



Dated: 24.07.2020

MINUTES OF THE MEETING OF BOARD OF STUDIES

The meeting of the Board of Studies in Pharmaceutical Sciences, was scheduled on 24.07.2020 at 11:30 AM by online Google meet at Institute of Pharmaceutical Sciences, Guru Ghasidas Vishwavidyalaya, Bilaspur. The following members were present for the online Google meet.

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|---------------------------|---|------------------------|
| 1. Prof. Vinod D. Rangari | - | Chair Person |
| 2. Prof. Moorthy N.S.H.N. | - | External Expert Member |
| 3. Dr. K.P. Namdev | - | Member |
| 4. Dr. K.P. Meena | - | Member |

Agenda: Approval for the adoption of the New PCI syllabus for M. Pharm. Courses: -

- (1) Pharmaceutics (2) Pharmaceutical Chemistry (3) Pharmacology and
(4) Pharmacognosy from Academic Session 2020-21.

Recommendation:

Pharmacy Council of India, New Delhi has made it mandatory to adopt the New M. Pharm. Syllabus for the courses run by all the University Departments, Government & Private Institutions. The committee discussed the issue in details.

The committee recommended the adoption of the New M. Pharm. Syllabus for all the M. Pharm. Courses run by the Pharmacy Department, namely (1) Pharmaceutics (2) Pharmaceutical Chemistry (3) Pharmacology and (4) Pharmacognosy, from the academic session 2020-21 and onward.

The committee further recommended to adopt the changes if any, made in the syllabus of all the above M. Pharm. Courses by Pharmacy Council of India in future and so communicated for their adoption from time to time.

List of New courses introduced for M. Pharm. from the academic year 2020-2021 and onward shall be as follows.

M. Pharm. (Pharmaceutics) [2020-21]

MPH101T	Modern Pharmaceutical Analytical Techniques
MPH102T	Drug Delivery System
MPH103T	Modern Pharmaceutics
MPH104T	Regulatory Affair
MPH105P	Pharmaceutics Practical I
MPH106P	Seminar/Assignment
MPH201T	Molecular Pharmaceutics (Nano Tech and Targeted DDS)
MPH202T	Advanced Biopharmaceutics & Pharmacokinetics
MPH203T	Computer Aided Drug Delivery System
MPH204T	Cosmetic and Cosmeceuticals
MPH205P	Pharmaceutics Practical II
MPH206P	Seminar/Assignment

M. Pharm. (Pharmaceutical Chemistry) [2020-21]

MPC101T	Modern Pharmaceutical Analytical Techniques
MPC1012T	Advanced Organic Chemistry -I
MPC103T	Advanced Medicinal chemistry
MPC104T	Chemistry of Natural Products

MPC105P	Pharmaceutical Chemistry Practical I
MPC106P	Seminar/Assignment
MPC201T	Advanced Spectral Analysis
MPC202T	Advanced Organic Chemistry -II
MPC203T	Computer Aided Drug Design
MPC204T	Pharmaceutical Process Chemistry
MPC205P	Pharmaceutical Chemistry Practical II
MPC206P	Seminar/Assignment

M. Pharm. (Pharmacology) [2020-21]

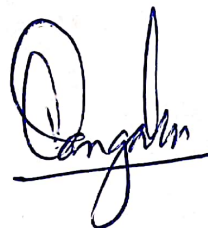
MPL101T	Modern Pharmaceutical Analytical Techniques
MPL102T	Advanced Pharmacology-I
MPL103T	Pharmacological and Toxicological Screening Methods-I
MPL104T	Cellular and Molecular Pharmacology
MPL105P	Pharmacology Practical I
MPL106P	Seminar/Assignment
MPL201T	Advanced Pharmacology II
MPL202T	Pharmacological and Toxicological Screening Methods-II
MPL203T	Principles of Drug Discovery
MPL204T	Clinical Research and Pharmacovigilance
MPL205P	Pharmacology Practical II
MPL206P	Seminar/Assignment

M. Pharm. (Pharmacognosy) [2020-21]

MPG101T	Modern Pharmaceutical Analytical Techniques
MPG102T	Advanced Pharmacognosy-1
MPG103T	Phytochemistry
MPG104T	Industrial Pharmacognostical Technology
MPG105P	Pharmacognosy Practical I
MPG106P	Seminar/Assignment
MPG201T	Medicinal Plant biotechnology
MPG102T	Advanced Pharmacognosy-II
MPG203T	Indian system of medicine
MPG204T	Herbal cosmetics
MPG205P	Pharmacognosy Practical II
MPG206P	Seminar/Assignment

M. Pharm. (All Specializations) [2021-22]

MRM301T	Research Methodology and Biostatistics
MRM302P	Journal Club
MRM303P	Discussion/ Presentation (Proposal Presentation)
MRM304P	Research work
MRM401P	Journal Club
MRM402P	Discussion/ Presentation (Proposal Presentation)
MRM403P	Research Work



HEAD
S.L.T. Institute of Pharm. Sciences
Guru Ghasidas Vishwavidyalaya,
Bilaspur (C.G.)



Scheme and Syllabus

M. Pharm. (Pharmaceutics)

Course Code	Course	Credit Hours	Credit Points	Hrs./w k	Marks
Semester I					
MPH101T	Modern Pharmaceutical Analytical Techniques	4	4	4	100
MPH102T	Drug Delivery System	4	4	4	100
MPH103T	Modern Pharmaceutics	4	4	4	100
MPH104T	Regulatory Affair	4	4	4	100
MPH105P	Pharmaceutics Practical I	12	6	12	150
MPH106P	Seminar/Assignment	7	4	7	100
	Total	35	26	35	650
Semester II					
MPH 201T	Molecular Pharmaceutics (Nano Tech and Targeted DDS)	4	4	4	100
MPH 202T	Advanced Biopharmaceutics & Pharmacokinetics	4	4	4	100
MPH 203T	Computer Aided Drug Delivery System	4	4	4	100
MPH204T	Cosmetic and Cosmeceuticals	4	4	4	100
MPH 205P	Pharmaceutics Practical II	12	6	12	150
MPH 206P	Seminar/Assignment	7	4	7	100
	Total	35	26	35	650



PHARMACEUTICS (MPH)
FIRST SEMESTER

MODERN PHARMACEUTICAL ANALYTICAL TECHNIQUES
(MPH 101T)

Scope

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

Objectives

After completion of course student is able to know, Chemicals and Excipients

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

THEORY

60 HOURS

1. a. UV-Visible spectroscopy: Introduction, Theory, Laws, Instrumentation associated with UV-Visible spectroscopy. Choice of solvents and solvent effect and Applications of UV-Visible spectroscopy. 11 Hrs
- b. IR spectroscopy: Theory, Modes of Molecular vibrations, Sample handling, Instrumentation of Dispersive and Fourier - Transform IR Spectrometer, Factors affecting vibrational frequencies and Applications of IR spectroscopy.
- c. Spectrofluorimetry: Theory of Fluorescence, Factors affecting fluorescence, Quenchers, Instrumentation and Applications of fluorescence spectrophotometer.
- d. Flame emission spectroscopy and Atomic absorption spectroscopy: Principle, Instrumentation Interference and Applications.
2. NMR spectroscopy: Quantum numbers and their role in NMR, Principle, Instrumentation, Solvent requirement in NMR, Relaxation process, NMR signals in various compounds, Chemical shift, Factors influencing chemical shift, Spin-Spin coupling, Coupling constant, Nuclear magnetic double resonance, Brief outline of principles of FT-NMR and ¹³C NMR. Applications of NMR spectroscopy. 11 Hrs
3. Mass Spectroscopy: Principle, Theory, Instrumentation of Mass Spectroscopy, Different types of ionization like electron impact, chemical, field, FAB and MALDI, APCI, ESI, APPI Analyzers of Quadrupole and Time of Flight, Mass fragmentation and its rules, Meta stable ions, Isotopic peaks and Applications of Mass spectroscopy 11 Hrs
4. Chromatography: Principle, apparatus, instrumentation, chromatographic parameters, factors affecting resolution and applications of the following: 11 Hrs
 - a) Paper chromatography
 - b) Thin Layer chromatography
 - c) Ion exchange chromatography
 - d) Column chromatography
 - e) Gas chromatography
 - f) High Performance Liquid chromatography
 - g) Affinity chromatography



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|---|---|-----------|
| 5 | a. Electrophoresis: Principle, Instrumentation, Working conditions, factors affecting separation and applications of the following:
a) Paper electrophoresis b) Gel electrophoresis c) Capillary electrophoresis d) Zone electrophoresis e) Moving boundary electrophoresis f) Iso electric focusing
b. X ray Crystallography: Production of X rays, Different X ray diffraction methods, Bragg's law, Rotating crystal technique, X ray powder technique, Types of crystals and applications of X-ray diffraction. | 11
Hrs |
| 6 | Immunological assays: RIA (Radio immuno assay), ELISA, Bioluminescence assays. | 5Hrs |

DRUG DELIVERY SYSTEMS (MPH 102T)

SCOPE

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

OBJECTIVES

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

The various approaches for development of novel drug delivery systems.

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

The formulation and evaluation of Novel drug delivery systems.

THEORY

60 Hrs

1. Sustained Release (SR) and Controlled Release (CR) formulations: Introduction & 10 basic concepts, advantages/disadvantages, factors influencing, Physicochemical & biological approaches for SR/CR formulation, Mechanism of Drug Delivery from SR/CR formulation. Polymers: introduction, definition, classification, properties and application Dosage Forms for Personalized Medicine: Introduction, Definition, Pharmacogenetics, Categories of Patients for Personalized Medicines: Customized drug delivery systems, Bioelectronic Medicines, 3D printing of pharmaceuticals, Telepharmacy. Hrs
2. Rate Controlled Drug Delivery Systems: Principles & Fundamentals, Types, 10 Activation; Modulated Drug Delivery Systems; Mechanically activated, pH activated, Enzyme activated, and Osmotic activated Drug Delivery Systems Hrs
Feedback regulated Drug Delivery Systems; Principles & Fundamentals.
3. Gastro-Retentive Drug Delivery Systems: Principle, concepts advantages and 10 disadvantages, Modulation of GI transit time approaches to extend GI transit. Hrs
Buccal Drug Delivery Systems: Principle of muco adhesion, advantages and disadvantages, Mechanism of drug permeation, Methods of formulation and its evaluations.



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



MODERN PHARMACEUTICS
(MPH 103T)

Scope

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

Objectives

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

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

THEORY

60

HRS

1. a. **Preformation Concepts** - Drug Excipient interactions - different methods, kinetics of stability, Stability testing. Theories of dispersion and pharmaceutical Dispersion (Emulsion and Suspension, SMEDDS) preparation and stability Large and small volume parental - physiological and formulation consideration, Manufacturing and evaluation. 10 Hrs
b. Optimization techniques in Pharmaceutical Formulation: Concept and parameters of optimization, Optimization techniques in pharmaceutical formulation and processing. Statistical design, Response surface method, Contour designs, Factorial designs and application in formulation
2. Validation: Introduction to Pharmaceutical Validation, Scope & merits of Validation, Validation and calibration of Master plan, ICH & WHO guidelines for calibration and validation of equipments, Validation of specific dosage form, Types of validation. Government regulation, Manufacturing Process Model, URS, DQ, IQ, OQ & P.Q. of facilities. 10 Hrs
3. **cGMP & Industrial Management:** Objectives and policies of current good manufacturing practices, layout of buildings, services, equipments and their maintenance Production management: Production organization, materials management, handling and transportation, inventory management and control, production and planning control, Sales forecasting, budget and cost control, industrial and personal relationship. Concept of Total Quality Management. 10 Hrs
4. Compression and compaction: Physics of tablet compression, consolidation, effect of friction, distribution of forces, compaction profiles. Solubility. 10 Hrs
5. Study of consolidation parameters; Diffusion parameters, Dissolution parameters and Pharmacokinetic parameters, Heckel Hrs plots, Similarity factors - f2 and f1, Higuchi and Peppas plot, Linearity Concept of significance, Standard deviation, Chi square test, students T-test, ANOVA test. 10 Hrs



REGULATORY AFFAIRS
(MPH 104T)

Scope

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

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

Objectives:

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

- The Concepts of innovator and generic drugs, drug development process
- The Regulatory guidance's and guidelines for filing and approval process
- reparation 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
- Pharmacovigilance and process of monitoring in clinical trials.

THEORY

60 Hrs

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



PHARMACEUTICS PRACTICALS - I
(MPH 105P)

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



PHARMACEUTICS (MPH)
SECOND SEMESTER

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

Scope

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

Objectives

Upon completion of the course student shall be able to understand

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

THEORY

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



**ADVANCED BIOPHARMACEUTICS & PHARMACOKINETICS
(MPH 202T)**

Scope

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

Objectives

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

THEORY

60 Hrs

1. Drug Absorption from the Gastrointestinal Tract: Gastrointestinal tract, 12 Hrs
Mechanism of drug absorption, Factors affecting drug absorption, pH-partition theory of drug absorption. Formulation and physicochemical factors: Dissolution rate, Dissolution process, Noyes-Whitney equation and drug dissolution, Factors affecting the dissolution rate. Gastrointestinal absorption: role of the dosage form: Solution (elixir, syrup and solution) as a dosage form, Suspension as a dosage form, Capsule as a dosage form, Tablet as a dosage form, Dissolution methods, Formulation and processing factors, Correlation of in vivo data with in vitro dissolution data. Transport model: Permeability-Solubility-Charge State and the pH Partition Hypothesis, Properties of the Gastrointestinal Tract (GIT), pH Microclimate Intracellular pH Environment, Tight-Junction Complex.
2. Biopharmaceutic considerations in drug product design 12 Hrs
and In Vitro Drug Product Performance: Introduction, biopharmaceutic factors affecting drug bioavailability, rate-limiting steps in drug absorption, physicochemical nature of the drug formulation factors affecting drug product performance, in vitro: dissolution and drug release testing, compendial methods of dissolution, alternative methods of dissolution testing, meeting dissolution requirements, problems of variable control in dissolution testing performance of drug products. In vitro-in vivo correlation, dissolution profile comparisons, drug product stability, considerations in the design of a drug product.
3. Pharmacokinetics: Basic considerations, pharmacokinetic models, 12 Hrs
compartment modeling: one compartment model- IV bolus, IV infusion,



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- extra-vascular. Multi compartment model two compartment - model in brief, non-linear pharmacokinetics: cause of non-linearity, Michaelis – Menten equation, estimation of k_{max} and v_{max} . Drug interactions: introduction, the effect of protein-binding interactions, the effect of tissue-binding interactions, cytochrome p450-based drug interactions, drug interactions linked to transporters.
- 4 Drug Product Performance, In Vivo: Bioavailability and 12
Bioequivalence: drug product performance, purpose of bioavailability Hrs
studies, relative and absolute availability. Methods for assessing
bioavailability, bioequivalence studies, design and evaluation of
bioequivalence studies, study designs, crossover study designs,
evaluation of the data, bioequivalence example, study submission and drug
review process. Biopharmaceutics classification system, methods.
Permeability: In-vitro, in-situ and In-vivo methods. generic biologics
(biosimilar drug products), clinical significance of bioequivalence
studies, special concerns in bioavailability and bioequivalence studies,
generic substitution.
- 5 Application of Pharmacokinetics: Modified-Release Drug Products, Targeted 12
Drug Delivery Systems and Biotechnological products. Introduction to Hrs
Pharmacokinetics and pharmacodynamic, drug interactions.
Pharmacokinetics and pharmacodynamics of biotechnology drugs.
Introduction, Proteins and peptides, Monoclonal antibodies,
Oligonucleotides, Vaccines (immunotherapy), Gene therapies.
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COMPUTER AIDED DRUG DEVELOPMENT (MPH 203T)

Scope

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

Objectives

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

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

THEORY

60 Hrs

1. a. **Computers in Pharmaceutical Research and Development:** A General Overview: History of Computers in Pharmaceutical Research and Development. Statistical modeling in Pharmaceutical research and development: Descriptive versus Mechanistic Modeling, Statistical Parameters, Estimation, Confidence Regions, Nonlinearity at the Optimum, Sensitivity Analysis, Optimal Design, Population Modeling. 12 Hrs
b. **Quality-by-Design In Pharmaceutical Development:** Introduction, ICH Q8 guideline, Regulatory and industry views on QbD, Scientifically based QbD - examples of application.
2. **Computational Modeling of Drug Disposition:** Introduction, Modeling Techniques: Drug Absorption, Solubility, Intestinal Permeation, Drug Distribution, Drug Excretion, Active Transport; P-gp, BCRP, Nucleoside Transporters, hPEPT1, ASBT, OCT, OATP, BBB-Choline Transporter. 12 Hrs
3. **Computer-aided formulation development::** Concept of optimization, Optimization parameters, Factorial design, Optimization technology & Screening design. Computers in Pharmaceutical Formulation: Development of pharmaceutical emulsions, microemulsion drug carriers Legal Protection of Innovative Uses of Computers in R&D, The Ethics of Computing in Pharmaceutical Research, Computers in Market analysis 12 Hrs
4. a. **Computer-aided biopharmaceutical characterization:** Gastrointestinal absorption simulation. Introduction, Theoretical background, Model construction, Parameter sensitivity analysis, Virtual trial, Fed vs. fasted state, In vitro dissolution and in vitro- in vivo correlation, Biowaiver 12 Hrs



considerations

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

COSMETICS AND COSMECEUTICALS (MPH 204T)

Scope

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

Objectives

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

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

THEORY

60 Hrs

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



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- Perfumes; Classification of perfumes. Perfume ingredients listed as allergens in EU regulation
- Controversial ingredients: Parabens, formaldehyde liberators, dioxane.
- 4 Design of cosmeceutical products: Sun protection, sunscreens classification and regulatory aspects. Addressing dry skin, acne, sun-protection, pigmentation, prickly heat, wrinkles, body odor, dandruff, dental cavities, bleeding gums, mouth odor and sensitive teeth through cosmeceutical formulations. 12 Hrs
- 5 Herbal Cosmetics: Herbal ingredients used in Hair care, skin care and oral care. Review of guidelines for herbal cosmetics by private bodies like cosmos with respect to preservatives, emollients, foaming agents, emulsifiers and rheology modifiers. Challenges in formulating herbal cosmetics. 12 Hrs
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PHARMACEUTICS PRACTICALS - II
(MPH 205P)

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



Scheme and Syllabus

M. Pharm. (Pharmaceutical Chemistry)

Course Code	Course	Credit Hours	Credit Points	Hrs./w k	Marks
Semester I					
MPC101T	Modern Pharmaceutical Analytical Techniques	4	4	4	100
MPC102T	Advanced Organic Chemistry - I	4	4	4	100
MPC103T	Advanced Medicinal chemistry	4	4	4	100
MPC104T	Chemistry of Natural Product	4	4	4	100
MPC105P	Pharmaceutical Chemistry Practical I	12	6	12	150
MPC106P	Seminar/Assignment	7	4	7	100
	Total	35	26	35	650
Semester II					
MPC201T	Advanced Spectral Analysis	4	4	4	100
MPC202T	Advanced Organic Chemistry -II	4	4	4	100
MPC203T	Computer Aided Drug Design	4	4	4	100
MPC204T	Pharmaceutical Process Chemistry	4	4	4	100
MPC205P	Pharmaceutical Chemistry Practical II	12	6	12	150
MPC206P	Seminar/Assignment	7	4	7	100
	Total	35	26	35	650



PHARMACEUTICAL CHEMISTRY (MPC)
FIRST SEMESTER

MODERN PHARMACEUTICAL ANALYTICAL TECHNIQUES
(MPC 101T)

Scope

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

Objectives

After completion of course student is able to know, Chemicals and Excipients

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

THEORY

60 Hrs

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



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- d) Column chromatography
e) Gas chromatography
f) High Performance Liquid chromatography
g) Ultra High Performance Liquid chromatography
h) Affinity chromatography
i) Gel Chromatography
- 5 a. Electrophoresis: Principle, Instrumentation, Working conditions, factors affecting separation and applications of the following: 10 Hrs
a) Paper electrophoresis b) Gel electrophoresis c) Capillary electrophoresis
d) Zone electrophoresis e) Moving boundary electrophoresis f) Iso electric focusing
b. X-ray Crystallography: Production of X rays, Different X ray methods, Bragg's law, Rotating crystal technique, X ray powder technique, Types of crystals and applications of X-ray diffraction.
- 6 a. Potentiometry: Principle, working, Ion selective Electrodes and Application of potentiometry. 10 Hrs
b. Thermal Techniques: Principle, thermal transitions and Instrumentation (Heat flux and power-compensation and designs), Modulated DSC, Hyper DSC, experimental parameters (sample preparation, experimental conditions, calibration, heating and cooling rates, resolution, source of errors) and their influence, advantage and disadvantages, pharmaceutical applications. Differential Thermal Analysis (DTA): Principle, instrumentation and advantage and disadvantages, pharmaceutical applications, derivative differential thermal analysis (DDTA). TGA: Principle, instrumentation, factors affecting results, advantage and disadvantages, pharmaceutical applications.
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ADVANCED ORGANIC CHEMISTRY - I
(MPC 102T)

Scope

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

Objectives

Upon completion of course, the student shall be to understand

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

THEORY

60 Hrs

- | | | |
|---|---|-----------|
| 1 | Basic Aspects of Organic Chemistry:
Organic intermediates: Carbocations, carbanions, free radicals, carbenes and nitrenes. Their method of formation, stability and synthetic applications.
Types of reaction mechanisms and methods of determining them,
Detailed knowledge regarding the reactions, mechanisms and their relative reactivity and orientations. | 12
Hrs |
| | Addition reactions | |
| | a) Nucleophilic uni- and bimolecular reactions (SN1 and SN2) | |
| | b) Elimination reactions (E1 & E2; Hoffman & Saytzeff's rule) | |
| | c) Rearrangement reaction | |
| 2 | Study of mechanism and synthetic applications of following named Reactions:
Ugi reaction, Brook rearrangement, Ullmann coupling reactions, Dieckmann Reaction, Doebner-Miller Reaction, Sandmeyer Reaction, Mitsunobu reaction, Mannich reaction, Vilsmeier-Haack Reaction, Sharpless asymmetric epoxidation, Baeyer-Villiger oxidation, Shapiro & Suzuki reaction, Ozonolysis and Michael addition reaction | 12
Hrs |
| 3 | Synthetic Reagents & Applications:
Aluminium isopropoxide, N-bromosuccinamide, diazomethane, dicyclohexylcarbodiimide, Wilkinson reagent, Wittig reagent. Osmium tetroxide, titanium chloride, diazopropane, diethyl azodicarboxylate, Triphenylphosphine, Benzotriazol-1-yloxy tris (dimethylamino) phosphonium hexafluoro-phosphate (BOP). | 12
Hrs |
| | Protecting groups | |
| | a. Role of protection in organic synthesis | |
| | b. Protection for the hydroxyl group, including 1,2- and 1,3-diols: ethers, | |



- esters, carbonates, cyclic acetals & ketals
- c. Protection for the Carbonyl Group: Acetals and Ketals
 - d. Protection for the Carboxyl Group: amides and hydrazides, esters
 - e. Protection for the Amino Group and Amino acids: carbamates and amides
- 4 Heterocyclic Chemistry: 12 Hrs
- Organic Name reactions with their respective mechanism and application involved in synthesis of drugs containing five, six membered and fused hetrocyclics such as Debus-Radziszewski imidazole synthesis, Knorr Pyrazole Synthesis Pinner Pyrimidine Synthesis, Combes Quinoline Synthesis, Bernthsen Acridine Synthesis, Smiles rearrangement and Traube purine synthesis.
- Synthesis of few representative drugs containing the sehetrocyclic nucleus such as Ketoconazole, Metronidazole, Miconazole, celecoxib, antipyrin, Metamizole sodium, Terconazole, Alprazolam, Triamterene, Sulfamerazine, Trimethoprim, Hydroxychloroquine, Quinine, Chloroquine, Quinacrine, Amsacrine, Prochlorpherazine, Promazine, Chlorpromazine, Theophylline, Mercaptopurine and Thioguanine.
- 5 Synthon approach and retrosynthesis applications 12 Hrs
- I. Basic principles, terminologies and advantages of retrosynthesis; guidelines for dissection of molecules. Functional group interconversion and addition (FGI and FGA)
 - I. C-X disconnections; C-C disconnections - alcohols and carbonyl compounds; 1,2-, 1,3-, 1,4-, 1,5-, 1,6-difunctionalized compounds
 - I. Strategies for synthesis of three, four, five and six-membered ring.



ADVANCED MEDICINAL CHEMISTRY
(MPC 103T)

Scope

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

Objectives

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

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

THEORY

60Hrs

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

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

2. Prodrug Design and Analog design: 12 Hrs

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

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

c) **Analog Design:** Introduction, Classical & Non classical, Bioisosteric replacement strategies, rigid analogs, alteration of chain branching, changes in ring size, ring position isomers, design of stereo isomers and geometric isomers, fragments of a lead molecule, variation in inter atomic distance.

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

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

a) **Anti-hypertensive drugs, Psychoactive drugs, Anticonvulsant drugs, H1 & H2 receptor antagonist, COX1 & COX2 inhibitors, Adrenergic &**



Cholinergic agents, Antineoplastic and Antiviral agents.

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

4	Rational Design of Enzyme Inhibitors	12
	Enzyme kinetics & Principles of Enzyme inhibitors, Enzyme inhibitors in medicine, Enzyme inhibitors in basic research, rational design of non-covalently and covalently binding enzyme inhibitors.	Hrs
5	Peptidomimetics	12
	Therapeutic values of Peptidomimetics, design of peptidomimetics by manipulation of the amino acids, modification of the peptide backbone, incorporating conformational constraints locally or globally. Chemistry of prostaglandins, leukotrienes and thromboxones.	Hrs



CHEMISTRY OF NATURAL PRODUCTS
(MPC 104T)

Scope

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

Objectives

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

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

THEORY 60 Hrs

1. Study of Natural products as leads for new pharmaceuticals for the following 12 hrs
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
f) Chemistry of macrolid antibiotics (Erythromycin,
Azithromycin, Roxithromycin, and Clarithromycin) and β - Lactam
antibiotics (Cephalosporins and Carbapenem)
- 2 a) Alkaloids 12 hrs
General introduction, classification, isolation, purification, molecular
modification and biological activity of alkaloids, general methods of structural
determination of alkaloids, structural elucidation and stereochemistry of
ephedrine, morphine, ergot, emetine and reserpine.
b) Flavonoids
Introduction, isolation and purification of flavonoids, General methods of
structural determination of flavonoids; Structural elucidation of quercetin.
c) Steroids
General introduction, chemistry of sterols, sapogenin and cardiac glycosides.
Stereochemistry and nomenclature of steroids, chemistry of contraceptive
agents male & female sex hormones (Testosterone, Estradiol, Progesterone),
adrenocorticoids (Cortisone), contraceptive agents and steroids (Vit - D).



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- 3 a) Terpenoids 12
Classification, isolation, isoprene rule and general methods of structural elucidation of Terpenoids; Structural elucidation of drugs belonging to mono (citral, menthol, camphor), di (retinol, Phytol, taxol) and tri terpenoids (Squalene, Ginsenoside) carotinoids (β carotene) hrs
- b) Vitamins
Chemistry and Physiological significance of Vitamin A, B1, B2, B12, C, E, Folic acid and Niacin.
- 4 a) Recombinant DNA technology and drug discovery rDNA technology, hybridoma technology, New pharmaceuticals derived from biotechnology; Oligonucleotide therapy. Gene therapy: Introduction, Clinical application and recent advances in gene therapy, principles of RNA & DNA estimation hrs
- b) Active constituent of certain crude drugs used in Indigenous system Diabetic therapy - *Gymnemasylvestre*, *Salacia reticulata*, *Pterocarpus marsupium*, *Swertia chirata*, *Trigonella foenumgraccum*; Liver dysfunction - *Phyllanthus niruri*; Antitumor - *Curcuma longa* Linn.
- 5 **Structural Characterization of natural compounds** Structural characterization of natural compounds using IR, ¹HNMR, ¹³CNMR and MS Spectroscopy of specific drugs e.g., Penicillin, Morphine, Camphor, Vit-D, Quercetin and Digitalis glycosides. 12 hrs
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PHARMACEUTICAL CHEMISTRY PRACTICAL - I
(MPC 105P)

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

To perform the following reactions of synthetic importance

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



PHARMACEUTICAL CHEMISTRY (MPC)
SECOND SEMESTER

ADVANCED SPECTRAL ANALYSIS
(MPC 201T)

Scope

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

Objectives

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

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

THEORY

60Hrs

- | | | |
|----|---|-----------|
| 1. | UV and IR spectroscopy:
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. | 12
Hrs |
| 2 | NMR spectroscopy:
1-D and 2-D NMR, NOESY and COSY, HECTOR, INADEQUATE techniques, Interpretation of organic compounds. | 12
Hrs |
| 3 | Mass Spectroscopy

Mass fragmentation and its rules, Fragmentation of important functional groups like alcohols, amines, carbonyl groups and alkanes, Meta stable ions, Mc Lafferty rearrangement, Ring rule, Isotopic peaks, Interpretation of organic compounds. | 12
Hrs |
| 4 | Chromatography:
Principle, Instrumentation and Applications of the following:a) GC-MS b) GC-AAS c) LC-MS d) LC-FTIR e) LC-NMR f) CE- MS g) High Performance Thin Layer chromatography h) Super critical fluid chromatography i) Ion Chromatography j) I-EC (Ion-Exclusion Chromatography) k) Flash chromatograph | 12
Hrs |
| 5 | 1. Thermal methods of analysis
Introduction, principle, instrumentation and application of DSC, DTA and TGA.

2. Raman Spectroscopy
Introduction, Principle, Instrumentation and Applications. | 12
Hrs |



3. Radio immuno assay

Biological standardization, bioassay, **ELISA**, Radioimmunoassay of digitalis and insulin.



ADVANCED ORGANIC CHEMISTRY - II
(MPC 202T)

Scope

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

Objectives

Upon completion of course, the student shall able to understand

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

THEORY

60

Hrs

- | | | |
|----|---|-----|
| 1. | Green Chemistry: | 12 |
| | a. Introduction, principles of green chemistry | Hrs |
| | b. Microwave assisted reactions: Merit and demerits of its use, increased reaction rates, mechanism, superheating effects of microwave, effects of solvents in microwave assisted synthesis, microwave technology in process optimization, its applications in various organic reactions and heterocycles synthesis | |
| | c. Ultrasound assisted reactions: Types of sonochemical reactions, homogenous, heterogeneous liquid-liquid and liquid-solid reactions, synthetic applications | |
| | d. Continuous flow reactors: Working principle, advantages and synthetic applications | |
| 2 | Chemistry of peptides | 12 |
| | a. Coupling reactions in peptide synthesis | Hrs |
| | b. Principles of solid phase peptide synthesis, t-BOC and Fmoc protocols, various solid supports and linkers: Activation procedures, peptide bond formation, deprotection and cleavage from resin, low and high HF cleavage protocols, formation of free peptides and peptide amides, purification and case studies, site-specific chemical modifications of peptides | |
| | c. Segment and sequential strategies for solution phase peptide synthesis with any two case studies | |
| | d. Side reactions in peptide synthesis: Deletion peptides, side reactions initiated by proton abstraction, protonation, over-activation and side reactions of individual amino acids. | |
| 3 | Photochemical Reactions | 12 |
| | Basic principles of photochemical reactions. Photo-oxidation, photo-addition and photo-fragmentation. | Hrs |
| | Pericyclic reactions | |
| | Mechanism, Types of pericyclic reactions such as cyclo addition, electrocyclic | |



reaction and sigmatropic rearrangement reactions with examples.

- 4 Catalysis: 12 Hrs
- Types of catalysis, heterogeneous and homogenous catalysis, advantages and disadvantages
 - Heterogeneous catalysis - preparation, characterization, kinetics, supported catalysts, catalyst deactivation and regeneration, some examples of heterogeneous catalysis used in synthesis of drugs.
 - Homogenous catalysis, hydrogenation, hydroformylation, hydrocyanation, Wilkinson catalysts, chiral ligands and chiral induction, Ziegler-Natta catalysts, some examples of homogenous catalysis used in synthesis of drugs
 - Transition-metal and Organo-catalysis in organic synthesis: Metal-catalyzed reactions
 - Biocatalysis:** Use of enzymes in organic synthesis, immobilized enzymes/cells in organic reaction.
 - Phase transfer catalysis - theory and applications
- 5 Stereochemistry & Asymmetric Synthesis 12 Hrs
- 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, enantiopure separation and Stereo selective synthesis with examples.
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**COMPUTER AIDED DRUG DESIGN
(MPC 203T)**

Scope

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

Objectives

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

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

Theory

60 Hrs

- | | | |
|----|---|-----------|
| 1. | Introduction to Computer Aided Drug Design (CADD)
History, different techniques and applications.
Quantitative Structure Activity Relationships: Basics
History and development of QSAR: Physicochemical parameters and methods to calculate physicochemical parameters: Hammett equation and electronic parameters (sigma), lipophilicity effects and parameters (log P, pi-substituent constant), steric effects (Taft steric and MR parameters) Experimental and theoretical approaches for the determination of these physicochemical parameters. | 12
Hrs |
| 2 | Quantitative Structure Activity Relationships: Applications
Hansch analysis, Free Wilson analysis and relationship between them, Advantages and disadvantages; Deriving 2D-QSAR equations.
3D-QSAR approaches and contour map analysis.
Statistical methods used in QSAR analysis and importance of statistical parameters. | 12
Hrs |
| 3 | Molecular Modeling and Docking
a) Molecular and Quantum Mechanics in drug design.
b) Energy Minimization Methods: comparison between global minimum conformation and bioactive conformation
c) Molecular docking and drug receptor interactions: Rigid docking, flexible docking and extra-precision docking. Agents acting on enzymes such as DHFR, HMG-CoA reductase and HIV protease, choline esterase (AchE&BchE) | 12
Hrs |
| 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 | 12
Hrs |



components of cavities, Fragment based drug design.

c) Homology modeling and generation of 3D-structure of protein.

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



PHARMACEUTICAL PROCESS CHEMISTRY
(MPC 204T)

Scope

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

Objectives

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

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

Theory

60 Hrs

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|----|--|-----------|
| 1. | Process chemistry
Introduction, Synthetic strategy
Stages of scale up process: Bench, pilot and large scale process.
In-process control and validation of large scale process.
Case studies of some scale up process of APIs.
Impurities in API, types and their sources including genotoxic impurities | 12
Hrs |
| 2 | Unit operations
a) Extraction: Liquid equilibria, extraction with reflux, extraction with agitation, counter current extraction.
b) Filtration: Theory of filtration, pressure and vacuum filtration, centrifugal filtration,
c) Distillation: azeotropic and steam distillation
d) Evaporation: Types of evaporators, factors affecting evaporation.
e) Crystallization: Crystallization from aqueous, non-aqueous solutions factors affecting crystallization, nucleation. Principle and general methods of Preparation of polymorphs, hydrates, solvates and amorphous APIs. | 12
Hrs |
| 3 | Unit Processes - I
a) Nitration: Nitrating agents, Aromatic nitration, kinetics and mechanism of aromatic nitration, process equipment for technical nitration, mixed acid for nitration,
b) Halogenation: Kinetics of halogenations, types of halogenations, catalytic halogenations. Case study on industrial halogenation process.
c) Oxidation: Introduction, types of oxidative reactions, Liquid phase oxidation with oxidizing agents. Nonmetallic Oxidizing agents such as H ₂ O ₂ , sodium hypochlorite, Oxygen gas, ozonolysis. | 12
Hrs |



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|------|---|-----|
| 4 | Unit Processes - II | 12 |
| | a) Reduction: Catalytic hydrogenation, Heterogeneous and homogeneous catalyst; Hydrogen transfer reactions, Metal hydrides. Case study on industrial reduction process. | Hrs |
| | b) Fermentation: Aerobic and anaerobic fermentation. Production of | |
| | i. Antibiotics; Penicillin and Streptomycin, | |
| | ii. Vitamins: B2 and B12 | |
| | iii. Statins: Lovastatin, Simvastatin | |
| | c) Reaction progress kinetic analysis | |
| | i. Streamlining reaction steps, route selection, | |
| | ii. Characteristics of expedient routes, characteristics of cost-effective routes, reagent selection, families of reagents useful for scale-up. | |
|
 | | |
| 5 | Industrial Safety | 12 |
| | a) MSDS (Material Safety Data Sheet), hazard labels of chemicals and Personal Protection Equipment (PPE) | Hrs |
| | b) Fire hazards, types of fire & fire extinguishers | |
| | c) Occupational Health & Safety Assessment Series 1800 (OHSAS-1800) and ISO-14001(Environmental Management System), Effluents and its management | |
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PHARMACEUTICAL CHEMISTRY PRACTICALS - II
(MPC 205P)

1. Synthesis of organic compounds by adapting different approaches involving (3 experiments)
 - a) Oxidation
 - b) Reduction/hydrogenation
 - c) Nitration
2. Comparative study of synthesis of APIs/intermediates by different synthetic routes (2 experiments)
3. Assignments on regulatory requirements in API (2 experiments)
4. Comparison of absorption spectra by UV and Woodward - Fieser rule
5. Interpretation of organic compounds by FT-IR
6. Interpretation of organic compounds by NMR
7. Interpretation of organic compounds by MS
8. Determination of purity by DSC in pharmaceuticals
9. Identification of organic compounds using FT-IR, NMR, CNMR and Mass Spectra
10. To carry out the preparation of following organic compounds
11. Preparation of 4-chlorobenzhydrylpiperazine. (an intermediate for cetirizine HCl).
12. Preparation of 4-iodotoluene from p-toluidine.
13. NaBH₄ reduction of vanillin to vanillyl alcohol
14. Preparation of umbelliferone by Pechmann reaction
15. Preparation of triphenyl imidazole
16. To perform the Microwave irradiated reactions of synthetic importance (Any two)
17. Determination of log P, MR, hydrogen bond donors and acceptors of selected drugs using softwares
18. Calculation of ADMET properties of drug molecules and its analysis using softwares
Pharmacophore modeling
19. 2D-QSAR based experiments
20. 3D-QSAR based experiments
21. Docking study based experiment
22. Virtual screening based experiment



Scheme and Syllabus

M. Pharm. (Pharmacology)

Course Code	Course	Credit Hours	Credit Points	Hrs./w k	Marks
Semester I					
MPL 101T	Modern Pharmaceutical Analytical Techniques	4	4	4	100
MPL 102T	Advanced Pharmacology-I	4	4	4	100
MPL 103T	Pharmacological and Toxicological Screening Methods-I	4	4	4	100
MPL 104T	Cellular and Molecular Pharmacology	4	4	4	100
MPL 105P	Pharmacology Practical I	12	6	12	150
MPL 106P	Seminar/Assignment	7	4	7	100
	Total	35	26	35	650
Semester II					
MPL 201T	Advanced Pharmacology II	4	4	4	100
MPL 202T	Pharmacological and Toxicological Screening Methods-II	4	4	4	100
MPL 203T	Principles of Drug Discovery	4	4	4	100
MPL 204T	Clinical Research and Pharmacovigilance	4	4	4	100
MPL 205P	Pharmacology Practical II	12	6	12	150
MPL 206P	Seminar/Assignment	7	4	7	100
	Total	35	26	35	650



PHARMACOLOGY (MPL)
FIRST SEMESTER

MODERN PHARMACEUTICAL ANALYTICAL TECHNIQUES
(MPH 101T)

Scope

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

Objectives

After completion of course student is able to know,

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

THEORY
HOURS

60

- | | | |
|----|---|-----|
| 1. | e. UV-Visible spectroscopy: Introduction, Theory, Laws, Instrumentation associated with UV-Visible spectroscopy. Choice of solvents and solvent effect and Applications of UV-Visible spectroscopy. | 10 |
| | f. IR spectroscopy: Theory, Modes of Molecular vibrations, Sample handling, Instrumentation of Dispersive and Fourier - Transform IR Spectrometer, Factors affecting vibrational frequencies and Applications of IR spectroscopy. | Hrs |
| | g. Spectrofluorimetry: Theory of Fluorescence, Factors affecting fluorescence, Quenchers, Instrumentation and Applications of fluorescence spectrophotometer. | |
| | h. Flame emission spectroscopy and Atomic absorption spectroscopy: Principle, Instrumentation Interference and Applications. | |
| | i. | |
| 2. | NMR spectroscopy: Quantum numbers and their role in NMR, Principle, Instrumentation, Solvent requirement in NMR, Relaxation process, NMR signals in various compounds, Chemical shift, Factors influencing chemical shift, Spin-Spin coupling, Coupling constant, Nuclear magnetic double resonance, Brief outline of principles of FT-NMR and ¹³ C NMR. Applications of NMR spectroscopy. | 10 |
| | | Hrs |
| 3. | Mass Spectroscopy: Principle, Theory, Instrumentation of Mass Spectroscopy, Different types of ionization like electron impact, chemical, field, FAB and MALDI, APCI, ESI, APPI Analyzers of Quadrupole and Time of Flight, Mass fragmentation and its rules, Meta stable ions, Isotopic peaks and Applications of Mass | 10 |
| | | Hrs |



spectroscopy

- 4 Chromatography: Principle, apparatus, instrumentation, 10
chromatographic parameters, factors affecting resolution, isolation Hrs
of drug from excipients, data interpretation and applications of the
following:
- j) Thin Layer chromatography
 - k) High Performance Thin Layer Chromatography
 - l) Ion exchange chromatography
 - m) Column chromatography
 - n) Gas chromatography
 - o) High Performance Liquid chromatography
 - p) Ultra High Performance Liquid chromatography
 - q) Affinity chromatography
 - r) Gel Chromatography
- 5 Electrophoresis: Principle, Instrumentation, Working conditions, 10
factors affecting separation and applications of the following: Hrs
- a) Paper electrophoresis
 - b) Gel electrophoresis
 - c) Capillary electrophoresis
 - d) Zone electrophoresis
 - e) Moving boundary electrophoresis
 - f) Iso electric focusing
- X ray Crystallography: Production of X rays, Different X ray
diffraction methods, Bragg's law, Rotating crystal technique, X ray powder
technique, Types of crystals and applications of X-ray diffraction.
- 6 Potentiometry: Principle, working, Ion selective Electrodes and 10Hr
Application of potentiometry. s
- Thermal Techniques:** Principle, thermal transitions and
Instrumentation (Heat flux and power-compensation and designs),
Modulated DSC, Hyper DSC, experimental parameters (sample preparation,
experimental conditions, calibration, heating and cooling rates,
resolution, source of errors) and their influence, advantage and
disadvantages, pharmaceutical applications. Differential Thermal
Analysis (DTA): Principle, instrumentation and advantage and
disadvantages, pharmaceutical applications, derivative differential
thermal analysis (DDTA). TGA: Principle, instrumentation, factors affecting
results, advantage and disadvantages, pharmaceutical applications.



ADVANCED PHARMACOLOGY - I
(MPL 102T)

SCOPE

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

OBJECTIVES

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

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

THEORY

60 Hrs

- | | | |
|----|---|-----------|
| 1. | General Pharmacology | 12
Hrs |
| | a. Pharmacokinetics: The dynamics of drug absorption, distribution, biotransformation and elimination. Concepts of linear and non-linear compartment models. Significance of Protein binding. | |
| | b. Pharmacodynamics: Mechanism of drug action and the relationship between drug concentration and effect. Receptors, structural and functional families of receptors, quantitation of drug receptors interaction and elicited | |
| 2 | Neurotransmission | 12
Hrs |
| | a. General aspects and steps involved in neurotransmission. | |
| | b. Neurohumoral transmission in autonomic nervous system (Detailed study about neurotransmitters- Adrenaline and Acetyl choline). | |
| | c. Neurohumoral transmission in central nervous system (Detailed study about neurotransmitters- histamine, serotonin, dopamine, GABA, glutamate and glycine]. | |
| | d. Non adrenergic non cholinergic transmission (NANC). Co-transmission | |

Systemic Pharmacology

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

Autonomic Pharmacology



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



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

Scope

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

Objectives

Upon completion of the course, student shall be able to

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

THEORY

60 HRS

1. Laboratory Animals Common laboratory animals: Description, handling and applications of different species and strains of animals. 12 Hrs
Transgenic animals: Production, maintenance and applications
Anaesthesia and euthanasia of experimental animals.
Maintenance and breeding of laboratory animals.
CPCSEA guidelines to conduct experiments on animals
Good laboratory practice.
Bioassay-Principle, scope and limitations and Methods
2. Preclinical screening of new substances for the pharmacological activity using in vivo, in vitro, and other possible animal alternative models. 12 Hrs
General principles of preclinical screening. CNS Pharmacology: behavioral and muscle co-ordination, CNS stimulants and depressants, anxiolytics, anti-psychotics, anti-epileptics and nootropics. Drugs for neurodegenerative diseases like Parkinsonism, Alzheimers and multiple sclerosis. Drugs acting on Autonomic Nervous System.



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|---|--|-----------|
| 3 | Preclinical screening of new substances for the pharmacological activity using in vivo, in vitro, and other possible animal alternative models. | 12
Hrs |
| | Respiratory Pharmacology: anti-asthmatics, drugs for COPD and anti allergics. Reproductive Pharmacology: Aphrodisiacs and antifertility agents, Analgesics, antiinflammatory and antipyretic agents. Gastrointestinal drugs: anti ulcer, anti -emetic, anti-diarrheal and laxatives. | |
| 4 | Preclinical screening of new substances for the pharmacological activity using in vivo, in vitro, and other possible animal alternative models. | 12
Hrs |
| | Cardiovascular Pharmacology: antihypertensives, antiarrhythmics, antianginal, antiatherosclerotic agents and diuretics. Drugs for metabolic disorders like anti-diabetic, antidyslipidemic agents. Anti cancer agents. Hepatoprotective screening methods. | |
| 5 | Preclinical screening of new substances for the pharmacological activity using in vivo, in vitro, and other possible animal alternative models. | 12
Hrs |
| | Immuno modulators, Immunosuppressants and immunostimulants

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

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



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- micro array technique, SDS page, ELISA and western blotting, Hrs
- Recombinant DNA technology and gene therapy
- Basic principles of recombinant DNA technology-Restriction enzymes, various types of vectors. Applications of recombinant DNA technology.
- Gene therapy- Various types of gene transfer techniques, clinical applications and recent advances in gene therapy.
- 4 Pharmacogenomics
- Gene mapping and cloning of disease gene.
- Genetic variation and its role in health/ pharmacology
- Polymorphisms affecting drug metabolism
- Genetic variation in drug transporters
- Genetic variation in G protein coupled receptors
- Applications of proteomics science: Genomics, proteomics, metabolomics, functionomics, nutrigenomics
- Immunotherapeutics
- Types of immunotherapeutics, humanisation antibody therapy,
- Immunotherapeutics in clinical practice
- 5 a. Cell culture techniques
- Basic equipments used in cell culture lab. Cell culture media, various types of cell culture, general procedure for cell cultures; isolation of cells, subculture, cryopreservation, characterization of cells and their application.
- Principles and applications of cell viability assays, glucose uptake assay, Calcium influx assays
- Principles and applications of flow cytometry
- b. Biosimilars
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PHARMACOLOGICAL PRACTICAL - I

(MPL 105P)

1. Analysis of pharmacopoeial compounds and their formulations by UV Vis spectrophotometer
 2. Simultaneous estimation of multi component containing formulations by UV spectrophotometry
 3. Experiments based on HPLC
 4. Experiments based on Gas Chromatography
 5. Estimation of riboflavin/quinine sulphate by fluorimetry
 6. Estimation of sodium/potassium by flame photometry
- Handling of laboratory animals.
1. Various routes of drug administration.
 2. Techniques of blood sampling, anesthesia and euthanasia of experimental animals.
 3. Functional observation battery tests (modified Irwin test)
 4. Evaluation of CNS stimulant, depressant, anxiogenics and anxiolytic, anticonvulsant activity.
 5. Evaluation of analgesic, anti-inflammatory, local anesthetic, mydriatic and miotic activity.
 6. Evaluation of diuretic activity.
 7. Evaluation of antiulcer activity by pylorus ligation method.
 8. Oral glucose tolerance test.
 9. Isolation and identification of DNA from various sources (Bacteria, Cauliflower, onion, Goat liver).
 10. Isolation of RNA from yeast
 11. Estimation of proteins by Bradford/Lowry's in biological samples.
 12. Estimation of RNA/DNA by UV Spectroscopy
 13. Gene amplification by PCR.
 14. Protein quantification Western Blotting.
 15. Enzyme based in-vitro assays (MPO, AChEs, α amylase, α glucosidase).
 16. Cell viability assays (MTT/Trypan blue/SRB).
 17. DNA fragmentation assay by agarose gel electrophoresis.
 18. DNA damage study by Comet assay.
 19. Apoptosis determination by fluorescent imaging studies.
 20. Pharmacokinetic studies and data analysis of drugs given by different routes of administration using softwares
 21. Enzyme inhibition and induction activity
 22. Extraction of drug from various biological samples and estimation of drugs in biological fluids using different analytical techniques (UV)
 23. Extraction of drug from various biological samples and estimation of drugs in biological fluids using different analytical techniques (HPLC)



PHARMACOLOGY (MPL)
FIRST SEMESTER

ADVANCED PHARMACOLOGY - II
(MPL 201T)

Scope

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

Objectives

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

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

THEORY

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



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



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

Scope

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

Objectives

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

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

THEORY

60 Hrs

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



industry perspective, list of studies needed for IND submission.

Hrs

Safety pharmacology studies- origin, concepts and importance of safety pharmacology.

Tier1- CVS, CNS and respiratory safety pharmacology, HERG assay. Tier2- GI, renal and other studies

PRINCIPLES OF DRUG DISCOVERY (MPL 203T)

Scope

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

Objectives

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

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

THEORY

60 Hrs

1. An overview of modern drug discovery process: Target identification, target validation, lead identification and lead Optimization. Economics of drug discovery. 12 Hrs

Target Discovery and validation-Role of Genomics, Proteomics and Bioinformatics. Role of Nucleic acid microarrays, Protein microarrays, Antisense technologies, siRNAs, antisense oligonucleotides, Zinc finger proteins. Role of transgenic animals in target validation.

- 2 Lead Identification- combinatorial chemistry & high throughput screening, in silico lead discovery techniques, Assay development for hit identification. 12 Hrs

Protein structure

Levels of protein structure, Domains, motifs, and folds in protein structure. Computational prediction of protein structure: Threading and homology modeling methods. Application of NMR and X-ray crystallography in protein structure prediction

- 3 Rational Drug Design 12 Hrs
- Traditional vs rational drug design, Methods followed in traditional drug design, High throughput screening, Concepts of Rational



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- Drug Design, Rational Drug Design Methods: Structure and Pharmacophore based approaches
- Virtual Screening techniques: Drug likeness screening, Concept of pharmacophore mapping and pharmacophore based Screening,
- 4 Molecular docking: Rigid docking, flexible docking, manual docking; Docking based screening. De novo drug design. 12 Hrs
- Quantitative analysis of Structure Activity Relationship
- History and development of QSAR, SAR versus QSAR, Physicochemical parameters, Hansch analysis, Fee Wilson analysis and relationship between them.
- 5 QSAR Statistical methods - regression analysis, partial least square analysis (PLS) and other multivariate statistical methods. 3D-QSAR approaches like COMFA and COMSIA 12 Hrs
- Prodrug design-Basic concept, Prodrugs to improve patient acceptability, Drug solubility, Drug absorption and distribution, site specific drug delivery and sustained drug action. Rationale of prodrug design and practical consideration of prodrug
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CLINICAL RESEARCH AND PHARMACOVIGILANCE
(MPL 204T)

Scope

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

Objectives

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

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

THEORY

60 Hrs

1. **Regulatory Perspectives of Clinical Trials:** 12 Hrs
Origin and Principles of International Conference on Harmonization - Good Clinical Practice (ICH-GCP) guidelines
Ethical Committee: Institutional Review Board, Ethical Guidelines for Biomedical Research and Human Participant-Schedule Y, ICMR
Informed Consent Process: Structure and content of an Informed Consent Process Ethical principles governing informed consent process
2. **Clinical Trials: Types and Design** 12 Hrs
Experimental Study- RCT and Non RCT,
Observation Study: Cohort, Case Control, Cross sectional
Clinical Trial Study Team
Roles and responsibilities of Clinical Trial Personnel: Investigator, Study Coordinator, Sponsor, Contract Research Organization and



-
- its management
- 3 **Clinical Trial Documentation-** Guidelines to the preparation of 12
documents, Preparation of protocol, Investigator Brochure, Case Hrs
Report Forms, Clinical Study Report Clinical Trial Monitoring
Safety Monitoring in CT
- Adverse Drug Reactions: Definition and types. Detection and
reporting methods. Severity and seriousness
assessment. Predictability and preventability assessment,
Management of adverse drug reactions; Terminologies of ADR.
- 4 **Basic aspects,** terminologies and establishment of 12
pharmacovigilance Hrs
- History and progress of pharmacovigilance, Significance of safety
monitoring, Pharmacovigilance in India and international aspects,
WHO international drug monitoring programme, WHO and
Regulatory terminologies of ADR, evaluation of medication safety,
Establishing pharmacovigilance centres in Hospitals, Industry and
National programmes related to pharmacovigilance. Roles and
responsibilities in Pharmacovigilance
- 5 **Methods, ADR reporting and tools used in** 12
Pharmacovigilance Hrs
- International classification of diseases, International Non-
proprietary names for drugs, Passive and Active surveillance,
Comparative observational studies, Targeted clinical investigations
and Vaccine safety surveillance. Spontaneous reporting system
and Reporting to regulatory authorities, Guidelines for ADRs
reporting. Argus, Aris G Pharmacovigilance, VigiFlow, Statistical
methods for evaluating medication safety data.
- 6 Pharmacoepidemiology, pharmacoconomics, safety 12
pharmacology Hrs
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PHARMACOLOGICAL PRACTICAL - II
(MPL 205P)

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



Scheme and Syllabus

M. Pharm. (Pharmacognosy)

Course of study for M. Pharm. (Pharmacognosy)

Course Code	Course	Credit Hours	Credit Points	Hrs./w k	Marks
Semester I					
MPG101T	Modern Pharmaceutical Analytical Techniques	4	4	4	100
MPG102T	Advanced Pharmacognosy-I	4	4	4	100
MPG103T	Phytochemistry	4	4	4	100
MPG104T	Industrial Pharmacognostical Technology	4	4	4	100
MPG105P	Pharmacognosy Practical I	12	6	12	150
MPG106P	Seminar/Assignment	7	4	7	100
	Total	35	26	35	650
Semester II					
MPG201T	Medicinal Plant biotechnology	4	4	4	100
MPG102T	Advanced Pharmacognosy-II	4	4	4	100
MPG203T	Indian system of medicine	4	4	4	100
MPG204T	Herbal cosmetics	4	4	4	100
MPG205P	Pharmacognosy Practical II	12	6	12	150
MPG206P	Seminar/Assignment	7	4	7	100
	Total	35	26	35	650



Scheme and Syllabus

PHARMACOGNOSY (MPG) FIRST SEMESTER

MODERN PHARMACEUTICAL ANALYTICAL TECHNIQUES (MPG 101T)

Scope

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

Objectives

After completion of course student is able to know,

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

THEORY HOURS

60

- | | | |
|----|---|-----------|
| 1. | UV-Visible spectroscopy: Introduction, Theory, Laws, Instrumentation associated with UV-Visible spectroscopy. Choice of solvents and solvent effect and Applications of UV-Visible spectroscopy. | 11
Hrs |
| | IR spectroscopy: Theory, Modes of Molecular vibrations, Sample handling, Instrumentation of Dispersive and Fourier - Transform IR Spectrometer, Factors affecting vibrational frequencies and Applications of IR spectroscopy. | |
| | Spectrofluorimetry: Theory of Fluorescence, Factors affecting fluorescence, Quenchers, Instrumentation and Applications of fluorescence spectrophotometer. | |
| | Flame emission spectroscopy and Atomic absorption spectroscopy: Principle, Instrumentation, Interferences and Applications. | |
| 2. | NMR spectroscopy: Quantum numbers and their role in NMR, Principle, Instrumentation, Solvent requirement in NMR, Relaxation process, NMR signals in various compounds, Chemical shift, Factors influencing chemical shift, Spin-Spin coupling, Coupling constant, Nuclear magnetic double resonance, Brief outline of principles of FT-NMR and ¹³ C NMR. Applications of NMR spectroscopy. | 11
Hrs |
| 3. | Mass Spectroscopy: Principle, Theory, Instrumentation of Mass Spectroscopy, Different types of ionization like electron impact, | 11 |



- chemical, field, FAB and MALDI, APCI, ESI, APPI Analyzers of Hrs
Quadrupole and Time of Flight, Mass fragmentation and its rules,
Meta stable ions, Isotopic peaks and Applications of Mass
spectroscopy
- 4 Chromatography: Principle, apparatus, instrumentation, 11
chromatographic parameters, factors affecting resolution and Hrs
applications of the following:
- a) Thin Layer chromatography
 - b) High Performance Thin Layer Chromatography
 - c) Ion exchange chromatography
 - d) Column chromatography
 - e) Gas chromatography
 - f) High Performance Liquid chromatography
 - g) Ultra High Performance Liquid chromatography
 - h) Affinity chromatography
 - i) Gel Chromatography
- 5 Electrophoresis: Principle, Instrumentation, Working conditions, 11
factors affecting separation and applications of the following: Hrs
- a) Paper electrophoresis
 - b) Gel electrophoresis
 - c) Capillary electrophoresis
 - d) Zone electrophoresis
 - e) Moving boundary electrophoresis
 - f) Iso electric focusing
- X ray Crystallography: Production of X rays, Different X ray
diffraction methods, Bragg's law, Rotating crystal technique, X ray powder
technique, Types of crystals and applications of X-ray diffraction.
- 6 Potentiometry: Principle, working, Ion selective Electrodes and 5Hrs
Application of potentiometry.
- Thermal Techniques:** Principle, thermal transitions and
Instrumentation (Heat flux and power-compensation and designs),
Modulated DSC, Hyper DSC, experimental parameters (sample
preparation, experimental conditions, calibration, heating and
cooling rates, resolution, source of errors) and their influence, advantage and
disadvantages, pharmaceutical applications.
- Differential Thermal Analysis (DTA): Principle, instrumentation
and advantage and disadvantages, pharmaceutical applications,
derivative differential thermal analysis (DDTA). TGA: Principle,
instrumentation, factors affecting results, advantage and
disadvantages, pharmaceutical applications



ADVANCED PHARMACOGNOSY - I
(MPG 102T)

SCOPE

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

OBJECTIVES

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

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

THEORY

60 Hrs

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



health benefits) of 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

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



PHYTOCHEMISTRY
(MPG 103T)

SCOPE

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

OBJECTIVES

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

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

THEORY

60 HRS

1. Biosynthetic pathways and Radio tracing techniques: Constituents & their Biosynthesis, Isolation, Characterization and purification with a special reference to their importance in herbal industries of following phyto-pharmaceuticals containing drugs: 12 Hrs
 - a) Alkaloids: Ephedrine, Quinine, Strychnine, Piperine, Berberine, Taxol, Vinca alkaloids.
 - b) Glycosides: Digitoxin, Glycyrrhizin, Sennosides, Bacosides, Quercetin.
 - c) Steroids: Hecogenin, guggulosterone and withanolides
 - d) Coumarin: Umbelliferone.
 - e) Terpenoids: Cucurbitacin
2. Drug discovery and development: History of herbs as source of drugs and drug discovery, the lead structure selection process, structure development, product discovery process and drug registration, Selection and optimization of lead compounds with suitable examples from the following source : artemesin,andrographolides. Clinical studies emphasising on phases of clinical trials, protocol design for lead molecules. 12 Hrs
3. Extraction and Phytochemical studies: Recent advances in extractions with emphasis on selection of method and choice of solvent for extraction, successive and exhaustive extraction and other methods of extraction commonly used like microwave assisted extraction, Methods of fractionation. Separation of phytoconstituents by latest CCET, SCFE techniques including preparative HPLC and Flash column chromatography 12 Hrs
4. Phytochemical finger printing: HPTLC and LCMS/GCMS applications in the characterization of herbal extracts. Structure elucidation of phytoconstituents. 12 Hrs
5. Structure elucidation of the following compounds by spectroscopic techniques like UV, IR, MS, NMR (1H, 13C) 12 Hrs

गुरु घासीदास विश्वविद्यालय
(केन्द्रीय विश्वविद्यालय अधिनियम 2009 क्र. 25 के अंतर्गत स्थापित केन्द्रीय विश्वविद्यालय)
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Koni, Bilaspur - 495009 (C.G.)

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



INDUSTRIAL PHARMACOGNOSTICAL TECHNOLOGY
(MPG 104T)

Scope

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

Objectives:

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

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

THEORY

60 Hrs

1. Herbal drug industry: Infrastructure of herbal drug industry involved in production of standardized extracts and various dosage forms. Current challenges in upgrading and modernization of herbal formulations. Entrepreneurship Development, Project selection, project report, technical knowledge, Capital venture, plant design, layout and construction. Pilot plant scale -up techniques, case studies of herbal extracts. Formulation and production management of herbals. 12 Hrs
2. Regulatory requirements for setting herbal drug industry: Global marketing management. Indian and international patent law as applicable herbal drugs and natural products. Export - Import (EXIM) policy, TRIPS. 12 Hrs
Quality assurance in herbal/natural drug products.
Concepts of TQM, GMP, GLP, ISO-9000
3. Monographs of herbal drugs: General parameters of monographs of herbal drugs and comparative study in IP, USP, Ayurvedic Pharmacopoeia, Siddha and Unani Pharmacopoeia, American herbal pharmacopoeia, British herbal pharmacopoeia, WHO guidelines in quality assessment of herbal drugs. 12 Hrs
4. Testing of natural products and drugs: Herbal medicines - clinical laboratory testing. Stability testing of natural products, protocols.
5. Patents: Indian and international patent laws, proposed amendments as applicable to herbal/natural products and 12 Hrs

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(केन्द्रीय विश्वविद्यालय अधिनियम 2009 क्र. 25 के अंतर्गत स्थापित केन्द्रीय विश्वविद्यालय)
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process. Geographical indication, 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



PHARMACOGNOSY PRACTICAL - I

(MPG I05P)

1. Analysis of Pharmacopoeial compounds of natural origin and their formulations by UV Vis spectrophotometer
 2. Analysis of recorded spectra of simple phytoconstituents
 3. Experiments based on Gas Chromatography
 4. Estimation of sodium/potassium by flame photometry
 5. Development of fingerprint of selected medicinal plant extracts commonly used in herbal drug industry viz. Ashwagandha, Tulsi, Bael, Amla, Ginger, Aloe, Vidang, Senna, Lawsonia by TLC/HPTLC method.
 6. Methods of extraction
 7. Phytochemical screening
 8. Demonstration of HPLC- estimation of glycerrhizin
 9. Monograph analysis of clove oil
 10. Monograph analysis of castor oil. 11. Identification of bioactive constituents from plant extracts
 11. Formulation of different dosage forms and their standardisation.
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PHARMACOGNOSY (MPG)
SECOND SEMESTER

MEDICINAL PLANT BIOTECHNOLOGY
(MPG 201T)

Scope

To explore the knowledge of Biotechnology and its application in the improvement of quality of medicinal plants

Objectives

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

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

THEORY

- 60 Hrs
1. Introduction to Plant biotechnology: Historical perspectives, prospects for development of plant biotechnology as a source of medicinal agents. Applications in pharmacy and allied fields. Genetic and molecular biology as applied to pharmacognosy, study of DNA, RNA and protein replication, genetic code, regulation of gene expression, structure and complicity of genome, cell signaling, DNA recombinant technology. 12 Hrs
 2. Different tissue culture techniques: Organogenesis and embryogenesis, synthetic seed and monoclonal variation, Protoplast fusion, Hairy root multiple shoot cultures and their applications. Micro propagation of medicinal and aromatic plants. Sterilization methods involved in tissue culture, gene transfer in plants and their applications. 15 Hrs
 3. Immobilisation techniques & Secondary Metabolite Production: Immobilization techniques of plant cell and its application on secondary metabolite Production. Cloning of plant cell: Different methods of cloning and its applications. Advantages and disadvantages of plant cell cloning. Secondary metabolism in tissue cultures with emphasis on production of medicinal agents. Precursors and elicitors on production of secondary metabolites. 15 Hrs
 4. Biotransformation and Transgenesis: Biotransformation, bioreactors for pilot and large scale cultures of plant cells and retention of biosynthetic potential in cell culture. Transgenic plants, methods used in gene identification, localization and sequencing of genes. Application of PCR in plant genome analysis. 13 Hrs



ADVANCED PHARMACOGNOSY - II
(MPG 202T)

Scope

To know and understand the Adulteration and Deterioration that occurs in herbal/natural drugs and methods of detection of the same. Study of herbal remedies and their validations, including methods of screening

Objectives

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

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

THEORY

60 Hrs

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| 1. | Herbal remedies – Toxicity and Regulations: Herbs vs Conventional drugs, Efficacy of Herbal medicine products, Validation of herbal therapies, Pharmacodynamic and Pharmacokinetic issues | 12 Hrs |
| 2. | Adulteration and Deterioration: Introduction, Types of Adulteration/ Substitution of Herbal drugs, Causes and Measures of Adulteration, Sampling Procedures, Determination of Foreign Matter, DNA Finger printing techniques in identification of drugs of natural origin, detection of heavy metals, pesticide residues, phytotoxin, microbial contamination in herbs and their formulations. | 12 Hrs |
| 3. | Ethnobotany and Ethnopharmacology: Ethnobotany in herbal drug evaluation, Impact of Ethnobotany in traditional medicine, New development in herbals, Bio-prospecting tools for drug discovery, Role of Ethnopharmacology in drug evaluation, Reverse Pharmacology. | 12 Hrs |
| 4. | Analytical Profiles of herbal drugs: Andrographis paniculata, Boswellia serata, Coleus forskholii, Curcuma longa, Embelica officinalis, Psoralea corylifolia. | 12 Hrs |
| 5. | Biological screening of herbal drugs: Introduction and Need for Phyto-Pharmacological Screening, New Strategies for evaluating 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 | 12 Hrs |



INDIAN SYSTEMS OF MEDICINE
(MPG 203T)

Scope

To make the students understand thoroughly the principles, preparations of medicines of various Indian systems of medicine like Ayurveda, Siddha, Homeopathy and Unani. Also focusing on clinical research of traditional medicines, quality assurance and challenges in monitoring the safety of herbal medicines.

Objectives

After completion of the course, student is able to

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

THEORY

60 Hrs

1. Fundamental concepts of Ayurveda, Siddha, Unani and Homoeopathy systems of medicine 12 Hrs

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).

2. Naturopathy, Yoga and Aromatherapy practices 12 Hrs

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.

3. Formulation development of various systems of medicine 12 Hrs
Salient features of the techniques of preparation of some of the important class of Formulations as per Ayurveda, Siddha, Homeopathy and Unani Pharmacopoeia and texts.

Standardization,



Shelf life and Stability studies of ISM formulations

- 4 Schedule T - Good Manufacturing Practice of Indian systems of medicine 12 Hrs
- Components of GMP (Schedule - T) and its objectives, Infrastructural requirements, working space, storage area, machinery and equipments, standard operating procedures, health and hygiene, documentation and records.
- Quality assurance in 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.
- 5 TKDL, Geographical indication Bill, Government bills in AYUSH, ISM, CCRAS, CCRS, CCRH, CCRU 12 Hrs
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HERBAL COSMETICS
(MPG 204T)

SCOPE

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

OBJECTIVES

After completion of the course, the students shall be able to

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

THEORY

60 Hrs

1. Introduction: Herbal/natural cosmetics, Classification & 12 Hrs
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.

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

3. Herbal Cosmetics : Physiology and chemistry of skin and 12 Hrs
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.

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

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



HERBAL COSMETICS PRACTICALS

(MPG 205P)

1. Isolation of nucleic acid from cauliflower heads
2. Isolation of RNA from yeast
3. Quantitative estimation of DNA
4. Immobilization technique
5. Establishment of callus culture
6. Establishment of suspension culture
7. Estimation of aldehyde contents of volatile oils
8. Estimation of total phenolic content in herbal raw materials
9. Estimation of total alkaloid content in herbal raw materials
10. Estimation of total flavonoid content in herbal raw materials
11. Preparation and standardization of various simple dosage forms from Ayurvedic, Siddha, Homoeopathy and Unani formulary
12. Preparation of certain Aromatherapy formulations
13. Preparation of herbal cosmetic formulation such as lip balm, lipstick, facial cream, herbal hair and nail care products
14. Evaluation of herbal tablets and capsules
15. Preparation of sunscreen, UV protection cream, skin care formulations.
16. Formulation & standardization of herbal cough syrup.