# 2016

## THE MASTER OF PHARMACY (M. PHARM.)

# COURSE REGULATION 2014

(BASED ON NOTIFICATION IN THE GAZETTE OF INDIA NO. 362, DATED DECEMBER 11, 2014)

# SCHEME AND SYLLABUS

**PHARMACY COUNCIL OF INDIA**
Combined Council's Building, Kotla Road,
Aiwan-E-Ghalib Marg, New Delhi-110 002.
Website : www.pci.nic.

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## PHARMACY COUNCIL OF INDIA
## NOTIFICATION

New Delhi, the 10th December, 2014

### The Master of Pharmacy (M.Pharm) Course Regulations, 2014

**No. 14-136/ 2014-PCI.**—In exercise of the powers conferred by Sections 10 and 18 of the Pharmacy Act, 1948 (8 of 1948), the Pharmacy Council of India, with the approval of the Central Government hereby makes the following regulations; namely–

# CHAPTER – I: REGULATIONS

## 1. Short Title and Commencement

These regulations shall be called as "The Revised Regulations for the Master of Pharmacy (M. Pharm.)Degree Program - Credit Based Semester System (CBSS) of the Pharmacy Council of India, New Delhi". They shall come into effect from the Academic Year 2016-17. The regulations framed are subject to modifications from time to time by the authorities of the university.

## 2. Minimum qualification for admission

A Pass in the following examinations

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

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

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

## 3. Duration of the program

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

## 4. Medium of instruction and examinations

Medium of instruction and examination shall be in English.

## 5. Working days in each semester

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

## 6. Attendance and progress

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

## 7. Program/Course credit structure

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

### *7.1. Credit assignment*

#### *7.1.1. Theory and Laboratory courses*

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

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

### *7.2. Minimum credit requirements*

The minimum credit points required for the award of M. Pharm. degree is 95. However based on the credit points earned by the students under the head of co-curricular activities, a student shall earn a maximum of 100 credit points. These credits are divided into Theory courses, Practical, Seminars, Assignments,Research work, Discussions with the supervisor, Journal club and Co-Curricular activities over the duration of four semesters. The credits

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

## 8. Academic work

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

## 9. Course of study

The specializations in M.Pharm program is given in Table 1.

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

| S. No. | Specialization | Code |
|---|---|---|
| **1.** | Pharmaceutics | MPH |
| **2.** | Industrial Pharmacy | MIP |
| **3.** | Pharmaceutical Chemistry | MPC |
| **4.** | Pharmaceutical Analysis | MPA |
| **5.** | Pharmaceutical Quality Assurance | MQA |
| **6.** | Pharmaceutical Regulatory Affairs | MRA |
| **7.** | Pharmaceutical Biotechnology | MPB |
| **8.** | Pharmacy Practice | MPP |
| **9.** | Pharmacology | MPL |
| **10.** | Pharmacognosy | MPG |

The course of study for M.Pharm specializations shall include Semester wise Theory & Practical as given in Table – 2 to 11. The number of hours to be devoted to each theory and practical course in any semester shall not be less than that shown in Table – 2 to 11.

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

| Course Code | Course | Credit Hours | Credit Points | Hrs./wk | Marks |
|---|---|---|---|---|---|
| **Semester I** | | | | | |
| **MPH101T** | Modern Pharmaceutical Analytical Techniques | 4 | 4 | 4 | 100 |
| **MPH102T** | Drug Delivery System | 4 | 4 | 4 | 100 |
| **MPH103T** | Modern Pharmaceutics | 4 | 4 | 4 | 100 |
| **MPH104T** | Regulatory Affair | 4 | 4 | 4 | 100 |
| **MPH105P** | Pharmaceutics Practical I | 12 | 6 | 12 | 150 |
| **-** | Seminar/Assignment | 7 | 4 | 7 | 100 |
| **Total** | | **35** | **26** | **35** | **650** |
| **Semester II** | | | | | |
| **MPH201T** | Molecular Pharmaceutics (Nano Tech and Targeted DDS) | 4 | 4 | 4 | 100 |
| **MPH202T** | Advanced Biopharmaceutics & Pharmacokinetics | 4 | 4 | 4 | 100 |
| **MPH203T** | Computer Aided Drug Delivery System | 4 | 4 | 4 | 100 |
| **MPH204T** | Cosmetic and Cosmeceuticals | 4 | 4 | 4 | 100 |
| **MPH205P** | Pharmaceutics Practical II | 12 | 6 | 12 | 150 |
| **-** | Seminar/Assignment | 7 | 4 | 7 | 100 |
| | **Total** | **35** | **26** | **35** | **650** |

Table – 3: Course of study for M. Pharm. (Industrial Pharmacy)

| Course Code | Course | Credit Hours | Credit Points | Hrs./wk | Marks |
|---|---|---|---|---|---|
| **Semester I** | | | | | |
| **MIP101T** | Modern Pharmaceutical Analytical Techniques | 4 | 4 | 4 | 100 |
| **MIP102T** | Pharmaceutical Formulation Development | 4 | 4 | 4 | 100 |
| **MIP103T** | Novel drug delivery systems | 4 | 4 | 4 | 100 |
| **MIP104T** | Intellectual Property Rights | 4 | 4 | 4 | 100 |
| **MIP105P** | Industrial Pharmacy Practical I | 12 | 6 | 12 | 150 |
| - | Seminar/Assignment | 7 | 4 | 7 | 100 |
| **Total** | | 35 | 26 | 35 | 650 |
| **Semester II** | | | | | |
| **MIP201T** | Advanced Biopharmaceutics and Pharmacokinetics | 4 | 4 | 4 | 100 |
| **MIP202T** | Scale up and Technology Transfer | 4 | 4 | 4 | 100 |
| **MIP203T** | Pharmaceutical Production Technology | 4 | 4 | 4 | 100 |
| **MIP204T** | Entrepreneurship Management | 4 | 4 | 4 | 100 |
| **MIP205P** | Industrial Pharmacy Practical II | 12 | 6 | 12 | 150 |
| - | Seminar/Assignment | 7 | 4 | 7 | 100 |
| | **Total** | 35 | 26 | 35 | 650 |

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

| Course Code | Course | Credit Hours | Credit Points | Hrs./wk | Marks |
|---|---|---|---|---|---|
| **Semester I** | | | | | |
| **MPC101T** | Modern Pharmaceutical Analytical Techniques | 4 | 4 | 4 | 100 |
| **MPC1012T** | Advanced Organic Chemistry -I | 4 | 4 | 4 | 100 |
| **MPC103T** | Advanced Medicinal chemistry | 4 | 4 | 4 | 100 |
| **MPC104T** | Chemistry of Natural Products | 4 | 4 | 4 | 100 |
| **MPC105P** | Pharmaceutical Chemistry Practical I | 12 | 6 | 12 | 150 |
| **-** | Seminar/Assignment | 7 | 4 | 7 | 100 |
| | **Total** | **35** | **26** | **35** | **650** |
| **Semester II** | | | | | |
| **MPC201T** | Advanced Spectral Analysis | 4 | 4 | 4 | 100 |
| **MPC202T** | Advanced Organic Chemistry -II | 4 | 4 | 4 | 100 |
| **MPC203T** | Computer Aided Drug Design | 4 | 4 | 4 | 100 |
| **MPC204T** | Pharmaceutical Process Chemistry | 4 | 4 | 4 | 100 |
| **MPC205P** | Pharmaceutical Chemistry Practical II | 12 | 6 | 12 | 150 |
| **-** | Seminar/Assignment | 7 | 4 | 7 | 100 |
| | **Total** | **35** | **26** | **35** | **650** |

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

| Course Code | Course | Credit Hours | Credit Points | Hrs./wk | Marks |
|---|---|---|---|---|---|
| **Semester I** | | | | | |
| **MPA101T** | Modern Pharmaceutical Analytical Techniques | 4 | 4 | 4 | 100 |
| **MPA102T** | Advanced Pharmaceutical Analysis | 4 | 4 | 4 | 100 |
| **MPA103T** | Pharmaceutical Validation | 4 | 4 | 4 | 100 |
| **MPA104T** | Food Analysis | 4 | 4 | 4 | 100 |
| **MPA105P** | Pharmaceutical Analysis Practical I | 12 | 6 | 12 | 150 |
| **-** | Seminar/Assignment | 7 | 4 | 7 | 100 |
| **Total** | | **35** | **26** | **35** | **650** |
| **Semester II** | | | | | |
| **MPA201T** | Advanced Instrumental Analysis | 4 | 4 | 4 | 100 |
| **MPA202T** | Modern Bio-Analytical Techniques | 4 | 4 | 4 | 100 |
| **MPA203T** | Quality Control and Quality Assurance | 4 | 4 | 4 | 100 |
| **MPA204T** | Herbal and Cosmetic Analysis | 4 | 4 | 4 | 100 |
| **MPA205P** | Pharmaceutical Analysis Practical II | 12 | 6 | 12 | 150 |
| **-** | Seminar/Assignment | 7 | 4 | 7 | 100 |
| | **Total** | **35** | **26** | **35** | **650** |

Table – 6: Course of study for M. Pharm. (Pharmaceutical Quality Assurance)

| Course Code | Course | Credit Hours | Credit Points | Hrs./wk | Marks |
|---|---|---|---|---|---|
| **Semester I** | | | | | |
| **MQA101T** | Modern Pharmaceutical Analytical Techniques | 4 | 4 | 4 | 100 |
| **MQA102T** | Quality Management System | 4 | 4 | 4 | 100 |
| **MQA103T** | Quality Control and Quality Assurance | 4 | 4 | 4 | 100 |
| **MQA104T** | Product Development and Technology Transfer | 4 | 4 | 4 | 100 |
| **MQA105P** | Pharmaceutical Quality Assurance Practical I | 12 | 6 | 12 | 150 |
| **-** | Seminar/Assignment | 7 | 4 | 7 | 100 |
| **Total** | | **35** | **26** | **35** | **650** |
| **Semester II** | | | | | |
| **MQA201T** | Hazards and Safety Management | 4 | 4 | 4 | 100 |
| **MQA202T** | Pharmaceutical Validation | 4 | 4 | 4 | 100 |
| **MQA203T** | Audits and Regulatory Compliance | 4 | 4 | 4 | 100 |
| **MQA204T** | Pharmaceutical Manufacturing Technology | 4 | 4 | 4 | 100 |
| **MQA205P** | Pharmaceutical Quality Assurance Practical II | 12 | 6 | 12 | 150 |
| **-** | Seminar/Assignment | 7 | 4 | 7 | 100 |
| | **Total** | **35** | **26** | **35** | **650** |

Table – 7: Course of study for M. Pharm. (Regulatory Affairs)

| Course Code | Course | Credit Hours | Credit Points | Hrs./ wk | Marks |
|---|---|---|---|---|---|
| **Semester I** | | | | | |
| **MRA 101T** | Good Regulatory Practices | 4 | 4 | 4 | 100 |
| **MRA 102T** | Documentation and Regulatory Writing | 4 | 4 | 4 | 100 |
| **MRA 103T** | Clinical Research Regulations | 4 | 4 | 4 | 100 |
| **MRA 104T** | Regulations and Legislation for Drugs & Cosmetics, Medical Devices, Biologicals & Herbals, and Food & Nutraceuticals In India and Intellectual Property Rights | 4 | 4 | 4 | 100 |
| **MRA 105P** | Regulatory Affairs Practical I | 12 | 6 | 12 | 150 |
| | Seminar/Assignment | 7 | 4 | 7 | 100 |
| | **Total** | **35** | **26** | **35** | **650** |
| **Semester II** | | | | | |
| **MRA 201T** | Regulatory Aspects of Drugs & Cosmetics | 4 | 4 | 4 | 100 |
| **MRA 202T** | Regulatory Aspects of Herbal & Biologicals | 4 | 4 | 4 | 100 |
| **MRA 203T** | Regulatory Aspects of Medical Devices | 4 | 4 | 4 | 100 |
| **MRA 204T** | Regulatory Aspects of Food & Nutraceuticals | 4 | 4 | 4 | 100 |
| **MRA 205P** | Regulatory Affairs Practical II | 12 | 6 | 12 | 150 |
| | Seminar/Assignment | 7 | 4 | 7 | 100 |
| | **Total** | **35** | **26** | **35** | **650** |

Table – 8: Course of study for M. Pharm. (Pharmaceutical Biotechnology)

| Course Code | Course | Credit Hours | Credit Points | Hrs./wk | Marks |
|---|---|---|---|---|---|
| **Semester I** | | | | | |
| **MPB 101T** | Modern Pharmaceutical Analytical Techniques | 4 | 4 | 4 | 100 |
| **MPB 102T** | Microbial And Cellular Biology | 4 | 4 | 4 | 100 |
| **MPB 103T** | Bioprocess Engineering and Technology | 4 | 4 | 4 | 100 |
| **MPB 104T** | Advanced Pharmaceutical Biotechnology | 4 | 4 | 4 | 100 |
| **MPB 105P** | Pharmaceutical Biotechnology Practical I | 12 | 6 | 12 | 150 |
| **-** | Seminar/Assignment | 7 | 4 | 7 | 100 |
| **Total** | | **35** | **26** | **35** | **650** |
| **Semester II** | | | | | |
| **MPB 201T** | Proteins and protein Formulation | 4 | 4 | 4 | 100 |
| **MPB 202T** | Immunotechnology | 4 | 4 | 4 | 100 |
| **MPB 203T** | Bioinformatics and Computer Technology | 4 | 4 | 4 | 100 |
| **MPB 204T** | Biological Evaluation of Drug Therapy | 4 | 4 | 4 | 100 |
| **MPB 205P** | Pharmaceutical Biotechnology Practical II | 12 | 6 | 12 | 150 |
| **-** | Seminar/Assignment | 7 | 4 | 7 | 100 |
| | **Total** | **35** | **26** | **35** | **650** |

Table – 9: Course of study for M. Pharm. (Pharmacy Practice)

| Course Code | Course | Credit Hours | Credit Points | Hrs./wk | Marks |
|---|---|---|---|---|---|
| **Semester I** | | | | | |
| **MPP 101T** | Clinical Pharmacy Practice | 4 | 4 | 4 | 100 |
| **MPP 102T** | Pharmacotherapeutics-I | 4 | 4 | 4 | 100 |
| **MPP 103T** | Hospital & Community Pharmacy | 4 | 4 | 4 | 100 |
| **MPP 104T** | Clinical Research | 4 | 4 | 4 | 100 |
| **MPP 105P** | Pharmacy Practice Practical I | 12 | 6 | 12 | 150 |
| **-** | Seminar/Assignment | 7 | 4 | 7 | 100 |
| **Total** | | **35** | **26** | **35** | **650** |
| **Semester II** | | | | | |
| **MPP 201T** | Principles of Quality Use of Medicines | 4 | 4 | 4 | 100 |
| **MPP 102T** | Pharmacotherapeutics II | 4 | 4 | 4 | 100 |
| **MPP 203T** | Clinical Pharmacokinetics and Therapeutic Drug Monitoring | 4 | 4 | 4 | 100 |
| **MPP 204T** | Pharmacoepidemiology & Pharmacoeconomics | 4 | 4 | 4 | 100 |
| **MPP 205P** | Pharmacy Practice Practical II | 12 | 6 | 12 | 150 |
| **-** | Seminar/Assignment | 7 | 4 | 7 | 100 |
| | **Total** | **35** | **26** | **35** | **650** |

Table – 10: Course of study for (Pharmacology)

| Course Code | Course | Credit Hours | Credit Points | Hrs./wk | Marks |
|---|---|---|---|---|---|
| **Semester I** | | | | | |
| **MPL 101T** | Modern Pharmaceutical Analytical Techniques | 4 | 4 | 4 | 100 |
| **MPL 102T** | Advanced Pharmacology-I | 4 | 4 | 4 | 100 |
| **MPL 103T** | Pharmacological and Toxicological Screening Methods-I | 4 | 4 | 4 | 100 |
| **MPL 104T** | Cellular and Molecular Pharmacology | 4 | 4 | 4 | 100 |
| **MPL 105P** | Pharmacology Practical I | 12 | 6 | 12 | 150 |
| **-** | Seminar/Assignment | 7 | 4 | 7 | 100 |
| **Total** | | **35** | **26** | **35** | **650** |
| **Semester II** | | | | | |
| **MPL 201T** | Advanced Pharmacology II | 4 | 4 | 4 | 100 |
| **MPL 102T** | Pharmacological and Toxicological Screening Methods-II | 4 | 4 | 4 | 100 |
| **MPL 203T** | Principles of Drug Discovery | 4 | 4 | 4 | 100 |
| **MPL 204T** | Experimental Pharmacology practical- II | 4 | 4 | 4 | 100 |
| **MPL 205P** | Pharmacology Practical II | 12 | 6 | 12 | 150 |
| **-** | Seminar/Assignment | 7 | 4 | 7 | 100 |
| | **Total** | **35** | **26** | **35** | **650** |

Table – 11: Course of study for M. Pharm. (Pharmacognosy)

| Course Code | Course | Credit Hours | Credit Points | Hrs./wk | Marks |
|---|---|---|---|---|---|
| **Semester I** | | | | | |
| **MPG101T** | Modern Pharmaceutical Analytical Techniques | 4 | 4 | 4 | 100 |
| **MPG102T** | Advanced Pharmacognosy-1 | 4 | 4 | 4 | 100 |
| **MPG103T** | Phytochemistry | 4 | 4 | 4 | 100 |
| **MPG104T** | Industrial Pharmacognostical Technology | 4 | 4 | 4 | 100 |
| **MPG105P** | Pharmacognosy Practical I | 12 | 6 | 12 | 150 |
| **-** | Seminar/Assignment | 7 | 4 | 7 | 100 |
| **Total** | | **35** | **26** | **35** | **650** |
| **Semester II** | | | | | |
| **MPG201T** | Medicinal Plant biotechnology | 4 | 4 | 4 | 100 |
| **MPG102T** | Advanced Pharmacognosy-II | 4 | 4 | 4 | 100 |
| **MPG203T** | Indian system of medicine | 4 | 4 | 4 | 100 |
| **MPG204T** | Herbal cosmetics | 4 | 4 | 4 | 100 |
| **MPG205P** | Pharmacognosy Practical II | 12 | 6 | 12 | 150 |
| **-** | Seminar/Assignment | 7 | 4 | 7 | 100 |
| | **Total** | **35** | **26** | **35** | **650** |

Table – 12: Course of study for M. Pharm. III Semester

**(Common for All Specializations)**

| Course Code | Course | Credit Hours | Credit Points |
|---|---|---|---|
| **MRM 301T** | Research Methodology and Biostatistics* | 4 | 4 |
| - | Journal club | 1 | 1 |
| - | Discussion / Presentation (Proposal Presentation) | 2 | 2 |
| - | Research Work | 28 | 14 |
| **Total** | | **35** | **21** |

***** Non University Exam

Table – 13: Course of study for M. Pharm. IV Semester

**(Common for All Specializations)**

| Course Code | Course | Credit Hours | Credit Points |
|---|---|---|---|
| - | Journal Club | 1 | 1 |
| - | Research Work | 31 | 16 |
| - | Discussion/Final Presentation | 3 | 3 |
| **Total** | | **35** | **20** |

Table – 14: Semester wise credits distribution

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

*Credit Points for Co-curricular Activities

Table – 15: Guidelines for Awarding Credit Points for Co-curricular Activities

| Name of the Activity | Maximum Credit Points Eligible / Activity |
|---|---|
| **Participation in National Level Seminar/Conference/Workshop/Symposium/ Training Programs (related to the specialization of the student)** | 01 |
| **Participation in international Level Seminar/Conference/Workshop/Symposium/ Training Programs (related to the specialization of the student)** | 02 |
| **Academic Award/Research Award from State Level/National Agencies** | 01 |
| **Academic Award/Research Award from International Agencies** | 02 |
| **Research / Review Publication in National Journals (Indexed in Scopus / Web of Science)** | 01 |
| **Research / Review Publication in International Journals (Indexed in Scopus / Web of Science)** | 02 |

Note: International Conference: Held Outside India

International Journal: The Editorial Board Outside India

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

## 10. Program Committee

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

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

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

3. Duties of the Programme Committee:

i. Periodically reviewing the progress of the classes.
ii. Discussing the problems concerning curriculum, syllabus and the conduct of classes.
iii. Discussing with the course teachers on the nature and scope of assessment for the course and the same shall be announced to the students at the beginning of respective semesters.

iv. Communicating its recommendation to the Head of the institution on academic matters.
v. The Programme Committee shall meet at least twice in a semester preferably at the end of each sessionalexam and before the end semester exam.

## 11. Examinations/Assessments

The schemes for internal assessment and end semester examinations are given in Table – 16.

### *11.1. End semester examinations*

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

Tables – 16: Schemes for internal assessments and end semester examinations (Pharmaceutics- MPH)

| Course Code | Course | Internal Assessment | | | | End Semester Exams | | Total Marks |
|---|---|---|---|---|---|---|---|---|
| | | Continuous Mode | Sessional Exams | | Total | Marks | Duration | |
| | | | Marks | Duration | | | | |
| **SEMESTER I** | | | | | | | | |
| **MPH 101T** | Modern Pharmaceutical Analytical Techniques | 10 | 15 | 1 Hr | 25 | 75 | 3 Hrs | 100 |
| **MPH 102T** | Drug Delivery System | 10 | 15 | 1 Hr | 25 | 75 | 3 Hrs | 100 |
| **MPH 103T** | Modern Pharmaceutics | 10 | 15 | 1 Hr | 25 | 75 | 3 Hrs | 100 |
| **MPH 104T** | Regulatory Affair | 10 | 15 | 1 Hr | 25 | 75 | 3 Hrs | 100 |
| **MPH 105P** | Pharmaceutics Practical I | 20 | 30 | 6 Hrs | 50 | 100 | 6 Hrs | 150 |
| **-** | Seminar /Assignment | - | - | - | - | - | - | 100 |
| **Total** | | | | | | | | **650** |
| **SEMESTER II** | | | | | | | | |
| **MPH 201T** | Molecular Pharmaceutics(Nano Tech and Targeted DDS) | 10 | 15 | 1 Hr | 25 | 75 | 3 Hrs | 100 |
| **MPH 202T** | Advanced Biopharmaceutics & Pharmacokinetics | 10 | 15 | 1 Hr | 25 | 75 | 3 Hrs | 100 |
| **MPH 203T** | Computer Aided Drug Delivery System | 10 | 15 | 1 Hr | 25 | 75 | 3 Hrs | 100 |
| **MPH** | Cosmetic | 10 | 15 | 1 Hr | 25 | 75 | 3 Hrs | 100 |

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| **204T** | and Cosmeceuticals | | | | | | | |
| **MPH 205P** | Pharmaceutics Practical I | 20 | 30 | 6 Hrs | 50 | 100 | 6 Hrs | 150 |
| **-** | Seminar /Assignment | - | - | - | - | - | - | 100 |
| **Total** | | | | | | | | **650** |

Tables – 17: Schemes for internal assessments and end semester examinations (Industrial Pharmacy- MIP)

| Course Code | Course | Internal Assessment | | | | End Semester Exams | | Total Marks |
|---|---|---|---|---|---|---|---|---|
| | | Continuous Mode | Sessional Exams | | Total | Marks | Duration | |
| | | | Marks | Duration | | | | |
| **SEMESTER I** | | | | | | | | |
| **MIP101T** | Modern Pharmaceutical Analytical Techniques | 10 | 15 | 1 Hr | 25 | 75 | 3 Hrs | 100 |
| **MIP102T** | Pharmaceutical Formulation Development | 10 | 15 | 1 Hr | 25 | 75 | 3 Hrs | 100 |
| **MIP103T** | Novel drug delivery systems | 10 | 15 | 1 Hr | 25 | 75 | 3 Hrs | 100 |
| **MIP104T** | Intellectual Property Rights | 10 | 15 | 1 Hr | 25 | 75 | 3 Hrs | 100 |
| **MIP105P** | Industrial Pharmacy Practical I | 20 | 30 | 6 Hrs | 50 | 100 | 6 Hrs | 150 |
| **-** | Seminar /Assignment | - | - | - | - | - | - | 100 |
| **Total** | | | | | | | | **650** |
| **SEMESTER II** | | | | | | | | |
| **MIP201T** | Advanced Biopharmaceutics and Pharmacokinetics | 10 | 15 | 1 Hr | 25 | 75 | 3 Hrs | 100 |
| **MIP202T** | Scale up and Technology Transfer | 10 | 15 | 1 Hr | 25 | 75 | 3 Hrs | 100 |
| **MIP203T** | Pharmaceutical Production Technology | 10 | 15 | 1 Hr | 25 | 75 | 3 Hrs | 100 |
| **MIP204T** | Entrepreneurship Management | 10 | 15 | 1 Hr | 25 | 75 | 3 Hrs | 100 |

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| **MIP205P** | Industrial Pharmacy Practical II | 20 | 30 | 6 Hrs | 50 | 100 | 6 Hrs | 150 |
| - | Seminar /Assignment | - | - | - | - | - | - | 100 |
| **Total** | | | | | | | | **650** |

Tables – 18: Schemes for internal assessments and end semester examinations (Pharmaceutical Chemistry-MPC)

| Course Code | Course | Internal Assessment | | | | End Semester Exams | | Total Marks |
|---|---|---|---|---|---|---|---|---|
| | | Continuous Mode | Sessional Exams | | Total | Marks | Duration | |
| | | | Marks | Duration | | | | |
| **SEMESTER I** | | | | | | | | |
| **MPC101T** | Modern Pharmaceutical Analytical Techniques | 10 | 15 | 1 Hr | 25 | 75 | 3 Hrs | 100 |
| **MPC102T** | Advanced Organic Chemistry -I | 10 | 15 | 1 Hr | 25 | 75 | 3 Hrs | 100 |
| **MPC103T** | Advanced Medicinal chemistry | 10 | 15 | 1 Hr | 25 | 75 | 3 Hrs | 100 |
| **MPC104T** | Chemistry of Natural Products | 10 | 15 | 1 Hr | 25 | 75 | 3 Hrs | 100 |
| **MPC105P** | Pharmaceutical Chemistry Practical I | 20 | 30 | 6 Hrs | 50 | 100 | 6 Hrs | 150 |
| - | Seminar /Assignment | - | - | - | - | - | - | 100 |
| **Total** | | | | | | | | **650** |
| **SEMESTER II** | | | | | | | | |
| **MPC201T** | Advanced Spectral Analysis | 10 | 15 | 1 Hr | 25 | 75 | 3 Hrs | 100 |
| **MPC202T** | Advanced Organic Chemistry -II | 10 | 15 | 1 Hr | 25 | 75 | 3 Hrs | 100 |
| **MPC203T** | Computer Aided Drug Design | 10 | 15 | 1 Hr | 25 | 75 | 3 Hrs | 100 |
| **MPC204T** | Pharmaceutical Process Chemistry | 10 | 15 | 1 Hr | 25 | 75 | 3 Hrs | 100 |
| **MPC205P** | Pharmaceutic | 20 | 30 | 6 Hrs | 50 | 100 | 6 | 150 |

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | al Chemistry Practical II | | | | | | Hrs | |
| - | Seminar /Assignment | - | - | - | - | - | - | 100 |
| **Total** | | | | | | | | **650** |

Tables – 19: Schemes for internal assessments and end semester examinations (Pharmaceutical Analysis-MPA)

| Course Code | Course | Internal Assessment | | | | End Semester Exams | | Total Marks |
|---|---|---|---|---|---|---|---|---|
| | | Continuous Mode | Sessional Exams | | Total | Marks | Duration | |
| | | | Marks | Duration | | | | |
| **SEMESTER I** | | | | | | | | |
| **MPA101T** | Modern Pharmaceutical Analysis | 10 | 15 | 1 Hr | 25 | 75 | 3 Hrs | 100 |
| **MPA102T** | Advanced Pharmaceutical Analysis | 10 | 15 | 1 Hr | 25 | 75 | 3 Hrs | 100 |
| **MPA103T** | Pharmaceutical Validation | 10 | 15 | 1 Hr | 25 | 75 | 3 Hrs | 100 |
| **MPA104T** | Food Analysis | 10 | 15 | 1 Hr | 25 | 75 | 3 Hrs | 100 |
| **MPA105P** | Pharmaceutical Analysis-I | 20 | 30 | 6 Hrs | 50 | 100 | 6 Hrs | 150 |
| - | Seminar /Assignment | - | - | - | - | - | - | 100 |
| **Total** | | | | | | | | **650** |
| **SEMESTER II** | | | | | | | | |
| **MPA201T** | Advanced Instrumental Analysis | 10 | 15 | 1 Hr | 25 | 75 | 3 Hrs | 100 |
| **MPA202T** | Modern Bio-Analytical Techniques | 10 | 15 | 1 Hr | 25 | 75 | 3 Hrs | 100 |
| **MPA203T** | Quality Control and Quality | 10 | 15 | 1 Hr | 25 | 75 | 3 Hrs | 100 |

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | Assurance | | | | | | | |
| **MPA204T** | Herbal and Cosmetic analysis | 10 | 15 | 1 Hr | 25 | 75 | 3 Hrs | 100 |
| **MPA205P** | Pharmaceutical Analysis-II | 20 | 30 | 6 Hrs | 50 | 100 | 6 Hrs | 150 |
| - | Seminar /Assignment | - | - | - | - | - | - | 100 |
| **Total** | | | | | | | | **650** |

Tables – 20: Schemes for internal assessments and end semester examinations (Pharmaceutical Quality Assurance-MQA)

| Course Code | Course | Internal Assessment | | | | End Semester Exams | | Total Marks |
|---|---|---|---|---|---|---|---|---|
| | | Continuous Mode | Sessional Exams | | Total | Marks | Duration | |
| | | | Marks | Duration | | | | |
| **SEMESTER I** | | | | | | | | |
| **MQA101T** | Modern Pharmaceutical Analytical Techniques | 10 | 15 | 1 Hr | 25 | 75 | 3 Hrs | 100 |
| **MQA102T** | Quality Management System | 10 | 15 | 1 Hr | 25 | 75 | 3 Hrs | 100 |
| **MQA103T** | Quality Control and Quality Assurance | 10 | 15 | 1 Hr | 25 | 75 | 3 Hrs | 100 |
| **MQA104T** | Product Development and Technology Transfer | 10 | 15 | 1 Hr | 25 | 75 | 3 Hrs | 100 |
| **MQA105P** | Pharmaceutical Quality Assurance Practical I | 20 | 30 | 6 Hrs | 50 | 100 | 6 Hrs | 150 |
| **-** | Seminar /Assignment | - | - | - | - | - | - | 100 |
| **Total** | | | | | | | | **650** |
| **SEMESTER II** | | | | | | | | |
| **MQA201T** | Hazards and Safety Management | 10 | 15 | 1 Hr | 25 | 75 | 3 Hrs | 100 |
| **MQA202T** | Pharmaceutical Validation | 10 | 15 | 1 Hr | 25 | 75 | 3 Hrs | 100 |
| **MQA203T** | Audits and Regulatory Compliance | 10 | 15 | 1 Hr | 25 | 75 | 3 Hrs | 100 |
| **MQA204T** | Pharmaceutical Manufacturing Technology | 10 | 15 | 1 Hr | 25 | 75 | 3 Hrs | 100 |
| **MQA205P** | Pharmaceutical Quality Assurance Practical II | 20 | 30 | 6 Hrs | 50 | 100 | 6 Hrs | 150 |
| **-** | Seminar /Assignment | - | - | - | - | - | - | 100 |
| **Total** | | | | | | | | **650** |

Tables – 21: Schemes for internal assessments and end semester examinations (Pharmaceutical Regulatory Affairs-MRA)

| Course Code | Course | Internal Assessment | | | | End Semester Exams | | Total Marks |
|---|---|---|---|---|---|---|---|---|
| | | Continuous Mode | Sessional Exams | | Total | Marks | Duration | |
| | | | Marks | Duration | | | | |
| **SEMESTER I** | | | | | | | | |
| **MRA101T** | Good Pharmaceutical Practices | 10 | 15 | 1 Hr | 25 | 75 | 3 Hrs | 100 |
| **MRA102T** | Documentation and Regulatory Writing | 10 | 15 | 1 Hr | 25 | 75 | 3 Hrs | 100 |
| **MRA103T** | Clinical Research Regulations | 10 | 15 | 1 Hr | 25 | 75 | 3 Hrs | 100 |
| **MRA104T** | Regulations and Legislation for Drugs & Cosmetics, Medical Devices, Biologicals & Herbals, and Food & Nutraceuticals In India and Intellectual Property Rights | 10 | 15 | 1 Hr | 25 | 75 | 3 Hrs | 100 |
| **MRA105T** | Pharmaceutical Regulatory Affairs Practical I | 20 | 30 | 6 Hrs | 50 | 100 | 6 Hrs | 150 |
| **-** | Seminar /Assignment | - | - | - | - | - | - | 100 |
| **Total** | | | | | | | | **650** |
| **SEMESTER II** | | | | | | | | |
| **MRA201T** | Regulatory Aspects of Drugs & Cosmetics | 10 | 15 | 1 Hr | 25 | 75 | 3 Hrs | 100 |

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| **MRA202T** | Regulatory Aspects of Herbal & Biologicals | 10 | 15 | 1 Hr | 25 | 75 | 3 Hrs | 100 |
| **MRA203T** | Regulatory Aspects of Medical Devices | 10 | 15 | 1 Hr | 25 | 75 | 3 Hrs | 100 |
| **MRA204T** | Regulatory Aspects of Food & Nutraceuticals | 10 | 15 | 1 Hr | 25 | 75 | 3 Hrs | 100 |
| **MRA205P** | Pharmaceutical Regulatory Affairs Practical II | 20 | 30 | 6 Hrs | 50 | 100 | 6 Hrs | 150 |
| **-** | Seminar /Assignment | - | - | - | - | - | - | 100 |
| **Total** | | | | | | | | **650** |

Tables – 22: Schemes for internal assessments and end semester examinations (Pharmaceutical Biotechnology-MPB)

| Course Code | Course | Internal Assessment | | | | End Semester Exams | | Total Marks |
|---|---|---|---|---|---|---|---|---|
| | | Continuous Mode | Sessional Exams | | Total | Marks | Duration | |
| | | | Marks | Duration | | | | |
| **SEMESTER I** | | | | | | | | |
| **MPB101T** | Modern Pharmaceutical Analytical Techniques | 10 | 15 | 1 Hr | 25 | 75 | 3 Hrs | 100 |
| **MPB102T** | Microbial And Cellular Biology | 10 | 15 | 1 Hr | 25 | 75 | 3 Hrs | 100 |
| **MPB103T** | Bioprocess Engineering and Technology | 10 | 15 | 1 Hr | 25 | 75 | 3 Hrs | 100 |
| **MPB104T** | Advanced Pharmaceutical Biotechnology | 10 | 15 | 1 Hr | 25 | 75 | 3 Hrs | 100 |
| **MPB105P** | Pharmaceutical Biotechnology Practical I | 20 | 30 | 6 Hrs | 50 | 100 | 6 Hrs | 150 |
| **-** | Seminar /Assignment | - | - | - | - | - | - | 100 |
| **Total** | | | | | | | | **650** |
| **SEMESTER II** | | | | | | | | |
| **MPB201T** | Proteins and protein Formulation | 10 | 15 | 1 Hr | 25 | 75 | 3 Hrs | 100 |
| **MPB202T** | Immunotechnology | 10 | 15 | 1 Hr | 25 | 75 | 3 Hrs | 100 |
| **MPB203T** | Bioinformatics and Computer Technology | 10 | 15 | 1 Hr | 25 | 75 | 3 Hrs | 100 |
| **MPB204T** | Biological Evaluation of Drug Therapy | 10 | 15 | 1 Hr | 25 | 75 | 3 Hrs | 100 |
| **MPB205P** | Pharmaceutical Biotechnology Practical II | 20 | 30 | 6 Hrs | 50 | 100 | 6 Hrs | 150 |
| **-** | Seminar /Assignment | - | - | - | - | - | - | 100 |
| **Total** | | | | | | | | **650** |

Tables – 23: Schemes for internal assessments and end semester examinations (Pharmacy Practice-MPP)

| Course Code | Course | Internal Assessment | | | | End Semester Exams | | Total Marks |
|---|---|---|---|---|---|---|---|---|
| | | Continuous Mode | Sessional Exams | | Total | Marks | Duration | |
| | | | Marks | Duration | | | | |
| **SEMESTER I** | | | | | | | | |
| **MPP101T** | Clinical Pharmacy Practice | 10 | 15 | 1 Hr | 25 | 75 | 3 Hrs | 100 |
| **MPP102T** | Pharmacotherapeutics-I | 10 | 15 | 1 Hr | 25 | 75 | 3 Hrs | 100 |
| **MPP103T** | Hospital & Community Pharmacy | 10 | 15 | 1 Hr | 25 | 75 | 3 Hrs | 100 |
| **MPP104T** | Clinical Research | 10 | 15 | 1 Hr | 25 | 75 | 3 Hrs | 100 |
| **MPP105P** | Pharmacy Practice Practical I | 20 | 30 | 6 Hrs | 50 | 100 | 6 Hrs | 150 |
| **-** | Seminar /Assignment | - | - | - | - | - | - | 100 |
| **Total** | | | | | | | | **650** |
| **SEMESTER II** | | | | | | | | |
| **MPP201T** | Principles of Quality Use of Medicines | 10 | 15 | 1 Hr | 25 | 75 | 3 Hrs | 100 |
| **MPP102T** | Pharmacotherapeutics II | 10 | 15 | 1 Hr | 25 | 75 | 3 Hrs | 100 |
| **MPP203T** | Clinical Pharmacokinetics and Therapeutic Drug Monitoring | 10 | 15 | 1 Hr | 25 | 75 | 3 Hrs | 100 |
| **MPP204T** | Pharmacoepidemiology & Pharmacoeconomics | 10 | 15 | 1 Hr | 25 | 75 | 3 Hrs | 100 |
| **MPP205P** | Pharmacy Practice Practical II | 20 | 30 | 6 Hrs | 50 | 100 | 6 Hrs | 150 |
| **-** | Seminar /Assignment | - | - | - | - | - | - | 100 |
| **Total** | | | | | | | | **650** |

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

| Course Code | Course | Internal Assessment | | | | End Semester Exams | | Total Marks |
|---|---|---|---|---|---|---|---|---|
| | | Continuous Mode | Sessional Exams | | Total | Marks | Duration | |
| | | | Marks | Duration | | | | |
| **SEMESTER I** | | | | | | | | |
| **MPL101T** | Modern Pharmaceutical Analytical Techniques | 10 | 15 | 1 Hr | 25 | 75 | 3 Hrs | 100 |
| **MPL102T** | Advanced Pharmacology-I | 10 | 15 | 1 Hr | 25 | 75 | 3 Hrs | 100 |
| **MPL103T** | Pharmacological and Toxicological Screening Methods-I | 10 | 15 | 1 Hr | 25 | 75 | 3 Hrs | 100 |
| **MPL104T** | Cellular and Molecular Pharmacology | 10 | 15 | 1 Hr | 25 | 75 | 3 Hrs | 100 |
| **MPL105P** | Experimental Pharmacology - I | 20 | 30 | 6 Hrs | 50 | 100 | 6 Hrs | 150 |
| **-** | Seminar /Assignment | - | - | - | - | - | - | 100 |
| **Total** | | | | | | | | **650** |
| **SEMESTER II** | | | | | | | | |
| **MPL201T** | Advanced Pharmacology II | 10 | 15 | 1 Hr | 25 | 75 | 3 Hrs | 100 |
| **MPL102T** | Pharmacological and Toxicological Screening Methods-II | 10 | 15 | 1 Hr | 25 | 75 | 3 Hrs | 100 |
| **MPL203T** | Principles of Drug Discovery | 10 | 15 | 1 Hr | 25 | 75 | 3 Hrs | 100 |
| **MPL204T** | Clinical research and pharmacovigilance | 10 | 15 | 1 Hr | 25 | 75 | 3 Hrs | 100 |
| **MPL205P** | Experimental Pharmacology - II | 20 | 30 | 6 Hrs | 50 | 100 | 6 Hrs | 150 |
| **-** | Seminar /Assignment | - | - | - | - | - | - | 100 |
| **Total** | | | | | | | | **650** |

Tables – 25: Schemes for internal assessments and end semester examinations (Pharmacognosy-MPG)

| Course Code | Course | Internal Assessment | | | | End Semester Exams | | Total Marks |
|---|---|---|---|---|---|---|---|---|
| | | Continuous Mode | Sessional Exams | | Total | Marks | Duration | |
| | | | Marks | Duration | | | | |
| **SEMESTER I** | | | | | | | | |
| **MPG101T** | Modern Pharmaceutical Analytical Techniques | 10 | 15 | 1 Hr | 25 | 75 | 3 Hrs | 100 |
| **MPG102T** | Advanced Pharmacognosy-1 | 10 | 15 | 1 Hr | 25 | 75 | 3 Hrs | 100 |
| **MPG103T** | Phytochemistry | 10 | 15 | 1 Hr | 25 | 75 | 3 Hrs | 100 |
| **MPG104T** | Industrial Pharmacognostical Technology | 10 | 15 | 1 Hr | 25 | 75 | 3 Hrs | 100 |
| **MPG105P** | Pharmacognosy Practical I | 20 | 30 | 6 Hrs | 50 | 100 | 6 Hrs | 150 |
| **-** | Seminar /Assignment | - | - | - | - | - | - | 100 |
| **Total** | | | | | | | | **650** |
| **SEMESTER II** | | | | | | | | |
| **MPG201T** | Medicinal Plant biotechnology | 10 | 15 | 1 Hr | 25 | 75 | 3 Hrs | 100 |
| **MPG102T** | Advanced Pharmacognosy-II | 10 | 15 | 1 Hr | 25 | 75 | 3 Hrs | 100 |
| **MPG203T** | Indian system of medicine | 10 | 15 | 1 Hr | 25 | 75 | 3 Hrs | 100 |
| **MPG204T** | Herbal cosmetics | 10 | 15 | 1 Hr | 25 | 75 | 3 Hrs | 100 |
| **MPG205P** | Pharmacognosy Practical II | 20 | 30 | 6 Hrs | 50 | 100 | 6 Hrs | 150 |
| **-** | Seminar /Assignment | - | - | - | - | - | - | 100 |
| **Total** | | | | | | | | **650** |

Tables – 26: Schemes for internal assessments and end semester examinations (Semester III& IV)

| Course Code | Course | Internal Assessment | | | | End Semester Exams | | Total Marks |
|---|---|---|---|---|---|---|---|---|
| | | Continuous Mode | Sessional Exams | | Total | Marks | Duration | |
| | | | Marks | Duration | | | | |
| **SEMESTER III** | | | | | | | | |
| **MRM301T** | Research Methodology and Biostatistics* | 10 | 15 | 1 Hr | 25 | 75 | 3 Hrs | 100 |
| - | Journal club | - | - | - | 25 | - | - | 25 |
| - | Discussion / Presentation (Proposal Presentation) | - | - | - | 50 | - | - | 50 |
| - | Research work* | - | - | - | - | 350 | 1 Hr | 350 |
| **Total** | | | | | | | | **525** |
| **SEMESTER IV** | | | | | | | | |
| - | Journal club | - | - | - | 25 | - | - | 25 |
| - | Discussion / Presentation (Proposal Presentation) | - | - | - | 75 | - | - | 75 |
| - | Research work and Colloquium | - | - | - | - | 400 | 1 Hr | 400 |
| **Total** | | | | | | | | **500** |

***Non University Examination**

### *11.2. Internal assessment: Continuous mode*

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

Table – 27: Scheme for awarding internal assessment: Continuous mode

| Theory | |
|---|---|
| **Criteria** | **Maximum Marks** |
| **Attendance (Refer Table – 28)** | 8 |
| **Student – Teacher interaction** | 2 |
| **Total** | **10** |
| **Practical** | |
| **Attendance (Refer Table – 28** | 10 |
| **Based on Practical Records, Regular viva voce, etc.** | 10 |
| **Total** | **20** |

Table – 28: Guidelines for the allotment of marks for attendance

| Percentage of Attendance | Theory | Practical |
|---|---|---|
| **95 – 100** | 8 | 10 |
| **90 – 94** | 6 | 7.5 |
| **85 – 89** | 4 | 5 |
| **80 – 84** | 2 | 2.5 |
| **Less than 80** | 0 | 0 |

### *11.2.1. Sessional Exams*

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

## 12. Promotion and award of grades

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

## 13. Carry forward of marks

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

## 14. Improvement of internal assessment

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

## 15. Reexamination of end semester examinations

Reexamination of end semester examination shall be conducted as per the schedule given in table 29. The exact dates of examinations shall be notified from time to time.

Table – 29: Tentative schedule of end semester examinations

| Semester | For Regular Candidates | For Failed Candidates |
|---|---|---|
| **I and III** | November / December | May / June |
| **II and IV** | May / June | November / December |

## 16. Allowed to keep terms (ATKT):

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

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

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

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

## 17. Grading of performances

### *17.1. Letter grades and grade points allocations:*

Based on the performances, each student shall be awarded a final letter grade at the end of the semester for each course.The letter grades and their corresponding grade points are given in Table – 30.

**Table – 30: Letter grades and grade points equivalent to *Percentage of marks and performances***

| Percentage of Marks Obtained | Letter Grade | Grade Point | Performance |
|---|---|---|---|
| **90.00 – 100** | O | 10 | Outstanding |
| **80.00 – 89.99** | A | 9 | Excellent |
| **70.00 – 79.99** | B | 8 | Good |
| **60.00 – 69.99** | C | 7 | Fair |
| **50.00 – 59.99** | D | 6 | Average |
| **Less than 50** | F | 0 | Fail |
| **Absent** | AB | 0 | Fail |

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

## 18. The Semester grade point average (SGPA)

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

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

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

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

## 19. Cumulative Grade Point Average (CGPA)

The CGPA is calculated with the SGPA of all the IV semesters to two decimal points and is indicated in final grade report card/final transcript showing the grades of all IV semesters and their courses. The CGPA shall reflect the failed statusin case of F grade(s), till the course(s) is/are passed. When the course(s) is/are passedby obtaining a pass grade on subsequent examination(s) theCGPA

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 $C_1$, $C_2$, $C_3$,.... is the total number of credits for semester I,II,III,…. and $S_1$,$S_2$, $S_3$,....is the SGPA of semester I,II,III,…. .

## 20. Declaration of class

The class shall be awarded on the basis of CGPA as follows:

| | |
|---|---|
| First Class with Distinction | = CGPA of. 7.50 and above |
| First Class | = CGPA of 6.00 to 7.49 |
| Second Class | = CGPA of 5.00 to 5.99 |

## 21. Project work

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

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

***Evaluation of Dissertation Book:***

| | |
|---|---|
| Objective(s) of the work done | 50 Marks |
| Methodology adopted | 150 Marks |
| Results and Discussions | 250 Marks |
| Conclusions and Outcomes | 50 Marks |
| **Total** | **500 Marks** |

***Evaluation of Presentation:***

| | |
|---|---|
| Presentation of work | 100 Marks |
| Communication skills | 50 Marks |
| Question and answer skills | 100 Marks |
| **Total** | **250 Marks** |

## 22. Award of Ranks

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

## 23. Award of degree

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

## 24. Duration for completion of the program of study

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

## 25. Revaluation / Retotaling of answer papers

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

## 26. Re-admission after break of study

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

## 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

***THEORY*** ***60 HOURS***

1. a. **UV-Visible spectroscopy**: Introduction, Theory, Laws, Instrumentation associated with UV-Visible spectroscopy, Choice of solvents and solvent effect and Applications of UV-Visible spectroscopy. — 11 Hrs

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

   c. **Spectroflourimetry:** Theory of Fluorescence, Factors affecting fluorescence, Quenchers, Instrumentation and Applications of fluorescence spectrophotometer.

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

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

| | | |
|---|---|---|
| 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 | 11 Hrs |
| 4 | **Chromatography**: Principle, apparatus, instrumentation, chromatographic parameters, factors affecting resolution and applications of the following:<br>a) Paper chromatography b) Thin Layer chromatography<br>c) Ion exchange chromatography d) Column chromatography<br>e) Gas chromatography f) High Performance Liquid chromatography<br>g) Affinity chromatography | 11 Hrs |
| 5 | a. **Electrophoresis**: Principle, Instrumentation, Working conditions, factors affecting separation and applications of the following:<br>a) Paper electrophoresis b) Gel electrophoresis c) Capillary electrophoresis d) Zone electrophoresis e) Moving boundary electrophoresis f) Iso electric focusing<br>**b. X ray Crystallography**: Production of X rays, Different X ray diffraction methods, Bragg's law, Rotating crystal technique, X ray powder technique, Types of crystals and applications of X-ray diffraction. | 11 Hrs |
| 6 | **Immunological assays :** RIA (Radio immuno assay), ELISA, Bioluminescence assays. | 5 Hrs |

***REFERENCES***


1. Spectrometric Identification of Organic compounds - Robert M Silverstein, Sixth edition, John Wiley & Sons, 2004.
2. Principles of Instrumental Analysis - Doglas A Skoog, F. James Holler, Timothy A. Nieman, 5th edition, Eastern press, Bangalore, 1998.
3. Instrumental methods of analysis – Willards, 7th edition, CBS publishers.
4. Practical Pharmaceutical Chemistry – Beckett and Stenlake, Vol II, 4th edition, CBS Publishers, New Delhi, 1997.
5. Organic Spectroscopy - William Kemp, 3rd edition, ELBS, 1991.
6. Quantitative Analysis of Drugs in Pharmaceutical formulation - P D Sethi, 3rd Edition, CBS Publishers, New Delhi, 1997.
7. Pharmaceutical Analysis- Modern methods – Part B - J W Munson, Volume 11, Marcel Dekker Series

## DRUG DELIVERY SYSTEMS
## (MPH 102T)

***SCOPE***

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

***OBJECTIVES***

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

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

***THEORY*** ***60 Hrs***

| | | |
|---|---|---|
| 1. | **Sustained Release(SR) and Controlled Release (CR) formulations:** Introduction & basic concepts, advantages/ disadvantages, factors influencing, Physicochemical & 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. | 10 Hrs |
| 2 | **Rate Controlled Drug Delivery Systems:** Principles & Fundamentals, Types, Activation; Modulated Drug Delivery Systems;Mechanically activated, pH activated, Enzyme activated, and Osmotic activated Drug Delivery Systems Feedback regulated Drug Delivery Systems; Principles & Fundamentals. | 10 Hrs |
| 3 | **Gastro-Retentive Drug Delivery Systems**: Principle, concepts advantages and disadvantages, Modulation of GI transit time approaches to extend GI transit. Buccal Drug Delivery Systems: Principle of muco adhesion, advantages and disadvantages, Mechanism of drug permeation, Methods of formulation and its evaluations. | 10 Hrs |
| 4 | **Occular Drug Delivery Systems**: Barriers of drug permeation, Methods to overcome barriers. | 06 Hrs |

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| 5 | **Transdermal Drug Delivery Systems:** Structure of skin and barriers, Penetration enhancers, Transdermal Drug Delivery Systems, Formulation and evaluation. | 10 Hrs |
| 6 | **Protein and Peptide Delivery:** Barriers for protein delivery. Formulation and Evaluation of delivery systems of proteins and other macromolecules. | 08 Hrs |
| 7 | **Vaccine delivery systems:** Vaccines, uptake of antigens, single shot vaccines, mucosal and transdermal delivery of vaccines. | 06 Hrs |

***REFERENCES***


1. Y W. Chien, Novel Drug Delivery Systems, 2nd edition, revised and expanded,
Marcel Dekker, Inc., New York, 1992.
2. Robinson, J. R., Lee V. H. L, Controlled Drug Delivery Systems, Marcel Dekker,Inc., New York, 1992.
3. Encyclopedia of controlled delivery, Editor- Edith Mathiowitz, Published by WileyInterscience Publication, John Wiley and Sons, Inc, New York! Chichester/Weinheim
4. N.K. Jain, Controlled and Novel Drug Delivery, CBS Publishers & Distributors, New Delhi, First edition 1997 (reprint in 2001).
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.

***THEORY*** ***60 HRS***

| | | |
|---|---|---|
| 1. | a. **Preformation Concepts –** Drug Excipient interactions - different methods, kinetics of stability, Stability testing. Theories of dispersion and pharmaceutical Dispersion (Emulsion and Suspension, SMEDDS) preparation and stability Large and small volume parental – physiological and formulation consideration, Manufacturing and evaluation. | 10 Hrs |
| | 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 Hrs |
| 2 | **Validation :** Introduction to Pharmaceutical Validation, Scope & merits of Validation, Validation and calibration of Master plan, ICH & WHO guidelines for calibration and validation of equipments, Validation of specific dosage form, Types of validation. Government regulation, Manufacturing Process Model, URS, DQ, IQ, OQ & P.Q. of facilities. | 10 Hrs |
| 3 | **cGMP & Industrial Management**: Objectives and policies of current good manufacturing practices, layout of buildings, services, equipments and their maintenance Production management: Production organization, , materials management, handling and transportation, inventory management and control, production and planning control, Sales forecasting, budget and cost control, industrial and personal relationship. Concept of Total Quality Management. | 10 Hrs |

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| 4 | **Compression and compaction**: Physics of tablet compression, compression, consolidation, effect of friction, distribution of forces, compaction profiles. Solubility. | 10 Hrs |
| 5 | **Study of consolidation parameters**; Diffusion parameters, 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. | 10 Hrs |

***REFERENCES***


1. Theory and Practice of Industrial Pharmacy By Lachmann and Libermann
2. Pharmaceutical dosage forms: Tablets Vol. 1-3 by Leon Lachmann.
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.
6. Remington's Pharmaceutical Sciences.
7. Advances in Pharmaceutical Sciences Vol. 1-5; By H.S. Bean & A.H. Beckett.
8. Physical Pharmacy; By Alfred martin
9. Bentley's Textbook of Pharmaceutics – by Rawlins.
10. Good manufacturing practices for Pharmaceuticals: A plan for total quality control, Second edition; By Sidney H. Willig.
11. Quality Assurance Guide; By Organization of Pharmaceutical producers of India.
12. Drug formulation manual; By D.P.S. Kohli and D.H.Shah. Eastern publishers, New Delhi.
13. How to practice GMPs; By P.P.Sharma. Vandhana Publications, Agra.
14. Pharmaceutical Process Validation; By Fra. R. Berry and Robert A. Nash.
15. Pharmaceutical Preformulations; By J.J. Wells.
16. Applied production and operations management; By Evans, Anderson, Sweeney and Williams.
17. Encyclopaedia of Pharmaceutical technology, Vol I – III.

## REGULATORY AFFAIRS
## (MPH 104T)

***Scope***

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

- To know the approval process of
- To know the chemistry, manufacturing controls and their regulatory importance
- To learn the documentation requirements for
- To learn the importance and

***Objectives:***

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

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

***THEORY*** ***60 Hrs***

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

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

| | | |
|---|---|---|
| 2 | CMC, post approval regulatory affairs. Regulation for combination products and medical devices.CTD and ECTD format, industry and FDA liaison. ICH - Guidelines of ICH-Q, S E, M. Regulatory requirements of EU, MHRA, TGA and ROW countries. | 12 Hrs |
| 3 | **Non clinical drug development:** Global submission of IND, NDA, ANDA. Investigation of medicinal products dossier, dossier (IMPD) and investigator brochure (IB). | 12 Hrs |
| 4 | **Clinical trials:** Developing clinical trial protocols. Institutional review board/ independent ethics committee Formulation and working procedures informed Consent process and procedures. HIPAA- new, requirement to clinical study process, pharmacovigilance safety monitoring in clinical trials. | 12 Hrs |

***REFERENCES***


1. Generic Drug Product Development, Solid Oral Dosage forms, Leon Shargel and IsaderKaufer,Marcel Dekker series, Vol.143
2. The Pharmaceutical Regulatory Process, Second Edition Edited by Ira R. Berry and Robert P.Martin, Drugs and the Pharmaceutical Sciences,Vol.185, Informa Health care Publishers.
3. New Drug Approval Process: Accelerating Global Registrations By Richard A Guarino, MD,5th edition, Drugs and the Pharmaceutical Sciences,Vol.190.
4. Guidebook for drug regulatory submissions / Sandy Weinberg. By John Wiley & Sons.Inc.
5. FDA regulatory affairs: a guide for prescription drugs, medical devices, and biologics/edited By Douglas J. Pisano, David Mantus.
6. Clinical Trials and Human Research: A Practical Guide to Regulatory Compliance By Fay A.Rozovsky and Rodney K. Adams
7. www.ich.org/
8. www.fda.gov/
9. europa.eu/index_en.htm
10. https://www.tga.gov.au/tga-basics

## PHARMACEUTICS PRACTICALS - I
## (MPH 105P)

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

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

***Scope***

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

***Objectives***

Upon completion of the course student shall be able to understand

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

***THEORY*** ***60 Hrs***

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| 1. | **Targeted Drug Delivery Systems: C**oncepts, Events and biological process involved in drug targeting. Tumor targeting and Brain specific delivery. | 12 Hrs |
| 2 | **Targeting Methods**: introduction preparation and evaluation. Nano Particles & Liposomes: Types, preparation and evaluation. | 12 Hrs |
| 3 | **Micro Capsules / Micro Spheres:** Types, preparation and evaluation , Monoclonal Antibodies ; preparation and application, preparation and application of Niosomes, Aquasomes, Phytosomes, Electrosomes. | 12 Hrs |
| 4 | **Pulmonary Drug Delivery Systems** : Aerosols, propellents, ContainersTypes, preparation and evaluation, Intra Nasal Route Delivery systems; Types, preparation and evaluation. | 12 Hrs |
| 5 | Nucleic acid based therapeutic delivery system : Gene therapy, introduction (ex-vivo & in-vivo gene therapy). Potential target diseases for gene therapy (inherited disorder and cancer). Gene expression systems (viral and nonviral gene transfer). Liposomal gene delivery systems. Biodistribution and Pharmacokinetics. knowledge of therapeutic antisense molecules and aptamers as drugs of future. | 12 Hrs |

***REFERENCES***


1. Y W. Chien, Novel Drug Delivery Systems, 2nd edition, revised and expanded,Marcel Dekker, Inc., New York, 1992.
2. S.P.Vyas and R.K.Khar, Controlled Drug Delivery - concepts and advances, VallabhPrakashan, New Delhi, First edition 2002.
3. N.K. Jain, Controlled and Novel Drug Delivery, CBS Publishers & Distributors, NewDelhi, First edition 1997 (reprint in 2001).

## ADVANCED BIOPHARMACEUTICS & PHARMACOKINETICS (MPH 202T)

***Scope***

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

***Objectives***

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

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

***THEORY*** ***60 Hrs***

1. **Drug Absorption from the Gastrointestinal Tract**: Gastrointestinal tract, Mechanism of drug absorption, Factors affecting drug absorption, pH–partition theory of drug absorption. Formuulation and physicochemical factors: Dissolution rate, Dissolution process, Noyes–Whitney equation and drug dissolution, Factors affecting the dissolution rate. Gastrointestinal absorption: role of the dosage form: Solution (elixir, syrup and solution) as a dosage form ,Suspension as a dosage form, Capsule as a dosage form, Tablet as a dosage form ,Dissolution methods ,Formulation and processing factors, Correlation of in vivo data with in vitro dissolution data.Transport model: Permeability-Solubility-Charge State and the pH Partition Hypothesis, Properties of the Gastrointestinal Tract (GIT), pH Microclimate Intracellular pH Environment, Tight-Junction Complex. 12 Hrs

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| 2 | **Biopharmaceutic considerations in drug product design and In Vitro Drug Product Performance:** Introduction, biopharmaceutic factors affecting drug bioavailability, rate-limiting steps in drug absorption, physicochemical nature of the drug formulation factors affecting drug product performance, *in vitro*: dissolution and drug release testing, compendial methods of dissolution, alternative methods of dissolution testing,meeting dissolution requirements,problems of variable control in dissolution testingperformance of drug products. *In vitro–in vivo* correlation, dissolution profile comparisons, drug product stability,considerations in the design of a drug product. | 12 Hrs |
| 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 $k_{max}$ and $v_{max}$. 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 Hrs |
| 4 | **Drug Product Performance, In Vivo: Bioavailability and Bioequivalence**: drug product performance, purpose of bioavailability studies, relative and absolute availability. methods for assessing bioavailability, bioequivalence studies, design and evaluation of bioequivalence studies, study designs, crossover study designs, evaluation of the data, bioequivalence example, study submission and drug review process. biopharmaceutics classification system, methods. Permeability: In-vitro, in-situ and In-vivo methods.generic biologics (biosimilar drug products),clinical significance of bioequivalence studies, special concerns in bioavailability and bioequivalence studies, generic substitution. | 12 Hrs |
| 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 Hrs |

***REFERENCES***


1. Biopharmaceutics and Clinical Pharmacokinetics by Milo Gibaldi, 4th edition,Philadelphia, Lea and Febiger, 1991
2. Biopharmaceutics and Pharmacokinetics, A. Treatise, D .M. Brahmankar and Sunil B. Jaiswal., VallabPrakashan, Pitampura, Delhi
3. Applied Biopharmaceutics and Pharmacokinetics by Shargel. Land YuABC, 2nd edition, Connecticut Appleton Century Crofts, 1985
4. Textbook of Biopharmaceutics and Pharmacokinetics, Dr. Shobha Rani R. Hiremath,Prism Book
5. Pharmacokinetics by Milo Gibaldi and D. Perrier, 2nd edition, Marcel Dekker Inc.,New York, 1982
6. Current Concepts in Pharmaceutical Sciences: Biopharmaceutics, Swarbrick. J, Leaand Febiger, Philadelphia, 1970
7. Clinical Pharmacokinetics, Concepts and Applications 3rd edition by MalcolmRowland and Thom~ N. Tozer, Lea and Febiger, Philadelphia, 1995
8. Dissolution, Bioavailability and Bioequivalence, Abdou. H.M, Mack PublishingCompany, Pennsylvania 1989
9. Biopharmaceutics and Clinical Pharmacokinetics, An Introduction, 4th edition,revised and expande by Robert. E. Notari, Marcel Dekker Inc, New York and Basel,1987.
10. Biopharmaceutics and Relevant Pharmacokinetics by John. G Wagner and M.Pemarowski, 1st edition, Drug Intelligence Publications, Hamilton, Illinois, 1971.
11. Encyclopedia of Pharmaceutical Technology, Vol 13, James Swarbrick, James. G.Boylan, Marcel Dekker Inc, New York, 1996.
12. Basic Pharmacokinetics,1 st edition,Sunil S JambhekarandPhilip J Breen,pharmaceutical press, RPS Publishing,2009.
13. Absorption and Drug Development- Solubility, Permeability, and Charge State, Alex Avdeef, John Wiley & Sons, Inc,2003.

## COMPUTER AIDED DRUG DEVELOPMENT
## (MPH 203T)

***Scope***

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

***Objectives***

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

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

***THEORY*** ***60 Hrs***

| | | |
|---|---|---|
| 1. | a. **Computers in Pharmaceutical Research and Development**: A General Overview: History of Computers in Pharmaceutical Research and Development. Statistical modeling in Pharmaceutical research and development: Descriptive versus Mechanistic Modeling, Statistical Parameters, Estimation, Confidence Regions, Nonlinearity at the Optimum, Sensitivity Analysis, Optimal Design, Population Modeling<br>b. **Quality-by-Design In Pharmaceutical Development:** Introduction, ICH Q8 guideline, Regulatory and industry views on QbD, Scientifically based QbD - examples of application. | 12 Hrs |
| 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 Hrs |

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| 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 Hrs |
| 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<br>b. **Computer Simulations in Pharmacokinetics and Pharmacodynamics:** Introduction, Computer Simulation: Whole Organism, Isolated Tissues, Organs, Cell, Proteins and Genes.<br>c. **Computers in Clinical Development**: Clinical Data Collection and Management, Regulation of Computer Systems | 12 Hrs |
| 5 | **Artificial Intelligence (AI), Robotics and Computational fluid dynamics:** General overview, Pharmaceutical Automation, Pharmaceutical applications, Advantages and Disadvantages. Current Challenges and Future Directions. | 12 Hrs |

***REFERENCES***


1. Computer Applications in Pharmaceutical Research and Development, Sean Ekins, 2006, John Wiley & Sons.
2. Computer-Aided Applications in Pharmaceutical Technology, 1st Edition, Jelena Djuris, Woodhead Publishing
3. Encyclopedia of Pharmaceutical Technology, Vol 13, James Swarbrick, James. G.Boylan, Marcel Dekker Inc, New York, 1996.

## COSMETICS AND COSMECEUTICALS
## (MPH 204T)

***Scope***

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

***Objectives***

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

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

***THEORY*** ***60 Hrs***

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

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| | **Controversial ingredients:** Parabens, formaldehyde liberators, dioxane. | |
| 4 | **Design of cosmeceutical products:** Sun protection, sunscreens classification and regulatory aspects. Addressing dry skin, acne, sun-protection, pigmentation, prickly heat, wrinkles, body odor., dandruff, dental cavities, bleeding gums, mouth odor and sensitive teeth through cosmeceutical formulations. | 12 Hrs |
| 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 Hrs |

***REFERENCES***


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

## PHARMACEUTICS PRACTICALS - II
## (MPH 205P)

1. To study the effect of temperature change , non solvent addition, incompatible polymer addition in microcapsules preparation
2. Preparation and evaluation of Alginate beads
3. Formulation and evaluation of gelatin /albumin microspheres
4. Formulation and evaluation of liposomes/niosomes
5. Formulation and evaluation of spherules
6. Improvement of dissolution characteristics of slightly soluble drug by Solid dispersion technique.
7. Comparison of dissolution of two different marketed products /brands
8. Protein binding studies of a highly protein bound drug & poorly protein bound drug
9. Bioavailability studies of Paracetamol in animals.
10. Pharmacokinetic and IVIVC data analysis by Winnoline$^{R}$ 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
18. To carry out Sensitivity Analysis, and Population Modeling.
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

## INDUSTRIAL PHARMACY (MIP)
## MODERN PHARMACEUTICAL ANALYTICAL TECHNIQUES
## (MIP 101T)

***Scope***

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

***Objectives***

After completion of course student is able to know,

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

***THEORY*** ***60 HOURS***

1. **UV-Visible spectroscopy:** Introduction, Theory, Laws, Instrumentation associated with UV-Visible spectroscopy, Choice of solvents and solvent effect and Applications of UV-Visible spectroscopy. — 11 Hrs

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

   **Spectroflourimetry:** Theory of Fluorescence, Factors affecting fluorescence, Quenchers, Instrumentation and Applications of fluorescence spectrophotometer.

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

2 NMR spectroscopy: Quantum numbers and their role in NMR, Principle, 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. — 11 Hrs

| | | |
|---|---|---|
| 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 | 11 Hrs |
| 4 | **Chromatography:** Principle, apparatus, instrumentation, chromatographic parameters, factors affecting resolution and applications of the following:<br>a) Paper chromatography b) Thin Layer chromatography<br>c) Ion exchange chromatography d) Column chromatography<br>e) Gas chromatography f) High Performance Liquid chromatography<br>g) Affinity chromatography | 11 Hrs |
| 5 | **Electrophoresis:** Principle, Instrumentation, Working conditions, factors affecting separation and applications of the following:<br>a) Paper electrophoresis b) Gel electrophoresis c) Capillary electrophoresis d) Zone electrophoresis e) Moving boundary electrophoresis f) Iso electric focusing<br><br>**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. | 11 Hrs |
| 6. | **Immunological Assays:** Radioimmunology assay (RIA), ELISA (Theory & practical) and knowledge on Bioluminescence assays. | 5 Hrs |

***REFERENCES***


1. Spectrometric Identification of Organic compounds - Robert M Silverstein, 6th edition, John Wiley & Sons, 2004.
2. Principles of Instrumental Analysis - Doglas A Skoog, F. James Holler, Timothy A. Nieman, 5th edition, Eastern press, Bangalore, 1998.
3. Instrumental methods of analysis – Willards, 7th edition, CBS publishers.
4. Practical Pharmaceutical Chemistry – Beckett and Stenlake, Vol II, 4th edition, CBS Publishers, New Delhi, 1997.
5. Organic Spectroscopy - William Kemp, 3rd edition, ELBS, 1991.
6. Quantitative Analysis of Drugs in Pharmaceutical formulation - P D Sethi, 3rd Edition, CBS Publishers, New Delhi, 1997.
7. Pharmaceutical Analysis- Modern methods – Part B - J W Munson, Volume 11, Marcel Dekker Series

## PHARMACEUTICAL FORMULATION DEVELOPMENT
## (MIP 102T)

***Scope***

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

***Objectives***

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

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

***THEORY*** ***60 Hrs***

| | | |
|---|---|---|
| 1. | **Preformulation Studies:** Molecular optimization of APIs (drug substances), crystal morphology and variations, powder flow, structure modification, drug-excipient compatibility studies, methods of determination. | 12 Hrs |
| 2 | **Formulation Additives**: Study of different formulation additives, factors influencing their incorporation, role of formulation development and processing, new developments in excipient science. Design of experiments – factorial design for product and process development. | 12 Hrs |
| 3 | **Solubility:** Importance, experimental determination, phase-solubility analysis, pH-solubility profile, solubility techniques to improve solubility and utilization of analytical methods – cosolvency, salt formation, complexation, solid dispersion, micellar solubilization and hydrotropy. | 12 Hrs |
| 4 | **Dissolution:** Theories, mechanisms of dissolution, *in-vitro* dissolution testing models – sink and non-sink. Factors influencing dissolution and intrinsic dissolution studies. Dissolution test apparatus – designs, dissolution testing for conventional and controlled release products. Data handling and correction factor. Biorelevent media, *in-vitro* and *in-vivo* correlations, levels of correlations. | 12 Hrs |

| | | |
|---|---|---|
| 5 | **Product Stability:** Degradation kinetics, mechanisms, stability testing of drugs and pharmaceuticals, factors influencing-media effects and pH effects, accelerated stability studies, interpretation of kinetic data (API & tablets). Solid state stability and shelf life assignment. Stability protocols, reports and ICH guidelines. | 12 Hrs |

***REFERENCES***


1. Lachman L, Lieberman HA, Kanig JL. The Theory and Practice Of Industrial Pharmacy, 3rd ed., Varghese Publishers, Mumbai 1991.
2. Sinko PJ. Martin's physical pharmacy and pharmaceutical sciences, 5th ed., B.I. Publications Pvt. Ltd, Noida, 2006.
3. Lieberman HA, Lachman L, Schwartz JB. Pharmaceutical dosage forms: tablets Vol. I-III, 2nd ed., CBS Publishers & distributors, New Delhi, 2005.
4. Conners KA. A Text book of pharmaceutical analysi Wells JI. Pharmaceutical preformulation: The physicochemical properties of drug substances. Ellis Horwood Ltd., England, 1998.
5. Yalkowsky SH. Techniques of solubilization of drugs. Vol-12. Marcel Dekker Inc., New York, 1981
6. Dressman J, Kramer J. Pharmaceutical dissolution testing. Saurah printer pvt. Ltd., New Delhi,2005.
7. Sethi PD. Quantitative analysis of drugs in pharmaceutical formulations, 3rd ed., CBS publications, New Delhi, 2008.
8. Carstensen JT, Rhodes CT. Drug stability principles and practices, 3rd ed., CBS Publishers & distributors, New Delhi, 2005.
9. Yoshioka S, Stella VJ. Stability of drugs and dosage forms, Springer (India) Pvt. Ltd., New Delhi, 2006.
10. Banker GS, Rhodes CT. Modern Pharmaceutics, 4th ed., Marcel Dekker Inc, New York, 2005.
11. W. Grimm - Stability testing of drug products.
12. Mazzo DJ. International stability testing. Eastern Press Pvt. Ltd., Bangalore, 1999. 13. Beckett AH, Stenlake JB. Practical pharmaceutical chemistry, Part I & II., 4th ed., CBS Publishers & distributors, New Delhi, 2004.
14. Indian Pharmacopoeia. Controller of Publication. Delhi, 1996.
15. British Pharmacopoeia. British Pharmacopoeia Commission Office, London, 2008.
16. United States Pharmacopoeia. United States Pharmacopeial Convention, Inc, USA, 2003.
17. Encyclopaedia of Pharm. Technology, Vol I – III.
18. Wells J. I. Pharmaceutical Preformulation : The physicochemical properties of drug substances, Ellis Horwood Ltd. England, 1988.

## NOVEL DRUG DELIVERY SYSTEMS
## (MIP 103T)

***Scope***

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

***Objective***

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

- The need, concept, design and evaluation of various customized, sustained and controlled release dosage forms.
- To formulate and evaluate various novel drug delivery systems

***THEORY*** ***60 Hrs***

| | | |
|---|---|---|
| 1. | **Concept & Models for NDDS:** Classification of rate controlled drug delivery systems (DDS), rate programmed release, activation modulated & feedback regulated DDS, effect of system parameters in controlled drug delivery, computation of desired release rate and dose for controlled release DDS, pharmacokinetic design for DDS – intermittent, zero order & first order release.<br><br>**Carriers for Drug Delivery:** Polymers / co-polymers-introduction, classification, characterization, polymerization techniques, application in CDDS / NDDS, biodegradable & natural polymers. | 12 Hrs |
| 2 | **Study of Various DDS:** Concepts, design, formulation & evaluation of controlled release oral DDS, Mucoadhesive DDS (buccal, nasal, pulmonary) Pulsatile, colon specific, liquid sustained release systems, Ocular delivery systems | 12 Hrs |
| 3 | **Transdermal Drug Delivery Systems:** Theory, design, formulation & evaluation including iontophoresis and other latest developments in skin delivery systems. | 08 Hrs |
| 4 | **Sub Micron Cosmeceuticals:** Biology, formulation science and evaluation of various cosmetics for skin, hair, nail, eye etc and it's regulatory aspects. | 04 Hrs |

| | | |
|---|---|---|
| 5 | **Targeted Drug Delivery Systems:** Importance, concept, biological process and events involved in drug targeting, design, formulation & evaluation, methods in drug targeting – nanoparticles, liposomes, niosomes, pharmacosomes, resealed erythrocytes, microspheres, magnetic microspheres. Specialized pharmaceutical emulsions – multiple emulsions, micro-emulsions. | 12 Hrs |
| 6 | **Protein / Peptide Drug Delivery Systems:** Concepts, delivery techniques, formulation, stability testing, causes of protein destabilization, stabilization methods. | |
| 7 | **Biotechnology in Drug Delivery Systems:** Brief review of major areas-recombinant DNA technology, monoclonal antibodies, gene therapy. | 06 Hrs |
| 8 | **New trends for Personalized Medicine: I**ntroduction, Definition, Pharmacogenetics, Categories of Patients for Personalized Medicines: Customized drug delivery systems, Bioelectronic Medicines, 3D printing of pharmaceuticals, Telepharmacy. | 06 Hrs |

***REFERENCES***


1. Novel Drug Delivery System, Y.W. Chein, Vol 50, Marcel Dekker, NY.
2. Controlled Drug Delivery Systems, Robinson, Vol 29, Marcel Dekker, NY.
3. Transdermal Controlled Systemic Medications, YW Chein, Vol 31, Marcel Dekker, NY.
4. Bioadhesive DDS, E. Mathiowitz, Vol 98, Marcel Dekker, NY.
5. Nasal System Drug Delivery, K.S.E. Su, Vol 39, Marcel Dekker, NY.
6. Drug Delivery Devices, Vol 32, P Tyle Marcel Dekker, NY.
7. Polymers for Controlled Drug Delivery, P.J. Tarcha, CRC Press.
8. Pharmaceutical Biotechnology, Vyas, CBS, Delhi.
9. Biotechnology of Industrial Antibiotics, E.J. Vandamme, Marcel Dekker, NY.
10. Protein Formulation & Delivery, E.J. McNally, Vol 99, Marcel Dekker, NY.
11. Drug Targeting, M.H. Rubinstein, John Wiley, NY.

## INTELLECTUAL PROPERTY RIGHTS
## (MIP 104T)

***Scope***

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

***Objectives***

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

- Assist in Regulatory Audit process.
- Establish regulatory guidelines for drug and drug products
- The Regulatory requirements for contract research organization

***THEORY*** ***60 Hrs***

| | | |
|---|---|---|
| 1. | Definition, Need for patenting, Types of Patents, Conditions to be satisfied by an invention to be patentable, Introduction to patent search. Parts of patents. Filling of patents. The essential elements of patent; Guidelines for preparation of laboratory note book, Non-obviousness in Patent. | 12 Hrs |
| 2 | Role of GATT, TRIPS, and WIPO | 12 Hrs |
| 3 | Brief introduction to Trademark protection and WHO Patents. IPR's and its types, Major bodies regulating Indian Pharmaceutical sector. | 12 Hrs |
| 4 | Brief introduction to CDSCO. WHO, USFDA, EMEA, TGA, MHRA, MCC, ANVISA | 12 Hrs |
| 5 | Regulatory requirements for contract research organization. Regulations for Biosimilars. | 12 Hrs |

***REFERENCES :***


1. Pharmaceutical Process Validation: By Fra R. Berry and Robert A. Nash, Vol 57, 2nd Edition
2. Applied Production and Operation Management By Evans, Anderson and Williams
3. GMP for pharmaceuticals Material Management by K.K. Ahuja Published by CBS publishers
4. ISO 9000-Norms and explanations
5. GMP for pharmaceuticals- Willing S.H. Marcel and Dekker

## INDUSTRIAL PHARMACY PRACTICAL - I
## (MIP 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 / GC
4. Estimation of riboflavin/quinine sulphate by fluorimetry
5. Estimation of sodium/potassium by flame photometry
6. Effect of surfactants on the solubility of drugs.
7. Effect of pH on the solubility of drugs.
8. Stability testing of solution and solid dosage forms for photo degradation..
9. Stability studies of drugs in dosage forms at 25 $^{o}$C, 60% RH and 40 $^{o}$C, 75% RH.
10. Compatibility evaluation of drugs and excipients (DSC & FTIR).
11. Preparation and evaluation of different polymeric membranes.
12. Formulation and evaluation of sustained release oral matrix tablet/ oral reservoir system.
13. Formulation and evaluation of microspheres / microcapsules.
14. Formulation and evaluation of transdermal drug delivery systems.
15. Design and evaluation of face wash, body- wash, creams, lotions, shampoo, toothpaste, lipstick.
16. Electrophoresis of protein solution.
17. Preparation and evaluation of Liposome delivery system.

## ADVANCED BIOPHARMACEUTICS & PHARMACOKINETICS (MIP 201T)

***Scope***

This course is designed to impart knowledge and skills necessary for dose calculations, dose adjustments and to apply Biopharmaceutics theories in practical problem solving.

***Objectives***

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

- The basic concepts in Biopharmaceutics and pharmacokinetics.
- The use of raw data and derive the pharmacokinetic models and parameters the best describe the process of drug absorption, distribution, metabolism and elimination.
- To critically evaluate Biopharmaceutics studies involving drug product equivalency.
- To design and evaluate dosage regimens of the drugs using pharmacokinetic and biopharmaceutic parameters.

***THEORY*** ***60 Hrs***

1. **Drug Absorption From The Gastrointestinal Tract**: Gastrointestinal tract, Mechanism of drug absorption, Factors affecting, pH–partition theory, Formulation and physicochemical factors: Dissolution rate, Dissolution process, Noyes–Whitney equation and drug dissolution, Factors affecting the dissolution rate. Gastrointestinal absorption: role of the dosage form: Solution (elixir, syrup and solution) as a dosage form ,Suspension as a dosage form, Capsule as a dosage form, Tablet as a dosage form ,Dissolution methods ,Formulation and processing factors, Correlation of in vivo data with in vitro dissolution data. Transport model: Permeability-Solubility-Charge State and the pH Partition Hypothesis, Properties of the Gastrointestinal Tract (GIT), pH Microclimate Intracellular pH Environment, Tight-Junction Complex. Solubility: Experimental methods. Permeability: In-vitro, in-situ and In-vivo methods. — 12 Hrs

2 **Biopharmaceutic Considerations in Drug Product Design and In Vitro Drug Product Performance**: Introduction, Biopharmaceutic Factors Affecting Drug Bioavailability, Rate-Limiting Steps in Drug Absorption, Physicochemical Nature of the — 12 Hrs

| | | |
|---|---|---|
| | Drug Formulation Factors Affecting Drug Product Performance, *In Vitro*: Dissolution and Drug Release Testing, Compendial Methods of Dissolution, Alternative Methods of Dissolution Testing, Meeting Dissolution Requirements, Problems of Variable Control in Dissolution Testing Performance of Drug Products: *In Vitro–In Vivo* Correlation, Dissolution Profile Comparisons, Drug Product Stability, Considerations 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 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 Hrs |
| 4 | **Drug Product Performance, In Vivo: Bioavailability and Bioequivalence**: Drug Product Performance, Purpose of Bioavailability Studies, Relative and Absolute Availability, , Methods for Assessing Bioavailability, Bioequivalence Studies, Design and Evaluation of Bioequivalence Studies, Study Designs, Crossover Study Designs, Evaluation of the Data, Bioequivalence Example, Study Submission and Drug Review Process, The Biopharmaceutics Classification System, Generic Biologics (Biosimilar Drug Products),Clinical Significance of Bioequivalence Studies, Special Concerns in Bioavailability and Bioequivalence Studies, Generic Substitution. | 12 Hrs |
| 5 | **Application of Pharmacokinetics:** Modified-Release Drug Products, Targeted Drug Delivery Systems and Biotechnological Products. Relationship between Pharmacokinetics including Pharmacodynamics: Generation of a pharmacokinetic–pharmacodynamic (PKPD) equation, Pharmacokinetic and pharmacodynamic, interactions. Pharmacokinetics and pharmacodynamics of biotechnology drugs: Introduction, Proteins and peptides, Monoclonal antibodies, Oligonucleotides, Vaccines (immunotherapy),Gene therapies. | 12 Hrs |

***REFERENCES***


1. Biopharmaceutics and Clinical Pharmacokinetics by Milo Gibaldi, 4th edition,Philadelphia, Lea and Febiger, 1991
2. Biopharmaceutics and Pharmacokinetics, A. Treatise, D .M. Brahmankar and Sunil B.J aiswal., Vallab Prakashan, Pitampura, Delhi
3. Applied Biopharmaceutics and Pharmacokinetics by Shargel. Land YuABC, 2nd edition, Connecticut Appleton Century Crofts, 1985
4. Textbook of Biopharmaceutics and Pharmacokinetics, Dr. Shobha Rani R. Hiremath,Prism Book
5. Pharmacokinetics by Milo Gibaldi and D. Perrier, 2nd edition, Marcel Dekker Inc.,New York, 1982
6. Current Concepts in Pharmaceutical Sciences: Biopharmaceutics, Swarbrick. J, Lea and Febiger, Philadelphia, 1970
7. Clinical Pharmacokinetics, Concepts and Applications 3rd edition by Malcolm Rowland and Thom~ N. Tozer, Lea and Febiger, Philadelphia, 1995
8. Dissolution, Bioavailability and Bioequivalence, Abdou. H.M, Mack Publishing Company, Pennsylvania 1989
9. Biopharmaceutics and Clinical Pharmacokinetics, An Introduction, 4th edition, revised and expande by Robert. E. Notari, Marcel Dekker Inc, New York and Basel,1987.
10. Biopharmaceutics and Relevant Pharmacokinetics by John. G Wagner and M.Pemarowski, 1st edition, Drug Intelligence Publications, Hamilton, Illinois, 1971.
11. Encyclopedia of Pharmaceutical Technology, Vol 13, James Swarbrick, James. G.Boylan, Marcel Dekker Inc, New York, 1996.
12. Basic Pharmacokinetics,1 st edition, Sunil S Jambhekar and Philip J Breen,pharmaceutical press, RPS Publishing,2009.
13. Absorption and Drug Development- Solubility, Permeability, and Charge State, Alex Avdeef, John Wiley & Sons, Inc,2003.

## SCALE UP AND TECHNOLOGY TRANSFER
## (MIP 202T)

***Scope***

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

***Objectives:***

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

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

***THEORY*** ***60 Hrs***

| | | |
|---|---|---|
| 1. | **Pilot plant design:** Basic requirements for design, facility, equipment selection, for tablets, capsules, liquid orals, parentral and semisolid preparations.<br><br>**Scale up:** Importance, Technology transfer from R & D to pilot plant to plant scale, process scale up for tablets, capsules, liquid orals, semisolids, parentral, NDDS products – stress on formula, equipments, product uniformity, stability, raw materials, physical layout, input, in-process and finished product specifications, problems encountered during transfer of technology | 12 Hrs |
| 2 | **Validation:** General concepts, types, procedures & protocols, documentation, VMF. Analytical method validation, cleaning validation and vender qualification. | 12 Hrs |
| 3 | **Equipment Qualification:** Importance, IQ, OQ, PQ for equipments – autoclave, DHS, membrane filter, rapid mixer granulator, cone blender, FBD, tablet compression machine, liquid filling and sealing machine. Aseptic room validation. | 12 Hrs |
| 4 | **Process validation:** Importance, validation of mixing, granulation, drying, compression, tablet coating, liquid filling and sealing, sterilization, water process systems, environmental control. | 12 Hrs |

| | | |
|---|---|---|
| 5 | **Industrial safety:** Hazards – fire, mechanical, electrical, chemical and pharmaceutical, Monitoring & prevention systems, industrial effluent testing & treatment. Control of environmental pollution. | 12 Hrs |

***REFERENCES***


1. Pharmaceutical process validation, JR Berry, Nash, Vol 57, Marcel Dekker, NY.
2. Pharmaceutical Production facilities, design and applications, by GC Cole, Taylor and Francis.
3. Pharmaceutical project management, T.Kennedy, Vol 86, Marcel Dekker, NY.
4. The theory & Practice of Industrial Pharmacy, L.Lachman, H.A.Lieberman, Varghese Publ. Bombay.
5. Tablet machine instruments in pharmaceuticals, PR Watt, John Wiloy.
6. Pharmaceutical dosage forms, Tablets, Vol 1, 2, 3 by Lachman, Lieberman, Marcel Dekker, NY.
7. Pharmaceutical dosage forms, Parentral medications, Vol 1, 2 by K.E. Avis, Marcel Dekker, NY.
8. Dispersed system Vol 1, 2, 3 by Lachman, Lieberman, Marcel Dekker, NY.
9. Subrahmanyam, CVS, Pharmaceutical production and Management, 2007, Vallabh Prakashan,Dehli.

## PHARMACEUTICAL PRODUCTION TECHNOLOGY
## (MIP 203T)

***Scope***

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

***Objectives***

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

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

***THEORY*** ***60 Hrs***

| | | |
|---|---|---|
| 1. | **Improved Tablet Production:** Tablet production process, unit operation improvements, 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.<br><br>**Coating Technology:** Process, equipments, particle coating, fluidized bed coating, application techniques. Problems encountered. | 12 Hrs |
| 2 | **Parenteral Production:** Area planning & environmental control, wall and floor treatment, fixtures and machineries, change rooms, personnel flow, utilities & utilities equipment location, engineering and maintenance. | 12 Hrs |
| 3 | **Lyophilization & Spray drying Technology:** Principles, process, freeze-drying and spray drying equipments. | 12 Hrs |
| 4 | **Capsule Production:** Production process, improved capsule manufacturing and filling machines for hard and soft gelatin capsules. Layout and problems encountered.<br>**Disperse Systems Production:** Production processes, applications of mixers, mills, disperse equipments including fine solids dispersion, problems encountered. | 12 Hrs |

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

| | | |
|---|---|---|
| 5 | **Air Handling Systems:** Study of AHUs, humidity & temperature control, air filtration systems, dust collectors. **Water Treatment Process:** Techniques and maintenance – RO, DM, ultra – filtration, WFI. | 12 Hrs |

***REFERENCES***


1. The Theory & Practice of Industrial Pharmacy, L. Lachman, Varghese Publ, Bombay.
2. Modern Pharmaceutics by Banker, Vol 72, Marcel Dekker, NY.
3. Pharmaceutical Dosage Forms, Vol 1, 2, 3 by Lachman, Lieberman, Marcel Dekker, NY.
4. Pharmaceutical Dosage Forms, Parentral medications, Vol 1, 2 by K.E. Avis, Marcel Dekker, NY.
5. Pharmaceutical Production Facilities, design and applications, by G.C. Cole, Taylor and Francis.
6. Dispersed System Vol 1, 2, 3 by Lachman, Lieberman, Marcel Dekker, NY.
7. Product design and testing of polymeric materials by N.P. Chezerisionoff.
8. Pharmaceutical Project Management, T.Kennedy, Vol 86, Marcel Dekker, NY.
9. Packaging Pharmaceutical and Health Care, H.Lockhard.
10. Quality Control of Packaging Materials in Pharmaceutical Industy, .Kharburn, Marcel Dekker, NY.
11. Freeze drying / Lyophilization of Pharmaceuticals & Biological Products, L. Ray, Vol 96, Marcel Dekker, NY.
12. Tablet Machine Instrumentation In Pharmaceuticals, PR Watt, Ellis Horwoods, UK.

## ENTREPRENEURSHIP MANAGEMENT
## (MIP 204T)

***Scope***

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

***Objectives:***

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

- The Role of enterprise in national and global economy
- Dynamics of motivation and concepts of entrepreneurship
- Demands and challenges of Growth Strategies And Networking

***THEORY*** ***60 Hrs***

| | | |
|---|---|---|
| 1. | **Conceptual Frame Work:** Concept need and process in entrepreneurship development. Role of enterprise in national and global economy. Types of enterprise – Merits and Demerits. Government policies and schemes for enterprise development. Institutional support in enterprise development and management. | 12 Hrs |
| 2 | **Entrepreneur:** Entrepreneurial motivation – dynamics of motivation. Entrepreneurial competency –Concepts. Developing Entrepreneurial competencies - requirements and understanding the process of entrepreneurship development, self-awareness, interpersonal skills, creativity, assertiveness, achievement, factors affecting entrepreneur role. | 12 Hrs |
| 3 | **Launching And Organising An Enterprise:** Environment scanning – Information, sources, schemes of assistance, problems. Enterprise selection, market assessment, enterprise feasibility study, SWOT Analysis. Resource mobilisation - finance, technology, raw material, site and manpower. Costing and marketing management and quality control. Feedback, monitoring and evaluation. | 12 Hrs |
| 4 | **Growth Strategies And Networking:** Performance appraisal and assessment. Profitability and control measures, demands and challenges. Need for diversification. Future Growth – Techniques of expansion and diversification, vision strategies. Concept and dynamics. Methods, Joint venture, co-ordination and feasibility study. | 12 Hrs |

| | | |
|---|---|---|
| 5 | **Preparing Project Proposal To Start On New Enterprise**<br>Project work – Feasibility report; Planning, resource mobilisation and implementation. | 12 Hrs |

***REFERENCES***


1. Akhauri, M.M.P.(1990): Entrepreneurship for Women in India, NIESBUD, New Delhi.
2. Hisrich, R.D & Brush, C.G.(1996) The Women Entrepreneurs, D.C. Health & Co., Toranto.
3. Hisrich, R.D. and Peters, M.P. (1995): Entrepreneurship – Starting, Developing and Managing a New Enterprise, Richard D., Inwin, INC, USA.
4. Meredith, G.G. etal (1982): Practice of Entrepreneurship, ILO, Geneva.
5. Patel, V.C. (1987): Women Entrepreneurship – Developing New Entrepreneurs, Ahmedabad EDII.

## INDUSTRIAL PHARMACY PRACTICAL - II
## (MIP 205P)

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

## 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

| ***THEORY*** | | ***60 Hrs*** |
|---|---|---|
| 1. | a. **UV-Visible spectroscopy**: Introduction, Theory, Laws, Instrumentation associated with UV-Visible spectroscopy, Choice of solvents and solvent effect and Applications of UV-Visible spectroscopy, Difference/ Derivative spectroscopy.<br>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.<br>c. **Spectroflourimetry:** Theory of Fluorescence, Factors affecting fluorescence (Characterestics of drugs that can be analysed by flourimetry), Quenchers, Instrumentation and Applications of fluorescence spectrophotometer.<br>d. **Flame emission spectroscopy and Atomic absorption spectroscopy**: Principle, Instrumentation, Interferences and Applications. | 10 Hrs |
| 2 | **NMR spectroscopy**: Quantum numbers and their role in NMR, Principle, Instrumentation, Solvent requirement in NMR, Relaxation process, NMR signals in various compounds, Chemical shift, Factors influencing chemical shift, Spin-Spin coupling, Coupling constant, Nuclear magnetic double resonance, Brief outline of principles of FT-NMR and 13C NMR. Applications of NMR spectroscopy. | 10 Hrs |

| | | |
|---|---|---|
| 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 Hrs |
| 4 | **Chromatography**: Principle, apparatus, instrumentation, chromatographic parameters, factors affecting resolution, isolation of drug from excipients, data interpretation and applications of the following:<br>a) Thin Layer chromatography<br>b) High Performance Thin Layer Chromatography<br>c) Ion exchange chromatography<br>d) Column chromatography<br>e) Gas chromatography<br>f) High Performance Liquid chromatography<br>g) Ultra High Performance Liquid chromatography<br>h) Affinity chromatography<br>i) Gel Chromatography | 10 Hrs |
| 5 | a. **Electrophoresis**: Principle, Instrumentation, Working conditions, factors affecting separation and applications of the following:<br>a) Paper electrophoresis b) Gel electrophoresis c) Capillary electrophoresis d) Zone electrophoresis e) Moving boundary electrophoresis f) Iso electric focusing<br>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 Hrs |
| 6 | a. **Potentiometry:** Principle, working, Ion selective Electrodes and Application of potentiometry.<br><br>**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 | 10 Hrs |

and advantage and disadvantages, pharmaceutical applications, derivative differential thermal analysis (DDTA). TGA: Principle, instrumentation, factors affecting results, advantage and disadvantages, pharmaceutical applications.

***REFERENCES***


1. Spectrometric Identification of Organic compounds - Robert M Silverstein, Sixth edition, John Wiley & Sons, 2004.
2. Principles of Instrumental Analysis - Doglas A Skoog, F. James Holler, Timothy A. Nieman, 5th edition, Eastern press, Bangalore, 1998.
3. Instrumental methods of analysis – Willards, 7th edition, CBS publishers.
4. Practical Pharmaceutical Chemistry – Beckett and Stenlake, Vol II, 4th edition, CBS Publishers, New Delhi, 1997.
5. Organic Spectroscopy - William Kemp, 3rd edition, ELBS, 1991.
6. Quantitative Analysis of Drugs in Pharmaceutical formulation - P D Sethi, 3rd Edition, CBS Publishers, New Delhi, 1997.
7. Pharmaceutical Analysis - Modern Methods – Part B - J W Munson, Vol 11, Marcel. Dekker Series
8. Spectroscopy of Organic Compounds, 2nd edn., P.S/Kalsi, Wiley estern Ltd., Delhi.
9. Textbook of Pharmaceutical Analysis, KA.Connors, 3rd Edition, John Wiley & Sons, 1982.

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

***THEORY*** ***60 Hrs***

1. **Basic Aspects of Organic Chemistry:** 12 Hrs
    1. Organic intermediates: Carbocations, carbanions, free radicals, carbenes and nitrenes. Their method of formation, stability and synthetic applications.
    2. Types of reaction mechanisms and methods of determining them,
    3. Detailed knowledge regarding the reactions, mechanisms and their relative reactivity and orientations.

    **Addition reactions**

    a) Nucleophilic uni- and bimolecular reactions (SN1 and SN2)
    b) Elimination reactions (E1 & E2; Hoffman & Saytzeff's rule)
    c) Rearrangement reaction

2 **Study of mechanism and synthetic applications of following named Reactions:** 12 Hrs

Ugi reaction, Brook rearrangement, Ullmann coupling reactions, Dieckmann Reaction, Doebner-Miller Reaction, Sandmeyer Reaction, Mitsunobu reaction, Mannich reaction, Vilsmeyer-Haack Reaction, Sharpless asymmetric epoxidation, Baeyer-Villiger oxidation, Shapiro & Suzuki reaction, Ozonolysis and Michael addition reaction

3 **Synthetic Reagents & Applications**: 12 Hrs

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

**Protecting groups**

a. Role of protection in organic synthesis
b. Protection for the hydroxyl group, including 1,2-and1,3-diols: ethers, esters, carbonates, cyclic acetals & ketals
c. Protection for the Carbonyl Group: Acetals and Ketals
d. Protection for the Carboxyl Group: amides and hydrazides, esters
e. Protection for the Amino Group and Amino acids: carbamates and amides

4 **Heterocyclic Chemistry:** 12 Hrs

Organic Name reactions with their respective mechanism and application involved in synthesis of drugs containing five, six membered and fused hetrocyclics 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 hetrocyclic nucleus such as Ketoconazole, Metronidazole, Miconazole, celecoxib, antipyrin, Metamizole sodium, Terconazole, Alprazolam, Triamterene, Sulfamerazine, Trimethoprim, Hydroxychloroquine, Quinine, Chloroquine, Quinacrine, Amsacrine, Prochlorpherazine, Promazine, Chlorpromazine,Theophylline , Mercaptopurine and Thioguanine.

5 **Synthon approach and retrosynthesis applications** 12 Hrs

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

***REFERENCES***


1. "Advanced Organic chemistry, Reaction, Mechanisms and Structure", J March, John Wiley and Sons, New York.
2. "Mechanism and Structure in Organic Chemistry", ES Gould, Hold Rinchart and Winston, New York.
3. "Organic Chemistry" Clayden, Greeves, Warren and Woihers., Oxford University Press 2001.
4. "Organic Chemistry" Vol I and II. I.L. Finar. ELBS, Pearson Education Lts, Dorling Kindersley 9India) Pvt. Ltd.,.
5. A guide to mechanisms in Organic Chemistry, Peter Skyes (Orient Longman, New Delhi).
6. Reactive Intermediates in Organic Chemistry, Tandom and Gowel, Oxford & IBH Publishers.
7. Combinational Chemistry – Synthesis and applications – Stephen R Wilson & Anthony W Czarnik, Wiley – Blackwell.
8. Carey, Organic Chemistry, 5$^{th}$ Edition (Viva Books Pvt. Ltd.)
9. Organic Synthesis - The Disconnection Approach, S. Warren, Wily India
10. Principles of Organic Synthesis, ROC Norman and JM Coxan, Nelson Thorns.
11. Organic Synthesis - Special Techniques. VK Ahluwalia and R Agarwal, Narosa Publishers.
12. Organic Reaction Mechanisms IV$^{th}$ Edtn, VK Ahluwalia and RK Parashar, Narosa Publishers.

## ADVANCED MEDICINAL CHEMISTRY
## (MPC 103T)

***Scope***

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

***Objectives***

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

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

***THEORY*** ***60 Hrs***

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

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

2 **Prodrug Design and Analog design:** 12 Hrs

   a) **Prodrug design**: Basic concept, Carrier linked prodrugs/ Bioprecursors, Prodrugs of functional group, Prodrugs to improve patient acceptability, Drug solubility, Drug absorption and distribution, site specific drug delivery and sustained drug action. Rationale of prodrug design and practical consideration of prodrug design.

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

   c) **Analog Design:** Introduction, Classical & Non classical, Bioisosteric replacement strategies, rigid analogs,

alteration of chain branching, changes in ring size, ring position isomers, design of stereo isomers and geometric isomers, fragments of a lead molecule, variation in inter atomic distance.

3 a) Medicinal chemistry aspects of the following class of drugs 12 Hrs

Systematic study, SAR, Mechanism of action and synthesis of new generation molecules of following class of drugs:

a) Anti-hypertensive drugs, Psychoactive drugs, Anticonvulsant drugs, H1 & H2 receptor antagonist, COX1 & COX2 inhibitors, Adrenergic & Cholinergic agents, Antineoplastic and Antiviral agents.

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

4 **Rational Design of Enzyme Inhibitors** 12 Hrs

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

5 **Peptidomimetics** 12 Hrs

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

***REFERENCES***


1. Medicinal Chemistry by Burger, Vol I –VI.
2. Wilson and Gisvold's Text book of Organic Medicinal and Pharmaceutical Chemistry, 12th Edition, Lppincott Williams & Wilkins, Woltess Kluwer (India) Pvt.Ltd, New Delhi.
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.
6. Principles of Medicinal Chemistry by William Foye, 7th Edition, Ippincott Williams & Wilkins, Woltess Kluwer (India) Pvt.Ltd, New Delhi.
7. Drug Design Volumes by Arienes, Academic Press, Elsevier Publishers, Noida, Uttar Pradesh..
8. Principles of Drug Design by Smith.
9. The Organic Chemistry of the Drug Design and Drug action by Richard B.Silverman, II Edition, Elsevier Publishers, New Delhi.
10. An Introduction to Medicinal Chemistry, Graham L.Patrick, III Edition, Oxford University Press, USA.
11. Biopharmaceutics and pharmacokinetics, DM.Brahmankar, Sunil B. Jaiswal II Edition, 2014, Vallabh Prakashan, New Delhi.
12. Peptidomimetics in Organic and Medicinal Chemistry by Antonio Guarna and Andrea Trabocchi, First edition, Wiley publishers.

## CHEMISTRY OF NATURAL PRODUCTS
## (MPC 104T)

***Scope***

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

***Objectives***

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

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

***THEORY*** ***60 Hrs***

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

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

**b) Flavonoids**

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

**c) Steroids**

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

3 **a) Terpenoids** 12 Hrs

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

**b) Vitamins**

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

4 **a). Recombinant DNA technology and drug discovery** 12 Hrs

rDNA technology, hybridoma technology, New pharmaceuticals derived from biotechnology; Oligonucleotide therapy. Gene therapy: Introduction, Clinical application and recent advances in gene therapy, principles of RNA & DNA estimation

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

5 **Structural Characterization of natural compounds** 12 Hrs

Structural characterization of natural compounds using IR, 1HNMR, 13CNMR and MS Spectroscopy of specific drugs e.g., Penicillin, Morphine, Camphor, Vit-D, Quercetin and Digitalis glycosides.

***REFERENCES***


1. Modern Methods of Plant Analysis, Peech and M.V.Tracey, Springer – Verlag, Berlin, Heidelberg.
2. Phytochemistry Vol. I and II by Miller, Jan Nostrant Rein Hld.
3. Recent advances in Phytochemistry Vol. I to IV – Scikel Runeckles, Springer Science & Business Media.
4. Chemistry of natural products Vol I onwards IWPAC.
5. Natural Product Chemistry Nakanishi Gggolo, University Science Books, California.
6. Natural Product Chemistry "A laboratory guide" – Rapheal Khan.
7. The Alkaloid Chemistry and Physiology by RHF Manske, Academic Press.
8. Introduction to molecular Phytochemistry – CHJ Wells, Chapmannstall.
9. Organic Chemistry of Natural Products Vol I and II by Gurdeep and Chatwall, Himalaya Publishing House.
10. Organic Chemistry of Natural Products Vol I and II by O.P. Agarwal, Krishan Prakashan.
11. Organic Chemistry Vol I and II by I.L. Finar, Pearson education.
12. Elements of Biotechnology by P.K. Gupta, Rastogi Publishers.
13. Pharmaceutical Biotechnology by S.P.Vyas and V.K.Dixit, CBS Publishers.
14. Biotechnology by Purohit and Mathur, Agro-Bios, 13$^{th}$ edition.
15. Phytochemical methods of Harborne, Springer, Netherlands.
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. Benzyllic acid rearrangement.
4. Beckmann rearrangement.
5. Hoffmann rearrangement
6. Mannich reaction
7. Synthesis of medicinally important compounds involving more than one step along with purification and Characterization using TLC, melting point and IR spectroscopy (4 experiments)
8. Estimation of elements and functional groups in organic natural compounds
9. Isolation, characterization like melting point, mixed melting point, molecular weight determination, functional group analysis, co-chromatographic technique for identification of isolated compounds and interpretation of UV and IR data.
10. Some typical degradation reactions to be carried on selected plant constituents

## ADVANCED SPECTRAL ANALYSIS
## (MPC 201T)

***Scope***

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

***Objectives***

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

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

***THEORY*** ***60Hrs***

1. **UV and IR spectroscopy:** 12 Hrs

   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.

2 **NMR spectroscopy:** 12 Hrs

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

3 **Mass Spectroscopy** 12 Hrs

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

4 **Chromatography:** 12 Hrs

   Principle, Instrumentation and Applications of the following :
   a) GC-MS b) GC-AAS c) LC-MS d) LC-FTIR e) LC-NMR f) CE-MS g) High Performance Thin Layer chromatography h) Super critical fluid chromatography i) Ion Chromatography j) I-EC (Ion-Exclusion Chromatography) k) Flash chromatography

5 **a). Thermal methods of analysis** 12 Hrs

Introduction, principle, instrumentation and application of DSC, DTA and TGA.

**b). Raman Spectroscopy**

Introduction, Principle, Instrumentation and Applications.

**c). Radio immuno assay**

Biological standardization , bioassay, ELISA, Radioimmuno assay of digitalis and insulin.

***REFERENCES***


1. Spectrometric Identification of Organic compounds - Robert M Silverstein, Sixth edition, John Wiley & Sons, 2004.
2. Principles of Instrumental Analysis - Doglas A Skoog, F. James Holler, Timothy A. Nieman, 5th edition, Eastern press, Bangalore, 1998.
3. Instrumental methods of analysis – Willards, 7th edition, CBS publishers.
4. Organic Spectroscopy - William Kemp, 3rd edition, ELBS, 1991.
5. Quantitative analysis of Pharmaceutical formulations by HPTLC - P D Sethi, CBS Publishers, New Delhi.
6. Quantitative Analysis of Drugs in Pharmaceutical formulation - P D Sethi, 3rd Edition, CBS Publishers, New Delhi, 1997.
7. Pharmaceutical Analysis- Modern methods – Part B - J W Munson, Volume 11, Marcel Dekker Series

## ADVANCED ORGANIC CHEMISTRY - II
## (MPC 202T)

***Scope***

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

***Objectives***

Upon completion of course, the student shall able to understand

- The principles and applications of Green chemistry
- The concept of peptide chemistry.
- The various catalysts used in organic reactions
- The concept of stereochemistry and asymmetric synthesis.

***THEORY*** ***60 Hrs***

1. **Green Chemistry:** 12 Hrs
   a. Introduction, principles of green chemistry
   b. Microwave assisted reactions: Merit and demerits of its use, increased reaction rates, mechanism, superheating effects of microwave, effects of solvents in microwave assisted synthesis, microwave technology in process optimization, its applications in various organic reactions and heterocycles synthesis
   c. Ultrasound assisted reactions: Types of sonochemical reactions, homogenous, heterogeneous liquid-liquid and liquid-solid reactions, synthetic applications
   d. Continuous flow reactors: Working principle, advantages and synthetic applications.
2. **Chemistry of peptides** 12 Hrs
   a. Coupling reactions in peptide synthesis
   b. Principles of solid phase peptide synthesis, t-BOC and FMOC protocols, various solid supports and linkers: Activation procedures, peptide bond formation, deprotection and cleavage from resin, low and high HF cleavage protocols, formation of free peptides and peptide amides, purification and case studies, site-specific chemical modifications of peptides
   c. Segment and sequential strategies for solution phase peptide synthesis with any two case studies
   d. Side reactions in peptide synthesis: Deletion peptides, side

reactions initiated by proton abstraction, protonation, over-activation and side reactions of individual amino acids.

3 **Photochemical Reactions** 12 Hrs

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

**Pericyclic reactions**

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

4 **Catalysis:** 12 Hrs

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

5 **Stereochemistry & Asymmetric Synthesis** 12 Hrs

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

***REFERENCES***


1. “Advanced Organic chemistry, Reaction, mechanisms and structure”, J March, John Wiley and sons, New York.
2. “Mechanism and structure in organic chemistry”, ES Gould, Hold Rinchart and Winston,NewYork.
3. “Organic Chemistry” Clayden, Greeves, Warren and Woihers., Oxford University Press 2001.
4. “Organic Chemistry” Vol I and II. I.L. Finar. ELBS, Sixth ed., 1995.
5. Carey, Organic chemistry, 5th edition (Viva Books Pvt. Ltd.)
6. Organic synthesis-the disconnection approach, S. Warren, Wily India
7. Principles of organic synthesis, ROCNorman and JMCoxan, Nelson thorns
8. Organic synthesis- Special techniques VK Ahluwalia and R Aggarwal, Narosa Publishers.
9. Organic reaction mechanisms IV edtn, VK Ahluwalia and RK Parashar, Narosa Publishers.

## COMPUTER AIDED DRUG DESIGN
## (MPC 203T)

***Scope***

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

***Objectives***

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

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

***Theory*** ***60 Hrs***

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

   History, different techniques and applications.

   **Quantitative Structure Activity Relationships: Basics**

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

2 **Quantitative Structure Activity Relationships: Applications** 12 Hrs

   Hansch analysis, Free Wilson analysis and relationship between them, Advantages and disadvantages; Deriving 2D-QSAR equations.

   3D-QSAR approaches and contour map analysis.

   Statistical methods used in QSAR analysis and importance of statistical parameters.

3 **Molecular Modeling and Docking** 12 Hrs

   a) Molecular and Quantum Mechanics in drug design.
   b) Energy Minimization Methods: comparison between global

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)

4 **Molecular Properties and Drug Design** 12 Hrs

a) Prediction and analysis of ADMET properties of new molecules and its importance in drug design.
b) *De novo* drug design: Receptor/enzyme-interaction and its analysis, Receptor/enzyme cavity size prediction, predicting the functional components of cavities, Fragment based drug design.
c) Homology modeling and generation of 3D-structure of protein.

5 **Pharmacophore Mapping and Virtual Screening** 12 Hrs

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

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

***REFERENCES***


1. Computational and structural approaches to drug discovery, Robert M Stroud and Janet. F Moore, RCS Publishers.
2. Introduction to Quantitative Drug Design by Y.C. Martin, CRC Press, Taylor & Francis group..
3. Drug Design by Ariens Volume 1 to 10, Academic Press, 1975, Elsevier Publishers.
4. Principles of Drug Design by Smith and Williams, CRC Press, Taylor & Francis.
5. The Organic Chemistry of the Drug Design and Drug action by Richard B. Silverman, Elsevier Publishers.
6. Medicinal Chemistry by Burger, Wiley Publishing Co.

7. An Introduction to Medicinal Chemistry –Graham L. Patrick, Oxford University Press.
8. Wilson and Gisvold's Text book of Organic Medicinal and Pharmaceutical Chemistry, Ippincott Williams & Wilkins.
9. Comprehensive Medicinal Chemistry – Corwin and Hansch, Pergamon Publishers.
10. Computational and structural approaches to drug design edited by Robert M Stroud and Janet. F Moore

## PHARMACEUTICAL PROCESS CHEMISTRY
## (MPC 204T)

***Scope***

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

***Objectives***

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

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

**THEORY** **60 Hrs**

1. **Process chemistry** 12 Hrs

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

2 **Unit operations** 12 Hrs

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

3 **Unit Processes - I** 12 Hrs

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

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

c) **Oxidation**: Introduction, types of oxidative reactions, Liquid phase oxidation with oxidizing agents. Nonmetallic Oxidizing agents such as $H_2O_2$, sodium hypochlorite, Oxygen gas, ozonolysis.

4 **Unit Processes - II** 12 Hrs

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

b) **Fermentation**: Aerobic and anaerobic fermentation. Production of

i. Antibiotics; Penicillin and Streptomycin,
ii. Vitamins: B2 and B12
iii. Statins: Lovastatin, Simvastatin

c) **Reaction progress kinetic analysis**

i. Streamlining reaction steps, route selection,
ii. Characteristics of expedient routes, characteristics of cost-effective routes, reagent selection, families of reagents useful for scale-up.

5 **Industrial Safety** 12 Hrs

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

b) Fire hazards, types of fire & fire extinguishers

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

***REFERENCES***


1. Process Chemistry in the Pharmaceutical Industry: Challenges in an Ever-Changing Climate-An Overview; K. Gadamasetti, CRC Press.
2. Pharmaceutical Manufacturing Encyclopedia, 3rd edition, Volume 2.
3. Medicinal Chemistry by Burger, 6th edition, Volume 1-8.
4. W.L. McCabe, J.C Smith, Peter Harriott. Unit operations of chemical engineering, 7th edition, McGraw Hill
5. Polymorphism in Pharmaceutical Solids .Dekker Series Volume 95 Ed: H G Brittain (1999)
6. Regina M. Murphy: Introduction to Chemical Processes: Principles, Analysis, Synthesis
7. Peter J. Harrington: Pharmaceutical Process Chemistry for Synthesis: Rethinking the Routes to Scale-Up
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
11. Clausen,Mattson: Principle of Industrial Chemistry, Wiley Publishing Co.,
12. Lowenheim & M.K. Moran: Industrial Chemicals
13. S.D. Shukla & G.N. Pandey: A text book of Chemical Technology Vol. II, Vikas Publishing House
14. J.K. Stille: Industrial Organic Chemistry (PH)
15. Shreve: Chemical Process, Mc Grawhill.
16. B.K.Sharma: Industrial Chemistry, Goel Publishing House
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
11. Preparation of 4-chlorobenzhydrylpiperazine. (an intermediate for cetirizine HCl).
12. Preparation of 4-iodotolene from p-toluidine.
13. $NaBH_4$ 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

## PHARMACEUTICAL ANALYSIS (MPA)

### MODERN PHARMACEUTICAL ANALYTICAL TECHNIQUES (MPA 101T)

***Scope***

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

***Objectives***

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

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

***THEORY*** ***60 Hrs***

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| 1. | a. **UV-Visible spectroscopy**: Introduction, Theory, Laws, Instrumentation associated with UV-Visible spectroscopy, Choice of solvents and solvent effect and Applications of UV-Visible spectroscopy, Difference/ Derivative spectroscopy.<br>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.<br>c. **Spectroflourimetry:** Theory of Fluorescence, Factors affecting fluorescence (Characterestics of drugs that can be analysed by flourimetry), Quenchers, Instrumentation and Applications of fluorescence spectrophotometer.<br>d. **Flame emission spectroscopy and Atomic absorption spectroscopy**: Principle, Instrumentation, Interferences and Applications. | 10 Hrs |
| 2 | **NMR spectroscopy**: Quantum numbers and their role in NMR, Principle, Instrumentation, Solvent requirement in NMR, Relaxation process, NMR signals in various compounds, Chemical shift, Factors influencing chemical shift, Spin-Spin coupling, Coupling constant, Nuclear magnetic double resonance, Brief outline of principles of FT-NMR and 13C NMR. Applications of NMR spectroscopy. | 10 Hrs |
| 3 | **Mass Spectroscopy**: Principle, Theory, Instrumentation of Mass | 10 |

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| | 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. | Hrs |
| 4 | **Chromatography**: Principle, apparatus, instrumentation, chromatographic parameters, factors affecting resolution, isolation of drug from excipients, data interpretation and applications of the following:<br>a. Thin Layer chromatography<br>b. High Performance Thin Layer Chromatography<br>c. Ion exchange chromatography<br>d. Column chromatography<br>e. Gas chromatography<br>f. High Performance Liquid chromatography<br>g. Ultra High Performance Liquid chromatography<br>h. Affinity chromatography<br>i. Gel Chromatography | 10 Hrs |
| 5 | a. **Electrophoresis**: Principle, Instrumentation, Working conditions, factors affecting separation and applications of the following:<br>a) Paper electrophoresis b) Gel electrophoresis c) Capillary electrophoresis d) Zone electrophoresis e) Moving boundary electrophoresis f) Iso electric focusing<br><br>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 Hrs |
| 6 | **Potentiometry:** Principle, working, Ion selective Electrodes and Application of potentiometry.<br><br>**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 | 10 Hrs |

and advantage and disadvantages, pharmaceutical applications, derivative differential thermal analysis (DDTA). TGA: Principle, instrumentation, factors affecting results, advantage and disadvantages, pharmaceutical applications.

***REFERENCES***


1. Spectrometric Identification of Organic compounds - Robert M Silverstein, Sixth edition, John Wiley & Sons, 2004.
2. Principles of Instrumental Analysis - Doglas A Skoog, F. James Holler, Timothy A. Nieman, 5th edition, Eastern press, Bangalore, 1998.
3. Instrumental methods of analysis – Willards, 7th edition, CBS publishers.
4. Practical Pharmaceutical Chemistry – Beckett and Stenlake, Vol II, 4th edition, CBS Publishers, New Delhi, 1997.
5. Organic Spectroscopy - William Kemp, 3rd edition, ELBS, 1991.
6. Quantitative Analysis of Drugs in Pharmaceutical formulation - P D Sethi, 3rd Edition, CBS Publishers, New Delhi, 1997.
7. Pharmaceutical Analysis - Modern Methods – Part B - J W Munson, Vol 11, Marcel. Dekker Series
8. Spectroscopy of Organic Compounds, 2nd edn., P.S/Kalsi, Wiley estern Ltd., Delhi.
9. Textbook of Pharmaceutical Analysis, KA.Connors, 3rd Edition, John Wiley & Sons, 1982.

## ADVANCED PHARMACEUTICAL ANALYSIS
## (MPA 102T)

***Scope***

This subject deals with the various aspects of Impurity, Impurities in new drug products, in residual solvents, Elemental impurities, Impurity profiling and characterization of degradents, Stability testing of phytopharmaceuticals and their protocol preparation. It also covers the biological testing of various vaccines and their principle and procedure.

***Objective***

After completion of the course students shall able to know,

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

***THEORY*** ***60 Hrs***

1. **Impurity and stability studies:** 10 Hrs

   Definition, classification of impurities in drug Substance or Active Pharmaceutical Ingredients and quantification of impurities as per ICH guidelines

   **Impurities in new drug products:**

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

   **Impurities in residual solvents:**

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

2 **Elemental impurities:** 10 Hrs

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

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

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| 3 | **Impurity profiling and degradent characterization:** Method development, Stability studies and concepts of validation accelerated stability testing & shelf life calculation, WHO and ICH stability testing guidelines, Stability zones, steps in development, practical considerations. Basics of impurity profiling and degradent characterization with special emphasis. Photostability testing guidelines, ICH stability guidelines for biological products | 10 Hrs |
| 4 | **Stability testing of phytopharmaceuticals:** Regulatory requirements, protocols, HPTLC/HPLC finger printing, interactions and complexity. | 10 Hrs |
| 5 | **Biological tests and assays of the following:** a. Adsorbed Tetanus vaccine b. Adsorbed Diphtheria vaccine c. Human anti haemophilic vaccine d. Rabies vaccine e. Tetanus Anti toxin f. Tetanus Anti serum g. Oxytocin h. Heparin sodium IP i. Antivenom. PCR, PCR studies for gene regulation, instrumentation (Principle and Procedures) | 10 Hrs |
| 6 | **Immunoassays (IA)** Basic principles, Production of antibodies, Separation of bound and unbound drug, Radioimmunoassay, Optical IA, Enzyme IA, Fluoro IA, Luminiscence IA, Quantification and applications of IA. | 10 Hrs |

***REFERENCES***


1. Vogel's textbook of quantitative chemical analysis - Jeffery J Bassett, J. Mendham, R. C. Denney, 5th edition, ELBS, 1991.
2. Practical Pharmaceutical Chemistry - Beckett and Stenlake, Vol II, 4th Edition, CBS publishers, New Delhi, 1997.
3. Textbook of Pharmaceutical Analysis - K A Connors, 3rd Edition, John Wiley & Sons, 1982.

4. Pharmaceutical Analysis - Higuchi, Brochmman and Hassen, 2nd Edition, Wiley – Inter science Publication, 1961.
5. Quantitative Analysis of Drugs in Pharmaceutical formulation – P D Sethi, 3rd Edition, CBS Publishers New Delhi, 1997.
6. Pharmaceutical Analysis- Modern methods - J W Munson – Part B, Volume 11, Marcel Dekker Series.
7. The Quantitative analysis of Drugs - D C Carratt, 3rd edition, CBS Publishers, NewDelhi, 1964.
8. Indian Pharmacopoeia Vol I , II & III 2007, 2010, 2014.
9. Methods of sampling and microbiological examination of water, first revision, BIS
10. Practical HPLC method development – Snyder, Kirkland, Glajch, 2nd edition, John Wiley & Sons.
11. Analytical Profiles of drug substances – Klaus Florey, Volume 1 – 20, Elsevier, 2005
12. Analytical Profiles of drug substances and Excipients – Harry G Brittan, Volume 21 – 30, Elsevier, 2005.
13. The analysis of drugs in biological fluids - Joseph Chamberlain, 2nd edition, CRC press, London.
14. ICH Guidelines for impurity profiles and stability studies.

## PHARMACEUTICAL VALIDATION
## (MPA 103T)

***Scope***

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

***Objectives***

Upon completion of the subject student shall be able to

- Explain the aspect of validation
- Carryout validation of manufacturing processes
- Apply the knowledge of validation to instruments and equipments
- Validate the manufacturing facilities

***THEORY*** ***60 Hrs***

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| 1. | **Introduction**: Definition of Qualification and Validation, Advantage of Validation, Streamlining of Qualification & Validation process and Validation Master Plan.<br>**Qualification:** User Requirement Specification, Design Qualification, Factory Acceptance Test (FAT)/ Site Acceptance Test (SAT), Installation Qualification, Operational Qualification, Performance Qualification, Re- Qualification (Maintaining status-Calibration Preventive Maintenance, Change management), Qualification of Manufacturing Equipments, Qualification of Analytical Instruments and Laboratory equipments. | 12 Hrs |
| 2 | **Qualification of analytical instruments:** Electronic balance, pH meter, UV-Visible spectrophotometer, FTIR, GC, HPLC, HPTLC<br>**Qualification of Glassware:** Volumetric flask, pipette, Measuring cylinder, beakers and burette. | 12 Hrs |
| 3 | **Validation of Utility systems:** Pharmaceutical Water System & pure steam, HVAC system, Compressed air and nitrogen.<br>**Cleaning Validation:** Cleaning Validation - Cleaning Method development, Validation and validation of analytical method used in cleaning. Cleaning of Equipment, Cleaning of Facilities. Cleaning in place (CIP). | 12 Hrs |
| 4 | **Analytical method validation:** General principles, Validation of analytical method as per ICH guidelines and USP. | 12 Hrs |

**Computerized system validation**: Electronic records and digital significance-21 CFR part 11 and GAMP 5.

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| 5 | **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. | 12 Hrs |

***REFERENCES***


1. B. T. Loftus & R. A. Nash, "Pharmaceutical Process Validation", Drugs and Pharm Sci. Series, Vol. 129, 3rd Ed., Marcel Dekker Inc., N.Y.
2. The Theory & Practice of Industrial Pharmacy, 3rd edition, Leon Lachman, Herbert A. Lieberman, Joseph. L. Karig, Varghese Publishing House, Bombay.
3. Validation Master plan by Terveeks or Deeks, Davis Harwood International publishing.
4. Validation of Aseptic Pharmaceutical Processes, 2nd Edition, by Carleton & Agalloco, (Marcel Dekker).
5. Michael Levin, Pharmaceutical Process Scale-Upll, Drugs and Pharm. Sci. Series, Vol. 157,2nd Ed., Marcel Dekker Inc., N.Y.
6. Validation Standard Operating Procedures: A Step by Step Guide for Achieving Compliance in the Pharmaceutical, Medical Device, and Biotech Industries, Syed Imtiaz Haider
7. Pharmaceutical Equipment Validation: The Ultimate Qualification Handbook, Phillip A. Cloud, Interpharm Press
8. Validation of Pharmaceutical Processes: Sterile Products, Frederick J. Carlton (Ed.) and James Agalloco (Ed.), Marcel Dekker, 2nd Ed.
9. Analytical Method validation and Instrument Performance Verification by Churg Chan, Heiman Lam, Y.C. Lee, Yue. Zhang, Wiley Inter Science.

## FOOD ANALYSIS
## (MPA 104T)

***Scope***

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

***Objectives***

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

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

***THEORY*** ***60 Hrs***

1. **Carbohydrates**: classification and properties of food carbohydrates, General methods of analysis of food carbohydrates, Changes in food carbohydrates during processing, Digestion, absorption and metabolism of carbohydrates, Dietary fibre, Crude fibre and application of food carbohydrates
   **Proteins**: Chemistry and classification of amino acids and proteins, Physico-Chemical properties of protein and their structure, general methods of analysis of proteins and amino acids, Digestion, absorption and metabolism of proteins. — 12 Hrs

2. **Lipids**: Classification, general methods of analysis, refining of fats and oils; hydrogenation of vegetable oils, Determination of adulteration in fats and oils, Various methods used for measurement of spoilage of fats and fatty foods.
   **Vitamins**: classification of vitamins, methods of analysis of vitamins, Principles of microbial assay of vitamins of B-series. — 12 Hrs

3. **Food additives**: Introduction, analysis of Preservatives, antioxidants, artificial sweeteners, flavors, flavor enhancers, stabilizers, thickening and jelling agents.
   **Pigments and synthetic dyes**: Natural pigments, their occurrence and characteristic properties, permitted synthetic — 12 Hrs

dyes, Non-permitted synthetic dyes used by industries, Method of detection of natural, permitted and non-permitted dyes.

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| 4 | **General Analytical methods** for milk, milk constituents and milk products like ice cream, milk powder, butter, margarine, cheese including adulterants and contaminants of milk.<br>**Analysis of fermentation products** like wine, spirits, beer and vinegar. | 12 Hrs |
| 5 | **Pesticide analysis**: Effects of pest and insects on various food, use of pesticides in agriculture, pesticide cycle, organophosphorus and organochlorine pesticides analysis, determination of pesticide residues in grain, fruits, vegetables, milk and milk products.<br>**Legislation regulations** of food products with special emphasis on BIS, Agmark, FDA and US-FDA. | 12 Hrs |

***REFERENCES***


1. The chemical analysis of foods – David Pearson, Seventh edition, Churchill Livingstone, Edinburgh London, 1976
2. Introduction to the Chemical analysis of foods – S. Nielsen, Jones & Bartlett publishers, Boston London, 1994.
3. Official methods of analysis of AOAC International, sixth edition, Volume I & II, 1997.
4. Analysis of Food constituents – Multon, Wiley VCH.
5. Dr. William Horwitz, Official methods of analysis of AOAC International, 18th edition, 2005.

## PHARMACEUTICAL ANALYSIS PRACTICALS - II
## (MPA 105P)

1. Analysis of Pharmacopoeial compounds and their formulations by UV Vis spectrophotometer
2. Simultaneous estimation of multi component containing formulations by UV spectrophotometry
3. Experiments based on HPLC
4. Experiments based on Gas Chromatography
5. Estimation of riboflavin/quinine sulphate by fluorimetry
6. Estimation of sodium/potassium by flame photometry
7. Assay of official compounds by different titrations
8. Assay of official compounds by instrumental techniques.
9. Quantitative determination of hydroxyl group.
10. Quantitative determination of amino group
11. Colorimetric determination of drugs by using different reagents
12. Imupurity profiling of drugs
13. Calibration of glasswares
14. Calibration of pH meter
15. Calibration of UV-Visible spectrophotometer
16. Calibration of FTIR spectrophotometer
17. Calibration of GC instrument
18. Calibration of HPLC instrument
19. Cleaning validation of any one equipment
20. Determination of total reducing sugar
21. Determination of proteins
22. Determination of saponification value, Iodine value, Peroxide value, Acid value in food products
23. Determination of fat content and rancidity in food products
24. Analysis of natural and synthetic colors in food
25. Determination of preservatives in food
26. Determination of pesticide residue in food products
27. Analysis of vitamin content in food products
28. Determination of density and specific gravity of foods
29. Determination of food additives

## ADVANCED INSTRUMENTAL ANALYSIS
## (MPA 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, and hyphenated techniques.

***Objectives***

After completion of course student is able to know,

- interpretation of the NMR, Mass and IR spectra of various organic compounds
- theoretical and practical skills of the hyphenated instruments
- identification of organic compounds

***THEORY*** ***60 Hrs***

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

2 **Biochromatography**: Size exclusion chromatography, ion exchange chromatography, ion pair chromatography, affinity chromatography general principles, stationary phases and mobile phases. — 12 Hrs

**Gas chromatography**: Principles, instrumentation, derivatization, head space sampling, columns for GC, detectors, quantification.

**High performance Thin Layer chromatography**: Principles, instrumentation, pharmaceutical applications.

3 **Super critical fluid chromatography:** Principles, instrumentation, pharmaceutical applications. — 12 Hrs

**Capillary electrophoresis:** Overview of **CE** in pharmaceutical analysis, basic configuration, CE characteristics, principles of CE, methods and modes of CE. General considerations and method

development in CE, Crown ethers as buffer additives in capillary electrophoresis. CE-MS hyphenation.

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| 4 | **Mass spectrometry:** Principle, theory, instrumentation of mass spectrometry, different types of ionization like electron impact, chemical, field, FAB and MALD, APCI, ESI, APPI mass fragmentation and its rules, meta stable ions, isotopic peaks and applications of mass spectrometry. LC-MS hyphenation and DART MS analysis. Mass analysers (Quadrpole, Time of flight, FT-ICR, ion trap and Orbitrap) instruments. MS/MS systems (Tandem: QqQ, TOF-TOF;Q-IT, Q-TOF, LTQ-FT, LTQ-Orbitrap. | 12 Hrs |
| 5 | **NMR spectroscopy:** Quantum numbers and their role in NMR, Principle, Instrumentation, Solvent requirement in NMR, Relaxation process, NMR signals in various compounds, Chemical shift, Factors influencing chemical shift, Spin-Spin coupling, Coupling constant, Nuclear magnetic double resonance, Brief outline of principles of FT-NMR with reference to 13CNMR: Spin spin and spin lattice relaxation phenomenon. 13C NMR, 1-D and 2-D NMR, NOESY and COSY techniques, Interpretation and Applications of NMR spectroscopy. LC-NMR hyphenations. | 12 Hrs |

***REFERENCES***


1. Spectrometric Identification of Organic compounds - Robert M Silverstein, Sixth edition, John Wiley & Sons, 2004.
2. Principles of Instrumental Analysis - Doglas A Skoog, F. James Holler, Timothy A. Nieman, 5th edition, Eastern press, Bangalore, 1998.
3. Instrumental methods of analysis – Willards, 7th edition, CBS publishers.
4. Organic Spectroscopy - William Kemp, 3rd edition, ELBS, 1991.
5. Quantitative analysis of Pharmaceutical formulations by HPTLC - P D Sethi, CBS Publishers, New Delhi.
6. Quantitative Analysis of Drugs in Pharmaceutical formulation - P D Sethi, 3rd Edition, CBS Publishers, New Delhi, 1997.
7. Pharmaceutical Analysis- Modern methods – Part B - J W Munson, Volume 11, Marcel Dekker Series.
8. Organic Spectroscopy by Donald L. Paviya, 5th Edition.

## MODERN BIO-ANALYTICAL TECHNIQUES
## (MPA 202T)

***Scope***

This subject is designed to provide detailed knowledge about the importance of analysis of drugs in biological matrices.

***Objectives***

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

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

***THEORY*** ***60 Hrs***

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

2 **Biopharmaceutical Consideration:** Introduction, Biopharmaceutical Factors Affecting Drug Bioavailability, *In Vitro:* Dissolution and Drug Release Testing, Alternative Methods of Dissolution Testing Transport models, Biopharmaceutics Classification System. Solubility: Experimental methods. Permeability: *In-vitro, in-situ* and *In-vivo* methods. — 12 Hrs

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

4 **Cell culture techniques** Basic equipments used in cell culture lab. Cell culture media, various types of cell culture, general procedure for cell cultures; isolation of cells, subculture, cryopreservation, characterization of — 12 Hrs

cells and their applications. Principles and applications of cell viability assays (MTT assays), Principles and applications of flow cytometry.

5 **Metabolite identification:** 12 Hrs

In-vitro / in-vivo approaches, protocols and sample preparation. Microsomal approaches (Rat liver microsomes (RLM) and Human liver microsomes (HLM) in Met –ID. Regulatory perspectives.
*In-vitro* assay of drug metabolites & drug metabolizing enzymes.

**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, Generic Biologics (Biosimilar Drug Products), Clinical Significance of Bioequivalence Studies.

***REFERENCES***


1. Analysis of drugs in Biological fluids - Joseph Chamberlain, 2nd Edition. CRC Press, Newyork. 1995.
2. Principles of Instrumental Analysis - Doglas A Skoog, F. James Holler, Timothy A. Nieman, 5th edition, Eastern press, Bangalore, 1998.
3. Pharmaceutical Analysis - Higuchi, Brochmman and Hassen, 2nd Edition, Wiley – Interscience Publications, 1961.
4. Pharmaceutical Analysis- Modern methods – Part B - J W Munson, Volume 11, Marcel Dekker Series
5. Practical HPLC method Development – Snyder, Kirkland, Glaich, 2nd Edition, John Wiley & Sons, New Jercy. USA.
6. Chromatographic Analysis of Pharmaceuticals – John A Adamovics, 2nd Edition, Marcel Dekker, Newyork, USA. 1997.
7. Chromatographic methods in clinical chemistry & Toxicology – Roger L Bertholf, Ruth E Winecker, John Wiley & Sons, New Jercy, USA. 2007.
8. Good Laboratory Practice Regulations, 2nd Edition, Sandy Weinberg Vol. 69, Marcel Dekker Series, 1995.
9. Good laboratory Practice Regulations – Allen F. Hirsch, Volume 38, Marcel Dekker Series, 1989.
10. ICH, USFDA & CDSCO Guidelines.
11. Palmer

## QUALITY CONTROL AND QUALITY ASSURANCE
## (MPA 203T)

***Scope***

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

***Objectives***

At the completion of this subject it is expected that the student shall be able to know

- the cGMP aspects in a pharmaceutical industry
- to appreciate the importance of documentation
- to understand the scope of quality certifications applicable to Pharmaceutical industries
- to understand the responsibilities of QA & QC departments

***THEORY*** ***60 hrs***

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

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

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

Purchase specifications and maintenance of stores for raw materials. In process quality control and finished products quality control for following formulation in Pharma industry according to Indian, US and British pharmacopoeias: tablets, capsules, ointments, suppositories, creams, parenterals, ophthalmic and surgical products (How to refer pharmacopoeias), Quality control test for containers, closures and secondary packing materials.

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

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. **12 Hrs**

***REFERENCES***


1. Quality Assurance Guide by organization of Pharmaceutical Procedures of India, 3rd revised edition, Volume I & II, Mumbai, 1996.
2. Good Laboratory Practice Regulations, 2nd Edition, Sandy Weinberg Vol. 69, Marcel Dekker Series, 1995.
3. Quality Assurance of Pharmaceuticals- A compedium of Guide lines and Related materials Vol I & II, 2nd edition, WHO Publications, 1999.
4. How to Practice GMP's – P P Sharma, Vandana Publications, Agra, 1991.
5. The International Pharmacopoeia – vol I, II, III, IV & V - General Methods of Analysis and Quality specification for Pharmaceutical Substances, Excepients and Dosage forms, 3rd edition, WHO, Geneva, 2005.
6. Good laboratory Practice Regulations – Allen F. Hirsch, Volume 38, Marcel Dekker Series, 1989.
7. ICH guidelines
8. ISO 9000 and total quality management

9. The drugs and cosmetics act 1940 – Deshpande, Nilesh Gandhi, 4th edition, Susmit Publishers, 2006.
10. QA Manual – D.H. Shah, 1st edition, Business Horizons, 2000.
11. Good Manufacturing Practices for Pharmaceuticals a plan for total quality control – Sidney H. Willig, Vol. 52, 3rd edition, Marcel Dekker Series.
12. Steinborn L. GMP/ISO Quality Audit Manual for Healthcare Manufacturers and Their Suppliers, Sixth Edition, (Volume 1 - With Checklists and Software Package). Taylor & Francis; 2003.
13. Sarker DK. Quality Systems and Controls for Pharmaceuticals. John Wiley & Sons; 2008.

## HERBAL AND COSMETIC ANALYSIS
## (MPA 204T)

***Scope***

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

***Objectives***

At completion of this course student shall be able to understand

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

***THEORY*** ***60 Hrs***

1. **Herbal remedies- Toxicity and Regulations:** Herbals vs Conventional drugs, Efficacy of herbal medicine products, Validation of Herbal Therapies, Pharmacodynamic and Pharmacokinetic issues. Herbal drug standardization**:** WHO and AYUSH guidelines. — 12 Hrs

2 **Adulteration and Deterioration:** Introduction, types of adulteration/substitution of herbal drugs, Causes and Measure of adulteration, Sampling Procedures, Determination of Foreign Matter, DNA Finger printing techniques in identification of drugs of natural origin, heavy metals, pesticide residues, phototoxin and microbial contamination in herbal formulations. — 12 Hrs

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

3 **Testing of natural products and drugs:** Effect of herbal medicine on clinical laboratory testing, Adulterant Screening using modern analytical instruments, Regulation and dispensing of herbal drugs, Stability testing of natural products, protocol. — 12 Hrs

**Monographs of Herbal drugs:** Study of monographs of herbal drugs and comparative study in IP, USP, Ayurvedic

Pharmacopoeia, American herbal Pharmacopoeia, British herbal Pharmacopoeia, Siddha and Unani Pharmacopoeia, WHO guidelines in quality assessment of herbal drugs.

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| 4 | **Herbal drug-drug interaction:** WHO and AYUSH guidelines for safety monitoring of natural medicine, Spontaneous reporting schemes for bio drug adverse reactions, bio drug-drug and bio drug-food interactions with suitable examples. Challenges in monitoring the safety of herbal medicines. | 12 Hrs |
| 5 | **Evaluation of cosmetic products**: Determination of acid value, ester value, saponification value, iodine value, peroxide value, rancidity, moisture, ash, volatile matter, heavy metals, fineness of powder, density, viscosity of cosmetic raw materials and finished products. Study of quality of raw materials and general methods of analysis of raw material used in cosmetic manufacture as per BIS.<br>Indian Standard specification laid down for sampling and testing of various cosmetics in finished forms such as baby care products, skin care products, dental products, personal hygiene preparations, lips sticks. Hair products and skin creams by the Bureau Indian Standards. | 12 Hrs |

***REFERENCES***


1. Pharmacognosy by Trease and Evans
2. Pharmacognosy by Kokate, Purohit and Gokhale
3. Quality Control Methods for Medicinal Plant, WHO, Geneva
4. Pharmacognosy & Pharmacobiotechnology by Ashutosh Kar
5. Essential of Pharmacognosy by Dr.S.H.Ansari
6. Cosmetics – Formulation, Manufacturing and Quality Control, P.P. Sharma, 4th edition, Vandana Publications Pvt. Ltd., Delhi
7. Indian Standard specification, for raw materials, BIS, New Delhi.
8. Indian Standard specification for 28 finished cosmetics BIS, New Delhi
9. Harry's Cosmeticology 8th edition
10. Suppliers catalogue on specialized cosmetic excipients
11. Wilkinson, Moore, seventh edition, George Godwin. Poucher's Perfumes, Cosmetics and Soaps
12. Hilda Butler, 10th Edition, Kluwer Academic Publishers. Handbook of Cosmetic Science and Technology, 3rd Edition,

## PHARMACEUTICAL ANALYSIS PRACTICALS - I
## (MPA 205P)

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

## PHARMACEUTICAL QUALITY ASSURANCE (MQA)

## MODERN PHARMACEUTICAL ANALYTICAL TECHNIQUES (MQA 101T)

***Scope***

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

***Objectives***

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

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

***THEORY*** ***60 Hrs***

1. a. **UV-Visible spectroscopy**: Introduction, Theory, Laws, Instrumentation associated with UV-Visible spectroscopy, Choice of solvents and solvent effect and Applications of UV-Visible spectroscopy, Difference/ Derivative spectroscopy. (12 Hrs)

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

   c. **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.

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. (12 Hrs)

| | | |
|---|---|---|
| 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. | 12 Hrs |
| 4 | **Chromatography**: Principle, apparatus, instrumentation, chromatographic parameters, factors affecting resolution, isolation of drug from excipients, data interpretation and applications of the following:<br>• Thin Layer chromatography<br>• High Performance Thin Layer Chromatography<br>• Ion exchange chromatography<br>• Column chromatography<br>• Gas chromatography<br>• High Performance Liquid chromatography<br>• Ultra High Performance Liquid chromatography<br>• Affinity chromatography<br>• Gel Chromatography | 12 Hrs |
| 5 | a. **Electrophoresis**: Principle, Instrumentation, Working conditions, factors affecting separation and applications of the following:<br>a) Paper electrophoresis b) Gel electrophoresis c) Capillary electrophoresis d) Zone electrophoresis e) Moving boundary electrophoresis f) Iso electric focusing<br>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. | 12 Hrs |
| 6 | a. **Potentiometry:** Principle, working, Ion selective Electrodes and Application of potentiometry.<br>**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 | 12 Hrs |

and advantage and disadvantages, pharmaceutical applications, derivative differential thermal analysis (DDTA). TGA: Principle, instrumentation, factors affecting results, advantage and disadvantages, pharmaceutical applications.

***REFERENCES***


1. Spectrometric Identification of Organic compounds - Robert M Silverstein, Sixth edition, John Wiley & Sons, 2004.
2. Principles of Instrumental Analysis - Doglas A Skoog, F. James Holler, Timothy A. Nieman, 5th edition, Eastern press, Bangalore, 1998.
3. Instrumental methods of analysis – Willards, 7th edition, CBS publishers.
4. Practical Pharmaceutical Chemistry – Beckett and Stenlake, Vol II, 4th edition, CBS Publishers, New Delhi, 1997.
5. Organic Spectroscopy - William Kemp, 3rd edition, ELBS, 1991.
6. Quantitative Analysis of Drugs in Pharmaceutical formulation - P D Sethi, 3rd Edition, CBS Publishers, New Delhi, 1997.
7. Pharmaceutical Analysis - Modern Methods – Part B - J W Munson, Vol 11, Marcel. Dekker Series
8. Spectroscopy of Organic Compounds, 2nd edn., P.S/Kalsi, Wiley estern Ltd., Delhi.
9. Textbook of Pharmaceutical Analysis, KA.Connors, 3rd Edition, John Wiley & Sons, 1982.
10. Textbook of Pharmaceutical Analysis, KA.Connors, 3rd Edition, John Wiley & Sons, 1982.

## 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

***THEORY*** ***60 Hrs***

1. **Introduction to Quality:** Evolution of Quality, Definition of Quality, Dimensions of Quality — 12 Hrs

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

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

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

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|---|---|---|
| 2 | **Pharmaceutical quality Management:** Basics of Quality Management, Total Quality Management (TQM), Principles of Six sigma, ISO 9001:2008, 9001:2015, ISO 14001:2004, Pharmaceutical Quality Management – ICH Q10, Knowledge management, Quality Metrics, Operational Excellence and Quality Management Review. OSHAS guidelines, NABL certification and accreditation, CFR-21 part 11, WHO-GMP requirements. | 12 Hrs |
| 3 | **Six System Inspection model:** Quality Management system, Production system, Facility and Equipment system, Laboratory control system, Materials system, Packaging and labeling system. Concept of self inspection.<br>**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. | 12 Hrs |
| 4 | **Drug Stability:** ICH guidelines for stability testing of drug substances and drug products.<br>**Study of ICH Q8, Quality by Design and Process development report**<br>**Quality risk management:** Introduction, risk assessment, risk control, risk review, risk management tools, HACCP, risk ranking and filtering according to ICH Q9 guidelines**.** | 12 Hrs |
| 5 | **Statistical Process control (SPC):** Definition and Importance of SPC, Quality measurement in manufacturing, Statistical control charts - concepts and general aspects, Advantages of statistical control, Process capability, Estimating Inherent or potential capability from a control chart analysis, Measuring process control and quality improvement, Pursuit of decreased process variability. | 8 Hrs |
| 6 | Regulatory Compliance through Quality Management and development of Quality Culture<br>Benchmarking: Definition of benchmarking, Reasons for benchmarking, Types of Benchmarking, Benchmarking process, Advantages of benchmarking, Limitations of benchmarking. | 4 Hrs |

***REFERENCES***


1. Implementing Juran's Road Map for Quality Leadership: Benchmarks and Results, By Al Endres, Wiley, 2000
2. Understanding, Managing and Implementing Quality: Frameworks, Techniques and Cases, By Jiju Antony; David Preece, Routledge, 2002
3. Organizing for High Performance: Employee Involvement, TQM, Reengineering, and Knowledge Management in the Fortune 1000: The CEO Report By Edward E. Lawler; Susan Albers Mohrman; George Benson, Jossey-Bass, 2001
4. Corporate Culture and the Quality Organization By James W. Fairfield-Sonn, Quorum Books, 2001
5. The Quality Management Sourcebook: An International Guide to Materials and Resources By Christine Avery; Diane Zabel, Routledge, 1997
6. The Quality Toolbox, Second Edition, Nancy R. Tague, ASQ Publications
7. Juran's Quality Handbook, Sixth Edition, Joseph M. Juran and Joseph A. De Feo, ASQ Publications
8. Root Cause Analysis, The Core of Problem Solving and Corrective Action, Duke Okes, 2009, ASQ Publications.

## 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.

***THEORY*** ***60 Hrs***

| | | |
|---|---|---|
| 1. | **Introduction:** Concept and evolution and scopes of Quality Control and Quality Assurance, Good Laboratory Practice, GMP, Overview of ICH Guidelines - QSEM, with special emphasis on Q-series guidelines.<br>**Good Laboratory Practices:** Scope of GLP, Definitions, Quality assurance unit, protocol for conduct of non clinical testing, control on animal house, report preparation and documentation. CPCSEA guidelines. | 12 Hrs |
| 2 | 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. | 12 Hrs |
| 3 | 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. | 12 Hrs |

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|---|---|---|
| | 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). | |
| 4 | **Documentation in pharmaceutical industry:** Three tier documentation, Policy, Procedures and Work instructions, and records (Formats), Basic principles- How to maintain, retention and retrieval etc. Standard operating procedures (How to write), Master Batch Record, Batch Manufacturing Record, Quality audit plan and reports. Specification and test procedures, Protocols and reports. Distribution records. Electronic data handling. Concepts of controlled and uncontrolled documents.<br>Submission documents for regulators DMFs, as Common Technical Document and Electronic Common Technical Documentation (CTD, eCTD). Concept of regulated and non regulated markets. | 12 Hrs |
| 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.<br>Introduction, scope and importance of intellectual property rights. Concept of trade mark, copyright and patents. | 12 Hrs |

***REFERENCES***


1. Quality Assurance Guide by organization of Pharmaceutical Procedures of India, 3rd revised edition, Volume I & II, Mumbai, 1996.
2. Good Laboratory Practice Regulations, 2nd Edition, Sandy Weinberg Vol. 69, Marcel Dekker Series, 1995.
3. Quality Assurance of Pharmaceuticals- A compedium of Guide lines and Related materials Vol I & II, 2nd edition, WHO Publications, 1999.
4. How to Practice GMP's – P P Sharma, Vandana Publications, Agra, 1991.

5. The International Pharmacopoeia – vol I, II, III, IV & V - General Methods of Analysis and Quality specification for Pharmaceutical Substances, Excepients and Dosage forms, 3rd edition, WHO, Geneva, 2005.
6. Good laboratory Practice Regulations – Allen F. Hirsch, Volume 38, Marcel Dekker Series, 1989.
7. ICH guidelines
8. ISO 9000 and total quality management
9. The drugs and cosmetics act 1940 – Deshpande, Nilesh Gandhi, 4th edition, Susmit Publishers, 2006.
10. QA Manual – D.H. Shah, 1st edition, Business Horizons, 2000.
11. Good Manufacturing Practices for Pharmaceuticals a plan for total quality control – Sidney H. Willig, Vol. 52, 3rd edition, Marcel Dekker Series.
12. Steinborn L. GMP/ISO Quality Audit Manual for Healthcare Manufacturers and Their Suppliers, Sixth Edition, (Volume 1 - With Checklists and Software Package). Taylor & Francis; 2003.
13. Sarker DK. Quality Systems and Controls for Pharmaceuticals. John Wiley & Sons; 2008.
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

***THEORY*** ***60 Hrs***

| | | |
|---|---|---|
| 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 Hrs |
| 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 Hrs |
| 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 Hrs |

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| 4 | **Pharmaceutical packaging:** Pharmaceutical dosage form and their packaging requirments, Pharmaceutical packaging materials, Medical device packaging, Enteral Packaging, Aseptic packaging systems, Container closure systems, Issues facing modern drug packaging, Selection and evaluation of Pharmaceutical packaging materials.<br>**Quality control test**: Containers, closures and secondary packing materials. | 12 Hrs |
| 5 | **Technology transfer:** Development of technology by R & D, Technology transfer from R & D to production, Optimization and Production, Qualitative and quantitative technology models.<br>Documentation in technology transfer: Development report, technology transfer plan and Exhibit. | 12 Hrs |

***REFERENCES***


1. The process of new drug discovery and development. I and II Edition (2006) by Charles G. Smith, James T and O. Donnell. CRC Press, Group of Taylor and Francis.
2. Leon Lac Lachman, Herbert A. Liberman, Theory and Practice of Industrial Pharmacy. Marcel Dekker Inc. New York.
3. Sidney H Willing, Murray M, Tuckerman. Williams Hitchings IV, Good manufacturing of pharmaceuticals (A Plan for total quality control) 3rd Edition. Bhalani publishing house Mumbai.
4. Tablets Vol. I, II, III by Leon Lachman, Herbert A. Liberman, Joseph B. Schwartz, 2nd Edn. (1989) Marcel Dekker Inc. New York.
5. Text book of Bio- Pharmaceutics and clinical Pharmacokinetics by Milo Gibaldi, 3rd Edn, Lea & Febriger, Philadelphia.
6. Pharmaceutical product development. Vandana V. Patrevale. John I. Disouza. Maharukh T.Rustomji. CRC Press, Group of Taylor and Francis.
7. Dissolution, Bioavailability and Bio-Equivalence by Abdou H.M, Mack Publishing company, Eastern Pennsylvania.
8. Remingtons Pharmaceutical Sciences, by Alfonso & Gennaro, 19th Edn.(1995)OO2C Lippincott; Williams and Wilkins A Wolters Kluwer Company, Philadelphia.
9. The Pharmaceutical Sciences; the Pharma Path way 'Pure and applied Pharmacy' by D. A Sawant, Pragathi Books Pvt. Ltd.
10. Pharmaceutical Packaging technology by D.A. Dean. E.R. Evans, I.H. Hall. 1st Edition(Reprint 2006). Taylor and Francis. London and New York.

## QUALITY ASSURANCE PRACTICAL - I
## (MQA 105P)

***PRACTICALS***

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)
19. Determination of Pka and Log p of drugs.

## 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.

***THEORY*** ***60Hrs***

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|---|---|---|
| 1. | **Multidisciplinary nature of environmental studies:** Natural Resources, Renewable and non-renewable resources, Natural resources and associated problems,<br>a) Forest resources; b) Water resources; c) Mineral resources; d) Energy resources; e) Land resources<br>**Ecosystems:** Concept of an ecosystem and Structure and function of an ecosystem. Environmental hazards: Hazards based on Air, Water, Soil and Radioisotopes. | 12 Hrs |
| 2 | **Air based hazards:** Sources, Types of Hazards, Air circulation maintenance industry for sterile area and non sterile area, Preliminary Hazard Analysis (PHA) Fire protection system: Fire prevention, types of fire extinguishers and critical Hazard management system. | 12 Hrs |
| 3 | **Chemical based hazards:** Sources of chemical hazards, Hazards of Organic synthesis, sulphonating hazard, Organic solvent hazard, Control measures for chemical hazards, | 12 Hrs |

Management of combustible gases, Toxic gases and Oxygen displacing gases management, Regulations for chemical hazard, Management of over-Exposure to chemicals and TLV concept.

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| 4 | **Fire and Explosion**: Introduction, Industrial processes and hazards potential, mechanical electrical, thermal and process hazards. Safety and hazards regulations, Fire protection system: Fire prevention, types of fire extinguishers and critical Hazard management system mechanical and chemical explosion, multiphase reactions, transport effects and global rates. Preventive and protective management from fires and explosion-electricity passivation, ventilation, and sprinkling, proofing, relief systems -relief valves, flares, scrubbers. | 12 Hrs |
| 5 | **Hazard and risk management:** Self-protective measures against workplace hazards. Critical training for risk management, Process of hazard management, ICH guidelines on risk assessment and Risk management methods and Tools<br>Factory act and rules, fundamentals of accident prevention, elements of safety programme and safety management, Physicochemical measurements of effluents, BOD, COD, Determination of some contaminants, Effluent treatment procedure, Role of emergency services. | 12 Hrs |

***REFERENCES***


1. Y.K. Sing, Environmental Science, New Age International Pvt, Publishers, Bangalore
2. “Quantitative Risk Assessment in Chemical Process Industries” American Institute of Chemical Industries, Centre for Chemical Process safety.
3. Bharucha Erach, The Biodiversity of India, Mapin Pu blishing Pvt. Ltd., Ahmedabad – 380 013, India,
4. Hazardous Chemicals: Safety Management and Global Regulations, T.S.S. Dikshith, CRC press

## 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

***THEORY*** ***60 Hrs***

1. **Introduction to validation:** Definition of Calibration, Qualification and Validation, Scope, frequency and importance. Difference between calibration and validation. Calibration of weights and measures. Advantages of Validation, scope of Validation, Organization for Validation, Validation Master plan, Types of Validation, Streamlining of qualification & Validation process and Validation Master Plan. 10 Hrs

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

2. **Qualification of manufacturing equipment:** Dry Powder Mixers, Fluid Bed and Tray dryers, Tablet Compression (Machine), Dry heat sterilization/Tunnels, Autoclaves, Membrane filtration, Capsule filling machine. 10 Hrs

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

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| 3 | **Qualification of laboratory equipments:** Hardness tester, Friability test apparatus, tap density tester, Disintegration tester, Dissolution test apparatus<br>**Validation of Utility systems:** Pharmaceutical water system & pure steam, HVAC system, Compressed air and nitrogen. | 10 Hrs |
| 4 | **Process Validation:** Concept, Process and documentation of Process Validation. Prospective, Concurrent & Retrospective Validation, Re validation criteria, Process Validation of various formulations (Coated tablets, Capsules, Ointment/Creams, Liquid Orals and aerosols.), Aseptic filling: Media fill validation, USFDA guidelines on Process Validation- A life cycle approach.<br>**Analytical method validation:** General principles, Validation of analytical method as per ICH guidelines and USP. | 10 Hrs |
| 5 | **Cleaning Validation:** Cleaning Method development, Validation of analytical method used in cleaning, Cleaning of Equipment, Cleaning of Facilities. Cleaning in place (CIP).<br>**Validation of facilities in sterile and non-sterile plant.**<br>**Computerized system validation:** Electronic records and digital signature - 21 CFR Part 11 and GAMP | 10 Hrs |
| 6 | **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. | 10 Hrs |

***REFERENCES***


1. B. T. Loftus & R. A. Nash, "Pharmaceutical Process Validation", Drugs and Pharm Sci. Series, Vol. 129, 3rd Ed., Marcel Dekker Inc., N.Y.
2. The Theory & Practice of Industrial Pharmacy, 3rd edition, Leon Lachman, Herbert A. Lieberman, Joseph. L. Karig, Varghese Publishing House, Bombay.
3. Validation Master plan by Terveeks or Deeks, Davis Harwood International publishing.
4. Validation of Aseptic Pharmaceutical Processes, 2nd Edition, by Carleton & Agalloco,
5. (Marcel Dekker).
6. Michael Levin, Pharmaceutical Process Scale-Up", Drugs and Pharm. Sci. Series, Vol. 157,2nd Ed., Marcel Dekker Inc., N.Y.
7. Validation Standard Operating Procedures: A Step by Step Guide for Achieving Compliance in the Pharmaceutical, Medical Device, and Biotech Industries, Syed Imtiaz Haider
8. Pharmaceutical Equipment Validation: The Ultimate Qualification Handbook, Phillip A. Cloud, Interpharm Press
9. Validation of Pharmaceutical Processes: Sterile Products, Frederick J. Carlton (Ed.) and James Agalloco (Ed.), Marcel Dekker
10. Analytical Method validation and Instrument Performance Verification by Churg Chan, Heiman Lam, Y.C. Lee, Yue. Zhang, Wiley Interscience.
11. Huber L. Validation and Qualification in Analytical Laboratories. Informa Healthcare
12. Wingate G. Validating Corporate Computer Systems: Good IT Practice for Pharmaceutical Manufacturers. Interpharm Press
13. LeBlanc DA. Validated Cleaning Technologies for Pharmaceutical Manufacturing. Interpharm Press

## 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

***THEORY*** ***60 Hrs***

| | | |
|---|---|---|
| 1. | **Introduction:** Objectives, Management of audit**,** Responsibilities, Planning process, information gathering, administration, Classifications of deficiencies | 12 Hrs |
| 2 | **Role of quality systems and audits in pharmaceutical manufacturing environment:** cGMP Regulations, Quality assurance functions, Quality systems approach, Management responsibilities, Resource**,** Manufacturing operations, Evaluation activities, Transitioning to quality system approach, Audit checklist for drug industries. | 12 Hrs |
| 3 | **Auditing of vendors and production department**: Bulk Pharmaceutical Chemicals and packaging material Vendor audit, Warehouse and weighing, Dry Production: Granulation, tableting, coating, capsules, sterile production and packaging. | 12 Hrs |
| 4 | **Auditing of Microbiological laboratory:** Auditing the manufacturing process, Product and process information, General areas of interest in the building raw materials, Water, Packaging materials. | 12 Hrs |

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|---|---|---|
| 5 | **Auditing of Quality Assurance and engineering department:** Quality Assurance Maintenance, Critical systems: HVAC, Water, Water for Injection systems, ETP. | 12 Hrs |

***REFERENCES***


1. Compliance auditing for Pharmaceutical Manufacturers. Karen Ginsbury and Gil Bismuth, Interpharm/CRC, Boca Raton, London New York, Washington D.C.
2. Pharmaceutical Manufacturing Handbook, Regulations and Quality by Shayne Cox Gad. Wiley-Interscience, A John Wiley and sons, Inc., Publications.
3. Handbook of microbiological Quality control. Rosamund M. Baird, Norman A. Hodges, Stephen P. Denyar. CRC Press. 2000.
4. Laboratory auditing for quality and regulatory compliance. Donald C. Singer, Raluca-loana Stefan, Jacobus F. Van Staden. Taylor and Francis (2005).

## 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

***THEORY*** ***60 Hrs***

1. **Pharmaceutical industry developments:** Legal requirements and Licenses for API and formulation industry, Plant location-Factors influencing. 12 Hrs

   **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.

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**).** 12 Hrs

   **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. | |
| 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). **Advance non-sterile solid product manufacturing technology**: Process Automation in Pharmaceutical Industry with specific reference to manufacturing of tablets and coated products, Improved Tablet Production: Tablet production process, granulation and pelletization equipments, continuous and batch mixing, rapid mixing granulators, rota granulators, spheronizers and marumerisers, and other specialized granulation and drying equipments. Problems encountered. **Coating technology**: Process, equipments, particle coating, fluidized bed coating, application techniques. Problems encountered. | 12 Hrs |
| 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. | 12 Hrs |
| 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. | 12 Hrs |

***REFERENCES***


1. Lachman L, Lieberman HA, Kanig JL. The theory and practice of industrial pharmacy, 3rd ed., Varghese Publishers, Mumbai 1991.
2. Sinko PJ. Martin's physical pharmacy and pharmaceutical sciences, 5th ed., B.I. Publications Pvt. Ltd, Noida, 2006.
3. Lieberman HA, Lachman L, Schwartz JB. Pharmaceutical dosage forms: tablets Vol. I-III, 2nd ed., CBS Publishers & distributors, New Delhi, 2005.
4. Banker GS, Rhodes CT. Modern Pharmaceutics, 4th ed., Marcel Dekker Inc, New York, 2005.
5. Sidney H Willing, Murray M, Tuckerman. Williams Hitchings IV, Good manufacturing of pharmaceuticals (A Plan for total quality control) 3rd Edition. Bhalani publishing house Mumbai.
6. Indian Pharmacopoeia. Controller of Publication. Delhi, 1996.
7. British Pharmacopoeia. British Pharmacopoeia Commission Office, London, 2008.
8. United States Pharmacopoeia. United States Pharmacopeial Convention, Inc, USA, 2003.
9. Dean D A, Evans E R and Hall I H. Pharmaceutical Packaging Technology. London, Taylor & Francis, 1st Edition. UK.
10. Edward J Bauer. Pharmaceutical Packaging Handbook. 2009. Informa Health care USA Inc. New york.
11. Shaybe Cox Gad. Pharmaceutical Manufacturing Handbook. John Willey and Sons, New Jersey, 2008.

## 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.
5. Estimation of Chlorine in Work Environment.
6. Sampling and analysis of $SO_2$ 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.

***THEORY*** ***60 Hrs***

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| 1. | **Current Good Manufacturing Practices:** Introduction, US cGMP Part 210 and Part 211.EC Principles of GMP (Directive 91/356/EEC) Article 6 to Article 14 and WHO cGMP guidelines GAMP-5; Medical device and IVDs Global Harmonization Task Force(GHTF) Guidance docs. | 12 Hrs |
| 2 | **Good Laboratory Practices:** 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 | 12 Hrs |
| 3 | **Good Automated Laboratory Practices:** Introduction to GALP, Principles of GALP, GALP Requirements, SOPs of GALP, Training Documentation,21 CFR Part 11, General check list of 21CFR Part 11, Software Evaluation checklist, relevant ISO and QCI Standards**.** | 12 Hrs |

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|---|---|---|
| 4 | **Good Distribution Practices**: Introduction to GDP, Legal GDP requirements put worldwide, Principles, Personnel, Documentation, Premises and Equipment, Deliveries to Customers, Returns, Self-Inspection, Provision of information, Stability testing principles, WHO GDP, USP GDP (Supply chain integrity), relevant CDSCO guidance and ISO standards | 12 Hrs |
| 5 | **Quality management systems:** Concept of Quality, Total Quality Management, Quality by design, Six Sigma concept, Out of Specifications (OOS), Change control. Validation: Types of Validation, Types of Qualification, Validation master plan (VMP), Analytical Method Validation. Validation of utilities, [Compressed air, steam, water systems, Heat Ventilation and Air conditioning (HVAC)]and Cleaning Validation. The International Conference on Harmonization (ICH) process, ICH guidelines to establish quality, safety and efficacy of drug substances and products, ISO 13485, Sch MIII and other relevant CDSCO regulatory guidance documents. | 12 Hrs |

***REFERENCES***


1. Good Laboratory Practice Regulations, by Sandy Weinberg, Fourth Edition Drugs and the Pharmaceutical Sciences, Vol.168
2. Good Pharmaceutical Manufacturing practice, Rational and compliance by John Sharp, CRC Press
3. Establishing a cGMP Laboratory Audit System, A practical Guide by David M.Bleisner, Wiley Publication.
4. How to practice GLP by PP Sharma, Vandana Publications.
5. Laboratory Auditing for Quality and Regulatory compliance bu 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

***THEORY*** ***60 Hrs***

1. **Documentation in pharmaceutical industry**: Exploratory Product Development Brief (EPDB) for Drug substance and Drug product, Product Development Plan (PDP), Product Development Report (PDR), Master Formula Record, Batch Manufacturing Record and its calculations, Batch Reconciliation, Batch Packaging Records, Print pack specifications, Distribution records, Certificate of Analysis (CoA), Site Master File and Drug Master Files (DMF). — 12 Hrs

2. **Dossier preparation and submission:** 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. — 12 Hrs

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| 3 | **Audits:** Introduction, Definition, Summary, Types of audits, GMP compliance audit, Audit policy, Internal and External Audits, Second Party Audits, External third party audits, Auditing strategies, Preparation and conducting audit, Auditing strategies, audit analysis, audit report, audit follow up. Auditing/inspection of manufacturing facilities by regulatory agencies. Timelines for audits/inspection. GHTF study group 4 guidance document. ISO 13485. | 12 Hrs |
| 4 | **Inspections:** Pre-approval inspections, Inspection of pharmaceutical manufacturers, Inspection of drug distribution channels, Quality systems requirements for national good manufacturing practice inspectorates, inspection report, model certificate of good manufacturing practices, Root cause analysis, Corrective and Preventive action (CAPA). | 12 Hrs |
| 5 | **Product life cycle management:** Prior Approval Supplement (PAS), Post Approval Changes [SUPAC], Changes Being Effected in 30 Days (CBE-30), Annual Report, Post marketing Reporting Requirements, Post approval Labeling Changes, Lifecycle Management, FDA Inspection and Enforcement, Establishment Inspection Report (EIR), Warning Letters, Recalls, Seizure and Injunctions. ISO Risk Management Standard | 12 Hrs |

***REFERENCES***


1. Compliance auditing for Pharmaceutical Manufacturers. Karen Ginsbury and Gil Bismuth, Interpharm/CRC, Boca Raton, London New York, Washington D.C.
2. Pharmaceutical Manufacturing Handbook, Regulations and Quality by Shayne Cox Gad. Wiley-Interscience, A John Wiley and sons, Inc., Publications.
3. Handbook of microbiological Quality control. Rosamund M. Baird, Norman A. Hodges, Stephen P. Denyar. CRC Press. 2000.
4. Laboratory auditing for quality and regulatory compliance. Donald C. Singer, Raluca-Ioana Stefan, Jacobus F. Van Staden. Taylor and Francis (2005).
5. Implementing Juran's Road Map for Quality Leadership: Benchmarks and Results, By Al Endres, Wiley, 2000
6. Understanding, Managing and Implementing Quality: Frameworks, Techniques and Cases, By Jiju Antony; David Preece, Routledge, 2002

7. Organizing for High Performance: Employee Involvement, TQM, Reengineering, and Knowledge Management in the Fortune 1000: The CEO Report By Edward E. Lawler; Susan Albers Mohrman; George Benson, Jossey-Bass, 2001
8. Corporate Culture and the Quality Organization By James W. Fairfield-Sonn, Quorum Books, 2001
9. The Quality Management Sourcebook: An International Guide to Materials and Resources By Christine Avery; Diane Zabel, Routledge, 1997
10. The Quality Toolbox, Second Edition, Nancy R. Tague, ASQ Publications
11. Juran's Quality Handbook, Sixth Edition, Joseph M. Juran and Joseph A. De Feo, ASQ Publications
12. Root Cause Analysis, The Core of Problem Solving and Corrective Action, Duke Okes, 2009, ASQ Publications
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

***Theory*** ***60 Hrs***

1. **Clinical Drug Development Process** 12 Hrs
   - Different types of Clinical Studies
   - Phases of clinical trials, Clinical Trial protocol
   - Phase 0 studies
   - Phase I and subtype studies (single ascending, multiple ascending, dose escalation, methods, food effect studies, drug – drug interaction, PK end points
   - Phase II studies (proof of concept or principle studies to establish efficacy)
   - Phase III studies (Multi ethnicity, global clinical trial, registration studies)
   - Phase IV studies (Post Marketing Studies; PSUR)

   **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:** 12 Hrs

- Historical Perspectives: Nuremberg Code, Thalidomide study , Nazis Trials, Tuskegee Syphilis Study, The Belmont Report, The declaration of Helsinki
- Origin of International Conference on Harmonization - Good Clinical Practice (ICH-GCP) guidelines.
- The ethics of randomized clinical trials
- The role of placebo in clinical trials
- Ethics of clinical research in special population
- Institutional Review Board/Independent Ethics Committee/Ethics Committee – composition, roles, responsibilities, review and approval process and ongoing monitoring of safety data
- Data safety monitoring boards.
- Responsibilities of sponsor, CRO, and investigator in ethical conduct of clinical research
    - Ethical principles governing informed consent process
    - Patient Information Sheet and Informed Consent Form
    - The informed consent process and documentation

3 **Regulations governing Clinical Trials** 12 Hrs

**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 Trials Guidance Document: Good Clinical Practice

**EU:** Clinical Research regulations in European Union (EMA)

4 **Clinical Research Related Guidelines** 12 Hrs

- 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** 12 Hrs

***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***


1. Clinical Trials and Human Research: A Practical Guide to Regulatory Compliance By Fay A. Rozovsky and Rodney K. Adams
2. HIPAA and Human Subjects Research: A Question and Answer Reference Guide By Mark Barnes, JD, LLM and Jennifer Kulynych, JD, PhD
3. Principles and Practices of Clinical Research, Second Edition Edited by John I. Gallin and Frederick P. Ognibene
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.
6. New Drug Approval Process: The Global Challenge; Guarino, Richard A; Marcel Dekker Inc., NY.
7. FDA regulatory affairs: a guide for prescription drugs, medical devices, and biologics; Douglas J. Pisano, David Mantus; CRC Press, USA
8. Country Specific Guidelines from official websites.
9. Drugs & Cosmetics Act & Rules and Amendments


***RECOMMENDED WEBSITES:***


1. EU Clinical Research Directive 2001: http://www.eortc.be/services/doc/clinical-eudirective-04-april-01.pdf
2. Code of Federal Regulations, FDA: http://www.accessdata.fda.gov/scripts /cdrh /cfdocs/cfcfr/cfrsearch.cfm
3. Guidelines of International Conference on Harmonization: http://www.ich.org /products/guidelines.html
4. Eudralex Guidelines: http://www.gmpcompliance.info/euguide.htm
5. FDA New Drug Application:
6. http://www.fda.gov/regulatoryinformation/legislation/FederalFoodDrugandCosmetic ActFDCAct/FDCActChapterVDrugsandDevices/ucm108125.htm
7. Medicines and Healthcare products Regulatory Agency: http://www.mhra.gov.uk
8. Central Drugs Standard Control Organization Guidance for Industry: http://cdsco.nic.in/CDSCO-GuidanceForIndustry.pdf
9. ICMR Ethical Guidelines for Biomedical Research: http://icmr.nic.in/ethical_guidelines.pdf

## REGULATIONS AND LEGISLATION FOR DRUGS & COSMETICS, MEDICAL DEVICES, BIOLOGICALS & HERBALS, AND FOOD & NUTRACEUTICALS IN INDIA AND INTELLECTUAL PROPERTY RIGHTS
## (MRA 104T)

***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

***THEORY*** ***60 Hrs***

1. **Biologicals & Herbals, and Food & Nutraceuticals** 12 Hrs

**Acts and Rules (with latest amendments):**

1. Drugs and Cosmetics Act 1940 and Rules 1945: DPCO and NPPA
2. Other relevant provisions (rules schedules and guidelines for approval of Drugs & Cosmetics, Medical Devices, Biologicals & Herbals, and Food & Nutraceuticals in India

**Other relevant Acts:** Narcotics Drugs and Psychotropic Substances Act; Medicinal and Toilet Preparations (Excise Duties) Act, 1955; Pharmacy Act, 1948; Drugs and Magic Remedies (Objectionable Advertisements) Act, 1955; Prevention of Cruelty to Animals Act.

| | | |
|---|---|---|
| 2 | **Regulatory requirements and approval procedures for Drugs & Cosmetics Medical Devices, Biologicals & Herbals, and Food & Nutraceuticals**<br>CDSCO (Central Drug Standard Control Organization) and State Licensing Authority: Organization, Responsibilities<br>• Rules, regulations, guidelines and standards for regulatory filing of Drugs & Cosmetics, Medical Devices, Biologicals & Herbals, and Food & Nutraceuticals<br>• Format and contents of Regulatory dossier filing<br>Clinical trial/ investigations | 12 Hrs |
| 3 | Indian Pharmacopoeial Standards, BIS standards and ISO and other relevant standards | 12 Hrs |
| 4 | Bioavailability and Bioequivalence data (BA &BE), BCS Classification of Drugs, Regulatory Requirements for Bioequivalence study<br>**Stability requirements:** ICH and WHO<br><br>**Guidelines for Drug testing in animals/**Preclinical Studies<br><br>Animal testing: Rationale for conducting studies, CPCSEA Guidelines<br>Ethical guidelines for human participants<br>ICMR-DBT Guidelines for Stem Cell Research | 12 Hrs |
| 5 | **Intellectual Property Rights**: Patent, Trademark, Copyright, Industrial Designs and Geographical Indications, Indian Patent Scenario. IPR vs Regulatory Affairs | 12 Hrs |

***REFERENCES***


1. Manual of Patent Practice & Procedure, 3rd Edition, by The Patent Office of India
2. Patent Failure How Judges, Bureaucrats, and Lawyers put innovators at risk by James Bessen and Michael J. Meurer
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

## REGULATORY AFFAIRS PRACTICAL - I
## (MRA 105P)

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

## SEMESTER II
## 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 countriesIt 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

***Theory*** ***60 Hrs***

1. **USA & CANADA:** Organization structure and functions of FDA. Federal register and Code of Federal Regulations (CFR), History and evolution of United States Federal, Food, Drug and Cosmetic Act (FFDCA), Hatch Waxman act and Orange book, Purple book, Drug Master Files (DMF) system in US, Regulatory Approval Process for Investigational New Drug (IND), New Drug Application (NDA), Abbreviated New Drug Application (ANDA), Supplemental New Drug Application (SNDA); Regulatory requirements for Orphan drugs and Combination Products, Changes to an approved NDA / ANDA. Regulatory considerations for manufacturing, packaging and labeling of pharmaceuticals in USA. Legislation and regulations for import, manufacture, distribution and sale of cosmetics in USA and Canada. — 12 Hrs

2 **European Union & Australia:** Organization and structure of EMA & EDQM, General guidelines, Active Substance Master Files (ASMF) system in EU, Content and approval process of IMPD, Marketing Authorization procedures in EU (Centralized procedure, — 12 Hrs

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|---|---|---|
| | Decentralized procedure, Mutual recognition procedure and National Procedure). Regulatory considerations for manufacturing, packaging and labeling of pharmaceuticals in EU, Eudralex directives for human medicines, Variations & extensions, Compliance of European Pharmacopoeia (CEP)/ Certificate of Suitability (CoS), Marketing Authorization (MA) transfers, Qualified Person (QP) in EU. Legislation and regulations for import, manufacture, distribution and sale of cosmetics in European Union & Australia. | |
| 3 | **Japan:** Organization of the PMDA, Pharmaceutical Laws and regulations, types of registration applications, DMF system in Japan, drug regulatory approval process, Regulatory considerations for manufacturing, packaging and labeling of pharmaceuticals in Japan, Post marketing surveillance in Japan. Legislation and regulations for import, manufacture, distribution and sale of cosmetics in Japan | 12 Hrs |
| 4 | **Emerging Market:** Introduction, Countries covered, Study of the world map,study of various committees across the globe (ASEAN, APEC, EAC, GCC, PANDRH, SADC)<br>**WHO:** WHO, GMP, Regulatory Requirements for registration of drugs and post approval requirements in WHO through prequalification programme, Certificate of Pharmaceutical Product (CoPP) - General and Country Specific (South Africa, Egypt, Algeria and Morocco, Nigeria, Kenya and Botswana) | 12 Hrs |
| 5 | **Brazil, ASEAN, CIS and GCC Countries:**<br>**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.<br>**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<br>Legislation and regulations for import, manufacture, distribution and sale of cosmetics in Brazil, ASEAN, CIS and GCC Countries. | 12 Hrs |

***REFERENCES :***


1. Generic Drug Product Development, Solid Oral Dosage forms, Leon Shargel and Isader Kaufer, Marcel Dekker series, Vol.143
2. The Pharmaceutical Regulatory Process, Edited by Ira R. Berry Marcel Dekker Series, Vol.144
3. The Pharmaceutical Regulatory Process, Second Edition Edited by Ira R. Berry and Robert P. Martin, Drugs and the Pharmaceutical Sciences, Vol.185 Informa Health care Publishers.
4. New Drug Approval Process: Accelerating Global Registrations By Richard A Guarino, MD, 5th edition, Drugs and the Pharmaceutical Sciences, Vol.190.
5. Guidebook for drug regulatory submissions / Sandy Weinberg. By John Wiley & Sons. Inc.
6. Drugs: From Discovery to Approval, Second Edition By Rick Ng
7. New Drug Development: A Regulatory Overview, Eighth Edition By Mark Mathieu
8. Pharmaceutical Risk Management By Jeffrey E. Fetterman, Wayne L. Pines and Gary H. Slatko
9. Preparation and Maintenance of the IND Application in eCTD Format By William K. Sietsema
10. Country Specific Guidelines from official websites.
11. http://www.who.int/medicines/areas/quality_safety/regulation_legislation/ListMRAWebsites.pdf
12. Roadmap to an ASEAN economic community Edited by Denis Hew. ISEAS Publications, Singapore 2005, ISBN981-230-347-2
13. ASEAN, Rodolfo C. Severino, ISEAS Publications, Singapore 2005, ISBN 978-981-230-750-7
14. Building a Future with Brics: The Next Decade for Offshoring, Mark Kobayashi-Hillary, Springer
15. Outsourcing to India: The Offshore Advantage, Mark Kobayashi-Hillary, Springer Trade performance and Regional Integration of the CIS Countries, Lev Freinkman,
16. The world Bank, Washington, DC, ISBN: 0-8212-5896-0
17. Global Pharmaceutical Policy: Ensuring Medicines for Tomorrow's World ByFrederick M. Abbott, Graham Dukes, Maurice Nelson Graham Dukes 139
18. The Gulf Cooperation Council: A Rising Power and Lessons for ASEAN by Linda Low and Lorraine Carlos Salazar (Nov 22, 2010)
19. Doing Business in the Asean Countries, Balbir Bhasin, Business Expert Press ISBN:13:978-1-60649-108-9
20. 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

***Theory*** ***60 Hrs***

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| 1. | **India :** Introduction, Applicable Regulations and Guidelines , Principles for Development of Similar Biologics, Data Requirements for Preclinical Studies, Data Requirements for Clinical Trial Application, Data Requirements for Market Authorization Application, Post-Market Data for Similar Biologics, Pharmacovigilance. GMP and GDP. | 12 Hrs |
| 2 | **USA:** Introduction to Biologics; biologics, biological and biosimilars, different biological products, difference between generic drug and biosimilars, laws, regulations and guidance on biologics/ biosimilars, development and approval of biologics and biosimilars (IND, PMA, BLA, NDA, 510(k), pre-clinical and clinical development considerations, advertising, labelling and packing of biologics | 12 Hrs |
| 3 | **European Union:** Introduction to Biologics; directives, scientific guidelines and guidance related to biologics in EU, comparability/ biosimilarity assessment, Plasma master file, TSE/ BSE evaluation, development and regulatory approval of biologics (Investigational medicinal products and biosimilars), pre-clinical | 12 Hrs |

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| | and clinical development considerations; stability, safety, advertising, labelling and packing of biologics in EU | |
| 4 | **Vaccine regulations in India, US and European Union:** 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) | 12 Hrs |
| 5 | **Herbal Products:** Quality, safety and legislation for herbal products in India, USA and European Union. | 12 Hrs |

***REFERENCES***


1. FDA Regulatory Affairs: A Guide for Prescription Drugs, Medical Devices, and Biologics, Douglas J. Pisano , David S. Mantus ; Informa ,2008
2. Biological Drug Products: Development and Strategies; Wei Wang , Manmohan Singh ; wiley ,2013
3. Development of Vaccines: From Discovery to Clinical Testing; Manmohan Singh , Indresh K. Srivastava ;Wiley, 2011
4. www.who.int/biologicals/en
5. www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/
6. www.ihn-org.com
7. www.isbtweb.org
8. Guidelines on Similar Biologics: Regulatory Requirements for Marketing Authorization in India
9. www.cdsco.nic.in
10. www.ema.europa.eu › scientific guidelines › Biologicals
11. www.fda.gov/biologicsbloodVaccines/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

| ***Theory*** | | ***60 Hrs*** |
|---|---|---|
| 1. | **Medical Devices:** 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.<br>**IMDRF/GHTF:** Introduction, Organizational Structure, Purpose and Functions, Regulatory Guidelines, Working Groups, Summary Technical Document (STED), Global Medical Device Nomenclature (GMDN). | 12 Hrs |
| 2 | **Ethics:** Clinical Investigation of Medical Devices, Clinical Investigation Plan for Medical Devices, Good Clinical Practice for Clinical Investigation of medical devices (ISO 14155:2011)<br>**Quality: Quality System Regulations of Medical Devices:** ISO 13485, Quality Risk Management of Medical Devices: ISO 14971, Validation and Verification of Medical device, Adverse Event Reporting of Medical device | 12 Hrs |

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| 3 | **USA:** Introduction, Classification, Regulatory approval process for Medical Devices (510k) Premarket Notification, Pre-Market Approval (PMA), Investigational Device Exemption (IDE) and *In vitro* Diagnostics, Quality System Requirements 21 CFR Part 820, Labeling requirements 21 CFR Part 801, Post marketing surveillance of MD and Unique Device Identification (UDI). Basics of *In vitro* diagnostics, classification and approval process. | 12 Hrs |
| 4 | **European Union:** 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. | 12 Hrs |
| 5 | **ASEAN, China & Japan:** Medical Devices and IVDs, Regulatory registration procedures, Quality System requirements and clinical evaluation and investigation. IMDRF study groups and guidance documents. | 12 Hrs |

***REFERENCES***


1. FDA regulatory affairs: a guide for prescription drugs, medical devices, and biologics by Douglas J. Pisano, David Mantus.
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
5. Country Specific Guidelines from official websites.

## 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.

***Theory*** ***60 Hrs***

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|---|---|---|
| 1. | **Nutraceuticals:** Introduction, History of Food and Nutraceutical Regulations, Meaning of Nutraceuticals, Dietary Supplements, Functional Foods, Medical Foods, Scope and Opportunities in Nutraceutical Market. | 12 Hrs |
| 2 | **Global Aspects:** WHO guidelines on nutrition. NSF International: Its Role in the Dietary Supplements and Nutraceuticals Industries, NSF Certification, NSF Standards for Food And Dietary Supplements. Good Manufacturing Practices for Nutraceuticals. | 12 Hrs |
| 3 | **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. | 12 Hrs |
| 4 | **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 | 12 Hrs |

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| 5 | **European Union:** European Food Safety Authority (EFSA): Organization and Functions. EU Directives and regulations for manufacture and sale of nutraceuticals and dietary supplements. Nutrition labelling. European Regulation on Novel Foods and Novel Food Ingredients. Recommended Dietary Allowances (RDA) in Europe. | 12 Hrs |

***REFERENCES***


1. Regulation of Functional Foods and Nutraceuticals: A Global Perspective by Clare M. Hasler (Wiley Online Library)
2. Nutraceutical and Functional Food Regulations in the United States and Around the World by Debasis Bagchi (Academic Press, Elsevier)
3. http://www.who.int/publications/guidelines/nutrition/en/
4. http://www.europarl.europa.eu/RegData/etudes/STUD/2015/536324/IPOL_STU(2015)536324_EN.pdf
5. Handbook of Nutraceuticals by Yashwant Pathak (CRC Press)
6. Food Regulation: Law, Science, Policy and Practice by Neal D. Fortin (Wiley)
7. Country Specific Guidelines from official websites.

## REGULATORY AFFAIRS PRACTICAL - II
## (MRA 205P)

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

## PHARMACEUTICAL BIOTECHNOLOGY (MPB)

## MODERN PHARMACEUTICAL ANALYTICAL TECHNIQUES (MPB 101T)

***Scope***

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

***Objectives***

After completion of course student is able to know,

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

***THEORY*** ***60 Hrs***

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

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

b. **Spectroflourimetry:** Theory of Fluorescence, Factors affecting fluorescence, Quenchers, Instrumentation and Applications of fluorescence spectrophotometer.

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

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

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| 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 | **12 Hrs** |
| 4 | **Chromatography**: Principle, apparatus, instrumentation, chromatographic parameters, factors affecting resolution and applications of the following:<br>a) Paper chromatography b) Thin Layer chromatography<br>c) Ion exchange chromatography d) Column chromatography<br>e) Gas chromatography f) High Performance Liquid chromatography<br>g) Affinity chromatography | **12 Hrs** |
| 5 | a. **Electrophoresis**: Principle, Instrumentation, Working conditions, factors affecting separation and applications of the following:<br>a) Paper electrophoresis b) Gel electrophoresis c) Capillary electrophoresis d) Zone electrophoresis e) Moving boundary electrophoresis f) Iso electric focusing<br>b. **X ray Crystallography**: Production of X rays, Different X ray methods, Bragg's law, Rotating crystal technique, X ray powder diffration technique, Types of crystals and applications of X-ray diffraction. | **12 Hrs** |

***REFERENCES***


1. Spectrometric Identification of Organic compounds - Robert M Silverstein, Sixth edition, John Wiley & Sons.
2. Principles of Instrumental Analysis - Doglas A Skoog, F. James Holler, Timothy A. Nieman, 5th edition, Eastern press, Bangalore.
3. Instrumental methods of analysis – Willards, 7th edition, CBS publishers.
4. Practical Pharmaceutical Chemistry – Beckett and Stenlake, Vol II, 4th edition, CBS Publishers, New Delhi.
5. Organic Spectroscopy - William Kemp, 3rd edition, ELBS.
6. Quantitative Analysis of Drugs in Pharmaceutical formulation - P D Sethi, 3rd Edition, CBS Publishers, New Delhi.
7. Pharmaceutical Analysis- Modern methods – Part B - J W Munson, Volume 11, Marcel Dekker Series

## MICROBIAL AND CELLULAR BIOLOGY
## (MPB 102T)

***Scope***

This subject is designed to provide the advanced knowledge to the biotechnology students in invaluable areas of advanced microbiology which plays a crucial role in determining its future use and applications in medicine, drug discovery and in pharmaceutical industry**.**

***Objective***

At the completion of this course it is expected that the students will get an understanding about the following aspects;

- Importance of Microorganisms in Industry
- Central dogma of molecular biology
- Structure and function of cell and cell communication
- Cell culture technology and its applications in pharmaceutical industries.
- Microbial pathogenesis and correlating it to rational use of antimicrobial agents.

***THEORY*** ***60Hrs***

1. **Microbiology** 12 Hrs

   Introduction – Prokaryotes and Eukaryotes. Bacteria, fungi, actionomycetes and virus - structure, chemistry and morphology, cultural, physiological and reproductive features. Methods of isolation, cultivation and maintenance of pure cultures. Industrially important microorganisms - examples and applications

2 **Molecular Biology:** Structure of nucleus and chromosome, Nucleic acids and composition, structure and types of DNA and RNA. Central dogma of molecular biology: Replication, Transcription and translation. 12 Hrs

   **Gene regulation**

   Gene copy number, transcriptional control and translational control.

   **RNA processing**

   Modification and Maturation, RNA splicing, RNA editing, RNA amplification. Mutagenesis and repair mechanisms, types of mutants, application of mutagenesis in stain improvement, gene mapping of plasmids- types purification and application. Phage genetics, geneticorganization, phage mutation and lysogeny.

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| 3 | **Cell structure and function**<br>Cell organelles, cytoskeleton & cell movements, basic aspectsof cell regulation, bioenergetics and fuelling reactions of aerobics and anaerobics,secondary metabolism & its applications. Cell communication, cell cycle and apoptosis, mechanism of cell division. Celljunctions/adhesion and extra cellular matrix, germ cells and fertilization, histology – thelife and death of cells in tissues.<br><br>**Cell Cycle and Cytoskeleton**<br>Cell Division and its Regulation, G-Protein CoupledReceptors, Kinases, Nuclear receptors, Cytoskeleton & cell movements, IntermediateFilaments.<br><br>**Apoptosis and Oncogenes**<br>Programmed Cell Death, Tumor cells, carcinogens & repair.<br><br>**Differentiation and Developmental Biology**<br>Fertilization, Events of Fertilization, *In vitro* Fertilization, Embryonic Germ Cells, Stem Cells and its Application. | 12 Hrs |
| 4 | **Principles of microbial nutrition**<br>Physical and chemical environment for microbial growth, Stability and degeneration of microbial cultures.<br><br>**Growth of animal cells in culture**<br>General procedure for cell culture, Nutrient composition, Primary, established and transformed cell cultures, applications of cell cultures in pharmaceutical industry and research. Growth of viruses in cell culture propagation and enumeration. *In-vitro* screening techniques- cytotoxicity, anti-tumor, anti-viral assays. | 12 Hrs |
| 5 | **Microbial pathology**<br>Identifying the features of pathogenic bacteria, fungi and viruses. Mechanism of microbial pathogenicity, etiology and pathology of common microbial diseases and currently recommended therapies for common bacterial, fungal & viral infections. Mechanism of action of antimicrobial agents and possible sites of chemotherapy. | 12 Hrs |

***REFERENCES***


1. W.B. Hugo and A.D. Russel: Pharmaceutical Microbiology, Blackwell Scientific publications, Oxford London.
2. Prescott and Dunn, Industrial Microbiology, CBS Publishers & Distributors, Delhi.
3. Pelczar, Chan Kreig, Microbiology, Tata McGraw Hill edn.
4. David Freifelder, Molecular Biology, 2nd edition, Narosa Publishing House.
5. R. Ian Freshney, Culture of animal cells – A manual of Basic techniques, 6th edition, Wileys publication house.
6. David Baltimore,Molecular cell biology, W H Freeman & Co publishers.
7. Cell biology vol-I,II,III by Julio E.Cells
8. Bergeys manual of systematic bacteriology, Williams and Wilkins- A Waverly company.

## BIOPROCESS ENGINEERING AND TECHNOLOGY
## (MPB 103T)

***Scope***

This paper has been designed to provide the knowledge to the biotechnology students in invaluable areas of bioprocess technology to develop skills to modify, design and operate different types of fermenters, to understand and implement various fermentation procedures, to train students in scale up fermentation operations.

***Objective***

At the completion of this subject it is expected that students will be able to,

- Understand basics and design of fermentation technology
- Scale up and scale down processing of fermentation technology
- Bioprocessing of the industrially important microbial metabolites in industries and R & D organizations.
- Regulation governing the manufacturing of biological products
- Understand and conduct fermentation process kinetics.

***THEORY*** ***60 Hrs***

1. **Introduction to fermentation technology** 12 Hrs

   Basic principles of fermentation

   **Study of the design and operation of bioreactor**

   Ancillary parts and function, impeller design and agitation, power requirements on measurements and control of dissolved oxygen, carbon dioxide, temperature, pH and foam.

   **Types of bioreactor**

   CSTR, tower, airlift, bubble column, packed glass bead, hollow fiber, configuration and application

   **Computer control of fermentation process**

   System configuration and application

2 **Mass transfer** 12 Hrs

   Theory, diffusional resistance to oxygen requirements of microorganisms, measurements of mass transfer co- efficient and factor affecting them, effects of aeration and agitation on mass transfer, supply of air, air compressing, cleaning and sterilization of air and plenum ventilation, air sampling and testing standards for air purity.

**Rheology**

Rheological properties of fermentation system and their importance in bioprocessing.

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| 3 | **Scale up of fermentation process**<br>Principles, theoretical considerations, techniques used, media for fermentation, HTST sterilization, advantage and disadvantage, liquid sterilization.<br>**Cultivation and immobilized culture system**<br>Cultivation system - batch culture, continuous culture, synchronous cultures, fed batch culture. Graphical plot representing the above systems.<br>**Introduction to immobilization**<br>Techniques, immobilization of whole cell, immobilized culture system to prepare fine chemicals. Immobilization of enzymes and their applications in the industry. Reactors for immobilized systems and perspective of enzyme engineering. | 12 Hrs |
| 4 | **Scale down of fermentation process**<br>Theory, equipment design and operation, methods of filtration, solvent extraction, chromatographic separation, crystallization turbidity analysis and cell yield determination, metabolic response assay, enzymatic assay, bioautographic techniques and disruption of cells for product recovery.<br>**Isolation and screening**<br>Primary and secondary, maintenance of stockculture, strain improvement for increased yield. | 12 Hrs |
| 5 | **Bioprocessing of the industrially important microbial metabolites**<br>a) Organic solvents – Alcohol and Glycerol<br>b) Organic acids - Citric acids, Lactic acids,<br>c) Amino acids - Glutamic acids, Lysine, Cyclic AMP and GMP<br>d) Antibiotics - Penicillin, Streptomycin, Griseofulvin,<br>e) Vitamins - B12, Riboflavin and Vitamin C<br>Biosynthetic pathways for some secondary metabolites, microbial transformation of steroids and alkaloids<br>Regulation governing the manufacturing of biological products . | 12 Hrs |

***REFERENCES***


1. Peter Stanbury, Allan Whitaker, Stephen Hall, Principles of Fermentation technology, Elsevier stores.
2. L.E. Casida, Industrial Microbiology, John Wiley & sons Inc.
3. F.M. Asubel, Current protocols in molecular biology, volume I and II, John Wiley Publishers.
4. Biotol Board, Bioreactor design and product yield, Butterworth and Helhemann Publishers.
5. H. Patel, Industrial microbiology, Macmillan India Limited.

## ADVANCED PHARMACEUTICAL BIOTECHNOLOGY
## (MPB 104T)

***Scope***

This paper has been designed to provide the knowledge to the students to develop skills of advanced techniques of isolation and purification of enzymes, to enrich students with current status of development of vaccines and economic importance of biotechnology products.

***Objective***

At the completion of this subject it is expected that students will be able to

- Understand about the latest technology development in biotechnology technique, tools and their uses in drug and vaccine development.
- Identify appropriate sources of enzymes.
- Understand and perform genetic engineering techniques in gene manipulation, r-DNA technology and gene amplification.
- Understand the overview of pharmacogenomics.
- Learn the regulatory approval process and key regulatory agencies for new drugs, biologics, devices, and drug-device combinations.

***THEORY*** ***60 Hrs***

1. **Enzyme Technology** 12 Hrs

Classification, general properties of enzymes, dynamics of enzymatic activity,sources of enzymes, extraction and purification, pharmaceutical,therapeutic and clinical application. Production of amyloglucosidase, glucose isomerase,amylase and trypsin.

2 **Genetic Engineering** 12 Hrs

Techniques of gene manipulation, cloning strategies,procedures, cloning vectors expression vectors, recombinant selection andscreening, expression in E.coli and yeast.

Site directed mutagenesis, polymerase chain reaction, and analysis of DNAsequences.

Gene library and cDNA

Applications of the above technique in the production of,

- Regulatory proteins - Interferon, Interleukins
- Blood products - Erythropoietin
- Vaccines - Hepatitis-B
- Hormones - Insulin

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| 3 | **Therapeutic peptides**<br>Study on controlled and site specified delivery of therapeutic peptides and proteins through various routes of administration.<br>**Transgenic animals**<br>Production of useful proteins in transgenic animals and gene therapy.<br>**Human Genome**<br>The human genome project-a brief study, Human chromosome – Structure and classification, chromosomal abnormalities – Syndromes | 12 Hrs |
| 4 | **Signal transduction**<br>Introduction, cell signaling pathways, Ion channels, Sensors and effectors, ON and OFF mechanisms, Spatial and temporal aspects of signaling, cellular process, development, cell cycle and proliferation, neuronal signaling, cell stress, inflammatory responses and cell death, signaling defects and diseases.<br>**Oncogenes**<br>Introduction, definition, various oncogenes and their proteins. | 12 Hrs |
| 5 | **Microbial Biotransformation**<br>Biotransformation for the synthesis of chiral drugs and steroids.<br>**Microbial Biodegradation**<br>Biodegradation of xenobiotics, chemical and industrial wastes,<br>Production of single-cell protein,<br>Applications of microbes in environmental monitoring.<br>**Biosensors**<br>Definition, characteristics of ideal biosensors, types of biosensors, biological recognition elements, transducers, application of biosensors. | 12 Hrs |

***REFERENCES***


1. Biotechnology-The biological principles: MD Trevan, S Boffey, KH Goulding and P.F. Stanbury.
2. Immobilization of cells and enzymes: HosevearKennadycabral& Bicker staff
3. Principles of Gene Manipulating: RW Old and S.B.Primrose.
4. Molecular Cell Biology: Harvey Lodish, David Baltimore, Arnold Berk, S LawenceZipursky, Paul Matsudaira, James Darnell.
5. Modern Biotechnology: S.B Primrose

6. Gene transfer and expression protocols-methods in Molecular Biology, vol. VII, Edit E.T. Murray
7. Current protocols in Molecular Biology, Vo1.I & II:F.M. Asubel, John wiley Publishers
8. Current protocols in cellular biology, Vo1.1 & II John wiley publishers.
9. Principles of human genetics; by Curt Stern, published by W.H. Freeman.

## PHARMACEUTICAL BIOTECHNOLOGY PRACTICAL - I
## (MPB 105P)

1. Analysis of Pharmacopoeial compounds and their formulations by UV Vis spectrophotometer
2. Simultaneous estimation of multi component containing formulations by UV spectrophotometry
3. Experiments based on HPLC
4. Experiments based on Gas Chromatography
5. Estimation of riboflavin/quinine sulphate by fluorimetry
6. Estimation of sodium/potassium by flame photometry
7. Isolation and Purification of microorganism from the soil
8. Microbial contamination of Water and biochemical parameters.
9. Determination of Minimum Inhibitory concentration by gradient plate technique and serial dilution method.
10. UV- survival curve and Dark repair
11. Sterility test for pharmaceutical preparations
12. Sub culturing of cells and cytotoxicity assays.
13. Construction of growth curve and determination of specific growth rate and doubling time
14. Fermentation process of alcohol and wine production
15. Fermentation of vitamins and antibiotics
16. Whole cell immobilization engineering
17. Thermal death kinetics of bacteria
18. Replica plating
19. Bio-autography.
20. Isolation and estimation of DNA
21. Isolation and estimation of RNA
22. Isolation of plasmids
23. Agarose gel electrophoresis.
24. Transformation techniques
25. SDS – polyacrylamide gel electrophoresis for proteins
26. Polymerase chain reaction technique.

## PROTEINS AND PROTEIN FORMULATIONS
## (MPB 201T)

***Scope***

This course is designed to impart knowledge and skills necessary for knowing fundamental aspects of proteins and their formulations is a part of drug research and development process. Basic theoretical discussions of the principles of more integrated and coherent use of information for protein formulation and design are provided to help the students to clarify the various biological concepts of protein.

***Objective***

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

- Various methods of purification of proteins
- Peptides in drug development
- Protein identification and characterization
- Protein based formulations
- Sequencing proteins

***THEORY*** ***60 Hrs***

1. **Protein engineering** — 12 Hrs

   Concepts for protein engineering. Isolation and purification of proteins, Stability and activity based approaches of protein engineering, Chemical and Physical Considerations in Protein and Peptide Stability, Different methods for protein engineering, gene shuffling, and direct evolution.

2. **Peptidomimetics** — 12 Hrs

   Introduction, classification; Conformationally restricted peptides, design, pseudopeptides, peptidomimetics and transition state analogs; Biologically active template; Amino acid replacements; Peptidomimetics and rational drug design; CADD techniques in peptidomimetics; Development of non peptide peptidomimetics.

3. **Proteomics** — 12 Hrs

   Protein identification and characterization: Methods/strategies, protein identification, de novo protein characterization, Isotope labelling, N- and C-terminal tags.

**2-Dimensional gel electrophoresis**

Methods including immobilized pH gradients (IPGs), resolution, reproducibility and image analysis, future developments

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| 4 | **Protein formulation**<br>Different strategies used in the formulation of DNA and proteins, Analytical and biophysical parameters of proteins and DNA in pre-formulation, Liposomes, Neon-spears, Neon-particulate system, PEGylation, Biological Activity, Biophysical Characterization Techniques, Forced degradation studies of protein. | 12 Hrs |
| 5 | **Methods of protein sequencing**<br>Various methods of protein sequencing, characterisation, Edman degradation, Tryptic and/or Chymotryptic Peptide Mapping. | 12 Hrs |

***REFERENCES***


1. H. Lodhishet. Al. Molecular Cell Biology, W. H. Freeman and Company
2. Protein Purification – Hand Book, Amersham pharmacia biotech
3. EngelbertBuxbaum, Fundamentals of Protein Structure and Function, Springer Science
4. Sheldon J. Park, Jennifer R. Cochran, Protein Engineering and Design, CRC press.
5. Robert K. Skopes. Protein purification, principle and practice, springer link.
6. David Whitford, Proteins-Structure and Function, John Wiley & Sons Ltd.
7. James Swarbrick, Protein Formulation and Delivery Informa Healthcare USA,Inc.
8. Rodney Pearlman, Y. John Wang Formulation, Characterization, and Stability of Protein Drugs, Kluwer Academic Publishers.

## IMMUNOTECHNOLOGY
## (MPB 202T)

***Scope***

This course is designed to impart knowledge on production and engineering of antibodies, the application of antigens, the design of (recombinant) vaccines, strategies for immune intervention, etc. The Immunotechnology - based techniques will be used for therapeutics and diagnostics, industries in the production, quality control and quality assurance, and in R&D.

***Objective***

After this course, the students will be able to:-

- Understand the techniques like immunodiagnostic tests,
- Characterization of lymphocytes, purification of antigens and antibody, etc.
- Access health problems with immunological background;
- Develop approaches for the immune intervention of diseases

***THEORY*** ***60 Hrs***

1. **Fundamental aspects of immunology** 12 Hrs

   Introduction, cells and organs of the immune system, cellular basis of Immune response, primary and secondary lymphoid organs, antigen antibody and their structure.

   Types of immune responses, anatomy of immune response.

   Overview of innate and adaptive Immunity.

   **Humoral Immunity**

   B – Lymphocytes and their activation. Structure and function of immunoglobulins, idiotypes and anti idiotypic antibodies.

   **Cell mediated Immunity**

   Thymus derived lymphocytes (T cells) – their ontogeny and types, MHC complex, antigen presenting cells (APC), mechanisms of T cell activation, macrophages, dendritic cells, langerhans cells, mechanism of phagocytosis

2 **Immune Regulation and Tolerance** 12 Hrs

   Complement activation and types and their biological functions, cytokines and their role in immune response.

   **Hypersensitivity**

   Hypersensitivity Types I-IV, Hypersensitivity reactions and treatment

   **Autoimmune diseases**

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| 3 | **Vaccine technology**<br>Vaccine and their types, conventional vaccines, novel methods for vaccine production, antiidiotype vaccine, DNA vaccine, genetically engineered vaccine, iscoms, synthetic peptides, and immunodiagnostics.<br>**Stem cell technology**<br>Stem cell technology and applications to immunology | 12 Hrs |
| 4 | **Hybridoma Technology**<br>Hybridoma techniques – fusion methods for myeloma cells and B-Lymphocytes, selection and screening techniques. Production and purification of monoclonal antibodies and their applications in Pharmaceutical industry. | 12 Hrs |
| 5 | **Immunological Disorder**<br>Autoimmune disorders and types, pathogenic mechanisms, treatment, experimental models of auto immune diseases, primary and secondary immunodeficiency disorders.<br>**Immunodiagnosis**<br>Antigen antibody interaction – Precipitation reaction, Agglutination reactions, Principles and applications of ELISA, Radio Immuno Assay, Western blot analysis, immune-electrophoresis, immuno fluorescence, chemiluminescence assay, complement fixation reaction. | 12 Hrs |

***REFERENCES***


1. J. Kubey, Immunology – an Introduction.
2. S.C. Rastogi, Immunodiagonstics, New Age International.
3. Ashim Chakravarthy, Immunology and Immunotechnology, Oxford University Press.
4. E. Benjamini, Molecular Immunology.

## BIOINFORMATICS AND COMPUTATIONAL BIOTECHNOLOGY (MPB 203T)

***Scope***

This paper has been designed to provide the advanced knowledge to the biotechnology students in invaluable areas of advanced bioinformatics which plays a crucial role in determining its future use and applications in medicine, drug discovery and in pharmaceutical industry.

***Objectives***

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

- Use of computers in developing a new drugs
- Biological concepts for bioinformatics
- Proteins and their diversity
- Various gene finding methods
- Searching the biological databases
- Target searching
- Various methods of drug designing

***THEORY*** ***60 Hrs***

1. **Introduction to Bioinformatics** — 12 Hrs

   Definition and History of Bioinformatics, Internet and Bioinformatics, Introduction to Data Mining, Applications of Data Mining to Bioinformatics,

   **Biological Database**

   Protein and nucleic acid databases. Structural data bases. Collecting and storing the sequence and Applications of Bioinformatics.

2 **Sequence analysis** — 12 Hrs

   Sequence alignment, pair wise alignment techniques, multiple sequence analysis, multiple sequence alignment; Flexible sequence similarity searching with the FAST3 program package, the use of CLUSTAL W and CLUSTAL X for the multiple sequence alignment. Tools used for sequence analysis.

3 **Protein informatics** — 12 Hrs

   Introduction; Force field methods; Energy, buried and exposed residues, side chains and neighbours; Fixed regions, hydrogen bonds, mapping properties onto surfaces; Fitting monomers, R &

S fit of conformers, assigning secondary structures; Sequence alignment-methods, evaluation, scoring; Protein completion, backbone construction and side chain addition; Small peptide methodology, software accessibility, building peptides; Protein displays; Substructure manipulations, annealing.

**Protein structure prediction**

Protein folding and model generation; Secondary structure prediction, analyzing secondary structures; Protein loop searching, loop generating methods, loop analysis; Homology modeling, concepts of homology modeling, potential applications, description, methodology, homologous sequence identification; Align structures, align model sequence; Construction of variable and conserved regions, threading techniques, Topology fingerprint approach for prediction, evaluation of alternate models; Structure prediction on a mystery sequence, structure aided sequence techniques of structure prediction, structural profiles, alignment algorithms, mutation tables, prediction, validation, sequence based methods of structure prediction, prediction using inverse folding, fold prediction; Significance analysis, scoring techniques, sequence- sequence scoring.

**Docking**

Docking problems, methods for protein- ligand docking, validation studies and applications; Screening small molecule databases, docking of combinatorial libraries, input data, analyzing docking results.

4 **Diversity of Genomes** 12 Hrs

Prokaryotic and Eukaryotic Gene Families. Genome Analysis: Introduction, Gene prediction methods, Gene mapping and applications- Genetic and Physical Mapping, Integrated map, Sequence assembly and gene expression.

**Completed Genomes**

Bacterium, Nematode, Plant and Human

**Evolution of Genomes**

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

**Phylogenetic analysis**

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

| | | |
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| 5 | **Target searching and Drug Designing**<br>Target and lead, timeline for drug development, target discovery, target modulators, *In-silico* gene expression, microarray, and lead discovery, libraries of ligands, active site analysis, and prediction of drug quality. | 12 Hrs |

***REFERENCES***


1. David W. Mount, Bioinformatics Sequence and Genome Analysis, CBS Publishers and Distributors
2. S. C. Rastogiet. al. Bioinformatics- Concepts Skill and Applications, CBS Publishers and Distributors
3. T. E. Creighton, Protein Structure and Molecular Properties, W. H.Freeman and Company
4. Andreas D. Baxevanis, B. F. Francis Ouellette, Bioinformatics; A Practical Guide to the Analysis of Genes and Proteins, John Wiley & Sons, Inc.
5. Arthur M. Lesk, Introduction to Bioinformatics, Oxford University Press.
6. Shui Qing Ye. Bioinformatics: A Practical Approach, Chapman & Hall/CRC.
7. David Posada, Bioinformatics for DNA Sequence Analysis, Humana press.
8. Lesk, A.M. Introduction to Bioinformatics. Oxford University Press.
9. Letovsky, S.I. Bioinformatics. Kluwer Academic Publishers.
10. Baldi, P. and Brunak, S. Bioinformatics. The MIT Press.

## BIOLOGICAL EVALUATION OF DRUG THERAPY
## (MPB 204T)

***Scope***

This paper has been designed to provide the knowledge to the biotechnology students to understand the importance of biological and evaluation of drug therapy of biological medicines.

***Objective***

At the completion of this subject it is expected that students will be able to,

- Understand about the general concept of standardization of biological.
- Understand the importance of transgenic animals and knockout animals.
- Understand the biological medicines in development of various diseases.
- Learn the biological evaluation of drugs *in vitro* and *in vivo*

***THEORY*** ***60 Hrs***

1. **Biological Standardization** 12 Hrs

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

**Preclinical drug evaluation**

Preclinical drug evaluation of its biological activity, potency and toxicity-Toxicity test in animals including acute, sub-acute and chronic toxicity, ED50 and LD50 determination, special toxicity test like teratogenecity and mutagenecity.

**Guidelines for toxicity studies**

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

2 **Pyrogens** 12 Hrs

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

**Microbiological assay**

Assay of antibiotics and vitamins.

**Biological evaluation of drugs**

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

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| 3 | **Biologic Medicines in Development for various diseases - By Therapeutic Category**<br>• Genetic Disorders<br>• Eye related Disorders<br>• Digestive Disorders<br>• Diabetes/Related Conditions<br>• Cardiovascular Disease<br>• Cancer/Related Conditions<br>• Blood Disorders<br>• Autoimmune Disorders<br>• Infectious Diseases<br>• Neurologic Disorders<br>• Skin Diseases<br>• Organe Transplantation<br><br>**Biologic Medicines in Development for various diseases – by Product Category**<br>• Antisense<br>• Vaccines<br>• Recombinant Hormones/Proteins<br>• Monoclonal Antibodies (mAb)<br>• Interferons<br>• Growth Factors<br>• Gene Therapy<br>• RNA Interference | 12 Hrs |
| 4 | **Regulatory aspects : drugs, biologics and medical devices**<br>An introduction to the regulations and documents necessary for approval of a medical product.<br>**Regulatory consideration**<br>Regulatory consideration for pre-clinical testing and clinical testing of drugs, biologics and medical devices.<br>New Drug Applications for Global Pharmaceutical Product Approvals | 12 Hrs |
| 5 | **Bioavailability**<br>Objectives and consideration in bio-availability studies of Biopharmaceuticals, Concept of equivalents, Measurements of bio-availability. | 12 Hrs |

Determination of the rate of absorption, Bioequivalence and its importance, Regulatory aspects of bio-availability and bioequivalence studies for conventional dosage forms and controlled drug delivery systems of Biopharmaceuticals.

**Pharmacokinetics**

Pharmacokinetics:- Basic consideration, Pharmacokinetic models, Application of Pharmacokinetics in new drug development of Biopharmaceuticals and designing of dosage forms and Novel drug delivery systems of Biopharmaceuticals.

***REFERENCES***


1. Perkins F.T., Hennessen W. Standardization and Control of Biologicals Produced by Recombinant DNA Technology, International Association of Biological Standardization
2. J.H. Burn., Biological Standardization, Oxford University Press
3. Drug Discovery and Evaluation in Pharmacology assay: Vogel
4. Chow, Shein, Ching, Design and analysis of animal studies in pharmaceutical development,
5. Nodine and Siegler, Animal and Clinical pharmacologic Techniques in Drug Evaluation.
6. Screening methods in pharmacology (vol I & II), R.A. Turner.

## PHARMACEUTICAL BIOTECHNOLOGY PRACTICAL - II
## (MPB 205P)

1. Protein identification
2. Protein characterization
3. Protein biochemistry
4. Recombinant DNA Technology
5. Protein expression
6. Protein formulations
7. Database searching
8. Sequence analysis methods
9. Protein structure prediction
10. Gene annotation methods
11. Phylogenetic analysis
12. Protein, DNA binding studies
13. Preparation of DNA for PCR applications – Isolation, Purity and Quantification
14. Introduction to PCR – working of PCR, Programming.
15. Introduction to RT-PCR – working, programming.
16. Primer design using softwares.
17. Gene DNA amplification by random / specific primers.
18. Southern Hybridization
19. Western Blotting
20. Gene transformation

## PHARMACY PRACTICE (MPP)

## CLINICAL PHARMACY PRACTICE (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

***THEORY*** ***60 Hrs***

| | | |
|---|---|---|
| 1. | **Introduction to Clinical Pharmacy:** Definition, evolution and scope of clinical pharmacy, International and national scenario of clinical pharmacy practice, Pharmaceutical care<br>**Clinical Pharmacy Services:** Ward round participation, Drug therapy review (Drug therapy monitoring including medication order review, chart endorsement, clinical review and pharmacist interventions) | 12 Hrs |
| 2 | **Clinical Pharmacy Services:** Patient medication history interview, Basic concept of medicine and poison information services, Basic concept of pharmacovigilance, Hemovigilance, Materiovigilance and AEFI, Patient medication counselling, Drug utilisation evaluation, Documentation of clinical pharmacy services**,** Quality assurance of clinical pharmacy services. | 12 Hrs |
| 3 | **Patient Data Analysis:**<br>***Patient Data & Practice Skills****:* Patient's case history - its structure and significances in drug therapy management, Common medical abbreviations and terminologies used in clinical practice*,* Communication skills: verbal and non-verbal communications, its applications in patient care services. | 12 Hrs |

***Lab Data Interpretation:*** Hematological tests, Renal function tests, Liver function tests

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| 4 | **Lab Data Interpretation:** Tests associated with cardiac disorders, Pulmonary function tests, Thyroid function tests, Fluid and electrolyte balance, Microbiological culture sensitivity tests | 12 Hrs |
| 5 | **Medicines & Poison Information Services**<br>***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.<br>***Poison Information Service:*** Definition, need, organization and functions of poison information centre. | 12 Hrs |

***REFERENCES***


1. A Textbook of Clinical Pharmacy Practice – Essential concepts and skills – Parthasarathi G, Karin Nyfort-Hansen and Milap Nahata
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)

***THEORY*** ***60 Hrs***

**Etiopathogenesis and pharmacotherapy of diseases associated with following systems**

| | | |
|---|---|---|
| 1. | **Cardiovascular system:** Hypertension, Congestive cardiac failure, Acute coronary syndrome, Arrhythmias, Hyperlipidemias. | 12 Hrs |
| 2 | **Respiratory system:** Asthma, Chronic obstructive airways disease, Drug induced pulmonary diseases<br>**Endocrine system:** Diabetes, Thyroid diseases | 12 Hrs |
| 3 | **Gastrointestinal system:** Peptic ulcer diseases, Reflux esophagitis, Inflammatory bowel diseases, Jaundice & hepatitis | 12 Hrs |
| 4 | **Gastrointestinal system:** Cirrhosis, Diarrhea and Constipation, Drug-induced liver disease | 12 Hrs |
| | **Hematological diseases:** Anemia, Deep vein thrombosis, Drug induced hematological disorders | |

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| 5 | **Bone and joint disorders:** Rheumatoid arthritis, Osteoarthritis, Gout, Osteoporosis | 12 Hrs |

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

**Ophthalmology:** Conjunctivitis, Glaucoma

***REFERENCES***


1. Roger and Walker. Clinical Pharmacy and Therapeutics - Churchill Livingstone publication
2. Joseph T. Dipiro et al. Pharmacotherapy: A Pathophysiologic Approach- Appleton & Lange
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
6. Chisholm- Burns Wells Schwinghammer Malone and Joseph P Dipiro. Pharmacotherapy Principles and practice-– McGraw Hill Publication
7. Carol Mattson Porth. Principles of Pathophysiology- Lippincott Williams and Wilkins
8. Harrison's. Principles of Internal Medicine - McGraw Hill
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

***THEORY*** ***60 Hrs***

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|---|---|---|
| 1. | **Introduction to Hospitals** – Definition, classification, organizational structure<br>**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<br>**Hospital Drug Policy:** Pharmacy & Therapeutics Committee, Infection Control committee, Research & Ethics Committee, Management of Medicines as per NABH | 12 Hrs |
| 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 Hrs |
| 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.<br>**Community Pharmacy Practice:** Definition, roles & responsibilities of community pharmacists, and their relationship with other health care providers. | 12 Hrs |

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| | **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. | |
| 4 | **Prescription** – Legal requirements & interpretation, prescription related problems<br>**Responding to symptoms of minor ailments:** Head ache, pyrexia, menstrual pains, food and drug allergy,<br>**OTC medication:** Rational use of over the counter medications<br>Medication counseling and use of patient information leaflets<br>Medication adherence – Definition, factors influencing adherence behavior, strategies to improve medication adherence<br>Patient referrals to the doctors<br>ADR monitoring in community pharmacies | 12 Hrs |
| 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<br>**National Health Programs**- Role of Community Pharmacist in Malaria and TB control programs<br>**Home Medicines review program** – Definition, objectives, Guidelines, method and outcomes<br>**Research in community pharmacy Practice** | 12 Hrs |

***REFERENCES***


1. Hospital Pharmacy - Hassan WE. Lea and Febiger publication.
2. Textbook of hospital pharmacy - Allwood MC and Blackwell.
3. Avery's Drug Treatment, Adis International Limited.
4. Community Pharmacy Practice – Ramesh Adepu, BSP Publishers, Hyderabad
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

***THEORY*** ***60 Hrs***

1. **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. — 12 Hrs

2. **Types and Designs used in Clinical Research:** Planning and execution of clinical trials, Various Phases of clinical trials, Bioavailability and Bioequivalence studies, Randomization techniques (Simple randomization, restricted randomization, blocking method and stratification), Types of research designs based on Controlling Method (Experimental, Quasi experimental, and Observational methods) Time Sequences (Prospective and Retrospective), Sampling methods (Cohort study, case Control study and cross sectional study), Health outcome measures (Clinical & Physiological, Humanistic and economic)
**Clinical Trial Study team:** Roles and responsibilities of: Investigator, Study Coordinator, Sponsor, Monitor, Contract Research Organization. — 12 Hrs

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| 3 | **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<br>**Clinical Trial Start up activities:** Site Feasibility Studies**,** Site/Investigator selection**,** Pre-study visit**,** Investigator meeting**,** Clinical trial agreement execution**,** Ethics committee document preparation and submission | 12 Hrs |
| 4 | **Investigational Product:** Procurement and Storage of investigation product<br>**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<br>**Clinical Trial Monitoring and Close out:**<br>***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<br>**Close-Out visit**: Study related documents collection, Archival requirement, Investigational Product reconciliation and destruction, Close-Out visit report. | 12 Hrs |
| 5 | **Quality Assurance and Quality Control in Clinical Trials:** Types of audits, Audit criteria, Audit process**,** Responsibilities of stakeholders in audit process**,** Audit follow-up and documentation, Audit resolution and Preparing for FDA inspections, Fraud and misconduct management<br>**Data Management**<br>***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<br>***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 Hrs |

***REFERENCES***


1. Principles and practice of pharmaceutical medicine, Second edition. Authors:Lionel. D. Edward, Aadrew.J.Flether Anthony W Fos , Peter D Sloaier Publisher:Wiley;
2. Handbook of clinical research. Julia Lloyd and Ann Raven Ed. Churchill Livingstone
3. Principles of Clinical Research edited by Giovanna di Ignazio, Di Giovanna and Haynes.
4. Central Drugs Standard Control Organization. Good Clinical Practices-Guidelines for Clinical Trials on Pharmaceutical Products in India. New Delhi: Ministry of Health.
5. International Conference on Harmonisation of Technical requirements for registration of Pharmaceuticals for human use. ICH Harmonised Tripartite Guideline. Guideline for Good Clinical Practice.E6; May 1996.
6. Ethical Guidelines for Biomedical Research on Human Subjects. Indian Council of Medical Research, New Delhi.
7. Textbook of Clinical Trials edited by David Machin, Simon Day and Sylvan Green, John Wiley and Sons.
8. Clinical Data Management edited by R K Rondels, S A Varley, C F Webbs. Second Edition, Jan 2000, Wiley Publications.
9. Goodman & Gilman: JG Hardman, LE Limbard, McGraw Hill Publications.
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

***THEORY*** ***60 Hrs***

| | | |
|---|---|---|
| 1. | **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. | 12 Hrs |
| 2 | **Concepts in QUM**<br>***Evidence based medicine:*** Definition, concept of evidence based medicine, Approach and practice of evidence based medicine in clinical settings<br>***Essential drugs:*** Definition, need, concept of essential drug, National essential drug policy and list<br>***Rational drug use:*** Definition, concept and need for rational drug use, Rational drug prescribing, Role of pharmacist in rational drug use. | 12 Hrs |
| 3 | **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.<br>**QUM in special population:** Pediatric prescribing, Geriatric prescribing, Prescribing in pregnancy and lactation, Prescribing in immune compromised and organ failure patients. | 12 Hrs |

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|---|---|---|
| 4 | **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. | 12 Hrs |
| 5 | **Medication errors:** Definition, categorization and causes of medication errors, Detection and prevention of medication errors, Role of pharmacist in monitoring and management of medication errors<br>**Pharmacovigilance:** Definition, aims and need for pharmacovigilance, Types, predisposing factors and mechanism of adverse drug reactions (ADRs), Detection, reporting and monitoring of ADRs, Causality assessment of ADRs, Management of ADRs, Role of pharmacist in pharmacovigilance. | 12 Hrs |

***REFERENCES:***


1. A Textbook of Clinical Pharmacy Practice – Essential concepts and skills – Parthasarathi G, Karin Nyfort-Hansen and Milap Nahata
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
6. Online:
   - http://medicinesaustralia.com.au/files/2012/05/MA_QUM_External_Reduced.pdf
   - http://curriculum.racgp.org.au/statements/quality-use-of-medicines/
   - http://www.rug.nl/research/portal/files/14051541/Chapter_2.pdf
7. 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)

***THEORY*** ***60 Hrs***

| | | |
|---|---|---|
| 1. | **Nervous system:** Epilepsy, Parkinson's disease, Stroke, Headache, Alzheimer's disease, Neuralgias and Pain pathways and Pain management. | 12 Hrs |
| 2 | **Psychiatric disorders:** Schizophrenia, Depression, Anxiety disorders, Sleep disorders, Drug induced psychiatric disorders<br>**Renal system:** Acute renal failure, Chronic renal failure, Renal dialysis, Drug induced renal disease | 12 Hrs |
| 3 | **Infectious diseases:** General guidelines for the rational use of antibiotics and surgical prophylaxis, Urinary tract infections, Respiratory tract infections, Gastroenteritis, Tuberculosis, Malaria, Bacterial endocarditis, Septicemia. | 12 Hrs |
| 4 | **Infectious diseases:** Meningitis, HIV and opportunistic infections, Rheumatic fever, Dengue fever, H1N1, Helmenthiasis, Fungal infections<br>**Gynecological disorders:** Dysmenorrhea, Hormone replacement therapy. | 12 Hrs |

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| 5 | **Oncology:** General principles of cancer chemotherapy, pharmacotherapy of breast cancer, lung cancer, head & neck cancer, hematological malignancies, Management of nausea and vomiting, Palliative care | 12 Hrs |

***REFERENCES***


1. Roger and Walker. Clinical Pharmacy and Therapeutics - Churchill Livingstone publication.
2. Joseph T. Dipiro et al. Pharmacotherapy: A Pathophysiologic Approach- Appleton & Lange
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
6. Chisholm- Burns Wells Schwinghammer Malone and Joseph P Dipiro. Pharmacotherapy Principles and practice-– McGraw Hill Publication
7. Carol Mattson Porth. Principles of Pathophysiology- Lippincott Williams and Wilkins
8. Harrison's. Principles of Internal Medicine - McGraw Hill
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

***THEORY*** ***60 Hrs***

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 — 12 Hrs

   **Designing of dosage regimens:** Determination of dose and dosing intervals, Conversion from intravenous to oral dosing, Nomograms and Tabulations in designing dosage regimen.

| | | |
|---|---|---|
| 2 | **Pharmacokinetics of Drug Interaction:** Pharmacokinetic drug interactions**,** Inhibition and Induction of Drug metabolism**,** Inhibition of Biliary Excretion<br>**Pharmacogenetics:** Genetic polymorphism in Drug metabolism: Cytochrome P-450 Isoenzymes, Genetic Polymorphism in Drug Transport and Drug Targets, Pharmacogenetics and Pharmacokinetic / Pharmacodynamic considerations<br>**Introduction to Pharmacometrics:** Introduction to Bayesian Theory, Adaptive method or Dosing with feedback, Analysis of Population pharmacokinetic Data. | 12 Hrs |
| 3 | **Non Linier Mixed Effects Modelling:** The Structural or Base Model, Modeling Random Effects, Modeling Covariate Relationships, Mixture Model, Estimation Methods, Model Building Techniques, Covariate Screening Methods, Testing the model assumptions, Precision of the parameter estimates and confidence intervals, Model misspecification and violation of the model assumptions, Model Validation, Simulation of dosing regimens and dosing recommendations, Pharmacometrics software. | 12 Hrs |
| 4 | **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. | 12 Hrs |
| 5 | **Therapeutic Drug monitoring:** Introduction, Individualization of drug dosage regimen (Variability – Genetic, age, weight, disease and Interacting drugs), Indications for TDM, Protocol for TDM, Pharmacokinetic/Pharmacodynamic Correlation in drug therapy, TDM of drugs used in the following conditions: Cardiovascular disease: Digoxin, Lidocaine, Amiodarone**;** Seizure disorders: Phenytoin, Carbamazepine, Sodium Valproate**;** Psychiatric conditions: Lithium, Fluoxetine, Amitriptyline; Organ transplantations: Cyclosporine**;** Cytotoxic Agents: Methotrexate, 5-FU, Cisplatin; Antibiotics: Vancomycin, Gentamicin, Meropenem. | 12 Hrs |

***REFERENCES***


1. Leon Shargel, Susanna Wu-Pong, Andrew Yu. Applied Biopharmaceutics & Pharmacokinetics. New York: Mc Graw Hill.
2. Peter L. Bonate. Pharmacokinetic - Pharmacodynamic Modeling and Simulation. Springer Publications.
3. Michael E. Burton, Leslie M. Shaw, Jerome J. Schentag, William E.Evans. Applied Pharmacokinetics & Pharmacodynamics: Principles of Therapeutic Drug Monitoring. lippincott Williams & Wilkins.
4. Steven How-Yan Wong, Irving Sunshine. Handbook of Analytical Therapeutic Drug Monitoring and Toxicology. CRC Press, USA.
5. Soraya Dhillon, Andrzej Kostrzewski. Clinical pharmacokinetics. 1st edition. London: Pharmaceutical Press.
6. Joseph T.Dipiro, William J.Spruill, William E.Wade, Robert A.Blouin and Jane M.Pruemer .Concepts in Clinical Pharmacokinetics. American Society of Health-System Pharmacists, USA.
7. Malcolm Rowland, Thomas N. Tozer .Clinical Pharmacokinetics and pharmacodynamics: concepts and applications. lippincott Williams & Wilkins, USA.
8. Evans, Schentag, Jusko. Applied pharmacokinetics. American Society of Health system Pharmacists, USA.
9. Michael E. Winter. Basic Clinical Pharmacokinetics. lippincott Williams & Wilkins, USA.
10. Milo Gibaldi. Biopharmaceutics and Clinical Pharmacokinetics. Pharma Book Syndicate, USA.
11. Dhillon and Kostrzewski. Clinical pharmacokinetics. Pharmaceutical Press, London.
12. John E .Murphy. Clinical Pharmacokinetics. 5th edition. US: American Society of Health- System Pharmacist, 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.

***THEORY*** ***60 Hrs***

1. **Introduction to Pharmacoepidemiology**: Definition, Scope, Need, Aims & Applications; Outcome measurement: Outcome measures, Drug use measures: Monetary units, Number of prescriptions, units of drug dispensed, defined daily doses, prescribed daily doses, Diagnosis and Therapy surveys, Prevalence, Incidence rate, Monetary units, number of prescriptions, unit of drugs dispensed, defined daily doses and prescribed daily doses, medications adherence measurements. **Concept of risk:** Measurement of risk, Attributable risk and relative risk, Time- risk relationship and odds ratio — 12 Hrs

2. **Pharmacoepidemiological Methods**: Qualitative models: Drug Utilization Review; Quantitative models: case reports, case series, Cross sectional studies, Cohort and case control studies, Calculation of Odds' ratio, Meta analysis models, Drug effects study in populations: Spontaneous reporting, Prescription event — 12 Hrs

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| | monitoring, Post marketing surveillance, Record linkage systems, Applications of Pharmacoepidemiology | |
| 3 | **Introduction to Pharmacoeconomics:** Definition, history of Pharmacoeconomics, Need of Pharmacoeconomic studies in Indian healthcare system.<br>**Cost categorization and resources for cost estimation:** Direct costs. Indirect costs. Intangible costs.<br>**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. | 12 Hrs |
| 4 | **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). | 12 Hrs |
| 5 | **Definition, Steps involved, Applications, Advantages and disadvantages of the following:**<br>**Health related quality of life (HRQOL):** Definition, Need for measurement of HRQOL, Common HRQOL measures.<br>**Definition, Steps involved, Applications of the following:** Decision Analysis and Decision tree, Sensitivity analysis, Markov Modeling, Software used in pharmacoeconomic analysis, Applications of Pharmacoeconomics. | 12 Hrs |

***REFERENCES***


1. Rascati K L. Essentials of Pharmacoeconomics, Woulters Kluwer Lippincott Williams & Wilkins, Philadelphia.
2. Thomas E Getzen. Health economics. Fundamentals and Flow of Funds. John Wiley & Sons, USA.
3. Andrew Briggs, Karl Claxton, Mark Sculpher. Decision Modelling for Health Economic Evaluation, Oxford University Press, London.
4. Michael Drummond, Mark Sculpher, George Torrence, Bernie O'Brien and Greg Stoddart. Methods for the Economic Evaluation of Health Care Programmes Oxford University Press, London.

5. George E Mackinnon III. Understanding health outcomes and pharmacoeconomics.
6. Graker, Dennis. Pharmacoeconomics and outcomes.
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

***THEORY*** ***60 Hrs***

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| **1.** | **UV-Visible spectroscopy**: Introduction, Theory, Laws, Instrumentation associated with UV-Visible spectroscopy, Choice of solvents and solvent effect and Applications of UV-Visible spectroscopy, Difference/ Derivative spectroscopy.<br>**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.<br>**Spectroflourimetry:** Theory of Fluorescence, Factors affecting fluorescence (Characterestics of drugs that can be analysed by flourimetry), Quenchers, Instrumentation and Applications of fluorescence spectrophotometer.<br>**Flame emission spectroscopy and Atomic absorption spectroscopy**: Principle, Instrumentation, Interferences and Applications. | **10 Hrs** |
| **2** | **NMR spectroscopy**: Quantum numbers and their role in NMR, Principle, Instrumentation, Solvent requirement in NMR, Relaxation process, NMR signals in various compounds, Chemical shift, Factors influencing chemical shift, Spin-Spin coupling, Coupling constant, Nuclear magnetic double resonance, Brief outline of principles of FT-NMR and 13C NMR. Applications of NMR spectroscopy. | **10 Hrs** |

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| 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 Hrs** |
| 4 | **Chromatography**: Principle, apparatus, instrumentation, chromatographic parameters, factors affecting resolution, isolation of drug from excipients, data interpretation and applications of the following:<br>j) Thin Layer chromatography<br>k) High Performance Thin Layer Chromatography<br>l) Ion exchange chromatography<br>m) Column chromatography<br>n) Gas chromatography<br>o) High Performance Liquid chromatography<br>p) Ultra High Performance Liquid chromatography<br>q) Affinity chromatography<br>r) Gel Chromatography | **10 Hrs** |
| 5 | **Electrophoresis**: Principle, Instrumentation, Working conditions, factors affecting separation and applications of the following:<br>a) Paper electrophoresis b) Gel electrophoresis c) Capillary electrophoresis d) Zone electrophoresis e) Moving boundary electrophoresis f) Iso electric focusing<br>**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 Hrs** |
| 6 | **Potentiometry:** Principle, working, Ion selective Electrodes and Application of potentiometry.<br>**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. | **10 Hrs** |

***REFERENCES***


1. Spectrometric Identification of Organic compounds - Robert M Silverstein, Sixth edition, John Wiley & Sons, 2004.
2. Principles of Instrumental Analysis - Doglas A Skoog, F. James Holler, Timothy A. Nieman, 5th edition, Eastern press, Bangalore, 1998.
3. Instrumental methods of analysis – Willards, 7th edition, CBS publishers.
4. Practical Pharmaceutical Chemistry – Beckett and Stenlake, Vol II, 4th edition, CBS Publishers, New Delhi, 1997.
5. Organic Spectroscopy - William Kemp, 3rd edition, ELBS, 1991.
6. Quantitative Analysis of Drugs in Pharmaceutical formulation - P D Sethi, 3rd Edition, CBS Publishers, New Delhi, 1997.
7. Pharmaceutical Analysis - Modern Methods – Part B - J W Munson, Vol 11, Marcel. Dekker Series
8. Spectroscopy of Organic Compounds, 2nd edn., P.S/Kalsi, Wiley estern Ltd., Delhi.
9. Textbook of Pharmaceutical Analysis, KA.Connors, 3rd Edition, John Wiley & Sons, 1982.

## ADVANCED PHARMACOLOGY - I
## (MPL 102T)

***Scope***

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

***Objectives***

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

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

***THEORY*** ***60 Hrs***

1. **General Pharmacology** 12 Hrs

   a. Pharmacokinetics: The dynamics of drug absorption, distribution, biotransformation and elimination. Concepts of linear and non-linear compartment models. Significance of Protein binding.

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

2 **Neurotransmission** 12 Hrs

   a. General aspects and steps involved in neurotransmission.

   b. Neurohumoral transmission in autonomic nervous system (Detailed study about neurotransmitters- Adrenaline and Acetyl choline).

   c. Neurohumoral transmission in central nervous system (Detailed study about neurotransmitters- histamine, serotonin, dopamine, GABA, glutamate and glycine].

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

**Systemic Pharmacology**

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

**Autonomic Pharmacology**

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

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| 3 | **Central nervous system Pharmacology**<br>General and local anesthetics<br>Sedatives and hypnotics, drugs used to treat anxiety.<br>Depression, psychosis, mania, epilepsy, neurodegenerative diseases.<br>Narcotic and non-narcotic analgesics. | 12 Hrs |
| 4 | **Cardiovascular Pharmacology**<br>Diuretics, antihypertensives, antiischemics, anti- arrhythmics, drugs for heart failure and hyperlipidemia.<br>Hematinics, coagulants , anticoagulants, fibrinolytics and anti-platelet drugs | 12 Hrs |
| 5 | **Autocoid Pharmacology**<br>The physiological and pathological role of Histamine, Serotonin, Kinins Prostaglandins Opioid autocoids.<br>Pharmacology of antihistamines, 5HT antagonists. | 12 Hrs |

***REFEERENCES***


1. The Pharmacological Basis of Therapeutics, Goodman and Gillman's
2. Principles of Pharmacology. The Pathophysiologic basis of drug Therapy by David E Golan, Armen H, Tashjian Jr, Ehrin J,Armstrong, April W, Armstrong, Wolters, Kluwer-Lippincott Williams & Wilkins Publishers.
3. Basic and Clinical Pharmacology by B.G Katzung
4. Hand book of Clinical Pharmacokinetics by Gibaldi and Prescott.
5. Applied biopharmaceutics and Pharmacokinetics by Leon Shargel and Andrew B.C.Yu.
6. Graham Smith. Oxford textbook of Clinical Pharmacology.
7. Avery Drug Treatment
8. Dipiro Pharmacology, Pathophysiological approach.
9. Green Pathophysiology for Pharmacists.

10. Robbins & Cortan Pathologic Basis of Disease, 9th Ed. (Robbins Pathology)
11. A Complete Textbook of Medical Pharmacology by Dr. S.K Srivastava published by APC Avichal Publishing Company
12. KD.Tripathi. Essentials of Medical Pharmacology.
13. Modern Pharmacology with Clinical Applications, Craig Charles R. & Stitzel Robert E., Lippincott Publishers.
14. Clinical Pharmacokinetics & Pharmacodynamics : Concepts and Applications – Malcolm Rowland and Thomas N.Tozer, Wolters Kluwer, Lippincott Williams & Wilkins Publishers.
15. Applied biopharmaceutics and Pharmacokinetics, Pharmacodynamics and Drug metabolism for industrial scientists.
16. Modern Pharmacology, Craig CR. & Stitzel RE, Little Brown & Company.

## PHARMACOLOGICAL AND TOXICOLOGICAL SCREENING METHODS - I
## (MPL 103T)

***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

***THEORY*** ***60 Hrs***

1. **Laboratory Animals** 12 Hrs

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

Transgenic animals: Production, maintenance and applications
Anaesthesia and euthanasia of experimental animals.
Maintenance and breeding of laboratory animals.
CPCSEA guidelines to conduct experiments on animals

Good laboratory practice.
Bioassay-Principle, scope and limitations and methods

2 **Preclinical screening of new substances for the pharmacological activity using *in vivo*, *in vitro*, and other possible animal alternative models.** 12 Hrs

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

depressants, anxiolytics, anti-psychotics, anti epileptics and nootropics. Drugs for neurodegenerative diseases like Parkinsonism, Alzheimers and multiple sclerosis. Drugs acting on Autonomic Nervous System.

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| 3 | **Preclinical screening of new substances for the pharmacological activity using *in vivo*, *in vitro*, and other possible animal alternative models.**<br>Respiratory Pharmacology: anti-asthmatics, drugs for COPD and anti allergics. Reproductive Pharmacology: Aphrodisiacs and antifertility agents Analgesics, antiinflammatory and antipyretic agents. Gastrointestinal drugs: anti ulcer, anti -emetic, anti-diarrheal and laxatives. | 12 Hrs |
| 4 | **Preclinical screening of new substances for the pharmacological activity using *in vivo*, *in vitro*, and other possible animal alternative models.**<br>Cardiovascular Pharmacology: antihypertensives, antiarrythmics, antianginal, antiatherosclerotic agents and diuretics. Drugs for metabolic disorders like anti-diabetic, antidyslipidemic agents. Anti cancer agents. Hepatoprotective screening methods. | 12 Hrs |
| 5 | **Preclinical screening of new substances for the pharmacological activity using *in vivo*, *in vitro*, and other possible animal alternative models.**<br>Iimmunomodulators, Immunosuppressants and immunostimulants<br><br>**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<br>Limitations of animal experimentation and alternate animal experiments.<br>Extrapolation of *in vitro* data to preclinical and preclinical to humans | 12 Hrs |

***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
4. Methods in Pharmacology by Arnold Schwartz.
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.
8. Experimental Pharmacology by R.K.Goyal.
9. Preclinical evaluation of new drugs by S.K. Guta
10. Handbook of Experimental Pharmacology, SK.Kulkarni
11. Practical Pharmacology and Clinical Pharmacy, SK.Kulkarni, 3rd Edition.
12. David R.Gross. Animal Models in Cardiovascular Research, 2nd Edition, Kluwer Academic Publishers, London, UK.
13. Screening Methods in Pharmacology, Robert A.Turner.
14. Rodents for Pharmacological Experiments, Dr.Tapan Kumar chatterjee.
15. Practical Manual of Experimental and Clinical Pharmacology by Bikash Medhi (Author), Ajay Prakash (Author)

## CELLULAR AND MOLECULAR PHARMACOLOGY
## (MPL 104T)

***Scope:***

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

***Objectives:***

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

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

***THEORY*** ***60 Hrs***

1. **Cell biology** 12 Hrs

   Structure and functions of cell and its organelles

   Genome organization. Gene expression and its regulation, importance of siRNA and micro RNA, gene mapping and gene sequencing

   Cell cycles and its regulation.

   Cell death– events, regulators, intrinsic and extrinsic pathways of apoptosis.

   Necrosis and autophagy.

2 **Cell signaling** 12 Hrs

   Intercellular and intracellular signaling pathways.

   Classification of receptor family and molecular structure ligand gated ion channels; G-protein coupled receptors, tyrosine kinase receptors and nuclear receptors.

   Secondary messengers: cyclic AMP, cyclic GMP, calcium ion, inositol 1,4,5-trisphosphate, (IP3), NO, and diacylglycerol.

   Detailed study of following intracellular signaling pathways: cyclic AMP signaling pathway, mitogen-activated protein kinase (MAPK) signaling, Janus kinase (JAK)/signal transducer and activator of transcription (STAT) signaling pathway.

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| 3 | **Principles and applications of genomic and proteomic tools**<br>DNA electrophoresis, PCR (reverse transcription and real time), Gene sequencing, micro array technique, SDS page, ELISA and western blotting,<br>**Recombinant DNA technology and gene therapy**<br>Basic principles of recombinant DNA technology-Restriction enzymes, various types of vectors. Applications of recombinant DNA technology.<br>Gene therapy- Various types of gene transfer techniques, clinical applications and recent advances in gene therapy. | 12 Hrs |
| 4 | **Pharmacogenomics**<br>Gene mapping and cloning of disease gene.<br>Genetic variation and its role in health/ pharmacology<br>Polymorphisms affecting drug metabolism<br>Genetic variation in drug transporters<br>Genetic variation in G protein coupled receptors<br>Applications of proteomics science: Genomics, proteomics, metabolomics, functionomics, nutrigenomics<br>**Immunotherapeutics**<br>Types of immunotherapeutics, humanisation antibody therapy, Immunotherapeutics in clinical practice | 12 Hrs |
| 5 | **a. Cell culture techniques**<br>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.<br>Principles and applications of cell viability assays, glucose uptake assay, Calcium influx assays<br>Principles and applications of flow cytometry<br>**b.** Biosimilars | 12 Hrs |

***REFERENCES:***


1. The Cell, A Molecular Approach. Geoffrey M Cooper.
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)
8. Current porotocols in molecular biology vol I to VI edited by Frederick M.Ausuvel et la.

## 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.
6. Evaluation of diuretic activity.
7. Evaluation of antiulcer activity by pylorus ligation method.
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).
16. Cell viability assays (MTT/Trypan blue/SRB).
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
3. Handbook of Experimental Pharmacology by S.K. Kulkarni.
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

| ***THEORY*** | | ***60 Hrs*** |
|---|---|---|
| 1. | **Endocrine Pharmacology**<br>Molecular and cellular mechanism of action of hormones such as growth hormone,<br>prolactin, thyroid, insulin and sex hormones<br>Anti-thyroid drugs, Oral hypoglycemic agents, Oral contraceptives, Corticosteroids.<br>Drugs affecting calcium regulation | 12 Hrs |
| 2 | **Chemotherapy**<br>Cellular and molecular mechanism of actions and resistance of antimicrobial agents<br>such as ß-lactams, aminoglycosides, quinolones, Macrolide antibiotics. Antifungal, antiviral, and anti-TB drugs. | 12 Hrs |
| 3 | **Chemotherapy**<br>Drugs used in Protozoal Infections<br>Drugs used in the treatment of Helminthiasis<br>Chemotherapy of cancer<br>**Immunopharmacology**<br>Cellular and biochemical mediators of inflammation and immune response. Allergic or<br>hypersensitivity reactions. Pharmacotherapy of asthma and COPD.<br>Immunosuppressants and Immunostimulants | 12 Hrs |

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|---|---|---|
| 4 | **GIT Pharmacology**<br>Antiulcer drugs, Prokinetics, antiemetics, anti-diarrheals and drugs for constipation<br>and irritable bowel syndrome.<br>**Chronopharmacology**<br>Biological and circadian rhythms, applications of chronotherapy in various diseases like<br>cardiovascular disease, diabetes, asthma and peptic ulcer | 12 Hrs |
| 5 | **Free radicals Pharmacology**<br>Generation of free radicals, role of free radicals in etiopathology of various diseases<br>such as diabetes, neurodegenerative diseases and cancer.<br>Protective activity of certain important antioxidant<br>**Recent Advances in Treatment:**<br>Alzheimer's disease, Parkinson's disease, Cancer, Diabetes mellitus | 12 Hrs |

***REFERENCES***


1. The Pharmacological basis of therapeutics- Goodman and Gill man's
2. Principles of Pharmacology. The Pathophysiologic basis of drug therapy by David E Golan et al.
3. Basic and Clinical Pharmacology by B.G -Katzung
4. Pharmacology by H.P. Rang and M.M. Dale.
5. Hand book of Clinical Pharmacokinetics by Gibaldi and Prescott.
6. Text book of Therapeutics, drug and disease management by E T. Herfindal and Gourley.
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)
10. A Complete Textbook of Medical Pharmacology by Dr. S.K Srivastava published by APC Avichal Publishing Company.
11. KD.Tripathi. Essentials of Medical Pharmacology
12. Principles of Pharmacology. The Pathophysiologic basis of drug Therapy by David E Golan, Armen H, Tashjian Jr, Ehrin J,Armstrong, April W, Armstrong, Wolters, Kluwer-Lippincott Williams & Wilkins Publishers

## PHARMACOLOGICAL AND TOXICOLOGICAL SCREENING METHODS-II
## (MPL 202T)

***Scope:***

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

***Objectives:***

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

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

***THEORY*** ***60 Hrs***

| | | |
|---|---|---|
| 1. | Basic definition and types of toxicology (general, mechanistic, regulatory and descriptive)<br>Regulatory guidelines for conducting toxicity studies OECD, ICH, EPA and Schedule Y<br>OECD principles of Good laboratory practice (GLP)<br>History, concept and its importance in drug development | 12 Hrs |
| 2 | Acute, sub-acute and chronic- oral, dermal and inhalational studies as per OECD guidelines.<br>Acute eye irritation, skin sensitization, dermal irritation & dermal toxicity studies.<br>Test item characterization- importance and methods in regulatory toxicology studies | 12 Hrs |
| 3 | Reproductive toxicology studies, Male reproductive toxicity studies, female reproductive studies (segment I and segment III), teratogenecity studies (segment II)<br>Genotoxicity studies (Ames Test*, in vitro* and *in vivo* Micronucleus and Chromosomal aberrations studies)<br>*In vivo* carcinogenicity studies | 12 Hrs |
| 4 | IND enabling studies (IND studies)- Definition of IND, importance of IND, industry perspective, list of studies needed for IND submission. | 12 Hrs |

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|---|---|---|
| | Safety pharmacology studies- origin, concepts and importance of safety pharmacology.<br>Tier1- CVS, CNS and respiratory safety pharmacology, HERG assay. Tier2- GI, renal and other studies | |
| 5 | Toxicokinetics- Toxicokinetic evaluation in preclinical studies, saturation kinetics Importance and applications of toxicokinetic studies.<br>Alternative methods to animal toxicity testing. | 12 Hrs |

***REFERENCES***


1. Hand book on GLP, Quality practices for regulated non-clinical research and development (http://www.who.int/tdr/publications/documents/glp-handbook.pdf).
2. Schedule Y Guideline: drugs and cosmetics (second amendment) rules, 2005, ministry of health and family welfare (department of health) New Delhi
3. Drugs from discovery to approval by Rick NG.
4. Animal Models in Toxicology, 3rd Edition, Lower and Bryan
5. OECD test guidelines.
6. Principles of toxicology by Karen E. Stine, Thomas M. Brown.
7. Guidance for Industry M3(R2) Nonclinical Safety Studies for the Conduct of Human Clinical Trials and Marketing Authorization for Pharmaceuticals (http://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm073246.pdf)

## PRINCIPLES OF DRUG DISCOVERY
## (MPL 203T)

***Scope:***

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

***Objectives:***

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

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

| ***THEORY*** | | ***60 Hrs*** |
|---|---|---|
| 1. | An overview of modern drug discovery process: Target identification, target validation, lead identification and lead Optimization. Economics of drug discovery.<br>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. | 12 Hrs |
| 2 | Lead Identification- combinatorial chemistry & high throughput screening, in silico lead discovery techniques, Assay development for hit identification.<br>Protein structure<br>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 | 12 Hrs |
| 3 | Rational Drug Design<br>Traditional vs rational drug design, Methods followed in traditional drug design, High throughput screening, Concepts of Rational Drug Design, Rational Drug Design Methods: Structure and Pharmacophore based approaches | 12 Hrs |

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|---|---|---|
| | Virtual Screening techniques: Drug likeness screening, Concept of pharmacophore mapping and pharmacophore based Screening, | |
| 4 | Molecular docking: Rigid docking, flexible docking, manual docking; Docking based screening. De novo drug design. Quantitative analysis of Structure Activity Relationship History and development of QSAR, SAR versus QSAR, Physicochemical parameters, Hansch analysis, Fee Wilson analysis and relationship between them. | 12 Hrs |
| 5 | QSAR Statistical methods – regression analysis, partial least square analysis (PLS) and other multivariate statistical methods. 3D-QSAR approaches like COMFA and COMSIA Prodrug design-Basic concept, Prodrugs to improve patient acceptability, Drug solubility, Drug absorption and distribution, site specific drug delivery and sustained drug action. Rationale of prodrug design and practical consideration of prodrug design | 12 Hrs |

***REFERENCES***


1. MouldySioud. Target Discovery and Validation Reviews and Protocols: Volume 2 Emerging Molecular Targetsand Treatment Options. 2007 Humana Press Inc.
2. Darryl León. Scott MarkelIn. Silico Technologies in Drug Target Identification and Validation. 2006 by Taylor and Francis Group, LLC.
3. Johanna K. DiStefano. Disease Gene Identification. Methods and Protocols. Springer New York Dordrecht Heidelberg London.
4. Hugo Kubiny. QSAR: Hansch Analysis and Related Approaches. Methods and Principles in Medicinal Chemistry. Publisher Wiley-VCH
5. Klaus Gubernator, Hans-Joachim Böhm. Structure-Based Ligand Design. Methods and Principles in Medicinal Chemistry. Publisher Wiley-VCH
6. Abby L . Parrill. M . Rami Reddy. Rational Drug Design. Novel Methodology and Practical Applications. ACS Symposium Series; American Chemical Society: Washington, DC, 1999.
7. J. Rick Turner. New drug development design, methodology and, analysis. John Wiley & Sons, Inc., New Jersey.

## CLINICAL RESEARCH AND PHARMACOVIGILANCE
## (MPL 204T)

***Scope:***

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

***Objectives:***

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

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

***THEORY*** ***60 Hrs***

1. **Regulatory Perspectives of Clinical Trials:** 12 Hrs

   Origin and Principles of International Conference on Harmonization - Good Clinical Practice (ICH-GCP) guidelines

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

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

2. **Clinical Trials:** Types and Design 12 Hrs

   Experimental Study- RCT and Non RCT,

   Observation Study: Cohort, Case Control, Cross sectional

   **Clinical Trial Study Team**

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

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| 3 | **Clinical Trial Documentation-** Guidelines to the preparation of documents, Preparation of protocol, Investigator Brochure, Case Report Forms, Clinical Study Report Clinical Trial Monitoring-Safety Monitoring in CT<br>**Adverse Drug Reactions:** Definition and types. Detection and reporting methods. Severity and seriousness assessment.Predictability and preventability assessment, Management of adverse drug reactions; Terminologies of ADR. | 12 Hrs |
| 4 | **Basic aspects, terminologies and establishment of pharmacovigilance**<br>History and progress of pharmacovigilance, Significance of safety monitoring, Pharmacovigilance in India and international aspects, WHO international drug monitoring programme, WHO and Regulatory terminologies of ADR, evaluation of medication safety, Establishing pharmacovigilance centres in Hospitals, Industry and National programmes related to pharmacovigilance. Roles and responsibilities in Pharmacovigilance | 12 Hrs |
| 5 | **Methods, ADR reporting and tools used in Pharmacovigilance**<br>International classification of diseases, International Non-proprietary names for drugs, Passive and Active surveillance, Comparative observational studies, Targeted clinical investigations and Vaccine safety surveillance. Spontaneous reporting system and Reporting to regulatory authorities, Guidelines for ADRs reporting. Argus, Aris G Pharmacovigilance, VigiFlow, Statistical methods for evaluating medication safety data. | 12 Hrs |
| 6 | **Pharmacoepidemiology, pharmacoeconomics, safety pharmacology** | 12 Hrs |

***REFERENCES***


1. Central Drugs Standard Control Organization- Good Clinical Practices, Guidelines for Clinical Trials on Pharmaceutical Products in India. New Delhi: Ministry of Health;2001.
2. International Conference on Harmonization of Technical requirements for registration of Pharmaceuticals for human use. ICH Harmonized Tripartite Guideline. Guideline for Good Clinical Practice.E6; May 1996.

3. Ethical Guidelines for Biomedical Research on Human Subjects 2000. Indian Council of Medical Research, New Delhi.
4. Textbook of Clinical Trials edited by David Machin, Simon Day and Sylvan Green, March 2005, John Wiley and Sons.
5. Clinical Data Management edited by R K Rondels, S A Varley, C F Webbs. Second Edition, Jan 2000, Wiley Publications.
6. Handbook of clinical Research. Julia Lloyd and Ann Raven Ed. Churchill Livingstone.
7. Principles of Clinical Research edited by Giovanna di Ignazio, Di Giovanna and Haynes.

## PHARMACOLOGICAL PRACTICAL - II
## (MPL 205P)

1. To record the DRC of agonist using suitable isolated tissues preparation.
2. To study the effects of antagonist/potentiating agents on DRC of agonist using suitable isolated tissue preparation.
3. To determine to the strength of unknown sample by matching bioassay by using suitable tissue preparation.
4. To determine to the strength of unknown sample by interpolation bioassay by using suitable tissue preparation
5. To determine to the strength of unknown sample by bracketing bioassay by using suitable tissue preparation
6. To determine to the strength of unknown sample by multiple point bioassay by using suitable tissue preparation.
7. Estimation of $PA_2$ values of various antagonists using suitable isolated tissue preparations.
8. To study the effects of various drugs on isolated heart preparations
9. Recording of rat BP, heart rate and ECG.
10. 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.
14. Repeated dose toxicity studies- Serum biochemical, haematological, urine analysis, functional observation tests and histological studies.
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
2. Hand book of Experimental Pharmacology-S.K.Kulakarni
3. Text book of *in-vitro* practical Pharmacology by Ian Kitchen
4. Bioassay Techniques for Drug Development by Atta-ur-Rahman, Iqbal choudhary and William Thomsen
5. Applied biopharmaceutics and Pharmacokinetics by Leon Shargel and Andrew B.C.Yu.
6. Handbook of Essential Pharmacokinetics, Pharmacodynamics and Drug Metabolism for Industrial Scientists.

## PHARMACOGNOSY (MPG)

## MODERN PHARMACEUTICAL ANALYTICAL TECHNIQUES (MPG 101T)

***Scope***

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

***Objectives***

After completion of course student is able to know,

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

***THEORY*** ***60 Hrs***

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| **1.** | **UV-Visible spectroscopy**: Introduction, Theory, Laws, Instrumentation associated with UV-Visible spectroscopy, Choice of solvents and solvent effect and Applications of UV-Visible spectroscopy.<br>**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<br>**Spectroflourimetry:** Theory of Fluorescence, Factors affecting fluorescence, Quenchers, Instrumentation and Applications of fluorescence spectrophotometer.<br>**Flame emission spectroscopy and Atomic absorption spectroscopy**: Principle, Instrumentation, Interferences and Applications. | **12 Hrs** |
| **2** | **NMR spectroscopy**: Quantum numbers and their role in NMR, Principle, Instrumentation, Solvent requirement in NMR, Relaxation process, NMR signals in various compounds, Chemical shift, Factors influencing chemical shift, Spin-Spin coupling, Coupling constant, Nuclear magnetic double resonance, Brief outline of principles of FT-NMR and 13C NMR. Applications of NMR spectroscopy.1 | **12 Hrs** |

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| 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 Hrs |
| 4 | **Chromatography**: Principle, apparatus, instrumentation, chromatographic parameters, factors affecting resolution, isolation of drug from excipients, data interpretation and applications of the following:<br>a) Thin Layer chromatography<br>b) High Performance Thin Layer Chromatography<br>c) Ion exchange chromatography<br>d) Column chromatography<br>e) Gas chromatography<br>f) High Performance Liquid chromatography<br>g) Ultra High Performance Liquid chromatography<br>h) Affinity chromatography<br>i) Gel Chromatography | 10 Hrs |
| 5 | **Electrophoresis**: Principle, Instrumentation, Working conditions, factors affecting separation and applications of the following:<br>a) Paper electrophoresis<br>b) Gel electrophoresis<br>c) Capillary electrophoresis<br>d) Zone electrophoresis<br>e) Moving boundary electrophoresis<br>f) Iso electric focusing<br><br>**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 Hrs |
| 6 | **Potentiometry:** Principle, working, Ion selective Electrodes and Application of potentiometry.<br><br>**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 | 10 Hrs |

cooling rates, resolution, source of errors) and their influence, advantage and disadvantages, pharmaceutical applications. Differential Thermal Analysis (DTA): Principle, instrumentation and advantage and disadvantages, pharmaceutical applications, derivative differential thermal analysis (DDTA). TGA: Principle, instrumentation, factors affecting results, advantage and disadvantages, pharmaceutical applications.

***REFERENCES***


1. Spectrometric Identification of Organic compounds - Robert M Silverstein, Sixth edition, John Wiley & Sons, 2004.
2. Principles of Instrumental Analysis - Doglas A Skoog, F. James Holler, Timothy A. Nieman, 5th edition, Eastern press, Bangalore, 1998.
3. Instrumental methods of analysis – Willards, 7th edition, CBS publishers.
4. Practical Pharmaceutical Chemistry – Beckett and Stenlake, Vol II, 4th edition, CBS Publishers, New Delhi, 1997.
5. Organic Spectroscopy - William Kemp, 3rd edition, ELBS, 1991.
6. Quantitative Analysis of Drugs in Pharmaceutical formulation - P D Sethi, 3rd Edition, CBS Publishers, New Delhi, 1997.
7. Pharmaceutical Analysis - Modern Methods – Part B - J W Munson, Vol 11, Marcel. Dekker Series
8. Spectroscopy of Organic Compounds, 2nd edn., P.S/Kalsi, Wiley estern Ltd., Delhi.

## ADVANCED PHARMACOGNOSY - I
## (MPG 102T)

***SCOPE***

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

***OBJECTIVES***

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

- advances in the cultivation and production of drugs
- various phyto-pharmaceuticals and their source, its utilization and medicinal value.
- various nutraceuticals/herbs and their health benefits
- Drugs of marine origin
- Pharmacovigilance of drugs of natural origin

***THEORY*** ***60 Hrs***

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| 1. | **Plant drug cultivation:** General introduction to the importance of Pharmacognosy in herbal drug industry, Indian Council of Agricultural Research, Current Good Agricultural Practices, Current Good Cultivation Practices, Current Good Collection Practices, Conservation of medicinal plants- *Ex-situ* and *In-situ* conservation of medicinal plants. | 12 Hrs |
| 2 | **Marine natural products:** General methods of isolation and purification, Study of Marine toxins, Recent advances in research in marine drugs, Problems faced in research on marine drugs such as taxonomical identification, chemical screening and their solution. | 12 Hrs |
| 3 | **Nutraceuticals:** Current trends and future scope, Inorganic mineral supplements, Vitamin supplements, Digestive enzymes, Dietary fibres, Cereals and grains, Health drinks of natural origin, Antioxidants, Polyunsaturated fatty acids, Herbs as functional foods, Formulation and standardization of neutraceuticals, Regulatory aspects, FSSAI guidelines, Sources, name of marker compounds and their chemical nature, medicinal uses and health benefits of following<br>i) Spirulina ii) Soya bean iii) Ginseng iv) Garlic v) Broccoli vi) Green and Herbal Tea vii) Flax seeds viii) Black cohosh ix) Turmeric. | 12 Hrs |

4 **Phytopharmaceuticals:** Occurrence, isolation and characteristic features (Chemical nature, uses in pharmacy, medicinal and health benefits) of following. 12 Hrs

a) Carotenoids – i) α and β - Carotene ii) Xanthophyll (Lutein)
b) Limonoids – i) d-Limonene ii) α – Terpineol
c) Saponins – i) Shatavarins
d) Flavonoids – i) Resveratrol ii) Rutin iii) Hesperidin iv) Naringin v) Quercetin
e) Phenolic acids- Ellagic acid
f) Vitamins
g) Tocotrienols and Tocopherols
h) Andrographolide, Glycolipids, Gugulipids, Withanolides, Vascine, Taxol
i) Miscellaneous

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

***REFERENCES*** *(Latest Editions of)*


1. Pharmacognosy - G. E. Trease and W.C. Evans. Saunders Edinburgh, New York.
2. Pharmacognosy-Tyler, Brady, Robbers
3. Modem Methods of Plant Analysis- Peach & M.V. Tracey, Vol. I&II
4. Text Book of Pharmacognosy by T.E. Wallis
5. Marine Natural Products-Vol.I to IV.
6. Natural products: A lab guide by Raphael Ikan , Academic Press 1991.
7. Glimpses of Indian Ethano Pharmacology, P. Pushpangadam. Ulf Nyman. V.George Tropical Botanic Garden & Research Institute, 1995.
8. Medicinal natural products (a biosynthetic approach), Paul M. Dewick, John Wiley & Sons Ltd., England, 1998.
9. Chemistry of Marine Natural Products- Paul J. Schewer 1973.
10. Herbal Drug Industry by RD. Choudhary, Eastern Publisher, New Delhi, 1996.
11. Cultivation of Medicinal Plants by C.K. Atal & B.M. Kapoor.
12. Cultivation and Utilization of Aromatic Plants, C.K. Atal & B.M. Kapoor
13. Cultivation of medicinal and aromatic crops, AA Farooqui and B.S. Sreeramu. University Press, 2001.

14. Natural Products from Plants, 1st edition, by Peter B. Kaufman, CRC Press, New York, 1998
15. Recent Advances in Phytochemistry- Vol. 1&4: Scikel Runeckles- Appleton Century crofts.
16. Text book of Pharmacognosy, C.K.Kokate, Purohit, Ghokhale, Nirali Prakasshan, 1996.
17. Pharmacognosy and Pharmacobiotechnology, Ashutoshkar, New Age Publications, New Delhi.

## PHYTOCHEMISTRY
## (MPG 103T)

***SCOPE***

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

***OBJECTIVES***

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

- different classes of phytoconstituents, their biosynthetic pathways, their properties, extraction and general process of natural product drug discovery
- phytochemical fingerprinting and structure elucidation of phytoconstituents.

***THEORY*** ***60 Hrs***

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

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

3 **Extraction and Phytochemical studies:** Recent advances in extractions with emphasis on selection of method and choice of solvent for extraction, successive and exhaustive extraction and other methods of extraction commonly used like microwave 12 Hrs

assisted extraction, Methods of fractionation. Separation of phytoconstituents by latest CCCET, SCFE techniques including preparative HPLC and Flash column chromatography.

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| 4 | **Phytochemical finger printing:** HPTLC and LCMS/GCMS applications in the characterization of herbal extracts. Structure elucidation of phytoconstituents. | 12 Hrs |
| 5 | Structure elucidation of the following compounds by spectroscopic techniques like UV, IR, MS, NMR (1H, 13C)<br>a. Carvone, Citral, Menthol<br>b. Luteolin, Kaempferol<br>**c.** Nicotine, Caffeine iv) Glycyrrhizin. | 12 Hrs |

***REFERENCES*** *(Latest Editions of)*


1. Organic chemistry by I.L. Finar Vol.II
2. Pharmacognosy by Trease and Evans, ELBS.
3. Pharmacognosy by Tylor and Brady.
4. Text book of Pharmacognosy by Wallis.
5. Clark's isolation and Identification of drugs by A.C. Mottal.
6. Plant Drug Analysis by Wagner & Bladt.
7. Wilson and Gisvolds text book of Organic Medicinnal and Pharmaceutical Chemistry by Deorge. R.F.
8. The Chemistry of Natural Products, Edited by R.H. Thomson, Springer International Edn. 1994.
9. Natural Products Chemistry Practical Manual by Anees A Siddiqui and SeemiSiddiqui
10. Organic Chemistry of Natural Products, Vol. 1&2. Gurdeep R Chatwal.
11. Chemistry of Natural Products- Vol. 1 onwards IWPAC.
12. Modem Methods of Plant Analysis- Peach & M.V. Tracey, Vol. I&II
13. Medicinal Natural products – a biosynthetic approach, Dewick PM, John Wiley & Sons, Toronto, 1998.
14. Chemistry of Natural Products, Bhat SV, Nagasampagi BA, Meenakshi S, Narosa Publishing House, New Delhi.
15. Pharmacognosy & Phytochemistry of Medicinal Plants, 2nd edition, Bruneton J, Interceptt Ltd., New York, 1999.

## INDUSTRIAL PHARMACOGNOSTICAL TECHNOLOGY
## (MPG 104T)

***SCOPE***

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

***OBJECTIVES***

By the end of the course the student shall be able to know,

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

***THEORY*** ***60 Hrs***

1. **Herbal drug industry:** Infrastructure of herbal drug industry involved in production of standardized extracts and various dosage forms. Current challenges in upgrading and modernization of herbal formulations. Entrepreneurship Development, Project selection, project report, technical knowledge, Capital venture, plant design, layout and construction. Pilot plant scale –up techniques, case studies of herbal extracts. Formulation and production management of herbals. — 12 Hrs

2 **Regulatory requirements for setting herbal drug industry:** Global marketing management. Indian and international patent law as applicable herbal drugs and natural products. Export - Import (EXIM) policy, TRIPS.
Quality assurance in herbal/natural drug products.
Concepts of TQM, GMP, GLP, ISO-9000. — 12 Hrs

3 **Monographs of herbal drugs:** General parameters of monographs of herbal drugs and comparative study in IP, USP, Ayurvedic Pharmacopoeia, Siddha and Unani Pharmacopoeia, American herbal pharmacopoeia, British herbal pharmacopoeia, WHO guidelines in quality assessment of herbal drugs.

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| 4 | **Testing of natural products and drugs:** Herbal medicines - clinical laboratory testing. Stability testing of natural products, protocols. | 12 Hrs |
| 5 | **Patents:** Indian and international patent laws, proposed amendments as applicable to herbal/natural products and process. Geographical indication, Copyright, Patentable subject maters, novelty, non obviousness, utility, enablement and best mode, procedure for Indian patent filing, patent processing, grant of patents, rights of patents, cases of patents, opposition and revocation of patents, patent search and literature, Controllers of patents. | 12 Hrs |

***REFERENCES*** (Latest Editions of)


1. Herbal drug industry by R.D. Choudhary (1996), Eastern Publisher, New Delhi.
2. GMP for Botanicals - Regulatory and Quality issues on Phytomedicine by Pulok K Mukharjee (2003), Ist Edition, Business horizons Robert Verpoorte, New Delhi.
3. Quality control of herbal drugs by Pulok K Mukarjee (2002), Business Horizons Pharmaceutical Publisher, New Delhi.
4. PDR for Herbal Medicines (2000), Medicinal Economic Company, New Jersey.
5. Indian Herbal Pharmacopoeia (2002), IDMA, Mumbai.
6. Text book of Pharmacognosy by C.K. Kokate, Purohit, Gokhlae (1996), Nirali Prakashan, New Delhi.
7. Text book of Pharmacognosy and Phytochemistry by Vinod D. Rangarl (2002), Part I & II, Career Publication, Nasik, India.
8. Plant drug analysis by H.Wagner and S.Bladt, Springer, Berlin.
9. Standardization of Botanicals. Testing and extraction methods of medicinal herbs by V. Rajpal (2004), Vol.I, Eastern Publisher, New Delhi.
10. Phytochemical Dictionary. Handbook of Bioactive Compounds from Plants by J.B.Harborne, (1999), IInd Edition, Taylor and Francis Ltd, UK.
11. Herbal Medicine. Expanded Commission E Monographs by M.Blumenthal, (2004), IST Edition,
12. Drug Formulation Manual by D.P.S.Kohli and D.H.Shah (1998), Eastern Publisher, New Delhi.

## PHARMACOGNOSY PRACTICAL - I
## (MPG I05P)

1. Analysis of Pharmacopoeial compounds of natural origin and their formulations by UV Vis spectrophotometer
2. Analysis of recorded spectra of simple phytoconstituents
3. Experiments based on Gas Chromatography
4. Estimation of sodium/potassium by flame photometry
5. Development of fingerprint of selected medicinal plant extracts commonly used in herbal drug industry viz. Ashwagandha, Tulsi, Bael, Amla, Ginger, Aloe, Vidang, Senna, Lawsonia by TLC/HPTLC method.
6. Methods of extraction
7. Phytochemical screening
8. Demonstration of HPLC- estimation of glycerrhizin
9. Monograph analysis of clove oil
10. Monograph analysis of castor oil.
11. Identification of bioactive constituents from plant extracts
12. Formulation of different dosage forms and their standardisation.

## MEDICINAL PLANT BIOTECHNOLOGY
## (MPG 201T)

***SCOPE***

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

***OBJECTIVES***

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

- Know the process like genetic engineering in medicinal plants for higher yield of Phytopharmaceuticals.
- Use the biotechnological techniques for obtaining and improving the quality of natural products/medicinal plants

***THEORY*** ***60 Hrs***

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| 1. | **Introduction to Plant biotechnology:** Historical perspectives, prospects for development of plant biotechnology as a source of medicinal agents. Applications in pharmacy and allied fields. Genetic and molecular biology as applied to pharmacognosy, study of DNA, RNA and protein replication, genetic code, regulation of gene expression, structure and complicity of genome, cell signaling, DNA recombinant technology. | 12 Hrs |
| 2 | **Different tissue culture techniques:** Organogenesis and embryogenesis, synthetic seed and monoclonal variation, Protoplast fusion, Hairy root multiple shoot cultures and their applications. Micro propagation of medicinal and aromatic plants. Sterilization methods involved in tissue culture, gene transfer in plants and their applications. | 15 Hrs |
| 3 | **Immobilisation techniques & Secondary Metabolite Production:** Immobilization techniques of plant cell and its application on secondary metabolite Production. Cloning of plant cell: Different methods of cloning and its applications. Advantages and disadvantages of plant cell cloning. Secondary metabolism in tissue cultures with emphasis on production of medicinal agents. Precursors and elicitors on production of secondary metabolites. | 15 Hrs |
| 4 | **Biotransformation and Transgenesis:** Biotransformation, bioreactors for pilot and large scale cultures of plant cells and retention of biosynthetic potential in cell culture. Transgenic | 13 Hrs |

plants, methods used in gene identification, localization and sequencing of genes. Application of PCR in plant genome analysis.

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| 5 | **Fermentation technology:** Application of Fermentation technology, Production of ergot alkaloids, single cell proteins, enzymes of pharmaceutical interest. | 05 Hrs |

***REFERENCES (Latest Editions of)***


1. Plant tissue culture, Bhagwani, vol 5, Elsevier Publishers.
2. Plant cell and Tissue Culture (Lab. Manual), JRMM. Yeoman.
3. Elements in biotechnology by PK. Gupta, Rastogi Publications, New Delhi.
4. An introduction to plant tissue culture by MK. Razdan, Science Publishers.
5. Experiments in plant tissue culture by John HD and Lorin WR., Cambridge University Press.
6. Pharmaceutical biotechnology by SP. Vyas and VK. Dixit, CBS Publishers.
7. Plant cell and tissue culture by Jeffrey W. Pollard and John M Walker, Humana press.
8. Plant tissue culture by Dixon, Oxford Press, Washington DC, 1985
9. Plant tissue culture by Street.
10. Pharmacognosy by G. E. Trease and WC. Evans, Elsevier.
11. Biotechnology by Purohit and Mathur, Agro-Bio, 3rd revised edition.
12. Biotechnological applications to tissue culture by Shargool, Peter D, Shargoal, CKC Press.
13. Pharmacognosy by Varo E. Tyler, Lynn R. Brady and James E. Robberrt, That Tjen, NGO.
14. Plant Biotechnology, Ciddi Veerasham.

## ADVANCED PHARMACOGNOSY - II
## (MPG 202T)

***SCOPE***

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

***OBJECTIVES***

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

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

***THEORY*** ***60 Hrs***

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|---|---|---|
| 1. | **Herbal remedies – Toxicity and Regulations:** Herbals vs Conventional drugs, Efficacy of Herbal medicine products, Validation of herbal therapies, Pharmacodynamic and Pharmacokinetic issues. | 12 Hrs |
| 2 | **Adulteration and Deterioration:** Introduction, Types of Adulteration/ Substitution of Herbal drugs, Causes and Measures of Adulteration, Sampling Procedures, Determination of Foreign Matter, DNA Finger printing techniques in identification of drugs of natural origin, detection of heavy metals, pesticide residues, phytotoxin, microbial contamination in herbs and their formulations. | 12 Hrs |
| 3 | **Ethnobotany and Ethnopharmacology:** Ethnobotany in herbal drug evaluation, Impact of Ethnobotany in traditional medicine, New development in herbals, Bio-prospecting tools for drug discovery, Role of Ethnopharmacology in drug evaluation, Reverse Pharmacology. | 12 Hrs |
| 4 | **Analytical Profiles of herbal drugs:** Andrographis paniculata, Boswellia serata, Coleus forskholii, Curcuma longa, Embelica officinalis, Psoralea corylifolia. | 12 Hrs |
| 5 | **Biological screening of herbal drugs:** Introduction and Need for Phyto-Pharmacological Screening, New Strategies for evaluating | 12 Hrs |

Natural Products, *In vitro* evaluation techniques for Antioxidants, Antimicrobial and Anticancer drugs. In vivo evaluation techniques for Anti-inflammatory, Antiulcer, Anticancer, Wound healing, Antidiabetic, Hepatoprotective, Cardio protective, Diuretics and Antifertility, Toxicity studies as per OECD guidelines.

***REFERENCES*** *(Latest Editions of)*


1. Glimpses of Indian Ethano Pharmacology by P. Pushpangadam. Ulf Nyman. V.George Tropical Botanic Garden & Research Institute.
2. Natural products: A lab guide by Raphael Ikan, Academic Press.
3. Pharmacognosy - G. E. Trease and W.C. Evans. WB. Saunders Edinburgh, New York.
4. Pharmacognosy-Tyler, Brady, Robbers, Lee & Fetiger.
5. Modem Methods of Plant Analysis- Peach & M.V. Tracey, Vol. I & II, Springer Publishers.
6. Herbal Drug Industry by RD. Choudhary, Eastern Publishers, New Delhi.
7. Text book of Pharmacognosy by C.K.Kokate, Purohit, Ghokhale, Nirali Prakashan.
8. Text Book of Pharmacognosy by T.E. Wallis, J & A Churchill Ltd., London.
9. Quality control of herbal drugs by Pulok K Mukherjee, Business Horizons Pharmaceutical Publishers, New Delhi.
10. Indian Herbal Pharmacopoeia, IDMA, Mumbai.
11. Text book of Pharmacognosy and Phytochemistry by Vinod D. RangarI, Part I & II, Career Publication, Nasik, India.
12. Plant drug analysis by H.Wagner and S.Bladt, 2nd edition, Springer, Berlin.
13. Standardization of Botanicals. Testing and extraction methods of medicinal herbs by V. Rajpal (2004), Vol.I, Eastern PublisherS, New Delhi.
14. Herbal Medicine. Expanded Commission E Monographs, M.Blumenthal.

## INDIAN SYSTEMS OF MEDICINE
## (MPG 203T)

***SCOPE***

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

***OBJECTIVES***

After completion of the course, student is able to

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

***THEORY*** ***60 Hrs***

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|---|---|---|
| 1. | Fundamental concepts of Ayurveda, Siddha, Unani and Homoeopathy systems of medicine<br>Different dosage forms of the ISM.<br>**Ayurveda:** Ayurvedic Pharmacopoeia, Analysis of formulations and bio crude drugs with references to: Identity, purity and quality.<br>**Siddha:** Gunapadam (Siddha Pharmacology), raw drugs/Dhatu/Jeevam in Siddha system of medicine, Purification process (Suddhi). | 12 Hrs |
| 2 | **Naturopathy, Yoga and Aromatherapy practices**<br>a) Naturopathy - Introduction, basic principles and treatment modalities.<br>b) Yoga - Introduction and Streams of Yoga. Asanas, Pranayama, Meditations and Relaxation techniques.<br>c) Aromatherapy – Introduction, aroma oils for common problems, carrier oils. | 12 Hrs |
| 3 | **Formulation development of various systems of medicine**<br>Salient features of the techniques of preparation of some of the important class of Formulations as per Ayurveda, Siddha, Homeopathy and Unani Pharmacopoeia and texts. Standardization,<br>Shelf life and Stability studies of ISM formulations. | 12 Hrs |

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| 4 | Schedule T – Good Manufacturing Practice of Indian systems of medicine<br>Components of GMP (Schedule – T) and its objectives, Infrastructural requirements, working space, storage area, machinery and equipments, standard operating procedures, health and hygiene, documentation and records.<br>Quality assurance in ISM formulation industry - GAP, GMP and GLP. Preparation of documents for new drug application and export registration.<br>Challenges in monitoring the safety of herbal medicines: Regulation, quality assurance and control, National/Regional Pharmacopoeias. | 12 Hrs |
| 5 | TKDL, Geographical indication Bill, Government bills in AYUSH, ISM, CCRAS, CCRS, CCRH, CCRU | 12 Hrs |

***REFERENCES*** *(Latest Editions of )*


1. Ayurvedic Pharmacopoeia, The Controller of Publications, Civil Lines, Govt. of India, New Delhi.
2. Hand Book on Ayurvedic Medicines, H. Panda, National Institute of Industrial Research, New Delhi.
3. Ayurvedic System of Medicine, Kaviraj Nagendranath Sengupata, Sri Satguru Publications, New Delhi.
4. Ayurvedic Pharmacopoeia. Formulary of Ayurvedic Medicines, IMCOPS, Chennai.
5. Homeopathic Pharmacopoeia. Formulary of Homeopathic Medicines, IMCOPS, Chennai.
6. Homeopathic Pharmacy : An introduction & Hand book, Steven B. Kayne, Churchill Livingstone, New York.
7. Indian Herbal Pharmacopoeia, IDMA, Mumbai.
8. British Herbal Pharmacopoeia, bRITISH Herbal Medicine Association, UK.
9. GMP for Botanicals - Regulatory and Quality issues on Phytomedicine, Pulok K Mukharjee, Business Horizons, New Delhi.
10. Indian System of Medicine and Homeopathy in India, Planning and Evaluation Cell, Govt. of India, New Delhi.
11. Essential of Food and Nutrition, Swaminathan, Bappco, Bangalore.
12. Clinical Dietitics and Nutrition, F.P. Antia, Oxford University Press, Delhi.
13. Yoga - The Science of Holistic Living by V.K.Yoga, Vivekananda Yoga Prakashna Publishing, Bangalore.

## HERBAL COSMETICS
## (MPG 204T)

***SCOPE***

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

***OBJECTIVES***

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

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

***THEORY*** ***60 Hrs***

| | | |
|---|---|---|
| 1. | **Introduction:** Herbal/natural cosmetics, Classification & Economic aspects.<br>Regulatory Provisions relation to manufacture of cosmetics: - License, GMP, offences & Penalties, Import & Export of Herbal/natural cosmetics, Industries involved in the production of Herbal/natural cosmetics. | 12 Hrs |
| 2 | Commonly used herbal cosmetics, raw materials, preservatives, surfactants, humectants, oils, colors, and some functional herbs, preformulation studies, compatibility studies, possible interactions between chemicals and herbs, design of herbal cosmetic formulation. | 12 Hrs |
| 3 | **Herbal Cosmetics :** Physiology and chemistry of skin and pigmentation, hairs, scalp, lips and nail, Cleansing cream, Lotions, Face powders, Face packs, Lipsticks, Bath products, soaps and baby product, Preparation and standardisation of the following :<br>Tonic, Bleaches, Dentifrices and Mouth washes & Tooth Pastes, Cosmetics for Nails**.** | 12 Hrs |
| 4 | **Cosmeceuticals of herbal and natural origin:** Hair growth formulations, Shampoos, Conditioners, Colorants & hair oils, Fairness formulations, vanishing & foundation creams, anti-sun burn preparations, moisturizing creams, deodorants. | 12 Hrs |

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| 5 | Analysis of Cosmetics, Toxicity screening and test methods: Quality control and toxicity studies as per Drug and Cosmetics Act. | 12 Hrs |

***REFERENCES*** *(Latest Editions of)*


1. Panda H. Herbal Cosmetics (Hand book), Asia Pacific Business Press Inc, New Delhi.
2. Thomson EG. Modern Cosmetics, Universal Publishing Corporation, Mumbai.
3. P.P.Sharma. Cosmetics - Formulation, Manufacturing & Quality Control, Vandana Publications, New Delhi.
4. Supriya K B. Handbook of Aromatic Plants, Pointer Publishers, Jaipur.
5. Skaria P. Aromatic Plants (Horticulture Science Series), New India Publishing Agency, New Delhi.
6. Kathi Keville and Mindy Green. Aromatheraphy (A Complete Guide to the Healing Art), Sri Satguru Publications, New Delhi.
7. Chattopadhyay PK. Herbal Cosmetics & Ayurvedic Medicines (EOU), National Institute of Industrial Research, Delhi.
8. Balsam MS & Edward Sagarin. Cosmetics Science and Technology, Wiley Interscience, New York.

## *HERBAL COSMETICS PRACTICALS*
## *(MPG 205P)*

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

## Semester III
## MRM 301T - Research Methodology & Biostatistics

**UNIT – I**

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

**UNIT – II**

**Biostatistics:** Definition, application, sample size, importance of sample size, factors influencing sample size, dropouts, statistical tests of significance, type of significance tests, parametric tests(students "t" test, ANOVA, Correlation coefficient, regression), non-parametric tests (wilcoxan 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.

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