FACULTY OF LIFE SCIENCES

SYLLABUS

For

MASTER OF PHARMACY
(Credit Based Evaluation & Grading System)

(Semester: I-IV)

Examinations: 2019-20

GURU NANAK DEV UNIVERSITY
AMRITSAR

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Please visit the University website time to time.
Semester I  
**M. Pharm. (Pharmaceutics)**

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Semester I  
**M. Pharm. (Pharmaceutical Chemistry)**

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# MASTER OF PHARMACY (SEMESTER SYSTEM)
(Credit Based Evaluation & Grading System)

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Semester II
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<td>Clinical Research and Pharmacovigilance</td>
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<td>Experimental Pharmacology - II</td>
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(Pharmacognosy-MPG)

<table>
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<tr>
<th>Course Code</th>
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<th>End Semester Exams</th>
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<td>Medicinal Plant biotechnology</td>
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<td>Advanced Pharmacognosy-II</td>
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<td>Herbal cosmetics</td>
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**Scheme for awarding internal assessment**

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<th>Theory</th>
<th>Criteria</th>
<th>Maximum Marks</th>
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<tr>
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**Guidelines for the allotment of marks for attendance#**

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<th>Percentage of Attendance</th>
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<td>85 – 89</td>
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<td>80 – 84</td>
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<tr>
<td>Less than 80</td>
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### M. Pharm. (Pharmaceutics) III Semester

<table>
<thead>
<tr>
<th>Course Code</th>
<th>Course</th>
<th>Credit Hours</th>
<th>Credit Points</th>
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<tbody>
<tr>
<td>MRM301T</td>
<td>Research Methodology and Biostatistics*</td>
<td>4</td>
<td>4</td>
</tr>
<tr>
<td>MPH303S</td>
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<tr>
<td>MPH304S</td>
<td>Discussion / Presentation (Proposal Presentation)</td>
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<tr>
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* Non University Exam

### M. Pharm. (Pharmaceutical Chemistry) III Semester

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<tr>
<td>MRM 301T</td>
<td>Research Methodology and Biostatistics*</td>
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* Non University Exam

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* Non University Exam

### M. Pharm. (Pharmacognosy) III Semester

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<td>MPG305S</td>
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<td><strong>Total</strong></td>
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* Non University Exam
## M. Pharm. (Pharmaceutics) IV Semester

<table>
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## M. Pharm. (Pharmaceutical Chemistry) IV Semester

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## M. Pharm. (Pharmacology) IV Semester

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<td>MPL404S</td>
<td>Co-curricular Activities (Attending Conference, Scientific Presentations and Other Scholarly Activities)</td>
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## M. Pharm. (Pharmacognosy) IV Semester

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<th>Credit Points</th>
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<td>MPG402S</td>
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<td>MPG403S</td>
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<td><strong>Total</strong></td>
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MASTER OF PHARMACY (SEMESTER SYSTEM)
(Credit Based Evaluation & Grading System)

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<th>Semester wise credits distribution</th>
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<td>II</td>
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<td>III</td>
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<td>IV</td>
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<td>Minimum=95 Maximum=100*</td>
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*Credit Points for Co-curricular Activities

*Guidelines for Awarding Credit Points for Co-curricular Activities

<table>
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<th>Name of the Activity</th>
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<td>Participation in National Level Seminar/Conference/Workshop/Symposium/ Training Programs (related to the specialization of the student)</td>
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<tr>
<td>Participation in international Level Seminar/Conference/Workshop/Symposium/ Training Programs (related to the specialization of the student)</td>
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</tr>
<tr>
<td>Academic Award/Research Award from State Level/National Agencies</td>
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</tr>
<tr>
<td>Academic Award/Research Award from International Agencies</td>
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</tr>
<tr>
<td>Research / Review Publication in National Journals (Indexed in Scopus / Web of Science)</td>
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<tr>
<td>Research / Review Publication in International Journals (Indexed in Scopus / Web of Science)</td>
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Note: International Conference: Held Outside India
International Journal: The Editorial Board outside India
MASTER OF PHARMACY (SEMESTER-I)  
(Credit Based Evaluation & Grading System)

MPH101T: MODERN PHARMACEUTICAL ANALYSIS  
Max. Marks: 75  
Internal Assessment: 25  
Total Marks: 100

Scope

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

Objectives

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

THEORY  
60 HOURS


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 13C NMR. Applications of NMR spectroscopy.

4. **Chromatography**: Principle, apparatus, instrumentation, chromatographic parameters, factors affecting resolution and applications of the following:
   a) Paper chromatography
   b) Thin Layer chromatography
   c) Ion exchange chromatography
   d) Column chromatography
   e) Gas chromatography
   f) High Performance Liquid chromatography
   g) Affinity chromatography
   **11 Hrs**

5. **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
   **11 Hrs**

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

**REFERENCES**

MASTER OF PHARMACY (SEMESTER-I)
(Credit Based Evaluation & Grading System)

MPH102T: DRUG DELIVERY SYSTEM

Max. Marks: 75
Internal Assessment: 25
Total Marks: 100

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 The formulation and evaluation of Novel drug delivery systems.

THEORY


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

5. Trans Dermal Drug Delivery Systems: Structure of skin and barriers, Penetration enhancers, Transdermal Drug Delivery Systems, Formulation and evaluation


7. Vaccine delivery systems: Vaccines, uptake of antigens, single shot vaccines, mucosal and transdermal delivery of vaccines.
REFERENCES
3. Encyclopedia of controlled delivery, Editor- Edith Mathiowitz, Published by WileyInterscience Publication, John Wiley and Sons, Inc, New York! Chichester/Weinheim
5. S.P.Vyas and R.K.Khar, Controlled Drug Delivery - concepts and advances, Vallabh Prakashan, New Delhi, First edition 2002

JOURNALS
1. Indian Journal of Pharmaceutical Sciences (IPA)
2. Indian drugs (IDMA)
3. Journal of controlled release (Elsevier Sciences) desirable
4. Drug Development and Industrial Pharmacy (Marcel & Decker) desirable
MPH103T: MODERN PHARMACEUTICS

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

THEORY

1. **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

2. **Optimization techniques in Pharmaceutical Formulation**: Concept and parameters of optimization, Optimization techniques in pharmaceutical formulation and processing. Statistical design, Response surface method, Contour designs, Factorial designs and application in formulation.

3. **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

4. **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
5. **Compression and compaction:** Physics of tablet compression, compression, consolidation, effect of friction, distribution of forces, compaction profiles. Solubility enhancement techniques.

10 Hrs

6. **Study of consolidation parameters:** Diffusion parameters, Dissolution parameters and Pharmacokinetic parameters, Heckal plats, Similarity factors – f2 and f1, Higuchi and peppas plot, Linearity Concept of significance, Standard deviation , chi square test , student T-test , Anova test.

10 Hrs

**REFERENCES**

1. Theory and Practice of Industrial Pharmacy By Lachmann and Libermann
3. Pharmaceutical Dosage forms: Disperse systems, Vol, 1-2; By Leon Lachmann.
4. Pharmaceutical Dosage forms: Parenteral medications Vol. 1-2; By Leon Lachmann.
5. Modern Pharmaceutics; By Gillbert and S. Banker.
8. Physical Pharmacy; By Alfred martin
11. Quality Assurance Guide; By Organization of Pharmaceutical producers of India.
13. How to practice GMPs; By P.P.Sharma. Vandhana Publications, Agra.
15. Pharmaceutical Preformulations; By J.J. Wells.
16. Applied production and operations management; By Evans, Anderson, Sweeney and Williams.
MASTER OF PHARMACY (SEMESTER-I)
(Credit Based Evaluation & Grading System)

MPH104T: PHARMACEUTICAL REGULATORY AFFAIR
Max. Marks: 75
Internal Assessment: 25
Total Marks: 100

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

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

THEORY 60 Hr

1. **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 11 Hrs

2. **Regulatory requirement for product approval**: API, biologics, novel, therapies obtaining NDA, ANDA for generic drugs ways and means of US registration for foreign drugs 12Hrs

3. CMC, post approval regulatory affairs. Regulation for combination products and medical devices. CTD and ECTD format, industry and FDA liaison. ICH - Guidelines of ICH-Q,S E,M.
   Regulatory requirements of EU, MHRA, TGA and ROW countries. 12Hrs
4. **Non clinical drug development**: Global submission of IND, NDA, ANDA. Investigation medicinal products dossier, dossier (IMPD) and investigator brochure (IB)  

5. **Clinical trials**: Developing clinical trial protocols. Institutional review board/independent ethics committee Formulation and working procedures informed Consent process and procedures. HIPAA-new, requirement to clinical study process, pharmacovigilance safety monitoring in clinical trials.  

**REFERENCES**

7. www.ich.org/  
8. www.fda.gov/  
9. europa.eu/index_en.htm  
MPH105P: Pharmaceutics Practical I

1. Analysis of pharmacopoeial compounds and their formulations by UV Vis spectrophotometer
2. Simultaneous estimation of multi component containing formulations by UV spectrophotometry
3. Experiments based on HPLC
4. Experiments based on Gas Chromatography
5. Estimation of riboflavin/quinine sulphate by fluorimetry
6. Estimation of sodium/potassium by flame photometry
7. To perform In-vitro dissolution profile of CR/ SR marketed formulation
8. Formulation and evaluation of sustained release matrix tablets
9. Formulation and evaluation osmotically controlled DDS
10. Preparation and evaluation of Floating DDS- hydro dynamically balanced DDS
11. Formulation and evaluation of 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.
MPC 101T: MODERN PHARMACEUTICAL ANALYTICAL TECHNIQUES

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

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

THEORY

   b. IR spectroscopy: Theory, Modes of Molecular vibrations, Sample handling, Instrumentation of Dispersive and Fourier - Transform IR Spectrometer, Factors affecting vibrational frequencies and Applications of IR spectroscopy, Data Interpretation.
   c. Spectroflourimetry: Theory of Fluorescence, Factors affecting fluorescence (Characterestics of drugs that can be analysed by flourimetry), Quenchers, Instrumentation and Applications of fluorescence spectrophotometer.

2. NMR spectroscopy: Quantum numbers and their role in NMR, Principle, Instrumentation, Solvent requirement in NMR, Hrs 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.

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

- Thin Layer chromatography
- High Performance Thin Layer Chromatography
- Ion exchange chromatography
- Column chromatography
- Gas chromatography
- High Performance Liquid chromatography
- Ultra High Performance Liquid chromatography
- Affinity chromatography
- Gel Chromatography

5 a. Electrophoresis: Principle, Instrumentation, Working conditions, factors affecting separation and applications of the following:

- Paper electrophoresis
- Gel electrophoresis
- Capillary electrophoresis
- Zone electrophoresis
- Moving boundary electrophoresis
- 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.

REFERENCES
1. Spectrometric Identification of Organic compounds - Robert M Silverstein, Sixth edition,
2. Principles of Instrumental Analysis - Douglas A Skoog, F. James Holler, Timothy A.
6. Quantitative Analysis of Drugs in Pharmaceutical formulation - P D Sethi, 3rd Edition,
   Dekker Series
   1982.
MPC102T: ADVANCED ORGANIC CHEMISTRY-I

Max. Marks: 75
Internal Assessment: 25
Total Marks: 100

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

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

2 Study of mechanism and synthetic applications of following named Reactions: 12 Hrs
   Ugi reaction, Brook rearrangement, Ullmann coupling reactions, Dieckmann Reaction, Doebner-Miller Reaction, Sandmeyer Reaction, Mitsunobu reaction, Mannich reaction, Vilsmeyer-Haack Reaction, Sharpless asymmetric epoxidation, Baeyer-Villiger oxidation, Shapiro & Suzuki reaction, Ozonolysis and Michael addition reaction
3 Synthetic Reagents & Applications: 12 Hrs
Aluminiumisoproploxide, N-bromosuccinamide, diazomethane, dicyclohexylcarbodiimide, Wilkinson reagent, Witting reagent. Osmium tetroxide, titanium chloride, diazopropane, diethyl azodicarboxylate, Triphenylphosphine, Benzotriazol-1-yloxy) tris (dimethylamino) phosphonium hexafluoro-phosphate (BOP).

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

4 Heterocyclic Chemistry: 12 Hrs.
Organic Name reactions with their respective mechanism and application involved in synthesis of drugs containing five, six membered and fused heterocyclics such as Debus-Radziszewski imidazole synthesis, Knorr Pyrazole Synthesis Pinner Pyrimidine Synthesis, Combes Quinoline Synthesis, Bernthsen Acridine Synthesis, Smiles rearrangement and Traube purine synthesis.

Synthesis of few representative drugs containing these heterocyclic nucleus such as Ketoconazole, Metronidazole, Miconazole, celecoxib, antipyrin, Metamizole sodium, Terconazole, Alprazolam, Triamterene, Sulfamerazine, Trimethoprim, Hydroxychloroquine, Quinine, Chlorquine, Quinacrine, Amsacrine, Prochloropherazine, Promazine, Chlorpromazine,Theophylline, Mercaptopurine and Thioguanine.

5 Synthon approach and retrosynthesis applications 12 Hrs.
i. Basic principles, terminologies and advantages of Hrs retrosynthesis; guidelines for dissection of molecules. Functional group interconversion and addition (FGI and FGA)
ii. C-X disconnections; C-C disconnections – alcohols and carbonyl compounds; 1,2-, 1,3-,1,4-, 1,5-, 1,6-difunctionalized compounds
iii. Strategies for synthesis of three, four, five and six-membered ring.
REFERENCES

9. Organic synthesis-The disconnection approach, S. Warren, Wily India
11. Organic synthesis- Special techniques VK Ahluwalia and R Agarwal, Narosa Publishers
12. Organic reaction mechanisms IV edtn, VK Ahluwalia and RK Parashar, Narosa Publishers
MASTER OF PHARMACY (SEMESTER-I)  
(Credit Based Evaluation & Grading System)  

MPC103T: ADVANCED MEDICINAL CHEMISTRY  
Max. Marks: 75  
Internal Assessment: 25  
Total Marks: 100

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  
- Peptidomimetic

THEORY  

1. **Drug discovery:** Stages of drug discovery, lead discovery; identification, validation and diversity of drug targets. Chemistry of prostaglandins, leukotrienes and thromboxones.

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

   12 Hrs

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

   **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.

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

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

   12 Hrs

3. **Chemistry of Synthetic drugs:** Systematic study, SAR, Mechanism of action and synthesis of new generation molecules of following class of drugs: Anti-hypertensive drugs, Psychoactive drugs, Anticonvulsant drugs, H1 & H2 receptor antagonist, COX1 & COX2 inhibitors, Adrenergic & Cholinergic agents, Antineoplastic and Antiviral agents.

   **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.

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

5. **Peptidomimetics:** Therapeutic values of Peptidomimetics, design of peptidomimetics by manipulation of the amino acids, modification of the peptide backbone, incorporating conformational constraints locally or globally. **12 Hrs**

REFERENCES:

1. Medicinal Chemistry by Burger.
3. Comprehensive Medicinal Chemistry – Corwin and Hansch.
4. Computational and structural approaches to drug design edited by Robert M Stroud and Janet. F Moore
5. Introduction to Quantitative Drug Design by Y.C. Martin.
10. An Introduction to Medicinal Chemistry – Graham L.Patrick, (III Edition.)
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

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

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

   Flavonoids
   Introduction, isolation and purification of flavonoids, General methods of structural determination of flavonoids; Structural elucidation of quercetin.
c) Steroids
General introduction, chemistry of sterols, sapogenin and cardiac glycosides. Stereochemistry and nomenclature of steroids, chemistry of contraceptive agents male & female sex hormones (Testosterone, Estradiol, Progesterone), adrenocorticoids (Cortisone), contraceptive agents and steroids (Vit – D).

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

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

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

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

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

4. Chemistry of natural products Vol I onwards IWPAC.
5. Natural Product Chemistry Nakanishi Gggolo.
7. The Alkaloid Chemistry and Physiology by THF Manske.
8. Introduction to molecular Phytochemistry – CHJ Wells, Chapmannstall.
14. Biotechnology by Purohit and Mathoor.
15. Phytochemical methods of Harborne.
16. Burger’s Medicinal Chemistry.
MPC105P: Pharmaceutical Chemistry Practical I

1. Analysis of pharmacopeial 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-schimdt reaction.
3. Benzylic acid rearrangement.
5. Hoffmann rearrangement
6. Mannich reaction
7. Synthesis of medicinally important compounds involving more than one step along with purification and Characterization using TLC, melting point and IR spectroscopy (4 experiments)
8. Estimation of elements and functional groups in organic natural compounds
9. Isolation, characterization like melting point, mixed melting point, molecular weight determination, functional group analysis, co-chromatographic technique for identification of isolated compounds and interpretation of UV and IR data.
10. Some typical degradation reactions to be carried on selected plant constituents
MPL 101T: MODERN PHARMACEUTICAL ANALYTICAL TECHNIQUES

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

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

THEORY 60 Hrs
   e. 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.
   f. Spectrofluorimetry: Theory of Fluorescence, Factors affecting fluorescence (Characterestics of drugs that can be analysed by flourimetry), Quenchers, Instrumentation and Applications of fluorescence spectrophotometer.
   g. 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, Hrs 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.
MASTER OF PHARMACY (SEMESTER-I)
(Credit Based Evaluation & Grading System)


4 Chromatography: Principle, apparatus, instrumentation, chromatographic parameters, factors affecting resolution, isolation of drug from excipients, data interpretation and applications of the following:
   Thin Layer chromatography
   a) High Performance Thin Layer Chromatography
   b) Ion exchange
   c) chromatography
   d) Column chromatography
   e) Gas chromatography
   f) High Performance Liquid chromatography
   g) Ultra High Performance Liquid chromatography
   h) Affinity chromatography
   i) Gel Chromatography

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

6 a. Potentiometry: Principle, working, Ion selective Electrodes and Application of potentiometry. thermal transitions 10 Hrs

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

REFERENCES

MPL102T: ADVANCED PHARMACOLOGY-I

Max. Marks: 75
Internal Assessment: 25
Total Marks: 100

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

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

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

THEORY
60HOURS

UNIT-I
General Pharmacology 12Hrs

a. Pharmacokinetics: The dynamics of drug absorption, distribution, biotransformation and elimination. Concepts of linear and non-linear compartment models. Significance of Protein binding. 06 hrs
b. Pharmacodynamics: Mechanism of drug action and the relationship between drug concentration and effect. Receptors, structural and functional families of receptors, quantitation of drug receptors interaction and elicited effects. 06 hrs

UNIT-II
Neurotransmission 12 Hrs

a. General aspects and steps involved in neurotransmission.
b. Neurohumoral transmission in autonomic nervous system (Detailed study about neurotransmitters- Adrenalin 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 06 Hrs
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
a. Autonomic Pharmacology
Parasympathomimetics and lytics, sympathomimetics and lytics, agents affecting neuromuscular junction

UNIT-III 12 Hrs
Central nervous system Pharmacology
General and local anesthetics 02 hrs
Sedatives and hypnotics, drugs used to treat anxiety. 02 hrs
Depression, psychosis, mania, epilepsy, neurodegenerative diseases. 05 hrs
Narcotic and non-narcotic analgesics. 03 hrs

UNIT-IV 12 Hrs
Cardiovascular Pharmacology
Diuretics, antihypertensives, antiischemics, anti-arrhythmics, drugs for heart failure and hyperlipidemia. 07 hrs
Hematinics, coagulants, anticoagulants, fibrinolytics and anti-platelet drugs 05 hrs

UNIT-V 12 Hrs
Autocoid Pharmacology
The physiological and pathological role of Histamine, Serotonin, Kinins Prostaglandins
Opioid autocoids. 08 hrs
Pharmacology of antihistamines, 5HT antagonists. 04 hrs

REFERENCES
1 The Pharmacological basis of therapeutics- Goodman and Gill man’s
2 Principles of Pharmacology. The Pathophysiologic basis of drug Therapy by David E Golan et al.
3 Basic and Clinical Pharmacology by B.G –Katzung
4 Pharmacology by H.P. Rang and M.M. Dale.
5 Hand book of Clinical Pharmacokinetics by Gibaldi and Prescott
7 Applied biopharmaceutics and Pharmacokinetics by Leon Shargel and Andrew B.C.Yu.
8 Handbook of Essential Pharmacokinetics, Pharmacodynamics and Drug Metabolism for Industrial Scientists
MPL103T: PHARMACOLOGICAL AND TOXICOLOGICAL SCREENING
METHODS-I

Max. Marks: 75
Internal Assessment: 25
Total Marks: 100

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

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

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

THEORY 60 HOURS
Unit-I 12 Hrs

Laboratory Animals
Common lab animals: Description, handling and applications of different species and strains of animals. 02 hrs
Transgenic animals: Production, maintenance and applications 02 hrs
Anaesthesia and euthanasia of experimental animals. 03 hrs
Maintenance and breeding of laboratory animals. 02 hrs
CPCSEA guidelines to conduct experiments on animals 02 hrs
Good laboratory practice. 01 hrs
Bioassay-Principle, scope and limitations and methods

Unit-II 12 Hrs
Preclinical screening of new substances for the pharmacological activity using in vivo, in vitro, and other possible animal alternative models.
General principles of preclinical screening. CNS Pharmacology: behavioral and muscle co ordination, CNS stimulants and depressants, anxiolytics, anti-psychotics, anti epileptics and nootropics. Drugs for neurodegenerative diseases like Parkinsonism, Alzheimers and multiple sclerosis. Drugs acting on Autonomic Nervous System
Unit-III  12 Hrs

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


Unit-IV  12 hrs

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


Unit V  12 hrs

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

Immunosuppressants and immunomodulators and immunostimulants 02 hrs

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 08 hrs

Limitations of animal experimentation and alternate animal experiments. 01 hr

Extrapolation of in vitro data to preclinical and preclinical to humans. 01 hr

REFERENCES

1. Biological standardization by J.H. Burn D.J. Finney and I.G. Goodwin
2. Indian Pharmacopeia and other Pharmacopeias
3. Screening methods in Pharmacology by Robert Turner. A
4. Evaluation of drugs activities by Laurence and Bachrach
7. Pharmacological experiment on intact preparations by Churchill Livingstone
8. Drug discovery and Evaluation by Vogel H.G.
MASTER OF PHARMACY (SEMESTER-I)
(Credit Based Evaluation & Grading System)

MPL104T: CELLULAR AND MOLECULAR PHARMACOLOGY

Max. Marks: 75
Internal Assessment: 25
Total Marks: 100

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

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

Unit I
Cell biology
Structure and functions of cell and its organelles
Genome organization. Gene expression and its regulation, importance of siRNA and micro RNA, gene mapping and gene sequencing
Cell cycles and its regulation.
Cell death– events, regulators, intrinsic and extrinsic pathways of apoptosis.
Necrosis and autophagy.

Unit II
Cell signaling
Intercellular and intracellular signaling pathways.
Classification of receptor family and molecular structure ligand gated ion channels; G-protein coupled receptors, tyrosine kinase receptors and nuclear receptors.
Secondary messengers: cyclic AMP, cyclic GMP, calcium ion, inositol 1,4,5-trisphosphate, (IP3), NO, and diacylglycerol.
Detailed study of following intracellular signaling pathways: cyclic AMP signaling pathway, mitogen-activated protein kinase (MAPK) signaling, Janus kinase (JAK)/signal transducer and activator of transcription (STAT) signaling pathway.
Unit III 12Hrs
Principles and applications of genomic and proteomic tools 06 hrs
DNA electrophoresis, PCR (reverse transcription and real time), Gene sequencing, micro array technique, SDS page, ELISA and western blotting,
Recombinant DNA technology and gene therapy 06 hrs
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

Unit IV 12Hrs
Pharmacogenomics 08 hrs
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

Unit V 12Hrs
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

Unit VI
Biosimilars
References:

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

MPL105P: Experimental Pharmacology- I

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

Handling of laboratory animals.
1. Various routes of drug administration.
2. Techniques of blood sampling, anesthesia and euthanasia of experimental animals.
3. Functional observation battery tests (modified Irwin test)
4. Evaluation of CNS stimulant, depressant, anxiogenics and anxiolytic, anticonvulsant activity.
5. Evaluation of analgesic, anti-inflammatory, local anesthetic, mydriatic and miotic activity.
8. Oral glucose tolerance test.
9. Isolation and identification of DNA from various sources (Bacteria, Cauliflower, onion, Goat liver).
10. Isolation of RNA from yeast
11. Estimation of proteins by Braford/Lowry’s in biological samples.
12. Estimation of RNA/DNA by UV Spectroscopy
13. Gene amplification by PCR.
14. Protein quantification Western Blotting.
15. Enzyme based in-vitro assays (MPO, AChEs, α amylase, α glucosidase).
17. DNA fragmentation assay by agarose gel electrophoresis
18. DNA damage study by Comet assay.
19. Apoptosis determination by fluorescent imaging studies.
20. Pharmacokinetic studies and data analysis of drugs given by different routes of administration using softwares
21. Enzyme inhibition and induction activity
22. Extraction of drug from various biological samples and estimation of drugs in biological fluids using different analytical techniques (UV)
23. Extraction of drug from various biological samples and estimation of drugs in biological fluids using different analytical techniques (HPLC)
References
1. CPCSEA, OECD, ICH, USFDA, Schedule Y, EPA guidelines,
2. Fundamentals of experimental Pharmacology by M.N.Ghosh
4. Drug discovery and Evaluation by Vogel H.G.
5. Spectrometric Identification of Organic compounds - Robert M Silverstein,
6. Principles of Instrumental Analysis - Doglas A Skoog, F. James Holler, Timothy A. Nieman,
7. Vogel’s Text book of quantitative chemical analysis - Jeffery, Basset, Mendham, Denney,
8. Basic Cell Culture protocols by Cheril D. Helgason and Cindy L.Mille
9. Basic Cell Culture (Practical Approach ) by J. M. Davis (Editor)
10. Animal Cell Culture: A Practical Approach by John R. Masters (Editor)
MASTER OF PHARMACY (SEMESTER-I)
(Credit Based Evaluation & Grading System)

MPL 101T: MODERN PHARMACEUTICAL ANALYTICAL TECHNIQUES

Max. Marks: 75
Internal Assessment: 25
Total Marks: 100

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

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

THEORY
60 Hrs

h. 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.
i. Spectrofluorimetry: Theory of Fluorescence, Factors affecting fluorescence (Characteristics of drugs that can be analysed by fluorimetry), Quenchers, Instrumentation and Applications of fluorescence spectrophotometer.

2. NMR spectroscopy: Quantum numbers and their role in NMR, Principle, Instrumentation, Solvent requirement in NMR, Hrs 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.

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

5 a. Electrophoresis: Principle, Instrumentation, Working conditions, factors affecting separation and applications of the following:
   a) Paper electrophoresis
   b) Gel electrophoresis
   c) Capillary electrophoresis
   d) Zone electrophoresis
   e) Moving boundary electrophoresis
   f) Iso electric focusing
   g. 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, working, thermal transitions and their influence, advantage and disadvantages, pharmaceutical applications.

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

REFERENCES

1. Spectrometric Identification of Organic compounds - Robert M Silverstein, Sixth
2. Principles of Instrumental Analysis - Douglas A Skoog, F. James Holler, Timothy A.
6. Quantitative Analysis of Drugs in Pharmaceutical formulation - P D Sethi, 3rd Edition,
   Dekker Series
   1982.
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
1. Know the advances in the cultivation and production of drugs
2. Know the various phyto-pharmaceuticals and their source & utilization and medicinal value.
3. Know the various nutraceuticals/herbs and their health benefits

THEORY

1. **Plant drug cultivation:** General introduction to the importance of Pharmacognosy in herbal drug industry, Indian Council of Agricultural Research, Current good agricultural practices, Current good cultivation practices, Current good collection practices, Conservation of medicinal plants - *Ex-situ* and *In-situ* conservation of medicinal plants.  **12 Hr**
2. **Marine natural products:** General methods of isolation and purification, Study of Marine toxins, Recent advances in research in marine drugs, Problems faced in research on marine drugs such as taxonomical identification, chemical screening and their solution.  **12Hrs**
3. **Nutraceuticals:** Current trends and future scope, Inorganic mineral supplements, Vitamin supplements, Digestive enzymes, Dietary fibres, Cereals and grains, Health drinks from natural origin, Antioxidants, Polyunsaturated fatty acids, Herbs as functional foods, Formulation and standardization of nutraceuticals, Regulatory aspects, FSSAI guidelines, Sources, name of marker compounds and their chemical nature, medicinal uses and health benefits of following i) Spirulina ii) Soya bean iii) Ginseng iv) Garlic v) Broccoli vi) Green and Herbal Tea vii) Flax seeds viii) Black cohosh ix) Turmeric.  **12Hrs**
4. **Phytopharmaceuticals:** Occurrence, isolation and characteristic features (Chemical nature, uses in pharmacy, medicinal and health benefits) of 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 AYUSH guidelines for safety monitoring of natural medicine, Spontaneous reporting schemes for biodrug adverse reactions, bio drug-drug and bio drug-food interactions with suitable examples.

12Hrs

**REFERENCES:**


7) Pharmacognosy-Tyler, Brady, Robbers

8) Modern Methods of Plant Analysis- Peach & M.V. Tracey, Vol. I&II


11) Marine Natural Products-Vol.I to IV.


13) Cultivation and Utilization of Aromatic Plants By C.K. Atal & B.M. Kapoor


17) Text Book of Pharmacognosy by T.E. Wallis
Scope:

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

Objectives:

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

1. know the different classes of phytoconstituents and their properties and general process of natural product drug discovery
2. know the process isolation, purification and identification of phytoconstituents

THEORY 60Hrs

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:

   a) Alkaloids: Ephedrine, Quinine, Strychynine, Piperine, Berberine, Taxol, Vincaalkoloids.
   b) Glycosides: Digitoxin, Glycyrrhizin, Sennosides, Bacosides, Ginsenosides, Quercitin, Rutin.
   c) Steroids: Hecogenin, gugguloosterone and withanolides
   d) Coumarin: Umbelliferone.
   e) Terpenoids: Cucurbitacins

12Hrs

2. Drug discovery and development: History of herbs as source of drugs and drug discovery, the lead structure selection process, structure development, product discovery process and drug registration, Selection and optimization of lead compounds with suitable examples from anticancer, CNS cardiovascular drugs, antitubercular drugs and immunomodulators, Clinical studies emphasis on phase of clinical trials, protocol design for lead molecules

12Hrs

3. Extraction and Phytochemical studies: Recent advances in extractions with emphasis on selection of method and choice of Hrs 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 CCCET, SCFE techniques including preparative HPLC and Flash column chromatography.

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

5 Structure elucidation of the following compounds by spectroscopic techniques like UV, IR, MS, NMR (1H, 13C) Hrs
   a. Carvone, Citral, Menthol
   b. Luteolin, Kaempferol
   c. Nicotine, Caffeine iv) Glycyrrhizin.

REFERENCES:

1) Organic chemistry by I.L. Finar Vol.II
2) Pharmacognosy by Trease and Evans, ELBS.
3) Pharmacognosy by Tylor and Brady.
5) Clark’s isolation and Identification of drugs by A.C. Mottal.
6) Plant Drug Analysis by Wagner & Bladt.
9) Natural Products Chemistry Practical Manual by Anees A Siddiqui and Seemi Siddiqui
11) Chemistry of Natural Products- Vol. 1 onwards IWPAC.
12) Modem Methods of Plant Analysis- Peach & M.V. Tracey, Vol. I&II
MPG104T: INDUSTRIAL PHARMACOGNOSTICAL TECHNOLOGY

Max. Marks: 75
Internal Assessment: 25
Total Marks: 100

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

Objective:
By the end of the course the student shall be able to:-

1. Know the requirements for setting up the herbal/natural drug industry.
2. To know and understand the guidelines for quality of herbal/natural medicines and regulatory issues.
3. To know patenting/IPR of herbals/natural drugs and trade of raw and finished materials.

THEORY


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, IPR. Quality assurance in herbal/natural drug products. Concepts of TDM, GMP, GLP, ISO-9000. 12Hrs


4. Testing of natural products and drugs: Effect of herbal medicines on clinical laboratory testing. Regulation and dispensing of herbal drugs. Stability testing of natural products, protocols. 12 Hrs

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

4. The complete technology book on herbal perfumes and cosmetics, by H.Pande, National Institute of Industrial Research, Delhi.
Pharmacognosy Practical I

PRACTICALS (MPGI05P)

1. Analysis of pharmacopoeial compounds of natural origin and their formulations by UV Vis spectrophotometer
2. Simultaneous estimation of multi component containing formulations by UV spectrophotometry
3. Analysis of recorded spectra of simple phytoconstituents
4. Experiments based on Gas Chromatography
5. Estimation of sodium/potassium by flame photometry
6. Development of fingerprint of selected medicinal plant extracts commonly used in herbal drug industry viz. ashwagandha, tulsi, bael, amla, ginger, aloe, vidang, senna, lawronia by HPTLC method
7. Method of extraction
8. Phytochemical screening
9. Thin layer chromatography
10. Demonstration of HPLC- estimation of glycyzeizin
11. Monograph analysis of clove oil
13. Identification of bioactive constituents from plant extracts
14. Formulation using qualitative and quantitative methods.
MASTER OF PHARMACY (SEMESTER-II)
(Credit Based Evaluation & Grading System)

MPH201T: MOLECULAR PHARMACEUTICS
(NANO TECHNOLOGY & TARGETED DDS)

Max. Marks: 75
Internal Assessment: 25
Total Marks: 100

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


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

REFERENCES:


Journals

1. Indian Journal of Pharmaceutical Sciences (IPA)
2. Indian drugs (IDMA)
3. Journal of controlled release (Elsevier Sciences) desirable
4. Drug Development and Industrial Pharmacy (Marcel & Decker) desirable
MASTER OF PHARMACY (SEMESTER-II)  
(Credit Based Evaluation & Grading System)

MPH202T: ADVANCED BIOPHARMACEUTICS & PHARMACOKINETICS

Max. Marks: 75  
Internal Assessment: 25  
Total Marks: 100

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

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

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

THEORY 60 Hrs


   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, 


4 Drug Product Performance, In Vivo: Bioavailability and Bioequivalence: drug product performance, purpose of Hrs bioavailability studies, relative and absolute availability. Methods for assessing bioavailability, bioequivalence studies, design and evaluation of bioequivalence studies, study designs, crossover study designs, evaluation of the data, bioequivalence example, study submission and drug review process. Biopharmaceutics classification system, methods. Permeability: In-vitro, in-situ and In-vivo methods. Generic biologics (biosimilar drug products), clinical significance of bioequivalence studies, special concerns in bioavailability and bioequivalence studies, generic substitution.

REFERENCES:

2. Biopharmaceutics and Pharmacokinetics, A. Treatise, D.M. Brahmankar and Sunil B.J aiswal., VallabPrakashan, Pitampura, Delhi
4. Textbook of Biopharmaceutics and Pharmacokinetics, Dr. Shobha Rani R. Hiremath, Prism Book
**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**

At 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**


   **Quality-by-Design In Pharmaceutical Development**: Introduction, ICH Q8 guideline, Regulatory and industry views on QbD, Scientifically based QbD - examples of application

   12Hrs


   12Hrs

12Hrs

4. **Computer-aided biopharmaceutical characterization**: Gastrointestinal absorption simulation
   - Introduction, Theoretical background, Model construction, Parameter sensitivity analysis, Virtual trial, Fed vs. fasted state, In vitro dissolution and *in vitro-in vivo* correlation, Biowaiver considerations

   **Computer Simulations in Pharmacokinetics and Pharmacodynamics:**

   **Computers in Clinical Development**: Clinical Data Collection and Management, Regulation of Computer Systems

12Hrs


12Hrs

**REFERENCES:**

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 will be able to understand

- The key ingredients used in cosmetics and Cosmeceutical.
- The key building blocks for various formulations.
- The current technologies in the market
- The various key ingredients and basic science to develop cosmetics and Cosmeceutical
- The scientific knowledge to develop cosmetics and Cosmeceutical with desired Safety, sensory, stability, and efficacy.

THEORY

1. Cosmetics – Regulatory: Definition of cosmetic products as per Indian regulation. 12 Hrs
   Indian regulatory requirements for labeling of cosmetics. Regulatory provisions relating to import of cosmetics, Misbranded and spurious cosmetics. Regulatory provisions relating to manufacture of cosmetics – Conditions for obtaining license, prohibition of manufacture and sale of certain cosmetics, loan license, offences and penalties.

2. Cosmetics - Biological aspects: Structure of skin relating to problems like dry skin, acne, pigmentation, prickly heat, wrinkles and body odor. Structure of hair and hair growth cycle. Common problems associated with oral cavity. Cleansing and care needs for face, eye lids, lips, hands, feet, nail, scalp, neck, body and under-arm.


   Perfumes: Classification of perfumes. Perfume ingredients listed as allergens in EU regulation.

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.

RECOMMENDED BOOKS:

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

PRACTICAL (MPH205P)

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
5. Formulation and evaluation of niosomes
6. Formulation and evaluation of spheruls
7. Improvement of dissolution characteristics of slightly soluble drug by Solid dispersion technique.
8. Comparison of dissolution of two different marketed products /brands
9. Protein binding studies of a highly protein bound drug & poorly protein bound drug
11. Pharmacokinetic and IVIVC data analysis by Winnoline® software
12. In vitro cell studies for permeability and metabolism
14. Formulation data analysis Using Design Expert® Software
15. Quality-by-Design in Pharmaceutical Development
16. Computer Simulations in Pharmacokinetics
17. Computer Simulations Pharmacodynamics
18. Computational Modeling Of Drug Disposition
19. To develop Clinical Data Collection manual
21. Development and evaluation of Creams
22. Development and evaluation of Shampoo and Toothpaste base
23. To Incorporate herbal and chemical actives to develop products
24. To address Dry skin, acne, blemish, Wrinkles, bleeding gums and dandruff
MPC201T: ADVANCED SPECTRAL ANALYSIS

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**: Woodward – Fiesures rule for 1,3- butadienes, cyclic dienes and \( \alpha, \beta \)-carbonyl compounds and interpretation compounds of enones. ATR-IR, IR Interpretation of organic compounds.

   12Hrs

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

   12Hrs

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.

   12Hrs

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 chromatography.

   12Hrs
5. **Thermal methods of analysis** – Introduction, principle, instrumentation and application of DSC, DTA and TGA.


   **Radio immuno assay**: Biological standardization, bioassay, ELISA, Radioimmuno assay of digitalis and insulin  

**REFERENCES**

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

1. Green Chemistry
   a. Introduction, principles of green chemistry
   b. Microwave assisted reactions: Merit and demerits of its use, increased reaction rates, mechanism, superheating effects of microwave, effects of solvents in microwave assisted synthesis, microwave technology in process optimization, its applications in various organic reactions and heterocycles synthesis
   c. Ultrasound assisted reactions: Types of sonochemical reactions, homogenous, heterogeneous liquid-liquid and liquid-solid reactions, synthetic applications
   d. Continuous flow reactors: Working principle, advantages and synthetic applications.

2. Chemistry of peptides
   a. Coupling reactions in peptide synthesis
   b. Principles of solid phase peptide synthesis, t-BOC and FMOC protocols, various solid supports and linkers: Activation procedures, peptide bond formation, deprotection and cleavage from resin, low and high HF cleavage protocols, formation of free peptides and peptide amides, purification and case studies, site-specific chemical modifications of peptides
   c. Segment and sequential strategies for solution phase peptide synthesis with any two case studies
   d. Side reactions in peptide synthesis: Deletion peptides, side reactions initiated by proton abstraction, protonation, over-activation and side reactions of individual amino acids.

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

   Pericyclic reactions
   Mechanism, Types of pericyclic reactions such as cyclo addition, electrocyclic reaction and sigmatropic rearrangement reactions with examples
4. Catalysis
   a. Types of catalysis, heterogeneous and homogenous catalysis, advantages and disadvantages
   b. Heterogeneous catalysis – preparation, characterization, kinetics, supported catalysts, catalyst deactivation and regeneration, some examples of heterogeneous catalysis used in synthesis of drugs.
   c. Homogenous catalysis, hydrogenation, hydroformylation, hydrocyanation, Wilkinson catalysts, chiral ligands and chiral induction, Ziegler-Natta catalysts, some examples of homogenous catalysis used in synthesis of drugs
   d. Transition-metal and Organo-catalysis in organic synthesis: Metal-catalyzed reactions
   f. Phase transfer catalysis - theory and applications

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

REFERENCES

6. Organic synthesis-the disconnection approach, S. Warren, Wily India
7. Principles of organic synthesis, ROCNorman and JMCoxan, Nelson thorns
8. Organic synthesis- Special techniques VK Ahluwalia and R Aggarwal, Narosa Publisher
MASTER OF PHARMACY (SEMESTER-II)
(Credit Based Evaluation & Grading System)

MPC203T: COMPUTER AIDED DRUG DESIGN

Max. Marks: 75
Internal Assessment: 25
Total Marks: 100

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

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
   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 components of cavities, Fragment based drug design.


5. **Pharmacophore Mapping and Virtual Screening**
   Concept of pharmacophore, pharmacophore mapping, identification of Pharmacophore features and Pharmacophore modeling; Conformational search used in pharmacophore mapping.

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

12 Hrs

REFERENCES:

1. Computational and structural approaches to drug design edited by Robert M Stroud and Janet. F Moore
2. Introduction to Quantitative Drug Design by Y.C. Martin.
10. Computational and structural approaches to drug design edited by Robert M Stroud and Janet. F Moore
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

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

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.

3. Unit Processes
   a. Nitration: Nitrating agents, Aromatic nitration, kinetics and mechanism of aromatic nitration, process equipment for technical nitration, mixed acid for nitration,
c. **Oxidation**: Introduction, types of oxidative reactions, Liquid phase oxidation with oxidizing agents. Nonmetallic Oxidizing agents such as H\textsubscript{2}O\textsubscript{2}, sodium hypochlorite, Oxygen gas, ozonolysis.  

4. **Unit Processes**
   a. **Reduction**: Catalytic hydrogenation, Heterogeneous and homogeneous catalyst; Hydrogen transfer reactions, Metal hydrides. Case study on industrial reduction process.
   b. **Fermentation**: Aerobic and anaerobic fermentation. Production of
      i. Antibiotics; Penicillin and Streptomycin,
      ii. Vitamins: B2 and B12
      iii. Statins: lovastatin, simvastatin

   **Reaction progress kinetic analysis**
   a. Streamlining reaction steps, route selection, 
   b. Characteristics of expedient routes, characteristics of cost-effective routes, reagent selection, families of reagents useful for scale-up.

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

REFERENCES:

8. P.H.Groggins: Unit processes in organic synthesis (MGH)
9. F.A.Henglein: Chemical Technology (Pergamon)
10. M.Gopal: Dryden’s Outlines of Chemical Technology
11. Clausen,Mattson: Principle of Industrial Chemistry
12. Lowenheim & M.K. Moran: Industrial Chemicals
15. Srreve: Chemical Procress
16. B.K.Sharma: Industrial Chemistry
17. ICH Guidelines
18. United States Food and Drug Administration official website www.fda.gov
Pharmaceutical Chemistry Practical II

PRACTICALS (MPC205P)

1. Synthesis of organic compounds by adapting different approaches involving (3 experiments)
   a. Oxidation
   b. Reduction/hydrogenation
   c. Nitration

2. Comparative study of synthesis of APIs/intermediates by different synthetic routes (2 experiments)
3. Assignments on regulatory requirements in API (2 experiments)
4. Comparison of absorption spectra by UV and Wood ward – Fiesue rule
5. Interpretation of organic compounds by FT-IR
6. Interpretation of organic compounds by NMR
7. Interpretation of organic compounds by MS
8. Determination of purity by DSC in pharmaceuticals
9. Identification of organic compounds using FT-IR, NMR, CNMR and Mass spectra
10. To carry out the preparation of following organic compounds

12. Preparation of 4-iodotolene from p-toluidine.
13. NaBH₄ reduction of vanillin to vanillyl alcohol
14. Preparation of umbelliferone by Pechman 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
22. Virtual screening based experiment
MASTER OF PHARMACY (SEMESTER-II)
(Credit Based Evaluation & Grading System)

MPL201T: ADVANCED PHARMACOLOGY-II

Max. Marks: 75
Internal Assessment: 25
Total Marks: 100

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

UNIT-I 12 Hrs
Endocrine Pharmacology
Molecular and cellular mechanism of action of hormones such as growth hormone, prolactin, thyroid, insulin and sex hormones
Anti-thyroid drugs, Oral hypoglycemic agents, Oral contraceptives,
Corticosteroids. Drugs affecting calcium regulation

UNIT-II 12 Hrs
Chemotherapy
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.

UNIT-III 12 Hrs
Chemotherapy 06 Hrs
Drugs used in Protozoal Infections
Drugs used in the treatment of Helminthiasis
Chemotherapy of cancer
Immunopharmacology 06 Hrs
Cellular and biochemical mediators of inflammation and immune response. Allergic or hypersensitivity reactions. Pharmacotherapy of asthma and COPD.
Immunosuppressants and Immunostimulants
UNIT-IV 08 Hrs

**GIT Pharmacology**
Antiulcer drugs, Prokinetics, antiemetics, anti-diarrheals and drugs for constipation and irritable bowel syndrome.

**Chronopharmacology** 04 Hrs

Biological and circadian rhythms, applications of chronotherapy in various diseases like cardiovascular disease, diabetes, asthma and peptic ulcer

UNIT-V 04 Hrs

**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:** 08 Hrs

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

**References**

1. The Pharmacological basis of therapeutics- Goodman and Gill man’s
3. Basic and Clinical Pharmacology by B.G -Katzung
7. Applied biopharmaceutics and Pharmacokinetics by Leon Shargel and Andrew B.C.Yu.
8. Handbook of Essential Pharmacokinetics, Pharmacodynamics and Drug Metabolism for Industrial Scientists
MPL202T: PHARMACOLOGICAL AND TOXICOLOGICAL SCREENING METHODS

Max. Marks: 75
Internal Assessment: 25
Total Marks: 100

Scope:
The 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.

Unit I
Basic definition and types of toxicology (general, mechanistic, regulatory and descriptive) Regulatory guidelines for conducting toxicity studies OECD, ICH, EPA and Schedule Y OECD principles of Good laboratory practice (GLP).
History, concept and its importance in drug development

Unit II
Acute, sub-acute and chronic- oral, dermal and inhalational studies as per OECD guidelines.
Acute eye irritation, skin sensitization, dermal irritation & dermal toxicity studies.
Test item characterization- importance and methods in regulatory toxicology studies

Unit III
Reproductive toxicology studies, Male reproductive toxicity studies, female reproductive studies (segment I and segment III), teratogenicity studies (segment II)
Genotoxicity studies (Ames Test, in vitro and in vivo Micronucleus and Chromosomal aberrations studies)
In vivo carcinogenicity studies

Unit IV
IND enabling studies (IND studies)- Definition of IND, importance of IND, industry perspective, list of studies needed for IND submission.
Safety pharmacology studies- origin, concepts and importance of safety pharmacology.
Tier1- CVS, CNS and respiratory safety pharmacology, HERG assay. Tier2- GI, renal and other studies
Unit V  
12 Hrs  
Toxicokinetics- Toxicokinetic evaluation in preclinical studies, saturation kinetics  
Importance and applications of toxicokinetic studies.  
Alternative methods to animal toxicity testing.  

REFERENCES  

3. Drugs from discovery to approval by Rick NG.  
5. OECD test guidelines.  
MPL203T: PRINCIPLES OF DRUG DISCOVERY

Max. Marks: 75
Internal Assessment: 25
Total Marks: 100

Scope:

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

Objectives:

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

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

Unit-I 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.

Unit-II 12 Hrs

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

Protein structure

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

Unit-III 12 Hrs

Rational Drug Design


Virtual Screening techniques: Drug likeness screening, Concept of pharmacophore mapping and pharmacophore based Screening,
Unit-IV

Molecular docking: Rigid docking, flexible docking, manual docking; Docking based screening. De novo drug design.

Quantitative analysis of Structure Activity Relationship

History and development of QSAR, SAR versus QSAR, Physicochemical parameters, Hansch analysis, Fee Wilson analysis and relationship between them.

Unit-V

QSAR Statistical methods – regression analysis, partial least square analysis (PLS) and other multivariate statistical methods. 3D-QSAR approaches like COMFA and COMSIA

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

References

2. Darryl León. Scott MarkelIn. Silico Technologies in Drug Target Identification and Validation. 2006 by Taylor and Francis Group, LLC.
MPL204T: CLINICAL RESEARCH AND PHARMACOVIGILANCE

Max. Marks: 75
Internal Assessment: 25
Total Marks: 100

Scope:
This subject will provide a value addition and current requirement for the students in clinical research and pharmacovigilance. It will teach the students on conceptualizing, designing, conducting, managing and reporting of clinical trials.

This subject also focuses on global scenario of Pharmacovigilance in different methods that can be used to generate safety data. It will teach the students in developing drug safety data in Pre-clinical, Clinical phases of Drug development and post market surveillance.

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

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

UNIT-I 12Hrs

Regulatory Perspectives of Clinical Trials:
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

UNIT- II 12 Hrs

Clinical Trials: Types and Design
Experimental Study- RCT and Non RCT,
Observation Study: Cohort, Case Control, Cross sectional

Clinical Trial Study Team
Roles and responsibilities of Clinical Trial Personnel: Investigator, Study Coordinator, Sponsor, Contract Research Organization and its management
UNIT- III  
**Clinical Trial Documentation**- Guidelines to the preparation of documents. Preparation of protocol, Investigator Brochure, Case Report Forms, Clinical Study Report Clinical Trial Monitoring-Safety Monitoring in CT


UNIT-IV  
**Basic aspects, terminologies and establishment of pharmacovigilance**

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

UNIT-V  
**Methods, ADR reporting and tools used in Pharmacovigilance**


UNIT-VI  
Pharmacoeipi Dermatology, pharmacoeconomics, safety pharmacology

References

3. Ethical Guidelines for Biomedical Research on Human Subjects 2000. Indian Council of Medical Research, New Delhi
MPL205P: Pharmacology Practical II

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

References

1. Fundamentals of experimental Pharmacology-by M.N.Ghosh
5. Applied biopharmaceutics and Pharmacokinetics by Leon Shargel and Andrew B.C.Yu.
6. Handbook of Essential Pharmacokinetics, Pharmacodynamics and Drug Metabolism for Industrial Scientists.
MASTER OF PHARMACY (SEMESTER-II)  
(Credit Based Evaluation & Grading System)

MPG201T: MEDICINAL PLANT BIOTECHNOLOGY  
Max. Marks: 75  
Internal Assessment: 25  
Total Marks: 100

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  
60Hrs

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

2. **Different tissue culture techniques:** Organogenesis and embryogenesis, synthetic seed and monoclonal variation, Protoplast fusion, Hairy root 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.  
   12 Hrs

   12Hrs

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.  
   12Hrs

5. **Fermentation technology:** Application of Fermentation technology, Production of ergot alkaloids, single cell proteins, enzymes of pharmaceutical interest.  
   12 Hrs
REFERENCES:

1. Plant tissue culture – Bhagwani, Vol 5. (Elsevier)
5. Experiments in plant tissue culture by John H. D and Lorin W. R.
7. Plant cell and tissue culture by Jeffrey W. Pollard and John M Walker.
9. Plant tissue culture by Street.
11. Biotechnology by Purohit and Mathur.
12. Biotechnological applications to tissue culture by Shargool.
MPG202T: ADVANCED PHARMACOGNOSY-II

Max. Marks: 75
Internal Assessment: 25
Total Marks: 100

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
- Know the methods of detection of adulteration and evaluation techniques for the herbal drugs
- To know the methods of screening of herbals for various biological properties

THEORY

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


4. **Analytical Profiles of herbal drugs**: *Andrographis paniculata, Boswellia serata, Coleus forskholii, Curcuma longa, Embelica officinalis, Psoralea corylifolia.*

REFERENCES:

4. Pharmacognosy-Tyler, Brady, Robbers
5. Modern Methods of Plant Analysis- Peach & M.V. Tracey, Vol. I&II
8. Text Book of Pharmacognosy by T.E. Wallis
MPG203T: INDIAN SYSTEMS OF MEDICINE

Max. Marks: 75
Internal Assessment: 25
Total Marks: 100

Scope

To make the students understand thoroughly on 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.

Objective

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 formulation.

THEORY 60Hrs

1. Fundamental concepts of Ayurveda, Siddha, Unani, and Homoeopathy systems of medicine:
   Different dosage forms of the ISM-
   - Siddha: Gunapadam (Siddha Pharmacology), raw drugs/Dhatu/Jeevam in siddha system of medicine, Purification process (Suddhi).
   - Unani: Knowledge of the important entries of the Unani Pharmacopoeia and their applications.
   - Homoeopathy: The basic principles and treatment modalities of Homoeopathy.

2. Naturopathy, Yoga and Aromatherapy practices:
   a) Naturopathy - Introduction, basic principles and treatment modalities.
   b) Yoga - Introduction and Streams of Yoga. Asanas, Pranayama, Meditations and Relaxation techniques.
   c) Aromatherapy – Introduction, aroma oils for common problems, carrier oils.

3. Formulation development of various systems of medicine:
   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:
   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 herbal drug industry of GAP, GMP and GLP in traditional system of medicine. 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 skill, Government skills in AYUSH, ISM, CCRAS, CCRS, CCRH, CCRU.  

REFERENCES:

8. British Herbal Pharmacopoeia British (1990), Herbal Medicine Association, UK.
10. Indian System of Medicine and Homeopathy in India (2001), Planning and Evaluation Cell, Govt.of India, New Delhi.
11. Essential of Food and Nutrition by Swaminathan (1999), Bappco, Bangalore.
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 Drug and cosmetic act.

Objective

After completion of the course, student is 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

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

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

3. Herbal Cosmetics : Physiology and chemistry of skin and pigmentation, hairs, scalp, lips and nail, Cleansing cream, Lotions, Face powders, Face packs, Lipsticks, Bath products, soaps and baby product, Preparation and standardisation of the following : Tonic, Bleaches, Dentifrices and Mouth washes & Tooth Pastes, Cosmetics for Nails.  

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

REFERENCES:

MPG205P: Pharmacognosy Practical II

1. Isolation of nucleic acid from cauliflower heads
2. Isolation of RNA from yeast
3. Quantitative estimation of DNA
4. Immobilization of whole cell
5. Establishment of callus culture
6. Establishment of suspension culture
7. Estimation of aldehyde
8. Estimation of phenolic content in herbal raw materials
9. Estimation of alkaloid content in herbal raw materials
10. Estimation of 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. Herbal cosmetic formulation such as lip balm, lipstick, facial cream, herbal hair and nail care products
14. Evaluation of herbal tablets and capsules
15. Dermatological preparation like sunscreen, UV protection cream, skin care formulations for fungal and dermato reaction
16. Formulation of cough syrup
UNIT – I

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

UNIT – II

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

UNIT – III

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

UNIT – IV

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

UNIT – V

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