# ACHARYA NAGARJUNA UNIVERSITY

**A State Government University, Accredited with "A" Grade by NAAC**

**Nagarjuna Nagar - 522 510, Guntur, Andhra Pradesh, India.**

# M.PHARMACY

# SYLLABUS

**2017- 2018 onwards**

-

## UNIVERSITY COLLEGE OF PHARMACEUTICAL SCIECNES

## PROGRAM CODE:

## ANUCPSPG 01 TO 05


ACHARYA NAGARJUNA UNIVERSITY
సత్యం సర్వం ప్రతిష్ఠితమ్

# ABOUT UNIVERSITY

## ACHARYA NAGARJUNA UNIVERSITY (ANU)

### - A Brief Profile

Acharya Nagarjuna University, a State University established in 1976, has been constantly striving towards achieving progress and expansion during its existence for over four decades, in terms of introducing new courses in the University Colleges, affiliated colleges and professional colleges. Spread over 300 acres of land on the National High Way (NH-16) between Vijayawada and Guntur of Andhra Pradesh, the University is one of the front ranking and fastest expanding Universities in the state of Andhra Pradesh. The University was inaugurated on 11th September, 1976 by the then President of India, Sri Fakruddin Ali Ahmed and celebrated its Silver Jubilee in 2001. The National Assessment and Accreditation Council (NAAC) awarded "A" grade to Acharya Nagarjuna University and also has achieved 108 International ranks, 39 National ranks UI Green Metrics rankings and many more It is named after Acharya Nagarjuna – one of the most brilliant preceptors and philosophers, whose depth of thought, clarity of perception and spiritual insight were such that even after centuries, he is a source of inspiration to a vast number of people in many countries. The University is fortunate to be situated on the very soil where he was born and lived, a soil made more sacred by the aspiration for light and a state of whole someness by generations of students. With campus student strength of over 5000, the University offers instruction for higher learning in 68 UG & PG programs and guidance for the award of M.Phil. and Ph.D. in 48 disciplines spread over six campus colleges and one PG campus at Ongole. It also offers 160 UG programs in 440 affiliated colleges in the regions of Guntur and Prakasam Districts. It has a Centre for Distance Education offering 87 UG & PG programs. Characterized by its heterogeneous students and faculty hailing from different parts of the state and the country, the University provides most hospitable environment for pursuing Higher Learning and Research. Its aim is to remain connected academically at the forefront of all higher educational institutions. The University provides an excellent infrastructure and on- Campus facilities such as University Library with over one lakh books & 350 journals; Computer Centre; University Scientific Instrumentation Centre; Central Research Laboratory with Ultra-modern Equipment; Well-equipped Departmental Laboratories; Career Guidance and Placement Cell; Health Centre; Sports Facilities with Indoor & Outdoor Stadiums and Multipurpose Gym; Sports Hostel; Separate hostels for Boys, Girls, Research Scholars and International Students; Pariksha Bhavan (Examinations Building); Computers to all faculty members; Wi-Fi connectivity to all Departments and Hostels; Canteen, Student Centre & Fast-food Centre; Faculty Club; Dr. H.H. Deichmann & Dr. S.John David Auditorium cum Seminar Hall; Post office; Telecom Centre; State Bank of India; Andhra Bank; Energy Park; Silver Jubilee Park; Fish ponds; internet center; xerox center; cooperative stores; Water harvesting structures.

# VISION, MISSION & OBJECTIVES OF THE UNIVERSITY

# ACHARYA NAGARJUNA UNIVERSITY

## VISION

To generate sources of knowledge that dispels ignorance and establish truth through teaching, learning and research.

## MISSION

To promote a bank of human talent in diversified faculties – Commerce & Management Studies, Education, Engineering & Technology, Humanities, Law, Natural Sciences, Pharmacy, Physical Education & Sports Sciences, Physical Sciences and Social Sciences that would become an investment for a prosperous society.

## OBJECTIVES

- To inspire and encourage all who would seek knowledge through higher education and research.
- To provide quality instruction and research for the advancement of science and technology.
- To promote teaching and research studies in disciplines of societal relevance.
- To bridge the gap between theory and practice of the principles of higher education.
- To develop human talent necessary for the industry.
- To open up avenues of higher education and research through non-formal means.
- To invite and implement collaborations with other institutes of higher learning on a continuous basis for mutual academic progress.
- To motivate and orient each academic department/centre to strive for and to sustain advanced levels of teaching and research so that the university emerges as an ideal institute of higher learning.
- To focus specially on the studies involving rural economy, justifying its existence in the rural setting.

# VISION

# &

# MISSION OF THE COLLEGE

# ACHARYA NAGARJUNA UNIVERSITY

# UNIVERSITY COLLEGE OF PHARMACEUTICAL SCIENCES

## VISION OF THE COLLEGE:

- To become a world class institution in Education and Research by providing Quality Education in Pharmaceutical Sciences with utmost care and discipline.
- To achieve highest Satisfaction by imparting Quality Pharmacy Education, Training, Research and Development.

## MISSION OF THE COLLEGE:

- To impart Technical Education in Cutting edge.
- To inoculate Research and Creative endeavour in the minds of students.
- To provide information and direction to stuents about Career oriented programmes needed for full fledged Pharmacy Practice by having Collborations with industries and Foreign Universities

# ACHARYA NAGARJUNA UNIVERSITY

# UNIVERSITY COLLEGE OF PHARMACEUTICAL SCIENCES

# M.PHARMACY

## PROGRAMME EDUCATIONAL OBJECTIVES (PEO's):

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
- 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
- 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
- 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
- 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
- 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

## PROGRAMME OUTCOMES (PO's):

| | |
|---|---|
| PO1. | **Pharmacy Knowledge**: Possess knowledge and comprehension of the core and basic knowledge associated with the profession of pharmacy, including biomedical sciences; pharmaceutical sciences; behavioral, social, and administrative pharmacy sciences; and manufacturing practices. |
| PO2 | **Development of Therpeutical agent:** analyze and interpret experimental data in the development of therapeutic agents. |
| PO3 | **Problem based learning strategy**: In his or her academic and professional life, develop a problem-based learning strategy and analytical thinking. |
| PO4 | **Critical thinking:** Use critical thinking abilities to do research, including investigation, application, analysis, innovation, and evaluation of information, data, and documents. |
| PO5 | **Research skills:** Develop scientific communication and research writing skills. |
| PO6 | **Leadership skills**: Understand and consider the human reaction to change, motivation issues, leadership and team-building when planning changes required for fulfillment of practice, professional and societal responsibilities. Assume participatory roles as responsible citizens or leadership roles when appropriate to facilitate improvement in health and well-being. |
| PO7 | **Multidisciplinary Research:** Conduct multidisciplinary research in collaboration with other health-care communities to develop novel solutions. |
| PO8 | **Healthcare activities:** Take part in healthcare activities to raise public knowledge regarding the proper and safe use of medications. |
| PO9 | **Environment and sustainability:** Demonstrate environmentally sustainable products and procedures in order to protect public health. |
| PO10 | **Professional Ethics:** In both personal and professional efforts, practice ethical behaviours and moral principles. |
| PO11 | **Life-long learning:** Recognize the need for, and have the preparation and ability to engage in independent and life-long learning in the broadest context of technological change. Self-assess and use feedback effectively from others to identify learning needs and to satisfy these needs on an ongoing basis. |

# ACHARYA NAGARJUNA UNIVERSITY
# UNIVERSITY COLLEGE OF PHARMACEUTICAL SCIENCES
# M.PHARMACY

## PHARMACOLOGY
## COURSE STRUCTURE
## SEMESTER-I

| Course Code | Name of the Course | No. of Hours | Tutorial | Credit Points | Activities/Content with direct bearing on Employability/ Entrepreneurship/ Skill development |
|---|---|---|---|---|---|
| **MPL101T** | Modern Pharmaceutical Analytical Techniques | 4 | 4 | 4 | EMPLOYABILITY |
| **MPL102T** | Advanced Pharmaceutical Analysis | 4 | 4 | 4 | EMPLOYABILITY |
| **MPL103T** | Pharmaceutical Validation | 4 | 4 | 4 | EMPLOYABILITY |
| **MPL104T** | Food Analysis | 4 | 4 | 4 | SKILL DEVELOPMENT |
| **Total** | | **35** | 26 | **35** | |

### SEMESTER-II

| Course Code | Name of the Course | No. of Hours | Tutorial | Credit Points | Activities/Content with direct bearing on Employability/ Entrepreneurship/ Skill development |
|---|---|---|---|---|---|
| **MPL201T** | Advanced Instrumental Analysis | 4 | 4 | 4 | EMPLOYABILITY |
| **MPL202T** | Modern Bio-Analytical Techniques | 4 | 4 | 4 | EMPLOYABILITY |
| **MPL203T** | Quality Control and Quality Assurance | 4 | 4 | 4 | EMPLOYABILITY |
| **MPL204T** | Herbal and Cosmetic Analysis | 4 | 4 | 4 | SKILL DEVELOPMENT |
| **Total** | | **35** | 26 | **35** | |

## SEMESTER-III

| 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**

## SEMESTER-IV

| Course Code | Course | Credit Hours | Credit Points |
|---|---|---|---|
| - | Journal club | 1 | 1 |
| - | Discussion/Presentation (Proposal Presentation) | 3 | 3 |
| - | Research Work | 31 | 16 |
| **Total** | | **35** | **20** |

# ACHARYA NAGARJUNA UNIVERSITY
# UNIVERSITY COLLEGE OF PHARMACEUTICAL SCIENCES
# M.PHARMACY
# SEMESTER-I

## MODERN PHARMACEUTICAL ANALYTICALTECHNIQUES (MPL 101T)

**OBJECTIVES:**

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. 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.Spectroflourimetry: Theory of Fluorescence, Factors affecting fluorescence (Characterestics of drugs that can be analysed by flourimetry), Quenchers, Instrumentation and Applications of fluorescence spectrophotometer. Flame emission spectroscopy and Atomic absorption pectroscopy: 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 ofFT-NMR and 13C NMR. Applications of NMR spectroscopy.

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

4 Chromatography: Principle, apparatus, instrumentation, chromatographic parameters, factors affecting resolution, isolation of drug from excipients, data interpretation and applications of the following: j)Thin Layer chromatography High Performance Thin Layer Chromatography l) Ion exchange chromatography m) Column chromatography n) Gas chromatography o) High Performance Liquid chromatography p) Ultra HighPerformance Liquid chromatography q) Affinity chromatography r) Gel Chromatography

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

ray Crystallography: Production of X rays, Different X ray methods, Bragg‘ s law, Rotating crystal technique, X ray powder technique, Types of crystals and applications of X-ray diffraction.Potentiometry: Principle, working, Ion selective Electrodes and Application of potentiometry. Thermal Techniques: Principle, thermal transitions and Instrumentation (Heat flux and power-compensation and designs), Modulated DSC, Hyper DSC, experimental parameters (sample preparation, experimental conditions, calibration, heating and cooling rates, resolution, source of errors) and their influence, advantage and disadvantages, pharmaceutical applications. Differential Thermal Analysis (DTA): Principle, instrumentation and advantage and disadvantages, pharmaceutical applications, derivative differential thermal analysis (DDTA). TGA: Principle, instrumentation, factors affecting results, advantage and disadvantages, pharmaceutical applications.

**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, 5 th 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, 2 nd 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)
# (MPL102) ADVANCED PHARMACOLOGY-I

**OBJECTIVES:**

After completing this course, the students must demonstrate the knowledge and ability to:

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

**COURSE OUTCOMES:**

| S.NO | COURSE OUTCOMES | Knowledge level (BLOOMS Level) |
|---|---|---|
| After successful completion of the course student shall be able to | | |
| CO1: | Identify various mechanisms and how the drug acts. | L1:Remember<br>L2:Understand<br>L3:Apply |
| CO2: | General pharmacology dealing with basics of pharmacology. | L3:Apply<br>L4:Analyse<br>L5:Evaluate |
| CO3: | Information regarding neurohumoral transmission of neuro-transmitters | L1:Remember<br>L3:Apply<br>L4:Analyse |
| CO4: | Identify, diagnose and treat various cardiac diseases | L3:Apply<br>L4:Analyse<br>L5:Evaluate |
| CO5: | Treatment regimen for neuro pharmacology is understood | L3:Apply<br>L4:Analyse<br>L5:Evaluate |

**Course Outcomes and Program Out comes (CO-PO)**

**Mapping: LEVEL: 1 – Slight (low), 2- Moderate (medium), 3- Substantial (High)**

| | PO1 | PO2 | PO3 | PO4 | PO5 | PO6 | PO7 | PO8 | PO9 | PO10 | PO11 |
|---|---|---|---|---|---|---|---|---|---|---|---|
| CO1 | 3 | 3 | 2 | 3 | 3 | 3 | 3 | 3 | 2 | 3 | 2 |
| CO2 | 3 | 3 | 3 | 2 | 3 | 2 | 2 | 3 | 2 | 2 | 2 |
| CO3 | 3 | 2 | 3 | 2 | 3 | 1 | 3 | 3 | 2 | 3 | 2 |
| CO4 | 3 | 2 | 3 | 3 | 3 | 1 | 3 | 3 | 2 | 2 | 2 |
| CO5 | 3 | 3 | 3 | 3 | 3 | 1 | 3 | 3 | 2 | 2 | 2 |
| Avg | 3 | 2.6 | 2.8 | 2.6 | 3 | 1.6 | 2.8 | 3 | 2 | 2.4 | 2 |

## (MPL102) ADVANCED PHARMACOLOGY-I SYLLABUS

1. General Pharmacology

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

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

3 Central nervous system Pharmacology General and local anesthetics Sedatives and hypnotics, drugs used to treat anxiety. Depression, psychosis, mania, epilepsy, neurodegenerative diseases.

Narcotic and non-narcotic analgesics.

4 Cardiovascular Pharmacology

Diuretics, antihypertensives, antiischemics, anti- arrhythmics, drugs for heart failure and hyperlipidemia.

Hematinics, coagulants , anticoagulants, fibrinolytics and anti- platelet drugs

5 Autocoid Pharmacology

The physiological and pathological role of Histamine, Serotonin, Kinins Prostaglandins Opioid autocoids.

Pharmacology of antihistamines, 5HT antagonists.

**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.

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

**OBJECTIVES:**

After completing this course, the students must demonstrate the knowledge and ability 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

**COURSE OUTCOMES:**

| S.NO | COURSE OUTCOMES | Knowledge level (BLOOMS Level) |
|---|---|---|
| After successful completion of the course student shall be able to | | |
| CO1: | To know about commonly used laboratory animals in various screening methods. | L1:Remember<br>L2:Understand<br>L3:Apply<br>L4:Analyse |
| CO2: | To know about the various screening methods used in preclinical research. | L3:Apply<br>L4:Analyse<br>L5:Evaluate |
| CO3: | To understand the importance of biostatistics and research methodology in the interpretation of results. | L1:Remember<br>L3:Apply<br>L4:Analyse<br>L5:Evaluate |
| CO4: | Design and execute a research hypothesis independently. | L3:Apply<br>L4:Analyse<br>L5:Evaluate |
| CO5: | To know the principles of toxicology and treatment of various poisonings. | L1:Remember<br>L2:Understand<br>L3:Apply<br>L5:Evaluate |

**Course Outcomes and Program Out comes (CO-PO)**

**Mapping: LEVEL: 1 – Slight (low), 2- Moderate (medium), 3- Substantial (High)**

| | PO1 | PO2 | PO3 | PO4 | PO5 | PO6 | PO7 | PO8 | PO9 | PO10 | PO11 |
|---|---|---|---|---|---|---|---|---|---|---|---|
| CO1 | 3 | 3 | 2 | 3 | 3 | 3 | 3 | 3 | 2 | 3 | 3 |
| CO2 | 3 | 3 | 3 | 2 | 3 | 2 | 2 | 3 | 2 | 2 | 3 |
| CO3 | 3 | 2 | 3 | 2 | 3 | 1 | 3 | 3 | 2 | 3 | 3 |
| CO4 | 3 | 2 | 3 | 3 | 3 | 1 | 3 | 3 | 2 | 2 | 3 |
| CO5 | 3 | 3 | 3 | 3 | 3 | 1 | 3 | 3 | 2 | 2 | 3 |
| Avg | 3 | 2.6 | 2.8 | 2.6 | 3 | 1.6 | 2.8 | 3 | 2 | 2.4 | 3 |

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

SYLLABUS

1. Laboratory Animals

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

Transgenic animals: Production, maintenance and applications Anaesthesia and euthanasia of experimental animals. Maintenance and breeding of laboratory animals. CPCSEA guidelines to conduct experiments on animals Good laboratory practice. Bioassay-Principle, scope and limitations and methods

2 Preclinical screening of new substances for the pharmacological activity using in vivo,

in vitro, and other possible animal alternative models. 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.

3 Preclinical screening of new substances for the pharmacological activity using in vivo, in vitro, and other possible animal alternative models. Respiratory Pharmacology: anti-asthmatics, drugs for COPD and anti allergics.Reproductive Pharmacology: Aphrodisiacs and antifertility agents Analgesics,

antiinflammatory and antipyretic agents. Gastrointestinal drugs: anti ulcer, anti -emetic, anti- diarrheal and laxatives.

4 Preclinical screening of new substances for the pharmacological activity using in vivo, in vitro, and other possible animal alternative models. Cardiovascular Pharmacology: antihypertensives, antiarrythmics, antianginal, antiatherosclerotic agents and diuretics. Drugs for metabolic disorders like anti-diabetic, antidyslipidemic agents. Anti cancer agents. Hepatoprotective screening methods.

5 Preclinical screening of new substances for the pharmacological activity using in vivo, in vitro, and other possible animal alternative models. Iimmunomodulators, Immunosuppressants and immunostimulants General principles of immunoassay: theoretical basis and

optimization of immunoassay, heterogeneous and homogenous immunoassay systems. Immunoassay methods evaluation; protocol outline, objectives and preparation. Immunoassay for digoxin and insulin

**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, 2 nd 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

## CELLULAR AND MOLECULAR PHARMACOLOGY (MPL 104T)

**OBJECTIVES:**

After completing this course, the students must demonstrate the knowledge and ability 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
- **COURSE OUTCOMES:**

| S.NO | COURSE OUTCOMES | Knowledge level (BLOOMS Level) |
|---|---|---|
| After successful completion of the course student shall be able to | | |
| **CO1:** | Explain about the structural and functional role of cells and their organelles | L1:Remember<br>L2:Understand |
| **CO2:** | Understand the signal transduction process.. | L1:Remember<br>L2:Understand |
| **CO3:** | Explain about the intercellular and intracellular signaling pathways | L1:Remember<br>L4:Analyse |
| **CO4:** | Explain about the principles and applications of various genomic<br>and proteomic tools. | L3:Apply<br>L4:Analyse<br>L5:Evaluate |
| **CO5:** | To knowe about the role of Pharmacogenomics in health and Pharmacology. | L3:Apply<br>L5:Evaluate |

**Course Outcomes and Program Out comes (CO-PO)**

**Mapping: LEVEL: 1 – Slight (low), 2- Moderate (medium), 3- Substantial (High)**

| | PO1 | PO2 | PO3 | PO4 | PO5 | PO6 | PO7 | PO8 | PO9 | PO10 | PO11 |
|---|---|---|---|---|---|---|---|---|---|---|---|
| CO1 | 3 | 1 | 1 | 3 | 3 | 1 | 3 | 3 | 2 | 3 | 3 |
| CO2 | 3 | 1 | 1 | 3 | 3 | 1 | 2 | 3 | 2 | 3 | 3 |
| CO3 | 3 | 1 | 1 | 3 | 3 | 1 | 3 | 3 | 2 | 3 | 3 |
| CO4 | 3 | 1 | 1 | 3 | 3 | 1 | 3 | 3 | 2 | 3 | 3 |
| CO5 | 3 | 1 | 1 | 3 | 3 | 1 | 3 | 3 | 2 | 3 | 3 |
| Avg | 3 | 1 | 1 | 3 | 3 | 1 | 2.8 | 3 | 2 | 3 | 3 |

**CELLULAR AND MOLECULAR PHARMACOLOGY (MPL 104T) SYLLABUS**

1. Cell biology 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 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.

3 Principles and applications of genomic and proteomic tools DNA electrophoresis, PCR (reverse transcription and real time), Gene sequencing, micro array technique, SDS page, ELISA and western blotting, Recombinant DNA technology and gene therapy Basic principles of recombinant DNA technology-Restrictionenzymes, various types of vectors. Applications of recombinantDNA technology. Gene therapy- Various types of gene transfer techniques, clinical applications and recent advances in gene therapy.

4 Pharmacogenomics Gene mapping and cloning of disease gene.

Genetic variation and its role in health/ pharmacology Polymorphisms affecting drug metabolism Genetic variation in drug transporters Genetic variation in G protein coupled receptors Applications of

proteomics science: Genomics, proteomics, metabolomics, functionomics, nutrigenomics Immunotherapeutics Types of immunotherapeutics, humanisation antibody therapy, Immunotherapeutics in clinical practice

5 a. Cell culture techniques Basic equipments used in cell culture lab. Cell culture media, various types of cell culture, general procedure for cell cultures; isolation of cells, subculture, cryopreservation, characterization of cells and their application. Principles and applications of cell viability assays, glucose uptake assay, Calcium influx assaysPrinciples and applications of flow cytometryb. Biosimilars

**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.

# UNIVERSITY COLLEGE OF PHARMACEUTICAL SCIENCES
## M.PHARMACY
## SEMESTER-II
## Paper-I: ADVANCED PHARMACOLOGY - II (MPL 201T)

**OBJECTIVES:**

After completing this course, the students must demonstrate the knowledge and ability 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

**COURSE OUTCOMES:**

| S.NO | COURSE OUTCOMES | Knowledge level (BLOOMS Level) |
|---|---|---|
| After successful completion of the course student shall be able to | | |
| CO1: | Understand the free radical pharmacology | L2:Understand |
| CO2: | Gain sound knowledge on endocrine pharmacology and treatment regimen | L3:Apply<br>L4:Analyse<br>L5:Evaluate |
| CO3: | Know Information regarding treatment of infectious diseasess | L1:Remember<br>L3:Apply<br>L4:Analyse |
| CO4: | Understand brief pharmacological actions of drugs regarding GIT associated diseases | L2:Understand<br>L3:Apply |
| CO5: | Recent advances in treatment regimens of various CNS diseases are known | L3:Apply |

**Course Outcomes and Program Out comes (CO-PO)**

**Mapping: LEVEL: 1 – Slight (low), 2- Moderate (medium), 3- Substantial (High)**

| | PO1 | PO2 | PO3 | PO4 | PO5 | PO6 | PO7 | PO8 | PO9 | PO10 | PO11 |
|---|---|---|---|---|---|---|---|---|---|---|---|
| CO1 | 3 | 3 | 3 | 3 | 3 | 1 | 3 | 3 | 2 | 3 | 2 |
| CO2 | 3 | 3 | 3 | 2 | 3 | 1 | 2 | 3 | 2 | 2 | 2 |
| CO3 | 3 | 3 | 3 | 2 | 3 | 1 | 3 | 3 | 2 | 3 | 2 |
| CO4 | 3 | 3 | 3 | 3 | 3 | 1 | 3 | 3 | 2 | 2 | 2 |
| CO5 | 3 | 3 | 3 | 3 | 3 | 1 | 3 | 3 | 2 | 2 | 2 |
| Avg | 3 | 3 | 3 | 2.6 | 3 | 1 | 2.8 | 3 | 2 | 2.4 | 2 |

**ADVANCED PHARMACOLOGY - II (MPL 201T) SYLLABUS**

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

2 Chemotherapy

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

3 Chemotherapy

Drugs used in Protozoal InfectionsDrugs used in the treatment of Helminthiasis Chemotherapy of cancer Immunopharmacology Cellular and biochemical mediators of inflammation and immune response. Allergic or hypersensitivity reactions. Pharmacotherapy of asthma and COPD. Immunosuppressants and Immunostimulants

4 GIT PharmacologyAntiulcer drugs, Prokinetics, antiemetics, anti-diarrheals and drugs for constipationand irritable bowel syndrome. Chronopharmacology Biological and circadian rhythms, applications of chronotherapy in various diseases like cardiovascular disease, diabetes, asthma and peptic ulcer

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

Recent Advances in Treatment:

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

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

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

**OBJECTIVES:**

After completing this course, the students must demonstrate the knowledge and ability 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

**COURSE OUTCOMES**

| S.NO | COURSE OUTCOMES | Knowledge level (BLOOMS Level) |
|---|---|---|
| After successful completion of the course student shall be able to | | |
| CO1: | . Describe the applications of common laboratory animals, explain CPCSEA and OECD guidelines governing the for maintenance, breeding and conduct of experiments on laboratory animals. | L1:Remember<br>L2:Understand<br>L3:Apply |
| CO2: | Explain dose, dose calculations grouping of animals, species selection, sex in conducting the animal experimentation | L3:Apply<br>L4:Analyse<br>L5:Evaluate |
| CO3: | Toxicological and allergen screening techniques. | L1:Remember<br>L3:Apply |
| CO4: | They would have understood the maintenance of laboratory animals as per the guidelines, basic knowledge of various in-vitro and in vivo preclinical evaluation processes. | L2:Understand<br>L3:Apply<br>L5:Evaluate |
| CO5: | They would have learnt to describe the various animals used in the drug discovery process and good laboratory practices in maintenance and handling of experimental animals. | L3:Apply<br>L5:Evaluate |

**Course Outcomes and Program Out comes (CO-PO) Mapping: LEVEL: 1 – Slight (low), 2- Moderate (medium), 3- Substantial (High)**

| PHARMACOLOGY | PO1 | PO2 | PO3 | PO4 | PO5 | PO6 | PO7 | PO8 | PO9 | PO10 | PO11 |
|---|---|---|---|---|---|---|---|---|---|---|---|
| CO1 | 3 | 3 | 3 | 3 | 3 | 1 | 3 | 3 | 1 | 3 | 2 |
| CO2 | 3 | 3 | 3 | 3 | 3 | 1 | 3 | 3 | 1 | 2 | 2 |
| CO3 | 3 | 3 | 3 | 3 | 3 | 1 | 3 | 3 | 1 | 3 | 2 |
| CO4 | 3 | 3 | 3 | 3 | 3 | 1 | 3 | 3 | 1 | 2 | 2 |
| CO5 | 3 | 3 | 3 | 3 | 3 | 1 | 3 | 3 | 1 | 2 | 2 |
| Avg | 3 | 3 | 3 | 3 | 3 | 1 | 3 | 3 | 1 | 2.4 | 2 |

**GICAL AND TOXICOLOGICAL SCREENING METHODS-II (MPL 202T) SYLLABUS**

1. Basic definition and types of toxicology (general, mechanistic, regulatory and descriptive) Regulatory guidelines for conducting toxicity studies OECD, ICH,

EPA and Schedule Y OECD principles of Good laboratory practice (GLP) History, concept and its importance in drug development

2 Acute, sub-acute and chronic- oral, dermal and inhalational studies as per OECD guidelines. Acute eye irritation, skin sensitization, dermal irritation & dermal

toxicity studies. Test item characterization- importance and methods in regulatory

toxicology studies

3 Reproductive toxicology studies, Male reproductive toxicity studies, female reproductive studies (segment I and segment III),teratogenecity studies (segment Genotoxicity studies (Ames Test, in vitro and in vivo Micronucleus

and Chromosomal aberrations studies)In vivo carcinogenicity studies 4 IND enabling studies (IND studies)- Definition of IND, importance

of IND, industry perspective, list of studies needed for IND submission.

4Safety pharmacology studies- origin, concepts and importance of safety pharmacology. 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. Alternative methods to animal toxicity testing.

**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)

# Paper-III: PRINCIPLES OF DRUG DISCOVERY (MPL 203T)

**OBJECTIVES:**

After completing this course, the students must demonstrate the knowledge and ability 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.

**COURSE OUTCOMES:**

| S.NO | COURSE OUTCOMES | Knowledge level (BLOOMS Level) |
|---|---|---|
| After successful completion of the course student shall be able to | | |
| CO1: | Explain the various stages of drug discovery | L1:Remember<br>L2:Understand |
| CO2: | Appreciate the importance of the role of genomics, proteomics and bioinformatics in drug discovery | L1:Remember<br>L2:Understand |
| CO3: | Explain various targets for drug discovery | L1:Remember<br>L4:Analyse |
| CO4: | Explain various lead seeking method and lead optimization | L3:Apply<br>L4:Analyse<br>L5:Evaluate |
| CO5: | Appreciate the importance of the role of computer aided drug design in drug discovery | L3:Apply<br>L5:Evaluate |

**Course Outcomes and Program Out comes (CO-PO)**

**Mapping: LEVEL: 1 – Slight (low), 2- Moderate (medium), 3- Substantial (High)**

| | PO1 | PO2 | PO3 | PO4 | PO5 | PO6 | PO7 | PO8 | PO9 | PO10 | PO11 |
|---|---|---|---|---|---|---|---|---|---|---|---|
| CO1 | 3 | 3 | 3 | 3 | 3 | 1 | 3 | 3 | 1 | 3 | 1 |
| CO2 | 3 | 3 | 3 | 3 | 3 | 1 | 2 | 3 | 1 | 3 | 1 |
| CO3 | 3 | 3 | 3 | 3 | 3 | 1 | 3 | 3 | 1 | 3 | 1 |
| CO4 | 3 | 3 | 3 | 3 | 3 | 1 | 3 | 3 | 1 | 3 | 1 |
| CO5 | 3 | 3 | 3 | 3 | 3 | 1 | 3 | 3 | 1 | 3 | 1 |
| Avg | 3 | 3 | 3 | 3 | 3 | 1 | 2.6 | 3 | 1 | 3 | 1 |

**PRINCIPLES OF DRUG DISCOVERY (MPL 203T) SYLLABUS**

1. An overview of modern drug discovery process: Target identification, target validation, lead identification and lead Optimization. Economics of drug discovery. Target Discovery and validation- Role of Genomics, Proteomics

and Bioinformatics. Role of Nucleic acid microarrays, Proteinmicroarrays, Antisense technologies, siRNAs, antisense oligonucleotides, Zinc fi nger proteins. Role of transgenic animals in target validation.

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

3 Rational Drug Design 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 approachesVirtual 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.

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

**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

# CLINICAL RESEARCH AND PHARMACOVIGILANCE (MPL 204T)

**OBJECTIVES:**

After completing this course, the students must demonstrate the knowledge and ability to:

- Explain the regulatory requirements for conducting clinical tria
- 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

**COURSE OUTCOMES:**

| S.NO | COURSE OUTCOMES | Knowledge level (BLOOMS Level) |
|---|---|---|
| After successful completion of the course student shall be able to | | |
| CO1: | 1. Explain about the various phases of drug discovery. | L1:Remember<br>L2:Understand |
| CO2: | Understand the applications of genomics, proteomics and bioinformatics in drug discovery. | L1:Remember<br>L2:Understand |
| CO3: | Understand the concept of target identification, target validation, lead<br>identification and lead optimization in drug discovery. | L1:Remember<br>L4:Analyse<br>L5:Evaluate |
| CO4: | Explain about the concepts of rational drug design | L1:Remember<br>L2:Understand<br>L3:Apply |
| CO5: | . To know the role and importance of the tools used in Computer aided Drug Design and Discovery. | L1:Remember<br>L2:Understand<br>L3:Apply<br>L5:Evaluate |

**Course Outcomes and Program Out comes (CO-PO)**

**Mapping: LEVEL: 1 – Slight (low), 2- Moderate (medium), 3- Substantial (High)**

| | PO1 | PO2 | PO3 | PO4 | PO5 | PO6 | PO7 | PO8 | PO9 | PO10 | PO11 |
|---|---|---|---|---|---|---|---|---|---|---|---|
| CO1 | 3 | 3 | 3 | 3 | 3 | 1 | 3 | 3 | 1 | 3 | 1 |
| CO2 | 3 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 |
| CO3 | 3 | 3 | 3 | 3 | 3 | 1 | 3 | 3 | 1 | 3 | 1 |
| CO4 | 3 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 |
| CO5 | 3 | 3 | 3 | 3 | 3 | 1 | 3 | 3 | 1 | 3 | 1 |
| Avg | 3 | 2.2 | 2.2 | 2.2 | 2.2 | 1 | 2.2 | 2.2 | 1 | 2.2 | 1 |

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

1. Regulatory Perspectives of Clinical Trials: Origin and Principles of International Conference onHarmonization - Good Clinical Practice (ICH-GCP) guidelinesEthical Committee: Institutional Review Board, Ethical Guidelines for Biomedical Research and Human Participant- Schedule Y, ICMR Informed Consent Process: Structure and content of anInformed Consent Process Ethical principles governing informed consent process

2 Clinical Trials: Types and Design

Experimental Study- RCT and Non RCT, Observation Study: Cohort, Case Control, Cross sectionalClinical Trial Study Team Roles and responsibilities of Clinical Trial Personnel: Investigator, Study Coordinator, Sponsor, Contract Research Organization andits management

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 Adverse Drug Reactions: Definition and types. Detection andreporting methods. Severity and seriousness assessment.Predictability and preventability assessment, Management of adverse drug reactions; Terminologies of ADR.

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

5 Methods, ADR reporting and tools used in PharmacovigilanceInternational 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 systemand Reporting to regulatory authorities, Guidelines for ADRsreporting. Argus, Aris GPharmacovigilance, VigiFlow, Statistical methods for evaluating medication safety data.

6 Pharmacoepidemiology, pharmacoeconomics, safety pharmacology

**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. 229

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.

# UNIVERSITY COLLEGE OF PHARMACEUTICAL SCIENCES
# M.PHARMACY
# SEMESTER-III

**Paper-I: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

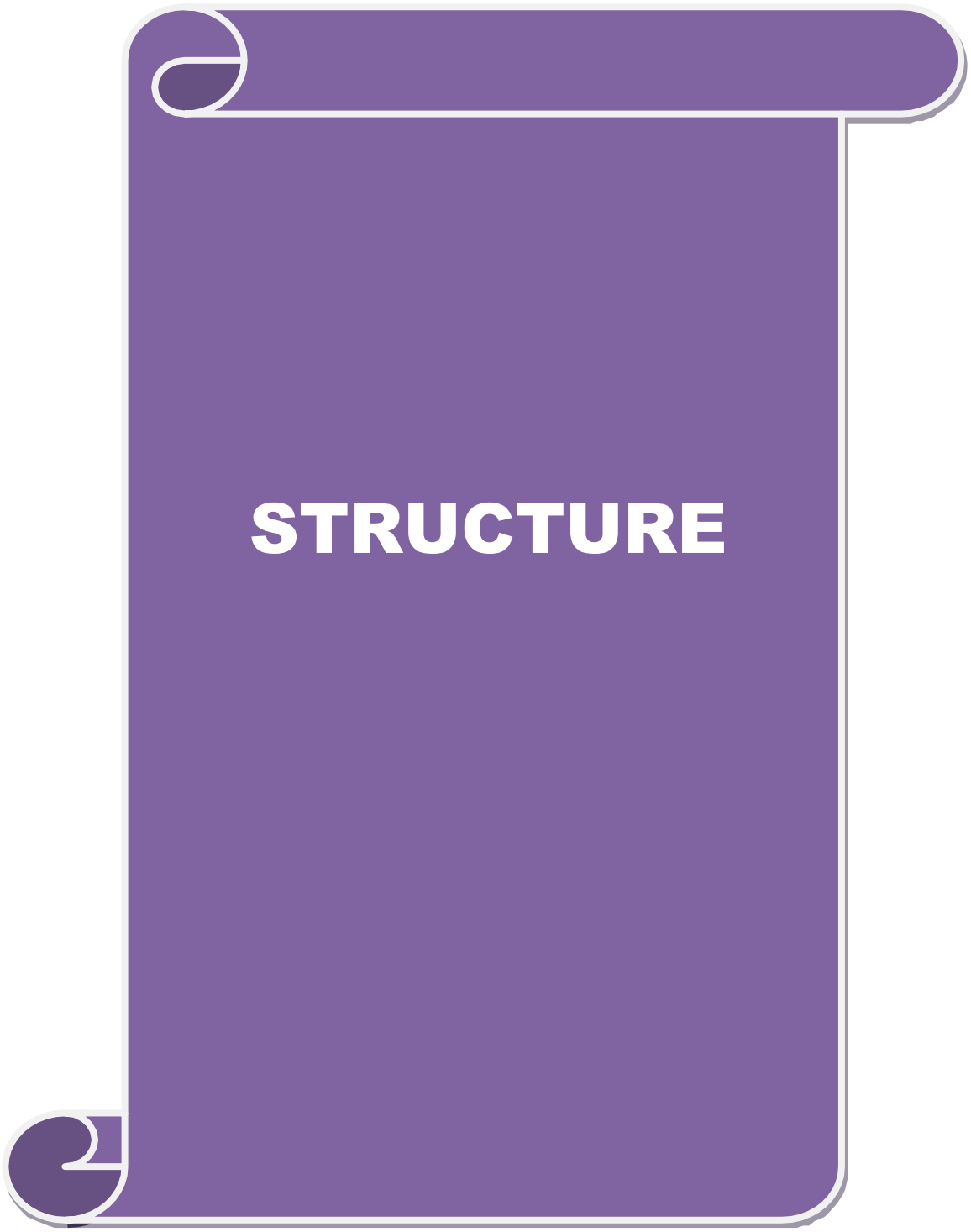
hygiene, location of animal facilities to laboratories, anesthesia, euthanasia, physical facilities, environment, animal husbandry, record keeping, SOPs, personnel and training, transport of lab animals.

**UNIT – V** Declaration of Helsinki: History, introduction, basic principles for all medical

research, and additional principles for medical research combined with medical care.

# UNIVERSITY COLLEGE OF PHARMACEUTICAL SCIENCES
## M.PHARMACY
## SEMESTER-IV

- Journal Club
- Research Work
- Final Presentation


STRUCTURE

# ACHARYA NAGARJUNA UNIVERSITY

# UNIVERSITY COLLEGE OF PHARMACEUTICAL SCIENCES

# M.PHARMACY

## PHARMACEUTICAL CHEMISTRY

### SEMESTER I

| Course Code | Course | Credit Hours | Credit Points | Hrs./wk | Marks | Activities/Content with direct bearing on Employability/ Entrepreneurship/ Skill development |
|---|---|---|---|---|---|---|
| **MPC101T** | Modern Pharmaceutical Analytical Techniques | 4 | 4 | 4 | 100 | EMPLOYABILITY |
| **MPC1012T** | Advanced Organic Chemistry -I | 4 | 4 | 4 | 100 | EMPLOYABILITY |
| **MPC103T** | Advanced Medicinal chemistry | 4 | 4 | 4 | 100 | ENTERPERNEURSHIP |
| **MPC104T** | Chemistry of Natural Products | 4 | 4 | 4 | 100 | EMPLOYABILITY |
| **MPC105P** | Pharmaceutical Chemistry Practical I | 12 | 6 | 12 | 150 | EMPLOYABILITY |
| - | Seminar/Assignment | 7 | 4 | 7 | 100 | ENTERPERNEURSHIP |
| | Total | 35 | 26 | 35 | 650 | |

### SEMESTER II

| Course Code | Course | Credit Hours | Credit Points | Hrs./ w k | Marks | Activities/Content with direct bearing on Employability / Entrepreneurship/ Skill development |
|---|---|---|---|---|---|---|
| **MPC201T** | Advanced Spectral Analysis | 4 | 4 | 4 | 100 | EMPLOYABILITY |
| **MPC202T** | Advanced Organic Chemistry -II | 4 | 4 | 4 | 100 | EMPLOYABILITY |
| **MPC203T** | Computer Aided Drug Design | 4 | 4 | 4 | 100 | ENTERPERNEURSHIP |
| **MPC204T** | Pharmaceutical Process Chemistry | 4 | 4 | 4 | 100 | EMPLOYABILITY |
| **MPC205P** | Pharmaceutical Chemistry Practical II | 12 | 6 | 12 | 150 | EMPLOYABILITY |
| - | Seminar/Assignment | 7 | 4 | 7 | 100 | ENTERPERNEURSHIP |
| | Total | 35 | 26 | 35 | 650 | |

## SEMESTER-III

| 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**

## SEMESTER-IV

| Course Code | Course | Credit Hours | Credit Points |
|---|---|---|---|
| - | Journal club | 1 | 1 |
| - | Discussion/Presentation (Proposal Presentation) | 3 | 3 |
| - | Research Work | 31 | 16 |
| **Total** | | **35** | **20** |

# SEMESTER-I

# M. PHARMACY

# PHARMACEUTICAL CHEMISTRY

# (MPC)

## MPC 101T: MODERN PHARMACEUTICAL ANALYTICAL TECHNIQUES

**Course Objectives**

- 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.
- 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

**Course Outcomes**

| S. No | Course Outcomes | Knowledge level (BLOOMS Level) |
|---|---|---|
| After successful completion of the course student shall be able to | | |
| **CO1:** | Explain the theoretical principles of UV, IR, MASS and NMR spectroscopy | L1: Remember<br>L2: Understand<br>L3: Apply |
| **CO2:** | Discuss structural elucidation of organic and natural compounds by IR, NMRand MASS spectral data. Understand the theoretical principles of Woodward-Fieser rule. | L3: Apply<br>L4: Analyse<br>L5: Evaluate |
| **CO3:** | Learn instrumentation and Interpretation of organic compounds by Ramanspectroscopy | L3: Apply<br>L4: Analyse<br>L5: Evaluate |
| **CO4:** | Learn the general theory and principles of thermal analysis | L2:Understand<br>L3: Apply<br>L4: Analyse |
| **CO5:** | Learn the general theory and principles of Hyphenated Techniques | L3: Apply<br>L4: Analyse<br>L5: Evaluate |

BLOOMS Taxonomy- L1: Remember, L2: Understand, L3: Apply, L4: Analyse, L5: Evaluate,L6:Create

**How program out comes are assessed:**

| Program Outcome | | Level | Proficiency assessed by |
|---|---|---|---|
| **PO1:** | Pharmacy Knowledge | 3 | Assignments/ Internals/Viva |
| **PO2:** | Planning Abilities | 2 | Assignments/ Internals |
| **PO3:** | Conduct Investigations of ComplexProblems | 3 | Assignments/ Internals/ Practicals |
| **PO4:** | Problem Analysis | 2 | Assignments/ Internals |
| **PO5:** | Modern Tool Usage | 3 | Seminars/academic activities |
| **PO6:** | Leadership Skills | 2 | Group discussion / Role play |
| **PO7:** | Professional Identity | 2 | Group discussion |
| **PO8:** | Pharmaceutical Ethics | 2 | Personality development seminars |
| **PO9:** | Communication | 3 | Students' seminars/ student -teacher interaction |
| **PO10:** | The Pharmacist and Society | 2 | Group discussion / Role play |
| **PO11:** | Environment And Sustainability | 2 | Students' seminars |
| **PO12** | Life-Long Learning | 3 | Assignments/ Internals |

**LEVEL: 1- Slight (Low), 2- Moderate(Medium), 3- Substantial(High)**

**Course Outcomes and Program Outcomes (CO-PO) Mapping:**

| | PO1 | PO2 | PO3 | PO4 | PO5 | PO6 | PO7 | PO8 | PO9 | PO10 | PO11 | PO12 |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| **CO1** | 3 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 |
| **CO2** | 3 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 |
| **CO3** | 3 | 3 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 |
| **CO4** | 3 | 3 | 2 | 2 | 3 | 3 | 2 | 2 | 2 | 2 | 2 | 2 |
| **CO5** | 3 | 3 | 3 | 3 | 3 | 3 | 2 | 2 | 2 | 2 | 2 | 2 |
| **CO6** | 3 | 3 | 2 | 3 | 3 | 3 | 2 | 2 | 2 | 2 | 2 | 2 |
| **Avg** | 3 | 2.6 | 2.2 | 2.3 | 2.5 | 2.5 | 2 | 2 | 2 | 2 | 2 | 2 |

**Course content**

**THEORY** **60Hrs**

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.

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

**Spectroflourimetry**: Theory of Fluorescence, Factors affecting fluorescence (Characterestics of drugs that can be analysed by flourimetry), Quenchers, Instrumentation and Applications of fluorescence spectrophotometer

Flame emission spectroscopy and Atomic absorption spectroscopy: Principle, Instrumentation, Interferencesand 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.

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.

4. **Chromatography**: Principle, apparatus, instrumentation, chromatographic parameters, factors affecting resolution, isolation of drug from excipients, data interpretation and applications of the following:

Thin Layer chromatography,High Performance Thin Layer Chromatography,Ion exchange chromatography Column chromatography,Gas chromatography,High Performance Liquid chromatography

Ultra High Performance Liquid chromatography,Affinity chromatography,Gel Chromatography

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

6.**X ray Crystallography**: Production of X rays, Different X ray methods, Bragg's law, Rotating crystal technique, X ray powder technique, Types of crystals and applications of X-ray diffraction Potentiometry: Principle, working, Ion selective Electrodes and Application of potentiometry.

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

**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 publisher
4. Quantitative analysis of Pharmaceutical formulations by HPTLC - P D Sethi, CBS Publishers, New Delhi. 5.Quantitative Analysis of Drugs in Pharmaceutical formulation - P D Sethi, 3rd Edition, CBS Publishers, New Delhi, 1997.
6. Pharmaceutical Analysis- Modern methods – Part B - J W Munson, Volume 11.

# MPC102T: ADVANCED ORGANIC CHEMISTRY – I

**Objectives**

- This course 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.
- Upon completion of the course student shall be able to
    - The principles and applications of retero synthesis.
    - The mechanism and 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.

**Course outcomes**

| S. No | Course Outcomes | Knowledge level (BLOOMS Level) |
|---|---|---|
| After successful completion of the course student shall be able to explain | | |
| **CO1** | To describe mechanisms for reactions in organic chemistry. | L1: Remember<br>L2: Understand |
| **CO2** | To apply all the naming reactions in multistep process in manufacturing<br>of drugs and drug intermediates special reactive intermediates includingcarbenes, carbanions and free radicals. | L1: Remember<br>L2: Understand<br>L3: Apply |
| **CO3** | To understand the applications of reagents and protecting groups. | L1: Remember<br>L2: Understand<br>L3: Apply |
| **CO4** | To understand and apply the structure and theory to the study of organicreaction in heterocyclic chemistry. | L1: Remember<br>L2: Understand<br>L6: Create |
| **CO5** | To develop synthetic route for small molecules. To carry out an organicreaction, including isolating, purifying, and characterizing the product. | L1: Remember<br>L2: Understand<br>L3: Apply<br>L4: Analyze<br>L5: Evaluate<br>L6: Create |

BLOOMS Taxonomy- L1: Remember, L2: Understand, L3: Apply, L4: Analyse, L5: Evaluate, L6:Create

**How program out comes are assessed**

| Program Outcome | | Level | Proficiency assessed by |
|---|---|---|---|
| **PO1:** | Pharmacy Knowledge | 3 | Assignments/ Internals/Viva |
| **PO2:** | Planning Abilities | 2 | Assignments/ Internals |
| **PO3:** | Conduct Investigations of ComplexProblems | 3 | Assignments/ Internals/ Practicals |
| **PO4:** | Problem Analysis | 3 | Assignments/ Internals |
| **PO5:** | Modern Tool Usage | 2 | Seminars/academic activities |
| **PO6:** | Leadership Skills | 2 | Group discussion / Role play |
| **PO7:** | Professional Identity | 2 | Group discussion |
| **PO8:** | Pharmaceutical Ethics | 2 | Personality development seminars |
| **PO9:** | Communication | 3 | Students' seminars/ student - teacherinteraction |
| **PO10:** | The Pharmacist and Society | 2 | Group discussion / Role play |
| **PO11:** | Environment And Sustainability | 2 | Students' seminars |
| **PO12** | Life-Long Learning | 3 | Assignments/ Internals |

**LEVEL: 1- Slight (Low), 2- Moderate (Medium), 3- Substantial (High)**

**Course Outcomes and Program Outcomes (CO-PO) Mapping:**

| | PO1 | PO2 | PO3 | PO4 | PO5 | PO6 | PO7 | PO8 | PO9 | PO10 | PO11 | PO12 |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| **CO1** | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 |
| **CO2** | 3 | 3 | 3 | 2 | 2 | 3 | 3 | 3 | 3 | 3 | 3 | 3 |
| **CO3** | 2 | 3 | 3 | 2 | 2 | 3 | 3 | 3 | 3 | 3 | 3 | 3 |
| **CO4** | 3 | 3 | 2 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 |
| **CO5** | 2 | 2 | 2 | 3 | 3 | 2 | 2 | 2 | 2 | 2 | 2 | 3 |
| **Avg** | 2.6 | 2.8 | 2.6 | 2.6 | 2.6 | 2.8 | 2.8 | 2.8 | 2.8 | 2.8 | 2.8 | 3 |

**Course Content:**

**THEORY** **60Hrs**

**UNIT-I** **12 Hours**

**Basic Aspects of Organic Chemistry:**

i. Organic intermediates : Carbocations, carbanions, free radicals, carbenes and nitrenes. Their methods offormation,stability and synthetic applications.

ii. Mechanisms and methods of determining them :

Types of reactions ,Types of mechanism and methods of determining mechanisms.

iii. Detailed knowledge regarding the reactions, mechanisms and their relative reactivity andorientations of the following reactions.

a) Nucleophilic uni and bimolecular substitution reactions ($SN^1$ ,$SN^2$ and $SN^i$)

b) Elimination reactions ($E_1$ & $E_2$; Hoffman &Saytzeff's rule)

**UNIT-II** **12 Hours**

**Study of mechanism and synthetic applications of following named Reactions:** Ullmann coupling reactions, Dieckmann Reaction, Doebner-Miller Reaction, Sandmeyer Reaction,Mannich reaction, Vilsmeyer-Haack Reaction, Baeyer-Villiger oxidation, Shapiro & Suzuki reaction, Ozonolysis and Michael addition reaction.

**UNIT-III** **12 Hours**

**Synthetic Reagents & Applications:** Aluminiumisopropoxide, N-bromosuccinamide, diazomethane, dicyclohexylcarbodimide, Wilkinson reagent, Witting reagent, Osmium tetroxide, diethyl azodicarboxylate, Triphenylphosphine, Benzotriazol-1-yloxy) tris (dimethylamino)phosphoniumhexafluoro-phosphate (BOP).

**Protecting groups**

a) Role of protection in organic synthesis

b) Protection for the hydroxyl group, ethers, esters, carbonates, cyclic acetals& ketals

c) Protection for the Carbonyl Group: Acetals and Ketals

d) Protection for the Carboxyl Group: amides and hydrazides esters

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

**UNIT-IV** **12 Hours**

**Heterocyclic Chemistry:** Organic Name reactions with their respective mechanism and application involved in synthesis of drugs containing five, six membered and fused heterocyclics such as Debus- Radziszewski imidazole synthesis, Knorr Pyrazole Synthesis,

Pinner Pyrimidine Synthesis, Combes Quinoline Synthesis, Bernthsen Acridine Synthesis, Smiles rearrangement and Traube purine synthesis.

Synthesis of few representative drugs containing these heterocyclic nucleus such as, Metronidazole, Miconazole, celecoxib, Metamizole sodium, Terconazole, Alprazolam, Triamterene, Trimethoprim, Chloroquine, Prochlorperazine, Chlorpromazine, Theophylline, and mercaptopurine.

**UNIT-V** **12 Hours**

**Synthon approach and retrosynthesis applications:**

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

iii. Strategies for synthesis of three, four, five and six- membered ring.

# MPC 103T: ADVANCED MEDICINAL CHEMISTRY

**Objectives**

- 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.
- 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
  - Peptidomimetics

**Course Outcomes**

| S.No | Course Outcomes | Knowledge level(BLOOMS Level) |
|---|---|---|
| After successful completion of the course student shall be able to | | |
| **CO1:** | Design around the various market approved drug molecules. A detailed understanding of the processes involved in the design, development anddiscovery of medicinal compounds. | L1: Remember<br>L2: Understand |
| **CO2:** | Study on different biological targets | L1: Remember<br>L2: Understand<br>L3: Apply |
| **CO3:** | To understand the mechanism of action of drugs belonging to the classesof Antihypertensive and Psychoactive. | L1: Remember<br>L2: Understand<br>L3: Apply |
| **CO4:** | Anticonvulsant, H1/H2 receptor antagonistic, COX1 & COX2 inhibiting,adrenergic & cholinergic, antineoplastic and antiviral agents. | L1: Remember<br>L2: Understand<br>L6: Create |
| **CO5:** | Various strategies to design and develop new drug like molecules forbiological targets | L3: Apply<br>L4: Analyse<br>L5: Evaluate<br>L6: Create |

BLOOMS Taxonomy- L1: Remember, L2: Understand, L3: Apply, L4: Analyse, L5: Evaluate, L6:Create

**How program outcomes are assessed:**

| Program Outcome | | Level | Proficiency assessed by |
|---|---|---|---|
| **PO1:** | Pharmacy Knowledge | 3 | Assignments/ Internals/Viva |
| **PO2:** | Planning Abilities | 2 | Assignments/ Internals |
| **PO3:** | Conduct Investigations of Complex Problems | 3 | Assignments/ Internals/ Practicals |
| **PO4:** | Problem Analysis | 3 | Assignments/ Internals |
| **PO5:** | Modern Tool Usage | 2 | Seminars/academic activities |
| **PO6:** | Leadership Skills | 2 | Group discussion / Role play |
| **PO7:** | Professional Identity | 2 | Group discussion |
| **PO8:** | Pharmaceutical Ethics | 2 | Personality development seminars |
| **PO9:** | Communication | 3 | Students' seminars/ student -teacher interaction |
| **PO10:** | The Pharmacist and Society | 3 | Group discussion / Role play |
| **PO11:** | Environment And Sustainability | 3 | Students' seminars |
| **PO12** | Life-Long Learning | 3 | Assignments/ Internals |

**LEVEL: 1- Slight (Low), 2- Moderate (Medium), 3- Substantial (High)**

**Course Outcomes and Program Outcomes (CO-PO) Mapping:**

| | PO1 | PO2 | PO3 | PO4 | PO5 | PO6 | PO7 | PO8 | PO9 | PO10 | PO11 | PO12 |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| **CO1** | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 |
| **CO2** | 3 | 3 | 3 | 2 | 2 | 3 | 3 | 3 | 3 | 3 | 3 | 3 |
| **CO3** | 2 | 3 | 3 | 2 | 2 | 3 | 3 | 3 | 3 | 3 | 3 | 3 |
| **CO4** | 3 | 3 | 2 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 |
| **CO5** | 2 | 2 | 2 | 3 | 3 | 2 | 2 | 2 | 2 | 2 | 2 | 3 |
| **Avg** | 2.6 | 2.8 | 2.6 | 2.6 | 2.6 | 2.8 | 2.8 | 2.8 | 2.8 | 2.8 | 2.8 | 3 |

**Course Content**

**THEORY** **60Hrs**

**1.** Drug discovery: Stages of drug discovery, lead discovery; identification, validation and diversity of drug targets. Biological drug targets: Receptors, types, binding and activation, theories of drug receptor interaction, drug receptor interactions, agonists Vs antagonists, artificial enzymes. **12Hrs**

**2. Prodrug Design and Analog design:**

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

**b) 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.

**c) Drug Metabolism:** Structure metabolism relationship, metabolism and drug designing. Metabolism and toxicity of drugs. **12Hrs**

**3. Medicinal chemistry aspects of the following class of drugs:** Systematic study, Classification, SAR, mechanism of action and recent advances of following classes of drugs: synthesisof drugs superscripted by(*)

**a) Anti-hypertensives(Albuterol*,Lisinopril*,Diazoxide*),** Antidiabetic(Meglitinide*,Meglitol*), Antiulcer(Pantoprazole*), Antihyperlipidemic agents(Clofibrate*,Lovastatin*), Antineoplastic (Floxuridine*,Carboplatin*,), Antiviral and Anti-HIV agents(Lamivudine*,Saquinavir* and Vidarabin*), Drugs for the treatment of Alzheimer's disease(Besiperidine*,Tacrine*,Donepezil*).

**b) Stereochemistry and Drug action:** Role of chirality in selective and specific therapeutic agents. Case studies. **18Hrs**

**4. a) Rational Design of Enzyme Inhibitors**

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

**b) Oligonucleotide therapy :** Oligonucleotides as drugs, interaction with nucleic acids, modification of bases, sugars and backbone,Antisense Oligonucleotides. **8Hrs**

**5.a) Peptidomimetics :** Therapeutic values of Peptidomimetics, design of peptidomimetics by manipulation of the amino acids, modificationof the peptide backbone, cyclization of peptides

**b) Recombinant DNA technology and drug discovery :** rDNA technology, hybridoma technology,New pharmaceuticals derived from biotechnology. **10hrs**

**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 andJanet. 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.

# MPC 104T: CHEMISTRY OF NATURAL PRODUCTS

**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
- General methods of structural elucidation of compounds of natural origin
- Isolation, purification and characterization of simple chemical constituents from natural source

**Course outcomes**

| S. No | Course Outcomes | Knowledge level (BLOOMS Level) |
|---|---|---|
| After successful completion of the course student shall be able to explain | | |
| **CO1:** | Drugs affecting the Central Nervous System: Morphine Alkaloids Anticancer Drugs: Paclitaxel and Docetaxel, Etoposide, and Teniposide Cardiovascular Drugs: Lovastatin, Teprotide and Dicoumarol Neuromuscular Blocking Drugs: Curare alkaloids Anti-malarial drugs and Analogues :Quinine and Artemisinin Chemistry of macrolide antibiotics (Erythromycin, Azithromycin,Roxithromycin, and Clarithromycin) and β -Lactam antibiotics (Cephalosporins and Carbapenem) | L1:Remember L2:Understand L3: Apply |
| **CO2:** | General introduction, Classification, Isolation,Purification,Molecular Modification and Biological Activity of alkaloids, General methods of Structural Determination of alkaloids, Structural Elucidation and Stereochemistry of Morphine, Reserpine and Ephedrine.<br>**Flavonoids**<br>Introduction, Isolation and Purification of flavonoids, General methods of Structural Determination of flavonoids; Structural Elucidation of Quercetin.**Steroids**<br>General introduction, Chemistry (Structural features only ) of sterols, sapogenin and cardiac glycosides .Stereochemistry and Nomenclature of steroids, Chemistry of Contraceptive agents, Male & Female sex hormones (Testosterone, Estradiol, Progesterone), Adrenocorticoids (Cortisone) and Vitamin D | L3: Apply L4: Analyse L5: Evaluate |

| | | |
|---|---|---|
| **CO3:** | **Terpenoids**<br>Classification, Isolation, isoprene rule and General methods of Structural Elucidation of Terpenoids . Chemistry (Structural features only ) of Citral, Menthol, Phytol,Taxol,Squalene, Ginsenoside and β carotene . Structural Elucidation of Camphor and Menthol.<br>**Vitamins**<br>Chemistry (Structural features only ) and Physiological Si gnificance of<br>Vitamin A, $B_1$, $B_2$,$B_{12}$, C, E, Folic acid and Niacin | L3: Apply L4: AnalyseL5: Evaluate |
| **CO4:** | Chemistry (Structural features only) and Biological Significance | L2:Underst dL3: Apply |
| | Prostaglandins and Leukotrienes.<br>**Marine Natural products with therapeutic Potential:**<br>Cardiovascularagents,Anti-inflammatory,Antimicrobial,Antiviral and Antiparasitic agents | L4: Analyse |
| **CO5:** | **Structural Characterization of natural compounds**<br>Structural characterization of natural compounds using IR,$^{1}$HNMR, $^{13}$CNMR<br>and MS Spectroscopy of specific drugs e.g., Citral, Quercetin, Morphine,Luteolin-7-o-glucoside and Estrone. | L3: Apply L4: AnalyseL5: Evaluate |

BLOOMS Taxonomy- L1: Remember, L2: Understand, L3: Apply, L4: Analyse, L5: Evaluate,L6:Create

**How program out comes are assessed:**

| **Program Outcome** | | **Level** | **Proficiency assessed by** |
|---|---|---|---|
| **PO1:** | Pharmacy Knowledge | 2 | Assignments/ Internals/Viva |
| **PO2:** | Planning Abilities | 1 | Assignments/ Internals |
| **PO3:** | Conduct Investigations o | 1 | Assignments/ Internals/ Practicals |
| **PO4:** | Problem Analysis | 2 | Assignments/ Internals |
| **PO5:** | Modern Tool Usage | 2 | Seminars/academic activities |
| **PO6:** | Leadership Skills | 1 | Group discussion / Role play |
| **PO7:** | Professional Identity | 2 | Group discussion |
| **PO8:** | Pharmaceutical Ethics | 2 | Personality development seminars |
| **PO9:** | Communication | 3 | Students' seminars/ student -teacher interaction |
| **PO10:** | The Pharmacist and Society | 2 | Group discussion / Role play |

| | | | |
|---|---|---|---|
| **PO11:** | Environment And Sustainability | 2 | Students' seminars |
| **PO12** | Life-Long Learning | 2 | Assignments/ Internals |

**LEVEL: 1- Slight (Low), 2- Moderate(Medium), 3-**

**Substantial(High)Course Outcomes and Program Outcomes**

**(CO-PO) Mapping:**

| | PO1 | PO2 | PO3 | PO4 | PO5 | PO6 | PO7 | PO8 | PO9 | PO10 | PO11 | PO12 |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| CO1 | 2 | 3 | 3 | 3 | 3 | 2 | 3 | 2 | 3 | 3 | 3 | 3 |
| CO2 | 3 | 2 | 2 | 3 | 3 | 3 | 3 | 3 | 2 | 2 | 3 | 3 |
| CO3 | 3 | 2 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 2 | 3 |
| CO4 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 |
| CO5 | 2 | 3 | 3 | 3 | 3 | 3 | 3 | 2 | 3 | 3 | 2 | 3 |
| Avg | 2.6 | 2.8 | 2.8 | 3 | 3 | 2.8 | 3 | 2.6 | 2.8 | 2.8 | 2.6 | 3 |

**Course Content**

**THEORY** **60Hrs**

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

a) Drugs affecting the Central Nervous System: Morphine Alkaloids

b) Anticancer Drugs: Paclitaxel and Docetaxel, Etoposide, and Teniposide

c) Cardiovascular Drugs: Lovastatin, Teprotide and Dicoumarol

d) Neuromuscular Blocking Drugs: Curare alkaloids

e) Anti-malarial drugs and Analogues :Quinine and Artemisinin

f) Chemistry of macrolide antibiotics (Erythromycin, Azithromycin,Roxithromycin, andClarithromycin) and β - Lactam antibiotics (Cephalosporins and Carbapenem) **12Hrs**

**a) Alkaloids**

General introduction, Classification, Isolation,Purification,Molecular Modification and Biological Activity of alkaloids, General methods of Structural Determination of alkaloids, Structural Elucidation and Stereochemistry of Morphine, Reserpine and Ephedrine.

**b) Flavonoids**

Introduction, Isolation and Purification of flavonoids, General methods of Structural Determination of flavonoids; Structural Elucidation of Quercetin.

**c) Steroids**

General introduction, Chemistry (Structural features only ) of sterols, sapogenin and cardiac glycosides .Stereochemistry and Nomenclature of steroids, Chemistry of Contraceptive agents, Male & Female sex hormones (Testosterone, Estradiol, Progesterone), Adrenocorticoids (Cortisone) and Vitamin D. **12Hrs**

**2. a) Terpenoids**

Classification, Isolation, isoprene rule and General methods of Structural Elucidation of Terpenoids . Chemistry (Structural features only ) of Citral, Menthol, Phytol,Taxol,Squalene, Ginsenoside and β carotene . Structural Elucidation of Camphor and Menthol.

**b) Vitamins**

Chemistry (Structural features only ) and Physiological Significance of Vitamin A, $B_1$, $B_2$,$B_{12}$, C, E, Folic acid and Niacin. **12Hrs**

**3.** a) Chemistry (Structural features only) and Biological Significance of Prostaglandins andLeukotrienes.

**b) Marine Natural products with therapeutic Potential:** Cardiovascular agents,Anti-inflammatory,Antimicrobial,Antiviral and Antiparasitic agents. **12Hrs**

**2 .Structural Characterization of natural compounds**

Structural characterization of natural compounds using IR, $^{1}$HNMR, $^{13}$CNMR and MS Spectroscopy ofspecific drugs e.g., Citral, Quercetin, Morphine, Luteolin-7-o-glucoside and Estrone.
**12Hrs**

**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 – ScikelRuneckles,Springer Science & BusinessMedia.

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 GurdeepandChatwall, Himalaya PublishingHouse.

10. Organic Chemistry of Natural Products Vol I and II by O.P. Agarwal,KrishanPrakashan.

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, 13th edition.

15. Phytochemical methods of Harborne, Springer, Netherlands.

16. Burger's Medicinal Chemistry

# SEMESTER-II

# MPC 201T: ADVANCED SPECTRAL ANALYSIS

**Objectives**

- 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.
- 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

**Course Outcomes**

| S. No | Course Outcomes | Knowledge level (BLOOMS Level) |
|---|---|---|
| After successful completion of the course student shall be able to | | |
| **CO1:** | Explain the theoretical principles of UV, IR, MASS and NMR spectroscopy | L1: Remember L2: Understand L3: Apply |
| **CO2:** | Discuss structural elucidation of organic and natural compounds by IR, NMRand MASS spectral data. Understand the theoretical principles of Woodward-Fieser rule. | L3: Apply L4: Analyse L5: Evaluate |
| **CO3:** | Learn instrumentation and Interpretation of organic compounds by Ramanspectroscopy | L3: Apply L4: AnalyseL5: Evaluate |
| **CO4:** | Learn the general theory and principles of thermal analysis | L2:UnderstandL3: Apply L4: Analyse |
| **CO5:** | Learn the general theory and principles of Hyphenated Techniques | L3: Apply L4: AnalyseL5: Evaluate |

Blooms Taxonomy- L1: Remember, L2: Understand, L3: Apply, L4: Analyse, L5: Evaluate,L6:Create

**How program out comes are assessed:**

| ProgramOutcome | | Level | Proficiency assessed by |
|---|---|---|---|
| **PO1:** | Pharmacy Knowledge | 3 | Assignments/ Internals/Viva |
| **PO2:** | Planning Abilities | 2 | Assignments/ Internals |
| **PO3:** | Conduct Investigations of ComplexProblems | 3 | Assignments/ Internals/ Practicals |
| **PO4:** | Problem Analysis | 2 | Assignments/ Internals |
| **PO5:** | Modern Tool Usage | 3 | Seminars/academic activities |
| **PO6:** | Leadership Skills | 2 | Group discussion / Role play |
| **PO7:** | Professional Identity | 2 | Group discussion |
| **PO8:** | Pharmaceutical Ethics | 2 | Personality development seminars |
| **PO9:** | Communication | 3 | Students' seminars/ student -teacher interaction |
| **PO10:** | The Pharmacist and Society | 2 | Group discussion / Role play |
| **PO11:** | Environment And Sustainability | 2 | Students' seminars |
| **PO12** | Life-Long Learning | 3 | Assignments/ Internals |

**LEVEL: 1- Slight (Low), 2- Moderate(Medium), 3- Substantial(High)**

**Course Outcomes and Program Outcomes (CO-PO) Mapping:**

| | PO1 | PO2 | PO3 | PO4 | PO5 | PO6 | PO7 | PO8 | PO9 | PO10 | PO11 | PO12 |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| **CO1** | 3 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 |
| **CO2** | 3 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 |
| **CO3** | 3 | 3 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 |
| **CO4** | 3 | 3 | 2 | 2 | 3 | 3 | 2 | 2 | 2 | 2 | 2 | 2 |
| **CO5** | 3 | 3 | 3 | 3 | 3 | 3 | 2 | 2 | 2 | 2 | 2 | 2 |
| **CO6** | 3 | 3 | 2 | 3 | 3 | 3 | 2 | 2 | 2 | 2 | 2 | 2 |
| **Avg** | 3 | 2.6 | 2.2 | 2.3 | 2.5 | 2.5 | 2 | 2 | 2 | 2 | 2 | 2 |

**Course content**

**THEORY** **60Hrs**

**1. UV and IR spectroscopy:**

Wood ward – Fieser rule for 1,3- butadienes, cyclic dienes and α,β-carbonyl compoundsand interpretation compounds of enones. ATR-IR, IR Interpretation of organic compounds. **12Hrs**

**2. NMR spectroscopy:**

Spin-Spin coupling & double irradiation, Nuclear magnetic double resonance, Nuclear Overhauser Effect (NOE), Variable Temperature NMR. Brief outline of principles of FTNMR ,13C NMR and applications of 13C NMR .

NMR of other atoms: 19F, 31P, 14N, 15N & 17O NMR.Spectrum editing:

DEPT spectra.

Magnetic resonance imaging (MRI), 1-D and 2-D NMR, NOESY and COSY, HECTORtechniques. Interpretation of organic compounds. **12Hrs**

**3.Mass Spectroscopy**

Different types of ionization like APCI, ESI, APPI Analyzers of Quadrupole and Time of Flight. Fragmentation of important functional groups like alcohols, amines, carbonyl groupsand alkanes, Metastable ions, Mc Lafferty rearrangement, Ring rule,Isotopic peaks, Interpretation of organic compounds. **12Hrs**

**4. Chromatography:**

Principle, Instrumentation and Applications of the following :
GC-MS b) GC-AAS c) LC-MS d) LC-FTIR e) LC-NMR f) CEMS g) High PerformanceThin Layer chromatography h) Super critical fluid chromatography i) Ion exchange Chromatography j) I- EC (Ion-Exclusion Chromatography) k) Flash chromatography **12Hrs**

**5. a) Thermal Techniques:** Principle, thermal transitions and Instrumentation (Heat flux andpower-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, pharmaceuticalapplications.

**Differential Thermal Analysis (DTA):** Principle, instrumentation and advantage and disadvantages,pharmaceutical applications, derivative differential thermal analysis (DDTA).**Thermogravimetric analysis (TGA*):*** Principle, instrumentation, factors affecting results, advantage and disadvantages, pharmaceutical applications.

**a) Raman Spectroscopy**

Introduction, Principle, Instrumentation and Applications. **12Hrs**

**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, CBSPublishers, 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, MarcelDekker Series

# MPC 202T - ADVANCED ORGANIC CHEMISTRY - II

**Objectives**

- 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.
- 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.

**Course Outcomes**

| S. No | Course Outcomes | Knowledge level (BLOOMS Level) |
|---|---|---|
| After successful completion of the course student shall be able to understand | | |
| **CO1:** | Introduction, principles of green chemistry. Microwave assisted reactions andUltrasound assisted reactions | L1: Remember L2: UnderstandL3: Apply |
| **CO2:** | Coupling reactions in peptide synthesis. Principles of solid phase peptide synthesis, Segment and sequential strategies for solution phase peptide synthesis with any two case Studies and Side reactions in peptide synthesis | L3: Apply L4: Analyse L5: Evaluate |
| **CO3:** | Combinatorial Chemistry and Libraries and Pericyclic reactions | L3: Apply L4: Analyse L5: Evaluate |
| **CO4:** | Types of catalysis, Use of enzymes in organic synthesis, immobilized enzymes/cells in organic reaction and Phase transfer catalysis. | L2:UnderstandL3: Apply L4: Analyse |
| **CO5:** | Stereochemistry & Asymmetric Synthesis an.d its methods | L3: Apply L4: Analyse L5: Evaluate |

BLOOMS Taxonomy- L1: Remember, L2: Understand, L3: Apply, L4: Analyse, L5: Evaluate,L6:Create

**How program out comes are assessed:**

| Program Outcome | | Level | Proficiency assessed by |
|---|---|---|---|
| **PO1:** | Pharmacy Knowledge | 3 | Assignments/ Internals/Viva |
| **PO2:** | Planning Abilities | 2 | Assignments/ Internals |
| **PO3:** | Conduct Investigations of Complex Problems | 3 | Assignments/ Internals/ Practicals |
| **PO4:** | Problem Analysis | 2 | Assignments/ Internals |
| **PO5:** | Modern Tool Usage | 3 | Seminars/academic activities |
| **PO6:** | Leadership Skills | 2 | Group discussion / Role play |
| **PO7:** | Professional Identity | 2 | Group discussion |
| **PO8:** | Pharmaceutical Ethics | 2 | Personality development seminars |
| **PO9:** | Communication | 3 | Students' seminars/ student -teacher interaction |
| **PO10:** | The Pharmacist and Society | 2 | Group discussion / Role play |
| **PO11:** | Environment And Sustainability | 2 | Students' seminars |
| **PO12** | Life-Long Learning | 3 | Assignments/ Internals |

**LEVEL: 1- Slight (Low), 2- Moderate(Medium), 3- Substantial(High)**

**Course Outcomes and Program Outcomes (CO-PO) Mapping:**

| | PO1 | PO2 | PO3 | PO4 | PO5 | PO6 | PO7 | PO8 | PO9 | PO10 | PO11 | PO12 |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| **CO1** | 3 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 |
| **CO2** | 3 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 |
| **CO3** | 3 | 3 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 |
| **CO4** | 3 | 3 | 2 | 2 | 3 | 3 | 2 | 2 | 2 | 2 | 2 | 2 |
| **CO5** | 3 | 3 | 3 | 3 | 3 | 3 | 2 | 2 | 2 | 2 | 2 | 2 |
| **CO6** | 3 | 3 | 2 | 3 | 3 | 3 | 2 | 2 | 2 | 2 | 2 | 2 |
| **Avg** | 3 | 2.6 | 2.2 | 2.3 | 2.5 | 2.5 | 2 | 2 | 2 | 2 | 2 | 2 |

**Course content**

**THEORY** **60Hrs**

**1. Green Chemistry:**

a) Introduction, principles of green chemistry

b) Microwave assisted reactions: Merits 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. **12Hrs**

**2. Chemistry of peptides**

a) Coupling reactions in peptide synthesis

b) Principles of solid phase peptide synthesis, t-BOC and FMOC protocols, various solid supports and linkers: Activation procedures, peptide bond formation, deprotection and cleavage from resin, low and high HF cleavage protocols, formation of free peptides and peptide amides, purification , 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 reactions initiated by proton abstraction, protonation, over-activation and side reactions of individual amino acids**.** **12Hrs**

**3. a) Combinatorial Chemistry and Libraries**

Concepts: Tea bag method, Pin method, Heterocyclic libraries (Benzodiazepine etc)

Deconvolution methods of identification, A brief account on methods of Protection an deprotection.

**b) Pericyclic reactions**

Mechanism, Types of pericyclic reactions such as cycloaddition, electrocyclic reaction and sigmatropic rearrangement reactions with examples **12Hrs**

**4. Catalysis:**

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

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

c) Homogenous catalysis, hydrogenation, hydroformylation, Wilkinson catalysts,

Ziegler- Nattacatalysts, some examples of homogenous catalysis used in synthesis of drugs

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

**e)** Phase transfer catalysis - theory and applications **12Hrs**

**5. Stereochemistry & Asymmetric Synthesis**

a) Basic concepts in stereochemistry – optical activity, specific rotation, racemates and resolution of racemates, the Cahn,Ingold, Prelog (CIP) sequence rule, meso compounds, pseudo asymmetric centres, axes of symmetry, Fischers D and L notation, cis-trans isomerism, E and Z notation.

**b)** Methods of asymmetric synthesis using chiral pool, chiral auxiliaries and catalytic asymmetric synthesis, enantio pure separation and Stereo selective synthesis with examples. **12Hrs**

**REFERENCES**

1. "Advanced Organic chemistry, Reaction, mechanisms and structure", JMarch, 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.

10. Theory and Practice of Green Chemistry, Paul T. Anastas& John C. Warner.

11.Combinational Chemistry – Synthesis and applications – Stephen R Wilson & Anthony W Czarnik,Wiley – Blackwell.

12. Phase transfer catalysis - Principles & Techniques – 1st Edition Charless Liotta 13.Introduction to Biocatalysis using Enzymes & Micro organisms – Stanley M.Roberts,Nicholas J.Turner,Andrew J.Willetts,Michel K.Turner.

14. Ultrasound in Synthesis – Kenneth S.Suslick.

# MPC 203T - COMPUTER AIDED DRUG DESIGN

**Objectives**

- The subject is designed to impart knowledge on the current state of the art techniques involvedin computer assisted drug design.
- 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 modelling softwares to design new drug molecules
  - The *in silico* virtual screening protocols

**Course Outcomes**

| S. No | Course Outcomes | Knowledge level (BLOOMS Level) |
|---|---|---|
| After successful completion of the course student shall be able to | | |
| CO1: | Explain the Role of CADD in drug discovery. Understand the physicochemicalProperties and the techniques involved in QSAR | L1: Remember L2: Understand L3: Apply |
| CO2: | Learn the working with molecular modeling softwares to design new drug molecules. Understand in silico virtual screening protocols | L3: Apply L4: Analyse L5: Evaluate |
| CO3: | Learn the concept of molecular and quantum mechanics. Explain pharmacophore concept and the techniques involved in modeling | L3: Apply L4: Analyse L5: Evaluate |
| CO4: | Learn various structure based drug design methods (Denovo drug design, fragment based drug design) | L2:UnderstandL3: Apply L4: Analyse |
| CO5: | Elaborate homology modelling and its experimental procedures | L3: Apply L4: Analyse L5: Evaluate |

BLOOMS Taxonomy- L1: Remember, L2: Understand, L3: Apply, L4: Analyse, L5: Evaluate,L6:Create

**How program out comes are assessed:**

| Program Outcome | | Level | Proficiency assessed by |
|---|---|---|---|
| **PO1:** | Pharmacy Knowledge | 3 | Assignments/ Internals/Viva |
| **PO2:** | Planning Abilities | 3 | Assignments/ Internals |
| **PO3:** | Conduct Investigations of Complex Problems | 3 | Assignments/ Internals/ Practicals |
| **PO4:** | Problem Analysis | 2 | Assignments/ Internals |
| **PO5:** | Modern Tool Usage | 3 | Seminars/academic activities |
| **PO6:** | Leadership Skills | 2 | Group discussion / Role play |
| **PO7:** | Professional Identity | 2 | Group discussion |
| **PO8:** | Pharmaceutical Ethics | 2 | Personality development seminars |
| **PO9:** | Communication | 3 | Students' seminars/ student -teacher interaction |
| **PO10:** | The Pharmacist and Society | 2 | Group discussion / Role play |
| **PO11:** | Environment And Sustainability | 2 | Students' seminars |
| **PO12** | Life-Long Learning | 3 | Assignments/ Internals |

**LEVEL: 1- Slight (Low), 2- Moderate (Medium), 3- Substantial (High)**

**Course Outcomes and Program Outcomes (CO-PO) Mapping:**

| | PO1 | PO2 | PO3 | PO4 | PO5 | PO6 | PO7 | PO8 | PO9 | PO10 | PO11 | PO12 |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| **CO1** | 3 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 |
| **CO2** | 3 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 |
| **CO3** | 3 | 3 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 |
| **CO4** | 3 | 3 | 2 | 2 | 3 | 3 | 2 | 2 | 2 | 2 | 2 | 2 |
| **CO5** | 3 | 3 | 3 | 3 | 3 | 3 | 2 | 2 | 2 | 2 | 2 | 2 |
| **CO6** | 3 | 3 | 2 | 3 | 3 | 3 | 2 | 2 | 2 | 2 | 2 | 2 |
| **Avg** | 3 | 2.6 | 2.2 | 2.3 | 2.5 | 2.5 | 2 | 2 | 2 | 2 | 2 | 2 |

**Course content**

**THEORY** **60Hrs**

**1. Introduction to Computer Aided Drug Design (CADD)** History, different techniques and applications. Quantitative Structure Activity Relationships: Basics History and development of QSAR: Physicochemical parameters and methods to calculate physicochemical parameters: Hammett equationand 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. **12Hrs**

**2. Quantitative Structure Activity Relationships:** Applications Hansch analysis, Free Wilson analysis and relationship between them, Advantages and disadvantages; Deriving 2DQSAR equations.3D-QSAR approaches like COMFA and COMSIA. QSAR statistical methods: regression analysis and partial least square analysis. **12Hrs**

**3. Molecular Modelling and Docking**

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

b)Methods to derive three-dimensional structure of protein : X-Ray Crystallography, NMR, homologous modeling.

**c)** Molecular docking and drug receptor interactions: Rigid docking, flexible docking, manual docking and extra-precision docking. Agents acting on enzymes such as DHFR, HMG-Co A reductase and HIV protease, choline esterase ( AchE & BchE) **15Hrs**

**4. Molecular Properties and Drug Design**

a) Prediction and analysis of ADMET properties of new molecules and its importance in drug design.

b) De novo drug design: Receptor/enzyme-interaction and its analysis, Receptor/enzyme cavity sizeprediction, predicting the functional components of cavities, Fragment based drug design. **9Hrs**

**5 .Pharmacophore Mapping and Virtual Screening**

a) Concept of pharmacophore, pharmacophore mapping,identification of Pharmacophore features andPharmacophore modeling; Conformational search used in pharmacophore mapping.

**b)** Virtual Screening Techniques Drug-likeness screening, Similarity based methods and

Pharmacophore based screening, structure based *in-silico* virtual screening protocols.

**12Hrs**

**REFERENCES**

1. Computational and structural approaches to drug discovery, Robert MStroud 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, ElsevierPublishers.
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, ElsevierPublishers.
6. Medicinal Chemistry by Burger, Wiley Publishing Co.
7. An Introduction to Medicinal Chemistry –Graham L. Patrick, OxfordUniversity Press.
8. Wilson and Gisvold's Text book of Organic Medicinal and PharmaceuticalChemistry, IppincottWilliams & Wilkins.
9. Comprehensive Medicinal Chemistry – Corwin and Hansch, PergamonPublishers.
10. Hugo Kubiny. QSAR: Hansch Analysis and Related Approaches. Methods and Principles inMedicinal Chemistry. Publisher Wiley-VCH
11. Klaus Gubernator, Hans-Joachim Böhm. Structure-Based Ligand Design. Methods andPrinciples in Medicinal Chemistry. Publisher Wiley-VCH
12. Abby L . Parrill. M . Rami Reddy. Rational Drug Design. Novel Methodology and Practical Applications. ACS Symposium Series; American Chemical Society: Washington, DC, 1999.
13. J. Rick Turner. New drug development design, methodology and, analysis. John Wiley &Sons, Inc., New Jersey.

# MPC 204T: PHARMACEUTICAL PROCESS CHEMISTRY

**Objectives**

- The subject is designed to impart knowledge on the current state of the art techniques involved in pharmaceutical process chemistry.
- 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
Various unit operations and various reactions in process chemistry
Various precautions of handling hazards chemicals

Fermentation of various aerobic & anaerobic production of antibiotics

**Course Outcomes**

| S. No | Course Outcomes | Knowledge level (BLOOMS Level) |
|---|---|---|
| After successful completion of the course student shall be able to | | |
| **CO1:** | Develop synthetic routes that is safe, cost-effective, environmentally friendly,and efficient | L1:Remember<br>L2:Understand<br>L3: Apply |
| **CO2:** | Impart knowledge on the development and optimization of a synthetic routes. | L3: Apply L4: Analyse<br>L5: Evaluate |
| **CO3:** | Pilot plant procedure for the manufacture of Active Pharmaceutical Ingredients and new chemical entities for the drug development phase | L3: Apply L4: Analyse<br>L5: Evaluate |
| **CO4:** | Create and carry out work up and separation procedure | L2:Understand<br>L3: Apply<br>L4: Analyse |
| **CO5:** | Predict the outcome of organic reactions using a basic understanding of thegeneral reactivity of functional groups and mechanism | L3: Apply L4: Analyse<br>L5: Evaluate |

BLOOMS Taxonomy- L1: Remember, L2: Understand, L3: Apply, L4: Analyse, L5: Evaluate,L6:Create

**How program out comes are assessed:**

| Program Outcome | | Level | Proficiency assessed by |
|---|---|---|---|
| **PO1:** | Pharmacy Knowledge | 3 | Assignments/ Internals/Viva |
| **PO2:** | Planning Abilities | 3 | Assignments/ Internals |
| **PO3:** | Conduct Investigations of Complex Problems | 3 | Assignments/ Internals/ Practicals |
| **PO4:** | Problem Analysis | 2 | Assignments/ Internals |
| **PO5:** | Modern Tool Usage | 3 | Seminars/academic activities |
| **PO6:** | Leadership Skills | 2 | Group discussion / Role play |
| **PO7:** | Professional Identity | 2 | Group discussion |
| **PO8:** | Pharmaceutical Ethics | 2 | Personality development seminars |
| **PO9:** | Communication | 3 | Students' seminars/ student - teacherinteraction |
| **PO10:** | The Pharmacist and Society | 2 | Group discussion / Role play |
| **PO11:** | Environment And Sustainability | 2 | Students' seminars |
| **PO12** | Life-Long Learning | 3 | Assignments/ Internals |

**LEVEL: 1- Slight (Low), 2- Moderate (Medium), 3- Substantial (High)**

**Course Outcomes and Program Outcomes (CO-PO) Mapping:**

| | PO1 | PO2 | PO3 | PO4 | PO5 | PO6 | PO7 | PO8 | PO9 | PO10 | PO11 | PO12 |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| **CO1** | 3 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 |
| **CO2** | 3 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 |
| **CO3** | 3 | 3 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 |
| **CO4** | 3 | 3 | 2 | 2 | 3 | 3 | 2 | 2 | 2 | 2 | 2 | 2 |
| **CO5** | 3 | 3 | 3 | 3 | 3 | 3 | 2 | 2 | 2 | 2 | 2 | 2 |
| **CO6** | 3 | 3 | 2 | 3 | 3 | 3 | 2 | 2 | 2 | 2 | 2 | 2 |
| **Avg** | 3 | 2.6 | 2.2 | 2.3 | 2.5 | 2.5 | 2 | 2 | 2 | 2 | 2 | 2 |

**Course content**

**THEORY** **60Hrs**

**1.** Process Chemistry

**12Hrs**

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** **12Hrs**

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, nonaqueous solutions factors affecting crystallization, nucleation. Principle and general methods of Preparation of polymorphs, hydrates, solvates and amorphous APIs

**3. Unit Processes I** **12Hrs**

a) Nitration: Nitrating agents, Aromatic nitration, kinetics and mechanism of aromatic nitration, process equipment for technical nitration, mixed acid for nitration, b) Halogenation: Kinetics of halogenations, types of halogenations, catalytic halogenations. Case study on industrial halogenation process. c) Oxidation: Introduction, types of oxidative reactions, Liquid phase oxidation with oxidizing agents. Nonmetallic Oxidizing agents such as H2O2, sodium hypochlorite, Oxygen gas, ozonolysis.

**4. Unit Processes - II**

a) Reduction: Catalytic hydrogenation, Heterogeneous and homogeneous catalyst; Hydrogen transfer reactions, Metal hydrides. Case study on industrial reduction process. b) Fermentation: Aerobic and anaerobic fermentation. Production of i. Antibiotics; Penicillin and Streptomycin, ii. Vitamins: B2 and B12 iii. Statins: Lovastatin, Simvastatin c) Reaction progress kinetic analysis i. Streamlining reaction steps, route selection, ii. Characteristics of expedient routes, characteristics of cost-effective routes,reagent selection, families of reagents useful for scale-up.

**5. Industrial Safety**

a) MSDS (Material Safety Data Sheet), hazard labels of chemicals and Personal Protection
Equipment (PPE) b) Fire hazards, types of fire & fire extinguishers c) Occupational Health & Safety Assessment Series 1800 (OHSAS-1800) and ISO-14001(Environmental Management System), Effluents and its management

**REFERENCES**

1. Process Chemistry in the Pharmaceutical Industry: Challenges in an Ever-ChangingClimate-An Overview; K. Gadamasetti, CRC Press.
2. Pharmaceutical Manufacturing Encyclopedia, 3 rd edition, Volume 2.
3. Medicinal Chemistry by Burger, 6 th edition, Volume 1-8.
4. W.L. McCabe, J.C Smith, Peter Harriott. Unit operations of chemical engineering, 7thedition, 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 theRoutes 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, VikasPublishing 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.go

# Semester III

# UNIVERSITY COLLEGE OF PHARMACEUTICAL SCIENCES
# M.PHARMACY
# SEMESTER-III

**Paper-I: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.

# Semester IV

# UNIVERSITY COLLEGE OF PHARMACEUTICAL SCIENCES
## M.PHARMACY
## SEMESTER-IV

- Journal Club
- Research Work
- Final Presentation

# STRUCTURE

# ACHARYA NAGARJUNA UNIVERSITY
# UNIVERSITY COLLEGE OF PHARMACEUTICAL SCIENCES
## M.PHARM
## (PHARMACEUTICAL ANALYSIS)
## SEMESTER I

| Course Code | Course | Credit Hours | Credit Points | Hrs. /w k | Marks | Activities/Content with direct bearing on Employability/ Entrepreneurship/ Skill development |
|---|---|---|---|---|---|---|
| MPA101T | Modern Pharmaceutical Analytical Techniques | 4 | 4 | 4 | 100 | ENTERPERNEURSHIP |
| MPA102T | Advanced Pharmaceutical Analysis | 4 | 4 | 4 | 100 | EMPLOYABILITY |
| MPA103T | Pharmaceutical Validation | 4 | 4 | 4 | 100 | EMPLOYABILITY |
| MPA104T | Food Analysis | 4 | 4 | 4 | 100 | EMPLOYABILITY |
| MPA105P | Pharmaceutical Analysis Practical I | 12 | 6 | 12 | 150 | EMPLOYABILITY |
| - | Seminar/Assignment | 7 | 4 | 7 | 100 | ENVIRONMENTAL SCIENCE |
| | **Total** | 35 | 26 | 35 | 650 | |

## SEMESTER II

| Course Code | Course | Credit Hours | Credit Points | Hrs./ w k | Marks | Activities/Content with direct bearing on Employability/ Entrepreneurship/ Skill development |
|---|---|---|---|---|---|---|
| MPA201T | Advanced Instrumental Analysis | 4 | 4 | 4 | 100 | ENTERPERNEURSHIP |
| MPA202T | Modern Bio-Analytical Techniques | 4 | 4 | 4 | 100 | EMPLOYABILITY |
| MPA203T | Quality Control and Quality Assurance | 4 | 4 | 4 | 100 | EMPLOYABILITY |
| MPA204T | Herbal and Cosmetic Analysis | 4 | 4 | 4 | 100 | EMPLOYABILITY |
| MPA205P | Pharmaceutical Analysis Practical II | 12 | 6 | 12 | 150 | ENTERPERNEURSHIP |
| - | Seminar/Assignment | 7 | 4 | 7 | 100 | EMPLOYABILITY |
| | **Total** | 35 | 26 | 35 | 650 | |

## SEMESTER-III

| 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

## SEMESTER-IV

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

# SEMESTER-I

# M.PHARMACY PHARMACEUTICAL ANALYSIS (MPA)

## SEMESTER I

## MODERN PHARMACEUTICAL ANALYTICAL TECHNIQUES

## (MPC 101T)

**Course Objectives**

- 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.
- 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

**Course Outcomes**

| S. No | Course Outcomes | Knowledge level (BLOOMS Level) |
|---|---|---|
| After successful completion of the course student shall be able to | | |
| CO1: | Explain the theoretical principles of UV, IR, MASS and NMR spectroscopy | L1: Remember L2: UnderstandL3: Apply |
| CO2: | Discuss structural elucidation of organic and natural compounds by IR, NMR and MASS spectral data. Understand the theoretical principles of Woodward-Fieser rule. | L3: Apply L4: Analyse L5: Evaluate |
| CO3: | Learn instrumentation and Interpretation of organic compounds by Ramanspectroscopy | L3: Apply L4: Analyse L5: Evaluate |
| CO4: | Learn the general theory and principles of thermal analysis | L2:UnderstandL3: Apply L4: Analyse |
| CO5: | Learn the general theory and principles of Hyphenated Techniques | L3: Apply L4: Analyse L5:Evaluate |

BLOOMS Taxonomy- L1: Remember, L2: Understand, L3: Apply, L4: Analyse, L5: Evaluate,L6:Create

**How program out comes are assessed:**

| ProgramOutcome | | Level | Proficiency assessed by |
|---|---|---|---|
| PO1: | Pharmacy Knowledge | 3 | Assignments/ Internals/Viva |
| PO2: | Planning Abilities | 2 | Assignments/ Internals |
| PO3: | Conduct Investigations of Complex Problems | 3 | Assignments/ Internals/ Practicals |
| PO4: | Problem Analysis | 2 | Assignments/ Internals |
| PO5: | Modern Tool Usage | 3 | Seminars/academic activities |
| PO6: | Leadership Skills | 2 | Group discussion / Role play |
| PO7: | Professional Identity | 2 | Group discussion |
| PO8: | Pharmaceutical Ethics | 2 | Personality development seminars |
| PO9: | Communication | 3 | Students' seminars/ student - teacherinteraction |
| PO10: | The Pharmacist and Society | 2 | Group discussion / Role play |
| PO11: | Environment And Sustainability | 2 | Students' seminars |
| PO12 | Life-Long Learning | 3 | Assignments/ Internals |

**LEVEL: 1- Slight (Low), 2- Moderate(Medium), 3- Substantial(High)**

**Course Outcomes and Program Outcomes (CO-PO) Mapping:**

| | PO1 | PO2 | PO3 | PO4 | PO5 | PO6 | PO7 | PO8 | PO9 | PO10 | PO11 | PO12 |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| CO1 | 3 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 |
| CO2 | 3 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 |
| CO3 | 3 | 3 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 |
| CO4 | 3 | 3 | 2 | 2 | 3 | 3 | 2 | 2 | 2 | 2 | 2 | 2 |
| CO5 | 3 | 3 | 3 | 3 | 3 | 3 | 2 | 2 | 2 | 2 | 2 | 2 |
| CO6 | 3 | 3 | 2 | 3 | 3 | 3 | 2 | 2 | 2 | 2 | 2 | 2 |
| Avg | 3 | 2.6 | 2.2 | 2.3 | 2.5 | 2.5 | 2 | 2 | 2 | 2 | 2 | 2 |

**Course content**

**1. THEORY** **60Hrs**

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.

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.

**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.

**4.** Chromatography: Principle, apparatus, instrumentation, chromatographic parameters, factors affectingresolution, isolationof drug from excipients, data interpretation and applications of the following:

a) Thin Layer chromatography,High Performance Thin Layer Chromatography,Ion exchange chromatography
b) Column chromatography
c) Gas chromatography
d) High Performance Liquid chromatography
e) Ultra High Performance Liquid chromatography
f) Affinity chromatography
g) Gel Chromatography

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

**6.X ray Crystallography**: Production of X rays, Different X ray methods, Bragg‘s law, Rotating crystaltechnique, X ray powder technique, Types of crystals and applications of X-ray diffraction

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

**b) Thermal Techniques:** Principle, thermal transitions and Instrumentation (Heat flux and power-compensation anddesigns), 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 anddisadvantages, 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, Sixthedition,John Wiley & Sons, 2004.
2.Principles of Instrumental Analysis - Doglas A Skoog, F. James

Holler, Timothy A.Nieman, 5thedition, Eastern press, Bangalore, 1998.
3.Instrumental methods of analysis – Willards, 7th edition, CBS publisher
4. Quantitative analysis of Pharmaceutical formulations by HPTLC - P DSethi, CBSPublishers, New Delhi.
5.Quantitative Analysis of Drugs in Pharmaceutical formulation - P D Sethi, 3rdEdition,CBS Publishers, New Delhi, 1997.
6.Pharmaceutical Analysis- Modern methods – Part B - J W Munson, Volume 11.

# MPA 102TADVANCED PHARMACEUTICAL ANALYSIS

**Objectives**

After completing this course, the students must demonstrate the knowledge and ability to:

- 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.

**COURSE OUTCOMES:**

| S.NO | COURSE OUTCOMES | Knowledge level (BLOOMS Level) |
|---|---|---|
| After successful completion of the course student shall be able to | | |
| **CO1:** | Understand the concepts of Impurity profiling and categorize theimpurities like (inorganic, organic and residual solvents) | L1:Remember<br>L2:Understand<br>L3:Apply |
| **CO2:** | Gain appropriate knowledge about analytical skills required for theanalysis of impurities in the bulk drugs and various formulations. | L3:Apply<br>L4:Analyse<br>L5:Evaluate |
| **CO3:** | Understand the official and non-official methods to analyses therelated substance. | L3:Apply<br>L4:Analyse<br>L5:Evaluate |
| **CO4:** | Demonstrate stability testing protocols and stability testing of<br><br>pharmaceuticals. | L3:Apply<br>L4:Analyse<br>L5:Evaluate |
| **CO5:** | Understand and explain bioassays and immunoassays. | L3:Apply<br>L4:Analyse<br>L5:Evaluate |

**How program outcomes are assessed:**

| Program Outcome | | Level | Proficiency assessed by |
|---|---|---|---|
| **PO1** | Pharmacy knowledge | 3 | Assignments/viva/Internals |
| **PO2** | Planning abilities | 2 | Assignments/Internals |
| **PO3** | Conduct Investigations of complex problems | 3 | Practical's |
| **PO4** | Problem Analysis | 2 | Assignments/ Internals |
| **PO5** | Modern Tool Usage | 2 | Academic activity |
| **PO6** | Leadership Skills | 2 | Role play |
| **PO7** | Professional Identity | 3 | Group discussion |
| **PO8** | Pharmaceutical Ethics | 2 | Personality development seminars |
| **PO9** | Communication | 3 | Student Interaction |

| | | | |
|---|---|---|---|
| **P010** | The Pharmacist and society | 3 | Awareness program/Role play |
| **PO11** | Environment and Sustainability | 2 | Seminars |
| **PO12** | Life Long Learning | 3 | Assignments |

**LEVEL: 1 – Slight (low), 2- Moderate (medium), 3- Substantial (High)**

## Course Outcomes and Program Out comes (CO-PO) Mapping:

| | PO1 | PO2 | PO3 | PO4 | PO5 | PO6 | PO7 | PO8 | PO9 | PO10 | PO11 | PO12 |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| **CO1** | 3 | 3 | 2 | 3 | 2 | 3 | 2 | 3 | 2 | 3 | 2 | 3 |
| **CO2** | 2 | 3 | 3 | 2 | 3 | 3 | 2 | 3 | 2 | 2 | 2 | 3 |
| **CO3** | 3 | 2 | 3 | 2 | 2 | 2 | 2 | 3 | 3 | 3 | 3 | 2 |
| **CO4** | 3 | 2 | 3 | 3 | 3 | 2 | 3 | 2 | 3 | 2 | 3 | 2 |
| **CO5** | 3 | 3 | 3 | 2 | 3 | 2 | 2 | 3 | 2 | 2 | 2 | 2 |
| **Avg** | | | | | | | | | | | | |

**LEVEL: 1 – Slight (low), 2- Moderate (medium), 3- Substantial (High)**

### Course content

**THEORY** **60 Hr**

**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.

**3.** Impurity profiling and degradent characterization: **10 Hrs**

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

4. Stability testing of phytopharmaceuticals: **10 Hrs** Regulatory requirements, protocols, HPTLC/HPLC finger printing, Interactions and complexity.

5.Biological tests and assays of the following: **10 Hrs**

a. Adsorbed Tetanus vaccine b. Adsorbed Diphtheria vaccinec. 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 generegulation, instrumentation (Principle and Procedures)

6.Immunoassays (IA) **10 Hrs**

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.

**REFERENCES**

1. Vogel‘s textbook of quantitative chemical analysis - Jeffery J Bassett, J. Mendham, R. C. Denney, 5thedition, ELBS, 1991.
2. Practical Pharmaceutical Chemistry - Beckett and Stenlake, Vol II, 4th Edition, CBS publishers, NewDelhi, 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 sciencePublication, 1961.
5. Quantitative Analysis of Drugs in Pharmaceutical formulation – P D Sethi, 3rd Edition, CBS PublishersNew 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

# MPA 103T: PHARMACEUTICAL VALIDATION

**Objectives**

After completing this course, the students must demonstrate the knowledge and ability to:

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

**COURSE OUTCOMES:**

| S.NO | COURSE OUTCOMES | Knowledge level (BLOOMS Level) |
|---|---|---|
| After successful completion of the course student shall be able to | | |
| CO1: | Understand the concepts of calibration, qualification and validation, qualification of various pharmaceutical equipment and instruments. | L1:Remember L2:Understand L3:Apply |
| CO2: | Study the Process validation of different dosage forms and validation of analytical method for estimation of drugs. | L3:Apply L4:Analyse L5:Evaluate |
| CO3: | Understand Cleaning validation of equipment employed in the manufacture of pharmaceuticals. | L3:Apply L4:Analyse L5:Evaluate |
| CO4: | Understand Intellectual property rights and patent filing and know about the concept of qualification of laboratory instruments. | L3:Apply L4:Analyse L5:Evaluate |
| CO5: | Understand validation of sterile and non-sterile plant and computerized system validation. | L3:Apply L4:Analyse L5:Evaluate |

**How program outcomes are assessed:**

| Program Outcome | | Level | Proficiency assessed by |
|---|---|---|---|
| **PO1** | Pharmacy knowledge | 3 | Assignments/viva/Internals |
| **PO2** | Planning abilities | 2 | Assignments/Internals |
| **PO3** | Conduct Investigations of complex problems | 3 | Practical's |
| **PO4** | Problem Analysis | 2 | Assignments/ Internals |
| **PO5** | Modern Tool Usage | 2 | Academic activity |
| **PO6** | Leadership Skills | 2 | Role play |
| **PO7** | Professional Identity | 3 | Group discussion |
| **PO8** | Pharmaceutical Ethics | 2 | Personality development seminars |
| **PO9** | Communication | 3 | Student Interaction |
| **P010** | The Pharmacist and society | 3 | Awareness program/Role play |
| **PO11** | Environment and Sustainability | 2 | Seminars |
| **PO12** | Life Long Learning | 3 | Assignments |

**LEVEL: 1 – Slight (low), 2- Moderate (medium), 3- Substantial (High)**

**Course Outcomes and Program Out comes (CO-PO) Mapping:**

| | PO1 | PO2 | PO3 | PO4 | PO5 | PO6 | PO7 | PO8 | PO9 | PO10 | PO11 | PO12 |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| CO1 | 3 | 3 | 2 | 3 | 2 | 3 | 2 | 3 | 2 | 3 | 2 | 3 |
| CO2 | 2 | 3 | 3 | 2 | 3 | 3 | 2 | 3 | 2 | 2 | 2 | 3 |
| CO3 | 3 | 2 | 3 | 2 | 2 | 2 | 2 | 3 | 3 | 3 | 3 | 2 |
| CO4 | 3 | 2 | 3 | 3 | 3 | 2 | 3 | 2 | 3 | 2 | 3 | 2 |
| CO5 | 3 | 3 | 3 | 2 | 3 | 2 | 2 | 3 | 2 | 2 | 2 | 2 |
| Avg | | | | | | | | | | | | |

**LEVEL: 1 – Slight (low), 2- Moderate (medium), 3- Substantial (High)**

## COURSR CONTENT

**THEORY** **60 Hrs**

**1.** Introduction: **12 Hr**

Definition of Qualification and Validation, Advantage of Validation, Streamlining of Qualification & Validation process and Validation Master Plan.

Qualification: User Requirement Specification, Design Qualification, Factory Acceptance Test (FAT)/ Site Acceptance Test (SAT), Installation Qualification, Operational Qualification, Performance Qualification, Re- Qualification (Maintaining status-Calibration Preventive Maintenance, Change management), Qualification of ManufacturingEquipments, Qualification of Analytical Instruments and Laboratory equipments.

**2.** Qualification of analytical instruments**:** **12 Hrs**

Electronic balance, pHmeter, UV-Visible spectrophotometer, FTIR, GC, HPLC, HPTLC Qualification of Glassware: Volumetric flask, pipette, Measuring cylinder, beakers and burette.

**3.** Validation of Utility systems: **12 Hrs**

Pharmaceutical Water System & pure steam, HVAC system, Compressed air and nitrogen. Cleaning Validation:

Cleaning Validation - Cleaning Method development, Validation and validation of analytical method usedin cleaning. Cleaning of Equipment, Cleaning of Facilities.Cleaning in place (CIP).

**4.** Analytical method validation: **12 Hrs**

General principles, Validation of analytical method as per ICH guidelines and USP.

Computerized system validation: Electronic records and digital significance-21 CFR part 11 and GAMP 5.General Principles of Intellectual Property: **12 Hrs**

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

technology (TOT), IP and ethics-positive and negative aspects of IPP; Societal responsibility, avoiding unethical practices.

**REFERENCES**

1. B. T. Loftus & R. A. Nash, "Pharmaceutical Process Validation", Drugs and Pharm Sci.eries, Vol. 129, 3rdEd., 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-Up|| , Drugs and Pharm. Sci. Series, Vol. 157,2nd Ed., MarcelDekker Inc., N.Y.

6. Validation Standard Operating Procedures: A Step by Step Guide for Achieving Compliance in thePharmaceutical, 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.

# MPA104T: FOOD ANALYSIS

**Objectives**

After completing this course, the students must demonstrate the knowledge and ability to:

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. 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

**COURSE OUTCOMES:**

| S.No | Course outcomes | Knowledge level (BLOOMS Level) |
|---|---|---|
| After successful completion of the course student shall be able to explain | | |
| CO1 | Understand the different classes of carbohydrates and their digestion and absorption. Classification properties, analysis, digestion, absorption and metabolism of proteins. | L1: Remember; L2: Understand; L4: Analyse; |
| CO2 | Classification methods of analysis, hydrogenation and adulteration in fats and oils Classification, method of analysis and microbial assays of vitamins. | L2: Understand; L4: Analyse; L5 Evaluate |
| CO3 | To provide theoretical knowledge on the definition of food additives, and their role in the food industry in the context of current food regulations; functional classification and safety assessment of food additives. | L2: Understand; L3: Apply; L4: Analyse |
| CO4 | Applications of common techniques for analysing food components from specific food products to determine proximate composition | L1: Remember; L2: Understand; L4: Analyse |
| CO5 | Pesticide analysis in grains, fruits, vegetables, milk and milk products. Legislative regulations like BIS Agmark FDA-USFDA. | L2: Understand; L4: Analyse; L5 Evaluate; |

BLOOMS TOXONOMY: L1: Remember; L2: Understand; L3: Apply; L4: Analyse; L5 Evaluate; L6: Create

**How program outcomes are assessed:**

| Program Outcome | Level | Proficiency assessed by |
|---|---|---|

| | | | |
|---|---|---|---|
| **PO1** | Pharmacy knowledge | 3 | Assignments/viva/Internals |
| **PO2** | Planning abilities | 2 | Assignments/Internals |
| **PO3** | Conduct Investigations of complex problems | 3 | Practical's |
| **PO4** | Problem Analysis | 2 | Assignments/ Internals |
| **PO5** | Modern Tool Usage | 2 | Academic activity |
| **PO6** | Leadership Skills | 2 | Role play |
| **PO7** | Professional Identity | 3 | Group discussion |
| **PO8** | Pharmaceutical Ethics | 2 | Personality development seminars |
| **PO9** | Communication | 3 | Student Interaction |
| **P010** | The Pharmacist and society | 3 | Awareness program/Role play |
| **PO11** | Environment and Sustainability | 2 | Seminars |
| **PO12** | Life Long Learning | 3 | Assignments |

**LEVEL: 1 – Slight (low), 2- Moderate (medium), 3- Substantial (High)**

**Course Outcomes and Program Out comes (CO-PO) Mapping:**

| | **PO1** | **PO2** | **PO3** | **PO4** | **PO5** | **PO6** | **PO7** | **PO8** | **PO9** | **PO10** | **PO11** | **PO12** |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| **CO1** | 2 | 3 | 2 | 3 | 2 | 3 | 2 | 3 | 2 | 3 | 2 | 3 |
| **CO2** | 2 | 3 | 3 | 3 | 2 | 3 | 3 | 2 | 3 | 2 | 2 | 3 |
| **CO3** | 3 | 2 | 3 | 2 | 2 | 3 | 2 | 3 | 3 | 3 | 3 | 3 |
| **CO4** | 3 | 3 | 3 | 3 | 3 | 2 | 3 | 2 | 3 | 2 | 3 | 2 |
| **CO5** | 3 | 3 | 3 | 2 | 3 | 2 | 2 | 3 | 2 | 3 | 2 | 2 |
| **Avg** | 2.6 | 2.8 | 2.8 | 2.4 | 2.4 | 2.6 | 2.4 | 2.6 | 2.6 | 2.6 | 2.4 | 2.6 |

## COURSE CONTENT

**THEORY** **60 Hrs**

**1.** Carbohydrates: **12 Hrs**

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

2.Lipids: **12 Hrs**

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 ofvitamins of B-series.

3.Food additives: **12Hrs**

Introduction, analysis of Preservatives, 12 antioxidants, artificial sweeteners, flavors, flavor enhancers, stabilizers, thickening and jelling agents.Pigments and synthetic dyes: Natural pigments,

their occurrence and characteristic properties, permitted synthetic dyes, Non-permitted synthetic dyes used by industries, Method ofdetection of natural, permitted and non-permitted dyes.

**4.** General Analytical methods for milk, milk constituents and milk products like ice cream, milk powder, **12Hrs**

butter, margarine, cheese including adulterants and contaminants of milk. Analysis of fermentation products likewine, spirits, beer and vinegar.

5.Pesticide analysis: **12Hrs**

Effects of pest and insects on various food, use of pesticides in agriculture, pesticide cycle, Organophosphorus and organochlorine pesticides analysis,determination of pesticide residues in grain,fruits, vegetables,milk and milk products.Legislation regulations of food products with special emphasis on BIS, Agmark, FDA and US-FDA.

**REFERENCES**

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.

# MPA 105P : PHARMACEUTICAL ANALYSIS PRACTICALS – II

1. Analysis of Pharmacopoeial compounds and their formulations by UV Vis spectrophotometer
2. Simultaneous estimation of multi component containing formulationsby 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

# SEMESTER-II

# MPA 201T: ADVANCED INSTRUMENTAL ANALYSI

**Objectives**

After completing this course, the students must demonstrate the knowledge and ability to:

- Identification of organic compounds
- Interpretation of the NMR, Mass and IR spectra of various organic compounds
- Theoretical and practical skills of the hyphenated instruments like LC-NMR, LC-MS, CE- MS etc.

## COURSE OUTCOMES

| S NO | COURSE OUTCOMES | Knowledge level (BLOOMS Level) |
|---|---|---|
| After completing this course, the student must demonstrate the knowledge and ability to: | | |
| **CO1** | Acquire Practical aspects and troubleshooting techniques for HPLC techniques To understand the principles and instrumentation and pharmaceutical applications on HPLC, UPLC, nano HPLC. | L2: Understand; L3: Apply; L4: Analyse |
| **CO2** | To understand the principles and procedures of size exclusion chromatography, ion exchange chromatography, affinity, GC and HPTLC with their pharmaceutical applications. | L2: Understand; L4: Analyse; L5 Evaluate |
| **CO3** | To understand the principles, procedures and pharmaceutical applications of Super critical fluid chromatography and Capillary electrophoresis. Theoretical aspects of hyphenated analytical techniques like CE-MS. | L2: Understand; L3: Apply; L4: Analyse; |
| **CO4** | To understand the principle and procedure involved in selected instrumental analytical techniques and theoretical aspects of hyphenated analytical techniques like LC-MS , DRAT-MS and tandems | L3: Apply; L4: Analyse; L5 Evaluate |
| **CO5** | To gain knowledge on interaction of EMR with matter and to build the analytical understanding at the level of atom, group and molecular structure of organic and inorganic compounds with different functional groups and their applications in pharmacy. To detail the principle, instrumentation and applications of hyphenated techniques like LC-NMR | L3: Apply; L4: Analyse; L5 Evaluate |

BLOOMS TOXONOMY: L1: Remember; L2: Understand; L3: Apply

## How program outcomes are assessed:

| Program Outcome | | Level | Proficiency assessed by |
|---|---|---|---|
| **PO1** | Pharmacy knowledge | 3 | Assignments/viva/Internals |
| **PO2** | Planning abilities | 2 | Assignments/Internals |
| **PO3** | Conduct Investigations of complex problems | 3 | Practical's |
| **PO4** | Problem Analysis | 2 | Assignments/ Internals |
| **PO5** | Modern Tool Usage | 2 | Academic activity |
| **PO6** | Leadership Skills | 2 | Role play |
| **PO7** | Professional Identity | 3 | Group discussion |
| **PO8** | Pharmaceutical Ethics | 2 | Personality development seminars |
| **PO9** | Communication | 3 | Student Interaction |
| **P010** | The Pharmacist and society | 3 | Awareness program/Role play |
| **PO11** | Environment and Sustainability | 2 | Seminars |
| **PO12** | Life Long Learning | 3 | Assignments |

**LEVEL: 1 – Slight (low), 2- Moderate (medium), 3- Substantial (High)**

**Course Outcomes and Program Out comes (CO-PO) Mapping:**

| | PO1 | PO2 | PO3 | PO4 | PO5 | PO6 | PO7 | PO8 | PO9 | PO10 | PO11 | PO12 |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| **CO1** | 3 | 2 | 2 | 3 | 2 | 3 | 2 | 3 | 2 | 3 | 2 | 3 |
| **CO2** | 2 | 3 | 3 | 3 | 2 | 3 | 2 | 3 | 3 | 2 | 2 | 3 |
| **CO3** | 3 | 2 | 3 | 2 | 2 | 2 | 2 | 3 | 3 | 3 | 3 | 2 |
| **CO4** | 3 | 3 | 3 | 3 | 3 | 2 | 3 | 2 | 3 | 3 | 3 | 2 |
| **CO5** | 3 | 3 | 3 | 2 | 3 | 2 | 2 | 3 | 2 | 2 | 2 | 2 |
| **Avg** | 2.8 | 2.6 | 2.8 | 2.6 | 2.4 | 2.4 | 2.2 | 2.8 | 2.6 | 2.6 | 2.4 | 2.4 |

## COURSE CONTENT

**THEORY** **60 Hrs**

**1.**HPLC: 12Hrs

Principle, instrumentation, pharmaceutical applications, 12 peak shapes, capacity factor, selectivity, plate number, plate Hrs 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.

**2.**Biochromatography: 12Hrs

Size exclusion chromatography, ion exchange chromatography, ion pair chromatography, affinity Hrs chromatography general principles, stationary phases and mobile phases.

Gas chromatography: Principles, instrumentation, derivatization, head space sampling, columns for GC, detectors, quantification. High performance Thin Layer chromatography: Principles, instrumentation, pharmaceutical applications.

**3.**Super critical fluid chromatography: 12Hrs

instrumentation, pharmaceutical applications. 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.

**4.** Mass spectrometry: 12Hrs

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.

**5.** NMR spectroscopy: 12 Hrs

Quantum numbers and their role in NMR, Principle,Instrumentation,SolventrequirementinNMR, 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.

**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.

# MPA 202T: MODERN BIO ANALYTICAL TECHNIQUES

**Objectives**

After completing this course, the students must demonstrate the knowledge and ability to:

- Extraction of drugs from biological samples
- Separation of drugs from biological samples using different techniques
- Guidelines for BA/BE studies.
- The cGMP aspects in a pharmaceutical industry

**COURSE OUTCOMES:**

| S.NO | COURSE OUTCOMES | Knowledge level (BLOOMS Level) |
|---|---|---|
| After successful completion of the course student shall be able to | | |
| CO1: | Quantification of analyte present in the biological fluids and analyte enrichment techniques as well the instrumentation technique. | L1:Remember L2:Understand L3:Apply |
| CO2: | Invitro, In-situ and In-vivo methods for bioavailability. | L3:Apply L4:Analyse L5:Evaluate |
| CO3: | Importance and applications of pharmacokinetic and toxicokinetic studies | L3:Apply L4:Analyse L5:Evaluate |
| CO4: | Various types of cell cultures and their applications. | L3:Apply L4:Analyse L5:Evaluate |
| CO5: | Metabolite identification, In-vitro assay of drug metabolites & drug metabolizing enzymes.Bioequivalence study for formulations by utilizing the proper regulatory guidelines and updating information on the current trend in GCP and GLP | L3:Apply L4:Analyse L5:Evaluate |

**How program outcomes are assessed:**

| Program Outcome | | Level | Proficiency assessed by |
|---|---|---|---|
| **PO1** | Pharmacy knowledge | 3 | Assignments/viva/Internals |
| **PO2** | Planning abilities | 2 | Assignments/Internals |
| **PO3** | Conduct Investigations of complex problems | 3 | Practical's |
| **PO4** | Problem Analysis | 2 | Assignments/ Internals |
| **PO5** | Modern Tool Usage | 2 | Academic activity |
| **PO6** | Leadership Skills | 2 | Role play |
| **PO7** | Professional Identity | 3 | Group discussion |
| **PO8** | Pharmaceutical Ethics | 2 | Personality development seminars |
| **PO9** | Communication | 3 | Student Interaction |
| **P010** | The Pharmacist and society | 3 | Awareness program/Role play |
| **PO11** | Environment and Sustainability | 2 | Seminars |
| **PO12** | Life Long Learning | 3 | Assignments |

**LEVEL: 1 – Slight (low), 2- Moderate (medium), 3- Substantial (High)Course Outcomes and Program Out comes (CO-PO) Mapping:**

| | PO1 | PO2 | PO3 | PO4 | PO5 | PO6 | PO7 | PO8 | PO9 | PO10 | PO11 | PO12 |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| **CO1** | 3 | 3 | 2 | 3 | 2 | 3 | 2 | 3 | 2 | 3 | 2 | 3 |
| **CO2** | 2 | 3 | 3 | 2 | 3 | 3 | 2 | 3 | 2 | 2 | 2 | 3 |
| **CO3** | 3 | 2 | 3 | 2 | 2 | 2 | 2 | 3 | 3 | 3 | 3 | 2 |
| **CO4** | 3 | 2 | 3 | 3 | 3 | 2 | 3 | 2 | 3 | 2 | 3 | 2 |
| **CO5** | 3 | 3 | 3 | 2 | 3 | 2 | 2 | 3 | 2 | 2 | 2 | 2 |
| **Avg** | 2.8 | 2.6 | 2.8 | 2.6 | 2.8 | 2.4 | 2.2 | 2.8 | 2.4 | 2.4 | 2.4 | 2.4 |

## COURSE CONTENT

**THEORY** **60 Hrs**

1. Extraction of drugs and metabolites from biological matrices: 12 Hrs 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.

**2.** Biopharmaceutical Consideration: **12 Hrs**

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.

3.Pharmacokinetics and Toxicokinetics: **12 Hrs**

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.

4.Cell culture techniques media: **12 Hrs**

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

**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 DrugProducts), 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, Easternpress, 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 Practical HPLC method Development – Snyder, Kirkland, Glaich, 2nd Edition, John Wiley & Sons, New Jercy
5) Chromatographic Analysis of Pharmaceuticals – John A Adamovics, 2nd Edition, Marcel Dekker, Newyork,USA. 1997.
6) Chromatographic methods in clinical chemistry & Toxicology – Roger L Bertholf, Ruth E Winecker, John Wiley & Sons, New Jercy, USA. 2007.
7) Good Laboratory Practice Regulations, 2nd Edition, Sandy Weinberg Vol. 69, Marcel Dekker Series, 1995.
8.Good laboratory Practice Regulations – Allen F. Hirsch, Volume 38, Marcel Dekker Series, 1989.
8) ICH, USFDA & CDSCO Guidelines.
10.Palmer

# MPA 203T: QUALITY CONTROL AND QUALITY ASSURANCE

**Objectives**

After completing this course, the students must demonstrate the knowledge and ability to:

- 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
- The cGMP aspects in a pharmaceutical industry

**COURSE OUTCOMES:**

| S.NO | COURSE OUTCOMES | Knowledge level (BLOOMS Level) |
|---|---|---|
| After successful completion of the course student shall be able to | | |
| CO1: | The student shall get the knowledge on cGMP aspects in a pharmaceutical industry and importance of documentation | L1:Remember<br>L2:Understand<br>L3:Apply |
| CO2: | Understands the scope of quality certifications applicable to pharmaceutical industries, the responsibilities of QA & QC departments, and GLP, protocol for conduct of non-clinical trials& regulatory affairs. | L3:Apply<br>L4:Analyse<br>L5:Evaluate |
| CO3: | Students shall be able to understand the control of contamination and Good Warehousing Practice. | L3:Apply<br>L4:Analyse<br>L5:Evaluate |
| CO4: | Gains skills on methods of analysis of raw materials, finished products, packaging materials, in process quality control (IPQC), and developing specification (ICH Q6 and Q3). | L3:Apply<br>L4:Analyse<br>L5:Evaluate |
| CO5: | Gets acquaintance with manufacturing operations and controls like sanitation of manufacturing premises, mix-ups, and cross-contamination, processing of intermediates and bulk products, packaging operations, process deviations, charge-in of components, time limitations on production, drug product inspection, expiry date calculation, calculation of yields, etc. | L3:Apply<br>L4:Analyse<br>L5:Evaluate |

**How program outcomes are assessed:**

| Program Outcome | | Level | Proficiency assessed by |
|---|---|---|---|
| **PO1** | Pharmacy knowledge | 3 | Assignments/viva/Internals |
| **PO2** | Planning abilities | 2 | Assignments/Internals |
| **PO3** | Conduct Investigations of complex problems | 3 | Practical's |
| **PO4** | Problem Analysis | 2 | Assignments/ Internals |
| **PO5** | Modern Tool Usage | 2 | Academic activity |
| **PO6** | Leadership Skills | 2 | Role play |
| **PO7** | Professional Identity | 3 | Group discussion |
| **PO8** | Pharmaceutical Ethics | 2 | Personality development seminars |
| **PO9** | Communication | 3 | Student Interaction |
| **P010** | The Pharmacist and society | 3 | Awareness program/Role play |
| **PO11** | Environment and Sustainability | 2 | Seminars |
| **PO12** | Life Long Learning | 3 | Assignments |

## LEVEL: 1 – Slight (low), 2- Moderate (medium), 3- Substantial (High)

**Course Outcomes and Program Out comes (CO-PO) Mapping:**

| | PO1 | PO2 | PO3 | PO4 | PO5 | PO6 | PO7 | PO8 | PO9 | PO10 | PO11 | PO12 |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| **CO1** | 3 | 3 | 2 | 3 | 2 | 3 | 2 | 3 | 2 | 3 | 2 | 3 |
| **CO2** | 2 | 3 | 3 | 2 | 3 | 3 | 2 | 3 | 2 | 2 | 2 | 3 |
| **CO3** | 3 | 2 | 3 | 2 | 2 | 2 | 2 | 3 | 3 | 3 | 3 | 2 |
| **CO4** | 3 | 2 | 3 | 3 | 3 | 2 | 3 | 2 | 3 | 2 | 3 | 2 |
| **CO5** | 3 | 3 | 3 | 2 | 3 | 2 | 2 | 3 | 2 | 2 | 2 | 2 |
| **Avg** | 2.8 | 2.6 | 2.8 | 2.4 | 2.6 | 2.4 | 2.2 | 2.8 | 2.4 | 2.4 | 2.4 | 2.4 |

**COURSE CONTENT**

**THEORY** **60 hrs**

**1.** Concept and Evolution of Quality Control and Quality Assurance 12Hrs 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 nonclinical testing, control on animal house, report preparation and documentation.

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

**3.** Analysis of raw materials, finished products, packaging 12 materials, in process quality control (IPQC), Developing Hrs specification (ICH Q6 and Q3) Purchase specifications and maintenance of stores for raw materials. In process quality control and finished products quality control for following formulation in Pharma industry according to Indian, US and British pharmacopoeias:

tablets, capsules, ointments, suppositories, creams, parenterals, ophthalmic and surgical products (How to refer pharmacopoeias), Quality control test for containers, closures and secondary packing materials.

**4.** Documentation in pharmaceutical industry: 12 Hrs

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.

**5.** Manufacturing operations and controls: 12 Hrs

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

**REFERENCES**

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.

# MPA 204 T: HERBAL AND COSMETIC ANALYSIS

**Objectives**

After completing this course, the students must demonstrate the knowledge and ability to:

- 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.

## COURSE OUTCOMES

| S NO. | COURSE OUTCOMES | Knowledge level (BLOOMS Level) |
|---|---|---|
| After completing this course, the student must demonstrate the knowledge and ability to: | | |
| **CO1** | Knowledge on herbal remedies, herbal drug standardization and herbal drug regulations and pharmacokinetic studies | L1: Remember<br>L2: Understand<br>L3: Apply |
| **CO2** | Able to perform herbal analysis to find out the adulterants and substitutions for herbal drug industry | L1: Remember<br>L2: Understand<br>L3: Apply<br>L5: Analyze |
| **CO3** | Know the analytical techniques and instruments for natural drug testing and standardization | L1: Remember<br>L2: Understand<br>L3: Apply<br>L4: Analyze |
| **CO4** | Proper understanding of herbal drug interactions and challenges in safety monitoring of herbal drugs | L1: Remember<br>L2: Understand |
| **CO5** | Know the legislation regulation of BIS and evaluation of cosmetics, dental and hair products | L1: Remember<br>L2: Understand<br>L3: Apply<br>L5: Evaluate |

BLOOMS TOXONOMY: L1: Remember; L2: Understand; L3: Apply; L4: Analyze; L5: Evaluate

**How program outcomes are assessed:**

| Program Outcome | | Level | Proficiency assessed by |
|---|---|---|---|
| **PO1** | Pharmacy knowledge | 3 | Assignments/viva/Internals |
| **PO2** | Planning abilities | 2 | Assignments/Internals |
| **PO3** | Problem Analysis | 2 | Assignments/ Internals |
| **PO4** | Modern Tool Usage | 2 | Academic activity |
| **PO5** | Leadership Skills | 2 | Role play |
| **PO6** | Professional Identity | 3 | Group discussion |
| **PO7** | Pharmaceutical Ethics | 2 | Personality development seminars |
| **PO8** | Communication | 3 | Student Interaction |
| **P09** | The Pharmacist and society | 3 | Awareness program/Role play |
| **PO10** | Environment and Sustainability | 2 | Seminars |
| **PO11** | Life Long Learning | 3 | Assignments |

**LEVEL: 1 – Slight (low), 2- Moderate (medium), 3- Substantial (High)**

**Course outcomes and program outcomes (CO-PO) Mapping:**

| | PO1 | PO2 | PO3 | PO4 | PO5 | PO6 | PO7 | PO8 | PO9 | PO10 | PO11 |
|---|---|---|---|---|---|---|---|---|---|---|---|
| **CO1** | 2 | 2 | 3 | 2 | 3 | 3 | 2 | 3 | 2 | 2 | 3 |
| **CO2** | 3 | 2 | 3 | 3 | 2 | 2 | 1 | 2 | 3 | 3 | 1 |
| **CO3** | 1 | 1 | 1 | 2 | 1 | 1 | 2 | 2 | 1 | 2 | 2 |
| **CO4** | 3 | 2 | 2 | 1 | 2 | 2 | 3 | 3 | 3 | 1 | 3 |
| **CO5** | 1 | 3 | 1 | 3 | 3 | 2 | 2 | 2 | 1 | 3 | 1 |
| **Avg** | **2** | **2** | **2.3** | **2.2** | **2.2** | **2.1** | **2** | **2.4** | **2** | **2** | **2** |

## COURSE CONTENT

**1.Herbal remedies- Toxicity and Regulations** **12Hrs**

Herbals vs Conventional drugs, Efficacy of herbal medicine products, Validation of Herbal Therapies, Pharmacodynamic and Pharmacokinetic issues. Herbal drug standardization: WHO and AYUSH guidelines.

**2.Adulteration and Deterioration:** **12Hrs**

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.

**Regulatory requirements for setting herbal drug industry:**

Global marketing management, Indian and international patent law as applicable to herbal drugs and natural productsand its protocol.

**3.Testing of natural products and drugs:** **12Hrs**

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.

**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.

4. **Herbal drug-drug interaction: 12Hrs**

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.

5. **Evaluation of cosmetic products: 12Hrs**

Determination of acid value, ester value, saponification value, iodine value, peroxide value, rancidity, moisture, ash, volatile matter, heavy metals, fineness of powder, density, viscosity of cosmetic raw materials and finished products. Study of quality of raw materials and general methods of analysis of raw material used in cosmetic manufacture as per BIS.

Indian Standard specification laid down for sampling and testing of various cosmetics in finished forms such as baby care products, skin care products, dental products, personal hygiene preparations, lips sticks. Hair products and skin creams by the Bureau Indian Standards.

**REFERENCES**

1. Pharmacognosy by Trease and Evans
2. Pharmacognosy by Kokate, Purohit and Gokhale
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, 3rdEdition.

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

a. Comparison of absorption spectra by UV and Wood ward – Fiesure rule
b. Interpretation of organic compounds by FT-IR

c. Interpretation of organic compounds by NMR
d. Interpretation of organic compounds by MS
e. Determination of purity by DSC in pharmaceuticals
f. Identification of organic compounds using FT-IR, NMR, CNMR and Mass spectra
g. Bio molecules separation utilizing various sample preparation techniques and Quantitative analysis of components by gel electrophoresis.
h. Bio molecules separation utilizing various sample preparation techniques and Quantitative analysis ofcomponents by HPLC techniques.
i. Isolation of analgesics from biological fluids (Blood serum and urine).
j. Protocol preparation and performance of analytical/Bioanalytical method validation.
k. Protocol preparation for the conduct of BA/BE studies according to guidelines.
l. In process and finished product quality control tests for tablets, capsules, parenterals and creams
m. Quality control tests for Primary and secondary packing materials
n. Assay of raw materials as per official monographs
o. Testing of related and foreign substances in drugs and raw materials
p. Preparation of Master Formula Record.
q. Preparation of Batch Manufacturing Record.
r. Quantitative analysis of rancidity in lipsticks and hair oil
s. Determination of aryl amine content and Developer in hair dye
t. Determination of foam height and SLS content of Shampoo.
u. Determination of total fatty matter in creams (Soap, skin and hair creams)
v. Determination of acid value and saponification value.
w. Determination of calcium thioglycolate in depilatories

# UNIVERSITY COLLEGE OF PHARMACEUTICAL SCIENCES
## M.PHARMACY
## SEMESTER-III

**Paper-I: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

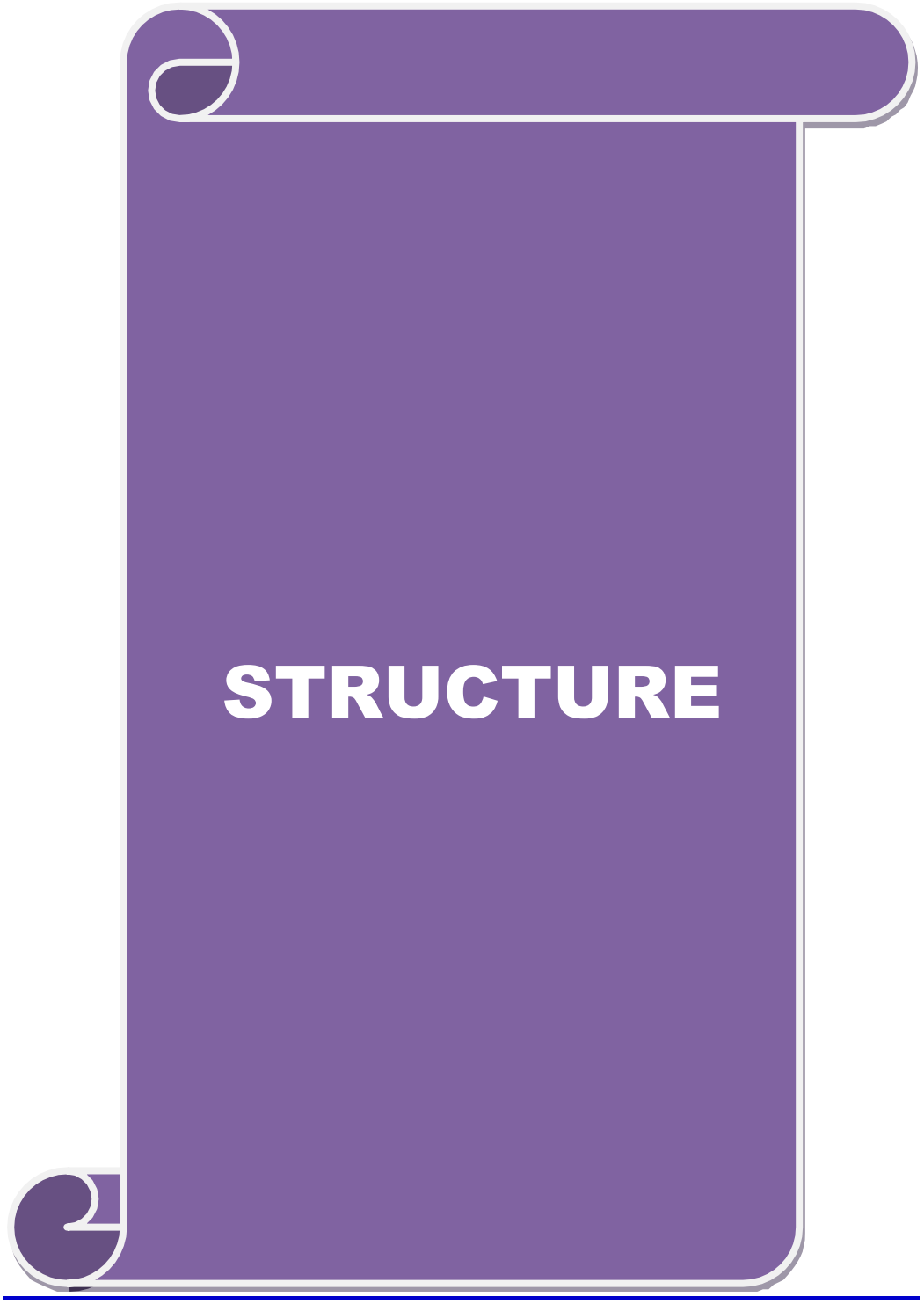
research, and additional principles for medical research combined with medical care.

# UNIVERSITY COLLEGE OF PHARMACEUTICAL SCIENCES

## M.PHARMACY

## SEMESTER-IV

- Journal Club
- Research Work
- Final Presentation


STRUCTURE

# ACHARYA NAGARJUNA UNIVERSITY
# UNIVERSITY COLLEGE OF PHARMACEUTICAL SCIENCES

## M.PHARM

## M. PHARM. (PHARMACEUTICS)

## SEMESTER I

| Course Code | Course | Credit Hours | Credit Points | Hrs./w k | Marks | Activities/Content with direct bearing on Employability/ Entrepreneurship/ Skill development |
|---|---|---|---|---|---|---|
| MPH101T | Modern Pharmaceutical Analytical Techniques | 4 | 4 | 4 | 100 | EMPLOYABILITY |
| MPH102T | Drug Delivery System | 4 | 4 | 4 | 100 | EMPLOYABILITY |
| MPH103T | Modern Pharmaceutics | 4 | 4 | 4 | 100 | EMPLOYABILITY |
| MPH104T | Regulatory Affair | 4 | 4 | 4 | 100 | EMPLOYABILITY |
| MPH105P | Pharmaceutics Practical I | 12 | 6 | 12 | 150 | SKILL DEVELOPMENT |
| - | Seminar/Assignment | 7 | 4 | 7 | 100 | ENVIRONMENTAL SCIENCE |
| | Total | 35 | 26 | 35 | 650 | |

## SEMESTER II

| Course Code | Course | Credit Hours | Credit Points | Hrs./w k | Marks | Activities/Content with direct bearing on Employability/ Entrepreneurship/ Skill development |
|---|---|---|---|---|---|---|
| MPH201T | Molecular Pharmaceutics (Nano Tech and Targeted DDS) | 4 | 4 | 4 | 100 | EMPLOYABILITY |
| MPH202T | Advanced Biopharmaceutics & Pharmacokinetics | 4 | 4 | 4 | 100 | EMPLOYABILITY |
| MPH203T | Computer Aided Drug Delivery System | 4 | 4 | 4 | 100 | EMPLOYABILITY |
| MPH204T | Cosmetic and Cosmeceuticals | 4 | 4 | 4 | 100 | EMPLOYABILITY |
| MPH205P | Pharmaceutics Practical II | 12 | 6 | 12 | 150 | SKILL DEVELOPMENT |
| - | Seminar/Assignment | 7 | 4 | 7 | 100 | EMPLOYABILITY |
| | Total | 35 | 26 | 35 | 650 | |

## SEMESTER-III

| 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**

## SEMESTER-IV

| Course Code | Course | Credit Hours | Credit Points |
|---|---|---|---|
| - | Journal club | 1 | 1 |
| - | Discussion/Presentation (Proposal Presentation) | 3 | 3 |
| - | Research Work | 31 | 16 |
| **Total** | | **35** | **20** |

# Semester I

# M.PHARMACY

# PHARMACEUTICS (MPH)

# SEMESTER-I

## MPH 101T:MODERN PHARMACEUTICAL ANALYTICAL TECHNIQUES

### OBJECTIVES

After completion of course student is able to know:

CO1: Different Chemicals and Excipients

CO2: The analysis of various drugs in single and combination dosage forms

CO3: Theoretical and practical skills of the instruments

**How program outcomes are assessed:**

| Program outcomes | | level | Proficiency Assessed by |
|---|---|---|---|
| **PO1:** | To Impart knowledge on the novel drug delivery systems | 3 | Assignments/ Internals/Viva |
| **PO2:** | To know various preformulation elements, industrial management and GMP considerations | 2 | Assignments/ Internals |
| **PO3:** | To impart knowledge and skills in generic drug development | 2 | Assignments/ Internals/ Practicals |
| **PO4:** | To impart knowledge and skills for dose calculations, dose adjustments | 2 | Assignments/ Internals |
| **PO5:** | To impart knowledge and skills necessary for cosmetics and cosmeceuticals | 2 | Seminars/academic activities |
| **PO6:** | To gain knowledge in use of advanced instrumentation | 1 | Group discussion / Role play |
| **PO7:** | To train the students and develop their technical skill knowledge in computer simulations | 1 | Group discussion |
| **PO8:** | To create a talent pool by involving students in research projects | 2 | Personality development seminars |

| | | | |
|---|---|---|---|
| **PO9:** | To foster ambitious desire among students to undertake higher studies and career growth. | 2 | Students' seminars/ student -teacher interaction |

**Level: 1 – slight (low), Level: 2- Moderate (medium), level: 3- Substantial (high)**

**Course outcomes and program outcomes (CO-PO) mapping:**

| **Course outcomes** | **Program outcomes (PO)** | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| | **PO 1** | **PO2** | **PO3** | **PO4** | **PO5** | **PO6** | **PO7** | **PO8** | **PO9** |
| **CO1** | 3 | 3 | 2 | 3 | 3 | 2 | 1 | 2 | 3 |
| **CO2** | 3 | 1 | 2 | 2 | 1 | 2 | 1 | 2 | 1 |
| **CO3** | 3 | 2 | 2 | 1 | 2 | 3 | 1 | 2 | 2 |
| **AVG** | 3 | 2 | 2 | 2 | 2 | 2 | 1 | 2 | 2 |

**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.

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 andApplications of fluorescence spectrophotometer.
d.Flame emission spectroscopy and Atomic absorption spectroscopy: Principle, Instrumentation, Interferences andApplications. **11 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. **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 11Hrs

4.Chromatography: Principle, apparatus, instrumentation, chromatographic parameters, factors affecting resolution and applications of the following: a) Paper chromatography b) Thin Layer

chromatography c) Ion exchange chromatography d) Column chromatography e) Gas chromatography f) High Performance Liquid chromatography g) Affinity chromatography**11 Hrs**

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

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 Xray diffraction.

6.Immunological assays : RIA (Radio immuno assay), ELISA, Bioluminescence assays. **5Hrs**

**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, Easternpress, 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, NewDelhi, 1997.

7.Pharmaceutical Analysis- Modern methods – Part B - J W Munson, Volume 11, Marcel Dekker Series

# MPH102T: DRUG DELIVERY SYSTEMS

## OBJECTIVES

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

CO1: The various approaches for development of novel drug delivery systems.

CO2: The criteria for selection of drugs and polymers for the development of delivering system

CO3: The formulation and evaluation of Novel drug delivery systems

**How program outcomes are assessed:**

| Program outcomes | | Proficiency Assessed by | Level |
|---|---|---|---|
| **PO1:** | To Impart knowledge on the novel drug delivery systems | Assignments/ Internals/Viva | 3 |
| **PO2:** | To know various preformulation elements, industrial management and GMP considerations | Assignments/ Internals | 2 |
| **PO3:** | To impart knowledge and skills in generic drug development | Assignments/ Internals/ Practicals | 2 |
| **PO4:** | To impart knowledge and skills for dose calculations, dose adjustments | Assignments/ Internals | 2 |
| **PO5:** | To impart knowledge and skills necessary for cosmetics and cosmeceuticals | Seminars/academic activities | 2 |
| **PO6:** | To gain knowledge in use of advanced instrumentation | Group discussion / Role play | 1 |
| **PO7:** | To train the students and develop their technical skill knowledge in computer simulations | Group discussion | 1 |
| **PO8:** | To create a talent pool by involving students in research projects | Personality development seminars | 2 |
| **PO9:** | To foster ambitious desire among students to undertake higher studies and career growth. | Students' seminars/ student -teacher interaction | 2 |

**Level: 1 – slight (low), Level: 2- Moderate (medium), level: 3- Substantial (high)**

**Course outcomes and program outcomes (CO-PO) mapping:**

| Course outcomes | Program outcomes (PO) | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| | PO 1 | PO2 | PO3 | PO4 | PO5 | PO6 | PO7 | PO8 | PO9 |
| CO1 | 3 | 3 | 2 | 3 | 3 | 2 | 1 | 2 | 2 |
| CO2 | 3 | 1 | 2 | 2 | 1 | 2 | 1 | 1 | 2 |
| CO3 | 3 | 2 | 2 | 1 | 2 | 2 | 1 | 3 | 2 |
| AVG | 3 | 2 | 2 | 2 | 2 | 2 | 1 | 2 | 2 |

## COURSE CONTENT

**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**

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 ofvaccines. **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, JohnWiley 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, Firstedition 2002

# MPH 103 T : MODERN PHARMACEUTICS

**Objectives**

Upon completion of the course, student shall be able to understandCO1: The elements of preformulation studies.

CO2: The Active Pharmaceutical Ingredients and Generic drug Product developmentCO3: Industrial Management and GMP Considerations.

CO4: Optimization Techniques & Pilot Plant Scale Up Techniques

CO5: Stability Testing, sterilization process & packaging of dosage forms.

**How program outcomes are assessed:**

| Program outcomes | | level | Proficiency Assessed by |
|---|---|---|---|
| **PO1:** | To Impart knowledge on the novel drug delivery systems | 3 | Assignments/ Internals/Viva |
| **PO2:** | To know various preformulation elements, industrial management and GMP considerations | 2 | Assignments/ Internals |
| **PO3:** | To impart knowledge and skills in generic drug development | 2 | Assignments/ Internals/ Practicals |
| **PO4:** | To impart knowledge and skills for dose calculations, dose adjustments | 2 | Assignments/ Internals |
| **PO5:** | To impart knowledge and skills necessary for cosmetics and cosmeceuticals | 2 | Seminars/academic activities |
| **PO6:** | To gain knowledge in use of advanced instrumentation | 1 | Group discussion / Role play |
| **PO7:** | To train the students and develop their technical skill knowledge in computer simulations | 1 | Group discussion |
| **PO8:** | To create a talent pool by involving students in research projects | 2 | Personality development seminars |
| **PO9:** | To foster ambitious desire among students to undertake higher studies and career growth. | 2 | Students' seminars/ student -teacher interaction |

**Level: 1 – slight (low), Level: 2- Moderate (medium), level: 3- Substantial (high)**

**Course outcomes and program outcomes (CO-PO) mapping:**

| Course outcomes | Program outcomes (PO) | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| | **PO1** | **PO2** | **PO3** | **PO4** | **PO5** | **PO6** | **PO7** | **PO8** | **PO9** |
| **CO1** | 3 | 2 | 3 | 2 | 3 | 2 | 2 | 3 | 2 |
| **CO2** | 2 | 3 | 2 | 3 | 2 | 3 | 3 | 2 | 2 |
| **CO3** | 2 | 1 | 2 | 2 | 1 | 2 | 2 | 1 | 2 |
| **CO4** | 1 | 2 | 2 | 1 | 2 | 1 | 1 | 2 | 2 |
| **CO5** | 2 | 2 | 1 | 2 | 2 | 2 | 2 | 2 | 2 |
| **AVG** | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 |

## COURSE CONTENT

**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. 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**

**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 SidneyH. 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. Encyclopaedia of Pharmaceutical technology, Vol I – III. 4

# MPH 104 T: REGULATORY AFFAIRS

**Objectives**

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

CO1: The Concepts of innovator and generic drugs, drug development process

CO2: The Regulatory guidance's and guidelines for filing and approval process

CO3: Preparation of Dossiers and their submission to regulatory agencies in differentcountries

CO4: Post approval regulatory requirements for actives and drug productsCO5: Submission of global documents in CTD/eCTD formats

CO6: Clinical trials requirements for approvals for conducting clinical trials

CO7: Pharmacovigilance and process of monitoring in clinical trials

**How program outcomes are assessed:**

| Program outcomes | | level | Proficiency Assessed by |
|---|---|---|---|
| **PO1:** | To Impart knowledge on the novel drug delivery systems | 3 | Assignments/ Internals/Viva |
| **PO2:** | To know various preformulation elements, industrial management and GMP considerations | 2 | Assignments/ Internals |
| **PO3:** | To impart knowledge and skills in generic drug development | 2 | Assignments/ Internals/ Practicals |
| **PO4:** | To impart knowledge and skills for dose calculations, dose adjustments | 2 | Assignments/ Internals |
| **PO5:** | To impart knowledge and skills necessary for cosmetics and cosmeceuticals | 2 | Seminars/academic activities |
| **PO6:** | To gain knowledge in use of advanced instrumentation | 1 | Group discussion / Role play |
| **PO7:** | To train the students and develop their technical skill knowledge in computer simulations | 1 | Group discussion |
| **PO8:** | To create a talent pool by involving students in research projects | 2 | Personality development seminars |
| **PO9:** | To foster ambitious desire among students to undertake higher studies and career growth. | 2 | Students' seminars/ student -teacher interaction |

**Level: 1 – slight (low), Level: 2- Moderate (medium), level: 3- Substantial (high)**

**Course outcomes and program outcomes (CO-PO) mapping:**

| Course outcomes | Program outcomes (PO) | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| | **PO1** | **PO2** | **PO3** | **PO4** | **PO5** | **PO6** | **PO7** | **PO8** | **PO9** |
| **CO1** | 3 | 2 | 2 | 2 | 2 | 1 | 1 | 2 | 2 |
| **CO2** | 2 | 2 | 3 | 2 | 2 | 3 | 3 | 3 | 2 |
| **CO3** | 2 | 1 | 1 | 2 | 2 | 3 | 2 | 2 | 2 |
| **CO4** | 3 | 3 | 2 | 2 | 1 | 2 | 2 | 1 | 2 |
| **CO5** | 2 | 2 | 2 | 1 | 2 | 1 | 1 | 3 | 1 |
| **CO6** | 1 | 2 | 3 | 3 | 3 | 2 | 3 | 2 | 3 |
| **CO7** | 1 | 2 | 1 | 2 | 2 | 2 | 2 | 1 | 2 |
| **AVG** | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 |

**Course content**

**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. 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. **12 Hrs**

**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 Dekkerseries, Vol.143

2. The Pharmaceutical Regulatory Process, Second Edition Edited by Ira R. Berry and Robert P.Martin, Drugs andthe Pharmaceutical Sciences,Vol.185, Informa Health care Publishers.

3. New Drug Approval Process: Accelerating Global Registrations By Richard A Guarino, MD,5th edition, Drugsand 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 andRodney K. Adams

www.ich.org/ 8. www.fda.gov/ 9. europa.eu/index_en.htm 10. https://www.tga.gov.au/tga-basics

# MPH 105P : PHARMACEUTICS PRACTICALS - I

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 Mucoadhesive tablets.
12. Formulation and evaluation of transdermal 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.
    To plot Heckel plot, Higuchi and peppas plot and determine similarity factors.

# SEMESTER-II

# MPH 201T: MOLECULAR PHARMACEUTICS (NANO TECH AND TARGETED

**Objectives**

- The various approaches for development of novel drug delivery systems.
- The criteria for selection of drugs and polymers for the development of NTDS.
- The design development and evaluation of novel drug delivery systems.
- Knowledge about Vaccines and its drug delivery systems, gene therapy.

**How program outcomes are assessed:**

| Program outcomes | | level |
|---|---|---|
| **PO1:** | Possess the skills to use modern pharmaceutical tools, software, equipments to analyze & solve problems. | 3 |
| **PO2:** | Demonstrate an adaptable, flexible and effective approach towards organizational development. | 2 |
| **PO3:** | Acquire adequate scientific information regarding basic principles of pharmaceutics including cosmetology and specialized drug delivery systems. | 2 |
| **PO4:** | Trained on the practical aspects of formulation development, analysis and quality assurance of various pharmaceutical dosage forms. | 2 |
| **PO5:** | Develop the ability to conduct, analyze and interpret data as per the needs of pharmaceutical industries | 2 |

**Level: 1 – slight (low), Level: 2- Moderate (medium), level: 3- Substantial (high)**

## *Course outcomes and program outcomes (CO-PO) mapping:*

| | Program outcomes (PO) | | | | |
|---|---|---|---|---|---|
| | **PO1** | **PO2** | **PO3** | **PO4** | **PO5** |
| **CO1** | **3** | **2** | **2** | **3** | **2** |
| **CO2** | **2** | **3** | **2** | **1** | **2** |
| **CO3** | **2** | **1** | **1** | **2** | **2** |
| **CO4** | **1** | **2** | **3** | **2** | **2** |
| **AVG** | **2** | **2** | **2** | **2** | **2** |

**Course Content**

**THEORY** **60 Hrs**

1.Targeted Drug Delivery Systems: Concepts, 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 andevaluation. **12 Hrs**

3.Micro Capsules / Micro Spheres: Types, preparation and evaluation , Monoclonal Antibodies ; preparation and application, preparation and application of Niosomes, Aquasomes, Phytosomes, Electrosomes. **12Hrs**

4. Pulmonary Drug Delivery Systems : Aerosols, propellents, Containers Types, preparation and evaluation, Intra Nasal Route Delivery systems; Types, preparation and evaluation. **12 Hrs**

**5. N**ucleic 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, Ballabh Prakashan, New Delhi, Firstedition 2002.

3. N.K. Jain, Controlled and Novel Drug Delivery, CBS Publishers & Distributors, NewDelhi, First edition 1997(reprint in 2001).

# MPH 202 T: ADVANCED BIOPHARMACEUTICS AND PHARMACOKINETICS

**Objectives**

- The basic concepts in biopharmaceutics and pharmacokinetics.
- Use of raw data and derive the pharmacokinetic models and parameters the best describe the process of drugabsorption, 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 biopharmaceuticparameters.
- The potential clinical pharmacokinetic problems and application of basics of pharmacokinetics.

**How program outcomes are assessed:**

| Program outcomes | | level |
|---|---|---|
| **PO1:** | Possess the skills to use modern pharmaceutical tools, software, equipments to analyze & solve problems. | 3 |
| **PO2:** | Demonstrate an adaptable, flexible and effective approach towards organizational development. | 2 |
| **PO3:** | Acquire adequate scientific information regarding basic principles of pharmaceutics including cosmetology and specialized drug delivery systems. | 2 |
| **PO4:** | Trained on the practical aspects of formulation development, analysis and quality assurance of various pharmaceutical dosageforms. | 2 |
| **PO5:** | Develop the ability to conduct, analyze and interpret data as per the needs of pharmaceutical industries | 2 |

**Level: 1 – slight (low), Level: 2- Moderate (medium), level: 3- Substantial (high)**

**Course outcomes and program outcomes (CO-PO) mapping:**

| Course outcomes | Program outcomes (PO) | | | | |
|---|---|---|---|---|---|
| | **PO1** | **PO2** | **PO3** | **PO4** | **PO5** |
| **CO1** | **3** | **2** | **2** | **3** | **2** |
| **CO2** | **2** | **3** | **2** | **1** | **2** |
| **CO3** | **2** | **1** | **1** | **2** | **2** |
| **CO4** | **1** | **2** | **3** | **2** | **2** |
| **AVG** | **2** | **2** | **2** | **2** | **2** |

**Course Content**

**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. 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 invivo 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**

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 testing performance 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 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. 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 andBiotechnological Products. Introduction to Pharmacokinetics and pharm acodynamic, drug interactions. Pharmacokinetics and pharmacodynamics of biotechnology drugs. Introduction, Proteins and peptides, Monoclonal antibodies, oligonucleotides, Vaccines (immunotherapy), Gene therapies. **12Hrs**

**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, 2ndedition, 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, Leaand 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, DrugIntelligence 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, RPSPublishing,2009.
13. Absorption and Drug Development- Solubility, Permeability, and Charge State, Alex Avdeef, John Wiley &Sons, Inc,2003.

# MPH 203 T: COMPUTER AIDED DRUG DELIVERY SYSTEM

**Objectives**

- 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)

**How program outcomes are assessed:**

| Program outcomes | | level |
|---|---|---|
| **PO1:** | Possess the skills to use modern pharmaceutical tools, software, equipments to analyze & solve problems. | 3 |
| **PO2:** | Demonstrate an adaptable, flexible and effective approach towards organizational development. | 2 |
| **PO3:** | Acquire adequate scientific information regarding basic principles of pharmaceutics including cosmetology and specialized drug delivery systems. | 2 |
| **PO4:** | Trained on the practical aspects of formulation development, analysis and quality assurance of various pharmaceutical dosage forms. | 2 |
| **PO5:** | Develop the ability to conduct, analyze and interpret data as per the needs of pharmaceutical industries | 2 |

**Level: 1 – slight (low), Level: 2- Moderate (medium), level: 3- Substantial (high)**

## Course outcomes and program outcomes (CO-PO) mapping:

| Course outcomes | Program outcomes (PO) | | | | |
|---|---|---|---|---|---|
| | **PO1** | **PO2** | **PO3** | **PO4** | **PO5** |
| **CO1** | **3** | **2** | **2** | **3** | **2** |
| **CO2** | **2** | **3** | **2** | **1** | **2** |
| **CO3** | **2** | **1** | **1** | **2** | **2** |

| | | | | | |
|---|---|---|---|---|---|
| **CO4** | **1** | **2** | **3** | **2** | **2** |
| **AVG** | **2** | **2** | **2** | **2** | **2** |

**Course Content**

**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 12 Hrs 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**

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

# MPH 204 T: COSMETICS AND COSMECEUTICALS

**Objectives**

- Key ingredients used in cosmetics and cosmeceuticals.
- Key building blocks for various formulations.
- Various key ingredients and basic science to develop cosmetics and Scientific knowledge tocosmeceuticals
- To develop cosmetics and with desired safety, stability, and efficacy.

**How program outcomes are assessed:**

| Program outcomes | | level |
|---|---|---|
| **PO1:** | Possess the skills to use modern pharmaceutical tools, software, equipments to analyze & solve problems. | 3 |
| **PO2:** | Demonstrate an adaptable, flexible and effective approach towards organizational development. | 2 |
| **PO3:** | Acquire adequate scientific information regarding basic principles of pharmaceutics including cosmetology and specialized drug delivery systems. | 2 |
| **PO4:** | Trained on the practical aspects of formulation development, analysis and quality assurance of various pharmaceutical dosage forms. | 2 |
| **PO5:** | Develop the ability to conduct, analyze and interpret data as per the needs of pharmaceutical industries | 2 |

**Level: 1 – slight (low), Level: 2- Moderate (medium), level: 3- Substantial (high)**

**Course outcomes and program outcomes (CO-PO) mapping:**

| Course outcomes | Program outcomes (PO) | | | | |
|---|---|---|---|---|---|
| | **PO1** | **PO2** | **PO3** | **PO4** | **PO5** |
| **CO1** | **3** | **2** | **2** | **3** | **2** |
| **CO2** | **2** | **3** | **2** | **1** | **2** |
| **CO3** | **2** | **1** | **1** | **2** | **2** |
| **CO4** | **1** | **2** | **3** | **2** | **2** |
| **AVG** | **2** | **2** | **2** | **2** | **2** |

**Course Content**

**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 oral cavity.Cleansing and care needs for face, eye lids, lips, hands, feet, nail, scalp, neck, body and under-arm. **12 Hrs**

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

**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**

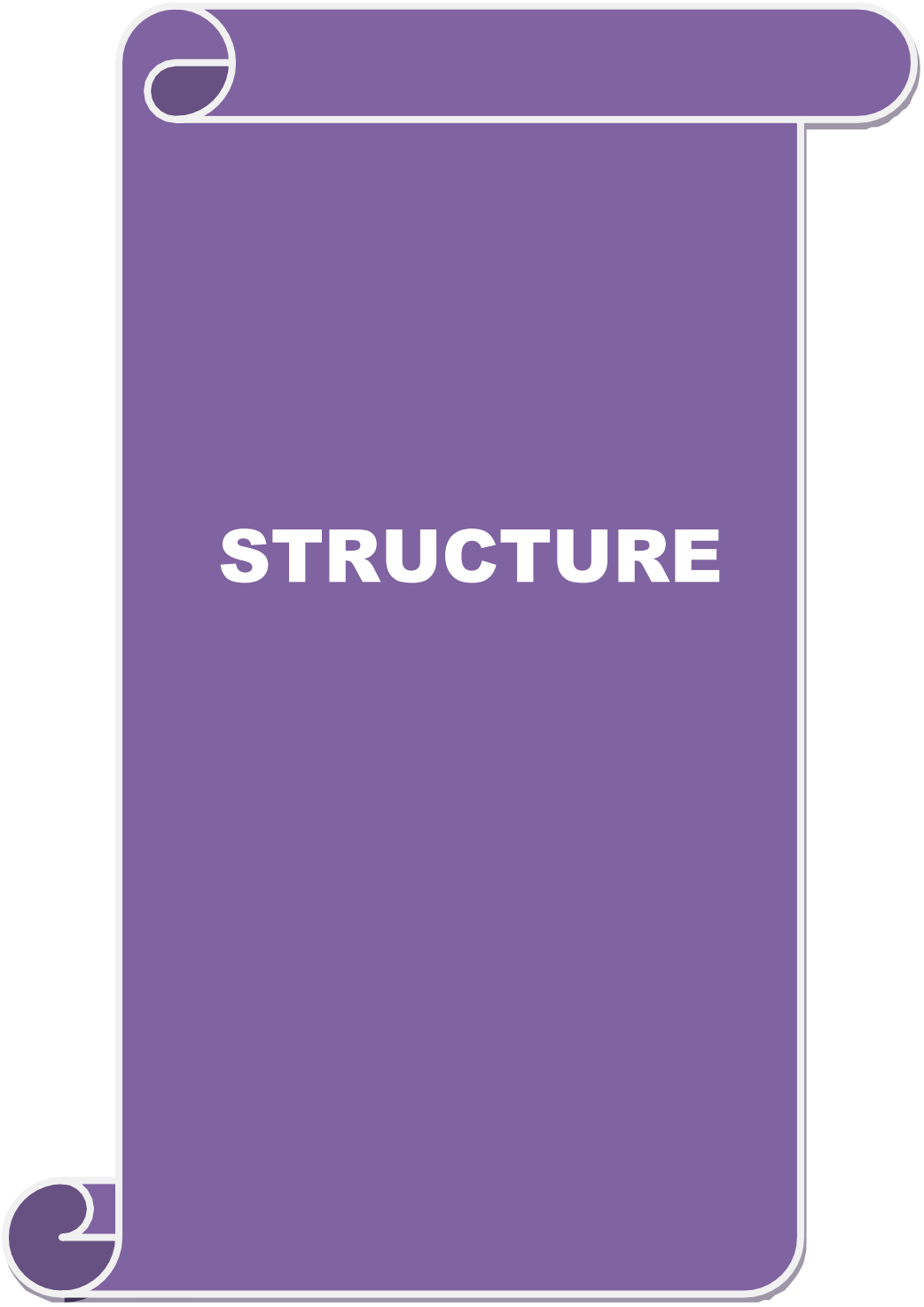
**5.** Herbal Cosmetics : Herbal ingredients used in Hair care, skin care and oral care. Review of guidelines for herbalcosmetics by private bodies like cosmos with respect to preservatives, emollients, foaming agents, emulsifiers and rheology modifiers. Challenges in formulating herbal cosmetics. **12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

**REFERENCES**

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

# MPH205P : PHARMACEUTICS PRACTICALS - II

1. To study the effect of temperature change , non solvent addition, incompatible polymer addition in microcapsulespreparation
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


STRUCTURE

# ACHARYA NAGARJUNA UNIVERSITY
# UNIVERSITY COLLEGE OF PHARMACEUTICAL SCIENCES
# M.PHARM
# (PHARMACEUTICAL (INDUSTRIAL PHARMACY)
# SEMESTER I

| Course Code | Course | Credit Hours | Credit Points | Hrs./w k | Marks | Activities/Content with direct bearing on Employability/ Entrepreneurship/ Skill development |
|---|---|---|---|---|---|---|
| **MIP101T** | Modern Pharmaceutical Analytical Techniques | 4 | 4 | 4 | 100 | SKILL DEVELOPMENT |
| **MIP102T** | Pharmaceutical Formulation Development | 4 | 4 | 4 | 100 | EMPLOYABILITY |
| **MIP103T** | Novel drug delivery systems | 4 | 4 | 4 | 100 | EMPLOYABILITY |
| **MIP104T** | Intellectual Property Rights | 4 | 4 | 4 | 100 | ENTERPERNEURSHIP |
| **MIP105P** | Industrial Pharmacy Practical I | 12 | 6 | 12 | 150 | EMPLOYABILITY |
| - | Seminar/Assignment | 7 | 4 | 7 | 100 | EMPLOYABILITY |
| | Total | 35 | 26 | 35 | 650 | |

## SEMESTER II

| Course Code | Course | Credit Hours | Credit Points | Hrs./w k | Marks | Activities/Content with direct bearing on Employability/ Entrepreneurship/ Skill development |
|---|---|---|---|---|---|---|
| **MIP201T** | Advanced Biopharmaceutics and Pharmacokinetics | 4 | 4 | 4 | 100 | SKILL DEVELOPMENT |
| **MIP202T** | Scale up and Technology Transfer | 4 | 4 | 4 | 100 | EMPLOYABILITY |
| **MIP203T** | Pharmaceutical Production Technology | 4 | 4 | 4 | 100 | EMPLOYABILITY |
| **MIP204T** | Entrepreneurship Management | 4 | 4 | 4 | 100 | ENTERPERNEURSHIP |
| **MIP205P** | Industrial Pharmacy Practical II | 12 | 6 | 12 | 150 | EMPLOYABILITY |
| - | Seminar/Assignment | 7 | 4 | 7 | 100 | EMPLOYABILITY |
| | Total | 35 | 26 | 35 | 650 | |

## SEMESTER-III

| 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**

## SEMESTER-IV

| Course Code | Course | Credit Hours | Credit Points |
|---|---|---|---|
| - | Journal club | 1 | 1 |
| - | Discussion/Presentation (Proposal Presentation) | 3 | 3 |
| - | Research Work | 31 | 16 |
| **Total** | | **35** | **20** |

# Semester I

# INDUSTRIAL PHARMACY (MIP)I SEMESTER

## MIP 101T : MODERN PHARMACEUTICAL ANALYTICAL TECHNIQUES

**Objectives**

- 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.
- 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

**Course Outcomes**

| S. No | Course Outcomes | Knowledge level (BLOOMS Level) |
|---|---|---|
| After successful completion of the course student shall be able to | | |
| **CO1:** | Explain the theoretical principles of UV, IR, MASS and NMR spectroscopy | L1: RememberL2: Understand L3: Apply |
| **CO2:** | Discuss structural elucidation of organic and natural compounds by IR, NMRand MASS spectral data. Understand the theoretical principles of Woodward-Fieser rule. | L3: Apply L4: Analyse L5: Evaluate |
| **CO3:** | Learn instrumentation and Interpretation of organic compounds by Ramanspectroscopy | L3: Apply L4: AnalyseL5: Evaluate |
| **CO4:** | Learn the general theory and principles of thermal analysis | L2:Understan dL3: Apply L4: Analyse |
| **CO5:** | Learn the general theory and principles of Hyphenated Techniques | L3: Apply L4: AnalyseL5: Evaluate |

BLOOMS Taxonomy- L1: Remember, L2: Understand, L3: Apply, L4: Analyse, L5: Evaluate,L6:Create

**How program out comes are assessed:**

| Program Outcome | | Level | Proficiency assessed by |
|---|---|---|---|
| **PO1:** | Pharmacy Knowledge | 3 | Assignments/ Internals/Viva |
| **PO2:** | Planning Abilities | 2 | Assignments/ Internals |
| **PO3:** | Conduct Investigations of Complex Problems | 3 | Assignments/ Internals/ Practicals |
| **PO4:** | Problem Analysis | 2 | Assignments/ Internals |
| **PO5:** | Modern Tool Usage | 3 | Seminars/academic activities |
| **PO6:** | Leadership Skills | 2 | Group discussion / Role play |
| **PO7:** | Professional Identity | 2 | Group discussion |
| **PO8:** | Pharmaceutical Ethics | 2 | Personality development seminars |
| **PO9:** | Communication | 3 | Students' seminars/ student -teacherinteraction |
| **PO10:** | The Pharmacist and Society | 2 | Group discussion / Role play |
| **PO11:** | Environment And Sustainability | 2 | Students' seminars |
| **PO12** | Life-Long Learning | 3 | Assignments/ Internals |

**LEVEL: 1- Slight (Low), 2- Moderate(Medium), 3- Substantial(High)**

**Course Outcomes and Program Outcomes (CO-PO) Mapping:**

| | PO1 | PO2 | PO3 | PO4 | PO5 | PO6 | PO7 | PO8 | PO9 | PO10 | PO11 | PO12 |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| **CO1** | 3 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 |
| **CO2** | 3 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 |
| **CO3** | 3 | 3 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 |
| **CO4** | 3 | 3 | 2 | 2 | 3 | 3 | 2 | 2 | 2 | 2 | 2 | 2 |
| **CO5** | 3 | 3 | 3 | 3 | 3 | 3 | 2 | 2 | 2 | 2 | 2 | 2 |
| **CO6** | 3 | 3 | 2 | 3 | 3 | 3 | 2 | 2 | 2 | 2 | 2 | 2 |
| **Avg** | 3 | 2.6 | 2.2 | 2.3 | 2.5 | 2.5 | 2 | 2 | 2 | 2 | 2 | 2 |

**Course content**

**THEORY** **60Hrs**

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.
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.

Spectroflourimetry: Theory of Fluorescence, Factors affecting fluorescence (Characterestics of drugs that can be analysed by flourimetry), Quenchers, Instrumentation and Applications of fluorescence spectrophotometer Flame emission spectroscopy and Atomic absorption spectroscopy: Principle, Instrumentation, Interferences and Applications.

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.
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.
4. Chromatography: Principle, apparatus, instrumentation, chromatographic parameters, factors affecting resolution, isolation of drug from excipients, data interpretation and applications of the following:
Thin Layer chromatography,High Performance Thin Layer Chromatography,Ion exchange chromatography Column chromatography,Gas chromatography,High Performance Liquid chromatography

Ultra High Performance Liquid chromatography,Affinity chromatography,Gel Chromatography 5.a.Electrophoresis: Principle, Instrumentation, Working conditions, factors affecting separation and applications of the following a)Paper electrophoresis b) Gel electrophoresis c) Capillary electrophoresis d) Zone electrophoresis e) Moving boundary electrophoresis f) Iso electric focusing

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

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

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

**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, Easternpress, Bangalore, 1998.
3. Instrumental methods of analysis – Willards, 7th edition, CBS publisher 4.Quantitative analysis of Pharmaceutical formulations by HPTLC - P D Sethi, CBSPublishers, New Delhi.
5. Quantitative Analysis of Drugs in Pharmaceutical formulation - P D Sethi, 3rd Edition,CBS Publishers, New Delhi, 1997.
6. Pharmaceutical Analysis- Modern methods – Part B - J W Munson, Volume 11.

# MIP 102T: Pharmaceutical Formulation Development

**Objectives**

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

## *How program outcomes are assessed:*

| Program outcomes | | Level |
|---|---|---|
| **PO1:** | Possess the skills to use modern pharmaceutical tools, software, equipments to analyze & solve problems. | 3 |
| **PO2:** | Demonstrate an adaptable, flexible and effective approach towards organizational development. | 2 |
| **PO3:** | Acquire adequate scientific information regarding basic principles of pharmaceutics including cosmetology and specialized drug delivery systems. | 2 |
| **PO4:** | Trained on the practical aspects of formulation development, analysis and quality assurance of various pharmaceutical dosage forms. | 2 |
| **PO5:** | Develop the ability to conduct, analyze and interpret data as per the needs of pharmaceutical industries | 2 |

**Level: 1 – slight (low), Level: 2- Moderate (medium), level: 3- Substantial (high)**

**Course outcomes and program outcomes (CO-PO) mapping:**

| Course outcomes | Program outcomes (PO) | | | | |
|---|---|---|---|---|---|
| | **PO1** | **PO2** | **PO3** | **PO4** | **PO5** |
| **CO1** | **3** | **2** | **2** | **3** | **2** |
| **CO2** | **2** | **3** | **2** | **1** | **2** |
| **CO3** | **2** | **1** | **1** | **2** | **2** |
| **CO4** | **1** | **2** | **3** | **2** | **2** |
| **AVG** | **2** | **2** | **2** | **2** | **2** |

**Course Content**

**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 andprocess development. **12 Hrs**

3. Solubility: Importance, experimental determination, phasesolubility analysis, pH-solubility profile, solubility techniques to improve solubility and utilization of analytical methods – cosolvency, salt formation, complexation, solid dispersion, micellarsolubilization and hydrotropy. **12 Hrs**

**2** Dissolution: Theories, mechanisms of dissolution, in-vitro dissolution testing models – sink and non-sink. Factors influencingdissolution 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**

**3** Product Stability: Degradation kinetics, mechanisms, stability testing of drugs and pharmaceuticals, factors influencing-mediaeffects 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, 3 ed., Varghese Publishers,Mumbai 1991. Th
2. Sinko PJ. Martin's physical pharmacy and pharmaceutical sciences, 5 ed., B.I. Publications Pvt. Ltd, Noida, 2006.
3. Lieberman HA, Lachman L, Schwartz JB. Pharmaceutical dosage forms: nd tablets Vol. I-III, 2 ed., CBS Publishers &distributors, New Delhi, 2005.
4. Conners KA. A Text book of pharmaceutical analysi Wells JI. Pharmaceutical preformulation: The physicochemicalproperties 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. rd
7. Sethi PD. Quantitative analysis of drugs in pharmaceutical formulations, 3 ed., CBS publications, New Delhi, 2008. rd
8. Carstensen JT, Rhodes CT. Drug stability principles and practices, 3 CBS Publishers & distributors,

New Delhi, 2005. ed.,

9. Yoshioka S, Stella VJ. Stability of drugs and dosage forms, Springer (India) Pvt. Ltd., New Delhi, 2006. Th
10. Banker GS, Rhodes CT. Modern Pharmaceutics, 4 Inc, New York, 2005.
11. W. Grimm - Stability testing of drug products. ed., Marcel Dekker
12. Mazzo DJ. International stability testing. Eastern Press Pvt. Ltd., Bangalore, 1999.
13. Beckett AH, Stenlake JB. Practical pharmaceutical th chemistry, Part I & II., 4 2004. ed., CBS Publishers & distributors,New Delhi,
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.

# MIP 103T:Novel Drug Delivery System

**Objectives**

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

**How program outcomes are assessed:**

| Program outcomes | | Level |
|---|---|---|
| **PO1:** | Possess the skills to use modern pharmaceutical tools, software, equipments to analyze & solve problems. | 3 |
| **PO2:** | Demonstrate an adaptable, flexible and effective approach towards organizational development. | 2 |
| **PO3:** | Acquire adequate scientific information regarding basic principles of pharmaceutics including cosmetology and specialized drug delivery systems. | 2 |
| **PO4:** | Trained on the practical aspects of formulation development, analysis and quality assurance of various pharmaceutical dosage forms. | 2 |
| **PO5:** | Develop the ability to conduct, analyze and interpret data as per the needs of pharmaceutical industries | 2 |

**Level: 1 – slight (low), Level: 2- Moderate (medium), level: 3- Substantial (high)**

**Course outcomes and program outcomes (CO-PO) mapping:**

| Course outcomes | Program outcomes (PO) | | | | |
|---|---|---|---|---|---|
| | **PO1** | **PO2** | **PO3** | **PO4** | **PO5** |
| **CO1** | **3** | **2** | **2** | **3** | **2** |
| **CO2** | **2** | **3** | **2** | **1** | **2** |
| **CO3** | **2** | **1** | **1** | **2** | **2** |
| **CO4** | **1** | **2** | **3** | **2** | **2** |
| **AVG** | **2** | **2** | **2** | **2** | **2** |

**Course content**

***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. Carriers for Drug Delivery: Polymers / co-polymersintroduction, 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 andother 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 – multipleemulsions,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: Introduction, 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.

# MIP 104T: Intellectual Property Rights

**Objectives**

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

**How program outcomes are assessed:**

| Program outcomes | | Level |
|---|---|---|
| **PO1:** | Possess the skills to use modern pharmaceutical tools, software, equipments to analyze & solve problems. | 3 |
| **PO2:** | Demonstrate an adaptable, flexible and effective approach towards organizational development. | 2 |
| **PO3:** | Acquire adequate scientific information regarding basic principles of pharmaceutics including cosmetology and specialized drug delivery systems. | 2 |
| **PO4:** | Trained on the practical aspects of formulation development, analysis and quality assurance of various pharmaceutical dosage forms. | 2 |
| **PO5:** | Develop the ability to conduct, analyze and interpret data as per the needs of pharmaceutical industries | 2 |

**Level: 1 – slight (low), Level: 2- Moderate (medium), level: 3- Substantial (high)**

**Course outcomes and program outcomes (CO-PO) mapping:**

| Course outcomes | Program outcomes (PO) | | | | |
|---|---|---|---|---|---|
| | **PO1** | **PO2** | **PO3** | **PO4** | **PO5** |
| **CO1** | **3** | **2** | **2** | **3** | **2** |
| **CO2** | **2** | **3** | **2** | **1** | **2** |
| **CO3** | **2** | **1** | **1** | **2** | **2** |
| **CO4** | **1** | **2** | **3** | **2** | **2** |
| **AVG** | **2** | **2** | **2** | **2** | **2** |

**Course Content**

**THEORY** **60 H**

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**

**3** Role of GATT, TRIPS, and WIPO **12 Hrs**

**4** Brief introduction to Trademark protection and WHO Patents. IPR's and its types, Major bodies regulating IndianPharmaceutical sector.

**12Hrs**

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

**12Hrs** 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, 2 nd 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

# MIP 105P: INDUSTRIAL PHARMACY PRACTICALS - I

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 RH. oC, 60% RH and 40 oC, 75%

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

# Semester II

# MIP 201T: ADVANCED BIOPHARMACEUTICS & PHARMACOKINETICS

On completion of this course, it is expected that students will be able to understand,CO1: The basic concepts in Biopharmaceutics and pharmacokinetics.

CO2: The use of raw data and derive the pharmacokinetic models and parameters the best describes theprocess of drug absorption, distribution, metabolism and elimination.

CO3: To critically evaluate Bio pharmaceutics studies involving drug product equivalency.

CO4: To design and evaluate dosage regimens of the drugs using pharmacokinetic and biopharmaceuticparameters

**How program outcomes are assessed:**

| Program outcomes | | level | Proficiency assessed by |
|---|---|---|---|
| PO1: | Possess the skills to use modern pharmaceutical tools, software, equipments to analyze & solve problems. | 3 | Assignments/ Internals/Viva |
| PO2: | Demonstrate an adaptable, flexible and effective approach towards organizational development. | 2 | Assignments/ Internals |
| PO3: | Acquire adequate scientific information regarding basic principles of pharmaceutics including cosmetology and specialized drug delivery systems. | 2 | Assignments/ Internals/ Practicals |
| PO4: | Trained on the practical aspects of formulation development, analysis and quality assurance of various pharmaceutical dosage forms. | 2 | Assignments/ Internals |
| PO5: | Develop the ability to conduct, analyze and interpret data as per the needs of pharmaceutical industries | 2 | Seminars/academic Activities |

**Level: 1 – slight (low), Level: 2- Moderate (medium),**

**level: 3- Substantial (high)Course outcomes and**

**program outcomes (CO-PO) mapping:**

| Course outcomes | Program outcomes (PO) | | | | |
|---|---|---|---|---|---|
| | PO1 | PO2 | PO3 | PO4 | PO5 |
| CO1 | 3 | 2 | 2 | 3 | 2 |
| CO2 | 2 | 3 | 2 | 1 | 2 |
| CO3 | 2 | 1 | 1 | 2 | 2 |
| CO4 | 1 | 2 | 3 | 2 | 2 |
| AVG | 2 | 2 | 2 | 2 | 2 |

## COURSE CONTENT

**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, RateLimiting Steps in Drug Absorption, Physicochemical Nature of the 12 Hrs 63 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, 4 th edition,Philadelphia, Lea and Febiger,1991

2. . Biopharmaceutics and Pharmacokinetics, A. Treatise, D .M. Brahmankar and Sunil B.J aiswal., VallabPrakashan, Pitampura, Delhi

3. Applied Biopharmaceutics and Pharmacokinetics by Shargel. Land YuABC, 2 nd edition, Connecticut AppletonCentury 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, DrugIntelligence 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.

# MIP202T: SCALE UP AND TECHNOLOGY TRANSFER

## COURSE OUTCOMES

On completion of this course it is expected that students will be able to understand,CO1: Manage the scale up process in pharmaceutical industry.

CO2: Assist in technology transfer.

CO3: To establish safety guidelines, which prevent industrial hazards.

## How program outcomes are assessed:

| Program outcomes | | level | Proficiency assessed by |
|---|---|---|---|
| PO1: | Possess the skills to use modern pharmaceutical tools, software, equipments to analyze & solve problems. | 3 | Assignments/ Internals/Viva |
| PO2: | Demonstrate an adaptable, flexible and effective approach towards organizational development. | 2 | Assignments/ Internals |
| PO3: | Acquire adequate scientific information regarding basic principles of pharmaceutics including cosmetology and specialized drug delivery systems. | 2 | Assignments/ Internals/ Practicals |
| PO4: | Trained on the practical aspects of formulation development, analysis and quality assurance of various pharmaceutical dosage forms. | 2 | Assignments/ Internals |
| PO5: | Develop the ability to conduct, analyze and interpret data as per the needs of pharmaceutical industries | 2 | Seminars/academic activities |

**Level: 1 – slight (low), Level: 2- Moderate (medium), level: 3- Substantial (high)**

**Course outcomes and program outcomes (CO-PO) mapping:**

| Course outcomes | Program outcomes (PO) | | | | |
|---|---|---|---|---|---|
| | PO1 | PO2 | PO3 | PO4 | PO5 |
| CO1 | 3 | 2 | 1 | 2 | 3 |
| CO2 | 2 | 2 | 3 | 1 | 1 |
| CO3 | 1 | 2 | 2 | 3 | 2 |
| AVG | 2 | 2 | 2 | 2 | 2 |

## COURSE CONTENT

**THEORY** **60 Hrs**

1. Pilot plant design: Basic requirements for design, facility, equipment selection, for tablets, capsules, liquid orals, parentral and semisolid preparations. Scale up: Importance, Technology transfer from R & D to pilot plant to plant scale, process scale up for tablets, capsules, liquid orals, semisolids, 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.

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 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 66

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.

# MIP 203T: PHARMACEUTICAL PRODUCTION TECHNOLOGY

## COURSE OUTCOMES

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

CO1: Handle the scheduled activities in a Pharmaceutical firm.

CO2: Manage the production of large batches of pharmaceutical formulations.

**How program outcomes are assessed:**

| Program outcomes | | level | Proficiency assessed by |
|---|---|---|---|
| PO1: | Possess the skills to use modern pharmaceutical tools, software, equipments to analyze & solve problems. | 3 | Assignments/ Internals/Viva |
| PO2: | Demonstrate an adaptable, flexible and effective approach towards organizational development. | 2 | Assignments/ Internals |
| PO3: | Acquire adequate scientific information regarding basic principles of pharmaceutics including cosmetology and specialized drug delivery systems. | 2 | Assignments/ Internals/ Practicals |
| PO4: | Trained on the practical aspects of formulation development, analysis and quality assurance of various pharmaceutical dosage forms. | 2 | Assignments/ Internals |
| PO5: | Develop the ability to conduct, analyze and interpret data as per the needs of pharmaceutical industries | 2 | Seminars/academic activities |

**Level: 1 – slight (low), Level: 2- Moderate (medium), level: 3- Substantial (high)**

**Course outcomes and program outcomes (CO-PO) mapping:**

| Course outcomes | Program outcomes (PO) | | | | |
|---|---|---|---|---|---|
| | PO1 | PO2 | PO3 | PO4 | PO5 |
| CO1 | 3 | 2 | 3 | 2 | 3 |
| CO2 | 1 | 2 | 1 | 2 | 1 |
| AVG | 2 | 2 | 2 | 2 | 2 |

## COURSE CONTENT

**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. 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. Disperse Systems Production: Production processes, applications of mixers, mills, disperse equipments including fine solids dispersion, problems encountered. Packaging Technology: Types of packaging materials, machinery, labeling, package printing for different dosage forms.12 Hrs
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.

# MIP 204T: ENTREPRENEURSHIP MANAGEMENT

## COURSE OUTCOMES

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

CO1: The Role of enterprise in national and global economy

CO2: Dynamics of motivation and concepts of entrepreneurship

CO3: Demands and challenges of Growth Strategies and Networking

**How program outcomes are assessed:**

| Program outcomes | | level | Proficiency assessed By |
|---|---|---|---|
| PO1 | Possess the skills to use modern pharmaceutical tools, software, equipments to analyze & solve problems. | 3 | Assignments/ Internals/Viva |
| PO2: | Demonstrate an adaptable, flexible and effective approach towards organizational development. | 2 | Assignments/ Internals |
| PO3: | Acquire adequate scientific information regarding basic principles of pharmaceutics including cosmetology and specialized drug delivery systems. | 2 | Assignments/ Internals/ Practicals |
| PO4: | Trained on the practical aspects of formulation development, analysis and quality assurance of various pharmaceutical dosage forms. | 2 | Assignments/ Internals |
| PO5: | Develop the ability to conduct, analyze and interpret data as per the needs of pharmaceutical industries | 2 | Seminars/academic activities |

**Level: 1 – slight (low), Level: 2- Moderate (medium), level: 3- Substantial (high)**

**Course outcomes and program outcomes (CO-PO) mapping:**

| Course outcomes | Program outcomes (PO) | | | | |
|---|---|---|---|---|---|
| | PO1 | PO2 | PO3 | PO4 | PO5 |
| CO1 | 3 | 2 | 2 | 3 | 1 |
| CO2 | 1 | 2 | 3 | 2 | 3 |
| CO3 | 2 | 2 | 1 | 1 | 2 |
| AVG | 2 | 2 | 2 | 2 | 2 |

## COURSE CONTENT

**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 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.

# MIP 205P INDUSTRIAL PHARMACY PRACTICAL - II

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

# ACHARYA NAGARJUNA UNIVERSITY

# UNIVERSITY COLLEGE OF PHARMACEUTICAL SCIENCES

# M.PHARMACY

## SEMESTER-III

**Paper-I: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.

# ACHARYA NAGARJUNA UNIVERSITY

# UNIVERSITY COLLEGE OF PHARMACEUTICAL SCIENCES

# M.PHARMACY

## SEMESTER-IV

- Journal Club
- Research Work
- Final Presentation