02 Hrs

UNIT II 12 Hrs

NMR spectroscopy: Quantum numbers and their role in NMR, Principle, Instrumentation, Solvent requirement in NMR, Relaxation process, NMR signals in various compounds, Chemical shift, Factors influencing chemical shift, Spin-Spin coupling, Coupling constant, Nuclear magnetic double resonance 08 Hrs
Brief outline of principles of FT-NMR and 13C NMR. Applications of NMR spectroscopy. 04 Hrs
UNIT III  

Mass Spectroscopy: Principle, Theory, Instrumentation of Mass Spectroscopy, Different types of ionization techniques like electron impact, chemical, field desorption, FAB and MALDI, APCI, ESI, APPI Analyzers and detectors. Meta stable ions, Isotopic peaks and Applications of Mass spectroscopy

UNIT IV  

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

UNIT V  

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

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

REFERENCES

ADVANCED PHARMACOLOGY-I (MPL101T)

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

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

UNIT-I
General Pharmacology 12 Hrs
a. Pharmacokinetics: The dynamics of drug absorption, distribution, biotransformation and elimination. Concepts of linear and non-linear compartment models. Significance of Protein binding. 06 hrs
b. Pharmacodynamics: Mechanism of drug action and the relationship between drug concentration and effect. Receptors, structural and functional families of receptors, quantitation of drug receptors interaction and elicited effects. 06 hrs

UNIT-II
Neurotransmission 06 Hrs
a. General aspects and steps involved in neurotransmission.
b. Neurohumoral transmission in autonomic nervous system (Detailed study about neurotransmitters- Adrenaline and Acetyl choline).
c. Neurohumoral transmission in central nervous system (Detailed study about neurotransmitters- histamine, serotonin, dopamine, GABA, glutamate and glycine).
d. Non-adrenergic non-cholinergic transmission (NANC). Co-transmission

Systemic Pharmacology
(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

General and local anesthetics
Sedatives and hypnotics, drugs used to treat anxiety.
Depression, psychosis, mania, epilepsy, neurodegenerative diseases.
Narcotic and non-narcotic analgesics.

UNIT-IV

Cardiovascular Pharmacology

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

UNIT- V

Autocoid Pharmacology

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

REFEREENCES:

1. Brunton, L. L., Lazo, J., & Parker, K. The pharmacological basis of therapeutics.
   pathophysiologic basis of drug therapy. Lippincott Williams & Wilkins.
5. Gibaldi, M., & Prescott, L. F. Handbook of clinical pharmacokinetics. ADIS Health
   Science Press.
   Lippincott Williams & Wilkins.
7. Leon Shargel., Andrew BC Yu., and Susanna Wu-Pong. Applied biopharmaceutics
Scope

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

Objectives

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

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

THEORY 60 Hrs

Unit-I 12 Hrs

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

Unit-II 12 Hrs

Preclinical screening of new substances for the pharmacological activity using in vivo, in vitro, and other possible animal alternative models.
Unit-III
12 Hrs
Preclinical screening of new substances for the pharmacological activity using in vivo, in vitro, and other possible animal alternative models.
Respiratory Pharmacology: anti-asthmatics, drugs for COPD and anti allergics.

Unit-IV
12 Hrs
Preclinical screening of new substances for the pharmacological activity using in vivo, in vitro, and other possible animal alternative models.
Cardiovascular Pharmacology: antihypertensives, antiarrythmics, antianginal, antiatherosclerotic agents and diuretics. Drugs for metabolic disorders like anti-diabetic, antihyperlipidemic, and anticancer agents

Unit V
12 Hrs
Preclinical screening of new substances for the pharmacological activity using in vivo, in vitro, and other possible animal alternative models.
Immunosuppressants and immunomodulators
General principles of immunoassay: theoretical basis and optimization of immunoassay, heterogeneous and homogenous immunoassay systems. Immunoassay methods evaluation; protocol outline, objectives and preparation. Immunoassay for digoxin and insulin

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

REFERENCES :
2. Indian Pharmacopeia and other Pharmacopeias
7. McLeod, L. J. Pharmacological experiments on intact preparations. Churchill Livingstone
CELLULAR AND MOLECULAR PHARMACOLOGY (MPL103T)

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

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

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

Unit I 12 Hrs
Cell biology
Structure and functions of cell and its organelles

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

Unit III 12Hrs
Principles and applications of genomic and proteomic tools 06 hrs
DNA electrophoresis, PCR (reverse transcription and real time), Gene sequencing, microarray technique, SDS page, ELISA and western blotting,
Recombinant DNA technology and gene therapy 06 hrs
Basic principles of recombinant DNA technology—Restriction enzymes, various types of vectors. Applications of recombinant DNA technology. 
Gene therapy—Various types of gene transfer techniques, clinical applications and recent advances in gene therapy

Unit IV
Pharmacogenomics
12 Hrs
Gene mapping and cloning of disease gene. Importance of siRNA and micro RNA
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
12 Hrs
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 and glucose uptake assay. Principles and applications of flow cytometry

References:
2. Licinio J & Wong M Pharmacogenomics: The Search for Individualized Therapies, Wiley. Weinheim (Germany).
PHARMACOLOGY PRACTICAL - I (MPL104P)

List of Experiments (20)
1. Various routes of drug administration in laboratory animals.
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, anxiogens and anxiolytic, anticonvulsant activity.
5. Evaluation of analgesic, anti-inflammatory, local anesthetic, mydriatic and miotic activity.
8. Oral glucose tolerance test.
9. Isolation and identification of DNA from various sources (Bacteria, Cauliflower, onion, Goat liver).
10. Isolation of RNA from yeast
11. Estimation of proteins by Braford/Lowry’s in biological samples.
12. Estimation of RNA/DNA by UV Spectroscopy
13. Gene amplification by PCR.
14. Protein quantification Western Blotting.
15. Enzyme based in-vitro assays (MPO, AChEs, α amylase, α glucosidase).
17. DNA fragmentation assay by agarose gel electrophoresis.
18. DNA damage study by Comet assay.
19. Extraction of drug from various biological samples and estimation of drugs in biological fluids using different analytical techniques (UV)
20. Extraction of drug from various biological samples and estimation of drugs in biological fluids using different analytical techniques (HPLC)

Reference
1. CPCSEA, OECD, ICH, USFDA, Schedule Y, EPA guidelines,
ADVANCED PHARMACOLOGY-II (MPL201T)

Scope

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

Objectives

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

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

UNIT-I

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

UNIT-II

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

UNIT-III

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

Immunopharmacology 06 Hrs
Cellular and biochemical mediators of inflammation and immune response. Allergic or hypersensitivity reactions. Pharmacotherapy of asthma and COPD.
Immunosuppressants and Immunostimulants
UNIT-IV

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

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

UNIT-V

Free radicals Pharmacology 04 Hrs
Generation of free radicals, role of free radicals in etiopathology of various diseases such as diabetes, neurodegenerative diseases and cancer.
Protective activity of certain important antioxidant

Recent Advances in Treatment of: 08 Hrs
Alzheimer’s disease, Parkinson’s disease, Cancer, Diabetes mellitus

References
PRINCIPLES OF TOXICOLOGY
(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.

**REFERENCES**

5. OECD test guidelines.
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**

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**

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

Prodrug design-Basic concept, Prodrugs to improve patient acceptability, Drug solubility, Drug absorption and distribution, site specific drug delivery and sustained drug action. Rationale of prodrug design and practical consideration of prodrug design

**References:**

2. León, D., & Markel, S. In Silico technologies in drug target identification and validation. CRC Press.
CLINICAL PHARMACOLOGY (MPL204T)

Scope:
This subject will provide in-depth knowledge of Clinical Pharmacology and current status of clinical research. This will help the student to excel in the field of Clinical Drug Development.

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

UNIT-I 12 Hrs

Introduction to Clinical Pharmacology 08 Hrs

Definition, scope and development of clinical pharmacology, role of pharmacist in healthcare system, prescription monitoring and rational use of drugs, essential drugs and national drug policy, pharmacoepidemiology, patient counselling, medication errors and drug information systems.

Concept of Pharmaceutical Care and its Implementation 04 Hrs

Plan, components and challenges, communication and behavioural skills in clinical pharmacology practice.
UNIT- II 12 Hrs

Drug Therapy in Specialized Patient Populations

Neonates : 04 Hrs
Special childhood diseases and their management, national immunization programmes, relevant paediatric management issues as dosages adjustment, pharmacokinetics of development stage and compliance.

Geriatrics : 04 Hrs
Pharmaceutical care plan based on age related physiological and pharmacokinetic/pharmacodynamic changes, compliance related issues.

Pregnancy and Lactation : 04 Hrs

UNIT- III 12 Hrs

Clinical Trials

Requirement of clinical trials, Helsinki declaration, ethical and legal issues in clinical trials.
Design (placebo, multicentre clinical trials, randomization, blinding) and different phases of clinical trials (Phase 1 to 4), principles of controlled clinical trials.
Protocol designing, CRF, patient informed consent, patient enrolment, inclusion and exclusion criteria, withdrawals and drop out, run-in period.
Clinical trial team, monitoring of clinical trial, report preparation, deviations in clinical trials.
Clinical data management.

UNIT-IV 12 Hrs

Basic aspects, terminologies and establishment of Pharmacovigilance

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

Roles and responsibilities in Pharmacovigilance

UNIT-V

Adverse Drug Reactions

Incidence, importance, surveillance and their monitoring WHO ADR reporting programmes in India and drug interactions.

National and International Guidelines and Drug Regulations and Recent Development in Clinical Research

Good Clinical practice, ICH guidelines, FDA/EMEA documentation preparation.

Telemedicine

History and advance in telemedicine, benefits and limitations of telemedicine.

References:

3. Shargel, L., & Swanson, L. N. Comprehensive pharmacy review. Lippincott Williams & Wilkins.
Pharmacology Practical-II (MPL205P)

List of Experiments (20)

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 $PA_2$ values of various antagonists using suitable isolated tissue preparations.
8. To study the effects of various drugs on isolated heart preparations
9. Recording of rat BP, heart rate and ECG.
10. Drug absorption studies by averted rat ileum preparation.
11. Acute oral toxicity studies as per OECD guidelines.
12. Acute dermal toxicity studies as per OECD guidelines.
13. Repeated dose toxicity studies- Serum biochemical, haematological, urine analysis, functional observation tests and histological studies.
15. Protocol design for clinical trial.
17. Design of ADR monitoring protocol.
18. In silico docking studies.
19. In silico pharmacophore based screening.
20. In silico QSAR studies.
References

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

UNIT I 12 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)

UNIT II 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

UNIT III 12 Hrs

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

**UNIT IV**

**Lab Data Interpretation:**
Tests associated with cardiac disorders, Pulmonary function tests, Thyroid function tests, Fluid and electrolyte balance, Microbiological culture sensitivity tests

**UNIT V**

**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

**REFERENCES**

2. The Society of Hospital Pharmacists of Australia. Practice Standards and Definitions.
3. Scott LT. Basic skills in interpreting laboratory data - American Society of Health System Pharmacists Inc.
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

UNIT I 12 Hrs

Cardiovascular system:

Hypertension, Congestive cardiac failure, Acute coronary syndrome, Arrhythmias, Hyperlipidemias, Rheumatic heart disease

UNIT II 12 Hrs

Respiratory system:

Asthma, Chronic obstructive airways disease, Drug induced pulmonary diseases

Endocrine system:
Diabetes, Thyroid diseases

UNIT III

Gastrointestinal system:
Peptic ulcer diseases, Reflux esophagitis, Inflammatory bowel diseases, Jaundice & hepatitis

UNIT IV

Gastrointestinal system:
Cirrhosis, Diarrhea and Constipation, Drug-induced liver disease

Hematological diseases:
Anemia, Deep vein thrombosis, Drug induced hematological disorders

UNIT V

Bone and joint disorders:
Rheumatoid arthritis, Osteoarthritis, Gout, Osteoporosis

Dermatological Diseases:
Psoriasis, Eczema and scabies, impetigo, drug induced skin disorders

Ophthalmology:
Conjunctivitis, Glaucoma

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 Publication
7. Carol Mattson Porth. Principles of Pathophysiology—Lippincott Williams and Wilkins Publication
9. Relevant review articles from recent medical and pharmaceutical literature
Hospital & Community Pharmacy (MPP103T)

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
- Understand drug policy and drug committees
- Know about procurement & drug distribution practices
- Know the admixtures of radiopharmaceuticals
- Understand the community pharmacy management
- Know about value added services in community pharmacies

THEORY 60 Hrs

UNIT I 12 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

UNIT II 12 Hrs

Hospital Drug Policy:
Hospital Formulary Guidelines and its development, Developing Therapeutic guidelines,

Drug House Management:
Drug procurement process, and methods of Inventory control, Methods of Drug distribution, Intravenous admixtures, Hospital Waste Management

UNIT III 12 Hrs
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

UNIT IV
12 Hrs

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

UNIT V
12 Hrs

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

REFERENCES
1. Hassan WE. Hospital Pharmacy. Lec and Febiger Publication.
3. Trevor M Speight and Nicholas H G Holford. Avery’s Drug Treatment. Wiley India Pvt. Ltd.
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

UNIT I

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
UNIT II  

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.

UNIT III  

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

UNIT IV  

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

UNIT V 12 Hrs

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

10. Relevant review articles from recent medical and pharmaceutical literature.
Pharmacy Practice Practical - I (MPP101P)

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 (20)
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 (five)
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 (one)
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 60 Hrs

UNIT I 12 Hrs

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

UNIT II 12 Hrs

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

UNIT III
12 Hrs

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

UNIT IV
12 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

UNIT V
12 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
REFERENCES:

6. Online:
7. 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

UNIT I 12 Hrs

Nervous system:
Epilepsy, Parkinson's disease, Stroke, Headache, Alzheimer’s disease, Neuralgias and Pain pathways and Pain management

UNIT II 12Hrs

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
UNIT III 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

UNIT IV 12 Hrs

**Infectious diseases:**
Meningitis, HIV and opportunistic infections, Dengue fever, H1N1, Helmenthiasis, Fungal infections

**Gynaecological disorders:**
Dysmenorrhea, Hormone replacement therapy

UNIT V 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

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 Publication
7. Carol Mattson Porth. Principles of Pathophysiology- Lippincott Williams and Wilkins Publication
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, pharmacometrics 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 pharmacometrics

THEORY 

UNIT I 

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
UNIT II

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 Pharmacometrics:
Introduction to Bayesian Theory, Adaptive method or Dosing with feedback, Analysis of Population pharmacokinetic Data

UNIT III

Non Linear 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, Pharmacometrics software

UNIT IV

Altered Pharmacokinetics:
Drug dosing in the elderly, Drug dosing in the paediatrics, Drug dosing in the obese patents, Drug dosing in the pregnancy and lactation, Drug dosing in the renal failure and extracorporeal removal of drugs, Drug dosing in the in 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

REFERENCES


12. Relevant review articles from recent medical and pharmaceutical literature
Pharmacoepidemiology & Pharmacoeconomics (MPP204T)

Scope

This course enables 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

UNIT I 12 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
UNIT II 12 Hrs

Pharmacoepidemiological Methods:
Qualitative models: Drug Utilization Review; Quantitative models: case reports, case series, Cross sectional studies, Cohort and case control studies, Calculation of Odds ratio, Meta analysis models, Drug effects study in populations: Spontaneous reporting, Prescription event monitoring, Post marketing surveillance, Record linkage systems, Applications of pharmacoepidemiology

UNIT III 12 Hrs

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.

UNIT IV 12 Hrs

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).

UNIT V 12 Hrs

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
REFERENCES

11. Relevant review articles from recent medical and pharmaceutical literature
Pharmacy Practice Practical - II (MPP205P)

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 Pharmacoepidemiology and Pharmacoeconomics.

List of Experiments (20)
1. Causality assessment of adverse drug reactions (three)
2. Detection and management of medication errors (two)
3. Rational use of medicines in special population (two)
4. Presentation of clinical cases of various disease conditions adopting Pharmaceutical Care Plan Model (six)
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)
PHARMACEUTICAL QUALITY ASSURANCE
(MQA)
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 spectroscopic analysis of various drugs in single and combination dosage forms
- Theoretical and practical skills of the spectroscopic and chromatographic instruments

THEORY 60 HOURS

UNIT I 12 Hrs

UV-Visible spectroscopy: Introduction, Theory, Laws, Instrumentation associated with UV-Visible spectroscopy, choice of solvents and solvent effect and applications of UV-Visible spectroscopy. 04 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 04 Hrs

Spectroflourimetry: Theory of Fluorescence, Factors affecting fluorescence, Quenchers, Instrumentation and Applications of fluorescence spectroscopy. 02 Hrs

Flame emission spectroscopy and Atomic absorption spectroscopy: Principle, Instrumentation, Interferences and Applications. 02 Hrs

UNIT II 12 Hrs

NMR spectroscopy: Quantum numbers and their role in NMR, Principle, Instrumentation, Solvent requirement in NMR, Relaxation process, NMR signals in various compounds, Chemical shift, Factors influencing chemical shift, Spin-Spin coupling, Coupling constant, Nuclear magnetic double resonance 08 Hrs

Brief outline of principles of FT-NMR and 13C NMR. Applications of NMR spectroscopy. 04 Hrs
UNIT III 12 Hrs

Mass Spectroscopy: Principle, Theory, Instrumentation of Mass Spectroscopy, Different types of ionization techniques like electron impact, chemical, field desorption, FAB and MALDI, APCI, ESI, APPI Analyzers and detectors. Meta stable ions, Isotopic peaks and Applications of Mass spectroscopy

UNIT IV 12 Hrs

Chromatography: 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

UNIT V 12 Hrs

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

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 4 Hrs

REFERENCES

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

UNIT I 12 Hrs

Introduction to Quality 02 Hrs

Evolution of Quality, Definition of Quality, Dimensions of Quality

Quality as a Strategic Decision 03 Hrs

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 04 Hrs

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

Cost of Quality 03 Hrs
Cost of quality, Categories of cost of quality, Models of cost of quality, Optimising costs, Preventing cost of quality

UNIT II  
Pharmaceutical quality Management


UNIT III  
Six System Inspection model

Quality Management system, Production system, Facility and Equipment system, Laboratory control system, Materials system, Packaging and labeling system.

Quality systems


UNIT IV  
Drug Stability

ICH guidelines for stability testing of drug substances and drug products.

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

UNIT V  
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

**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

**REFERENCES:**

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

- 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.

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Concept and evolution of Quality Control and Quality Assurance,

Good Laboratory Practice, GMP, Overview of ICH Guidelines - QSEM, with special emphasis on Q-series guidelines.

Good Laboratory Practices: Scope of GLP, Definitions, Quality assurance unit, protocol for conduct of non clinical testing, control on animal house, report preparation and documentation. CPCSEA guidelines.

UNIT- II | 12 Hrs |

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

UNIT-III | 12 Hrs |

Analysis of raw materials, finished products, packaging materials, in process quality control (IPQC), Developing specification (ICH Q6 and Q3), purchase specifications and maintenance of stores for raw materials.

In process quality control and finished products quality control for following formulation in Pharma industry according to Indian, US and British pharmacopoeias: tablets, capsules, ointments, suppositories, creams, parenterals, ophthalmic and surgical products, Quality control test for containers, closures and secondary packing materials.
UNIT-IV  12 Hrs

Documentation in pharmaceutical industry: Three tier documentation, Policy, Procedures and Work instructions, and records (Formats), Basic principles - How to maintain, retention and retrieval etc. Standard operating procedures (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.

Submission documents for regulators DMFs, as Common Technical Document and Electronic Common Technical Documentation (CTD, eCTD)

UNIT-V  12 Hrs

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

Introduction, scope and importance of intellectual property rights. Concept of trade mark, copyright and patents.

REFERENCES


7. ICH guidelines

8. ISO 9000 and total quality management


PRODUCT DEVELOPMENT AND TECHNOLOGY TRANSFER
(MQA103T)

Scope

This deals 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

UNIT I 12 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.

UNIT II 12 Hrs

Preformulation studies

Introduction/concept, organoleptic properties, purity, impurity profiles, particle size, shape and surface area. Solubility, Methods to improve solubility of Drugs: Surfactants & its importance, co-solvency. Techniques for the study of Crystal properties and polymorphism. Preformulation protocol, Stability testing during product development.
UNIT III  

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.

UNIT IV  

Pharmaceutical packaging  


Quality control test  

Containers, closures and secondary packing materials.

UNIT V  

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.

REFERENCES


QUALITY ASSURANCE PRACTICAL-I (MQA104P)

PRACTICALS

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. 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
8. Development of Stability study protocol
9. Estimation of process capability
10. In process and finished product quality control tests for tablets, capsules, parenterals and creams
11. Assay of raw materials as per official monographs
12. Testing of related and foreign substances in drugs and raw materials
13. To carry out preformulation study for tablets, parenterals (2 experiment).
14. To study the effect of pH on the solubility of drugs, (1 experiment)
15. Quality control tests for Primary and secondary packing materials
16. Accelerated stability studies (1 experiment)
17. Improved solubility of drugs using surfactant systems (1 experiment)
18. Improved solubility of drugs using co-solvency method (1 experiment)
HAZARDS AND SAFETY MANAGEMENT (MQA201T)

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 that safety in chemical 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 60 Hrs

UNIT I 12 Hrs

Multidisciplinary nature of environmental studies 07 Hrs

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 05 Hrs

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

UNIT III  
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.

UNIT IV  
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.

UNIT V  
12 Hrs

Hazard and risk management

Self-protective measures against workplace hazards. Critical training for risk management, Process of hazard management, ICH guidelines on risk assessment and Risk management methods and Tools

Factory act and rules, fundamentals of accident prevention, elements of safety programme and safety management, Physicochemical measurements of effluents, BOD, COD, Determination of some contaminants, Effluent treatment procedure,
REFERENCES:
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 60 Hrs

UNIT I 12 Hrs

Introduction to validation 06 Hrs
Definition of Qualification and Validation, 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 06 Hrs
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).
UNIT II  
12 Hrs  
Qualification of manufacturing equipment  
06 Hrs  
Dry Powder Mixers, Fluid Bed and Tray dryers, Tablet Compression (Machine), Dry heat sterilization/Tunnels, Autoclaves, Membrane filtration, Capsule filling machine.

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

UNIT III  
12 Hrs  
Qualification of laboratory equipments  
06 Hrs  
Hardness tester, Friability test apparatus, tap density tester, Disintegration tester, Dissolution test apparatus

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

UNIT IV  
12 Hrs  
Process Validation  
10 Hrs  
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  
02 Hrs  
General principles, Validation of analytical method as per ICH guidelines (Q2) and USP.

UNIT V  
12 Hrs  
Cleaning Validation  
04 Hrs  
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. 04 Hrs

Computerized system validation 04 Hrs

Electronic records and digital signature - 21 CFR Part 11 and GAMP 5. 12 Hrs

REFERENCES:


3. Terveeks and Deeks. Validation Master plan. Davis Harwood International publishing.


10. Huber L. Validation and Qualification in Analytical Laboratories. Informa Healthcare


AUDITS AND REGULATORY COMPLIANCE (MQA203T)

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 60 Hrs

UNIT I 12 Hrs
Introduction
Objectives, Management of audit, Responsibilities, Planning process, information gathering, administration, Classifications of deficiencies

UNIT II 12 Hrs
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.

UNIT III 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.

UNIT IV 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.

UNIT V

Auditing of Quality Assurance and engineering department 12 Hrs


REFERENCES

PHARMACEUTICAL MANUFACTURING TECHNOLOGY (MQA204)

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

UNIT I

Pharmaceutical industry developments

Licenses for 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.

60Hrs

UNIT I

12 Hrs

04 Hrs

04 Hrs
UNIT II

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.

Process Automation in Pharmaceutical Industry

With specific reference to manufacturing of sterile semisolids, Small Volume Parenterals & Large Volume Parenterals (SVP & LVP), Monitoring of Parenteral manufacturing facility, Cleaning in Place (CIP), Sterilization in Place (SIP), Prefilled Syringe, Powdered Jet, Needle Free Injections, and Form Fill Seal Technology (FFS).

Lyophilization technology: Principles, process, equipment.

UNIT III

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).

Advance non-sterile solid product manufacturing technology

Process Automation in Pharmaceutical Industry with specific reference to manufacturing of tablets and coated products, Improved Tablet Production: Tablet production process, granulation and pelletization equipments, continuous and batch mixing, rapid mixing granulators, rota granulators, spheronizers and marumerisers, and other specialized granulation and drying equipments. Problems encountered.
Coating technology  

02 Hrs

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

UNIT IV

Containers and closures for pharmaceuticals  

12 Hrs

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.

UNIT V

Quality by design (QbD) and process analytical technology (PAT)  

12 Hrs

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.
REFERENCES


QUALITY ASSURANCE PRACTICAL-II(MQA205P)

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
   a. Autoclave b. Hot air oven c. Powder Mixer (Dry) d. Tablet Compression Machine
8. Validation of an analytical method for a drug
9. Validation of a processing area
10. Qualification of at least two analytical instruments
11. Cleaning validation of one equipment
12. Qualification of Pharmaceutical Testing Equipment (Dissolution testing apparatus, Friability Apparatus, Disintegration Tester)
13. Check list for Bulk Pharmaceutical Chemicals vendors
14. Check list for tableting production.
15. Check list for sterile production area
16. Check list for Water for injection.
17. Design of plant layout: Sterile and non-sterile
18. Case study on application of QbD
19. Case study on application of PAT
PHARMACEUTICAL REGULATORY AFFAIRS
(MRA)
GOOD PHARMACEUTICAL PRACTICES (MRA 101T)

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

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

- The check lists for various Good Pharmaceutical Practices and
- Prepare SOPs for Good Pharmaceutical Practices
- Implement Good Pharmaceutical Practices in the Industries and
- Prepare for the Audit of the Pharmaceutical Industries.

THEORY 60Hrs

2. **Good Laboratory Practices:** Introduction, USFDA GLP Regulations (Subpart A to Subpart K), Controlling the GLP inspection process, GLP Documentation, Audit, goals of Laboratory Quality Audit, Audit tools, Future of GLP regulations 12Hrs


4. **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) 12Hrs

5. **Quality management systems:** Concept of Quality, Total Quality Management, Quality by design, Six Sigma concept, Out of Specifications (OOS), Change control. Validation: Types of Validation, Types of Qualification, Validation 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.

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.
PHARMACEUTICAL REGULATIONS IN INDIA (MRA 102T)

Scope:
This course is designed to impart fundamental knowledge on pharmaceutical regulations in India. It prepares the students for basic regulatory requirements in India of drug products for import, export, manufacture, 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 pharmaceutical industry in India.
- Understand the approval process and regulatory requirements for drugs and medical devices

THEORY 60 HOURS

UNIT I
- Pharmaceutical Research and Development, Indian Pharmaceutical Industry
- Acts and Rules (with latest amendments):
  - Drugs and Cosmetics Act 1940 and its Rules 1945: DPCO and NPPA
  - Legal definitions of schedules to the Act and Rules, Import of drugs, Manufacture of drugs, Sale of Drugs, Labelling & Packing of drugs
  - Registration of drugs /Medical devices in India 12 Hrs

UNIT II
CDSCO (Central Drug Standard Control Organization) and State Licensing Authority:
Organization, Responsibilities, Common Technical Document (CTD), Regulatory requirements and approval procedures for:
- Clinical Trials
- New Drugs
- Medical Devices
- Fixed Dose Combinations 12 Hrs
UNIT III
Regulatory requirements and approval procedures for:

- Existing Drugs
- Traditional Drugs
- Cosmetics
- Narcotics
- Recombinant DNA
- Types of regulatory approval /Licensing
- Nutraceuticals

12 Hrs

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/ humans
- Animal testing: Rationale for conducting studies, CPCSEA Guidelines
- Human testing: ICMR guidelines ethical guidelines for human participants
- ICMR-DBT Guidelines for Stem Cell Research

12 Hrs

UNIT V
Intellectual Property Rights: Patent, Trademark, Copyright, Industrial Designs and
Geographical Indications, Indian Patent Scenario. IPR vs Regulatory Affairs

12 Hrs

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 Practicel 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 PHARMACEUTICAL REGULATIONS-I (MRA103T)

Scope:
This course is designed to impart the fundamental knowledge on the drug development process, regulatory requirements for approval of new drugs, drug products in regulated countries like US, EU, and Japan. It prepares the students to learn in detail on the regulatory requirements, documentation requirements, and registration procedures for marketing the drug products in regulated countries.

Objectives: Upon completion of the course, the student shall be able to know
- process of drug discovery and development and generic product development
- regulatory approval process and registration procedures for API and drug products in US, EU and Japan

THEORY 60 Hours
Unit-I 12 Hours
Drug product development: New Drug Discovery and development, in vitro and in vivo drug product performance, BA/BE studies, outsourcing BA/BE studies to Contract research organizations (CRO), Investigator’s Brochure (IB), Chemistry and Manufacturing Controls (CMC), Genotoxic impurities.
Regulatory Submissions: Common Technical Document (CTD) modules and granularity, eCTD submissions

Unit-II 12 Hours
Generic drug product development: Introduction, Concept of generics, Active Pharmaceutical Ingredients, Analytical Method development and validation, Experimental Formulation Development, Scale-up, post approval changes (SUPAC), Post marketing surveillance, process validation and technology transfer, Quality control and quality assurance, Legal and legislative hurdles to Generic drug development, approval and marketing

Unit-III 12 Hours
(IND), New Drug Application (NDA), Abbreviated New Drug Application (ANDA), Supplemental New Drug Application (SNDA); Regulatory requirements for Orphan drugs and Combination Products, Changes to an approved NDA / ANDA. Regulatory considerations for manufacturing, packaging and labeling of pharmaceuticals in USA

**Unit-IV**

12 Hours

**European Union:** 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-V**

12 Hours

**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

**REFERENCES:**

2. The Pharmaceutical Regulatory Process, Edited by Ira R. Berry Marcel Dekker Series, Vol.144
6. Drugs: From Discovery to Approval, Second Edition By Rick Ng
9. 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 drugs and pharmaceuticals, phases and conduct of clinical trials and research, regulations and guidance governing the conduct of clinical research in USA and EU. 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 research.

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
- History, origin and ethics of clinical research
- regulatory requirements for conducting clinical trials and research
- regulations and guidance governing the conduct of clinical research

THEORY

Unit-I
Clinic drug development process
- 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, multinational, registration studies)
- Phase IV studies (Post marketing authorization studies; pits and practices)
- Ethical principles governing informed consent process
- Patient Information Sheet and Informed Consent Form
- The informed consent process and documentation

Unit-II
Ethics in Clinical Research:
- 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

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

UK: Clinical Research regulations in UK (MHRA)
EU: Clinical Research regulations in European Union (EMA)
India: Clinical Research regulations in India – Schedule Y

Unit-IV

Clinical Research Related Guidelines

• 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

12 Hours
USA & EU Guidance

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:

2. Code of Federal Regulations, 
   FDA: http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/cfrsearch.cfm
3. Guidelines of International Conference on Harmonization: 
5. FDA New Drug Application: 
7. Central Drugs Standard Control Organization Guidance for Industry: 
8. ICMR Ethical Guidelines for Biomedical Research: 
   http://icmr.nic.in/ethical_guidelines.pdf
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
DOCUMENTATION AND REGULATORY WRITING (MRA 201T)

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:
1. Know the various documents pertaining to drugs in pharmaceutical industry
2. Understand the basics of regulatory compilation
3. Create and assemble the regulation submission as per the requirements of agencies
4. Follow up the submissions and post approval document requirements

THEORY

60 Hours

12 Hrs

1. 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).

12 Hrs


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

12 Hrs

4. **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)  

5. **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
8. Corporate Culture and the Quality Organization By James W. Fairfield-Sonn, Quorum Books, 2001
BIOLOGICS REGULATIONS (MRA 202T)

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
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
3. 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
4. **Vaccine regulations in India, US and European Union**: Clinical evaluation, Marketing authorisation, Registration or licensing, Quality assessment, Pharmacovigilance, Additional requirements

12 Hrs

Unit V

5. **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 › Biologics
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

1. Emerging Market: Introduction, Countries covered, Study of the world map, study of various committees across the globe (ASEAN, APEC, EAC, GCC, PANDRH, SADC) 12Hrs

2. 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) 12Hrs

3. 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. 12Hrs

4. 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 12Hrs
5. **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

**REFERENCES**

5. Outsourcing to India: The Offshore Advantage, Mark Kobayashi-Hillary, Springer
10. Realizing the ASEAN Economic Community: A Comprehensive Assessment, Michael G Plummer (Editor), Chia Siow Yue (Editor), Instute of South east asian studies, Singapore
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 Asian 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, WHO and Asia
- clinical aspects of medical devices

THEORY

60 Hours

Unit-I 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 12 Hours
Ethics: 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 \textit{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 \textit{In vitro} diagnostics, classification and approval process.

\textbf{Unit-IV} \hspace{2cm} 12 Hours
\textbf{European Union:} Introduction, Classification, Regulatory approval process for Medical Devices (Medical Device Directive, Active Implantable Medical Device Directive) and \textit{In vitro} Diagnostics (\textit{In Vitro} Diagnostics Directive), CE certification process. Basics of \textit{In vitro} diagnostics, classification and approval process.

\textbf{Unit-V} \hspace{2cm} 12 Hours
\textbf{Medical Device Regulations in World Health Organization (WHO):} Registration Procedures, Quality System requirements and Regulatory requirements
\textbf{Asia:} Clinical Trial Regulations specific for Medical Devices, Registration Procedures, Quality System requirements and Regulatory requirements for Japan, India and China

\textbf{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
   - Change Management/ Change control. Deviations
   - Corrective & Preventive Actions (CAPA)
2. Documentation of raw materials analysis as per official monographs
3. Preparation of audit checklist for various agencies
4. Preparation of submission to FDA using eCTD software
5. Preparation of submission to EMA using eCTD software
6. Preparation of submission to MHRA using eCTD software
7. Preparation of Biologics License Applications (BLA)
8. Preparation of documents required for Vaccine Product Approval
9. Comparison of clinical trial application requirements of US, EU and India of Biologics
10. Preparation of Checklist for Registration of Blood and Blood Products
11. Registration requirement comparison study in 5 emerging markets (WHO) and preparing check list for market authorization
12. Registration requirement comparison study in emerging markets (BRICS) and preparing check list for market authorization
13. Registration requirement comparison study in emerging markets (China and South Korea) and preparing check list for market authorization
14. Registration requirement comparison study in emerging markets (ASEAN) and preparing check list for market authorization
15. Registration requirement comparison study in emerging markets (GCC) and preparing check list for market authorization
16. Checklists for 510k and PMA for US market
17. Checklist for CE marking for various classes of devices for EU
18. STED Application for Class III Devices
19. Audit Checklist for Medical Device Facility
20. Clinical Investigation Plan for Medical Devices