REGULATIONS AND COURSE CURRICULUM
FOR
MASTER OF PHARMACY (M.PHARM) - 2017
(Semester Scheme)

NITTE (Deemed to be University)
(Deemed to be University)
(Under Section (3) of UGC Act, 1956)
Placed under Category ‘A’ by MHRD, Govt. of India, Accredited with ‘A’ Grade by NAAC
University Enclave, Deralakatte, Mangaluru – 575 018
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Website: www.nitte.edu.in   E-mail: info@nitte.edu.in
Vision

To build a humane society through excellence in education and health care

Mission

To develop Nitte (Deemed to be University) as a centre of excellence imparting quality education, generating competent, skilled manpower to face the scientific and social challenges with a high degree of credibility, integrity, ethical standards and social concern.
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No. F.9-13/2007-U.3 (A)
Government of India
Ministry of Human Resource Development
(Department of Higher Education)
U.3(A) Section

Shastri Bhavan, New Delhi
Dated: 4th Jun, 2008

Notification
1. Whereas the Central Government is empowered under Section 3 of the University Grants Commission (UGC) Act, 1956 to declare, on the advice of the UGC, an institution of higher learning as a deemed-to-be-university;

2. And whereas, a proposal was received in February, 2007 from Nitte Education Trust, Mangaluru, Karnataka seeking grant of status of deemed-to-be university in the name of Nitte (Deemed to be University) under section 3 of the UGC Act, 1956;

3. And whereas, the University Grants Commission has examined the said proposal and vide its communication bearing No. F.26-10/2007(CPP-I/DU), dated the 10th March, 2008 has recommended conferment of status of ‘deemed-to-be-university’ in the name and style of Nitte (Deemed to be University), Mangaluru, Karnataka, comprising A. B. Shetty Memorial Institute of Dental Sciences, Mangaluru.

4. Now, therefore, in exercise of the powers conferred by section 3 of the UGC Act, 1956, the central Government, on the advice of the University Grants Commission (UGC), hereby declare that Nitte (Deemed to be University), Mangaluru, Karnataka, comprising A. B. Shetty Memorial Institute of Dental Sciences, Deralakatte, Mangaluru, shall be deemed to be a University for the Purposes of the aforesaid Act.

Sd/
(Sunil Kumar)
Joint Secretary to the Government of India

(True Extract of the Notification)
Office Memorandum

1. Whereas the Government of India, Ministry of Human Resource Development, Department of Higher Education vide Notification No. F.9-13/2007-U3(A) dated 4th June, 2008 declared Nitte (Deemed to be University), Mangaluru, Karnataka comprising A. B. Shetty Memorial Institute of Dental Sciences, Deralakatte, Mangaluru as Deemed to be University under Section 3 of UGC Act, 1956.

2. And whereas now, the University Grants Commission, on the recommendation of an Expert Committee constituted by the Chairman, UGC has agreed for bringing (i) K. S. Hegde Medical Academy, Deralakatte, Mangaluru (ii) Nitte Usha Institute of Nursing Sciences, Deralakatte, Mangaluru (iii) Nitte Gulabi Shetty Memorial Institute of Pharmaceutical Sciences, Deralakatte, Mangaluru, (iv) Nitte Institute of Physiotherapy, Deralakatte, Mangaluru under the ambit of Nitte (Deemed to be University), Deralakatte, Mangaluru.

Sd/
(K. P. Singh)
Joint Secretary,
University Grants Commission

(True Extract of the Office Memorandum)
Ref. No. NU/REG/AC/2016-17/655 Date: 20.03.2017

NOTIFICATION

Subject: Regulations and Course Curriculum pertaining to Master of Pharmacy

Reference: Minutes of the 31st Academic Council meeting held on 14.03.2017

In exercise of the Powers conferred under Rule R-08 (g) of the Memorandum of Association, the Academic Council has been pleased to approve the Regulations and Course Curriculum for the M.Pharm Course as per the All India Council for Technical Education (AICTE) and Pharmacy Council of India (PCI) norms in the Nitte Gulabi Shetty Memorial Institute of Pharmaceutical Sciences.

The Regulations and course curriculum shall come into force from the academic year 2017-18.

By Order,

Registrar

To:
1. The Principal, Nitte Gulabi Shetty Memorial Institute of Pharmaceutical Sciences, Deralakatte, Mangaluru
2. All the members of the Board of Management / Academic Council

Copy To:
1. The Chancellor
2. The Vice Chancellor
3. The Controller of Examinations
NITTE (DEEMED TO BE UNIVERSITY)
(Deemed University under section 3 of UGC Act, 1956)
Mangaluru, Karnataka, India

REGULATIONS AND COURSE CURRICULUM FOR
MASTER OF PHARMACY (M. PHARM)

Preamble:
Nitte Gulabi Shetty Memorial Institute of Pharmaceutical Sciences, imparting education and training in pharmaceutical sciences since 1983, started B. Pharm program in 1984. M.Pharm programs were introduced in 1991. From the year 2009-10 the Nitte Gulabi Shetty Memorial Institute of Pharmaceutical Sciences became a constitute college of Nitte (Deemed to be University). The Pharm.D program was started in the year 2012-13. Consequent to introducing semester system for M.Pharm program as per PCI course regulations 2014, the new regulations are formulated as under:

1. Introduction
   1.1. These regulations shall be called as revised regulations for the M.Pharm degree program of Nitte (Deemed to be University). The Regulations for M.Pharm program shall govern the policies and procedures including selection, admission, imparting of instructions, conduct of examinations, evaluation and certification of candidate’s performance and all amendments there to, leading to the award of M.Pharm degree. The regulations are in conformance with “The Revised Regulations for M.Pharm. degree program of Pharmacy Council of India” and All India Council for Technical Education (AICTE) regulations of Master of Pharmacy (M.Pharm) degree program.
   1.2. This set of regulations shall be binding on all the candidates undergoing the said degree programme. The regulations shall come into effect from the academic year 2017-18.
   1.3. These regulations may be modified from time to time as mandated by the statutes of the University, the AICTE and the PCI.
   1.4. This set of regulations may evolve and get refined or updated or amended or modified or changed through appropriate approvals from the Academic Council or the Board of Management from time to time and shall be binding on all parties concerned including the candidates, faculty, staff, departments and institute authorities.
   1.5. All disputes arising from this set of regulations shall be addressed to the Board of Management. The decision of the Board of Management is final and binding on all parties concerned. Further, any legal disputes arising out of this set of regulations shall be limited to the jurisdiction of Courts of Mangaluru only.

2. Definitions:
   Unless the context otherwise requires
   * **Academic Year** means two consecutive (one odd + one even) semesters
   * **BOM** means Board of Management of Nitte (Deemed to be University)
   * **BOS** means Board of Studies in Pharmaceutical Sciences
   * **College/Institution** means Nitte Gulabi Shetty Memorial Institute of Pharmaceutical Sciences
- He includes both genders He and She; similarly his and / or him, himself includes her, as well in all cases
- **Head of the Institution means the Principal of the College (Nitte Gulabi Shetty Memorial Institute of Pharmaceutical Sciences)**
- **Regulations means this set of academic regulations**
- **Regulatory Authority – Authority appointed / constituted by the central / state government/s to regulate Pharmaceutical Sciences Education**
- **University means Nitte (Deemed to be University)**
- **Program means a set of courses which the student has to complete for the award of M.Pharm. degree**
- **Course means a subject or a paper. A course may comprise either theory or practical listed under the program**
- **Credit means a unit by which the course work is measured. It determines the number of hours of instructions required per week. One credit is equivalent to one hour of teaching (lecture)/journal club/research work presentation/discussion with supervisor or two hours of research work/practical/seminar/assignment/project work per week.**
- **Semester Grade Point Average (SGPA) means a measure of performance of work done in a semester. It is ratio of total credit points secured by a student in various courses registered in a semester and the total course credits taken during that semester. It shall be expressed up to two decimal places**
- **Cumulative Grade Point Average (CGPA) means a measure of overall cumulative performance of a student over all semesters. The CGPA is the ratio of total credit points secured by a student in various courses in all semesters and the sum of the total credits of all courses in all the semesters. It is expressed up to two decimal places.**
- **Letter Grade is an index of the performance of a candidate in a said course. Grades are denoted by letters O, A, B, C, D, F and AB.**
- **Grade Point means a numerical weight allotted to each letter grade on a 10-point scale.**
- **IA means Internal Assessment comprising of continuous mode and sessional exams**
- **ESE means End Semester Examination**

3. **Minimum qualification for admission**

A Pass in the following examination

A candidate seeking admission to M. Pharm course must have a bachelor’s degree / B.Pharm degree awarded by an Indian University recognized by PCI/ AICTE and who has secured not less than 55% of the maximum marks (aggregate of four years) prescribed for the qualifying examination shall be eligible for the admission to the M. Pharm course.

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

Foreign nationals who have qualified from a foreign university should obtain permission from the Nitte (Deemed to be University) prior to the admission for equivalence of the degree.
Note: It is mandatory to submit a migration certificate obtained from the respective university where the candidate had passed his/her qualifying degree (B.Pharm.)

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

5. **Medium of instruction and examinations**
Medium of instruction and examination shall be in English.

6. **Maximum Period for completion of the course:**
The maximum period for completion of the M.Pharm course is four years.

7. **Selection of eligible candidates:**
Selection to the M.Pharm course shall be based on the basis of merit obtained in the qualifying examination.

8. **Withdrawal – Temporary and Permanent:**

8.1. **Temporary withdrawal:**

   8.1.1. A candidate who has been admitted to the course may be permitted to withdraw temporarily for a period of six months or more up to one year on the grounds of prolonged illness, grave calamity in the family etc., provided:
   
   a) He applied stating the reason of withdrawal with supporting documents and endorsement by parent / guardian.
   
   b) The Institute is satisfied that without counting the period of withdrawal candidate is likely to complete his requirement of the degree within maximum time specified.
   
   c) There are no outstanding dues or demands with the department, library, hostel, Institute etc.

   8.1.2. The tuition fee for the subsequent year may be collected in advance based on the severity of the case before giving approval for any such temporary withdrawal.

   8.1.3. Scholarship holders are bound by the appropriate rules applicable.

   8.1.4. The decision of the Institute / University regarding withdrawal of a candidate is final and binding.

8.2. **Permanent withdrawal:**

   8.2.1. A candidate who withdraws admission before closing date of admission for the academic session is eligible for the refund of the deposit only. The fees once paid will not be refunded on any account.

   8.2.2. Once the admission for the year is closed, and if a candidate wants to leave the Institution, he will be permitted to do so and take the Transfer Certificate from the institute, if required, only after remitting all the tuition fees for the remaining years.
8.2.3. Those candidates who have received any scholarship / stipend / other forms of assistance from the institute shall repay all such amounts in addition to those mentioned in the clause above.

8.2.4. The decision of the institute / university regarding withdrawal of a candidate is final and binding.

9. Conduct and discipline:

9.1. Candidates shall conduct themselves within and outside the premises of the Institute in a manner befitting the student of professional Institution.

9.2. As per the order of Honorable Supreme Court of India, ragging in any form is considered as a criminal offence and is banned. Any form of ragging will be severely dealt with.

9.3. The following act of omission and/or commission shall constitute gross violation of the code of conduct and are liable to invoke disciplinary measures:

9.3.1. Ragging as defined and described by the Supreme Court/Government

9.3.2. Lack of courtesy and decorum; indecent behaviour anywhere within or outside the campus.

9.3.3. Willful damage or stealthy removal of any property/belongings of the College/Hostel or of fellow candidates/citizens.

9.3.4. Possession, consumption or distribution of alcoholic drinks or any kind of hallucinogenic drugs.

9.3.5. Mutilation or unauthorized possession of library books.

9.3.6. Noisy or unseemly behavior, disturbing studies of fellow candidates.

9.3.7. Hacking in computer systems (such as entering into other person’s domain without prior permission, manipulation and/or damage to the computer hardware and software or any other cyber crime etc.)

9.3.8. Plagiarism of any nature.

9.3.9. Any other act of gross indiscipline as decided by the Board of management from time to time.

9.4. Commensurate with the gravity of offense, the punishment may be: reprimand, fine, expulsion from the hostel, debarment from an examination, disallowing the use of certain facilities of the Institute, rustication for a specific period or even outright expulsion from the Institute, or even handing over the case to appropriate law enforcement authorities or the judiciary, as required by the circumstances.

9.5. For any offence committed in (i) a hostel (ii) a department or in a classroom and (iii) elsewhere, the Chief Warden, the Head of the Department and the Head of the Institution, respectively, shall have the authority to reprimand or impose fine.

9.6. All cases involving punishment other than reprimand shall be reported to the Vice-chancellor.

9.7. Cases of adoption of unfair means and/or any malpractice in an examination shall be reported to the Controller of Examinations for taking appropriate action.
10. **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 July/August to December/January and the even semesters shall be conducted from the month of January/February to June/July in every calendar year.

11. **Attendance and Monitoring Progress of Students:**
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.

**11.1 Attendance**

11.1.1 A candidate pursuing M.Pharm course shall study in the concerned Department of the Institution for the entire period as a full time candidate. No candidate is permitted to work in any laboratory / Institution / industry / pharmacy, etc., during the period of study. No candidate should join any other course of study or appear for any other degree examination conducted by this university or any other university in India or abroad during the period of registration.

11.1.2 Each semester shall be taken as a unit for the purpose of calculating attendance.

11.1.3 A student shall attend symposia, seminars, conferences, journal review meetings, journal club and lectures during each semester as prescribed by the department / college / university and not absent himself / herself without valid reason.

11.1.4 A candidate who has put in a minimum of 80% of attendance in the theory and practical assignments separately and who has fulfilled all other requirements of the course shall be permitted to appear for the semester end examination.

11.1.5 Only the candidate who has put in a minimum of 80% of attendance in II year shall be eligible to submit the dissertation.

11.2 **Monitoring Progress of Studies:**

11.2.1 A student shall maintain a work diary and record of his participation in the training programmes such as review of journal, seminars etc. conducted by the department / institution.

11.2.2 The work diary shall be scrutinized and certified by the Head of the Department and Head of the Institution, and presented in the University practical examination.

11.2.3 Special mention may be made of the presentations by the student as well as details of experiments or laboratory procedures, conducted by the student.

12 **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.
12.1 Credit assignment
Theory and Laboratory courses: Courses are broadly classified as Theory and Practical. Theory courses consist of lecture (L) and Practical (P) courses consist of hours spent in the laboratory. Credits (C) for a course is dependent on the number of hours of instruction per week in that course, and is obtained by using a multiplier of one (1) for lecture and a multiplier of half (½) for practical (laboratory) hours. Thus, for example, a theory course having four lectures per week throughout the semester carries a credit of 4. Similarly, a practical having four laboratory hours per week throughout semester carries a credit of 2.

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

12.2 Minimum credit requirements
The minimum credit points required for the award of M.Pharm degree is 93. However based on the credit points earned by the students under the head of co-curricular activities, a student shall earn a maximum of 98 credit points. These credits are divided into Theory courses, Practical, Seminars, Assignments, Research work, Discussions with the supervisor, Journal club and Co-Curricular activities over the duration of four semesters. The credits are distributed semester-wise as shown in Table 10. 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.

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

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

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

<table>
<thead>
<tr>
<th>S. No.</th>
<th>Specialization</th>
<th>Code</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>Pharmaceutics</td>
<td>MPH</td>
</tr>
<tr>
<td>2.</td>
<td>Pharmaceutical Chemistry</td>
<td>MPC</td>
</tr>
<tr>
<td>3.</td>
<td>Pharmaceutical Quality Assurance</td>
<td>MQA</td>
</tr>
<tr>
<td>4.</td>
<td>Pharmaceutical Regulatory Affairs</td>
<td>MRA</td>
</tr>
<tr>
<td>5.</td>
<td>Pharmacy Practice</td>
<td>MPP</td>
</tr>
<tr>
<td>6.</td>
<td>Pharmacology</td>
<td>MPL</td>
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</tbody>
</table>
The course of study for M.Pharm specializations shall include Semester wise Theory & Practical as given in Tables 2 to 7. The number of hours to be devoted to each theory and practical course in any semester shall not be less than that shown in the tables.

### Table – 2: Course of study for M. Pharm. (Pharmaceutics)

<table>
<thead>
<tr>
<th>Course Code</th>
<th>Course</th>
<th>Credit Hours</th>
<th>Credit Points</th>
<th>Hrs./wk</th>
<th>Marks</th>
</tr>
</thead>
<tbody>
<tr>
<td>MPH101T</td>
<td>Modern Pharmaceutical Analytical</td>
<td>4</td>
<td>4</td>
<td>4</td>
<td>100</td>
</tr>
<tr>
<td></td>
<td>Techniques</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>MPH102T</td>
<td>Drug Delivery Systems</td>
<td>4</td>
<td>4</td>
<td>4</td>
<td>100</td>
</tr>
<tr>
<td>MPH103T</td>
<td>Modern Pharmaceutics</td>
<td>4</td>
<td>4</td>
<td>4</td>
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<tr>
<td>MPH104T</td>
<td>Regulatory Affair</td>
<td>4</td>
<td>4</td>
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<td>MPH105P</td>
<td>Pharmaceutics Practicals I</td>
<td>12</td>
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<td></td>
<td>Seminar/Assignment</td>
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<td>7</td>
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<td><strong>Total</strong></td>
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<td><strong>26</strong></td>
<td><strong>35</strong></td>
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### Semester II

<table>
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<tr>
<th>Course Code</th>
<th>Course</th>
<th>Credit Hours</th>
<th>Credit Points</th>
<th>Hrs./wk</th>
<th>Marks</th>
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<tr>
<td>MPH201T</td>
<td>Molecular Pharmaceutics (Nano Tech and Targeted DDS)</td>
<td>4</td>
<td>4</td>
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<td>MPH202T</td>
<td>Advanced Biopharmaceutics &amp; Pharmacokinetics</td>
<td>4</td>
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<tr>
<td>MPH203T</td>
<td>Computer Aided Drug Development</td>
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<tr>
<td>MPH204T</td>
<td>Cosmetics and Cosmeceuticals</td>
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<td>MPH205P</td>
<td>Pharmaceutics Practical - II</td>
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<td>Seminar/Assignment</td>
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<td>4</td>
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<tr>
<td><strong>Total</strong></td>
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<td><strong>35</strong></td>
<td><strong>26</strong></td>
<td><strong>35</strong></td>
<td><strong>650</strong></td>
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### Table – 3: Course of study for M. Pharm. (Pharmaceutical Chemistry)

<table>
<thead>
<tr>
<th>Course Code</th>
<th>Course</th>
<th>Credit Hours</th>
<th>Credit Points</th>
<th>Hrs./wk</th>
<th>Marks</th>
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<tbody>
<tr>
<td>MPC101T</td>
<td>Modern Pharmaceutical Analytical</td>
<td>4</td>
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<td></td>
<td>Techniques</td>
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Table – 4: Course of study for M. Pharm. (Pharmaceutical Quality Assurance)

<table>
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<th>Hrs./wk</th>
<th>Marks</th>
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<tbody>
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<td>Modern Pharmaceutical Analytical Techniques</td>
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<td>MQA102T</td>
<td>Quality Management System</td>
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<td>MQA103T</td>
<td>Quality Control and Quality Assurance</td>
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<td>Product Development and Technology Transfer</td>
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Table – 4: Course of study for M. Pharm. (Pharmaceutical Quality Assurance)

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<th>Hrs./wk</th>
<th>Marks</th>
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<td>MQA201T</td>
<td>Hazards and Safety Management</td>
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<td>Pharmaceutical Validation</td>
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<td>MQA203T</td>
<td>Audits and Regulatory Compliance</td>
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<td>Pharmaceutical Manufacturing Technology</td>
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### Table – 5: Course of study for M. Pharm. (Pharmaceutical Regulatory Affairs)

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<th>Course Code</th>
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<th>Marks</th>
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<tbody>
<tr>
<td>MRA101T</td>
<td>Good Regulatory Practices</td>
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<td>MRA102T</td>
<td>Documentation and Regulatory Writing</td>
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<td>MRA103T</td>
<td>Clinical Research Regulations</td>
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<td>Drugs Regulations and other Legislation in India and Intellectual Property Rights</td>
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**Semester II**

<table>
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<td>Regulatory Aspects of Drugs &amp; Cosmetics</td>
<td>4</td>
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<tr>
<td>MRA202T</td>
<td>Regulatory Aspects of Herbal &amp; Biologicals</td>
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<td>MRA203T</td>
<td>Regulatory Aspects of Medical Devices</td>
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<td>MRA204T</td>
<td>Regulatory Aspects of Food &amp; Nutraceuticals</td>
<td>4</td>
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<td>MRA205P</td>
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### Table – 6: Course of study for M. Pharm. (Pharmacy Practice)

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<th>Marks</th>
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<td>Clinical Pharmacy Practice</td>
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<td>MPP102T</td>
<td>Pharmacotherapeutics-I</td>
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<td>Principles of Quality Use of Medicines</td>
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Table – 7: Course of study for M. Pharm. (Pharmacology)

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<td>MPL101T</td>
<td>Modern Pharmaceutical Analytical Techniques</td>
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<th>Hrs./wk</th>
<th>Marks</th>
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<td>Clinical Research and Pharmacovigilance</td>
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### Table 8: Course of Study for M.Pharm III Semester
(Common for all Specializations)

<table>
<thead>
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<td>Research Methodology and Biostatistics*</td>
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<td>Journal Club</td>
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<td>Discussion / Presentation (proposal Presentation)</td>
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*Non University Examination

### Table 9: Course of Study for M.Pharm IV Semester
(Common for all Specializations)

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<td>Discussion / Final Presentation</td>
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<td>Co-curricular and extra-curricular activities</td>
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### Table 10: Semester Wise Credit Distribution

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<td>II</td>
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<td>III</td>
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<td>IV</td>
<td>20</td>
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<td>Co-curricular and extra-curricular activities</td>
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Table 11: Guidelines for awarding credit points for co-curricular and extra curricular activities

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<th>Sl.No.</th>
<th>Name of the Activity</th>
<th>Marks</th>
<th>Evidence</th>
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<tbody>
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<td>1.</td>
<td>Participation in National Level seminar/Conference/Workshop/Symposium/Training Programs (related to the specialization of the student)</td>
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<td>Participation certificate issued by the organizers</td>
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<tr>
<td>2.</td>
<td>Participation in international Level Seminar/Conference/Workshop/Symposium/Training Programs (related to the specialization of the student)</td>
<td>20</td>
<td>Participation certificate issued by the organizers</td>
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<td>3.</td>
<td>Academic Award/Research Award from State Level/National Agencies</td>
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<td>Award certificate</td>
</tr>
<tr>
<td>4.</td>
<td>Academic Award/Research Award from International Agencies</td>
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<td>Award certificate</td>
</tr>
<tr>
<td>5.</td>
<td>Research / Review Publication as first author in National/international Journals (Indexed in Scopus / Web of Science)</td>
<td>20</td>
<td>Publication re print</td>
</tr>
<tr>
<td>6.</td>
<td>Research / Review papers as first author communicated to national/International Journals (Indexed in Scopus / Web of Science)</td>
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<td>Proof of communication</td>
</tr>
<tr>
<td>7.</td>
<td>Active involvement in organizing seminars/guest lectures etc. of the department</td>
<td>05/event</td>
<td>Certification by event coordinator &amp; guide</td>
</tr>
<tr>
<td>8.</td>
<td>Contribution to institutional publication such as NGSM Herald, Pharmacy practice communicator</td>
<td>05/contribution</td>
<td>Proof of contribution</td>
</tr>
<tr>
<td>9.</td>
<td>Active participation in sports</td>
<td>05</td>
<td>Certification by Physical director and Guide</td>
</tr>
<tr>
<td>10.</td>
<td>Participation in annual day, cultural day, national festivals such as independence day, republic day etc.</td>
<td>2 marks/event</td>
<td>Certification by event coordinator &amp; guide</td>
</tr>
<tr>
<td>11.</td>
<td>Participation in NSS activities of the college</td>
<td>02 marks/program</td>
<td>Certification by NSS coordinator &amp; guide</td>
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<tr>
<td>12.</td>
<td>Participation in the campus placement activities/interviews</td>
<td>05/participation</td>
<td>Certification by Placement officer &amp; guide</td>
</tr>
<tr>
<td>13.</td>
<td>Involvement in guiding the junior students by delivering special talks to UG and diploma students</td>
<td>05</td>
<td>Certification by the guide with proof</td>
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<td>General skills, attitude and contribution to the vision and mission of the college</td>
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<td>Any other significant curricular / extra-curricular activity as certified by Heads of the department</td>
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The credit points assigned for extra-curricular and co-curricular activities shall be earned by the students on the basis of their performance in defined activities. The assessment of the extra-curricular and co-curricular attainment shall be made by the activity coordinators, guides and the heads of the departments. The marks obtained by the students shall be sent to the University by the Head of the Institution. However, the maximum marks for these activities shall not exceed 50. The marks obtained by the students shall be converted into letter grades and grade points as indicated in Table 22, which shall be taken into account while calculating CGPA. The criteria to acquire this credit point shall be defined by the college from time to time.

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

15 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 and before the end semester exam.

16 Examinations / Assessments:
The schemes for internal assessment and end semester examinations are given in Table 12-18

16.1 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 8 for which examinations shall be conducted by the subject experts at college level and the marks/grades shall be submitted to the university.
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Semester II

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Table 14: Schemes for internal assessments and end semester examinations
(Pharmaceutical Quality Assurance - MQA)

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Table 16: Schemes for internal assessments and end semester examinations  
(Pharmacy Practice - MPP)

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Table 17: Schemes for internal assessments and end semester examinations  
(Pharmacology - MPL)

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<td>10 15 1 Hr</td>
<td>25 75 3 Hrs</td>
<td>100</td>
<td></td>
</tr>
<tr>
<td>MPL104T</td>
<td>Cellular and Molecular Pharmacology</td>
<td>10 15 1 Hr</td>
<td>25 75 3 Hrs</td>
<td>100</td>
<td></td>
</tr>
<tr>
<td>MPL105P</td>
<td>Pharmacology Practical I</td>
<td>20 30 6 Hrs</td>
<td>50 100 6 Hrs</td>
<td>150</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Seminar/Assignment</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td></td>
<td>Total</td>
<td></td>
<td></td>
<td>650</td>
<td></td>
</tr>
<tr>
<td>Semester II</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>MPL201T</td>
<td>Advanced Pharmacology-II</td>
<td>10 15 1 Hr</td>
<td>25 75 3 Hrs</td>
<td>100</td>
<td></td>
</tr>
<tr>
<td>MPL202T</td>
<td>Pharmacological and Toxicological Screening Methods – II</td>
<td>10 15 1 Hr</td>
<td>25 75 3 Hrs</td>
<td>100</td>
<td></td>
</tr>
<tr>
<td>MPL203T</td>
<td>Principles of Drug Discovery</td>
<td>10 15 1 Hr</td>
<td>25 75 3 Hrs</td>
<td>100</td>
<td></td>
</tr>
<tr>
<td>MPL204T</td>
<td>Clinical Research and Pharmacovigilance</td>
<td>10 15 1 Hr</td>
<td>25 75 3 Hrs</td>
<td>100</td>
<td></td>
</tr>
<tr>
<td>MPL205P</td>
<td>Pharmacology Practical II</td>
<td>20 30 6 Hrs</td>
<td>50 100 6 Hrs</td>
<td>150</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Seminar/Assignment</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td></td>
<td>Total</td>
<td></td>
<td></td>
<td>650</td>
<td></td>
</tr>
</tbody>
</table>
### Table 18: Schemes for internal assessments and end semester examinations (Semester III & IV)

<table>
<thead>
<tr>
<th>Course Code</th>
<th>Course</th>
<th>Internal Assessment</th>
<th>End Semester Exams</th>
<th>Total Marks</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Continuous Mode</td>
<td>Sessional Exams</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Marks</td>
<td>Duration</td>
<td>Total Marks</td>
</tr>
<tr>
<td>Semester III</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>MRM 301T</td>
<td>Research Methodology and Biostatistics*</td>
<td>10</td>
<td>15</td>
<td>25</td>
</tr>
<tr>
<td>-</td>
<td>Journal Club</td>
<td>-</td>
<td>-</td>
<td>25</td>
</tr>
<tr>
<td>-</td>
<td>Discussion / Presentation (proposal Presentation)</td>
<td>-</td>
<td>-</td>
<td>50</td>
</tr>
<tr>
<td>-</td>
<td>Research Work*</td>
<td>-</td>
<td>-</td>
<td>350</td>
</tr>
<tr>
<td>Total</td>
<td></td>
<td></td>
<td></td>
<td>525</td>
</tr>
<tr>
<td>Semester IV</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>-</td>
<td>Journal Club</td>
<td>25</td>
<td>-</td>
<td>25</td>
</tr>
<tr>
<td>-</td>
<td>Discussion / Final Presentation</td>
<td>75</td>
<td>-</td>
<td>75</td>
</tr>
<tr>
<td>-</td>
<td>Research Work and Colloquium</td>
<td>-</td>
<td>400</td>
<td>400</td>
</tr>
<tr>
<td>Total</td>
<td></td>
<td></td>
<td></td>
<td>500</td>
</tr>
</tbody>
</table>

*Non University Examination

### 16.2 Internal Assessment: Continuous Mode

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

#### Table 19: Scheme for awarding internal assessment: Continuous Mode

<table>
<thead>
<tr>
<th>Theory</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Attendance (Refer Table – 20)</td>
<td>8</td>
</tr>
<tr>
<td>Student – Teacher interaction</td>
<td>2</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>10</strong></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Practical</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Attendance (Refer Table – 20)</td>
<td>10</td>
</tr>
<tr>
<td>Based on Practical Records, Regular viva voce, etc.</td>
<td>10</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>20</strong></td>
</tr>
</tbody>
</table>
Table 20: 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>5.0</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>

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

**Question paper pattern for sessional theory examinations**
1. Long Answers (Answer 1 out of 2) - 1 x 10 = 10
2. Short Answers (Answer 4 out of 5) - 4 x 5 = 20

---------------------
Total = 30 Marks

---------------------

**Question paper pattern for sessional Practical examinations**
1. Synopsis - 10
2. Experiment – I (Core Subject) - 25
3. Experiment – II (MPAT) - 15
4. Viva voce - 10

---------------------
Total = 60 Marks

---------------------

Question Paper pattern - Modern Pharmaceutical Analytical Techniques (MPAT)

**Sessional Practical examinations**

<table>
<thead>
<tr>
<th></th>
<th>Core subject</th>
<th>MPAT</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Synopsis</td>
<td>07</td>
<td>03</td>
<td>10</td>
</tr>
<tr>
<td>Experiment-I</td>
<td>25</td>
<td>-</td>
<td>25</td>
</tr>
<tr>
<td>Experiment-II</td>
<td>-</td>
<td>15</td>
<td>15</td>
</tr>
<tr>
<td>Viva-voce</td>
<td>08</td>
<td>02</td>
<td>10</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>40</strong></td>
<td><strong>20</strong></td>
<td><strong>60</strong></td>
</tr>
</tbody>
</table>
Scheme for awarding internal assessment in continuous mode

<table>
<thead>
<tr>
<th></th>
<th>Core subject</th>
<th>MPAT</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Attendance</td>
<td>07</td>
<td>03</td>
<td>10</td>
</tr>
<tr>
<td>Practical records and viva voce</td>
<td>07</td>
<td>03</td>
<td>10</td>
</tr>
<tr>
<td>Total</td>
<td>14</td>
<td>06</td>
<td>20</td>
</tr>
</tbody>
</table>

17. Promotion and award of grades:
A candidate shall be declared as pass if he secures 50% of marks (including internal assessment) in each subject in theory and practical examination separately in each semester provided he secures a minimum of 40% marks in the university theory and practical examination separately.

Theory and practical subjects are considered as independent subjects. The candidate who fails either in theory or practical subject has to appear only in theory or practical as the case may be in the subsequent examinations.

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

19. 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.

20. Re-examination of end semester examinations:
Re-examination of end semester examination shall be conducted as per the schedule given in table 21. The exact dates of examinations shall be notified from time to time.

Table – 21: Tentative schedule of end semester examinations

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

Question paper pattern for end semester theory examinations
1. Long Answers (Answer 3 out of 4)  - 3 x 10 = 30
2. Short Answers (Answer 9 out of 11) - 9 x 5 = 45

Total = 75 Marks

-----------------------
Question paper pattern for end semester Practical examinations

1. Synopsis - 15
2. Experiment – I - 40
3. Experiment – II - 30
4. Viva voce - 15

-------------------
Total = 100 Marks
-------------------

Question Paper pattern for end semester Practical examinations - Modern Pharmaceutical Analytical Techniques (MPAT)

<table>
<thead>
<tr>
<th>Core subject</th>
<th>MPAT</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Synopsis</td>
<td>10</td>
<td>05</td>
</tr>
<tr>
<td>Experiment 1</td>
<td>30</td>
<td>10</td>
</tr>
<tr>
<td>Experiment 2</td>
<td>20</td>
<td>10</td>
</tr>
<tr>
<td>Viva-voce</td>
<td>10</td>
<td>5</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>70</strong></td>
<td><strong>30</strong></td>
</tr>
</tbody>
</table>

21. Allowed To Keep Terms (ATKT):
No student shall be admitted to any examination unless he/she fulfills the norms given in 11. ATKT rules are applicable as follows:

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

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

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

22. Grading of performances
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 – 22.
Table – 22: Letter grades and grade points equivalent to Percentage of marks and performances

<table>
<thead>
<tr>
<th>Marks Range (%)</th>
<th>Grade Point</th>
<th>Letter Grade</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>90 &amp; Above</td>
<td>10</td>
<td>O</td>
<td>Outstanding First Class with Distinction</td>
</tr>
<tr>
<td>80-89.9</td>
<td>09</td>
<td>A</td>
<td>Excellent</td>
</tr>
<tr>
<td>75-79.9</td>
<td>08</td>
<td>B</td>
<td>Very Good</td>
</tr>
<tr>
<td>60-74.9</td>
<td>07</td>
<td>C</td>
<td>Good</td>
</tr>
<tr>
<td>55-59.9</td>
<td>06</td>
<td>D</td>
<td>Fair</td>
</tr>
<tr>
<td>50-54.9</td>
<td>05</td>
<td>E</td>
<td>Average</td>
</tr>
<tr>
<td>Less than 50</td>
<td>0</td>
<td>F</td>
<td>Fail</td>
</tr>
<tr>
<td>Absent</td>
<td>0</td>
<td>AB</td>
<td>Fail</td>
</tr>
</tbody>
</table>

A student who remains absent for any semester end 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.

23. The Semester grade point average (SGPA):

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

\[
SGPA = \frac{C1G1 + C2G2 + C3G3 + C4G4}{C1 + C2 + C3 + C4}
\]

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

\[
SGPA = \frac{C1G1 + C2G2 + C3G3 + C4* ZERO}{C1 + C2 + C3 + C4}
\]

24. Cumulative Grade Point Average (CGPA):

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

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

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

25. **Declaration of Results and Classification:**

The class shall be awarded to those who pass the examination in first attempt on the basis of CGPA as follows:

- **First Class with Distinction**: CGPA 7.50 and above
- **First Class**: CGPA 6.00 to 7.49
- **Second Class**: CGPA 5.00 to 5.99

Candidates who pass the examination in more than one attempt shall be declared as passed in “pass” class irrespective of the percentage of marks secured.

An attempt means the appearance of a candidate for one or more subjects either in part or full in a particular examination.

If a candidate submits application for appearing for the examination but does not appear for any of the subjects either in full or part in the University examination, he can appear supplementary examination provided other conditions such as attendance requirement, internal assessment marks, etc are fulfilled and his appearing in the supplementary examination shall be considered as the first attempt.

26. **Project work (Dissertation):**

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

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

<table>
<thead>
<tr>
<th>Evaluation of Dissertation Book:</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Objective(s) of the work done</td>
<td>25 Marks</td>
</tr>
<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>
<tr>
<td><strong>Total</strong></td>
<td><strong>250 Marks</strong></td>
</tr>
</tbody>
</table>
Evaluation of Presentation:

<table>
<thead>
<tr>
<th></th>
<th>Marks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Presentation of work</td>
<td>75</td>
</tr>
<tr>
<td>Communication skills</td>
<td>50</td>
</tr>
<tr>
<td>Question and answer skills</td>
<td>25</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>150</strong></td>
</tr>
</tbody>
</table>

The minimum Marks for Pass in the dissertation is 50% of marks of the aggregate marks for University Evaluation.

27. **Dissertation**

As a partial requirement of the course, a candidate is required to carry out a study in a select area of his specialty, under the supervision of a faculty Guide. The results of such a study shall be submitted to the University in the form of a dissertation as per the prescribed format and within the date stipulated by the University. Only a candidate who has put in a minimum of 80% attendance in the second year be eligible to submit the dissertation. The dissertation is aimed at training a postgraduate candidate in research methodology and techniques. It includes identification of the problem, formulation of a hypothesis, review of literature, getting acquainted with recent advances, designing of a research study, collection of data, critical analysis and comparison of results and drawing conclusions.

**27.1 Schedule**

<table>
<thead>
<tr>
<th>Submission of the synopsis to the University</th>
<th>Within one month of the commencement of II semester</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ethical clearance</td>
<td>Fifteen days before the end of second semester</td>
</tr>
<tr>
<td>Final submission of the dissertation</td>
<td>1 month before the IV semester University examination or as per dates specified by the University</td>
</tr>
</tbody>
</table>

**27.2 Guide**

A guide shall be a full time post graduate teacher of the Institution and recognized by the University as a Guide for supervision of dissertation work. However, a co-guide can be opted wherever required with prior permission of the Institution and University. The co-guide shall also be a postgraduate teacher recognized by the University as Guide. In the event of registered guide leaving the Institution or in the event of death of the guide, a change of guide shall be permitted by the University, on the specific recommendation of the Institution.

**27.3 Ethical Clearance:**

Ethical clearance should be obtained for a study involving any procedure on human subject. A candidate should apply for the certificate to the Ethics Committee of the Institute, through the Guide and present the study before the Committee for clearance. A copy of the certificate should be attached along with the synopsis forwarded at the time
of approval of synopsis. All such clearance should be sought within six months of the commencement of the course.

27.4 Submission of Synopsis
A candidate shall submit a synopsis to the University through the Guide and Head of the Institution, not later than nine months from the commencement of the I year OR within the date notified by the University, whichever is earlier. Once the synopsis is approved and registered by the University no change in the topic or Guide shall be made without the prior approval of the University.

27.5 Preparation of Dissertation:

a. The dissertation should be written under the following headings and order:
   i. Introduction
   ii. Aims or Objectives of the study
   iii. Review of literature
   iv. Material and methods
   v. Results
   vi. Discussion
   vii. Summary and Conclusions
   viii. References
   ix. Tables
   x. Annexure

b. The written text of dissertation shall be not less than 75 pages and shall not exceed 200 pages excluding references, tables, questionnaires and other annexure. It should be neatly typed with double line spacing on one side of the bond paper (A4 size, 8.27” x 11.69”) and bound properly. Spiral binding should be avoided.

27.6 Submission of Dissertation:
The final dissertation in the prescribed format and certified by the Guide and co-guide if any, Head of the Department and Head of the Institution should be submitted to the University one month before the final examination or as notified by the University.

27.7 Viva-Voce Examination:
The Viva-Voce examination shall aim at assessing the depth of knowledge, logical reasoning, confidence and oral communication skills.

The Viva-Voce examination shall be held after the submission of dissertation. If any candidate fails to submit the dissertation on or before the date prescribed, his Viva-Voce shall be conducted during the subsequent examination.
28 Graduation Requirements:
A candidate shall be declared eligible for the award of the degree if he has:
• Fulfilled Degree Requirement
• No dues to the University, Institute, Departments, Hostels, Library etc.
• No disciplinary action pending against him.
The award of the degree must be recommended by the Board of Management.

29 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.

30 Award of degree:
Candidates who fulfill the requirements mentioned above shall be eligible for award of degree during the ensuing convocation.

31 Revaluation / Re-totaling of answer papers:
There is no provision for revaluation of the answer papers in any examination. The candidates can apply for retotaling/photocopy of the answer scripts by paying prescribed fee.

32 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.

33 Convocation:
Degrees will be awarded in person for the candidates who have graduated during the preceding academic year. Degrees will be awarded in absentia to such candidates who are unable to attend the convocation. Candidates are required to apply for the convocation along with prescribed fee within the specified date, after having satisfactorily completed all degree requirements of the course.

Provisional pass certificate will be issued by the University provided the candidate fulfills requirements mentioned in clause (11) above. The provisional certificate will be issued on submission of an application through the college and will be valid until the convocation.
GUIDELINES FOR PHARMACY STUDENTS FOR CARRYING OUT INDUSTRIAL PROJECTS IN PARTIAL FULFILLMENT OF M.PHARM DEGREE

Preamble:

In an attempt to increase industry-academic collaboration, it was proposed to permit certain percentage of M.Pharm students to pursue the research work leading to the dissertation work of II year M.Pharm course at pharmaceutical industry/research laboratories of public or private section. The long term benefits of such initiatives are:

1. Possible better placement opportunities
2. Exposure to industrial environment while being a student
3. Institution-industry collaboration may result in funded projects from the industry
4. Relevance of curriculum up gradation.

In the past, some colleges have practiced this.

Care to be taken by the sponsoring institution to see that students pursue the projects seriously, serious monitoring of the work being done and work taken up is of high standard.

Guidelines:

1. The candidates desire of doing the projects in industry, after preliminary home work of selection of industry, co guide and project title, shall apply to the principal at least one month prior to the start of II Sem. M.Pharm University Examinations.
2. The Principal along with the Committee appointed for the purpose of scrutinizing the applications shall select and approve the projects with the following conditions:
   i. Not more than 30% of students from each branch will be permitted.
   ii. Not more than one student from the institutional guide will be permitted
   iii. The industry/research lab should be approved by the College/University. (The candidate has to supply the particulars regarding the organization and co-guide).
   iv. The name of the co-guide should be approved by the University BOS in the faculty.
   v. The candidates will be selected on the basis of merit (B.Pharm marks and M.Pharm internal assessment marks)
   vi. Only those students who have put minimum of 80% attendance and have passed all the subjects in I year M.Pharm will be eligible.
3. The candidates shall submit the project protocol along with the application to the college duly endorsed by the guide and co-guide.
4. The student shall do the project work at the selected centre for a minimum of 180 days and maximum of 220 days.
5. Letter of consent from the co-guide and No Objection from the Project Centre Head should be produced along with the application.
6. The first, second and third presentation of the Protocol by the student will be at the institution.

**Minimum qualification for Co-guideship for M.Pharm.**

- Industrial Pharmacy: M. Pharm or Ph.D. with 3 years of experience in manufacturing or in R & D / Quality Control in a reputed pharmaceutical industry.
- Pharmacy Practice: A recognized PG teacher of Nitte (Deemed to be University) belonging to any faculty of health sciences from any affiliated colleges having approved post graduate courses.
- A co-guide can guide a maximum of two students at a time.
PHARMACEUTICS (MPH)

MODERN PHARMACEUTICAL ANALYTICAL TECHNIQUES (MPH 101T)

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

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

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<tr>
<th>Units</th>
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<th>Hours</th>
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</table>
| 1     | a. **UV-Visible spectroscopy:** Introduction, Theory, Laws, Instrumentation associated with UV-Visible spectroscopy, Choice Hrs of solvents and solvent effect and Applications of UV-Visible spectroscopy, Difference/ Derivative spectroscopy.  
     b. **IR spectroscopy:** Theory, Modes of Molecular vibrations, Sample handling, Instrumentation of Dispersive and Fourier Transform IR Spectrometer, Factors affecting vibrational frequencies and Applications of IR spectroscopy, Data Interpretation.  
     c. **Spectrofluorimetry:** Theory of Fluorescence, Factors affecting fluorescence (Characteristics of drugs that can be analysed by fluorimetry), Quenchers, Instrumentation and Applications of fluorescence spectrophotometer.  
     d. **Flame emission spectroscopy and Atomic absorption spectroscopy:** Principle, Instrumentation, Interferences and Applications. | 10    |
<p>| 2     | <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, Brief outline of principles of FT-NMR and 13C NMR. Applications of NMR spectroscopy. | 10    |
| 3     | <strong>Mass Spectroscopy:</strong> Principle, Theory, Instrumentation of Mass Spectroscopy, Different types of ionization like electron impact, chemical, field, FAB and MALDI, APCI, ESI, APPI Analyzers of Quadrupole and Time of Flight, Mass fragmentation and its rules, Meta stable ions, Isotopic peaks and Applications of Mass | 10    |</p>
<table>
<thead>
<tr>
<th></th>
<th>Spectroscopy.</th>
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</table>
| 4 | **Chromatography:** Principle, apparatus, instrumentation, chromatographic parameters, factors affecting resolution, isolation of drug from excipients, data interpretation and applications of the following:  
  a. Thin Layer chromatography  
  b. High Performance Thin Layer Chromatography  
  c. Ion exchange chromatography  
  d. Column chromatography  
  e. Gas chromatography  
  f. High Performance Liquid chromatography  
  g. Ultra High Performance Liquid chromatography  
  h. Affinity chromatography  
  i. Gel Chromatography | 10 |
| 5 | a. **Electrophoresis:** Principle, Instrumentation, Working conditions, factors affecting separation and applications of the Hrs following:  
  a) Paper electrophoresis  
  b) Gel electrophoresis  
  c) Capillary electrophoresis  
  d) Zone electrophoresis  
  e) Moving boundary electrophoresis  
  f) Iso electric focusing  
  
  b. **X ray Crystallography:** Production of X rays, Different X ray methods, Bragg’s law, Rotating crystal technique, X ray powder technique, Types of crystals and applications of X-ray diffraction. | 10 |
| 6 | a. **Potentiometry:** Principle, working, Ion selective Electrodes and Application of potentiometry.  
  
  b. **Thermal Techniques:** Principle, thermal transitions and Instrumentation (Heat flux and power-compensation and designs), Modulated DSC, Hyper DSC, experimental parameters (sample preparation, experimental conditions, calibration, heating and cooling rates, resolution, source of errors) and their influence, advantage and disadvantages, pharmaceutical applications. Differential Thermal Analysis (DTA): Principle, instrumentation and advantage and disadvantages, pharmaceutical applications, derivative differential thermal analysis (DDTA). TGA: Principle, instrumentation, factors affecting results, advantage and disadvantages, pharmaceutical applications.  
  
  c. **Immunological assays:** RIA (Radio immuno assay), ELISA, Bioluminescence assays. | 10 |
References

DRUG DELIVERY SYSTEMS (MPH 102T)

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

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

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<tr>
<th>Units</th>
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<th>Hours</th>
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<tbody>
<tr>
<td>1</td>
<td>Sustained Release(SR) and Controlled Release (CR) formulations: Introduction &amp; basic concepts, advantages/ Hrs disadvantages, factors influencing, Physicochemical &amp; biological approaches for SR/CR formulation, Mechanism of Drug Delivery from SR/CR formulation. Polymers: introduction, definition, classification, properties and application 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.</td>
<td>10</td>
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<tr>
<td>4</td>
<td>Occular Drug Delivery Systems: Barriers of drug permeation, Methods to overcome barriers.</td>
<td>06</td>
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<td>5</td>
<td>Transdermal Drug Delivery Systems: Structure of skin and barriers, Penetration enhancers, Transdermal Drug Delivery Hrs Systems, Formulation and evaluation.</td>
<td>10</td>
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<tr>
<td>6</td>
<td>Protein and Peptide Delivery: Barriers for protein delivery. Formulation and Evaluation of delivery systems of proteins and other macromolecules.</td>
<td>08</td>
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<tr>
<td>7</td>
<td>Vaccine delivery systems: Vaccines, uptake of antigens, single shot vaccines, mucosal and transdermal delivery of vaccines.</td>
<td>06</td>
</tr>
</tbody>
</table>
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 (MPH 103T)

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

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

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

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<th>Units</th>
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     b. **Optimization techniques in Pharmaceutical Formulation:** Concept and parameters of optimization, Optimization techniques in pharmaceutical formulation and processing. Statistical design, Response surface method, Contour designs, Factorial designs and application in formulation | 10    |
| 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. | 10    |
| 3     | **cGMP & Industrial Management**: Objectives and policies of current good manufacturing practices, layout of buildings, Hrs services, equipments and their maintenance Production management: Production organization, , materials management, handling and transportation, inventory management and control, production and planning control, Sales forecasting, budget and cost control, industrial and personal relationship. Concept of Total Quality Management. | 10    |
| 4     | **Compression and compaction**: Physics of tablet compression, compression, consolidation, effect of friction, distribution of forces, compaction profiles. Solubility. | 10    |
| 5     | **Study of consolidation parameters**: Diffusion parameters, | 10    |
Dissolution parameters and Pharmacokinetic parameters, Heckel plots, Similarity factors – f2 and f1, Higuchi and Peppas plot, Linearity Concept of significance, Standard deviation , Chi square test, students T-test , ANOVA test.

References:
1. Theory and Practice of Industrial Pharmacy By Lachmann and Libermann
3. Pharmaceutical Dosage forms: Disperse systems, Vol, 1-2; By Leon Lachmann.
4. Pharmaceutical Dosage forms: Parenteral medications Vol. 1-2; By Leon Lachmann.
5. Modern Pharmaceutics; By Gillbert and S. Banker.
8. Physical Pharmacy; By Alfred martin
11. Quality Assurance Guide; By Organization of Pharmaceutical producers of India.
13. How to practice GMPs; By P.P.Sharma. Vandhana Publications, Agra.
15. Pharmaceutical Preformulations; By J.J. Wells.
16. Applied production and operations management; By Evans, Anderson, Sweeney and Williams.
17. Encyclopaedia of Pharmaceutical technology, Vol I – III.
REGULATORY AFFAIRS (MPH 104T)

Scope
Course designed to impart advanced knowledge and skills required to learn the concept of generic drug and their development, various regulatory filings in different countries, different phases of clinical trials and submitting regulatory documents: filing process of IND, NDA and ANDA
- To know the approval process of
- To know the chemistry, manufacturing controls and their regulatory importance
- To learn the documentation requirements for
- To learn the importance and

Objectives:
Upon completion of the course, it is expected that the students will be able to understand
- The Concepts of innovator and generic drugs, drug development process
- The Regulatory guidance’s and guidelines for filing and approval process
- Preparation of Dossiers and their submission to regulatory agencies in different countries
- Post approval regulatory requirements for actives and drug products
- Submission of global documents in CTD/eCTD formats
- Clinical trials requirements for approvals for conducting clinical trials
- Pharmacovigilence and process of monitoring in clinical trials.

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<th>Units</th>
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<tbody>
<tr>
<td>1</td>
<td>a. <strong>Documentation in Pharmaceutical industry</strong>: Master formula</td>
<td>12</td>
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<tr>
<td></td>
<td>record, DMF (Drug Master File), distribution records. Generic</td>
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<td></td>
<td>drugs product development Introduction, Hatch- Waxman</td>
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<td></td>
<td>act and amendments, CFR (CODE OF FEDERAL REGULATION) drug product</td>
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<td></td>
<td>performance, in-vitro, ANDA, regulatory approval process, NDA approval</td>
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<td>process, BE and drug product assessment, in –vivo, scale up process</td>
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<td>approval changes, post marketing surveillance, outsourcing BA and BE to</td>
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<td>CRO.</td>
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<td>b. <strong>Regulatory requirement for product approval</strong>: API, biologics, novel</td>
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<td>therapies obtaining NDA, ANDA for generic drugs ways and means of US</td>
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<td>registration for foreign drugs</td>
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<td>CMC, post approval regulatory affairs. Regulation for combination</td>
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<td>products and medical devices, CTD and ECTD format, industry and FDA</td>
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<td>liaison. ICH - Guidelines of ICH-Q, S E, M. Regulatory requirements of</td>
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<td>EU, MHRA, TGA and ROW countries.</td>
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<td>3</td>
<td><strong>Non clinical drug development</strong>: Global submission of IND, NDA, ANDA.</td>
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<td></td>
<td>Investigation of medicinal products dossier, dossier Hrs (IMPD) and</td>
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<td>investigator brochure (IB).</td>
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<tr>
<td>4</td>
<td><strong>Clinical trials</strong>: Developing clinical trial protocols. Institutional</td>
<td>12</td>
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</tbody>
</table>
review board/ independent ethics committee Formulation and Hrs working procedures informed Consent process and procedures, HIPAA- new, requirement to clinical study process, pharmacovigilance safety monitoring in clinical trials.

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

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

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

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<tbody>
<tr>
<td>1</td>
<td>Targeted Drug Delivery Systems: Concepts, Events and biological process involved in drug targeting. Tumor targeting and Hrs Brain specific delivery.</td>
<td>12</td>
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<tr>
<td>4</td>
<td>Pulmonary Drug Delivery Systems: Aerosols, propellents, ContainersTypes, preparation and evaluation, Intra Nasal Route Delivery systems; Types, preparation and evaluation.</td>
<td>12</td>
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</tbody>
</table>

References
ADVANCED BIOPHARMACEUTICS & PHARMACOKINETICS (MPH 202T)

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

Objectives
Upon completion of this course it is expected that students will be able understand,
- The basic concepts in biopharmaceutics and pharmacokinetics.
- The use raw data and derive the pharmacokinetic models and parameters the best describe the process of drug absorption, distribution, metabolism and elimination.
- The critical evaluation of biopharmaceutic studies involving drug product equivalency.
- The design and evaluation of dosage regimens of the drugs using pharmacokinetic and biopharmaceutic parameters.
- The potential clinical pharmacokinetic problems and application of basics of pharmacokinetic

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in the design of a drug product.

| 3 | **Pharmacokinetics:** Basic considerations, pharmacokinetic models, compartment modeling: one compartment model- IV bolus, IV infusion, extra-vascular. Multi compartment model: two compartment - model in brief, non-linear pharmacokinetics: cause of non-linearity, Michaelis – Menten equation, estimation of kmax and vmax. Drug interactions: introduction, the effect of protein-binding interactions, the effect of tissue-binding interactions, cytochrome p450-based drug interactions, drug interactions linked to transporters. | 12 |
|---|---|
| 4 | **Drug Product Performance, In Vivo: Bioavailability and Bioequivalence:** drug product performance, purpose of bioavailability studies, relative and absolute availability. Methods for assessing bioavailability, bioequivalence studies, design and evaluation of bioequivalence studies, study designs, crossover study designs, evaluation of the data, bioequivalence example, study submission and drug review process. Biopharmaceutics classification system, methods. Permeability: In-vitro, in-situ and In-vivo methods, generic biologics (biosimilar drug products), clinical significance of bioequivalence studies, special concerns in bioavailability and bioequivalence studies, generic substitution. | 12 |
| 5 | **Application of Pharmacokinetics:** Modified-Release Drug Products, Targeted Drug Delivery Systems and Biotechnological Products. Introduction to Pharmacokinetics and pharmacodynamic, drug interactions. Pharmacokinetics and pharmacodynamics of biotechnology drugs. Introduction, Proteins and peptides, Monoclonal antibodies, Oligonucleotides, Vaccines (immunotherapy), Gene therapies. | 12 |

**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 (MPH 203T)

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

Objectives
Upon completion of this course it is expected that students will be able to understand,
- History of Computers in Pharmaceutical Research and Development
- Computational Modeling of Drug Disposition
- Computers in Preclinical Development
- Optimization Techniques in Pharmaceutical Formulation
- Computers in Market Analysis
- Computers in Clinical Development
- Artificial Intelligence (AI) and Robotics
- Computational fluid dynamics (CFD)

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  b. **Quality-by-Design in Pharmaceutical Development:** Introduction, ICH Q8 guideline, Regulatory and industry views on QbD, Scientifically based QbD - examples of application. | 12 |
| 2     | **Computational Modeling Of Drug Disposition:** Introduction, Modeling Techniques: Drug Absorption, Solubility, Intestinal Permeation, Drug Distribution, Drug Excretion, Active Transport; P-gp, BCRP, Nucleoside Transporters, hPEPT1, ASBT, OCT, OATP, BBB-Choline Transporter. | 12 |
| 3     | **Computer-aided formulation development:** Concept of optimization, Optimization parameters, Factorial design, Optimization technology & Screening design. Computers in Pharmaceutical Formulation: Development of pharmaceutical emulsions, microemulsion drug carriers Legal Protection of Innovative Uses of Computers in R&D, The Ethics of Computing in Pharmaceutical Research, Computers in Market analysis | 12 |
| 4 | a. **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  
   c. **Computers in Clinical Development**: Clinical Data Collection and Management, Regulation of Computer Systems | 12 |
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<tr>
<td>5</td>
<td><strong>Artificial Intelligence (AI), Robotics and Computational fluid dynamics</strong>: General overview, Pharmaceutical Automation, Pharmaceutical applications, Advantages and Disadvantages. Current Challenges and Future Directions.</td>
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**References**

COSMETICS AND COSMECEUTICALS (MPH 204T)

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

Objectives
Upon completion of the course, the students shall be able to understand
- Key ingredients used in cosmetics and cosmeceuticals.
- Key building blocks for various formulations.
- Current technologies in the market
- Various key ingredients and basic science to develop cosmetics and cosmeceuticals
- Scientific knowledge to develop cosmetics and cosmeceuticals with desired Safety, stability, and efficacy.

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<tr>
<td>1</td>
<td><strong>Cosmetics – Regulatory:</strong> Definition of cosmetic products as per Indian regulation. Indian regulatory requirements for labeling of cosmetics Regulatory provisions relating to import of cosmetics, Misbranded and spurious cosmetics. Regulatory provisions relating to manufacture of cosmetics – Conditions for obtaining license, prohibition of manufacture and sale of certain cosmetics, loan license, offences and penalties.</td>
<td>12</td>
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<tr>
<td>2</td>
<td><strong>Cosmetics - Biological aspects:</strong> Structure of skin relating to problems like dry skin, acne, pigmentation, prickly heat, wrinkles and body odor. Structure of hair and hair growth cycle. Common problems associated with oral cavity. Cleansing and care needs for face, eye lids, lips, hands, feet, nail, scalp, neck, body and under-arm.</td>
<td>12</td>
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<tr>
<td>3</td>
<td><strong>Formulation Building blocks:</strong> Building blocks for different 12 product formulations of cosmetics/cosmeceuticals. Surfactants – Hrs Classification and application. Emollients, rheological additives: classification and application. Antimicrobial used as preservatives, their merits and demerits. Factors affecting microbial preservative efficacy. Building blocks for formulation of a moisturizing cream, vanishing cream, cold cream, shampoo and toothpaste. Soaps and syndetbars. <strong>Perfumes:</strong> Classification of perfumes. Perfume ingredients listed as allergens in EU regulation. <strong>Controversial ingredients:</strong> Parabens, formaldehyde liberators, dioxane.</td>
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<tr>
<td>4</td>
<td><strong>Design of cosmeceutical products:</strong> 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</td>
<td>12</td>
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through cosmeceutical formulations.

| 5 | **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. | 12 |

**References**

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

MODERN PHARMACEUTICAL ANALYTICAL TECHNIQUES (MPC 101T)

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

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

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<tbody>
<tr>
<td>1</td>
<td>a. <strong>UV-Visible spectroscopy:</strong> Introduction, Theory, Laws, Instrumentation associated with UV-Visible spectroscopy, Choice Hrs of solvents and solvent effect and Applications of UV-Visible spectroscopy, Difference/ Derivative spectroscopy.</td>
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<td></td>
<td>b. <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, Data Interpretation.</td>
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<td></td>
<td>c. <strong>Spectrofluorimetry:</strong> Theory of Fluorescence, Factors affecting fluorescence (Characterestics of drugs that can be analysed by flourimetry), Quenchers, Instrumentation and Applications of fluorescence spectrophotometer.</td>
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<td>d. <strong>Flame emission spectroscopy and Atomic absorption spectroscopy:</strong> Principle, Instrumentation, Interferences and Applications.</td>
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<td>2</td>
<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, Brief outline of principles of FT-NMR and 13C NMR. Applications of NMR spectroscopy.</td>
<td>10</td>
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<tr>
<td>3</td>
<td><strong>Mass Spectroscopy:</strong> Principle, Theory, Instrumentation of Mass Spectroscopy, Different types of ionization like electron impact, chemical, field, FAB and MALDI, APCI, ESI, APPI Analyzers of Quadrupole and Time of Flight, Mass fragmentation and its rules, Meta stable ions, Isotopic peaks and Applications of Mass spectroscopy.</td>
<td>10</td>
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</tbody>
</table>
Chromatography: Principle, apparatus, instrumentation, chromatographic parameters, factors affecting resolution, isolation of drug from excipients, data interpretation and applications of the following:
   a. Thin Layer chromatography
   b. High Performance Thin Layer Chromatography
   c. Ion exchange chromatography
   d. Column chromatography
   e. Gas chromatography
   f. High Performance Liquid chromatography
   g. Ultra High Performance Liquid chromatography
   h. Affinity chromatography
   i. Gel Chromatography

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

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

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

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

References
ADVANCED ORGANIC CHEMISTRY - I (MPC 102T)

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

Objectives
Upon completion of course, the student shall be to understand
- The principles and applications of retrosynthesis
- The mechanism & applications of various named reactions
- The concept of disconnection to develop synthetic routes for small target molecule.
- The various catalysts used in organic reactions
- The chemistry of heterocyclic compounds

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<td><strong>Basic Aspects of Organic Chemistry:</strong></td>
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<td>1. Organic intermediates: Carbocations, carbanions, free radicals,</td>
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<td></td>
<td>carbenes and nitrenes. Their method of formation, stability and</td>
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<td></td>
<td>synthetic applications.</td>
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<td>2. Types of reaction mechanisms and methods of determining them,</td>
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<td>3. Detailed knowledge regarding the reactions, mechanisms</td>
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<td></td>
<td>and their relative reactivity and orientations.</td>
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<td><strong>Addition reactions</strong></td>
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<td></td>
<td>a) Nucleophilic uni- and bimolecular reactions (SN1 and SN2)</td>
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<td>b) Elimination reactions (E1 &amp; E2; Hoffman &amp; Saytzeff’s rule)</td>
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<td>c) Rearrangement reaction</td>
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<td>2</td>
<td>**Study of mechanism and synthetic applications of following named</td>
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<td>reactions:**</td>
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<tr>
<td></td>
<td>Ugi reaction, Brook rearrangement, Ullmann coupling reactions,</td>
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<td>Dieckmann Reaction, Doebner-Miller Reaction, Sandmeyer Reaction,</td>
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<td>Mitsunobu reaction, Mannich reaction, Vilsmeier-Haack Reaction,</td>
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<td>Sharpless asymmetric epoxidation, Baeyer-Villiger oxidation, Shapiro &amp;</td>
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<td>Suzuki reaction, Ozonolysis and Michael addition reaction</td>
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<td><strong>Synthetic Reagents &amp; Applications:</strong></td>
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<td>Aluminiumisopropoxide, N-</td>
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<td></td>
<td>bromosuccinamide, diazomethane, dicyclohexylcarbodimide, Wilkinson</td>
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<td></td>
<td>reagent, Witting reagent. Osmium tetroxide, titanium chloroide,</td>
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<td></td>
<td>diazopropane, diethyl azodicarboxylate, Triphenylphosphine, Benzotriazol-1-yloxy) tris (dimethylamino) phosphonium hexafluoro-phosphate (BOP). Protecting groups</td>
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<td></td>
<td>a. Role of protection in organic synthesis</td>
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<td>b. Protection for the hydroxyl group, including 1,2-and1,3-diols:</td>
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<td>4</td>
<td><strong>Heterocyclic Chemistry:</strong> Organic Name reactions with their respective mechanism and application involved in synthesis of drugs containing five, six membered and fused heterocyclics such as Debus-Radziszewski imidazole synthesis, Knorr Pyrazole Synthesis Pinner Pyrimidine Synthesis, Combes Quinoline Synthesis, Bernthsen Acridine Synthesis, Smiles rearrangement and Traube purine synthesis. Synthesis of few representative drugs containing these heterocyclic nucleus such as Ketoconazole, Metronidazole, Miconazole, celecoxib, antipyrin, Metamizolesodium, Terconazole, Alprazolam, Triamterene, Sulfameterazine, Trimethoprim, Hydroxychloroquine, Quinine, Chloroquine, Quinacrine, Amsacrine, Prochlorperazine, Promazine, Chlorpromazine, Theophylline, Mercaptopurine and Thioguanine.</td>
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| 5 | **Synthon approach and retrosynthesis applications**<br> i. Basic principles, terminologies and advantages of retrosynthesis; guidelines for dissection of molecules. Functional group interconversion and addition (FGI and FGA)<br> ii. C-X disconnections; C-C disconnections – alcohols and carbonyl compounds; 1,2-, 1,3-,1,4-, 1,5-, 1,6-difunctionalized compounds<br> iii. Strategies for synthesis of three, four, five and six membered ring. | 12 |

**References**

ADVANCED MEDICINAL CHEMISTRY (MPC 103T)

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

Objectives
At completion of this course it is expected that students will be able to understand
- Different stages of drug discovery
- Role of medicinal chemistry in drug research
- Different techniques for drug discovery
- Various strategies to design and develop new drug like molecules for biological targets
- Peptidomimetics

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<tr>
<td>1</td>
<td><strong>Drug discovery:</strong> Stages of drug discovery, lead discovery; identification, validation and diversity of drug targets. <strong>Biological drug targets:</strong> Receptors, types, binding and activation, theories of drug receptor interaction, drug receptor interactions, agonists vs antagonists, artificial enzymes.</td>
<td>12</td>
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</tbody>
</table>
| 2     | **Prodrug Design and Analog design:**  
  a. **Prodrug design:** Basic concept, Carrier linked prodrugs/ Bioprecursors, Prodrugs of functional group, Prodrugs to improve patient acceptability, Drug solubility, Drug absorption and distribution, site specific drug delivery and sustained drug action. Rationale of prodrug design and practical consideration of prodrug design.  
  b. **Combating drug resistance:** Causes for drug resistance, strategies to combat drug resistance in antibiotics and anticancer therapy, Genetic principles of drug resistance.  
  c. **Analog Design:** Introduction, Classical & Non classical, Bioisosteric replacement strategies, rigid analogs, alteration of chain branching, changes in ring size, ring position isomers, design of stereo isomers and geometric isomers, fragments of a lead molecule, variation in inter atomic distance. | 12 |
| 3     | a) Medicinal chemistry aspects of the following class of drugs  
  Systematic study, SAR, Mechanism of action and synthesis of new generation molecules of following class of drugs:  
  b. Stereochemistry and Drug action: Realization that stereo selectivity is a pre-requisite for evolution. Role of chirality in | 12 |
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<th>4</th>
<th><strong>Rational Design of Enzyme Inhibitors</strong>: Enzyme kinetics &amp; Principles of Enzyme inhibitors, Enzyme inhibitors in medicine, Enzyme inhibitors in basic research, rational design of non-covalently and covalently binding enzyme inhibitors.</th>
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<td>5</td>
<td><strong>Peptidomimetics</strong>: Therapeutic values of Peptidomimetics, design of peptidomimetics by manipulation of the amino acids, modification of the peptide backbone, incorporating conformational constraints locally or globally. Chemistry of prostaglandins, leukotrienes and thromboxones.</td>
<td>12</td>
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</table>

**References**

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

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

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

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<th>Units</th>
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<tr>
<td>1</td>
<td><strong>Study of Natural products as leads for new pharmaceuticals for the following class of drugs</strong></td>
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<td>a) Drugs Affecting the Central Nervous System: Morphine Alkaloids</td>
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<td>b) Anticancer Drugs: Paclitaxel and Docetaxel, Etoposide, and Teniposide</td>
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<td>c) Cardiovascular Drugs: Lovastatin, Teprotide and Dicoumarol</td>
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<td>d) Neuromuscular Blocking Drugs: Curare alkaloids</td>
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<td></td>
<td>e) Anti-malarial drugs and Analogues</td>
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<td></td>
<td>f) Chemistry of macrolid antibiotics (Erythromycin, Azithromycin, Roxithromycin, and Clarithromycin) and β-Lactam antibiotics (Cephalosporins and Carbapenem)</td>
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<td>2</td>
<td>a) <strong>Alkaloids:</strong> General introduction, classification, isolation, purification, molecular modification and biological activity of alkaloids, general methods of structural determination of alkaloids, structural elucidation and stereochemistry of ephedrine, morphine, ergot, emetine and reserpine.</td>
<td>12</td>
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<td>b) <strong>Flavonoids:</strong> Introduction, isolation and purification of flavonoids, General methods of structural determination of flavonoids; Structural elucidation of quercetin.</td>
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<td>c) <strong>Steroids:</strong> General introduction, chemistry of sterols, sapogenin and cardiac glycosides. Stereochemistry and nomenclature of steroids, chemistry of contraceptive agents male &amp; female sex hormones (Testosterone, Estradiol, Progesterone), adrenocorticoids (Cortisone), contraceptive agents and steroids (Vit – D).</td>
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|   | a) **Terpenoids:** Classification, isolation, isoprene rule and general methods of structural elucidation of Terpenoids; Structural elucidation of drugs belonging to mono (citral, menthol, camphor), di(retinol, Phytol, taxol) and tri terpenoids (Squalene,Ginsenoside) carotinoids (β carotene).  
  b) **Vitamins:** Chemistry and Physiological significance of Vitamin A, B1, B2, B12, C, E, Folic acid and Niacin. | 12 |
|---|---|
| 4 | a) **Recombinant DNA technology and drug discovery:** rDNA technology, hybridoma technology, New pharmaceuticals derived from biotechnology; Oligonucleotide therapy. Gene therapy: Introduction, Clinical application and recent advances in gene therapy, principles of RNA & DNA estimation  
  b) **Active constituent of certain crude drugs used in Indigenous system Diabetic therapy** – Gymnema sylvestre, Salacia reticulate, Pterocarpus marsupiam, Swertia chirata, Trigonella foemum graccum; Liver dysfunction – Phyllanthus niruri; Antitumor – Curcuma longa Linn. | 12 |
| 5 | **Structural Characterization of natural compounds:** Structural characterization of natural compounds using IR, 1HNMR, 13CNMR and MS Spectroscopy of specific drugs e.g., Penicillin, Morphine, Camphor, Vit-D, Quercetin and Digitalis glycosides. | 12 |

**References**

4. Chemistry of natural products Vol I onwards IWPAC.  
5. Natural Product Chemistry Nakanishi Ggogo, University Science Books, California.  
8. Introduction to molecular Phytochemistry – CHJ Wells, Chapmannstall.  
16. Burger’s Medicinal Chemistry.
PHARMACEUTICAL CHEMISTRY PRACTICAL - I (MPC 105P)

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

To perform the following reactions of synthetic importance

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

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

Objectives
At completion of this course it is expected that students will be able to understand:
- Interpretation of the NMR, Mass and IR spectra of various organic compounds
- Theoretical and practical skills of the hyphenated instruments
- Identification of organic compounds

Units

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<td>1</td>
<td>UV and IR spectroscopy: Wood ward – Fieser rule for 1,3-butadienes, cyclic dienes and α, β-carbonyl compounds and interpretation compounds of enones. ATR-IR, IR Interpretation of organic compounds.</td>
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<td>2</td>
<td>NMR spectroscopy: 1-D and 2-D NMR, NOESY and COSY, HECTOR, INADEQUATE techniques, Interpretation of organic compounds.</td>
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<td>3</td>
<td>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.</td>
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<td>4</td>
<td>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</td>
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References
ADVANCED ORGANIC CHEMISTRY - II (MPC 202T)

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

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

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<td><strong>Green Chemistry:</strong></td>
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<td>a. Introduction, principles of green chemistry</td>
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<td>b. Microwave assisted reactions: Merit and demerits of its use, increased reaction rates, mechanism, superheating effects of microwave, effects of solvents in microwave assisted synthesis, microwave technology in process optimization, its applications in various organic reactions and heterocycles synthesis</td>
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<td>c. Ultrasound assisted reactions: Types of sonochemical reactions, homogenous, heterogeneous liquid-liquid and liquid-solid reactions, synthetic applications</td>
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<td>d. Continuous flow reactors: Working principle, advantages and synthetic applications</td>
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<td><strong>Chemistry of peptides</strong></td>
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<td>a. Coupling reactions in peptide synthesis</td>
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<td>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</td>
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<td>c. Segment and sequential strategies for solution phase peptide synthesis with any two case studies</td>
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<td>d. Side reactions in peptide synthesis: Deletion peptides, side reactions initiated by proton abstraction, protonation, overactivation and side reactions of individual amino acids</td>
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<td><strong>Photochemical Reactions:</strong> Basic principles of photochemical reactions. Photo-oxidation, photo-addition and photo-fragmentation. <strong>Pericyclic reactions:</strong> Mechanism, Types of pericyclic reactions such</td>
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as cyclo addition, electrocyclic reaction and sigmatrophic rearrangement reactions with examples

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<td>b.</td>
<td>Heterogeneous catalysis – preparation, characterization, kinetics, supported catalysts, catalyst deactivation and regeneration, some examples of heterogeneous catalysis used in synthesis of drugs.</td>
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<td>c.</td>
<td>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</td>
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<td>d.</td>
<td>Transition-metal and Organo-catalysis in organic synthesis: Metal-catalyzed reactions</td>
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<td>Phase transfer catalysis - theory and applications</td>
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<th>Stereochemistry &amp; Asymmetric Synthesis</th>
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<td>a.</td>
<td>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.</td>
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<tr>
<td>b.</td>
<td>Methods of asymmetric Synthesis using chiral pool, chiral auxiliaries and catalytic asymmetric synthesis, enantiopure separation and Stereo selective synthesis with examples.</td>
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References
6. Organic synthesis-the disconnection approach, S. Warren, Wily India
7. Principles of organic synthesis, ROCNorman and JMCoxan, Nelson thorns
COMPUTER AIDED DRUG DESIGN (MPC 203T)

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

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

Units | Contents | Hours |
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1 | **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: Hammet equation and electronic parameters (sigma), lipophilicity effects and parameters (log P, pi-substituent constant), steric effects (Taft steric and MR parameters) Experimental and theoretical approaches for the determination of these physicochemical parameters. | 12 |
2 | **Quantitative Structure Activity Relationships:** Applications Hansch analysis, Free Wilson analysis and relationship between them, Advantages and disadvantages; Deriving 2D-QSAR equations. 3D-QSAR approaches and contour map analysis. Statistical methods used in QSAR analysis and importance of statistical parameters. | 12 |
3 | **Molecular Modeling and Docking**
   a) Molecular and Quantum Mechanics in drug design.
   b) Energy Minimization Methods: comparison between global minimum conformation and bioactive conformation
   c) Molecular docking and drug receptor interactions: Rigid docking, flexible docking and extra-precision docking. Agents acting on enzymes such as DHFR, HMG-CoA reductase and HIV protease, choline esterase (AchE & BchE) | 12 |
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. | 12 |
c) Homology modeling and generation of 3D-structure of protein.

| 5 | Pharmacophore Mapping and Virtual Screening: Concept of pharmacophore, pharmacophore mapping, identification of Pharmacophore features and Pharmacophore modeling; Conformational search used in pharmacophore mapping. In Silico Drug Design and Virtual Screening Techniques Similarity based methods and Pharmacophore based screening, structure based In-silico virtual screening protocols. | 12 |

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

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

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

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<tr>
<td>1</td>
<td><strong>Process chemistry:</strong> Introduction, Synthetic strategy Stages of scale up process: Bench, pilot and large scale process. In-process control and validation of large scale process. Case studies of some scale up process of APIs. Impurities in API, types and their sources including genotoxic impurities</td>
<td>12</td>
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<td><strong>Unit operations</strong>&lt;br&gt;a) Extraction: Liquid equilibria, extraction with reflux, Hrs extraction with agitation, counter current extraction.&lt;br&gt;b) Filtration: Theory of filtration, pressure and vacuum filtration, centrifugal filtration,&lt;br&gt;c) Distillation: azeotropic and steam distillation&lt;br&gt;d) Evaporation: Types of evaporators, factors affecting evaporation.&lt;br&gt;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.</td>
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<td>3</td>
<td><strong>Unit Processes - I</strong>&lt;br&gt;a) Nitration: Nitrating agents, Aromatic nitration, kinetics and mechanism of aromatic nitration, process equipment for technical nitration, mixed acid for nitration&lt;br&gt;b) Halogenation: Kinetics of halogenations, types of halogenations, catalytic halogenations. Case study on industrial halogenation process.&lt;br&gt;c) Oxidation: Introduction, types of oxidative reactions, Liquid phase oxidation with oxidizing agents. Nonmetallic Oxidizing agents such as H2O2, sodium hypochlorite, Oxygen gas, ozonolysis.</td>
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<td>5</td>
<td><strong>Industrial Safety</strong></td>
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<td>a)</td>
<td>MSDS (Material Safety Data Sheet), hazard labels of Hrs chemicals and Personal Protection Equipment (PPE)</td>
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<td>b)</td>
<td>Fire hazards, types of fire &amp; fire extinguishers</td>
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<td>c)</td>
<td>Occupational Health &amp; Safety Assessment Series 1800 (OHSAS-1800) and ISO-14001(Environmental Management System), Effluents and its management</td>
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**References**

8. P.H.Groggins: Unit processes in organic synthesis (MGH)
9. F.A.Henglein: Chemical Technology (Pergamon)
10. M.Gopal: Dryden’s Outlines of Chemical Technology, WEP East-West Press
12. Lowenheim & M.K. Moran: Industrial Chemicals
17. ICH Guidelines
18. United States Food and Drug Administration official website www.fda.gov
PHARMACEUTICAL CHEMISTRY PRACTICALS – II (MPC 205P)

1. Synthesis of organic compounds by adapting different approaches involving (3 experiments)
   a) Oxidation
   b) Reduction/hydrogenation
   c) Nitration
2. Comparative study of synthesis of APIs/intermediates by different synthetic routes (2 experiments)
3. Assignments on regulatory requirements in API (2 experiments)
4. Comparison of absorption spectra by UV and Wood ward – Fieser rule
5. Interpretation of organic compounds by FT-IR
6. Interpretation of organic compounds by NMR
7. Interpretation of organic compounds by MS
8. Determination of purity by DSC in pharmaceuticals
9. Identification of organic compounds using FT-IR, NMR, CNMR and Mass spectra
10. To carry out the preparation of following organic compounds
12. Preparation of 4-iodotolene from p-toluidine.
13. NaBH4 reduction of vanillin to vanillyl alcohol
14. Preparation of umbelliferone by Pechhman reaction
15. Preparation of triphenyl imidazole
16. To perform the Microwave irradiated reactions of synthetic importance (Any two)
17. Determination of log P, MR, hydrogen bond donors and acceptors of selected drugs using softwares
18. Calculation of ADMET properties of drug molecules and its analysis using softwares
   Pharmacophore modeling
19. 2D-QSAR based experiments
20. 3D-QSAR based experiments
21. Docking study based experiment
22. Virtual screening based experiment
Scope
This subject deals with various advanced analytical instrumental techniques for identification, characterization and quantification of drugs. Instruments dealt are NMR, Mass spectrometer, IR, HPLC, GC etc.

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

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<tr>
<th>Units</th>
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<th>Hours</th>
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</thead>
</table>
| 1     | a. **UV-Visible spectroscopy:** Introduction, Theory, Laws, Instrumentation associated with UV-Visible spectroscopy, Choice Hrs of solvents and solvent effect and Applications of UV-Visible spectroscopy, Difference/ Derivative spectroscopy.  
   b. **IR spectroscopy:** Theory, Modes of Molecular vibrations, Sample handling, Instrumentation of Dispersive and Fourier - Transform IR Spectrometer, Factors affecting vibrational frequencies and Applications of IR spectroscopy, Data Interpretation.  
   c. **Spectrofluorimetry:** Theory of Fluorescence, Factors affecting fluorescence (Characterestics of drugs that can be analysed by flourimetry), Quenchers, Instrumentation and Applications of fluorescence spectrophotometer.  
   d. **Flame emission spectroscopy and Atomic absorption spectroscopy:** Principle, Instrumentation, Interferences and Applications. | 10 |
| 2     | **NMR spectroscopy:** Quantum numbers and their role in NMR, Principle, Instrumentation, Solvent requirement in NMR, Relaxation process, NMR signals in various compounds, Chemical shift, Factors influencing chemical shift, Spin-Spin coupling, Coupling constant, Nuclear magnetic double resonance, Brief outline of principles of FT-NMR and 13C NMR. Applications of NMR spectroscopy. | 10 |
| 3     | **Mass Spectroscopy:** Principle, Theory, Instrumentation of Mass Spectroscopy, Different types of ionization like electron impact, chemical, field, FAB and MALDI, APCI, ESI, APPI Analyzers of Quadrupole and Time of Flight, Mass fragmentation and its rules, Meta stable ions, Isotopic peaks and Applications of Mass spectroscopy. | 10 |
| 4     | **Chromatography:** Principle, apparatus, instrumentation, chromatographic parameters, factors affecting resolution, isolation of | 10 |
drug from excipients, data interpretation and applications of the following:
   a. Thin Layer chromatography
   b. High Performance Thin Layer Chromatography
   c. Ion exchange chromatography
   d. Column chromatography
   e. Gas chromatography
   f. High Performance Liquid chromatography
   g. Ultra High Performance Liquid chromatography
   h. Affinity chromatography
   i. Gel Chromatography

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

| 6 | a. **Potentiometry**: Principle, working, Ion selective Electrodes and Application of potentiometry.
   b. **Thermal Techniques**: Principle, thermal transitions and Instrumentation (Heat flux and power-compensation and designs), Modulated DSC, Hyper DSC, experimental parameters (sample preparation, experimental conditions, calibration, heating and cooling rates, resolution, source of errors) and their influence, advantage and disadvantages, pharmaceutical applications. Differential Thermal Analysis (DTA): Principle, instrumentation and advantage and disadvantages, pharmaceutical applications, derivative differential thermal analysis (DDTA). TGA: Principle, instrumentation, factors affecting results, advantage and disadvantages, pharmaceutical applications.
   c. **Immunological assays**: RIA (Radio immuno assay), ELISA, Bioluminescence assays. |

**References**
QUALITY MANAGEMENT SYSTEMS (MQA 102T)

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

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<th>Units</th>
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<tbody>
<tr>
<td>1</td>
<td>Introduction to Quality: Evolution of Quality, Definition of Quality, Dimensions of Quality</td>
<td>12</td>
</tr>
<tr>
<td></td>
<td>Quality as a Strategic Decision: Meaning of strategy and strategic quality management, mission and vision statements, quality policy, Quality Objectives, strategic planning and implementation, McKinsey 7s model, Competitive analysis, Management commitment to quality</td>
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<td></td>
<td>Customer Focus: Meaning of customer and customer focus, Classification of customers, Customer focus, Customer perception of quality, Factors affecting customer perception, Customer requirements, Meeting customer needs and expectations, Customer satisfaction and Customer delight, Handling customer complaints, Understanding customer behavior, concept of internal and external customers. Case studies.</td>
<td></td>
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<tr>
<td></td>
<td>Cost of Quality: Cost of quality, Categories of cost of Quality, Models of cost of quality, Optimising costs, Preventing cost of quality.</td>
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<tr>
<td>3</td>
<td>Six System Inspection model: Quality Management system, Production system, Facility and Equipment system, Laboratory</td>
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</table>
control system, Materials system, Packaging and labeling system. Concept of self inspection.

**Quality systems:** Change Management/ Change control, Deviations, Out of Specifications (OOS), Out of Trend (OOT), Complaints - evaluation and handling, Investigation and determination of root cause, Corrective & Preventive Actions (CAPA), Returns and Recalls, Vendor Qualification, Annual Product Reviews, Batch Review and Batch Release. Concept of IPQC, area clearance/ Line clearance.

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<tr>
<td>4</td>
<td><strong>Drug Stability:</strong></td>
<td>ICH guidelines for stability testing of drug substances and drug products. Study of ICH Q8, Quality by Design and Process development report <strong>Quality risk management:</strong> Introduction, risk assessment, risk control, risk review, risk management tools, HACCP, risk ranking and filtering according to ICH Q9 guidelines.</td>
</tr>
<tr>
<td>5</td>
<td><strong>Statistical Process control (SPC):</strong></td>
<td>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.</td>
</tr>
</tbody>
</table>

**References**

1. Implementing Juran's Road Map for Quality Leadership: Benchmarks and Results, By Al Endres, Wiley, 2000
2. Understanding, Managing and Implementing Quality: Frameworks, Techniques and Cases, By Jiju Antony; David Preece, Routledge, 2002
4. Corporate Culture and the Quality Organization By James W. Fairfield-Sonn, Quorum Books, 2001
QUALITY CONTROL AND QUALITY ASSURANCE (MQA 103T)

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

Objectives
Upon completion of this course the student should be able to
- Understand the cGMP aspects in a pharmaceutical industry
- To appreciate the importance of documentation
- To understand the Scope of quality certifications applicable to Pharmaceutical industries
- To understand the responsibilities of QA & QC departments.

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<th>Units</th>
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<tr>
<td>1</td>
<td><strong>Introduction:</strong> Concept and evolution and Scopes of Quality Control and Quality Assurance, Good Laboratory Practice, GMP, Overview of ICH Guidelines - QSEM, with special emphasis on Q-series guidelines. <strong>Good Laboratory Practices:</strong> Scope of GLP, Definitions, Quality assurance unit, protocol for conduct of non clinical testing, control on animal house, report preparation and documentation. CPCSEA guidelines.</td>
<td>12</td>
</tr>
<tr>
<td>2</td>
<td>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.</td>
<td>12</td>
</tr>
<tr>
<td>3</td>
<td>Analysis of raw materials, finished products, packaging materials, in process quality control (IPQC), Developing specification (ICH Q6 and Q3), purchase specifications and maintenance of stores for raw materials. In process quality control and finished products quality control for following dosage forms in Pharma industry according to Indian, US and British pharmacopoeias: tablets, capsules, ointments, suppositories, creams, parenterals, ophthalmic and surgical products (How to refer pharmacopoeias).</td>
<td>12</td>
</tr>
<tr>
<td>4</td>
<td><strong>Documentation in pharmaceutical industry:</strong> Three tier documentation, Policy, Procedures and Work instructions, and records (Formats), Basic principles- How to maintain, retention and retrieval etc. Standard operating procedures (How to write), Master Batch Record, Batch Manufacturing Record, Quality audit plan and</td>
<td>12</td>
</tr>
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</table>

5 Manufacturing operations and controls: Sanitation of manufacturing premises, mix-ups and cross contamination, processing of intermediates and bulk products, packaging operations, IPQC, release of finished product, process deviations, charge-in of components, time limitations on production, drug product inspection, expiry date calculation, calculation of yields, production record review, change control, sterile products, aseptic process control, packaging, reprocessing, salvaging, handling of waste and scrap disposal. Introduction, Scope and importance of intellectual property rights. Concept of trade mark, copyright and patents.

References
7. ICH guidelines
8. ISO 9000 and total quality management
14. Packaging of Pharmaceuticals.
15. Schedule M and Schedule N.
PRODUCT DEVELOPMENT AND TECHNOLOGY TRANSFER (MQA 104T)

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

Objectives
Upon completion of this course the student should be able to
- To understand the new product development process
- To understand the necessary information to transfer technology from R&D to actual manufacturing by sorting out various information obtained during R&D
- To elucidate necessary information to transfer technology of existing products between various manufacturing places

Units | Contents | Hours
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1 | Principles of Drug discovery and development: Introduction, Clinical research process. Development and informational content for Investigational New Drugs Application (IND), New Drug Application (NDA), Abbreviated New Drug Application (ANDA), Supplemental New Drug Application (SNDA), Scale Up Post Approval Changes (SUPAC) and Bulk active chemical Post approval changes (BACPAC), Post marketing surveillance, Product registration guidelines – CDSCO, USFDA. | 12
2 | Pre-formulation 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. Pre-formulation protocol, Stability testing during product development. | 12
3 | Pilot plant scale up: Concept, Significance, design, layout of pilot plant scale up study, operations, large scale manufacturing techniques (formula, equipment, process, stability and quality control) of solids, liquids, semisolid and parenteral dosage forms. New era of drug products: opportunities and challenges. | 12
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 (MQA 105P)

1. Analysis of Pharmacopoeial compounds in bulk and in their formulations (tablet/ capsules/ semisolids) by UV Vis spectrophotometer
2. Simultaneous estimation of multi-drug 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 or AAS
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 semisolid dosage forms.
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 pre formulation 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 packaging 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 (MQA 201T)

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

Objectives
At completion of this course it is expected that students will be able to
- Understand about environmental problems among learners.
- Impart basic knowledge about the environment and its allied problems.
- Develop an attitude of concern for the industry environment.
- Ensure safety standards in pharmaceutical industry
- Provide comprehensive knowledge on the safety management
- Empower an ideas to clear mechanism and management in different kinds of hazard management system
- Teach the method of Hazard assessment, procedure, methodology for provide safe industrial atmosphere.

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<tr>
<td>1</td>
<td>Multidisciplinary nature of environmental studies: Natural Resources, Renewable and non-renewable resources, Natural resources and associated problems, a) Forest resources; b) Water resources; c) Mineral resources; d) Energy resources; e) Land resources Ecosystems: Concept of an ecosystem and Structure and function of an ecosystem. Environmental hazards: Hazards based on Air, Water, Soil and Radioisotopes.</td>
<td>12</td>
</tr>
<tr>
<td>2</td>
<td>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.</td>
<td>12</td>
</tr>
<tr>
<td>3</td>
<td>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.</td>
<td>12</td>
</tr>
<tr>
<td>4</td>
<td>Fire and Explosion: Introduction, Industrial processes and hazards potential, mechanical electrical, thermal and process hazards. Safety and hazards regulations, Fire protection system: Fire prevention,</td>
<td>12</td>
</tr>
</tbody>
</table>

**References**

1. Y.K. Sing, Environmental Science, New Age International Pvt, Publishers, Bangalore
PHARMACEUTICAL VALIDATION (MQA 202T)

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

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<tr>
<td>1</td>
<td><strong>Introduction to validation:</strong> Definition of Calibration, Qualification and Validation, Scope, frequency and importance. Difference between calibration and validation. Calibration of weights and measures. Advantages of Validation, Scope of Validation, Organization for Validation, Validation Master plan, Types of Validation, Streamlining of qualification &amp; Validation process and Validation Master Plan.</td>
<td>10</td>
</tr>
<tr>
<td>2</td>
<td><strong>Qualification of manufacturing equipment:</strong> Dry Powder Mixers, Fluid Bed and Tray dryers, Tablet Compression (Machine), Dry heat sterilization/Tunnels, Autoclaves, Membrane filtration, Capsule filling machine. <strong>Qualification of analytical instruments:</strong> UV-Visible spectrophotometer, FTIR, DSC, GC, HPLC, HPTLC, LC-MS.</td>
<td>10</td>
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<tr>
<td>3</td>
<td><strong>Qualification of laboratory equipments:</strong> Hardness tester, Friability test apparatus, tap density tester, Disintegration tester, Dissolution test apparatus <strong>Validation of Utility systems:</strong> Pharmaceutical water system &amp; pure steam, HVAC system, Compressed air and nitrogen.</td>
<td>10</td>
</tr>
<tr>
<td>4</td>
<td><strong>Process Validation:</strong> Concept, Process and documentation of Process Validation. Prospective, Concurrent &amp; Retrospective Validation, Revalidation 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.</td>
<td>10</td>
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Analytical method validation: General principles, Validation of analytical method as per ICH guidelines and USP.

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

Validation of facilities in sterile and non-sterile plant.

Computerized system validation: Electronic records and digital signature - 21 CFR Part 11 and GAMP

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

References
3. Validation Master plan by Terveeks or Deeks, Davis Harwood International publishing.
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
AUDITS AND REGULATORY COMPLIANCE (MPA 203T)

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

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<tr>
<td>1</td>
<td><strong>Introduction</strong>: Objectives, Management of audit, Responsibilities, Planning process, information gathering, administration, Classifications of deficiencies</td>
<td>12</td>
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<tr>
<td>2</td>
<td><strong>Role of quality systems and audits in pharmaceutical manufacturing environment</strong>: 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</td>
<td>12</td>
</tr>
<tr>
<td>3</td>
<td><strong>Auditing of vendors and production department</strong>: Bulk Pharmaceutical Chemicals and packaging material Vendor audit, Warehouse and weighing, Dry Production: Granulation, tableting, coating, capsules, sterile production and packaging.</td>
<td>12</td>
</tr>
<tr>
<td>4</td>
<td><strong>Auditing of Microbiological laboratory</strong>: Auditing the manufacturing process, Product and process information, General areas of interest in the building raw materials, Water, Packaging materials</td>
<td>12</td>
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<tr>
<td>5</td>
<td><strong>Auditing of Quality Assurance and engineering department</strong>: Quality Assurance Maintenance, Critical systems: HVAC, Water, Water for Injection systems, ETP.</td>
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References
PHARMACEUTICAL MANUFACTURING TECHNOLOGY (MQA 204T)

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

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| 1     | **Pharmaceutical industry developments**: Legal requirements and Licenses for API and formulation industry, Plant location- Factors influencing.  
**Plant layout**: Factors influencing, Special provisions, Storage space requirements, sterile and aseptic area layout.  
**Production planning**: General principles, production systems, calculation of standard cost, process planning, routing, loading, scheduling, dispatching of records, production control. | 12    |
| 2     | **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. | 12    |
| 3     | **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). | 12    |
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.


| 4 | Containers and closures for pharmaceuticals: Types, performance, assuring quality of glass; types of plastics used, Drug plastic interactions, biological tests, modification of plastics by drugs; different types of closures and closure liners; film wrapper; blister packs; bubble packs; shrink packaging; foil / plastic pouches, bottle seals, tape seals, breakable seals and sealed tubes; quality control of packaging material and filling equipment, flexible packaging, product package compatibility, transit worthiness of package, Stability aspects of packaging. Evaluation of stability of packaging material. |

| 5 | Quality by design (QbD) and process analytical technology (PAT): Current approach and its limitations. Why QbD is required, Advantages, Elements of QbD. Terminology: QTPP. CMA, CQA, CPP, RLD, Design space, Design of Experiments, Risk Assessment and mitigation/minimization. Quality by Design, Formulations by Design, QbD for drug products, QbD for Drug Substances, QbD for Excipients, Analytical QbD. FDA initiative on process analytical technology. PAT as a driver for improving quality and reducing costs: quality by design (QbD), QA, QC and GAMP. PAT guidance, standards and regulatory requirements. |

References


QUALITY ASSURANCE PRACTICAL – II PRACTICALS (MQA 205P)

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 REGULATORY PRACTICES (MRA 101T)

Scope
This course is designed to impart fundamental knowledge on various Good Regulatory Practices viz., cGMP, GLP, GALP and GDP for Pharmaceuticals, Cosmetics, Food & Nutraceuticals, Medical devices, In-vitro Diagnostic Medical Devices (IVDs) and biological products 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 key regulatory and compliance elements with respect to Good Manufacturing Practices, Good Laboratory Practices, Good Automated Laboratory Practices and Good Documentation Practices.
- Prepare and implement the check lists and SOPs for various Good Regulatory Practices
- Implement Good Regulatory Practices in the Healthcare and related Industries
- Prepare for the readiness and conduct of audits and inspections.

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<td>2</td>
<td><strong>Good Laboratory Practices:</strong> Introduction, USFDA GLP Regulations (Subpart A to Subpart K), Controlling the GLP inspection process, Documentation, Audit, goals of Laboratory Quality Audit, Audit tools, Future of GLP regulations, relevant ISO and Quality Council of India (QCI) Standards</td>
<td>12</td>
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<tr>
<td>4</td>
<td><strong>Good Distribution Practices:</strong> 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), relevant CDSCO guidance and ISO standards</td>
<td>12</td>
</tr>
</tbody>
</table>
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, ISO 13485, Sch MIII and other relevant CDSCO regulatory guidance documents.

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.
6. Drugs & Cosmetics Act, Rules & Amendments
DOCUMENTATION AND REGULATORY WRITING (MRA 102T)

Scope
This course is designed to impart fundamental knowledge on documentation and general principles involved in regulatory writing and submission to agencies.

Objectives
Upon completion of the course the student shall be able to,
- Know the various documents pertaining to drugs in pharmaceutical industry
- Understand the basics of regulatory compilation
- Create and assemble the regulation submission as per the requirements of agencies
- Follow up the submissions and post approval document requirements

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<tr>
<td>1</td>
<td><strong>Documentation in pharmaceutical industry:</strong> 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).</td>
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<td>2</td>
<td><strong>Dossier preparation and submission:</strong> Introduction and overview of dossiers, contents and organization of dossier, binders and sections, compilation and review of dossier. Paper submissions, overview and modules of CTD, electronic CTD submissions; 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. Submission in Sugam system of CDSCO.</td>
<td>12</td>
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<td>4</td>
<td><strong>Inspections:</strong> 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).</td>
<td>12</td>
</tr>
</tbody>
</table>

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
13. International Medical Device Regulators Forum (IMDRF) Medical Device Single Audit Program (MDSAP)
CLINICAL RESEARCH REGULATIONS (MRA 103T)

Scope
This course is designed to impart the fundamental knowledge on the clinical development process of drugs, pharmaceuticals and Medical Devices, phases and conduct of clinical trials and research, regulations and guidance governing the conduct of clinical research in India, 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)
- History, origin and ethics of clinical and biomedical research and evaluation
- Clinical drug, medical device development process and different types and phases of clinical trials
- Regulatory requirements and guidance for conduct of clinical trials and research

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Clinical Investigation and Evaluation of Medical Devices & IVDs
Different Types of Studies, Key Concepts of Medical Device Clinical Evaluation, Key concepts of Clinical Investigation

2 | Ethics in Clinical Research: |
| | 3. The ethics of randomized clinical trials |
| | 4. The role of placebo in clinical trials |
| | 5. Ethics of clinical research in special population |
| | 6. Institutional Review Board/Independent Ethics Committee/ Ethics Committee – composition, roles, responsibilities, review and approval process and ongoing monitoring of safety data |

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- Data safety monitoring boards.
- Responsibilities of sponsor, CRO, and investigator in ethical conduct of clinical research
  - Ethical principles governing informed consent process
  - Patient Information Sheet and Informed Consent Form
  - The informed consent process and documentation

3 **Regulations governing Clinical Trials**

**India:** Clinical Research regulations in India – Schedule Y & Medical Device Guidance

**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 Trails Guidance Document: Good Clinical Practice

**EU:** Clinical Trials Guidance Document: Good Clinical Practice in European Union (EMA)

4 **Clinical Research Related Guidelines**

- Good Clinical Practice Guidelines (ICH GCP E6)
- Indian GCP Guidelines
- ICMR Ethical Guidelines for Biomedical Research
- CDSCO guidelines
- GHTF study group 5 guidance documents

**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
- General biostatics principle applied in clinical research

5 **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
- EU MDD with respect to clinical research
- ISO 14155

**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
9. Drugs & Cosmetics Act & Rules and Amendments

**Recommended websites:**

8. ICMR Ethical Guidelines for Biomedical Research: http://icmr.nic.in/ethical_guidelines.pdf
Scope
This course is designed to impart fundamental knowledge on regulations and legislation in India w.r.t. Drugs & Cosmetics, Medical Devices, Biologicals & Herbals, and Food & Nutraceuticals. It prepares the students for basic regulatory requirements in India of Drugs & Cosmetics, Medical Devices, Biologicals & Herbals, and Food & Nutraceuticals. for manufacture, import & registration, export, sale, marketing authorization, clinical trials and intellectual property rights.

Objectives
Upon the completion of the course the student shall be able to:
- Know different Acts and guidelines that regulate Drugs & Cosmetics, Medical Devices, Biologicals & Herbals, and Food & Nutraceuticals industry in India.
- Understand the approval process and regulatory requirements for Drugs & Cosmetics, Medical Devices, Biologicals & Herbals, and Food & Nutraceuticals.

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<td>Biologicals &amp; Herbals, and Food &amp; Nutraceuticals Acts and Rules (with latest amendments):</td>
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<td>1. Drugs and Cosmetics Act 1940 and Rules 1945: DPCO and NPPA</td>
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<td>2. Other relevant provisions (rules schedules and guidelines for approval of Drugs &amp; Cosmetics, Medical Devices, Biologicals &amp; Herbals, and Food &amp; Nutraceuticals in India)</td>
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<tr>
<td>2</td>
<td>Regulatory requirements and approval procedures for Drugs &amp; Cosmetics Medical Devices, Biologicals &amp; Herbals, and Food &amp; Nutraceuticals: CDSCO (Central Drug Standard Control Organization) and State Licensing Authority: Organization, Responsibilities Rules, regulations, guidelines and standards for regulatory filing of Drugs &amp; Cosmetics, Medical Devices, Biologicals &amp; Herbals, and Food &amp; Nutraceuticals Format and contents of Regulatory dossier filing Clinical trial/ investigations</td>
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<td>3</td>
<td>Indian Pharmacopoeial Standards, BIS standards and ISO and other relevant standards</td>
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<td>4</td>
<td>Bioavailability and Bioequivalence data (BA &amp;BE), BCS Classification of Drugs, Regulatory Requirements for Bioequivalence study Stability requirements: ICH and WHO</td>
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<td><strong>Guidelines for Drug testing in animals/Preclinical Studies Animal testing:</strong> Rationale for conducting studies, CPCSEA Guidelines Ethical guidelines for human participants ICMR-DBT Guidelines for Stem Cell Research</td>
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<td>5</td>
<td><strong>Intellectual Property Rights:</strong> Patent, Trademark, Copyright, Industrial Designs and Geographical Indications, Indian Patent Scenario. IPR vs Regulatory Affairs</td>
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References

3. Principles and Practice of Clinical Trial Medicine by Richard Chin and Bruce Y. Lee
4. Ethical Guidelines for Biomedical Research on Human Participants by Indian Council of Medical Research New delhi 2006.
5. CPCSEA Guidelines for Laboratory Animal Facility by Committee for the purpose of control and supervision on experiments on animals (CPCSEA)
6. ICH E6 Guideline — Good Clinical Practice by ICH Harmonised Tripartite
7. Guidance for Industry on Submission of Clinical Trial Application for Evaluating Safety and Efficacy by CDSCO (Central Drug Standard Control Organisation)
8. Guidance for Industry on Requirement of Chemical & Pharmaceutical Information including Stability Study Data before approval of clinical trials / BE studies by CDSCO
9. Guidelines for Import and Manufacture of Medical Devices by CDSCO
10. Guidelines from official website of CDSCO
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 and submission in SUGAM
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
REGULATORY ASPECTS OF DRUGS & COSMETICS (MRA 201T)

Scope
This course is designed to impart the fundamental knowledge on the drug development process, regulatory requirements for approval of new drugs, drug products and cosmetics in regulated and semi-regulated countries. It prepares the students to learn in detail on the regulatory requirements, documentation requirements, and registration procedures for marketing the drug products and cosmetics in regulated and semi-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
- Cosmetics regulations in regulated and semi-regulated countries
- A comparative study of India with other global regulated markets

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<tr>
<td>2</td>
<td><strong>European Union &amp; Australia:</strong> Organization and structure of EMA &amp; 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 &amp; extensions, Compliance of European Pharmacopoeia (CEP)/ Certificate of Suitability (CoS), Marketing Authorization (MA) transfers, Qualified Person (QP) in EU. Legislation and regulations for import, manufacture, distribution and sale of cosmetics in European Union &amp; Australia.</td>
<td>12</td>
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<td>3</td>
<td><strong>Japan</strong>: 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. Legislation and regulations for import, manufacture, distribution and sale of cosmetics in Japan</td>
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| 4 | **Emerging Market**: Introduction, Countries covered, Study of the world map, study of various committees across the globe (ASEAN, APEC, EAC, GCC, PANDRH, SADC)  
**WHO**: WHO, GMP, Regulatory Requirements for registration of drugs and post approval requirements in WHO through prequalification programme, Certificate of Pharmaceutical Product (CoPP) - General and Country Specific (South Africa, Egypt, Algeria and Morocco, Nigeria, Kenya and Botswana) | 12 |
| 5 | **Brazil, ASEAN, CIS and GCC Countries**:  
**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.  
**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  
**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  
Legislation and regulations for import, manufacture, distribution and sale of cosmetics in Brazil, ASEAN, CIS and GCC Countries. | 12 |

**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


19. Realizing the ASEAN Economic Community: A Comprehensive Assessment, Michael G Plummer (Editor), Chia Siow Yue (Editor), Instute of South east asian studies, Singapore
REGULATORY ASPECTS OF HERBAL AND BIOLOGICALS (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

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<td>1</td>
<td><strong>India</strong>: 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.</td>
<td>12</td>
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<td>2</td>
<td><strong>USA</strong>: 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</td>
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<td>3</td>
<td><strong>European Union</strong>: 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</td>
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<td><strong>Vaccine regulations in India, US and European Union</strong>: Clinical evaluation, Marketing authorisation, Registration or licensing, Quality assessment, Pharmacovigilance, Additional requirements 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)</td>
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Herbal Products: Quality, safety and legislation for herbal products in India, USA and European Union.

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/GuidanceCompliance Regulatory Information (Biologics)
REGULATORY ASPECTS OF MEDICAL DEVICES (MRA 203T)

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 and IVDs in regulated countries.

Objectives
Upon completion of the course, the student shall be able to know
- basics of medical devices and IVDs, process of development, ethical and quality considerations
- harmonization initiatives for approval and marketing of medical devices and IVDs
- regulatory approval process for medical devices and IVDs in India, US, Canada, EU, Japan and ASEAN
- clinical evaluation and investigation of medical devices and IVDs

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<td><strong>Medical Devices:</strong> Introduction, Definition, Risk based classification and Essential Principles of Medical Devices and IVDs, Differentiating medical devices IVDs and Combination Products from that of pharmaceuticals, History of Medical Device Regulation, Product Lifecycle of Medical Devices and Classification of Medical Devices. <strong>IMDRF/GHTF:</strong> Introduction, Organizational Structure, Purpose and Functions, Regulatory Guidelines, Working Groups, Summary Technical Document (STED), Global Medical DeviceNomenclature (GMDN).</td>
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<td>2</td>
<td><strong>Ethics:</strong> Clinical Investigation of Medical Devices, Clinical Investigation Plan for Medical Devices, Good Clinical Practice for Clinical Investigation of medical devices (ISO 14155:2011) <strong>Quality:</strong> 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</td>
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<td>3</td>
<td><strong>USA:</strong> Introduction, Classification, Regulatory approval process for Medical Devices (510k) Premarket Notification, Pre-Market Approval (PMA), Investigational Device Exemption (IDE) and In vitro Diagnostics, Quality System Requirements 21 CFR Part 820, Labeling requirements 21 CFR Part 801, Post marketing surveillance of MD and Unique Device Identification (UDI). Basics of In vitro diagnostics, classification and approval process.</td>
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<td><strong>European Union:</strong> Introduction, Classification, Regulatory approval process for Medical Devices (Medical Device Directive, Active Implantable Medical Device Directive) and In vitro Diagnostics (In Vitro Diagnostics Directive), CE certification process. Basics of In vitro diagnostics, classification and approval process.</td>
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<td><strong>ASEAN, China &amp; Japan:</strong> Medical Devices and IVDs, Regulatory registration procedures, Quality System requirements and clinical evaluation and investigation. IMDRF study groups and guidance documents.</td>
<td>12</td>
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**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
REGULATORY ASPECTS OF FOOD & NUTRACEUTICALS (MRA 204T)

Scope
This course is designed to impart the fundamental knowledge on Regulatory Requirements, Registration and Labeling Regulations of Nutraceuticals in India, USA and Europe. It prepares the students to learn in detail on Regulatory Aspects for nutraceuticals and food supplements.

Objectives
Upon completion of the course, the student shall be able to
- Know the regulatory Requirements for nutraceuticals
- Understand the regulation for registration and labeling of nutraceuticals and food supplements in India, USA and Europe.

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<td>3</td>
<td>India: Food Safety and Standards Act, Food Safety and Standards Authority of India: Organization and Functions, Regulations for import, manufacture and sale of nutraceutical products in India, Recommended Dietary Allowances (RDA) in India.</td>
<td>12</td>
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<td>4</td>
<td>USA: US FDA Food Safety Modernization Act, Dietary Supplement Health and Education Act. U.S. regulations for manufacture and sale of nutraceuticals and dietary supplements, Labelling Requirements and Label Claims for Dietary Supplements, Recommended Dietary Allowances (RDA) in the U.S</td>
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References
1. Regulation of Functional Foods and Nutraceuticals: A Global Perspective by Clare M. Hasler (Wiley Online Library)
6.  Food Regulation: Law, Science, Policy and Practice by Neal D. Fortin (Wiley)
1. Case studies on
2. Change Management/Change control. Deviations
3. Corrective & Preventive Actions (CAPA)
4. Documentation of raw materials analysis as per official monographs
5. Preparation of audit checklist for various agencies
6. Preparation of submission to FDA using eCTD software
7. Preparation of submission to EMA using eCTD software
8. Preparation of submission to MHRA using eCTD software
9. Preparation of Biologics License Applications (BLA)
10. Preparation of documents required for Vaccine Product Approval
11. Comparison of clinical trial application requirements of US, EU and India of Biologics
12. Preparation of Checklist for Registration of Blood and Blood Products
13. Registration requirement comparison study in 5 emerging markets (WHO) and preparing check list for market authorization
14. Registration requirement comparison study in emerging markets (BRICS) and preparing check list for market authorization
15. Registration requirement comparison study in emerging markets (China and South Korea) and preparing check list for market authorization
16. Registration requirement comparison study in emerging markets (ASEAN) and preparing check list for market authorization
17. Registration requirement comparison study in emerging markets (GCC) and preparing check list for market authorization
18. Checklists for 510k and PMA for US market
19. Checklist for CE marking for various classes of devices for EU
20. STED Application for Class III Devices
21. Audit Checklist for Medical Device Facility
22. Clinical Investigation Plan for Medical Devices
PHARMACY PRACTICE (MPP)

CLINICAL PHARMACY PRACTICE (MPP 101T)

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

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<td><strong>Introduction to Clinical Pharmacy:</strong> Definition, evolution and scope of clinical pharmacy, International and national scenario of clinical pharmacy practice, Pharmaceutical care. <strong>Clinical Pharmacy Services:</strong> Ward round participation, Drug therapy review (Drug therapy monitoring including medication order review, chart endorsement, clinical review and pharmacist interventions).</td>
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<td>2</td>
<td><strong>Clinical Pharmacy Services:</strong> 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.</td>
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<td>3</td>
<td><strong>Patient Data Analysis:</strong> <strong>Patient Data &amp; Practice Skills:</strong> 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. <strong>Lab Data Interpretation:</strong> Hematological tests, Renal function tests, Liver function tests</td>
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<td>4</td>
<td><strong>Lab Data Interpretation:</strong> Tests associated with cardiac disorders, Pulmonary function tests, Thyroid function tests, Fluid and electrolyte balance, Microbiological culture sensitivity tests</td>
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Medicines & Poison Information Services

**Medicine Information Service:** Definition and need for medicine information service, Medicine information resources, Systematic approach in answering medicine information queries, Preparation of verbal and written response, Establishing a drug information centre.

**Poison Information Service:** Definition, need, organization and functions of poison information centre.

**References**

2. Practice Standards and Definitions - The Society of Hospital Pharmacists of Australia
3. Basic skills in interpreting laboratory data - Scott LT, American Society of Health System Pharmacists Inc
4. Relevant review articles from recent medical and pharmaceutical literature.
PHARMACOTHERAPEUTICS-I (MPP 102T)

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 individualizing 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)

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<td>Cardiovascular system: Hypertension, Congestive cardiac failure, Acute coronary syndrome, Arrhythmias, Hyperlipidemias</td>
<td>12</td>
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<tr>
<td>2</td>
<td>Respiratory system: Asthma, Chronic obstructive airways disease, Drug induced pulmonary diseases Endocrine system: Diabetes, Thyroid diseases</td>
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<tr>
<td>3</td>
<td>Gastrointestinal system: Peptic ulcer diseases, Reflux esophagitis, Inflammatory bowel diseases, Jaundice &amp; hepatitis</td>
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</tr>
<tr>
<td>4</td>
<td>Gastrointestinal system: Cirrhosis, Diarrhea and Constipation, Drug-induced liver disease Hematological diseases: Anemia, Deep vein thrombosis, Drug induced hematological disorders</td>
<td>12</td>
</tr>
<tr>
<td>5</td>
<td>Bone and joint disorders: Rheumatoid arthritis, Osteoarthritis, Gout, Osteoporosis Dermatological Diseases: Psoriasis, Eczema and scabies, impetigo, drug induced skin disorders Ophthalmology: Conjunctivitis, Glaucoma</td>
<td>12</td>
</tr>
</tbody>
</table>

References
1. Roger and Walker. Clinical Pharmacy and Therapeutics - Churchill Livingstone publication
3. Robins SL. Pathologic basis of disease -W.B. Saunders publication
4. Eric T. Herfindal. Clinical Pharmacy and Therapeutics- Williams and Wilkins Publication
5. Lloyd Young and Koda-Kimble MA Applied Therapeutics: The clinical Use of Drugs- Lippincott Williams and Wilkins
7. Carol Mattson Porth. Principles of Pathophysiology- Lippincott Williams and Wilkins
9. Relevant review articles from recent medical and pharmaceutical literature
HOSPITAL & COMMUNITY PHARMACY (MPP 103T)

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

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<th>Units</th>
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</table>
| 1     | **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, Management of Medicines as per NABH | 12 |
| 2     | Hospital Formulary Guidelines and its development, Developing Therapeutic guidelines, Drug procurement process, and methods of Inventory control, Methods of Drug distribution, Intravenous admixtures, Hospital Waste Management | 12 |
| 3     | **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, and their relationship 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 and audits, Good dispensing practices, Different softwares & databases used in community pharmacies. Entrepreneurship in community pharmacy. | 12 |
| 4     | **Prescription** – Legal requirements & interpretation, prescription related problems | 12 |
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 counseling and use of patient information leaflets
Medication adherence – Definition, factors influencing adherence behavior, strategies to improve medication adherence
Patient referrals to the doctors
ADR monitoring in community pharmacies

5

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

National Health Programs - Role of Community Pharmacist in Malaria and TB control programs

Home Medicines review program – Definition, Objectives, Guidelines, method and outcomes

Research in community pharmacy Practice

References
1. Hospital Pharmacy - Hassan WE. Lea and Febiger publication.
3. Avery’s Drug Treatment, Adis International Limited.
5. Remington Pharmaceutical Sciences.
6. Relevant review articles from recent medical and pharmaceutical literature
CLINICAL RESEARCH (MPP 104T)

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 imparts 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

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<tr>
<td>1</td>
<td>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, ICH GCP guidelines and ICMR guidelines in conduct of Clinical trials, Drug Safety Reporting.</td>
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<tr>
<td>2</td>
<td>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 &amp; Physiological, Humanistic and economic) Clinical Trial Study team: Roles and responsibilities of: Investigator, Study Coordinator, Sponsor, Monitor, Contract Research Organization.</td>
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<tr>
<td>3</td>
<td>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,</td>
<td>12</td>
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</table>
| 4 | **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. | 12 |
| 5 | **Quality Assurance and Quality Control in Clinical Trials:** Types of audits, Audit criteria, Audit process, Responsibilities of Hrs 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. | 12 |

**References**

10. Relevant review articles from recent medical and pharmaceutical literature.
PHARMACY PRACTICE PRACTICAL – I (MPP 105P)

Pharmacy Practice practical component includes experiments covering important topics of the courses Clinical Pharmacy Practice, Pharmacotherapeutics-I, Hospital & Community Pharmacy and Clinical Research.

List of Experiments (24)

1. Treatment Chart Review (one)
2. Medication History Interview (one)
3. Patient Medication Counseling (two)
4. Drug Information Query (two)
5. Poison Information Query (one)
6. Lab Data Interpretation (two)
7. Presentation of clinical cases of various disease conditions adopting Pharmaceutical Care Plan Model (eight)
8. ABC Analysis of a given list of medications (one)
9. Preparation of content of a medicine, with proper justification, for the inclusion in the hospital formulary (one)
10. Formulation and dispensing of a given IV admixtures (one)
11. Preparation of a patient information leaflet (two)
12. Preparation of Study Protocol (one)
13. Preparation of Informed Consent Form (one)
PRINCIPLES OF QUALITY USE OF MEDICINES (MPP 201T)

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

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<tr>
<td>1</td>
<td>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.</td>
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<tr>
<td>3</td>
<td>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</td>
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<tr>
<td>4</td>
<td>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</td>
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<tr>
<td>5</td>
<td>Medication errors: Definition, categorization and causes of medication errors, Detection and prevention of medication errors,</td>
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</table>
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:**

2. Andrews EB, Moore N. Mann’s Pharmacovigilance
3. Dipiro JT, Talbert RL, Yee GC. Pharmacotherapy: A Pathophysiologic Approach
4. Straus SE, Richardson WS, Glasziou P, Haynes RB. Evidence-Based Medicine: How to practice and teach it
5. Cohen MR. Medication Errors Online:
6. Relevant review articles from recent medical and pharmaceutical literature.
PHARMACOTHERAPEUTICS II (MPP 202T)

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 individualizing 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)

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<tr>
<td>1</td>
<td>Nervous system: Epilepsy, Parkinson's disease, Stroke, Headache, Alzheimer’s disease, Neuralgias and Pain pathways Hrs and Pain management.</td>
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<td>2</td>
<td>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</td>
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<td>3</td>
<td>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.</td>
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<tr>
<td>4</td>
<td>Infectious diseases: Meningitis, HIV and opportunistic infections, Rheumatic fever, Dengue fever, H1N1, Helmenthiasis, Fungal infections Gynecological disorders: Dysmenorrhea, Hormone replacement therapy.</td>
<td>12</td>
</tr>
<tr>
<td>5</td>
<td>Oncology: General principles of cancer chemotherapy, pharmacotherapy of breast cancer, lung cancer, head &amp; neck cancer, hematological malignancies, Management of nausea and vomiting, Palliative care</td>
<td>12</td>
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</tbody>
</table>

References
3. Robins SL. Pathologic basis of disease - W.B. Saunders publication
4. Eric T. Herfindal. Clinical Pharmacy and Therapeutics - Williams and Wilkins Publication
5. Lloyd Young and Koda-Kimble MA. Applied Therapeutics: The clinical Use of Drugs - Lippincott Williams and Wilkins
7. Carol Mattson Porth. Principles of Pathophysiology - Lippincott Williams and Wilkins
9. Relevant review articles from recent medical and pharmaceutical literature
CLINICAL PHARMACOKINETICS AND
THERAPEUTIC DRUG MONITORING (MPP 203T)

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 enables 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

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<tr>
<th>Units</th>
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</table>
| 1     | **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. | 12 |
| 2     | **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. | 12 |
### 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.

### Altered Pharmacokinetics
Drug dosing in the elderly, Drug dosing in the paediatrics, Drug dosing in the obese patients, Drug dosing in the pregnancy and lactation, Drug dosing in the renal failure and extracorporeal removal of drugs, Drug dosing in the 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
4. Steven How-Yan Wong, Irving Sunshine. Handbook of Analytical Therapeutic Drug Monitoring and Toxicology. CRC Press, USA.
7. Malcolm Rowland, Thomas N. Tozer .Clinical Pharmacokinetics and pharmacodynamics: concepts and applications. Iippincott Williams & Wilkins, USA.
9. Michael E. Winter. Basic Clinical Pharmacokinetics. Iippincott Williams & Wilkins, USA.
13. Relevant review articles from recent medical and pharmaceutical literature
PHARMACOEPIDEMIOLOGY & PHARMACOECONOMICS (MPP 204T)

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.

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<tr>
<td>1</td>
<td><strong>Introduction to Pharmacoepidemiology:</strong> Definition, Scope, Need, Aims &amp; 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. <strong>Concept of risk:</strong> Measurement of risk, Attributable risk and relative risk, Time-risk relationship and odds ratio</td>
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<td>2</td>
<td><strong>Pharmacoepidemiological Methods:</strong> Qualitative models: DrugUtilization 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</td>
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<tr>
<td>3</td>
<td><strong>Introduction to Pharmacoeconomics:</strong> Definition, history of Pharmacoeconomics, Need of Pharmacoeconomic studies in Indian healthcare system. <strong>Cost categorization and resources for cost estimation:</strong> Direct costs. Indirect costs. Intangible costs.</td>
<td>12</td>
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### Outcomes and Measurements of Pharmacoeconomics:

Types of outcomes: Clinical outcome, Economic outcomes, Humanistic outcomes; Quality Adjusted Life Years, Disability Adjusted Life Years, Incremental Cost Effective Ratio, Average Cost Effective Ratio. Person Time, Willingness To Pay, Time Trade Off and Discounting.

### Pharmacoeconomic evaluations:

Definition, Steps involved, Applications, Advantages and disadvantages of the following Pharmacoeconomic models: Cost Minimization Analysis (CMA), Cost Benefit Analysis (CBA), Cost Effective Analysis (CEA), Cost Utility Analysis (CUA), Cost of Illness (COI), Cost Consequences Analysis (COA).

### Definition, Steps involved, Applications, Advantages and disadvantages of the following:

#### Health related quality of life (HRQOL):

Definition, Need for measurement of HRQOL, Common HRQOL measures.

### References

1. Rascati K L. Essentials of Pharmacoeconomics, Kluw Wouters Lippincott Williams & Wilkins, Philadelphia.
5. George E Mackinnon III. Understanding health outcomes and pharmacoeconomics.
7. Walley, Pharmacoeconomics.
8. Pharmacoeconomic – ed. by Nowakowska – University of Medical Sciences, Poznan.
9. Relevant review articles from recent medical and pharmaceutical literature
PHARMACY PRACTICE PRACTICAL - II (MPP 205P)

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 (24)
1. Causality assessment of adverse drug reactions (three)
2. Detection and management of medication errors (three)
3. Rational use of medicines in special population (three)
4. Presentation of clinical cases of various disease conditions adopting Pharmaceutical Care Plan Model (eight)
5. Calculation of Bioavailability and Bioequivalence from the given data (two)
6. Interpretation of Therapeutic Drug Monitoring reports of a given patient (three)
7. Calculation of various Pharmacoeconomic outcome analysis for the given data (two)
**PHARMACOLOGY (MPL)**

**MODERN PHARMACEUTICAL ANALYTICAL TECHNIQUES (MPL 101T)**

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

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

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<tr>
<th>Units</th>
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</table>
| 1     | a. **UV-Visible spectroscopy:** Introduction, Theory, Laws, Instrumentation associated with UV-Visible spectroscopy, Choice Hrs of solvents and solvent effect and Applications of UV-Visible spectroscopy, Difference/ Derivative spectroscopy.  
      b. **IR spectroscopy:** Theory, Modes of Molecular vibrations, Sample handling, Instrumentation of Dispersive and Fourier - Transform IR Spectrometer, Factors affecting vibrational frequencies and Applications of IR spectroscopy, Data Interpretation.  
      c. **Spectroflourimetry:** Theory of Fluorescence, Factors affecting fluorescence (Characterestics of drugs that can be analysed by flourimetry), Quenchers, Instrumentation and Applications of fluorescence spectrophotometer.  
      d. **Flame emission spectroscopy and Atomic absorption spectroscopy:** Principle, Instrumentation, Interferences and Applications. | 10 |
| 2     | **NMR spectroscopy:** Quantum numbers and their role in NMR, Principle, Instrumentation, Solvent requirement in NMR, Relaxation process, NMR signals in various compounds, Chemical shift, Factors influencing chemical shift, Spin-Spin coupling, Coupling constant, Nuclear magnetic double resonance, Brief outline of principles of FT-NMR and 13C NMR. Applications of NMR spectroscopy. | 10 |
| 3     | **Mass Spectroscopy:** Principle, Theory, Instrumentation of Mass Spectroscopy, Different types of ionization like electron impact, chemical, field, FAB and MALDI, APCI, ESI, APPI Analyzers of Quadrupole and Time of Flight, Mass fragmentation and its rules, Meta stable ions, Isotopic peaks and Applications of Mass spectroscopy. | 10 |
| 4 | **Chromatography:** Principle, apparatus, instrumentation, chromatographic parameters, factors affecting resolution, isolation of drug from excipients, data interpretation and applications of the following:  
|   | a. Thin Layer chromatography  
|   | b. High Performance Thin Layer Chromatography  
|   | c. Ion exchange chromatography  
|   | d. Column chromatography  
|   | e. Gas chromatography  
|   | f. High Performance Liquid chromatography  
|   | g. Ultra High Performance Liquid chromatography  
|   | h. Affinity chromatography  
|   | i. Gel Chromatography | 10 |
| 5 | **Electrophoresis:** Principle, Instrumentation, Working conditions, factors affecting separation and applications of the Hrs following:  
|   | a) Paper electrophoresis b) Gel electrophoresis c) Capillary electrophoresis d) Zone electrophoresis e) Moving boundary electrophoresis f) Iso electric focusing  
|   | **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. | 10 |
| 6 | **Potentiometry:** Principle, working, Ion selective Electrodes and Application of potentiometry.  
|   | **Thermal Techniques:** Principle, thermal transitions and Instrumentation (Heat flux and power-compensation and designs), Modulated DSC, Hyper DSC, experimental parameters (sample preparation, experimental conditions, calibration, heating and cooling rates, resolution, source of errors) and their influence, advantage and disadvantages, pharmaceutical applications. Differential Thermal Analysis (DTA): Principle, instrumentation and advantage and disadvantages, pharmaceutical applications, derivative differential thermal analysis (DDTA). TGA: Principle, instrumentation, factors affecting results, advantage and disadvantages, pharmaceutical applications.  
|   | **Immunological assays:** RIA (Radio immuno assay), ELISA, Bioluminescence assays. | 10 |

**References**

ADVANCED PHARMACOLOGY - I (MPL 102T)

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

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

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<tr>
<td>2</td>
<td><strong>Neurotransmission</strong>&lt;br&gt;a. General aspects and steps involved in neurotransmission.&lt;br&gt;b. Neurohumoral transmission in autonomic nervous system (Detailed study about neurotransmitters- Adrenaline and Acetyl choline).&lt;br&gt;c. Neurohumoral transmission in central nervous system (Detailed study about neurotransmitters- histamine, serotonin, dopamine, GABA, glutamate and glycine).&lt;br&gt;d. Non adrenergic non cholinergic transmission (NANC). Co-transmission</td>
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<td>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&lt;br&gt;<strong>Autonomic Pharmacology:</strong> Parasympathomimetics and lytics, sympathomimetics and lytics, agents affecting neuromuscular junction</td>
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<td>3</td>
<td><strong>Central nervous system Pharmacology</strong>&lt;br&gt;General and local anesthetics Sedatives and hypnotics, drugs used to treat anxiety. Depression, psychosis, mania, epilepsy, neurodegenerative diseases. Narcotic and non-narcotic analgesics.</td>
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<td>4</td>
<td><strong>Cardiovascular Pharmacology</strong>: Diuretics, antihypertensives, antiischemics, anti-arrhythmics, drugs for heart failure and hyperlipidemia. Hematinics, coagulants, anticoagulants, fibrinolytics and anti-platelet drugs</td>
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<td>5</td>
<td><strong>Autocoid Pharmacology</strong>: The physiological and pathological role of Histamine, Serotonin, Kinins Prostaglandins Opioid autocoids. Pharmacology of antihistamines, 5HT antagonists.</td>
<td>12</td>
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</table>

**References**

1. The Pharmacological Basis of Therapeutics, Goodman and Gillman’s
3. Basic and Clinical Pharmacology by B.G Katzung
5. Applied biopharmaceutics and Pharmacokinetics by Leon Shargel and Andrew B.C.Yu.
7. Avery Drug Treatment
10. Robbins & Cortan Pathologic Basis of Disease, 9th Ed. (Robbins Pathology)
Scope
This subject is designed to impart the knowledge on preclinical evaluation of drugs and recent experimental techniques in the drug discovery and development. The subject content helps the student to understand the maintenance of laboratory animals as per the guidelines, basic knowledge of various in-vitro and in-vivo preclinical evaluation processes

Objectives
Upon completion of the course the student shall be able to,
- 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 newer screening methods involved in the drug discovery process
- Appreciate and correlate the preclinical data to humans

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<tr>
<td>1</td>
<td><strong>Laboratory Animals</strong>: Common laboratory Description, handling and animals: applications of different species and strains of animals. Transgenic animals: Production, maintenance and applications Anaesthesia and euthanasia of experimental animals. Maintenance and breeding of laboratory animals. CPCSEA guidelines to conduct experiments on animals Good laboratory practice. Bioassay-Principle, Scope and limitations and methods</td>
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<td>4</td>
<td><strong>Preclinical screening of new substances for the pharmacological activity using in vivo, in vitro, and other possible animal alternative models.</strong> Cardiovascular Pharmacology:</td>
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5 Preclinical screening of new substances for the pharmacological activity using in vivo, in vitro, and other Hrs possible animal alternative models. Immunomodulators, Immunosuppressants and immunostimulants

General principles of immunoassay: theoretical basis and optimization of immunoassay, heterogeneous and homogenous immunoassay systems. Immunoassay methods evaluation; protocol outline, Objectives and preparation. Immunoassay for digoxin and insulin Limitations of animal experimentation and alternate animal experiments. Extrapolation of in vitro data to preclinical and preclinical to humans

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

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

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

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<tr>
<th>Units</th>
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<tr>
<td>2</td>
<td>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.</td>
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<td>3</td>
<td>Principles and applications of genomic and proteomic tools: DNA electrophoresis, PCR (reverse transcription and real time), Gene sequencing, micro array technique, SDS page, ELISA and western blotting, Recombinant DNA technology and gene Basic principles of recombinant DNA technology-Restriction therapy 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.</td>
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<tr>
<td>4</td>
<td>Pharmacogenomics: Gene mapping and cloning of disease gene. Genetic variation and its role in health/ pharmacology Polymorphisms affecting drug metabolism Genetic variation in drug transporters Genetic variation in G protein coupled receptors Applications of proteomics science: Genomics, proteomics, metabolomics, functionomics, nutrigenomics</td>
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<tr>
<td>Immunotherapeutics: Types of immunotherapeutics, humanisation</td>
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<tr>
<td>a. <strong>Cell culture techniques</strong>: 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</td>
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<tr>
<td>b. Biosimilars</td>
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</table>

**References:**
2. Pharmacogenomics: The Search for Individualized Therapies. Edited by J. Licinio and M.-L. Wong
3. Handbook of Cell Signaling (Second Edition) Edited by Ralph A. et.al
4. Molecular Pharmacology: From DNA to Drug Discovery. John Dickenson et.al
5. Basic Cell Culture protocols by Cheril D.Helgason and Cindy L.Miller
6. Basic Cell Culture (Practical Approach ) by J. M. Davis (Editor)
7. Animal Cell Culture: A Practical Approach by John R. Masters (Editor)
PHARMACOLOGICAL PRACTICAL - I (MPL 105P)

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

Handling of laboratory animals
1. Various routes of drug administration.
2. Techniques of blood sampling, anesthesia and euthanasia of experimental animals.
3. Functional observation battery tests (modified Irwin test)
4. Evaluation of CNS stimulant, depressant, anxiogenics and anxiolytic, anticonvulsant activity.
5. Evaluation of analgesic, anti-inflammatory, local anesthetic, mydriatic and miotic activity.
8. Oral glucose tolerance test.
9. Isolation and identification of DNA from various sources (Bacteria, Cauliflower, onion, Goat liver).
10. Isolation of RNA from yeast
11. Estimation of proteins by Braford/Lowry’s in biological samples.
12. Estimation of RNA/DNA by UV Spectroscopy
13. Gene amplification by PCR.
14. Protein quantification Western Blotting.
15. Enzyme based in-vitro assays (MPO, AChEs, α amylase, α glucosidase).
17. DNA fragmentation assay by agarose gel electrophoresis.
18. DNA damage study by Comet assay.
19. Apoptosis determination by fluorescent imaging studies.
20. Pharmacokinetic studies and data analysis of drugs given by different routes of administration using softwares
21. Enzyme inhibition and induction activity
22. Extraction of drug from various biological samples and estimation of drugs in biological fluids using different analytical techniques (UV)
23. Extraction of drug from various biological samples and estimation of drugs in biological fluids using different analytical techniques (HPLC)

References
1. CPCSEA, OECD, ICH, USFDA, Schedule Y, EPA guidelines.
2. Fundamentals of experimental Pharmacology by M.N.Ghosh
4. Drug discovery and Evaluation by Vogel H.G.
5. Spectrometric Identification of Organic compounds - Robert M Silverstein,
6. Principles of Instrumental Analysis - Doglas A Skoog, F. James Holler, Timothy A. Nieman,
7. Vogel's Text book of quantitative chemical analysis - Jeffery, Basset, Mendham, Denney,
8. Basic Cell Culture protocols by Cheril D. Helgason and Cindy L. Mille
9. Basic Cell Culture (Practical Approach) by J. M. Davis (Editor)
10. Animal Cell Culture: A Practical Approach by John R. Masters (Editor)
11. Practical Manual of Experimental and Clinical Pharmacology by Bikash Medhi (Author),
    Ajay Prakash (Author) Jaypee brothers’ medical publishers Pvt. Ltd
ADVANCED PHARMACOLOGY - II (MPL 201T)

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

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

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<tr>
<th>Units</th>
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<tr>
<td>1</td>
<td><strong>Endocrine Pharmacology:</strong> 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</td>
<td>12</td>
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<td>2</td>
<td><strong>Chemotherapy:</strong> Cellular and molecular mechanism of actions and resistance of antimicrobial agents such as ß-lactams, aminoglycosides, quinolones, Macrolide antibiotics. Antifungal, antiviral, and anti-TB drugs.</td>
<td>12</td>
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<td>3</td>
<td><strong>Chemotherapy:</strong> Drugs used in Protozoal Infections Drugs used in the treatment of Helminthiasis Chemotherapy of cancer <strong>Immunopharmacology:</strong> Cellular and biochemical mediators of inflammation and immune response. Allergic or hypersensitivity reactions. Pharmacotherapy of asthma and COPD. Immunosuppressants and Immunostimulants</td>
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<td>4</td>
<td><strong>GIT Pharmacology:</strong> Antiulcer drugs, Prokinetics, antiemetics, anti-diarrheals and drugs for constipation and irritable bowel syndrome. <strong>Chronopharmacology:</strong> Biological and circadian rhythms, applications of chronotherapy in various diseases like cardiovascular disease, diabetes, asthma and peptic ulcer</td>
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<td>5</td>
<td><strong>Free radicals Pharmacology:</strong> 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 <strong>Recent Advances in Treatment:</strong> Alzheimer’s disease, Parkinson’s disease, Cancer, Diabetes mellitus</td>
<td>12</td>
</tr>
</tbody>
</table>
References
1. The Pharmacological basis of therapeutics- Goodman and Gill man’s
3. Basic and Clinical Pharmacology by B.G -Katzung
7. Applied biopharmaceutics and Pharmacokinetics by Leon Shargel and Andrew B.C.Yu.
8. Handbook of Essential Pharmacokinetics, Pharmacodynamics and Drug Metabolism for Industrial Scientists
9. Robbins & Cortan Pathologic Basis of Disease, 9th Ed. (Robbins Pathology)
11. KD.Tripathi. Essentials of Medical Pharmacology
PHARMACOLOGICAL AND TOXICOLOGICAL SCREENING
METHODS-II (MPL 202T)

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

Objectives:
Upon completion of the course, the student shall be able to,
- Explain the various types of toxicity studies.
- Appreciate the importance of ethical and regulatory requirements for toxicity studies.
- Demonstrate the practical skills required to conduct the preclinical toxicity studies.

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<th>Units</th>
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<tr>
<td>1</td>
<td>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</td>
<td>12</td>
</tr>
<tr>
<td>2</td>
<td>Acute, sub-acute and chronic- oral, dermal and inhalational studies as per OECD guidelines. Acute eye irritation, skin sensitization, dermal irritation &amp; dermal toxicity studies. Test item characterization-importance and methods in regulatory toxicology studies</td>
<td>12</td>
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<td>3</td>
<td>Reproductive toxicology studies, Male reproductive toxicity studies, female reproductive studies (segment I and segment III), teratogenecity studies (segment II) Genotoxicity studies (Ames Test, in vitro and in vivo Micronucleus and Chromosomal aberrations studies) In vivo carcinogenicity studies</td>
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<td>4</td>
<td>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</td>
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<td>5</td>
<td>Toxicokinetics- Toxicokinetic evaluation in preclinical studies, saturation kinetics Importance and applications of toxicokinetic studies. Alternative methods to animal toxicity testing.</td>
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</tbody>
</table>

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

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

Objectives:
Upon completion of the course, the student shall be able to,
- Explain the various stages of drug discovery.
- Appreciate the importance of the role of genomics, proteomics and bioinformatics in drug discovery
- Explain various targets for drug discovery.
- Explain various lead seeking method and lead optimization
- Appreciate the importance of the role of computer aided drug design in drug discovery

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<tr>
<td>1</td>
<td><strong>An overview of modern drug discovery process:</strong> Target identification, target validation, lead identification and lead Optimization. Economics of drug discovery. 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.</td>
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<td>2</td>
<td><strong>Lead Identification</strong>- combinatorial chemistry &amp; high throughputscreening, 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</td>
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<td>4</td>
<td><strong>Molecular docking:</strong> 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.</td>
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<td>5</td>
<td><strong>QSAR Statistical methods</strong> – regression analysis, partial least square analysis (PLS) and other multivariate statistical methods. 3D-QSAR</td>
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approaches like COMFA and COMSIA

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

References

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

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

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

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<tr>
<td>1</td>
<td><strong>Regulatory Perspectives of Clinical Trials:</strong> Origin and Principles of International Conference on Harmonization - Good Clinical Practice (ICH-GCP) guidelines</td>
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<td><strong>Ethical Committee:</strong> Institutional Review Board, Ethical Guidelines for Biomedical Research and Human Participant- Schedule Y, ICMR</td>
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<td><strong>Informed Consent Process:</strong> Structure and content of an Informed Consent Process Ethical principles governing informed consent process</td>
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<td>2</td>
<td><strong>Clinical Trials:</strong> Types and Design Experimental Study- RCT and Non RCT, Observation Study: Cohort, Case Control, Cross sectional Clinical Trial Study Team Roles and responsibilities of Clinical Trial Personnel: Investigator, Study Coordinator, Sponsor, Contract Research Organization and its management</td>
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</table>
### References


1. To record the DRC of agonist using suitable isolated tissues preparation.
2. To study the effects of antagonist/potentiating agents on DRC of agonist using suitable isolated tissue preparation.
3. To determine to the strength of unknown sample by matching bioassay by using suitable tissue preparation.
4. To determine to the strength of unknown sample by interpolation bioassay by using suitable tissue preparation.
5. To determine to the strength of unknown sample by bracketing bioassay by using suitable tissue preparation.
6. To determine to the strength of unknown sample by multiple point bioassay by using suitable tissue preparation.
7. Estimation of PA2 values of various antagonists using suitable isolated tissue preparations.
8. To study the effects of various drugs on isolated heart preparations.
9. Recording of rat BP, heart rate and ECG.
10. Recording of rat ECG.
11. Drug absorption studies by averted rat ileum preparation.
12. Acute oral toxicity studies as per OECD guidelines.
13. Acute dermal toxicity studies as per OECD guidelines.
15. Drug mutagenicity study using mice bone-marrow chromosomal aberration test.
16. Protocol design for clinical trial.(3 Nos.)
17. Design of ADR monitoring protocol.
18. In-silico docking studies. (2 Nos.)
19. In-silico pharmacophore based screening.
20. In-silico QSAR studies.
21. ADR reporting.

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

MRM 301T - Research Methodology & Biostatistics

UNIT – I

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

UNIT – II

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

UNIT – III

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

UNIT – IV

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

UNIT – V

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