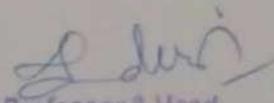


SRI PADMAVATI MAHILA VISVAVIDYALAYAM

INSTITUTE OF PHARMACEUTICAL TECHNOLOGY

COURSE OUTCOMES UG & PG



Professor & Head

Institute of Pharmaceutical Technology
Sri Padmavati Mahila Visvavidyalayam
(WOMEN'S UNIVERSITY)
Tirupati - 517 502

**INSTITUTE OF PHARMACEUTICAL TECHNOLOGY
SRI PADMAVATI MAHILA VISVSVIDYALAYAM**

Accredited by NAAC with 'A' Grade

M. PHARMACY PROGRAM OUTCOMES

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:	Planning Abilities: Demonstrate effective planning abilities including time management, resource management, delegation skills and organizational skills. Develop and implement plans and organize work to meet deadlines.
PO3:	Conduct investigations of complex problems: Use research-based knowledge and research methods including design of experiments, analysis and elucidation of data and synthesis to provide valid conclusions.
PO4:	Problem analysis: Utilize the principles of scientific enquiry, thinking analytically, clearly and critically, while solving problems and making decisions during daily practice. Find, analyze, evaluate and apply information systematically and shall make defensible decisions
PO5:	Modern tool usage: Learn, select, and apply appropriate methods and procedures, resources, and modern pharmacy-related computing tools with an understanding of the limitations
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 wellbeing.
PO7:	Professional Identity: Understand, analyze and communicate the value of their professional roles in society (e.g. health care professionals, promoters of health, educators, managers, employers, employees).
PO8:	Pharmaceutical Ethics: Honor personal values and apply ethical principles in professional and social contexts. Demonstrate behavior that recognizes cultural and personal variability in values, communication and lifestyles. Use ethical frameworks; apply ethical principles while making decisions and take responsibility for the outcomes associated with the decisions.
PO9:	Communication: Communicate effectively with the pharmacy community and with society at large, such as, being able to comprehend and write effective reports, make effective presentations and documentation, and give and receive clear instructions.
PO10:	The Pharmacist and society: Apply reasoning informed by the contextual knowledge to assess societal, health, safety and legal issues and the consequent responsibilities relevant to the professional pharmacy practice.
PO11:	Environment and sustainability: Understand the impact of the professional pharmacy solutions in societal and environmental contexts, and demonstrate the knowledge of, and need for sustainable development
PO12	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.

MPA 101T: MODERN PHARMACEUTICAL ANALYTICAL TECHNIQUES

Credits: T- 4, P-8

Sessional Marks: 25 (T)

L:T: 3:1

University Exams: 75 (T)

Course objectives

SCOPE

- This subject deals with various advanced analytical instrumental techniques for identification, characterization and quantification of drugs. Instruments dealt are NMR, Mass spectrometer, IR, HPLC, GC etc.
- **OBJECTIVES**
- After completion of course student is able to know about chemicals and excipients. The analysis of various drugs in single and combination dosage forms.
- Theoretical and practical skills of the instruments

Course Outcomes:

- The course enables the students to develop theoretical knowledge and practical skills in using various analytical instrumentation techniques like UV-Visible, IR, ¹HNMR and MASS spectroscopy.
- The students will gain expertise in analysis of various drugs in single and combination dosage forms by using various analytical instruments.
- The course imparts wide knowledge in students on various chromatographic techniques, electrophoresis methods, X-ray Crystallography and Immunoassays.
- It provides an overview on analysis of various pharmaceuticals and expands the knowledge in selecting suitable techniques for analysis of drugs and pharmaceuticals.
- By the end of course students will be capable of applying the knowledge in developing new procedures of their own analytical design.

COURSE OUTCOMES

S. No.	Course Outcomes (CO)	Knowledge Level (Blooms Level)
After completing this course the student must demonstrate the knowledge and ability to:		
CO1	The students shall understand and apply knowledge in UV-Visible, IR, spectrofluorimetry, atomic absorption and flame emission spectroscopy.	L2: Understand L3: Apply
CO2	The student shall understand and analyze the instrumentation and applications in NMR spectroscopy.	L2: Understand L3: Apply
CO3	The students will understand and apply the knowledge the instrumentation and applications of Mass spectroscopy.	L2: Understand L3 Apply
CO4	The students impart wide knowledge in students on various chromatographic techniques, electrophoresis methods, X-ray Crystallography and Immunoassays.	L2: Understand L3: Apply

CO5	The students shall understand and apply the knowledge in electrophoresis methods, X-ray Crystallography techniques.	L2: Understand L3: Apply
CO6	The students shall understand and apply the thermal techniques and Immunoassays.	L2: Understand L3: Apply

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

MPA 101T MODERN PHARMCEUTICAL ANALYTICAL TOOLS

	PO1	PO2	PO3	PO4	PO5	PO6	PO7	PO8	PO9	PO10	PO11	PO12
CO1	3	2	2	2	3	2	2	2	2	2	2	2
CO2	3	2	2	2	3	2	2	2	2	2	2	2
CO3	3	3	2	2	3	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	3	2.5	2	2	2	2	2	2

MPA 102T: ADVANCED PHARMACEUTICAL ANALYSIS

Credits: T- 4, P-8

Sessional Marks: 25 (T)

L:T: 3:1

University Exams: 75 (T)

Course objectives

Upon completion of the subject student shall be able to understand and explain

- Various aspects of Impurity, Impurities in new drug products, in residual solvents, Elemental impurities, Impurity profiling and characterization of degradants,
- Stability testing of phytopharmaceuticals and their protocol preparation.
- Biological testing of various vaccines and their principle and procedure.
- 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.

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 the impurities like (inorganic, organic and residual solvents)	L1: Remember L2: Understand L3: Apply L4: Analyse L5: Evaluate
CO2:	Gain appropriate knowledge about analytical skills required for the analysis of impurities in the bulk drugs and various formulations.	L3: Apply L4: Analyse L5: Evaluate
CO3:	Understand the official and non-official methods to analyses the related substance.	L3: Apply L4: Analyse L5: Evaluate
CO4:	Demonstrate stability testing protocols and stability testing of pharmaceuticals.	L3: Apply L4: Analyse L5: Evaluate
CO5:	Understand and explain bioassays and immunoassays,	L3: Apply L4: Analyse

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

How program out comes are assessed:

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

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	2	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	2	Group discussion / Role play
PO11:	Environment And Sustainability	2	Students' seminars
PO12:	Life-Long Learning	3	Assignments/ Internals

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	2	3	3	3	2	3	2	3
CO2	3	2	2	3	2	2	3	2	3	3	3	3
CO3	3	3	3	3	3	3	3	3	3	3	3	3
CO4	3	3	2	3	3	3	3	3	3	3	3	3
CO5	3	3	3	3	3	3	3	3	3	3	2	3
Avg	3	2.8	2.6	3	2.6	2.8	3	2.8	2.8	3	2.6	3

Course Content

Theory 60Hrs

Unit-1.

10Hrs

a. Impurity and stability studies:

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

b. 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

c. Impurities in residual solvents:

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

Unit-2.

10Hrs

Elemental impurities:

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.

Unit-3.

10 Hrs

Impurity profiling and degradant characterization:

Method development, Stability studies and concepts of validation accelerated stability testing & shelf-life calculation, WHO and ICH stability testing guidelines, Stability zones, steps in development, practical considerations. Basics of impurity profiling and degradant characterization with special emphasis. Photo stability testing guidelines, ICH stability guidelines for biological products.

Unit-4.

10Hrs

Stability testing of phytopharmaceuticals:

Regulatory requirements, protocols, HPTLC/HPLC finger printing, interactions and complexity.

Unit-5.

10Hrs

Biological tests and assays of the following:

- a. Adsorbed Tetanus vaccine
- b. Adsorbed Diphtheria vaccine
- c. Human anti haemophilic vaccine
- d. Rabies vaccine
- e. Tetanus Anti toxin
- f. Tetanus Anti serum
- g. Oxytocin
- h. Heparin sodium IP

Unit-6.**10Hrs****Immunoassays (IA):**

Basic principles, Production of antibodies, Separation of bound and unbound drug, Radioimmunoassay, Optical IA, Enzyme IA, Fluoro IA, Luminiscence IA, Quantification and applications of IA.

REFERENCES

1. Vogel's textbook of quantitative chemical analysis - Jeffery J Bassett, J.Mendham, R. C. Denney, 5th edition, ELBS, 1991.
2. Practical Pharmaceutical Chemistry - Beckett and Stenlake, Vol II, 4thEdition, CBS publishers, New Delhi, 1997.
3. Textbook of Pharmaceutical Analysis - K A Connors, 3rd Edition, JohnWiley & Sons, 1982.
4. Pharmaceutical Analysis - Higuchi, Brochmman and Hassen, 2nd Edition,Wiley – Inter science Publication, 1961.
5. Quantitative Analysis of Drugs in Pharmaceutical formulation – P D Sethi,3rd Edition, CBS Publishers New Delhi, 1997.
6. Pharmaceutical Analysis- Modern methods - J W Munson – Part B,Volume 11, Marcel Dekker Series.
7. The Quantitative analysis of Drugs - D C Carratt, 3rd edition, CBSPublishers, NewDelhi, 1964.
8. Indian Pharmacopoeia Vol I , II & III 2007, 2010, 2014.
9. Methods of sampling and microbiological examination of water, firstrevision, BIS
10. Practical HPLC method development – Snyder, Kirkland, Glajch, 2ndedition, John Wiley & Sons.
11. Analytical Profiles of drug substances – Klaus Florey, Volume 1 – 20,Elsevier, 2005
12. Analytical Profiles of drug substances and Excipients – Harry G Brittan,Volume 21 – 30, Elsevier, 2005.
13. The analysis of drugs in biological fluids - Joseph Chamberlain, 2ndedition, CRC press, London.
14. ICH Guidelines for impurity profiles and stability studies.

MPA 103T: PHARMACEUTICAL VALIDATION

Credits: T- 4, P-8

Sessional Marks: 25 (T)

L:T: 3:1

University Exams: 75 (T)

Course objectives

Upon completion of the subject student shall be able to

- Understand about validation, types, methodology and how it can be applied to industry and thus to improve the quality of the products.
- Explain the aspect of validation.
- Carryout validation of manufacturing processes.
- Apply the knowledge of validation to instruments and equipment.
- 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 L4: Analyse L5: Evaluate
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

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	2	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	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	2	3	2	2	3	3
CO2	3	3	3	3	3	3	3	3	3	3	2	3
CO3	2	3	3	3	3	3	3	2	2	3	3	3
CO4	3	3	3	3	3	3	3	3	3	3	3	3
CO5	2	3	3	2	3	3	3	2	3	3	3	3
Avg	2.6	3	3	2.8	3	3	2.8	2.6	2.6	2.8	2.8	3

Course Content

Theory 60Hrs

Unit-1. Introduction:

12Hrs

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 Manufacturing Equipment, Qualification of Analytical Instruments and Laboratory equipment.

Unit-2. Qualification of analytical instruments:

12Hrs

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

Unit-3.

12 Hrs

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

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

Unit-4.

12Hrs

Analytical method validation: 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 GAMP5.

Unit-5.

12Hrs

General Principles of Intellectual Property: Concepts of Intellectual Property (IP), Intellectual Property Protection (IPP), Intellectual Property Rights (IPR); Economic importance, mechanism for protection of Intellectual Property –patents, Copyright, Trademark; Factors affecting choice of IP protection; Penalties for violation; Role of IP in pharmaceutical industry; Filing a patent application; patent application forms and guidelines. Types of patent applications-provisional and non-provisional, 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. 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. Series, Vol. 129, 3rd Ed., Marcel Dekker Inc., N.Y.
2. The Theory & Practice of Industrial Pharmacy, 3rd edition, Leon Lachman, Herbert A. Lieberman, Joseph. L. Karig, Varghese Publishing House, Bombay.
3. Validation Master plan by Terveeks or Deeks, Davis Harwood International publishing.
4. Validation of Aseptic Pharmaceutical Processes, 2nd Edition, by Carleton & Agalloco, (Marcel Dekker).
5. Michael Levin, Pharmaceutical Process Scale-Up, Drugs and Pharm. Sci. Series, Vol.157, 2nd Ed., Marcel Dekker Inc., N.Y.
6. Validation Standard Operating Procedures: A Step-by-Step Guide for Achieving Compliance in the Pharmaceutical, Medical Device, and Biotech Industries, Syed Imtiaz Haider
7. Pharmaceutical Equipment Validation: The Ultimate Qualification Handbook, Phillip A. Cloud, Interpharm Press
8. Validation of Pharmaceutical Processes: Sterile Products, Frederick J. Carlton (Ed.) and James Agalloco (Ed.), Marcel Dekker, 2nd Ed.
9. Analytical Method validation and Instrument Performance Verification by Churg Chan, Heiman Lam, Y.C. Lee, Yue. Zhang, Wiley Inter Science.

MPA 104T: FOOD ANALYSIS

Credits: T- 4, P-8

Sessional Marks: 25 (T)

L:T:- 3:1

University Exams: 75 (T)

Course objectives

- 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		
CO1:	Apply valid sampling techniques and appropriate analytical techniques to food materials having widely diverse properties and volumes. Analyse, interpret and report on results obtained in a scientific format.	L1: Remember L2: Understand L3: Apply L4: Analyse L5: Evaluate
CO2:	Compare advanced and conventional techniques and instruments to analyse chemical and physical properties of foods and apply a range of chemical analyses of food components.	L3: Apply L4: Analyse L5: Evaluate
CO3:	Understand various analytical techniques in the determination of carbohydrates, proteins, lipids and Food additives	L3: Apply L4: Analyse L5: Evaluate
CO4:	Understand various analytical techniques in the determination of Pesticides in food, milk and milk products and adulterants, also the fermentation products like beer etc.	L3: Apply L4: Analyse L5: Evaluate
CO5:	Understand Legislation regulations of food products with special emphasis on BIS, Agmark, FDA and US-FDA.	L3: Apply L4: Analyse

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	2	Assignments/ Internals/ Practicals
PO4:	Problem Analysis	3	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	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	2	3	3	3	2	3	2	3
CO2	3	3	2	3	3	2	3	2	3	3	3	3
CO3	3	3	3	3	3	3	3	3	3	3	3	3
CO4	3	3	2	3	3	3	3	3	3	3	3	3
CO5	3	3	3	3	3	3	3	3	3	3	3	3
Avg	3	3	2.6	3	2.8	2.8	3	2.8	2.8	3	2.8	3

Course Content

Theory 60Hrs

Unit-1.

12Hrs

1. a) Carbohydrates: classification and properties of food carbohydrates, General methods of analysis of food carbohydrates, Changes in food carbohydrates during processing, Digestion, absorption and metabolism of carbohydrates, Dietary fibre, Crude fibre and application of food carbohydrates

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

Unit-2.

12 Hrs

Lipids: Classification, general methods of analysis, refining of fats and oils; hydrogenation of vegetable oils, Determination of adulteration in fats and oils, Various methods used for measurement of spoilage of fats and fatty foods.

Vitamins: classification of vitamins, methods of analysis of vitamins, Principles of microbial assay of vitamins of B-series (B2, B6 & B12).

Unit-3.

12 Hrs

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

b. Pigments and synthetic dyes: Natural pigments, their occurrence and characteristic properties, permitted synthetic dyes, Non-permitted synthetic dyes used by industries, Method of detection of natural, permitted and non-permitted dyes.

Unit-4.

12 Hrs

General Analytical methods for milk, milk constituents and milk products like ice cream, milk powder, butter, margarine, cheese including adulterants and contaminants of milk. Analysis of fermentation products like wine, spirits, beer and vinegar.

Unit-5.

12 Hrs

Pesticide analysis: Effects of pest and insects on various food, use of pesticides in agriculture, pesticide cycle, organophosphorus and organochlorine pesticides analysis, determination of pesticide residues in grain, fruits, vegetables, milk and milk products. 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 201T: ADVANCED INSTRUMENTAL ANALYSIS

Credits: T- 4, P-8

Sessional Marks: 25 (T)

L:T: 3:1

University Exams: 75 (T)

Course objectives

Upon completion of the subject student shall be able to understand and explain

- Various hyphenated analytical instrumental techniques for identification, characterization and quantification of drugs.
- 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:	New developments in HPLC and its practical aspects.	L1: Remember L2: Understand L3: Apply L4: Analyse L5: Evaluate
CO2:	Theoretical and practical aspects and troubleshooting techniques for HPLC and GC techniques.	L3: Apply L4: Analyse L5: Evaluate
CO3:	Knowledge and skills in advanced instrumentation techniques for drug analysis.	L3: Apply L4: Analyse L5: Evaluate
CO4:	Theoretical aspects of hyphenated analytical techniques.	L3: Apply L4: Analyse L5: Evaluate
CO5:	Critical analysis of analytical problem and selection of appropriate analytical tool for the quantification of chemicals and excipients.	L3: Apply L4: Analyse

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

How program out comes are assessed:

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

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	2	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	2	Group discussion / Role play
PO11:	Environment And Sustainability	2	Students' seminars
PO12	Life-Long Learning	3	Assignments/ Internals

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

Unit-1.

12 Hrs

HPLC: 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.

Unit-2.

12 Hrs

Biochromatography:

a. General principles, stationary phases and mobile phases of Size exclusion chromatography, ion exchange chromatography, ion pair chromatography.

b. Chromatography: Principles, instrumentation and applications of the following:

i. GC-MS ii. GC-AAS iii. LC-MS iv. LC-FTIR v. Flash chromatography.

Unit-3.

12 Hrs

Super critical fluid chromatography: Principles, 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.

Unit-4.

12 Hrs

Mass spectrometry: Difference types of ionization like APCI, ESI, APPI Analyzers of Quadrupole and Time of Flight. Fragmentation of important functional groups like alcohol, amines, carbonyl groups and alkanes, Meta stable ions, Mc Lafferty rearrangement, Ring rule, Isotopic peaks, Interpretation of organic compounds. MS/MS systems (Tandem: QqQ, TOF-TOF;Q-IT, Q-TOF, LTQ-FT, LTQ-Orbitrap.

Unit-5.

12 Hrs

NMR spectroscopy: Nuclear magnetic double resonance, Brief outline of principles of FT-NMR with reference to ^{13}C NMR: Spin spin and spin lattice relaxation phenomenon. 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 - Douglas 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

Credits: T- 4, P-8

Sessional Marks: 25 (T)

L:T:- 3:1

University Exams: 75 (T)

Course objectives

Upon completion of the subject student shall be able to understand and explain

- The importance of analysis of drugs in biological matrices.
- Extraction of drugs from biological samples.
- Separation of drugs from biological samples using different techniques.
- Guidelines for BA/BE studies.

Course outcomes

S.No	Course Outcomes	Knowledge level (BLOOMS Level)
After successful completion of the course student shall be able to understand and explain		
CO1:	Quantification of analyte present in the biological fluids and analyte enrichment techniques as well the instrumentation technique.	L1: Remember L2: Understand L3: Apply L4: Analyse
CO2:	Invitro, In-situ and In-vivo methods for bioavailability.	L3: Apply L4: Analyse
CO3:	Importance and applications of pharmacokinetic and toxicokinetic studies.	L3: Apply L4: Analyse
CO4:	Various types of cell cultures and their applications.	L3: Apply L4: Analyse
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

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	3	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	3	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	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	2	2	2	3	3	3	3	3
CO2	3	2	2	3	3	3	3	3	3	3	3	2
CO3	3	3	3	2	3	3	3	2	3	3	3	3
CO4	3	3	3	3	3	3	3	2	3	3	2	3
CO5	3	2	3	3	3	2	2	3	3	3	3	3
Avg	3	2.6	2.8	2.8	2.6	2.6	2.6	2.6	3	3	2.8	2.6

Course Content

Theory 60Hrs

Unit-1. **12 Hrs**

Extraction of drugs and metabolites from biological matrices:

General need, principle and procedure involved in the Bioanalytical methods such as Protein precipitation, Liquid - Liquid extraction and Solid phase extraction and other novel sample preparation approaches. Bioanalytical method validation: USFDA and EMEA guidelines.

Unit-2. **12 Hrs**

Biopharmaceutical Consideration:

Introduction, Biopharmaceutical Factors Affecting Drug Bioavailability, In Vitro: Dissolution and Drug Release Testing, Alternative Methods of Dissolution Testing Transport models, Biopharmaceutics Classification System. Solubility: Experimental methods. Permeability: Invitro, in-situ and In-vivo methods.

Unit-3. **12 Hrs**

Pharmacokinetics and Toxicokinetics:

a. 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
b. Toxicokinetics-Toxicokinetic evaluation in preclinical studies, Importance and applications of toxicokinetic studies. LC-MS in bioactivity screening and proteomics.

Unit-4. **12 Hrs**

Cell culture techniques:

Basic equipment 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 applications. Principles and applications of cell viability assays (MTT assays), Principles and applications of flow cytometry.

Unit-5. **12 Hrs**

Metabolite identification:

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, Cross over Study Designs, Generic Biologics (Biosimilar Drug Products), Clinical Significance of Bioequivalence Studies.

REFERENCES

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

MPA 203T: QUALITY CONTROL AND QUALITY ASSURANCE

Credits: T- 4

Sessional Marks: 25 (T)

L:T -

University Exams: 75 (T)

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

OBJECTIVES

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

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

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 L2: Understand L3: Apply L4: Analyse L5: Evaluate
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 L4: Analyse L5: Evaluate
CO3:	Students shall be able to understand the control of contamination and Good Warehousing Practice.	L3: Apply L4: Analyse 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).	L2: Understand L3: Apply L4: Analyse 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.	L2: Understand 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	2	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	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	2	3	3	3	3	2	3	2	3	3	3	3
CO2	3	2	2	3	3	3	3	3	3	2	3	3
CO3	3	2	3	3	3	3	3	3	3	3	3	3
CO4	2	3	3	3	3	3	3	3	3	3	3	3
CO5	3	3	3	3	3	3	3	3	3	3	3	3
Avg	2.6	2.8	2.8	3	3	2.8	3	2.8	3	2.8	3	3

MPA204T: HERBAL AND COSMETIC ANALYSIS

Credits: T- 4

Sessional Marks: 25 (T)

L:T- 3:1

University Exams: 75 (T)

Course objectives

- This course deals with the Regulatory requirements, herbal drug interaction with monographs. Performance evaluation of cosmetic products is included for the better understanding of the equipments used in cosmetic industries for the purpose.
- Upon completion of the course student shall be able 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 successful completion of the course student shall be able to explain		
CO1:	Student shall be able to understand the determination of herbal remedies	L1:Remember L2:Understand L3: Apply
CO2:	Student shall be able to understand various herbal regulations	L3: Apply L4: Analyse L5: Evaluate
CO3:	Student shall be able to understand various analytical techniques in the determination of herbal products	L3: Apply L4: Analyse L5: Evaluate
CO4:	Student shall be able to understand the herbal monographs	L3: Apply L4: Analyse L5: Evaluate
CO5:	Student shall be able to understand various herbal drug interactions	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	2	Assignments/ Internals/Viva
PO2:	Planning Abilities	2	Assignments/ Internals
PO3:	Conduct Investigations of Complex Problems	2	Assignments/ Internals/ Practicals
PO4:	Problem Analysis	1	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	1	Personality development seminars
PO9:	Communication	2	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	1	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	2	1	3	2	1	1	2	1	1	2	1
CO2	2	1	2	2	1	1	2	1	2	2	1	2
CO3	1	2	2	1	2	1	3	2	2	2	1	1
CO4	1	1	1	2	2	2	2	1	1	1	2	2
CO5	2	1	2	1	2	2	2	2	2	3	1	2
Avg	1.7	1.7	1.6	1.9	2	1.8	2.1	1.7	2.1	1.9	1.8	2.1

Course Content:

- 1. Herbal remedies-** Toxicity and Regulations: Herbals vs Conventional drugs, Efficacy of herbal medicine products, Validation of Herbal Therapies, Pharmacodynamic and Pharmacokinetic issues. Herbal drug standardization: WHO and AYUSH guidelines. **12 Hrs**
- 2. Adulteration and Deterioration:** Introduction, types of adulteration/substitution of herbal drugs, Causes and Measure of adulteration, Sampling Procedures, Determination of Foreign Matter, DNA Finger printing techniques in identification of drugs of natural origin, heavy metals, pesticide residues, phototoxin and microbial contamination in herbal formulations.
Regulatory requirements for setting herbal drug industry: Global marketing management, Indian and international patent law as applicable herbal drugs and natural products and its protocol. **12 Hrs**
- 3. Testing of natural products and drugs:** Effect of herbal medicine on clinical laboratory testing, Adulterant Screening using modern analytical instruments, Regulation and dispensing of herbal drugs, Stability testing of natural products, protocol.
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:** WHO and AYUSH guidelines for safety monitoring of natural medicine, Spontaneous reporting schemes for bio drug adverse reactions, bio drug-drug and bio drug-food interactions with suitable examples. Challenges in monitoring the safety of herbal medicines. **12 Hrs**
- 5. Evaluation of cosmetic products:** Determination of acid value, ester value, saponification value, iodine value, peroxide value, rancidity, moisture, ash, volatile matter, heavy metals, fineness of powder, density, viscosity of cosmetic raw materials and finished products. Study of quality of raw materials and general methods of analysis of raw material used in cosmetic manufacture as per BIS. 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

MPH 102T DRUG DELIVERY SYSTEMS

Credits: T- 4, P-2

Sessional Marks: 25 (T), 15(P)

L: T: P- 3:1:4

University Exams: 75 (T), 35(P)

Course objectives

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

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

Course outcomes

S.No	Course Outcomes	Knowledge level (BLOOMS Level)
After successful completion of the course student shall be able to explain		
CO1:	Basic concepts, advantages/ disadvantages, factors influencing, Physicochemical & biological approaches for SR/CR formulation, Mechanism of Drug Delivery from SR/CR formulation.	L1:Remember L2:Understand L3: Apply
CO2:	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 mucoadhesion, advantages and disadvantages, mechanism of drug permeation, Methods of formulation and its evaluations.	L3: Apply L4: Analyse L5: Evaluate
CO3:	a. Polymers: introduction, definition, classification, Molecular weight averages, Molecular weight determination from viscosity, Polymers as thickening agent, Preparation of polymer solution, Polymers in the solid state, Fabrication technology, and applications.	L3: Apply L4: Analyse L5: Evaluate
CO4:	Ocular Drug Delivery Systems: Barriers of drug permeation, Methods to overcome barriers. b) Transdermal Drug Delivery Systems: Structure of skin and barriers, Penetration enhancers, Formulation and evaluation of Transdermal Drug Delivery Systems.	L3: Apply L4: Analyse L5: Evaluate
CO5:	Barriers for protein delivery. Formulation and Evaluation of Delivery systems of proteins and other macromolecules. Vaccine delivery systems: Vaccines, uptake of antigens, single shot vaccines, mucosal and	L3: Apply L4: Analyse

transdermal delivery of vaccines.	L5: Evaluate
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BLOOMS Taxonomy- L1: Remember, L2: Understand, L3: Apply, L4: Analyse, L5: Evaluate,

L6: Create

How program out comes are assessed:

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

Program Outcome		Level	Proficiency assessed by
PO1:	Pharmacy Knowledge	2	Assignments/ Internals/Viva
PO2:	Planning Abilities	1	Assignments/ Internals
PO3:	Conduct Investigations of Complex Problems	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

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

	PO1	PO2	PO3	PO4	PO5	PO6	PO7	PO8	PO9	PO10	PO11	PO12
CO1	2	1	1	2	2	2	2	2	2	1	2	3
CO2	2	2	2	2	2	2	1	2	2	2	2	2
CO3	1	2	2	2	2	2	2	2	2	2	2	3
CO4	2	2	2	2	2	2	2	1	2	2	2	2
CO5	2	2	2	2	2	2	2	2	2	2	2	2
Avg	1.8	1.8	1.8	2	2	2	1.8	1.8	2	1.8	2	2.4

MPH 102T DRUG DELIVERY SYSTEMS

Course Content:

THEORY 60Hrs

THEORY 60Hrs

1. a. 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.
- b. 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. 12Hrs

2. a) Gastro-Retentive Drug Delivery Systems: Principle, concepts, advantages and disadvantages, Modulation of GI transit time approaches to extend GI transit. 5Hrs.
- b) Buccal Drug Delivery Systems: Principle of muco adhesion, advantages and disadvantages, mechanism of drug permeation, Methods of formulation and its evaluations. 5Hrs

3. a. Polymers: introduction, definition, classification, Molecular weight averages, Molecular

weight determination from viscosity, Polymers as thickening agent, Preparation of polymer solution, Polymers in the solid state, Fabrication technology, and applications.

b. Dosage Form for Personalized Medicine: Introduction, Definition, Pharmacogenetics, Categories of Patients for Personalized Medicines, Customized drug delivery systems, A brief note on Bio electronic Medicines, 3D printing of pharmaceuticals, Tele pharmacy.

10Hrs

4. a) Ocular Drug Delivery Systems: Barriers of drug permeation, Methods to overcome barriers. 5Hrs

b) Transdermal Drug Delivery Systems: Structure of skin and barriers, Penetration enhancers, Formulation and evaluation of Transdermal Drug Delivery Systems. 5Hrs

5. Protein and Peptide Delivery: Barriers for protein delivery. Formulation and Evaluation of Delivery systems of proteins and other macromolecules. Vaccine delivery systems: Vaccines, uptake of antigens, single shot vaccines, mucosal and transdermal delivery of vaccines. 12Hrs

6. Chronotherapeutics Drug Delivery Systems: Introduction, classification, physiology of circadian rhythmicity, circadian rhythm changes in cardiac and liver disease conditions. Chronopharmacokinetics of anti hypertensives and anti asthmatics. 6hrs

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 Wiley Interscience Publication, John Wiley and Sons, Inc, New York! Chichester/Weinheim

MPH103T: MODERN PHARMACEUTICS

Credits: T- 4, P-2

Sessional Marks: 25 (T), 15(P)

L: T: P- 3:1:4

University Exams: 75 (T), 35(P)

Course objectives

Scope:

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

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

Course outcomes

S.No	Course Outcomes	Knowledge level (BLOOMS Level)
After successful completion of the course student shall be able to explain		
CO1:	Preformulation concepts: Drug Excipient interactions - different methods, kinetics of stability, Stability testing.	L1:Remember L2:Understand L3: Apply
CO2:	Optimization techniques in pharmaceutical formulation and processing. Statistical design, Response surface method, Contour designs, Factorial designs and application in formulation development.	L3: Apply L4: Analyse L5: Evaluate
CO3:	Introduction to Pharmaceutical Validation, Scope & merits of Validation, Types of Validation, Government regulation, Manufacturing process Model, URS, DQ, IQ, OQ & P.Q. of facilities. Validation and calibration of Master plan, ICH & WHO guidelines	L3: Apply L4: Analyse L5: Evaluate
CO4:	Regulatory approval process for medical devices and IVDs in India, US, Canada, EU, Japan and ASEAN clinical evaluation and investigation of medical devices and IVDs	L3: Apply L4: Analyse L5: Evaluate
CO5:	Study of Diffusion parameters, Dissolution parameters and Pharmacokinetic parameters, Heckel plots, Similarity factors – f2 and f1, Higuchi and Peppas plot.	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	2	Assignments/ Internals/Viva
PO2:	Planning Abilities	1	Assignments/ Internals
PO3:	Conduct Investigations of Complex Problems	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	1	1	2	2	2	2	2	2	1	2	2
CO2	2	2	2	2	2	2	1	2	2	2	2	2
CO3	1	2	2	2	2	2	2	2	2	2	2	2
CO4	2	2	2	2	2	2	2	1	2	2	2	2
CO5	2	2	2	2	2	2	2	2	2	2	2	2
Avg	1.8	1.8	1.8	2	2	2	1.8	1.8	2	1.8	2	2

MODERN PHARMACEUTICS - (MPH 103T)

Course Content:

THEORY 60Hrs

1. a) Preformulation Concepts – Drug Excipient interactions - different methods, kinetics of stability, Stability testing.
b) Theories of dispersion: Emulsion and Suspension, SMEDDS. Its formulation and evaluation.
c) Preparation and stability of Large and small volume parenterals – physiological and formulation consideration, Manufacturing and evaluation. 12Hrs
2. Optimization techniques in Pharmaceutical Formulation: Concept and parameters of optimization, Optimization techniques in pharmaceutical formulation and processing. Statistical design, Response surface method, Contour designs, Factorial designs and application in formulation development. 12Hrs
3. Validation: Introduction to Pharmaceutical Validation, Scope & merits of Validation, Types of Validation, Government regulation, Manufacturing process Model, URS, DQ, IQ, OQ & P.Q. of facilities. Validation and calibration of Master plan, ICH & WHO guidelines for calibration and validation of equipment, Process Validation of Tablets, Capsules, Parenterals. 12Hrs
4. a) cGMP & Industrial Management: Objectives and policies of current good manufacturing practices, layout of buildings, services, equipment and their maintenance.
b) 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. 12Hrs
5. a) Compression and compaction: Physics of tablet compression, compression and consolidation, effect of friction, distribution of forces, compaction profiles.
b) Study of consolidation parameters; Diffusion parameters, Dissolution parameters and Pharmacokinetic parameters, Heckel plots, Similarity factors – f_2 and f_1 , Higuchi and Peppas plot.

REFERENCES:

1. Theory and Practice of Industrial Pharmacy By Lachmann and Libermann
2. Pharmaceutical dosage forms: Tablets Vol. 1-3 by Leon Lachmann.
3. Pharmaceutical Dosage forms: Disperse systems, Vol, 1-2; By Leon Lachmann.
4. Pharmaceutical Dosage forms: Parenteral medications Vol. 1-2; By Leon Lachmann.
5. Modern Pharmaceutics; By Gillbert and S. Banker.
6. Remington's Pharmaceutical Sciences.
7. Advances in Pharmaceutical Sciences Vol. 1-5; By H.S. Bean & A.H. Beckett.
8. Physical Pharmacy; By Alfred martin
9. Bentley's Textbook of Pharmaceutics – by Rawlins.
10. Good manufacturing practices for Pharmaceuticals: A plan for total quality control, Second edition; By Sidney H. Willig.

MPH 104T: REGULATORY AFFAIRS

Credits: T- 4

Sessional Marks: 25 (T)

L:T -

University Exams: 75 (T)

Course objectives

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

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

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 innovator and generic drugs and drug development process.	L1: Remember L2: Understand L3: Apply L4: Analyse L5: Evaluate
CO2:	Gain imperative knowledge on the Regulatory guidance's and guidelines for filing applications and approval process, preparation of dossiers and their submission to regulatory agencies in different countries.	L3: Apply L4: Analyse L5: Evaluate
CO3:	Expands the knowledge on post approval regulatory requirements for actives and drug products	L3: Apply L4: Analyse L5: Evaluate
CO4:	Gain idea on global documents in CTD/ eCTD formats	L3: Apply L4: Analyse L5: Evaluate
CO5:	Develop an understanding on clinical trials requirements for approvals to conduct clinical trials, importance of pharmacovigilence and process of monitoring in clinical trials.	L3: Apply L4: Analyse

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

How program out comes are assessed:**LEVEL: 1- Slight (Low), 2- Moderate(Medium), 3- Substantial(High)**

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	2	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	2	Group discussion / Role play
PO11:	Environment And Sustainability	2	Students' seminars
PO12:	Life-Long Learning	3	Assignments/ Internals

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	3	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	3	2.8	2.6	3

Course Content

Theory 60Hrs

1. Documentation in Pharmaceutical industry: Master formula record, DMF (Drug Master File), distribution records. Generic drugs product development: Introduction, HatchWaxman act and amendments, CFR (CODE OF FEDERAL REGULATION), in-vitro drug product performance. 12Hrs
2. Regulatory requirement for product approval: API, biologics, novel therapies, obtaining NDA, ANDA for generic drugs, ways and means of US registration for foreign drugs. 12Hrs
3. CMC, post approval regulatory affairs: Regulation for combination products and medical devices. CTD and ECTD format, industry and FDA liaison. ICH - Guidelines of ICHQ, S E, M Regulatory requirements of EU, MHRA, TGA and ROW countries. 12Hrs
4. Non clinical drug development: Global submission of IND, NDA, ANDA. Investigation of medicinal products dossier, (IMPD) and investigator brochure (IB). 12Hrs
5. Clinical trials: Developing clinical trial protocols. Institutional review board/ independent ethics committee Formulation and working procedures, informed Consent process and procedures. HIPAA-new, requirement to clinical study process, pharmaco vigilance ,safety monitoring in clinical trials. 12Hrs

REFERENCES

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

MPH 201T MOLECULAR PHARMACEUTICS

Credits: T- 4, P-2

Sessional Marks: 25 (T), 15(P)

L: T: P- 3:1:4

University Exams: 75 (T), 35(P)

Course objectives

Scope:

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

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

Course outcomes

S.No	Course Outcomes	Knowledge level (BLOOMS Level)
After successful completion of the course student shall be able to explain		
CO1:	Concepts, Events and biological process involved in drug targeting. Tumor targeting and Brain targeting	L1:Remember L2:Understand L3: Apply
CO2:	Targeting Methods: Introduction, types, preparation evaluation. Nano Particles & Liposomes, Niosomes.	L3: Apply L4: Analyse L5: Evaluate
CO3:	Types, preparation and evaluation ,and applications of Monoclonal Antibodies: Aquasomes, Phytosomes, Electrosomes.	L3: Apply L4: Analyse L5: Evaluate
CO4:	Types , Preparation and Evaluation of Aerosols, propellents, Containers, Types, preparation and evaluation. b) Intra Nasal Route Delivery systems; Types, preparation and evaluation.	L3: Apply L4: Analyse L5: Evaluate
CO5:	Gene therapy, introduction (ex-vivo & in-vivo gene therapy). Potential	L3: Apply

	target diseases for gene therapy (inherited disorder and cancer). Gene expression systems (viral and nonviral gene transfer).	L4: Analyse L5: Evaluate
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BLOOMS Taxonomy- L1: Remember, L2: Understand, L3: Apply, L4: Analyse, L5: Evaluate,

L6: Create

How program out comes are assessed:

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

Program Outcome		Level	Proficiency assessed by
PO1:	Pharmacy Knowledge	2	Assignments/ Internals/Viva
PO2:	Planning Abilities	1	Assignments/ Internals
PO3:	Conduct Investigations of Complex Problems	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

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

	PO1	PO2	PO3	PO4	PO5	PO6	PO7	PO8	PO9	PO10	PO11	PO12
CO1	2	1	1	2	2	2	2	2	2	1	2	3
CO2	2	2	2	2	2	2	1	2	2	2	2	2
CO3	2	2	2	2	2	2	2	2	2	2	2	3
CO4	2	2	2	2	2	2	2	1	2	2	2	2
CO5	2	2	2	2	2	2	2	2	2	2	2	2
Avg	2	1.8	1.8	2	2	2	1.8	1.8	2	1.8	2	2.4

MPH 201T MOLECULAR PHARMACEUTICS

Course Content:

THEORY 60Hrs

1. Targeted Drug Delivery Systems: Concepts, Events and biological process involved in

drug targeting. Tumor targeting and Brain targeting 12Hrs

2. Targeting Methods: Introduction , types, preparation evaluation. Nano Particles &

Liposomes, Niosomes. 12Hrs

3. Micro Capsules / Micro Spheres: Types, preparation and evaluation ,and applications of

Monoclonal Antibodies : Aquasomes, Phytosomes, Electrosomes. 12Hrs

4. a) Pulmonary Drug Delivery Systems : Types , Preparation and Evaluation of Aerosols,

propellents, Containers, Types, preparation and evaluation.

b) Intra Nasal Route Delivery systems; Types, preparation and evaluation. 12Hrs

5. Nucleic acid based therapeutic delivery system: Gene therapy, introduction (ex-vivo & in-vivo gene therapy). Potential target diseases for gene therapy (inherited disorder and cancer). Gene expression systems (viral and nonviral gene transfer). Liposomal gene delivery systems and its Biodistribution and Pharmacokinetics. Knowledge of therapeutic antisense molecules and aptamers as drugs of future.

References:

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

MPH 202 T: ADVANCED BIOPHARMACEUTICS & PHARMACOKINETICS

Credits: T- 4, P-2

Sessional Marks: 25 (T), 15(P)

L: T: P- 3:1:4

University Exams: 75 (T), 35(P)

Course objectives

Scope:

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

The basic concepts in Biopharmaceutics and Pharmacokinetics.

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

Course outcomes

S.No	Course Outcomes	Knowledge level (BLOOMS Level)
After successful completion of the course student shall be able to explain		
CO1:	Concepts, Events and biological process involved in drug targeting. Tumor targeting and Brain targeting	L1:Remember L2:Understand L3: Apply
CO2:	Targeting Methods: Introduction, types, preparation evaluation. Nano Particles & Liposomes, Niosomes.	L3: Apply L4: Analyse L5: Evaluate
CO3:	Types, preparation and evaluation ,and applications of Monoclonal Antibodies: Aquasomes, Phytosomes, Electrosomes.	L3: Apply L4: Analyse L5: Evaluate

CO4:	Types , Preparation and Evaluation of Aerosols, propellents, Containers, Types, preparation and evaluation. b) Intra Nasal Route Delivery systems; Types, preparation and evaluation.	L3: Apply L4: Analyse L5: Evaluate
CO5:	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).	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:

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

Program Outcome		Level	Proficiency assessed by
PO1:	Pharmacy Knowledge	2	Assignments/ Internals/Viva
PO2:	Planning Abilities	1	Assignments/ Internals
PO3:	Conduct Investigations of Complex Problems	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

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

	PO1	PO2	PO3	PO4	PO5	PO6	PO7	PO8	PO9	PO10	PO11	PO12
CO1	2	1	1	2	2	2	2	2	2	1	2	3
CO2	2	1	2	2	2	2	1	2	2	2	2	2
CO3	2	2	2	2	2	2	2	2	2	2	2	3
CO4	2	2	2	2	2	2	2	1	2	2	2	2
CO5	2	2	2	2	2	2	2	2	2	2	2	2
Avg	2	1.6	1.8	2	2	2	1.8	1.8	2	1.8	2	2.4

MPH 202 T: ADVANCED BIOPHARMACEUTICS & PHARMACOKINETICS

Course Content:

THEORY 60Hrs

1. Drug Absorption from the Gastrointestinal Tract:

Gastrointestinal tract, Mechanism of drug absorption, Factors affecting drug absorption, Formulation and Physicochemical factors. pH-partition theory of drug absorption.

Dissolution rate, Dissolution process, Noyes-Whitney equation, Factors affecting the dissolution rate, Formulation and processing factors.

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 , Correlation of invivo data with in vitro dissolution data.

Transport model: Permeability, Solubility, Charge State, Properties of the Gastrointestinal Tract (GIT), pH Microclimate, Intracellular pH Environment, Tight-Junction Complex, Oral Absorption enhancers.

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, dissolution profile comparisons, drug product stability, considerations in the design of a drug product. 12Hrs

3. Pharmacokinetics: Basic considerations, pharmacokinetic models, compartment modeling: one compartment model- IV bolus, IV infusion, extra-vascular; two compartment - model in brief, Non-linear pharmacokinetics: causes of non-linearity, Michaelis – Menten equation, estimation of K_m and V_{max} . Drug interactions: introduction, the effect of protein binding interactions, the effect of tissue-binding interactions, cytochrome p450-based drug interactions, drug interactions linked to transporters. Drug interactions involving digoxin, warfarin, theophylline. 12Hrs

4. a) 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 of bioequivalence example, study submission and drug review process. Biopharmaceutics classification system and methods.

b) 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, Bio waivers 12Hrs

5. a) Application of Pharmacokinetics: Modified-Release Drug Products, Targeted Drug Delivery Systems and Biotechnological Products. Introduction to Pharmacokinetics and pharmacodynamic drug interactions. Pharmacokinetics and pharmacodynamics of biotechnology drugs. 09Hrs

b) Chrono Therapeutic Drug Delivery System: Introduction, classification, physiology of circadian rhythmicity, circadian rhythm changes in cardiac and liver diseased conditions. Chronopharmacokinetics of anti hypertensives and anti asthmatics. 03Hrs

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. aiswal., VallabPrakashan, Pitampura, Delhi
3. Applied Biopharmaceutics and Pharmacokinetics by Shargel. Land YuABC, 2nd edition, Connecticut Appleton Century Crofts, 1985
4. Textbook of Biopharmaceutics and Pharmacokinetics, Dr. Shobha Rani R. Hiremath, Prism Book

MPH 204T: Cosmetic and cosmeceuticals

Credits: T- 4, P-2

Sessional Marks: 25 (T), 15(P)

L: T: P- 3:1:4

University Exams: 75 (T), 35(P)

Course objectives

- Scope: This course is intended to provide a comprehensive survey of ingredients fundamental to the cosmetic industry. The course will emphasize current trends in the selection of cosmetic ingredients. The chemistry and technology of cosmetic raw materials will be related to their behavioral properties as utilized in the construction of stable functional systems. In this way, it is intended to generate a better understanding of the contributions of ingredients to the performance of finished product formulations.

Course outcomes

S.No	Course Outcomes	Knowledge level (BLOOMS Level)
After successful completion of the course student shall be able to explain		
CO1 :	Classify and define Cosmetics and Cosmeceuticals as per Indian and EU regulations Describe the role of cosmetic excipients and building blocks in the formulation of cosmetics	L1:Remember L2:Understand L3: Apply
CO2 :	Explain the structure and function of the skin, hair, teeth and gums, bleeding gums, mouth odour, teeth discoloration and sensitive teeth.	L3: Apply L4: Analyse L5: Evaluate
CO3 :	Describe the fundamentals of sun protection and the formulation of Sunscreens, antiperspirants and deodorants	L3: Apply L4: Analyse L5: Evaluate
CO4 :	Evaluate cosmetics for various physico-chemical properties.	L3: Apply L4: Analyse L5: Evaluate
CO5 :	Design cosmetics and cosmeceuticals that address the problems of dry skin, acne, dermatitis, prickly heat, wrinkles, blemishes, hair fall, Dandruff, body odour	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:**LEVEL: 1- Slight (Low), 2- Moderate (Medium), 3- Substantial (High)**

Program Outcome		Level	Proficiency assessed by
PO1:	Pharmacy Knowledge	2	Assignments/ Internals/Viva
PO2:	Planning Abilities	1	Assignments/ Internals
PO3:	Conduct Investigations of Complex Problems	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

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

	PO1	PO2	PO3	PO4	PO5	PO6	PO7	PO8	PO9	PO10	PO11	PO12
CO1	1	1	1	1	2	2	2	2	2	1	2	2
CO2	2	2	2	2	2	1	1	1	2	2	1	2
CO3	1	2	2	2	2	1	2	1	2	2	1	2
CO4	1	2	2	2	2	1	2	1	2	2	2	2
CO5	2	1	2	2	2	2	2	2	1	2	2	2
Avg	1.4	1.6	1.8	1.8	2	1.4	1.8	1.4	1.8	1.8	1.6	2

Course Content:

MPH 203ET - COSMETIC and cosmeceuticals (Theory)

60Hrs

UNIT-I

10 Hours

Classification of cosmetic and cosmeceutical products

Definition of cosmetics as per Indian and EU regulations, Evolution of cosmeceuticals from cosmetics, cosmetics as quasi and OTC drugs

Cosmetic excipients: Surfactants, rheology modifiers, humectants, emollients, preservatives. Classification and application

Skin: Basic structure and function of skin.

Hair: Basic structure of hair. Hair growth cycle.

Oral Cavity: Common problem associated with teeth and gums.

UNIT II

10 Hours

Principles of formulation and building blocks of skin care products:

Face wash, Moisturizing cream, Cold Cream, Vanishing cream and their advantages and disadvantages. Application of these products in formulation of cosmeceuticals. Antiperspirants & deodorants- Actives & mechanism of action.

Principles of formulation and building blocks of Hair care products:

Conditioning shampoo, Hair conditioner, anti-dandruff shampoo. Hair oils.

Chemistry and formulation of Para-phenylene diamine based hair dye. Principles of formulation and building blocks of oral care products:

Toothpaste for bleeding gums, sensitive teeth. Teeth whitening, Mouthwash.

UNIT III

10 Hours

Sun protection, Classification of Sunscreens and SPF. Role of herbs in cosmetics:

Skin Care: Aloe and turmeric

Hair care: Henna and amla.

Oral care: Neem and clove

Analytical cosmetics: BIS specification and analytical methods for shampoo, skin- cream and toothpaste.

UNIT IV

08Hours.

Principles of Cosmetic Evaluation: Principles of sebumeter, corneometer. Measurement of TEWL, Skin Color, Hair tensile strength, Hair combing properties

Soaps, and syndet bars. Evolution and skin benefits.

UNIT V

07 Hours

Oily and dry skin, causes leading to dry skin, skin moisturisation. Basic understanding of the terms Comedogenic, dermatitis.

Cosmetic problems associated with Hair and scalp: Dandruff, Hair fall causes

Cosmetic problems associated with skin: blemishes, wrinkles, acne, prickly heat and body odor. Antiperspirants and Deodorants- Actives and mechanism of action

References

- 1) Harry's Cosmeticology, Wilkinson, Moore, Seventh Edition, George Godwin.
- 2) Cosmetics – Formulations, Manufacturing and Quality Control, P.P. Sharma, 4th Edition, Vandana Publications Pvt. Ltd., Delhi.
- 3) Text book of cosmeticology by Sanju Nanda & Roop K.

MPC102T: ADVANCED ORGANIC CHEMISTRY – I**Credits: T- 4****Sessional Marks: 25 (T), 15(P)****L:T:P- 3:1:4****University Exams: 75 (T), 35(P)**

Course 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 L2: Understand
CO2:	To apply all the naming reactions in multistep process in manufacturing of drugs and drug intermediates special reactive intermediates including carbenes, carbanions and free radicals.	L1: Remember L2: Understand L3: Apply
CO3:	To understand the applications of reagents and protecting groups.	L1: Remember L2: Understand L3: Apply
CO4:	To understand and apply the structure and theory to the study of organic reaction in heterocyclic chemistry.	L1: Remember L2: Understand L6: Create
CO5:	To develop synthetic route for small molecules. To carry out an organic reaction, including isolating, purifying, and characterizing the product.	L1: Remember L2: Understand L3: Apply L4: Analyse L5: Evaluate L6: Create

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

Course Content:

UNIT-I

12 Hours

Basic Aspects of Organic Chemistry:

i. Organic

intermediates : Carbocations, carbanions, free radicals, carbenes and nitrenes. Their methods of formation, 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 and orientations of the following reactions.

a) Nucleophilic uni and bimolecular substitution reactions (S_N^1 , S_N^2 and S_N^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, Vilsmeier-Haack Reaction, Baeyer-Villiger oxidation, Shapiro & Suzuki reaction, Ozonolysis and Michael addition reaction.

UNIT-III

12 Hours

Synthetic Reagents & Applications: Aluminium isopropoxide, N-bromosuccinamide, diazomethane, dicyclohexylcarbodiimide, Wilkinson reagent, Wittig 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 interconversion 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

Credits: T- 4, P-8

Sessional Marks: 25 (T)

L:T:- 3:1

University Exams: 75 (T)

Course 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 and discovery of medicinal compounds.	L1: Remember L2: Understand
CO2:	Study on different biological targets	L1: Remember L2: Understand L3: Apply
CO3:	To understand the mechanism of action of drugs belonging to the classes of Antihypertensive and Psychoactive.	L1: Remember L2: Understand L3: Apply
CO4:	Anticonvulsant, H1/H2 receptor antagonistic, COX1 & COX2 inhibiting, adrenergic & cholinergic, antineoplastic and antiviral agents.	L1: Remember L2: Understand L6: Create
CO5:	Various strategies to design and develop new drug like molecules for biological targets	L3: Apply L4: Analyse L5: Evaluate L6: Create

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

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 practical consideration 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: synthesis of 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, modification of 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 and Janet. F Moore
5. Introduction to Quantitative Drug Design by Y.C. Martin.
6. Principles of Medicinal Chemistry by William Foye, 7th Edition, Ippincott Williams & Wilkins, Woltess Kluwer (India) Pvt.Ltd, New Delhi.
7. Drug Design Volumes by Arienes, Academic Press, Elsevier Publishers, Noida, Uttar Pradesh.
8. Principles of Drug Design by Smith.

MPC 104T CHEMISTRY OF NATURAL PRODUCTS

Credits: T- 4, P-8

Sessional Marks: 25 (T)

L:T:- 3:1

University Exams: 75 (T)

Course 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. Flavonoids Introduction, Isolation and Purification of flavonoids, General methods of Structural Determination of flavonoids; Structural Elucidation of Quercetin. 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	L3: Apply L4: Analyse L5: Evaluate
CO3:	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. Vitamins Chemistry (Structural features only) and Physiological Significance of Vitamin A, B ₁ , B ₂ , B ₁₂ , C, E, Folic acid and Niacin	L3: Apply L4: Analyse L5: Evaluate
CO4:	Chemistry (Structural features only) and Biological Significance of	L2:Understand L3: Apply

	Prostaglandins and Leukotrienes. Marine Natural products with therapeutic Potential: Cardiovascular agents, Anti-inflammatory, Antimicrobial, Antiviral and Antiparasitic agents	L4: Analyse
CO5:	Structural Characterization of natural compounds Structural characterization of natural compounds using IR, ¹ HNMR, ¹³ CNMR and MS Spectroscopy of specific drugs e.g., Citral, Quercetin, Morphine, Luteolin-7-o-glucoside and Estrone.	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	2	Assignments/ Internals/Viva
PO2:	Planning Abilities	1	Assignments/ Internals
PO3:	Conduct Investigations of Complex Problems	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, and Clarithromycin) and β - Lactam antibiotics (Cephalosporins and Carbapenem) **12Hrs**

2. 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**

3. 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, B₁, B₂,B₁₂, C, E, Folic acid and Niacin. **12Hrs**

4. a) Chemistry (Structural features only) and Biological Significance of Prostaglandins and Leukotrienes.

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

5 .Structural Characterization of natural compounds

Structural characterization of natural compounds using IR, ¹HNMR, ¹³CNMR and MS Spectroscopy of specific 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 & Business Media.
4. Chemistry of natural products Vol I onwards IWPAC.
5. Natural Product Chemistry Nakanishi Gggolo, University Science Books, California.
6. Natural Product Chemistry “A laboratory guide” – Rapheal Khan.
7. The Alkaloid Chemistry and Physiology by RHF Manske, Academic Press.
8. Introduction to molecular Phytochemistry – CHJ Wells, Chapmanstall.
9. Organic Chemistry of Natural Products Vol I and II by GurdeepandChatwall, Himalaya Publishing House.
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

MPC 201T - ADVANCED SPECTRAL ANALYSIS

Credits: T- 4

Sessional Marks: 25 (T)

L:T- 3:1

University Exams: 75 (T)

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: Understand L3: 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 Raman spectroscopy	L3: Apply L4: Analyse L5: Evaluate
CO4:	Learn the general theory and principles of thermal analysis	L2: Understand L3: 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:

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. UV and IR spectroscopy:

Wood ward - Fieser rule for 1,3- butadienes, cyclic dienes and α , β -carbonyl compounds and interpretation compounds of enones. ATR-IR, IR Interpretation of organic compounds. **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, ^{13}C NMR and applications of ^{13}C NMR.

NMR of other atoms: ^{19}F , ^{31}P , ^{14}N , ^{15}N & ^{17}O NMR.

Spectrum editing: DEPT spectra.

Magnetic resonance imaging (MRI), 1-D and 2-D NMR, NOESY and COSY, HECTOR techniques. 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 groups and alkanes, Meta stable ions, Mc Lafferty rearrangement, Ring rule, Isotopic peaks, Interpretation of organic compounds. **12Hrs**

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4. Chromatography:

Principle, Instrumentation and Applications of the following :

a) GC-MS b) GC-AAS c) LC-MS d) LC-FTIR e) LC-NMR f) CEMS g) High Performance Thin 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 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).

Thermogravimetric analysis (TGA): Principle, instrumentation, factors affecting results, advantage and disadvantages, pharmaceutical applications.

b) 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 - Douglas 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

MPC 202T - ADVANCED ORGANIC CHEMISTRY - II

Credits: T- 4

Sessional Marks: 25 (T)

L:T- 3:1

University Exams: 75 (T)

Course 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 be 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 and Ultrasound assisted reactions	L1: Remember L2: Understand L3: 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: Understand L3: Apply L4: Analyse
CO5:	Stereochemistry & Asymmetric Synthesis and 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:

- Introduction, principles of green chemistry
- 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
- Ultrasound assisted reactions: Types of sonochemical reactions, homogenous, heterogeneous liquid-liquid and liquid-solid reactions, synthetic applications. **12Hrs**

2. Chemistry of peptides

- Coupling reactions in peptide synthesis
- Principles of solid phase peptide synthesis, t-BOC and Fmoc protocols, various solid supports and linkers: Activation procedures, peptide bond formation, deprotection and cleavage from resin, low and high HF cleavage protocols, formation of free peptides and peptide amides, purification, site-specific chemical modifications of peptides.
- Segment and sequential strategies for solution phase peptide synthesis with any two case studies
- Side reactions in peptide synthesis: Deletion peptides 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 and deprotection.

b) Pericyclic reactions

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

4. Catalysis:

- Types of catalysis, heterogeneous and homogenous catalysis, advantages and disadvantages
- Heterogeneous catalysis – preparation, characterization, supported catalysts, catalyst deactivation and regeneration, some examples of heterogeneous catalysis used in synthesis of drugs.
- Homogenous catalysis, hydrogenation, hydroformylation, Wilkinson catalysts, Ziegler-Natta catalysts, some examples of homogenous catalysis used in synthesis of drugs
- Biocatalysis: Use of enzymes in organic synthesis, immobilized enzymes/cells in organic reaction.
- Phase transfer catalysis - theory and applications **12Hrs**

5. Stereochemistry & Asymmetric Synthesis

- Basic concepts in stereochemistry – optical activity, specific rotation, racemates and resolution of racemates, the Cahn, Ingold, Prelog (CIP) sequence rule, meso compounds, pseudo asymmetric centres, axes of symmetry, Fischers D and L notation, cis-trans isomerism, E and Z notation.
- Methods of asymmetric synthesis using chiral pool, chiral auxiliaries and catalytic asymmetric synthesis, enantio pure separation and Stereo selective synthesis with examples. **12Hrs**

REFERENCES

- “Advanced Organic chemistry, Reaction, mechanisms and structure”, JMarch, John Wiley and sons, New York.
- “Mechanism and structure in organic chemistry”, ES Gould, Hold Rinchart and Winston, New York.
- “Organic Chemistry” Clayden, Greeves, Warren and Wothers., 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, Wiley 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

Credits: T- 4

Sessional Marks: 25 (T)

L:T- 3:1

University Exams: 75 (T)

Course Objectives

- The subject is designed to impart knowledge on the current state of the art techniques involved in 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 physicochemical Properties 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: Understand L3: 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

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 equation and electronic parameters (σ), lipophilicity effects and parameters ($\log P$, π -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 size prediction, 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 and Pharmacophore 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 M Stroud and Janet. F Moore, RCS Publishers.
2. Introduction to Quantitative Drug Design by Y.C. Martin, CRC Press, Taylor & Francis group..
3. Drug Design by Ariens Volume 1 to 10, Academic Press, 1975, Elsevier Publishers.
4. Principles of Drug Design by Smith and Williams, CRC Press, Taylor & Francis.
5. The Organic Chemistry of the Drug Design and Drug action by Richard B. Silverman, Elsevier Publishers.
6. Medicinal Chemistry by Burger, Wiley Publishing Co.
7. An Introduction to Medicinal Chemistry –Graham L. Patrick, Oxford University Press.
8. Wilson and Gisvold's Text book of Organic Medicinal and Pharmaceutical Chemistry, Ippincott Williams & Wilkins.
9. Comprehensive Medicinal Chemistry – Corwin and Hansch, Pergamon Publishers.
10. Hugo Kubiny. QSAR: Hansch Analysis and Related Approaches. Methods and Principles in Medicinal Chemistry. Publisher Wiley-VCH
11. Klaus Gubernator, Hans-Joachim Böhm. Structure-Based Ligand Design. Methods and Principles 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.

MPL 102T: ADVANCED PHARMACOLOGY - I

Credits: T- 4

Sessional Marks: 25 (T)

L:T- 3:1

University Exams: 75 (T)

COURSE SCOPE

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

COURSE OBJECTIVES

Upon completion of the course the student shall be able to

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

COURSE OUTCOMES:

S. No.	Course Outcomes (CO)	Knowledge Level (Blooms Level)
After completing this course, the student must demonstrate the knowledge and ability to:		
CO1	The student shall understand the general aspects and steps involved in neurotransmission, autonomic nervous system and central nervous system. They should comprehend details of different specific neurotransmission pathways of cholinergic, adrenergic, serotonergic, dopaminergic, GABA, glutamate and glycine pathways with knowledge of transmission and neuropeptides.	L2: Understand L3: Apply
CO2	They would have elaborately learnt the recent advances in pathophysiology, drugs used for the treatment of various diseases affecting autonomic nervous system, Central nervous system and cardio vascular system	L2: Understand L3: Apply L4: Analyse
CO3	To gain the knowledge of concepts of drug action and mechanisms involved in the autocoid pharmacology	L2: Understand L3 Apply L4: Analyse
CO4	The student shall apply the knowledge of learned principles of drug action in the pharmacotherapy of certain diseases	L2: Understand L3: Apply L4: Analyse
CO5	The student shall understand the underlying the cellular and molecular mechanisms of drug action in mentioned diseases	L2: Understand L3: Apply L4: Analyse
CO6	The student shall understand and apply the knowledge of adverse drug reactions, contraindications, drug interactions of the studied drugs in mentioned diseases	L2: Understand L3: Apply L4: Analyse

Bloom's Taxonomy: L1: Remember; L2: Understand; L3: Apply; L4: Analyse; L5: Evaluate; L6: Create

PO and CO's mapping for ADVANCED PHARMACOLOGY - I (MPL102T)

	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	2	2	2	2	2	1	2	2	2	2	2
CO4	3	2	2	2	3	3	1	2	2	2	1	2
CO5	3	3	3	3	3	3	1	2	2	2	1	2
CO6	3	3	2	3	3	3	1	2	2	2	2	2
Avg	3	2.3	2.2	2.3	2.5	2.5	2	2	2	2	1.6	2

MPL 103T: PHARMACOLOGICAL AND TOXICOLOGICAL SCREENING METHODS – I

Credits: T- 4

Sessional Marks: 25 (T)

L:T- 3:1

University Exams: 75 (T)

COURSE SCOPE

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

COURSE OBJECTIVES

Upon completion of the course the student shall be able to

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

COURSE OUTCOMES:

S. No.	Course Outcomes (CO)	Knowledge Level (Blooms Level)
After completing this course, the student must demonstrate the knowledge and ability to:		
CO1	The student shall understand about the need and application of Common laboratory animals, Transgenic animals, their maintenance and breeding animals as per the CPCSEA guidelines. Student shall need to apply this knowledge to conduct experiments on animals	L2: Understand L3: Apply L4: Analyse
CO2	The student should understand the basics of preclinical evaluation and recent experimental techniques used for screening	L2: Understand L3: Apply L4: Analyse
CO3	Student should gain the knowledge of in silico, in-vivo and in-vitro methods available in screening of drugs or chemical entities for the mentioned diseases	L2: Understand L3 Apply L4: Analyse
CO4	They would have learnt to describe the various screening methods involved in the drug discovery process	L2: Understand L3: Apply L4: Analyse
CO5	The student shall understand and apply alternatives for animal experimentation.	L2: Understand L3: Apply L4: Analyse
CO6	Students shall be able to extrapolate the <i>in vitro</i> data to preclinical and preclinical data to humans.	L2: Understand L3: Apply L4: Analyse

Bloom's Taxonomy: L1: Remember; L2: Understand; L3: Apply; L4: Analyse; L5: Evaluate; L6: Create

PO and CO's mapping for PHARMACOLOGICAL AND TOXICOLOGICAL SCREENING METHODS – I (MPL103T)

	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	2	2	2	2	2	1	2	2	2	2	2
CO4	3	2	2	2	3	3	1	2	2	2	1	2
CO5	3	3	3	3	3	3	1	2	2	2	1	2
CO6	3	3	2	3	3	3	1	2	2	2	2	2
Avg	3	2.3	2.2	2.3	2.5	2.5	2	2	2	2	1.6	2

MPL 104T: CELLULAR AND MOLECULAR PHARMACOLOGY

Credits: T- 4

Sessional Marks: 25 (T)

L:T- 3:1

University Exams: 75 (T)

COURSE SCOPE

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

COURSE OBJECTIVES

Upon completion of the course the student shall be able to

- Understand the fundamental knowledge of cellular components and the signalling mechanisms within the cell and between the cells
- Describe the receptor signal transduction processes.
- Understand and describe the molecular pathways affected by drugs.
- Appreciate the applicability of molecular pharmacology and biomarkers in drug discovery process.
- Demonstrate molecular biology techniques in the drug discovery process

COURSE OUTCOMES:

S. No.	Course Outcomes (CO)	Knowledge Level (Blooms Level)
After completing this course, the student must demonstrate the knowledge and ability to:		
CO1	The student shall understand about the fundamental knowledge of cellular components, genetic code, concept to g Gene, siRNA and miRNA technologies	L2: Understand L3: Apply L4: Analyse
CO2	To understand the receptor signal transduction process and apply that knowledge for understanding drug action	L2: Understand L3: Apply L4: Analyse
CO3	To gain the knowledge of molecular pathways affected by drugs and their role in therapy	L2: Understand L3 Apply L4: Analyse
CO4	The student shall understand and appreciate the components of cell cycle and cell death process	L2: Understand L3: Apply L4: Analyse
CO5	The student shall understand and apply the knowledge of cell culture techniques and their application in drug discovery and screening	L2: Understand L3: Apply L4: Analyse
CO6	The student shall gain knowledge of biosimilars and able to analyse the difference between biosimilars and generics. They should gain information about the technical problems in handling biosimilars.	L2: Understand L3: Apply L4: Analyse

Bloom's Taxonomy: L1: Remember; L2: Understand; L3: Apply; L4: Analyse; L5: Evaluate; L6: Create

PO and CO's mapping for CELLULAR AND MOLECULAR PHARMACOLOGY (MPL104T)

	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	2	2	2	2	2	1	2	2	2	2	2
CO4	3	2	2	2	3	3	1	2	2	2	1	2
CO5	3	3	3	3	3	3	1	2	2	2	1	2
CO6	3	3	2	3	3	3	1	2	2	2	2	2
Avg	3	2.3	2.2	2.3	2.5	2.5	2	2	2	2	1.6	2

MPL 201T: ADVANCED PHARMACOLOGY - II

Credits: T- 4

Sessional Marks: 25 (T)

L:T- 3:1

University Exams: 75 (T)

COURSE SCOPE

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

COURSE OBJECTIVES

Upon completion of the course the student shall be able to

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

COURSE OUTCOMES:

S. No.	Course Outcomes (CO)	Knowledge Level (Blooms Level)
After completing this course, the student must demonstrate the knowledge and ability to:		
CO1	The student shall understand the molecular and cellular mechanism of action of hormones and their disorders	L2: Understand L3: Apply
CO2	They would have elaborately learnt the recent advances in different fields of chemotherapy	L2: Understand L3: Apply L4: Analyse
CO3	To gain the knowledge of concepts of drug action and mechanisms involved in the immunopharmacology, drug allergy, and hypersensitivity reactions	L2: Understand L3 Apply L4: Analyse
CO4	The student shall apply the knowledge of learned principles of drug action in the pharmacotherapy of certain diseases. The student should analyse the underlying cellular and molecular mechanisms of drug action in mentioned diseases	L2: Understand L3: Apply L4: Analyse
CO5	The student shall comprehend the cellular and molecular mechanisms of free radicals and their role in diseases	L2: Understand L3: Apply L4: Analyse
CO6	The student shall understand and apply the knowledge of adverse drug reactions, contraindications, drug interactions of the studied drugs in mentioned diseases	L2: Understand L3: Apply L4: Analyse

Bloom's Taxonomy: L1: Remember; L2: Understand; L3: Apply; L4: Analyse; L5: Evaluate; L6: Create

PO and CO's mapping for ADVANCED PHARMACOLOGY - II (MPL201T)

	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	2	2	2	2	2	1	2	2	2	2	2
CO4	3	2	2	2	3	3	1	2	2	2	1	2
CO5	3	3	3	3	3	3	1	2	2	2	1	2
CO6	3	3	2	3	3	3	1	2	2	2	2	2
Avg	3	2.3	2.2	2.3	2.5	2.5	2	2	2	2	1.6	2

MPL 202T: PHARMACOLOGICAL AND TOXICOLOGICAL SCREENING METHODS – II

Credits: T- 4

Sessional Marks: 25 (T)

L:T- 3:1

University Exams: 75 (T)

COURSE SCOPE

This subject is designed to impart the knowledge on the preclinical safety and toxicological evaluation of drug & new chemical entity. This knowledge will make the student competent in regulatory toxicological evaluations.

COURSE OBJECTIVES

Upon completion of the course the student shall be able to

- Appraise the regulations and requirement for conducting 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 (CO)	Knowledge Level (Blooms Level)
After completing this course, the student must demonstrate the knowledge and ability to:		
CO1	The student shall understand regulatory guidelines for conducting toxicity studies as per OECD, ICH, EPA and Schedule Y guidelines. The student shall acquire knowledge about OECD principles of Good laboratory practice (GLP)	L2: Understand L3: Apply L4: Analyse
CO2	To understand and apply the OECD guidelines for conducting Acute, sub-acute and chronic- oral, dermal and inhalational studies.	L2: Understand L3: Apply L4: Analyse
CO3	To gain the knowledge about guidelines and protocols to conduct special toxicity studies Viz reproductive toxicity, carcinogenicity, safety pharmacology	L2: Understand L3 Apply L4: Analyse
CO4	The student shall appreciate the importance of ethical and regulatory requirements for toxicity studies and analyze the studies needed for IND application	L2: Understand L3: Apply L4: Analyse
CO5	The student shall understand and analyze usage of animals and alternatives in toxicity studies as per regulatory guidelines	L2: Understand L3: Apply L4: Analyse
CO6	The student shall understand the principles of toxicokinetics, saturation kinetics and their application in toxicity testing	L2: Understand L3: Apply L4: Analyse

Bloom's Taxonomy: L1: Remember; L2: Understand; L3: Apply; L4: Analyse; L5: Evaluate; L6: Create

PO and CO's mapping for PHARMACOLOGICAL AND TOXICOLOGICAL SCREENING METHODS – II (MPL202T)

	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	2	2	2	2	2	1	2	2	2	2	2
CO4	3	2	2	2	3	3	1	2	2	2	1	2
CO5	3	3	3	3	3	3	1	2	2	2	1	2
CO6	3	3	2	3	3	3	1	2	2	2	2	2
Avg	3	2.3	2.2	2.3	2.5	2.5	2	2	2	2	1.6	2

MPL 204T: CLINICAL RESEARCH AND PHARMACOVIGILANCE

Credits: T- 4

Sessional Marks: 25 (T)

L:T- 3:1

University Exams: 75 (T)

COURSE SCOPE

This subject will provide a value addition and updated knowledge about clinical research and pharmacovigilance. It will teach the students on conceptualizing, designing, conducting, managing and reporting of clinical trials. This subject also focuses on global scenario of Pharmacovigilance in different methods that can be used to generate safety data.

COURSE OBJECTIVES

Upon completion of the course the student shall be able to

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

COURSE OUTCOMES:

S. No.	Course Outcomes (CO)	Knowledge Level (Blooms Level)
After completing this course, the student must demonstrate the knowledge and ability to:		
CO1	The student shall understand regulatory perspectives and ethical issues of conducting clinical trails as per ICH, EPA, CDSCO, ICMR guidelines	L2: Understand L3: Apply L4: Analyse
CO2	Student should understand and demonstrate informed consent, types and study designs of clinical trials.	L2: Understand L3: Apply L4: Analyse
CO3	To gain the knowledge about role and responsibilities, key players, protocol design and execution methods to conduct clinical trials,	L2: Understand L3 Apply L4: Analyse
CO4	The student shall appreciate the importance and understand the safety monitoring, reporting and close-out activities.	L2: Understand L3: Apply L4: Analyse
CO5	The student shall understand and analyze the types of ADR, need and methods of pharmacovigilance	L2: Understand L3: Apply L4: Analyse
CO6	The student shall understand the principles of pharmacoepidemiology and able to apply the in detection and assessment of ADR	L2: Understand L3: Apply L4: Analyse

Bloom's Taxonomy: L1: Remember; L2: Understand; L3: Apply; L4: Analyse; L5: Evaluate; L6: Create

**PO and CO's mapping for CLINICAL RESEARCH AND PHARMACOVIGILANCE
(MPL204T)**

	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	2	2	2	2	2	1	2	2	2	2	2
CO4	3	2	2	2	3	3	1	2	2	2	1	2
CO5	3	3	3	3	3	3	1	2	2	2	1	2
CO6	3	3	2	3	3	3	1	2	2	2	2	2
Avg	3	2.3	2.2	2.3	2.5	2.5	2	2	2	2	1.6	2

M. Pharmacy Pharmacognosy- Program Outcomes

PO1: Fundamental Knowledge

Understands basic concepts and theory related to Indian Systems of Medicines, development, evaluation of herbal drugs and herbal cosmetics

PO2: Application of acquired knowledge

Applies acquired knowledge in development and evaluation of Indian Systems of Medicines, herbal drugs and herbal cosmetics

PO3: Problem solving and Analytical skills

Develops problem solving and analytical skills required to develop Indian Systems of Medicines and herbal products

PO4: Evaluation and creativity

Able to evaluate existing herbal products and create new herbal products

PO5: Leadership, Management and industry readiness

Gains technical skills, leadership and management abilities required at workplace

PO 6: Life-Long Learning

Becomes, inquisitive, creative, adapts to self-learning of current knowledge in the fields of Indian Systems of Medicines, herbal drugs and herbal cosmetics

Course outcomes

I Semester

MPG 102T:ADVANCED PHARMACOGNOSY - I

Credits: T- 4, P-2

Sessional Marks: 25 (T), 15(P)

L: T: P- 3:1:4

University Exams: 75 (T),35(P)

Course objectives

This course deals with the advances in the field of cultivation and isolation of drugs of natural origin, various phytopharmaceuticals, nutraceuticals and their medicinal use and health benefits.

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

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

Course outcomes

S.No	Course Outcomes	Knowledge level (BLOOMS Level)
After successful completion of the course student shall be able to explain		
CO1:	Cultivation of different types of medicinal plants by adapting Good Agricultural Practices (GAP), Organic farming and Biopesticides, Sound knowledge on conservation of medicinal plants.	L1:Remember L2:Understand L3: Apply
CO2:	Medicinal Plants Collection procedures and Ex-situ and In-situ conservation, isolation and characterization of phytochemicals of therapeutic importance, recent advances in research on marine drugs, general methods of isolation and purification of marine natural products.	L3: Apply L4: Analyse L5: Evaluate
CO3:	Current trend, future scope, formulation, standardization of Nutraceuticals, regulatory and FSSAI guidelines for nutraceuticals, health care management with Nutraceuticals. Pharmacovigilance of drugs of natural origin.	L3: Apply L4: Analyse L5: Evaluate
CO4:	Isolation, Chemical characterisation, pharmaceutical and medicinal applications of Phytopharmaceuticals.	L2:Understand L3: Apply L4: Analyse
CO5:	WHO and AYUSH guidelines on safety monitoring of natural medicines, Herb-food interactions, herb-herb interactions, herb-drug interactions, Adverse drug reactions of herbs, herbal formulations and spontaneous adverse drug reaction reporting schemes.	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	2	Assignments/ Internals/Viva
PO2:	Planning Abilities	1	Assignments/ Internals
PO3:	Conduct Investigations of Complex Problems	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	1	2	1	2	2	2	2	2	1	2	2
CO2	1	2	2	2	2	1	1	1	2	2	1	2
CO3	2	2	2	2	2	1	2	1	2	2	1	2
CO4	1	1	2	2	2	1	2	1	2	2	2	2
CO5	2	1	1	2	2	2	2	2	2	2	2	2
Avg	1.6	1.4	1.8	1.8	2	1.4	1.8	1.4	2	1.8	1.6	2

Course Content:

THEORY

60Hrs

1. Plant drug cultivation: General introduction to the importance of Pharmacognosy in drug industry, Indian Council of Agricultural Research, Current Good Agricultural Practices, Current Good Cultivation Practices, Current Good Collection Practices, Conservation of medicinal plants- Ex-situ and In-situ conservation of medicinal plants. **12Hrs**

2. Marine natural products: General methods of isolation and purification, Study of Marine toxins, Recent advances in research in marine drugs, Problems faced in research on marine drugs such as taxonomical identification, chemical screening and their solutions. **12Hrs**

3. Nutraceuticals: Current trends and future scope, Inorganic mineral supplements, Vitamin supplements, Digestive enzymes, Dietary fibres, Cereals and grains, Health drinks of natural origin, Antioxidants, Polyunsaturated fatty acids, Herbs as functional foods, Formulation and standardization of nutraceuticals, Regulatory aspects, FSSAI guidelines, Sources, name of marker compounds and their chemical nature, medicinal uses and health benefits of the following
i) Spirulina ii) Soya bean iii) Ginseng iv) Garlic v) Broccoli vi) Green and Herbal Tea vii) Flax seeds viii) Black cohosh ix) Turmeric. **12Hrs**

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

- a) Carotenoids – i) α and β - Carotene ii) Xanthophyll (Lutein)
- b) Limonoids – i) d-Limonene ii) α - Terpineol
- c) Saponins – i) Shatavarins
- d) Flavonoids – i) Resveratrol ii) Rutin iii) Hesperidin iv) Naringin v) Quercetin
- e) Phenolic acids- Ellagic acid
- f) Vitamins
- g) Tocotrienols and Tocopherols
- h) Andrographolide, Glycolipids, Gugulipids, Withanolides, Vascine, Taxol
- i) Miscellaneous **12Hrs**

5. Pharmacovigilance of drugs of natural origin: 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. **12Hrs**

MPG 103T: PHYTOCHEMISTRY

CO1: Knows the different classes of phytoconstituents, their properties, biosynthetic pathways, isolation, purification and characterization.

CO2: Understands general process of natural product drug discovery and development.

CO3: Able to perform extraction of phytochemicals using advanced techniques.

CO4: Can perform phytochemical fingerprinting of extracts using advanced analytical tools.

CO5: Able to do structure elucidation of phytoconstituents

Course Outcomes and Program Outcomes (CO-PO) Mapping

Course Outcome	Program Outcomes					
	PO1	PO2	PO3	PO4	PO5	PO6
CO1	3	2	1	1	2	3
CO2	3	3	1	1	2	3
CO3	3	3	3	3	3	3
CO4	3	3	3	3	3	3
CO5	3	3	3	3	3	3
Average	3	2.8	2.2	2.2	2.6	3

Level1- slight (Low), Level 2- Moderate (Medium), Level 3- Substantial (High)

MPG 104T: INDUSTRIAL PHARMACOGNOSTICAL TECHNOLOGY

CO1: Understands herbal drug industry infrastructure requirements, Current challenges in upgrading and modernization of herbal formulations and Entrepreneurship Development.

CO2: Recognizes the regulatory requirements for setting herbal drug industry, Global marketing management, Export - Import (EXIM) policy, TRIPS, Quality assurance in herbal/natural drug products, Concepts of TQM, GMP, GLP, ISO-9000

CO3: Understands differences among different ISM pharmacopeia monographs of herbal drugs and WHO guidelines in quality assessment of herbal drugs.

CO4: Able to implement protocols of clinical laboratory testing and stability testing of natural products.

CO5: Knows Indian and international patents, patent filing process and patent processing related to natural products and biological diversity act.

Course Outcomes and Program Outcomes (CO-PO) Mapping

Course Outcome	Program Outcomes					
	PO1	PO2	PO3	PO4	PO5	PO6
CO1	3	2	1	1	3	3
CO2	3	3	2	2	3	3
CO3	3	2	2	2	3	3
CO4	3	3	3	3	3	3
CO5	3	3	2	2	3	3
Average	3	2.6	2	2	3	3

Level1- slight (Low), Level 2- Moderate (Medium), Level 3- Substantial (High)

MPG 103T: PHYTOCHEMISTRY

Credits: T- 4, P-2

Sessional Marks: 25 (T), 15(P)

L: T: P- 3:1:4

University Exams: 75 (T), 35(P)

Course objectives

This course deals with the study of preparation and standardization of herbal/natural cosmetics. This subject gives emphasis on various national and international standards prescribed regarding herbal cosmeceuticals.

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

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

Course outcomes

S.No	Course Outcomes	Knowledge level (BLOOMS Level)
After successful completion of the course student shall be able to explain		
CO1:	Natural product drug discovery process, lead selection, structure development and product discovery process.	L1:Remember L2:Understand L3: Apply
CO2:	Biosynthesis, Isolation, Characterization and purification with a special reference to their importance in herbal industries phyto-pharmaceuticals.	L3: Apply L4: Analyse L5: Evaluate
CO3:	Identification and isolation of different classes of phytoconstituents by Continuous Counter Current Extraction Technique (CCCET), Super Critical Fluid Extraction (SCFE), preparative HPLC and Flash column chromatography.	L3: Apply L4: Analyse L5: Evaluate
CO4:	Phytochemical fingerprinting of herbal extracts using HPTLC, LCMS/GCMS and markers identification.	L2:Understand L3: Apply L4: Analyse
CO5:	Structure elucidation of phytoconstituents by MS, IR, NMR techniques	L2:Understand 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	2	Assignments/ Internals/Viva
PO2:	Planning Abilities	1	Assignments/ Internals
PO3:	Conduct Investigations of Complex Problems	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	1	2	1	2	2	2	2	2	1	2	2
CO2	1	2	2	2	2	1	1	1	2	2	1	1
CO3	2	2	2	2	2	1	2	1	2	2	1	2
CO4	2	2	2	2	1	2	2	1	2	2	2	2
CO5	1	2	1	2	2	2	2	2	1	2	2	2
Avg	1.6	1.8	1.8	1.8	1.8	1.6	1.8	1.4	1.8	1.8	1.6	1.8

Course Content:

THEORY

60 Hrs

1. Biosynthetic pathways and Radio tracing techniques:

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

- Alkaloids: Quinine, Vincaalkaloids.
- Glycosides: Digitoxin, Sennosides.
- Steroids: Hecogenin
- Coumarin: Umbelliferone.
- Terpenoids: Cucurbitacins **12Hrs**

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

3. Extraction and Phytochemical studies: Recent advances in extraction with emphasis on selection of method and choice of solvent for extraction, successive and exhaustive extraction and other methods of extraction commonly used like microwave assisted extraction, Methods of fractionation. Separation of phytoconstituents by latest Continuous Counter Current Extraction Technique (CCCET), Super Critical Fluid Extraction (SCFE) techniques including preparative HPLC and Flash column chromatography. **12Hrs**

4 Phytochemical finger printing: HPTLC and LCMS/GCMS applications in the characterization of herbal extracts. Structure elucidation of phytoconstituents. **12Hrs**

5. Structure elucidation of the following compounds by spectroscopic techniques like UV, IR, MS, NMR (^1H , ^{13}C)

- Carvone, Citral, Menthol
- Luteolin, Kaempferol
- Nicotine, Caffeine iv) Glycyrrhizin. **12Hrs**

REFERENCES (Latest Editions of)

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

MPG 104T: INDUSTRIAL PHARMACOGNOSTICAL TECHNOLOGY

Credits: T- 4, P-2

Sessional Marks: 25 (T), 15(P)

L: T: P- 3:1:4

University Exams: 75 (T),35(P)

Course objectives

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

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

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

Course outcomes

S.No	Course Outcomes	Knowledge level (BLOOMS Level)
After successful completion of the course student shall be able to explain		
CO1:	Basic principles, preparation, standardization and evaluation methods of herbal/natural cosmetics including cGMP as per the Regulatory requirements.	L1:Remember L2:Understand L3: Apply
CO2:	Regulatory requirements such as Global marketing management, patent law, Export - Import (EXIM) policy, TRIPS for setting herbal drug industry and Quality assurance in herbal drug products.	L3: Apply L4: Analyse L5: Evaluate
CO3:	WHO guidelines in quality assessment of herbal drugs and parameters of monographs of herbal drugs and comparative studies from IP, USP, Ayurvedic, Siddha and Unani, American and British herbal pharmacopoeias.	L3: Apply L4: Analyse L5: Evaluate
CO4:	Clinical laboratory and Stability testing of natural products and protocols.	L2:Understand L3: Apply L4: Analyse
CO5:	Thorough understanding of Indian and international patent laws and proposed amendments as applicable to herbal products and process	L2:Understand 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	2	Assignments/ Internals/Viva
PO2:	Planning Abilities	1	Assignments/ Internals
PO3:	Conduct Investigations of Complex Problems	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	2	2	2	2	2	2	1	2	1	2	2
CO2	1	2	2	2	2	1	2	1	2	2	1	2
CO3	2	1	2	1	2	1	1	2	2	2	2	2
CO4	2	2	2	2	1	1	2	1	2	2	1	1
CO5	2	1	1	2	2	2	2	2	2	2	2	2
Avg	1.8	1.6	1.8	1.8	1.8	1.4	1.8	1.4	2	1.8	1.6	1.8

Course Content:

THEORY

60 Hrs

1. Herbal drug industry:

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

2. Regulatory requirements for setting herbal drug industry:

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

3. Monographs of herbal drugs:

General parameters of monographs of herbal drugs and comparative study from IP, USP, Ayurvedic Pharmacopoeia, Siddha and Unani Pharmacopoeia, American herbal pharmacopoeia, British herbal pharmacopoeia, WHO guidelines in quality assessment of herbal drugs. **12Hrs**

4. Testing of natural products and drugs: Herbal medicines -clinical laboratory testing. Stability testing of natural products, protocols. **12Hrs**

5 Patents: Indian and international patent laws, proposed amendments as applicable to herbal/natural products and process. Biological diversity act, Geographical Indications, Copyright, Patentable subject matters, novelty, non obviousness, utility, enablement and best mode, procedure for Indian patent filing, patent processing, grant of patents, rights of patents, cases of patents, opposition and revocation of patents, patent search and literature, Controllers of patents. **12Hrs**

Recommended Books: (Latest Editions)

1. Herbal drug industry by R.D. Choudhary (1996), Eastern Publisher, New Delhi.
2. GMP for Botanicals - Regulatory and Quality issues on Phytomedicine by Pulok K Mukharjee (2003), 1st Edition, Business horizons Robert Verpoorte, New Delhi.
3. Quality control of herbal drugs by Pulok K Mukharjee (2002), Business Horizons Pharmaceutical Publisher, New Delhi.
4. PDR for Herbal Medicines (2000), Medicinal Economic Company, New Jersey.
5. Indian Herbal Pharmacopoeia (2002), IDMA, Mumbai.
6. Text book of Pharmacognosy by C.K. Kokate, Purohit, Gokhale (1996), Nirali Prakashan, New Delhi.
7. Text book of Pharmacognosy and Phytochemistry by Vinod D. Rangaraj (2002), Part I & II, Career Publication, Nasik, India.
8. Plant drug analysis by H. Wagner and S. Bladt, Springer, Berlin.
9. Standardization of Botanicals. Testing and extraction methods of medicinal herbs by V. Rajpal (2004), Vol. I, Eastern Publisher, New Delhi.
10. Phytochemical Dictionary. Handbook of Bioactive Compounds from Plants by J.B. Harborne, (1999), 1st Edition, Taylor and Francis Ltd, UK.
11. Herbal Medicine. Expanded Commission E Monographs by M. Blumenthal, (2004), 1st Edition,
12. Drug Formulation Manual by D.P.S. Kohli and D.H. Shah (1998), Eastern Publisher, New Delhi.
13. Product development- N.K. Jain

MPG 105P: PHARMACOGNOSY PRACTICAL –I

Course outcomes

S.No	Course Outcomes	Knowledge level (BLOOMS Level)
After successful completion of the course student shall be able to explain		
CO1:	Methods of extraction, phytochemical screening monograph analysis of pharmacopeia compounds.	L1:Remember L2:Understand L3: Apply
CO2:	Formulation of herbal powders, tablets, lotions, liniments, ointments, pastes, creams, gels and their quality testing.	L3: Apply L4: Analyse L5: Evaluate
CO3:	Identification and estimation of bioactive phytochemicals in natural substances and their formulations by PC, TLC, UV-VIS, HPLC, HPTLC methods.	L3: Apply L4: Analyse L5: Evaluate
CO4:	Analysis of recorded MS, IR and NMR spectra of simple phytoconstituents.	L2:Understand L3: Apply L4: Analyse
CO5:	Estimation of sodium/potassium by flame photometry, development of fingerprint profile of selected medicinal plant extracts commonly used in herbal drug industry by TLC/HPTLC.	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	2	Assignments/ Internals/Viva
PO2:	Planning Abilities	1	Assignments/ Internals
PO3:	Conduct Investigations of Complex Problems	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	1	2	1	2	2	2	2	2	1	2	2
CO2	1	2	2	2	2	1	1	1	2	2	1	2
CO3	2	2	2	2	2	1	2	1	2	2	1	2
CO4	1	1	2	2	2	1	2	1	2	2	2	2
CO5	2	1	1	2	2	2	2	2	2	2	2	2
Avg	1.6	1.4	1.8	1.8	2	1.4	1.8	1.4	2	1.8	1.6	2

Course Content

MPG 105P: PHARMACOGNOSY PRACTICAL –I

9 Hours / Week

1. Methods of extraction, phytochemical screening monograph analysis of pharmacopial compounds.
2. Formulation of herbal powders, tablets, lotions, liniments, ointments, pastes, creams, gels and their quality testing.
3. Identification and estimation of bioactive phytochemicals in natural substances and their formulations by PC, TLC, UV-VIS, HPLC, HPTLC methods.
4. Analysis of recorded MS, IR and NMR spectra of simple phytoconstituents. Estimation of sodium/potassium by flame photometry, development of fingerprint profile of selected medicinal plant extracts commonly used in herbal drug industry by TLC/HPTLC.

Recommended Books: (Latest Editions)

1. Glimpses of Indian Ethano Pharmacology by P. Pushpangadam. UlfNyman. V.George Tropical Botanic Garden & Research Institute.
2. Natural products: A lab guide by Raphael Ikan, Academic Press.
3. Pharmacognosy - G. E. Trease and W.C. Evans. WB. SaundersEdinburgh, New York.
4. Pharmacognosy-Tyler, Brady, Robbers, Lee &Fetiger.
5. Modern Methods of Plant Analysis- Peach & M.V. Tracey, Vol. I & II, Springer Publishers.
6. Herbal Drug Industry by RD. Choudhary, Eastern Publishers, New Delhi.
7. Text book of Pharmacognosy by C.K.Kokate, Purohit, Ghokhale, NiraliPrakashan.
8. Text Book of Pharmacognosy by T.E. Wallis, J & A Churchill Ltd., London.
9. Quality control of herbal drugs by Pulok K Mukherjee, Business HorizonsPharmaceutical Publishers, New Delhi.
10. Indian Herbal Pharmacopoeia, IDMA, Mumbai.
11. Text book of Pharmacognosy and Phytochemistry by Vinod D. RangarI,Part I & II, Career Publication, Nasik, India.
12. Plant drug analysis by H.Wagner and S.Bladt, 2nd edition, Springer, Berlin.
13. Standardization of Botanicals. Testing and extraction methods of medicinalherbs by V. Rajpal (2004), Vol.I, Eastern PublisherS, New Delhi.
14. Herbal Medicine. Expanded Commission E Monographs, M.Blumenthal.

MPG 201T- MEDICINAL PLANT BIOTECHNOLOGY

Credits: T- 4, P-2

Sessional Marks: 25 (T), 15(P)

L: T: P- 3:1:4

University Exams: 75 (T),35(P)

Course objectives

This course deals with the advances in the field of cultivation and isolation of drugs of natural origin, various phytopharmaceuticals, nutraceuticals and their medicinal use and health benefits.

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

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

- Know the process like genetic engineering in medicinal plants for higher yield of Phytopharmaceuticals.
- Use the biotechnological techniques for obtaining and improving the quality of natural products/medicinal plants.

Course outcomes

S.No	Course Outcomes	Knowledge level (BLOOMS Level)
After successful completion of the course student shall be able to explain		
CO1:	Production of various phytochemicals of pharmaceutical importance by Plant Tissue Culture using Callus culture, Suspension culture, hairy root culture, multiple shoot culture, immobilized plant cell culture, biotransformation reactions.	L1:Remember L2:Understand L3: Apply
CO2:	Applications of somatic embryogenesis, effect of precursors and elicitors on phytochemical production, micropropagation of endangered Medicinal and Aromatic plants.	L3: Apply L4: Analyse L5: Evaluate
CO3:	rDNA technology, PCR for improving the quality of medicinal plants.	L3: Apply L4: Analyse L5: Evaluate
CO4:	DNA fingerprinting of herbs and PCR in plant genome analysis.	L2:Understand L3: Apply L4: Analyse
CO5:	Applications of fermentation technology in the production of phytochemicals of pharmaceutical significance.	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	2	Assignments/ Internals/Viva
PO2:	Planning Abilities	1	Assignments/ Internals
PO3:	Conduct Investigations of Complex Problems	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	1	2	2	2	2	2	2	2	1	2	2
CO2	1	2	2	1	2	1	1	1	2	2	1	2
CO3	2	2	1	2	2	1	2	1	2	2	2	1
CO4	2	1	2	2	2	2	2	2	2	1	2	2
CO5	1	1	2	2	2	1	2	1	1	2	2	2
Avg	1.6	1.4	1.8	1.8	2	1.4	1.8	1.4	1.8	1.6	1.8	1.8

Course Content:

THEORY

60Hrs

1. Introduction to Plant biotechnology: Historical perspectives, prospects for development of plant biotechnology as a source of medicinal agents. Applications in pharmacy and allied fields. Genetic and molecular biology as applied to Pharmacognosy, study of DNA, RNA and protein replication, genetic code, regulation of gene expression, structure and complicity of genome, cell signaling, DNA recombinant technology. **12Hrs**

2. Different tissue culture techniques: Organogenesis and embryogenesis, synthetic seed and monoclonal variation, Protoplast fusion, Hairy root culture, multiple shoot culture and their applications. Micro propagation of medicinal and aromatic plants. Sterilization methods involved in tissue culture, gene transfer in plants and their applications. **15Hrs**

3. Immobilisation techniques & Secondary Metabolite Production: Immobilization techniques of plant cell and its application on secondary metabolite Production. Cloning of plant cell: Different methods of cloning and its applications. Advantages and disadvantages of plant cell cloning. Secondary metabolism in tissue cultures with emphasis on production of medicinal agents. Precursors and elicitors on production of secondary metabolites. **15Hrs**

4 . Biotransformation and Transgenesis: Biotransformation, bioreactors for pilot and large scale cultures of plant cells and retention of biosynthetic potential in cell culture. Transgenic plants, methods used in gene identification, localization and sequencing of genes. Application of PCR in plant genome analysis. **13Hrs**

5. Fermentation technology: Applications of Fermentation technology, Production of ergot alkaloids, single cell proteins, enzymes of pharmaceutical interest. **05Hrs**

Recommended Books: (Latest Editions)

1. Plant tissue culture, Bhagwani, vol 5, Elsevier Publishers.
2. Plant cell and Tissue Culture (Lab. Manual), JRMM. Yeoman.
3. Elements in biotechnology by PK. Gupta, Rastogi Publications, New Delhi.
4. An introduction to plant tissue culture by MK. Razdan, Science Publishers.
5. Experiments in plant tissue culture by John HD and Lorin WR., Cambridge University Press.
6. Pharmaceutical biotechnology by SP. Vyas and VK. Dixit, CBS Publishers.
7. Plant cell and tissue culture by Jeffrey W. Pollard and John M Walker, Humana press.
8. Plant tissue culture by Dixon, Oxford Press, Washington DC, 1985
9. Plant tissue culture by Street.
10. Pharmacognosy by G. E. Trease and WC. Evans, Elsevier.
11. Biotechnology by Purohit and Mathur, Agro-Bio, 3rd revised edition.
12. Biotechnological applications to tissue culture by Shargool, Peter D, Shargoal, CKC Press.
13. Pharmacognosy by Varo E. Tyler, Lynn R. Brady and James E. Robberbt, That Tjen, NGO.
14. Plant Biotechnology, CiddiVeerasham.

II Semester
MPG 201T: MEDICINAL PLANT BIOTECHNOLOGY

CO1: Basic concepts, applications of Medicinal plant biotechnology, plant genetics and molecular biology and rDNA technology for producing improved quality of medicines and medicinal plants.

CO2: Basic principles of different tissue culture techniques, gene transfer and applications.

CO3: Secondary metabolite production, immobilization technique and applications of cloning.

CO4: Biotransformation, bioreactors, Transgenic plants, methods used in gene identification, Localization sequencing of genes. Application of PCR in plant genome analysis.

CO5: Basic concepts, techniques and applications of Fermentation technology, production of Pharmaceutically interest products.

Course Outcomes and Program Outcomes (CO-PO) Mapping

Course Outcome	Program Outcomes					
	PO1	PO2	PO3	PO4	PO5	PO6
CO1	3	2	1	1	2	3
CO2	3	3	1	1	2	3
CO3	3	3	3	3	3	3
CO4	3	3	3	3	3	3
CO5	3	2	2	2	2	3
Average	3	2.6	2	2	2.4	3

Level1- slight (Low), Level 2- Moderate (Medium), Level 3- Substantial (High)

MPG 203T: INDIAN SYSTEMS OF MEDICINE

CO1: Fundamental concepts of Indian Systems of Medicines and evaluation of different ISM formulations.

CO2: Basic principles and treatment modalities of Naturopathy, Yoga and Aromatherapy.

CO3: Development and evaluation of ISM formulations.

CO4: GAP, GLP, GMP and Quality assurance, clinical research of ISM formulations, Challenges in monitoring the safety of herbal medicines.

CO5: AYUSH bills, TKDL, ISM Central research councils.

Course Outcomes and Program Outcomes (CO-PO) Mapping

Course Outcome	Program Outcomes					
	PO1	PO2	PO3	PO4	PO5	PO6
CO1	3	2	1	1	2	3
CO2	3	3	2	3	2	3
CO3	3	3	3	3	3	3
CO4	3	3	3	3	3	3
CO5	3	2	3	3	3	3
Average	3	2.6	2.4	2.6	2.6	3

Level1- slight (Low), Level 2- Moderate (Medium), Level 3- Substantial (High)

MPG 202T: ADVANCED PHARMACOGNOSY - II

Credits: T- 4, P-2

Sessional Marks: 25 (T), 15(P)

L: T: P- 3:1:4

University Exams: 75 (T), 35(P)

Course objectives

This course deals with the Adulteration and Deterioration that occurs in herbal/natural drugs and methods of detection of the same. Study of herbal remedies and their validations, including methods of screening

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

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

Course outcomes

S.No	Course Outcomes	Knowledge level (BLOOMS Level)
After successful completion of the course student shall be able to explain		
CO1:	Efficacy of Herbal products and validation of herbal therapies, Pharmacodynamic and Pharmacokinetic issues of Herbal remedies.	L1:Remember L2:Understand L3: Apply
CO2:	Identification and quality assessment of Crude drugs and detection of type of adulteration and type of adulterants in crude drugs.DNA Finger printing techniques for the identification of drugs of natural origin and detection of deterioration.	L3: Apply L4: Analyse L5: Evaluate
CO3:	Impact of Ethnobotany in traditional medicine, Bio-prospecting tools for drug discovery and role of Ethnopharmacology in drug evaluation	L3: Apply L4: Analyse L5: Evaluate
CO4:	Insight into the analytical profiles of various herbal drugs.	L2:Understand L3: Apply L4: Analyse
CO5:	New Strategies and need for Phyto-Pharmacological Screening of herbal drugs, In vitro and In vivo evaluation techniques for various drugs and Toxicity studies as per OECD guidelines.	L2:Understand 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	2	Assignments/ Internals/Viva
PO2:	Planning Abilities	1	Assignments/ Internals
PO3:	Conduct Investigations of Complex Problems	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	1	2	1	2	2	2	2	2	1	2	2
CO2	1	2	2	2	2	1	1	1	2	2	1	1
CO3	2	2	2	2	2	1	2	1	2	2	1	2
CO4	2	2	2	2	2	1	2	1	2	2	2	2
CO5	2	1	1	2	2	2	2	2	2	2	2	2
Avg	2	1.6	1.8	1.8	2	1.4	1.8	1.4	2	1.8	1.6	1.8

Course Content:

THEORY

60 Hrs

1. Herbal remedies – Toxicity and Regulations: Herbals vs Conventional drugs, Efficacy of Herbal medicine products, Validation of herbal therapies, Pharmacodynamic and Pharmacokinetic issues. **12Hrs**

2. Adulteration and Deterioration: Introduction, Types of Adulteration/ Substitution of Herbal drugs, Causes and Measures of Adulteration, Sampling Procedures, Determination of Foreign Matter, DNA Finger printing techniques in identification of drugs of natural origin, detection of heavy metals, pesticide residues, phytotoxin, microbial contamination in herbs and their formulations. **12Hrs**

3 Ethnobotany and Ethnopharmacology: Ethnobotany in herbal drug evaluation, Impact of Ethnobotany in traditional medicine, new development in herbals, Bio-prospecting tools for drug discovery, Role of Ethnopharmacology in drug evaluation, Reverse Pharmacology. **12Hrs**

4 Analytical Profiles of herbal drugs: *Andrographispaniculata, Boswelliaserata, Coleus forskholii, Curcuma longa, Embelicaofficinalis, Psoraleacorylifolia.* **12Hrs**

5 Biological screening of herbal drugs: Introduction and Need for Phyto-Pharmacological Screening, New Strategies for evaluating. Natural Products, In vitro evaluation techniques for Antioxidants, Antimicrobial and Anticancer drugs. In vivo evaluation techniques for Anti-inflammatory, Antiulcer, Anticancer, Wound healing, Antidiabetic, Hepatoprotective, Cardio protective, Diuretics and Antifertility, Toxicity studies as per OECD guidelines. **12Hrs**

MPG 203T: INDIAN SYSTEMS OF MEDICINE

Credits: T- 4, P-2

Sessional Marks: 25 (T), 15(P)

L: T: P- 3:1:4

University Exams: 75 (T), 35(P)

Course objectives

This course deals with the study of preparation and standardization of herbal/natural cosmetics. This subject gives emphasis on various national and international standards prescribed regarding herbal cosmeceuticals.

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

- To understand the basic principles of various Indian systems of medicine
- To know the clinical research of traditional medicines, Current Good Manufacturing Practice of Indian systems of medicine and their formulations.

Course outcomes

S.No	Course Outcomes	Knowledge level (BLOOMS Level)
After successful completion of the course student shall be able to explain		
CO1:	Indian systems of medicine (AYUSH) as alternative health care management for better health.	L1:Remember L2:Understand L3: Apply
CO2:	Principles, preparation methods, cGMP , quality assessment methods, standardization, shelf life of Ayurveda, Siddha, Homeopathy and Unani formulations.	L3: Apply L4: Analyse L5: Evaluate
CO3:	Clinical research on traditional medicines, quality assurance, challenges in monitoring the safety of herbal medicines.	L3: Apply L4: Analyse L5: Evaluate
CO4:	Aromatherapy methods, Naturopathy modes of treatment and Yoga procedures for improved quality of life	L2:Understand L3: Apply L4: Analyse
CO5:	Traditional Knowledge Digital Library (TKDL), Geographical Indications Bill, Government bills in AYUSH, Central Council for Research in Ayurvedic Sciences, Central Council for Research in Siddha, Central Council for Research in Homeopathy, Central Council for Research in Unani medicine.	L2:Understand 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	2	Assignments/ Internals/Viva
PO2:	Planning Abilities	1	Assignments/ Internals
PO3:	Conduct Investigations of Complex Problems	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	1	2	1	2	2	2	2	2	1	2	2
CO2	1	2	2	2	1	1	1	1	2	2	1	1
CO3	2	2	2	2	2	1	2	1	2	2	1	2
CO4	2	2	2	2	1	1	2	1	2	2	2	2
CO5	2	1	1	2	2	2	2	2	2	2	2	1
Avg	1.8	1.6	1.8	1.8	1.6	1.4	1.8	1.4	2	1.8	1.6	1.6

Course Content:

THEORY

60 Hrs

1. Fundamental concepts of Ayurveda, Siddha, Unani and Homoeopathy systems of medicine
Different dosage forms of the ISM.

Ayurveda: Ayurvedic Pharmacopoeia, Analysis of formulations and bio crude drugs with references to:
Identity, purity and quality.

Siddha: Gunapadam (Siddha Pharmacology), raw drugs/Dhatu/Jeevam in Siddha system of medicine,
Purification process (Suddhi). **12Hrs**

2 Naturopathy, Yoga and Aromatherapy practices
a) Naturopathy - Introduction, basic principles and treatment modalities.

b) Yoga - Introduction and Streams of Yoga. Asanas, Pranayama, Meditations and Relaxation techniques.

c) Aromatherapy – Introduction, aroma oils for common problems, carrier oils. **12Hrs**

3. Formulation development of various systems of medicine
Salient features of the techniques of preparation of some of the important classes of Formulations as per Ayurveda, Siddha, Homeopathy and Unani Pharmacopoeia and texts. Standardization, Shelf life and Stability studies of ISM formulations. **12Hrs**

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

Quality assurance in ISM formulation industry - GAP, GMP and GLP. Preparation of documents for new drug application and export registration.

Challenges in monitoring the safety of herbal medicines: Regulation, quality assurance and control, National/Regional Pharmacopoeias. **12Hrs**

5. Traditional Knowledge Digital Library (TKDL), Geographical Indications Bill, Government bills in Ayurveda, Yoga and Naturopathy, Unani, Siddha and Homeopathy (AYUSH), Indian Systems of Medicine (ISM), Central Council for Research in Ayurvedic Sciences (CCRAS), Central Council for Research in Siddha (CCRS), Central Council for Research in Homeopathy (CCRH), Central Council for Research in Unani medicine (CCRU) **12Hrs**

REFERENCES (Latest Editions of)

1. Ayurvedic Pharmacopoeia, The Controller of Publications, Civil Lines, Govt. of India, New Delhi.

2. Hand Book on Ayurvedic Medicines, H. Panda, National Institute of Industrial Research, New Delhi.

3. Ayurvedic System of Medicine, Kaviraj Nagendranath Sengupta, Sri Satguru Publications, New Delhi.

4. Ayurvedic Pharmacopoeia. Formulary of Ayurvedic Medicines, IMCOPS, Chennai.

5. Homeopathic Pharmacopoeia. Formulary of Homeopathic Medicines, IMCOPS, Chennai.

6. Homeopathic Pharmacy: An introduction & Hand book, Steven B. Kayne, Churchill Livingstone, New York.

7. Indian Herbal Pharmacopoeia, IDMA, Mumbai.

8. British Herbal Pharmacopoeia, British Herbal Medicine Association, UK.

9. GMP for Botanicals - Regulatory and Quality issues on Phytomedicine, Pulok K Mukharjee, Business Horizons, New Delhi.

10. Indian System of Medicine and Homeopathy in India, Planning and Evaluation Cell, Govt. of India, New Delhi.

11. Essential of Food and Nutrition, Swaminathan, Bappco, Bangalore.

MPG 204T: HERBAL COSMETICS

Credits: T- 4, P-2

Sessional Marks: 25 (T), 15(P)

L: T: P- 3:1:4

University Exams: 75 (T),35(P)

Course objectives

This course deals with the study of preparation and standardization of herbal/natural cosmetics. This subject gives emphasis on various national and international standards prescribed regarding herbal cosmeceuticals.

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

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

Course outcomes

S.No	Course Outcomes	Knowledge level (BLOOMS Level)
After successful completion of the course student shall be able to explain		
CO1:	Basic principles, preparation, standardization and evaluation methods of herbal/natural cosmetics including cGMP as per the Regulatory requirements.	L1:Remember L2:Understand L3: Apply
CO2:	Design of herbal cosmetic formulations and their pre-formulation and compatibility studies.	L3: Apply L4: Analyse L5: Evaluate
CO3:	Preparation and standardization of various herbal cosmetics. Herbal Cosmetic industries and their products, formulation of herbal cosmetic formulations for skin, nail, lips, hair, face, body and for oral hygiene, pre-formulation, compatibility studies, possible interactions between chemicals and herbs.	L3: Apply L4: Analyse L5: Evaluate
CO4:	Insight into various cosmeceuticals of herbal and natural origin applied for hair and skin.	L2:Understand L3: Apply L4: Analyse
CO5:	Quality control and toxicity studies as per Drugs and Cosmetics Act.	L2:Understand 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	2	Assignments/ Internals/Viva
PO2:	Planning Abilities	1	Assignments/ Internals
PO3:	Conduct Investigations of Complex Problems	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	1	2	1	2	2	2	2	2	1	2	2
CO2	1	2	2	2	2	1	1	1	2	2	1	1
CO3	2	2	2	2	2	1	2	1	2	2	1	2
CO4	2	2	2	2	1	1	2	1	2	2	2	2
CO5	2	1	1	2	2	2	2	2	2	2	2	2
Avg	1.8	1.6	1.8	1.8	1.8	1.4	1.8	1.4	2	1.8	1.6	1.8

Course Content:

THEORY 60 Hrs

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

Regulatory Provisions relation to manufacture of cosmetics: -License, GMP, offences & Penalties, Import & Export of Herbal/natural cosmetics, Industries involved in the production of Herbal/natural cosmetics. **12Hrs**

2. Commonly used herbal cosmetics, raw materials, preservatives, surfactants, humectants, oils, colors, and some functional herbs, preformulation studies, compatibility studies, possible interactions between chemicals and herbs, design of herbal cosmetic formulations. **12Hrs**

3. Herbal Cosmetics : Physiology and chemistry of skin and pigmentation, hairs, scalp, lips and nail, Cleansing cream, Lotions, Face powders, Face packs, Lipsticks, Bath products, soaps and baby product, Preparation and standardisation of the following :

Tonic, Bleaches, Dentifrices and Mouth washes & Tooth Pastes, Cosmetics for Nails. **12Hrs**

4. Cosmeceuticals of herbal and natural origin: Hair growth formulations, Shampoos, Conditioners, Colorants & hair oils, Fairness formulations, vanishing & foundation creams, anti-sunburn preparations, moisturizing creams, deodorants. **12Hrs**

5. Analysis of Cosmetics, Toxicity screening and test methods: Quality control and toxicity studies as per Drugs and Cosmetics Act. **12Hrs**

MPG 205P: PHARMACOGNOSY PRACTICAL –II

Course outcomes

S.No	Course Outcomes	Knowledge level (BLOOMS Level)
After successful completion of the course student shall be able to explain		
CO1:	Isolation of DNA from plants, Isolation of RNA from yeast, Quantitative estimation of DNA, Establishment of callus culture, suspension culture, Immobilized cell culture.	L1:Remember L2:Understand L3: Apply
CO2:	Estimation of aldehyde contents of volatile oils, Estimation of total phenolic content, total alkaloid content, total flavonoid content of herbal raw materials.	L3: Apply L4: Analyse L5: Evaluate
CO3:	Preparation and standardization of simple dosage forms from Ayurvedic, Siddha, Homoeopathy and Unani formulary.	L3: Apply L4: Analyse L5: Evaluate
CO4:	Preparation of herbal cosmetics such as lip balm, lipstick, facial cream, herbal hair and nail care products.	L2:Understand L3: Apply L4: Analyse
CO5:	Preparation of Aromatherapy formulations using carrier oils and aromatic oils. Preparation of sunscreen, UV protection cream, skin care formulations	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	2	Assignments/ Internals/Viva
PO2:	Planning Abilities	1	Assignments/ Internals
PO3:	Conduct Investigations of Complex Problems	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	1	2	1	2	2	2	2	2	1	2	2
CO2	1	2	2	2	2	1	1	1	2	2	1	2
CO3	2	2	2	2	2	1	2	1	2	2	1	2
CO4	1	1	2	2	2	1	2	1	2	2	2	2
CO5	2	1	1	2	2	2	2	2	2	2	2	2
Avg	1.6	1.4	1.8	1.8	2	1.4	1.8	1.4	2	1.8	1.6	2

Course Content

MPG 205P: PHARMACOGNOSY PRACTICAL –II

9 Hours / Week

1. Methods of extraction, phytochemical screening monograph analysis of pharmacopeial compounds.
2. Formulation of herbal powders, tablets, lotions, liniments, ointments, pastes, creams, gels and their quality testing.
3. Identification and estimation of bioactive phytochemicals in natural substances and their formulations by PC, TLC, UV-VIS, HPLC, HPTLC methods.
4. Analysis of recorded MS, IR and NMR spectra of simple phytoconstituents. Estimation of sodium/potassium by flame photometry, development of fingerprint profile of selected medicinal plant extracts commonly used in herbal drug industry by TLC/HPTLC.

Recommended Books: (Latest Editions)

1. Glimpses of Indian Ethano Pharmacology by P. Pushpangadam. Ulf Nyman. V.George Tropical Botanic Garden & Research Institute.
2. Natural products: A lab guide by Raphael Ikan, Academic Press.
3. Pharmacognosy - G. E. Trease and W.C. Evans. WB. Saunders Edinburgh, New York.
4. Pharmacognosy-Tyler, Brady, Robbers, Lee &Fetiger.
5. Modern Methods of Plant Analysis- Peach & M.V. Tracey, Vol. I & II, Springer Publishers.
6. Herbal Drug Industry by RD. Choudhary, Eastern Publishers, New Delhi.
7. Text book of Pharmacognosy by C.K.Kokate, Purohit, Ghokhale, NiraliPrakashan.
8. Text Book of Pharmacognosy by T.E. Wallis, J & A Churchill Ltd., London.
9. Quality control of herbal drugs by Pulok K Mukherjee, Business Horizons Pharmaceutical Publishers, New Delhi.
10. Indian Herbal Pharmacopoeia, IDMA, Mumbai.
11. Text book of Pharmacognosy and Phytochemistry by Vinod D. RangarI, Part I & II, Career Publication, Nasik, India.
12. Plant drug analysis by H.Wagner and S.Bladt, 2nd edition, Springer, Berlin.
13. Standardization of Botanicals. Testing and extraction methods of medicinal herbs by V. Rajpal (2004), Vol.I, Eastern PublisherS, New Delhi.
14. Herbal Medicine. Expanded Commission E Monographs, M.Blumenthal.

MRM 301T - Research Methodology & Biostatistics

Credits: T- 4

Sessional Marks: 25 (T)

L:T -

University Exams: 75 (T)

- Develop the ability to apply the methods while working on a research project work.
- Describe the appropriate statistical methods required for a particular research design.
- Helps to choose the appropriate research design and develop appropriate research hypothesis for a research project. Develops an appropriate framework for research studies.
- Helps to perform suitable descriptive statistics in a given situation.
- Guides to identify suitable statistical test procedures for a given data set.
- Provides guidance about how to perform literature searches and systematic reviews.
- Improves skills in developing a research protocol and in differentiating quantitative and qualitative research methods.
- Demonstrates how to perform statistical procedures using statistical software for a given data set.

Course outcomes

S.No	Course Outcomes	Knowledge level (BLOOMS Level)
After successful completion of the course student shall be able to		
CO1:	Understand the fundamentals of research methodology and imparts ability to apply the methods while working on a research project work	L1: Remember L2: Understand L3: Apply L4: Analyse L5: Evaluate
CO2:	Gain imperative knowledge on the concepts in Biostatics like sample size, hypothesis testing, regression analysis and apply the appropriate statistical methods required for a particular research design	L3: Apply L4: Analyse L5: Evaluate
CO3:	Expands the knowledge on Parametric and Non parametric tests and their application in research projects in Pharmacy	L3: Apply L4: Analyse L5: Evaluate
CO4:	Understand the values of medical ethics and the basic ethical concepts in Human and medical research	L2: Understand L3: Apply L4: Analyse L5: Evaluate
CO5:	Understand and apply the CPCSEA guidelines for laboratory animal facility	L2: Understand 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	2	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	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	2	3	3	3	3	2	3	2	3	3	3	3
CO2	3	2	2	3	3	3	3	3	3	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	3	3	3	3	3	3	3	3	3	3	2	3
Avg	2.8	2.8	2.8	3	3	2.8	3	2.8	3	2.8	2.6	3

