

**DEPARTMENT OF PHARMACUETICAL SCIENCES, MAHARSHI DAYANAND UNIVERSITY, ROHTAK.**

**TEACHING LOAD FOR THEORY AND PRACTICAL PAPERS AND SCHEME OF EXAMINATIONS FOR  
MASTER OF PHARMACY w.e.f. 2014-15**

**M. Pharm.- 1<sup>st</sup> Semester**

Name of the subject	Theory ( Teaching hours / week )	Marks	Practicals (Teaching hours / week per batch)	Marks
Paper - 1	04	100	06	100
Paper - 2	02	100	06	100
Paper - 3	02	100	06	
Paper - 4	02	100	06	
Total =	12	400	24	200

Total = 36 hrs / week ; 600 marks/semester

**M. Pharm.- 2<sup>nd</sup> Semester**

Name of the subject	Theory ( Teaching hours / week )	Marks	Practicals (Teaching hours / week per batch)	Marks
Paper - 5	04	100	06	100
Paper - 6	02	100	06	100
Paper - 7	02	100	06	
Paper - 8	02	100	06	
Total =	12	400	24	200

Total = 36 hrs / week ; 600 marks/semester

**M. Pharm. -3<sup>rd</sup> Semester**

Research Work	35 hrs / week
Research Work Synopsis	200 marks
Presentation	400 marks
Total =	600 marks

**M. Pharm. 4<sup>th</sup> Semester**

Research Work	35 hrs / week
Evaluation of thesis	300 marks
Viva voce	300 marks
Total =	600 marks

**Total Marks in M. Pharm. = 2400**

**Note:**

- There shall be 80 marks for Main Theory / Practical Examinations and 20 marks for Internal Assessment, in all theory / practical papers. For Internal Assessment, the "Rules for award of Internal Assessment for PG courses", as applicable from time to time, shall be implemented.
- The distribution of marks for Main Theory Examination (80 marks) shall be as follows:

Each Question shall be of 16 marks ; Total Marks = 80		
Question One	Covering the entire syllabus	Short answer type questions
Question Two	Covering the Unit One	Any two questions, out of three question, need to be answered
Question Three		
Question Four		
Question Five		
Question Six	Covering the Unit Two	Any two questions, out of three question, need to be answered
Question Seven		

**DETAILS OF SUBJECTS IN SEMESTER – 1 and 2**

Name of the subject	M.Pharm. Specialization				
	Pharmaceutical Chemistry	Industrial Pharmacy	Drug Regulatory Affairs	Pharmacognosy	Pharmacology
<b>Semester - 1</b>					
Paper-1	MPH – 01 Modern Analytical Techniques – I				
Paper-2	MHPCHM – 02 Pharmaceutical Chemistry - I	MPHIP – 02 Industrial Pharmacy - I	MPHDRA – 02 Drug Regulatory Affairs – I	MHPHCOG-02 Pharmacognosy-I	MHPHCOL-02 Pharmacology-I
Paper-3	MHPCHM – 03 Pharmaceutical Chemistry - II	MPHIP – 03 Industrial Pharmacy - II	MPHDRA – 03 Drug Regulatory Affairs – II	MHPHCOG-03 Pharmacognosy-II	MHPHCOL-03 Pharmacology-II
Paper-4	MHPCHM – 04 Pharmaceutical Chemistry - III	MPHIP – 04 Industrial Pharmacy - III	MPHDRA – 04 Drug Regulatory Affairs – III	MHPHCOG-03 Pharmacognosy-III	MHPHCOL-04 Pharmacology-IV
<b>Semester - 2</b>					
Paper-5	MPH – 02 Modern Analytical Techniques – II				
Paper-6	MHPCHM – 05 Pharmaceutical Chemistry - IV	MPHIP – 05 Industrial Pharmacy - IV	MPHDRA – 05 Drug Regulatory Affairs – IV	MHPHCOG-05 Pharmacognosy-IV	MHPHCOL-05 Pharmacology-IV
Paper-7	MHPCHM – 06 Pharmaceutical Chemistry -V	MPHIP – 06 Industrial Pharmacy - V	MPHDRA – 06 Drug Regulatory Affairs – V	MHPHCOG-06 Pharmacognosy-V	MHPHCOL-06 Pharmacology-V
Paper-8	MHPCHM – 07 Pharmaceutical Chemistry - VI	MPHIP – 07 Industrial Pharmacy - VI	MPHDRA – 07 Drug Regulatory Affairs – VI	MHPHCOG-07 Pharmacognosy-VI	MHPHCOL-07 Pharmacology-VI

**Department of Pharmaceutical Sciences**  
**Revised syllabus for M. Pharmacy Course**  
**w.e.f. 2014-15 academic session**

**M. PHARM. (PHARMACEUTICAL CHEMISTRY)**

**SEMESTER - 1**

**MPH – 01**

**Modern Analytical Techniques – I (Common for all streams)**

**THEORY**

**Lectures: 4 hrs / week**

**Unit – I**

UV-Visible Spectroscopy: Electromagnetic spectrum, UV-visible range, structural features, absorption of radiant energy, factors influencing absorption of radiant energy: Instrumentation — single-beam spectrophotometer, double-beam spectrophotometer, Assay methods, Applications in pharmaceutical analysis. Infrared Spectroscopy: Molecular vibrations, stretching vibrations, bending vibrations, vibrational frequencies, factors influencing vibrational frequencies, electronic effects, Instrumentation — Single-monochromator IR-spectrophotometer, experimental profile of IR-spectroscopy : Quantitative analysis, applications in the analysis of Pharmaceutical dosage forms, qualitative interpretation of IR-spectra, Recent advances in IR-spectroscopy, e.g. FT-IR, ATR, etc. Optical Rotatory Dispersion: Fundamental principles of ORD, Cotton-effect curves — their characteristics and interpretation, Octet rule and its applications, circular dichroism.

**Unit – II**

Nuclear Magnetic Resonance Spectroscopy: The NMR-phenomenon viz. spinning nucleus, effect of an external field, precessional motion, precessional frequency, energy transition, chemical shift, <sup>3</sup>H-NMR (Tritium NMR-spectroscopy), <sup>13</sup>C-NMR-spectroscopy, 2D-NMR, interpretations of NMR-spectrum, instrumentation, applications in pharmaceutical analysis. Mass Spectrometry: Basic principles and brief outline of instrumentation, ion formation and types: molecular ion, meta-stable ions, fragmentation processes. Fragmentation patterns and fragment characteristics in relation to parent structure and functional groups; Mass spectrum, its characteristics, presentation and interpretation. Recent advances in MS, viz. GC-MS, chemical ionization MS and Fast Atom Bombardment Mass Spectroscopy.

**PRACTICALS :**

**( 06 hrs / week )**

Practicals based on aforementioned theory

**MPHPCHM – 02**

**Pharmaceutical Chemistry - I**

**(Advanced Organic Chemistry – I )**

**THEORY**

**Lectures: 2 hrs / week**

**Unit I**

**Rearrangements-**

- a) Carbon to carbon migration- Wagner-Meerwein, Pinacol-pinacolone, Benzilic acid, Favorskii.
- b) C to N migration -Hoffmann, Curtius, Beckmann, Schmidt, Lossen.
- c) C to O migration- Bayer-Villiger, hydroperoxides.

**Pericyclic reactions-** Molecular orbital symmetry, Woodward-Hofmann rules. Electrocyclic (Diels-Alder reaction) and sigmatropic reactions-Cope, Benzidine rearrangements. Cycloaddition.

**Green Chemistry-** Water as solvent, ionic liquids, supercritical liquids, Supported reagents and catalysts, Solvent free reactions, activation by Microwave, Ultrasound.

**Importance of functional groups** in determining drug action, toxicity and stability of drugs

**Unit II**

**Synthon approach-** Concept, half-reactions, FGI, analysis of target molecule, synthetic strategies. Application to synthesis of benzocaine, propranolol, haloperidol, salbutamol, chlorphereamine.

**Reduction of Carbonyl and Other Functional Groups-**

Addition of hydrogen: Catalytic hydrogenation. Group III hydride-donor reagents: Reduction of carbonyl compounds, reduction of other functional groups by hydride donors. Group IV hydride donors.

Dissolving-Metal reductions: addition of hydrogen, reductive removal of functional groups, reductive carbon-carbon bond formation, reductive deoxygenation of carbonyl groups.

**Miscellaneous reactions.**

- a) Electrophilic Aromatic Substitution –Nitration, halogenation, sulphonation, Friedel-Crafts reactions.

- b) Nucleophilic Aromatic Substitution –via diazonium ions.
- c) Electrophilic addition to C=C double bond- halogens, halogen halides, water.
- d) Carboxylic acids- formation from alcohols and aldehydes, interconversions of carboxylic acid derivatives.

**Practicals: ( 6 hrs / week )**

1. Synthesis involving oxidation, reduction, nitration, halogenations.
2. Synthesis involving rearrangements and named reaction.
3. Paper Reading/Seminar with respect to the latest developments in pharmaceutical chemistry
4. Synthesis-
  - a. Cinnamic acid by Perkin reaction
  - b.  $\beta$ -Ddimethylamino propiophenone hydrochloride (Mannich base)
  - c. 2-Phenyl indole
  - d. Dimedone (5,5-dimethyl cyclohexane-1,3-dione)
  - e. 3-Bromo cyclohexene from cyclohexene using NBS.
  - f. p-Amino benzyl alcohol from p-amino benzaldehyde using sodium borohydride.
  - g. Cyclohexane-2,5-dicarboxylic acid from benzoic acid (hydrogenation).

**RECOMMENDED READINGS:**

1. Advanced Organic Chemistry — Reactions, Mechanisms & Structure, Jerry March
2. Organic Chemistry — Vol I to III, S.P. Mukherji, S.P.Singh and R.S.Kapoor
3. Reaction Mechanisms in Organic Chemistry, S.M. Mukherjee and S.P.Singh
4. A Guide Book to Mechanisms in Organic Chemistry, Peter Sykes
5. Stereochemistry of Carbon Compounds, Eliel
6. Structure and Mechanism in Organic Chemistry, C.K.Ingold
7. Organic Chemistry — Vols I & II, I.L. Finar
8. Molecular Reactions and Photochemistry, C.H.Depny and O.L.Chapman
9. Physical Organic Chemistry, Jack Hyne
10. Vogel's Text Book of Practical Organic Chemistry .
11. Practical Organic Chemistry, F.G.Mann and B.C.Saunders
12. Combinatorial Chemistry — Synthesis and Applications, Stephen R. Wilson and Anthony W. Czarnik
13. Remington — The Science and Practice of Pharmacy — Vol. I & II, A.R. Gennard
14. Applications of Absorption Spectroscopy, John R.Dyer
15. Organic Chemistry, Morrison & Boyd
16. Experimental Methods in Organic Chemistry, Moore and Dalrymple
17. Stereochemistry- R.S. Kalsi
18. Organic Chemistry-Solomons G. and Fryhle C., Wiley, New York
19. Organic Chemistry-Mc Murry J., Books/Cole, Pacific Grove (USA)
20. Synthon approach –Stuart Warren
21. Organic Chemistry- Pine, Hendrickson

**MPHPCM – 03                      Pharmaceutical Chemistry – II**  
**(Advanced Medicinal Chemistry – I)**

**THEORY**

**Lectures: 2 hrs / week**

**Unit I**

**Drug Design:** Approaches to drug design, method of variation, biochemical and physiological approaches. Lead compound - Search & Optimization : Search of lead compound from natural products and other sources, selection of test compounds. Methods of lead optimization – synthesis of analogs, variation of substituents, extension of structure, ring versus chain structures, ring contraction and expansion. Case study of Cimitidine and pantaprazole. Isosterism & bioisosterism- Concepts of isosterism in drug design; Classical and non classical isosterism, Application of bioisosterism

**Prodrugs:** Objectives of Prodrug Design – increasing bioavailability, improving membrane permeability, prolonging activity, reducing side effects, removing undesirable properties. Prodrugs from different functional groups-carboxyl, amino, hydroxyl etc.

**Designer Drugs:** Designer Drugs, Illegal Designer Drugs.

**Unit II**

**Combinatorial chemistry:** Solid phase synthesis, Solution phase synthesis, deconvolution techniques and applications of combinatorial chemistry. High Throughput Screening- general outline, importance and application

**Characterization of chemicals by Class & by Pharmacophore:** Introduction to pharmacophore; Identification of pharmacophore features; Building pharmacophore hypothesis; Searching databases using pharmacophores

**Basic concepts of chemoinformatics** – Introduction to Chemoinformatics; Molecular file formats and their conversions: smiles, smirks & smarts; Database search: sub structure search and similarity search

**Practicals:****( 6 hrs / week )**

1. Synthesis and characterization of biologically active hetero-cyclic nuclei such as hydantoin, indole, furan, benzofuran, benimidazole etc
2. Experiments based on Solution phase synthesis
3. Experiments based on drug design

**RECOMMENDED READINGS :**

1. Medicinal Chemistry — A molecular and Biochemical Approach, Thomas Nogrady and Donald F. Weaver
2. Medicinal Chemistry, A. Burger Vols. I to V
3. Principles of Medicinal Chemistry, W. O. Foye
4. The Organic Chemistry of the Drug Design and Drug Action, Richard B. Silverman
5. Goodman and Gilman's Text book of Pharmacology.
6. Wilson and Gisvold's Text book of Medicinal Chemistry

**MPPCHM – 04                      Pharmaceutical Chemistry – III  
(Chemistry of Natural Products - I)****THEORY****Lectures: 2 hrs / week****Unit I**

Mechanistic and biosynthetic approach to plant secondary metabolites.

Acetate-malonate pathway (Biosynthesis of plant fatty acids, biosynthesis and oxidation of ricinoleic acid.) Polyketides (Biosynthesis of 6-methylsalicylic acid, petulin, penicillanic acid, griseofulvin, tetracyclines). Acetate-mevalonate pathway (biosynthesis of psoralen, gibberellic acid, cholesterol, conessine). Shikimic acid pathway (Biosynthesis of chlorogenic acid, cichoriin). Mixed biogenesis of plant products:

**Unit II**

Flavonoids and anthocyanins. Biosynthesis of alkaloids: Hyoscyamine, Morphine, Vindoline. Compounds derived from Amino acids: Colchicine, Cephalosporin C. Biosynthesis of porphyrins: Cobalamine. Plant hormones including brassinosteroids. Marine products with therapeutic potential.

**Practicals:****( 6 hrs / week )**

Number of experiments based upon aforementioned theory, including the following :

1. Isolation and characterization of medicinally active constituents e.g.
  - (a) Eugenol from clove
  - (b) Curcumin from Turmeric
  - (c) Hesperidin from Orange Peel
  - (d) Glycyrrhizin from Glycyrrhiza
  - (e) Piperine from Black Pepper
  - (f) Trimyristin and Myristicin from Nutmeg
  - (g) Pectin from Orange Peel
  - (h) Ascorbic acid from Lemon
  - (i) Sennoside from Senna
  - (j) Menthol from Peppermint oil
  - (k)  $\beta$ -sitosterol from edible oils
  - (l) Glycosides
  - (m) Alkaloids
  - (n) Terpenoids from natural sources

**RECOMMENDED READINGS:**

1. Structure Elucidation of Natural Products by Mass Spectroscopy — Vol I & II, H. Budzikiewicz, C.Djerassic and D.H. Williams
2. Tables of Spectral Data for Structural Determination of Organic Compounds- E. Pretsch, T.Clerc, J. Seibl and W. Simon
3. Heterocyclic Chemistry-Albert
4. Biogenesis of Natural Compounds - Bernfeld
5. An Introduction to the Chemistry of Terpenoids and Steroids-Templeton
6. Organic Chemistry of secondary Plant Metabolism-Geissman and Crout
7. Chemistry of the Alkaloids-Pelletier
8. The Chemistry of the Natural Products- Butterworths.
9. Pharmacognosy and Pharmacobiotechnology - J.E. Robbers, M.K. Speedie and V.E. Tyler.

## SEMESTER – 2

MPH – 02

Modern Analytical Techniques – II (Common for all streams)

### THEORY

Lectures: 4 hrs / week

#### Unit – I

High Performance Liquid Chromatography (HPLC): Comparison of GC and HPLC, Instrumentation in HPLC, analytical, preparative, microbore columns, normal and reverse-phase packing materials, reverse-phase HPLC, column selection, mobile phase selection, efficiency parameters, resolution, detectors in HPLC- refractive index, photometric and electrochemical. Applications of these detectors. Size Exclusion Chromatography: Distribution coefficient, performance, materials, apparatus, applications in pharmaceutical analysis. Electrophoresis: Moving boundary electrophoresis, zone electrophoresis, continuous electrophoresis (preparative), isotadiphoresis, isoelectric focussing. Gas Chromatography (GC): Theory, Instrumentation- sample injector, columns, detectors, applications. High Performance Thin Layer Chromatography (HPTLC): Principles, instrumentation and applications.

#### Unit – II

X-Ray Diffraction Methods: Elementary crystallography, X-ray diffraction, Bragg's law, X-ray powder diffraction, X-ray powder diffractometer — interpretation of data. Errors in Pharmaceutical Analysis and Statistical Validation: Introduction, classification of errors, viz. determinate and indeterminate errors, accuracy, precision, minimizing systematic errors; Statistical Validation methods viz. Statistical treatment of finite samples, distribution of random errors, significant errors, comparison of results, method of least squares and criteria for rejection of an observation. Thermal Analysis: Principles and applications of thermogravimetric analysis (TGA), Differential thermal analysis (DTA), and Differential scanning Calorimetry (DSC).

### PRACTICALS

( 06 hrs / week )

Practicals based on aforementioned theory.

MPHPCHM – 05

Pharmaceutical Chemistry - IV

(Advanced Organic Chemistry – II )

### THEORY

Lectures: 2 hrs / week

#### Unit I

Stereochemistry- Optical isomerism- Plane, centre & axis of symmetry, chiral molecules-test and biological importance of chirality. Stereospecific and stereoselective synthesis. Resolution of racemic mixtures. Geometric isomerism- Resulting from double bonds, monocyclic compounds, fused ring systems. Conformational isomerism-conformations in cyclic compounds.

Reactive intermediates - structure, generation, stability and reactivity of carbocations, carbanions, carbenes, nitrenes and free radicals.

#### Unit II

Alkylation - Alkylation of nucleophilic carbon; enolates and enamines: generation & alkylation of enolates, dianions; oxygen vs. carbon as site of alkylation. Alkylation of aldehydes, esters, amides & nitriles. Enamines and imine anions. Study of individual reactions- Allylic rearrangement, Arndt-Eistert reaction, Bayer-villegger rearrangement, Beckmann rearrangement, Bischler Napieralski synthesis, Claisen condensation, Claisen-Schmidt reaction, Dakin reaction, Curtius reaction, Dieck-Mann reaction, Diels–Alder reaction, Fittig reaction, Fries rearrangement, Gabriel synthesis, Hell-Volhard Zelinsky reaction, Knoevenagel reaction, Leuckart reaction, Mannich reaction, Perkin reaction, Pechmann reaction, Pinacol-pinacolone rearrangement. Willgerodt reaction, Wittig reaction, Wolf rearrangement, Suzuki coupling.

Kinetic and thermodynamic requirements for reaction, kinetic versus thermodynamic control. Non-kinetic and kinetic methods for determining mechanisms.

#### Practicals:

( 06 hrs / week )

1. Synthesis involving oxidation, reduction, nitration, halogenations.
2. Synthesis involving rearrangements and named reaction.
3. Paper Reading/Seminar with respect to the latest developments in pharmaceutical chemistry Synthesis-
  - a. Cinnamic acid by Perkin reaction
  - b.  $\beta$ -Ddimethylamino propiophenone hydrochloride (Mannich base)

- c. 2-Phenyl indole
- d. Dimedone (5,5-dimethyl cyclohexane-1,3-dione)
- e. 3-Bromo cyclohexene from cyclohexene using NBS.
- f. p-Amino benzyl alcohol from p-amino benzaldehyde using sodium borohydride.
- g. Cyclohexane-2,5-dicarboxylic acid from benzoic acid (hydrogenation).

**RECOMMENDED READINGS:**

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3. Reaction Mechanisms in Organic Chemistry, S.M. Mukherjee and S.P.Singh
4. A Guide Book to Mechanisms in Organic Chemistry, Peter Sykes
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10. Vogel's Text Book of Practical Organic Chemistry .
11. Practical Organic Chemistry, F.G.Mann and B.C.Saunders

**MPPCHM – 06**

**Pharmaceutical Chemistry - V**

**(Advanced Medicinal Chemistry – II )**

**THEORY**

**Lectures: 2 hrs / week**

**Unit I**

Concept of external and internal coordinates and algorithms for their interconversion. Different representations of molecular structures and their relative merits and demerits.

The Protein Data Bank (PDB) and the Nucleic Acid Data Bank (NDB). The PDB and the mmCIF file formats for the storage and dissemination of molecular structures.

Concept of free energy of molecules. Introduction to various force fields and their relative merits and demerits. Techniques for Molecular energy minimization, Monte Carlo and Molecular Dynamics simulation.

**Unit II**

**Quantitative structure activity relationship (QSAR):** Physicochemical parameters – hydrophobicity, electronic and steric parameters, Hansch analysis – Steps involved, Facts to be considered, Development of one-target and multi-target QSAR models in case of antimicrobial agents, Free-Wilson analysis, Craig plot and Topliss scheme, Simplex method, 3D-QSAR approaches like Docking and CoMFA..

**Analogue based drug discovery** – Analogues as means of discovering new drugs, Drug likeliness and Analogue based drug discovery, Privileged Structures and Analogue-Based Drug Discovery.

**Peptidomimetic and Nucleotide drug design:** Use of peptidomimetics in drug design, cyclisation of peptides, constrained amino acids, amide bond isosteres, and oligonucleotide therapeutics.

**Practicals:**

**(6 hrs / week )**

1. Synthesis of medicinal compounds belongs to chemotherapeutic drugs
2. Number of experiments based on QSAR

**RECOMMENDED READINGS :**

1. Medicinal Chemistry — A molecular and Biochemical Approach, Thomas Nogrady and Donald F. Weaver
2. Medicinal Chemistry, A. Burger Vols. I to V
3. Principles of Medicinal Chemistry, W. O. Foye
4. Wilson and Gisvolds Text book of Medicinal Chemistry
5. The Organic Chemistry of the Drug Design and Drug Action, Richard B. Silverman
6. Analogue based Drug Discovery, János Fischer and C. Robin Ganellin
7. Goodman and Gilman's Text book of Pharmacology.
8. Chemoinformatics - Concepts, Methods, and Tools for Drug Discovery, Jürgen Bajorath

**MPHPCHEM – 07      Pharmaceutical Chemistry - VI**  
**(Chemistry of Natural Products – II )**

**THEORY**

**Lectures: 2 hrs / week**

**Unit I**

Study of the chemistry of natural products using degradative and synthetic methods and spectral techniques.

Biological significance will also be discussed.

Alkaloids: Emetine, Ricinine, Papaverine, Nicotine, Atropine, Cocaine.

Purines and Nucleic acids: Alloxan, Allantoin, Caffeine, Theobromine, DNA&RNA.

Flavonoids: Quercetin and Rutin.

Steroids: Cholesterol, Vitamin D and Cardiac glycosides.

Recent progress on plant derived Anti-HIV agent:- Calophyllum, Triterpenic Betulic acid.

Antimalarial: Artemisinin.

**Unit II**

Terpenoids: Zingiberene, Abietic acid and  $\beta$ -amyryn.

Antibacterials: Chemistry of Cephalosporin, Aminoglycoside, Ciprofloxacin, Norfloxacin, Sulfonamide, Macrolide and Chloramphenicol.

Antineoplastic agents obtained from Plants: Catharanthus alkaloids; Paclitaxel and derivatives; Podophyllotoxin, Etoposide and Teniposide.

**Practicals:**

**( 6 hrs / week )**

Number of experiments based upon aforementioned theory, including the following :

1. Degradation reactions of natural products and their identification by micro-TLC, qualitative tests and spectroscopic methods viz. Atropine, caffeine, ephedrine and nicotine.
2. Paper chromatography, electrophoresis of amino acids derived from plant sources.

**RECOMMENDED READINGS:**

1. Structure Elucidation of Natural Products by Mass Spectroscopy — Vol I & II, H. Budzikiewicz, C. Djerassi and D.H. Williams
2. Tables of Spectral Data for Structural Determination of Organic Compounds- E. Pretsch, T. Clerc, J. Seibl and W. Simon
3. Heterocyclic Chemistry-Albert
4. Biogenesis of Natural Compounds - Bernfeld
5. An Introduction to the Chemistry of Terpenoids and Steroids-Templeton
6. Organic Chemistry of secondary Plant Metabolism-Geissman and Crout
7. Chemistry of the Alkaloids-Pelletier
8. The Chemistry of the Natural Products- Butterworths.
9. Pharmacognosy and Pharmacobiotechnology - J.E. Robbers, M.K. Speedie and V.E. Tyler.



# M. PHARM. PHARMACEUTICS (DRUG REGULATORY AFFAIRS)

## SEMESTER - 1

MPHDRA – 02

Drug Regulatory Affairs – I

Lectures: 2 hrs / week

### THEORY

#### Unit I

A detailed study of the following laws, including latest amendments in India:

- a. The Drugs and Cosmetics Act, 1940 and Rules thereunder.
- b. **The Drugs (Prices Controls) Order, 2013.**

#### Unit II

- a. The Indian Patents and Designs, Act 1970, including recent amendments.
- b. Introduction to the Indian laws on Trade Marks and Copy Rights.

#### Practicals:

( 6 hrs / week )

Number of Practicals / assignments based on aforementioned theory.

MPHDRA – 03

Drug Regulatory Affairs - II

Lectures: 2 hrs / week

### THEORY

#### Unit I

A detailed study of Federal Food, Drugs and Cosmetics Act of USA, restricted to human drugs, cosmetics and biotechnological products, with special emphasis on :

- a. History of drug regulation in USA.
- b. Organization and functions of FDA, including historical developments.
- c. General definitions.
- d. Adulterated & misbranded drugs/cosmetics/biotechnological products.
- e. OTC drugs, Orphan drugs, Orange Book and Fast Track Products.
- f. General penalties as applicable to drugs, cosmetics and biotechnological products.

#### Unit II

A detailed study of Federal Food, Drugs and Cosmetics Act of USA, restricted to human drugs, cosmetics and biotechnological products, with special emphasis on :

- a. General drug approval process.
- b. Investigational New Drug application.
- c. New Drug Application and BLA.
- d. ANDA.
- e. SNDA, SUPAC and BACPAC.
- f. Post marketing surveillance.

#### Practicals:

( 6 hrs / week )

Number of Practicals / assignments based on aforementioned theory.

MPHDRA – 04

Drug Regulatory Affairs - III

Lectures: 2 hrs / week

### THEORY

#### Unit I

- a. Drug regulatory authorities in European Union (EU) -- Introduction, Organization and General Guidelines.
- b. Regulatory consideration for pre-clinical testing and clinical testing in EU.

#### Unit II

- a. Registration application for marketing approval (IND, NDA, ANDA) in EU.
- b. Drug Master Files in EU.

#### Practicals:

( 6 hrs / week )

Number of Practicals / assignments based on aforementioned theory.

## SEMESTER – 2

### MPHDRA – 05

### Drug Regulatory Affairs - IV

Lectures: 2 hrs / week

#### THEORY

#### Unit I

An introductory study of following laws of that affect drug product design, manufacture and distribution in India (with latest amendments) :

- a. The Environmental Protection Act
- b. Consumer Protection Act
- c. Law of Torts

#### Unit II

I. An introductory study of following laws of that affect drug product design, manufacture and distribution in India (with latest amendments) :

- a. Law of Contracts
- b. **Competition Act, 2002**

II. Auditing of manufacturing facilities by International regulatory agencies. The ISO 9000 series of quality systems standards.

#### Practicals:

( 6 hrs / week )

Number of Practical / assignments based on aforementioned theory.

### MPHDRA – 06

### Drug Regulatory Affairs - V

Lectures: 2 hrs / week

#### THEORY

#### Unit I

A detailed study of Federal Food, Drugs and Cosmetics Act of USA, restricted to human drugs, cosmetics and biotechnological products, with special emphasis on :

- a. Labelling and advertising requirements for drugs, cosmetics and biotechnological products.
- b. Introduction to environmental protection laws, as applicable to drugs, cosmetics and biotechnological products, including EPA and OSHA.
- c. Common Technical Document and Drug Master Files.
- d. Factory Inspection.

#### Unit II

**Harmonization of regulatory requirements** – The ICH process, guidelines issued by ICH for data collection to establish quality safety of drug substances and products. Study of ICH common technical documents, harmonization of pharmacopoeial standards.

#### Practicals:

( 6 hrs / week )

Number of Practical / assignments based on aforementioned theory.

### MPHDRA – 07

### Drug Regulatory Affairs - VI

Lectures: 2 hrs / week

#### THEORY

#### Unit I

Regulatory considerations for manufacturing, packaging and labeling of pharmaceuticals in EU.

#### Unit II

- a. The WHO Guidelines – The WHO Guidelines and their relevance in international registration. The WHO certification scheme on the quality of pharmaceutical products moving in international commerce.
- b. Introduction to Pharmacovigilance.

#### Practicals:

( 6 hrs / week )

Number of Practical / assignments based on aforementioned theory.

# M. PHARM. (INDUSTRIAL PHARMACY)

## SEMESTER – 1

MPHIP – 02

Industrial Pharmacy - I

### THEORY

Lectures: 2 hrs / week

#### Unit I

1. Preformulation: General considerations and recent developments.
2. Capsules: Advantages and applications, recent advances in capsule technology, formulation and large scale production of hard and soft gelatin capsules, Quality control of capsules, In-process quality control of capsules.
3. Microencapsulation Technology: General considerations, recent advances, various processes employed for microencapsulation, release kinetics of drugs from microcapsules.

#### Unit II

Tablets:

Type of tablets, formulation of tablets, granulation techniques, recent advances in granulation technology, equipments and processes involved in granulation, tableting machinery employed for production of single-layer, multi layer, compression coated, inlay tablets and lozenges and tablet tooling.

Physics of tablet making: Strain gauge, measurement of applied and transmitted pressure, distribution of forces during compression, effect of applied pressure on relative volume and forces affecting strength of tablets,

Coating of tablet: Coating processes, advances in coating technology and evaluation of coatings

Quality control of tablets, In-process quality control of tablets.

**Practicals:**

**( 6 hrs / week )**

Number of Practical / assignments based on aforementioned theory.

MPHIP – 03

Industrial Pharmacy - II

### THEORY

Lectures: 2 hrs / week

#### Unit I

1. Good Manufacturing Practices: GMP in Manufacturing, processing and quality control of drug, control of facility, personnel, production and process control packaging and labeling controls, documentation. OSHA
2. Pilot Plant, Scale up Techniques and Technology Transfer involved in different dosage forms.

#### Unit II

1. Pharmaceutical Process Validation, equipment validation and sterile products validation.
2. Optimization in pharmaceutical process and formulation , scope of experimental design in pharmaceutical formulations with special emphasis on factorial designs and central composite design, with suitable examples.

**Practicals:**

**( 6 hrs / week )**

Number of Practical / assignments based on aforementioned theory.

**THEORY****Lectures: 2 hrs / week****Unit I**

1. Nomenclature of cosmetic ingredients: IUPAC System, INN, INCI and other accepted modes of nomenclature, like CAS, etc
2. Legal aspects of Cosmetics: National, International and harmonized (ICCR,WHO, OECD, ICVAM, ASEAN)
3. Water in cosmetics
4. Colours in Cosmetics
5. Perfumes and fragrances in Cosmetics
6. Naturals in cosmetics
7. Stability of cosmetics
8. New Technologies in Cosmetics: Brief insight into Herbal, Nano and Biotechnology

**Unit II**

1. A study of Ethnic skin and Hair types.
2. Industrial Production, Quality Control, Packaging, and Regulatory Requirements of the following:
  - a. Skin Cosmetics: Skin creams (Cold, Vanishing, Foundation, Whitening, Sunscreen, Moisturizing, Barrier, Fairness, Anti aging), Deodorants and Antiperspirants, Astringents and Toners.
  - b. Hair Cosmetics: Shampoos, Conditioners, Dyes and Colorants, Shaving preparations, Depilatories, Hair creams and Hair Fixers.
  - c. Lipsticks and Nail cosmetics
  - d. Marketing, Brand Imaging and Advertising

**Practicals:****( 6 hrs / week )**

Number of Practical / assignments based on aforementioned theory.

## SEMESTER – 2

MPHIP – 05

Industrial Pharmacy - IV

### THEORY

Lectures: 2 hrs / week

#### Unit I

1. Disperse systems: General consideration and recent advances in disperse system technology with main emphasis on pharmaceutical suspensions and emulsions, formulation, stabilization and large scale production of pharmaceutical suspensions and emulsions. Quality control of disperse systems.
2. Aerosols: General considerations, recent developments, study of various components of aerosol system, formulation, aerosol filling processes and machinery, evaluation of aerosol. Quality control of aerosols.

#### Unit II

1. Semisolid dosage forms: General considerations, recent developments, formulation and large scale production of various types of semi solid dosage forms, factors affecting release of drugs from semisolid dosage forms. Quality control of semisolid dosage forms.
2. Parenterals: General considerations, recent developments, formulation, stabilization and manufacturing of small and large volume parenterals, production of injectable grade water, environmental controls and design consideration for parenteral production facility, freeze drying. Quality control of parenterals. In house quality control.

Practicals:

( 6 hrs / week )

Number of Practicals / assignments based on aforementioned theory.

MPHIP – 06

Industrial Pharmacy – V

### THEORY

Lectures: 2 hrs / week

#### Unit I

Novel Drug delivery Systems: General considerations, fundamentals and applications of controlled drug delivery, with special emphasis on following categories:

- a. Oral CDDS
- b. Parental CDDS
- c. Transdermal CDDS
- d. Ophthalmic CDDS.

#### Unit II

Fundamentals, general considerations and applications of

- a. Liposomes, microspheres and nanoparticles
- b. Targeted drug delivery systems.
- c. Implants, Nasal and Transmucosal CDDS.

Practicals:

( 6 hrs / week )

Number of Practicals / assignments based on aforementioned theory.

MPHIP – 07

Industrial Pharmacy - VI

### THEORY

Lectures: 2 hrs / week

#### Unit I

1. **Introduction: Materials used in packing, types of packages and container design considerations. Labeling considerations**
2. **Solid Formulation Packaging:** Blister, Strip, Pouches, Bottles, etc
3. **Liquid Formulation Packaging:** Types of bottles and other packages. Types of liquid filling machines
4. **Aerosol and other spray based Dosage Forms**

## Unit II

5. **Semi-Solid Packaging:** Various types of containers/packages used for semi-solid products, filling and sealing machinery (including collapsible tube filling and sealing machine) merits and limitations of various packages, evaluation of semi-solid product package.
6. **Sterile Product Packaging:** General principles of packaging of sterile products. Various types of containers used for sterile products including small volume and large volume parenterals. Types of closures used for the sterile products. Sterile product filling and sealing machinery i.e. ampoule filling and sealing machine. Limitations and merits of various packages. Evaluation of the sterile product packages
7. **Environmental considerations** and national and international laws related to it.

**NB:** The students are expected to study the evaluation methods and recent innovations of the above mentioned packages.

### Practicals:

( 6 hrs / week )

Number of Practical / assignments based on aforementioned theory.

### Books Recommended

1. Al Brody & K S Marsh, *"The Wiley Encyclopedia of Packaging Technology"*, John Wiley & Sons, New York
2. Leon Lachman, H A Liberman and J L Kanig, *"The Theory and Practice of Industrial Pharmacy"*, Lea & Febiger, Philadelphia
3. Deans and Evans, *Pharmaceutical packaging*
4. T C KacChesney, *"Packaging of Cosmetics and Toiletries"*, Newness- Butterworth, London
5. *"Remington' Pharmaceutical Sciences"*, Mack Publishing Co., P.A

# M. PHARM. (PHARMACOGNOSY)

## SEMESTER – 1

MPHPCOG-02

Pharmacognosy-I (Advanced Pharmacognosy-I)

Theory (2 hrs/week)

### Unit-I

1. Ethnopharmacology / ethnomedicine, its concept, scope and importance. *Ex situ* and *in situ* conservation of medicinal plants.
2. Introduction to Plant genetics and Molecular biology and its importance to Pharmaceutical Industry.
3. Recent development in the field of microscopical analysis (microchemical and histological studies), CCD camera etc.
4. Study of Toxic plants and pesticides of natural origin.

### Unit-II

5. Herbal taste enhancers and FDA approved colours.
6. Recent developments in the trade of medicinally important volatile oil and spices in India.
7. Recent development in field of phytopharmaceuticals for treatment of hepatic disorders, cancer, diabetes, inflammation and cardiovascular disorders.

### Practicals (6 hrs/week)

Number of practicals/assignments based on aforementioned theory.

### Books Recommended:

- 1) Introduction to flavonoids : Bruce A. Bohm, harwood academic publishers, 1998, Amsterdam.
- 2) Introduction to spices, plantation crops, medicinal and aromatic plants : N. Kumar et al, Oxford & IBH Publishing Co. pvt. Ltd., New Delhi, 1997.
- 3) Herbal Drug Industry : R.D. Chudhary, Eastern Publishers, New Delhi 1996.
- 4) Various journals related is spices, perfumes, food & nutrition.
- 5) Wealth of India, CSIR, New Delhi (Related Volumes)
- 6) Cultivation & Utilization of medicinal plants : Atal & Kapoor, RRL, Jammu.
- 7) Cultivation & utilization of aromatic plants : Atal & Kapoor, RRL, Jammu.
- 8) Drug & Cosmetic act, (with latest amendments including Ayurvedic GMP), Govt. of India.
- 9) Various journals related to medicinal plants.
- 10) Pharmacognosy : Trease W. C., Evans G.E. Bailliere & Tinball, London, 14th edtn.
- 11) British Herbal Pharmacopoeia, (Vol. I ,II & III) Her Majesty's Services, U.K.
- 12) Ayurvedic formulary of India, Govt. of India, 1962.
- 13) Various Research Journals on Medicinal natural products.
- 14) Glimpse of Indian EthanoPharmacology By P.Puspagadan, UIF Nyman, V. George Tropical Botanical Garden & Research institute, 1995.
- 15) Essential oil- Ernest Guenther-Robert E. Krieiger
- 16) Chemistry of Marine natural products- Paul J Schwer 1973
- 17) Marine Pharmacognosy Ed by Dean F. Martin & George padilla.
- 18) Marine natural products- Vol I to Vol IV
- 19) Cosmeceuticals- Drug Vs cosmetics by Peter elsner & howard D maibach
- 20) Harry's Cosmeticology
- 21) Plant in cosmetics Vol I & Vol II Prof Robert Anton, Dr. Franco Patni & Prof. Vittorio Silano
- 22) Research guidelines for evaluating the safety and efficacy of herbal medicines WHO Publication (ISBN)

MPHPCOG-03 Pharmacognosy-II (Phytochemistry)

Theory (2 hrs/week)

### Unit-I

1. Basic concepts of study of Phytochemical study of a plant drug. Lyophilisation, Preliminary phytochemical analysis, fractionation, etc.
2. Bioactive Compounds: Occurrence, Biogenesis and chemistry of alkaloids like, Berberine, quinine, atropine, caffeine, taxol and podophyllotoxin.

### Unit-II

3. Bioactive Compounds: Occurrence, biogenesis and chemistry of sennosides, digoxin, saponin glycosides and flavonoidal compounds of pharmaceutical significance.
4. Recent developments and scope of bioactive drugs (antibiotic, cardiovascular, anticancer, antimicrobial and anti-inflammatory) and toxins obtained from Marine sources.
5. Role of herbal supplements in prevention of diseases.

#### Practicals

(6 hrs/week)

Number of practicals /assignments based on aforementioned theory.

#### Recommended Books

1. New Natural products and plant drugs with pharmacological, Biological or Therapeutical activity. Eds. H. Wagner and Wolf, Springer Weslong, NY.
2. Natural products as medicinal agents, ed. J.L. Beal & E.Reinhard, Hippocratos Verlog Stuttgart.
3. Pharmacognosy, Ed. W.C. Evans Gopsons Papers Limited, Noida.
4. Tables of Spectral Data for Structural Determination of Organic Compounds, E. Pretsch, T,Clerc, J. Seibl and W. Simon
5. Heterocyclic Chemistry, Albert
6. Biogenesis of natural Compounds, Bernfeld
7. Practical evaluation of phytopharmaceuticals, Brain and Turner, Wright- Scientecnica.
8. Phytochemical methods, Harborne, J.B., Champman Hall
9. Modern Methods of Plant analysis, Peach and Tracey, All Volumes, Springer-Verlag
10. Isolation and Identification of Drugs, Clark E.C.G, The Pharmaceutical Press, London.
11. Herbal drugs industry by R.D. Chaudari.
12. Elements of Biotechnology : P.K.Gupta
13. Molecular biology and biotechnology: J.M. Walker, E.D.Gingo
14. Essentials of molecular biology: Dovid F.A., George M.M.

#### MPHPCOG-04 Pharmacognosy-III (Screening and standardization of Natural products-I)

Theory 2 hrs/week

##### Unit-I

1. Importance of standardization and quality control of natural products as per WHO guidelines.
2. Concept and preparation of standardized Herbal Extracts and formulations.
3. Safety evaluation of herbal formulations for standardization and quality control.
4. Recent advances in the chromatographic techniques like HPTLC, HPLC, GC and Flash chromatography etc. in the separation, isolation, and purification of the phytoconstituents.

##### Unit-II

5. Traditional and recent techniques adopted for the extraction of phytoconstituents (such as microwave assisted, ultrasound, super critical fluid, pressurized liquid extraction etc.).
6. Use of spectral techniques like UV-Vis, IR, MS and NMR for screening and standardization of bioactive compounds.

#### Practicals (6 hrs/week)

Number of practicals/assignments based on aforementioned theory.

#### Recommended Books

1. New Natural products and plant drugs with pharmacological, Biological or Therapeutical activity. Eds. H. Wagner and Wolf, Springer Weslong, NY.
2. Natural products as medicinal agents, Ed. J. L. Beal & E. Reinhard, Hippocratos Verlog Stuttgart.
3. Pharmacognosy, Ed. W.C. Evans Gopsons Papers Limited, Noida.
4. Biogenesis of natural compounds, Bernfeld.
5. Practical evaluation of phytopharmaceuticals, Brain and Turner, Wright- Scientecnica.
6. Phytochemical methods, Harborne, J. B., Champman Hall Publication.
7. Modern Methods of Plant analysis, Peach and Tracey, All Volumes, Springer- Verlag.
8. Isolation and Identification of Drugs, Clark E.C.G, The Pharmaceutical Press, London.
9. Phytochemical methods: J.B.Harborne
10. Thin layer chromatography: Stahl.



## SEMESTER – 2

### MPHPCOG-05 Pharmacognosy IV ((Herbal Drug Development and Cosmetics)

Theory 2 hrs/week

#### UNIT-I

1. Introduction: Prospects and problems encountered in discovering new drug from natural sources. Definition of herb, herbal medicine and herbal medicinal product. Herbal drug preparation and different sources of drugs.
2. Regulation and cGMP- Regulatory guidelines for the herbal formulation, cosmetics, nutraceuticals and Current good manufacturing practices (cGMP) for herbals in India. Packaging and labeling regulations for the of finished products
3. Biopharmaceutics and Pharmacokinetics of herbals: Bioavailability and pharmacokinetics aspects of well documented and clinically used herbal drugs

#### UNIT-II

4. Herbal Product Development: Design. Fabrication, evaluation and application of traditional (tablet, capsule, suspension and emulsion) and novel drug delivery system (vesicular, particulate and biphasic system), excipients used in herbal formulation and stability studies
5. Herbal Cosmetics: Brief Pharmacognosy of phytoconstituents used in the formulation of herbal cosmetics (antidandruff, shampoos, hair dyes, hair oil, creams, moisturizer, anti wrinkle, anti ageing) & method of preparation and evaluation of these formulations.

#### Practicals

(6 hrs/week)

Number of practicals/assignments based on aforementioned theory.

#### Recommended Books:

1. Cosmeceuticals- Drug Vs cosmetics by Peter elsner & howard D maibach
2. Harry's Cosmeticology
3. Plant in cosmetics Vol I & Vol II Prof Robert Anton, Dr. Franco Patni & Prof. Vittorio Silano
4. Research guidelines for evaluating the safety and efficacy of herbal medicines WHO Publication (ISBN)
5. herbal Drug Industry By R. D Chaudhary
6. Indian herbal Pharmacopoeia Vol I & Vol II
7. British Herbal Pharmacopoeia
8. The complet German Commission and monographs- Blumenthal, Busse, Goldberg, greenhold,hall, klein, Riggine, Rister
9. Theory and practice of industrial pharmacy by Lachman, and Liebermann kanig
10. Herbal medicinal Products, Fraunke gaedcke and barbane steinhoh
11. Pharmaceutics- The science of dosage form design- Aulton
12. Various research journals
13. Drug and cosmetic Act , 1940 and rules
14. L Shargel and BC Andrew ,” Applied Biopharmaceutics and Pharmacokinetics,” Prentice Hall Int, USA
15. JG Wagner, “ Fundamental of clinical Pharmacokinetics,” Drug Intelligence Publication, Hammliton

### MPHPCOG-06

### Pharmacognosy-V (Pharamaceutical Biotechnology)

Theory (2 hrs/week)

#### Unit-I

1. Formation of primary and secondary metabolites. Study of Calvin cycle, TCA cycle, Shikimic acid pathway, Embden-Maerhofs pathway, acetate hypothesis, isoprenoid pathway. Biosynthesis of carbohydrates, lipids and volatile oils.
2. Historical perspective and prospects for development of medicinal plant biotechnology. Application in pharmacy and allied fields.
3. Introduction of Plant tissue culture, totipotency, Ingredients used in plant tissue culture media.
4. Callus Culture, Suspension cultures, meristem culture, protoplast culture, haploid culture, organogenesis. Regeneration of plants from tissue culture.

#### Unit-II

1. Immobilized plant cell culture systems, immobilization techniques, effect of immobilization on secondary metabolism
2. Biosynthetic potential of tissue culture and factors affecting production of secondary metabolites by tissue culture technique.
3. Application of plant tissue culture in Pharmacognosy/ production of phytopharmaceuticals.
4. Screening and selection of high yielding cell lines.

5. ELISA methods used to certify pathogen in plants.
6. DNA fingerprinting techniques and significance.

**Practicals**

(6 hrs/week)

Number of practicals/assignments based on aforementioned theory.

**Recommended Books**

1. Elements of Biotechnology : P.K.Gupta
2. Molecular biology and biotechnology: J.M. Walker, E.D.Gingo
3. Essentials of molecular biology: Dovid F.A., George M.M.
4. An introduction to plant tissue culture : M.A.Razdan
5. Plant biotechnology: Samtel
6. Plant tissue culture: Narayanswamy
7. Plant tissue culture: Angela Stafford, Open University press, Buckingham, 1991.
8. Plant tissue culture: Dixon
9. Pharmaceutical Biotechnology: Vyas, Dixit, CBS Publishers, New Delhi, 1998.
10. Pharmacognosy: Trease W.C., Evans g.E., Bailliere & Tindall, 15th edth.

**MPHPCOG-07**

**Pharmacognosy-VI (Biological Screening of Natural products-II)**

**Theory**

**2 hrs/week**

**Unit-I**

1. Introduction of Biological Screening of bioactive compounds. Role of CPCSEA and OECD guidelines and approval processes. Description of common lab animals, their handling and transgenic animals.
2. Basic Principles, *in vitro* and *in vivo* methods involved in the biological screening of plant drugs used as :
  - Analgesics
  - Anti-inflammatory drugs
  - Hypoglycemic drugs
  - Antioxidant drugs
  - Antihyperlipidemic drugs

**Unit-II**

3. Fundamentals of Clinical trials of herbal drugs and formulations. Types of trials and ICH and ICMR guidelines.
4. Basics of Bio-Statistics,
  - a) Distributions (Normal and Binomial)
  - b) Central tendency (Mean, Mode and Median)
  - c) Variabilities (SD, SE and Co-efficient of Variation)
  - d) Null Hypothesis, Probability and Level of Confidence
  - e) Parametric Tests (Paired and Unpaired Student's t-test, Chi Square test)
  - f) ANOVA and related Post-Hoc test

**Practicals** (6 hrs/week)

Number of practicals/assignments based on aforementioned theory.

**Recommended Books**

1. Spectroscopic Identification of Organic Compounds-Silverstein *et. al.*
2. Instrumental Methods of Analysis-Willard,H.H.,Meritt,L.L. and Dean,J.A.
3. Handbook of Instrumental Techniques for Analytical Chemistry-Frank Settle (Ed.)
4. Practical Evaluation of Phytopharmaceuticals – Brain and Turnetr, Wright Scientecnica
5. Modern Methods of Plant Analysis-Peach and Tracy, Springer Verlag
6. New Natural products and plant drugs with pharmacological, Biological or Therapeutical activity. Eds. H. Wagner and Wolf, Springer Weslong, NY.
7. Natural products as medicinal agents, ed. J.L. Beal & E.Reinhard, Hippocratos Verlog Stuttgart.
8. Structure Elucidation of Natural Products by Mass Spectroscopy — Vol I & II, H. Budzikiewiez, C.Djerassic and D.H. Williams
9. Phytochemical methods, Harborne, J.B., Champman Hall
10. Modern Methods of Plant analysis, Peach and Tracey, All Volumes, Springer-Verlag.

# M. PHARM. (PHARMACOLOGY) SEMESTER - 1

MPHPCOL – 02

Pharmacology I

## THEORY

Lectures: 2 hrs / week

### UNIT-I

#### 1. GENERAL PHARMACOLOGY

- Pharmacodynamics - Mechanism of Drug Action, Receptor Theory, Receptor Regulation, Drug Interactions, Undesired Drug Effects, Therapeutic Drug Monitoring.
- Pharmacokinetics - Drug Absorption, Distribution, Biotransformation and Elimination. Bioavailability and Bioequivalence of Drug Products, Drug Clearance, Drug Use in Geriatric and Pediatric populations, Drug Use during Pregnancy and Lactation, Principles of Toxicology
- Regulations for the care and use of animals – Indian Guidelines, Limitations of animal tests, Alternatives to animal use, Transgenic animal models.

### UNIT II

#### 2. Receptor Structure and Functions

- Muscarinic receptors
- Adrenoceptors,
- 5-Hydroxytryptamine receptors
- GABA – chloride receptors complex
- Dopamine receptors
- Cannabinoid receptors
- Glutamate receptors

#### 3. Introduction to Autonomic Pharmacology

#### 4. Therapeutic agents for following diseases:

Anxiety, depression, psychosis, Epilepsy, migraine, Parkinson's, Alzheimers, Huntington, Multiple Sclerosis.

## PRACTICALS

(6 hrs/week)

### Intact animal experimentation

Evaluation of following activities using appropriate animal models:

- Anti-epileptic
- anti-parkinsonism
- Analgesic
- Anti-anxiety
- Anti-psychotic
- Antidepressant
- To determine brain levels of different neurotransmitters/hormones in given animals.
- To determine plasma/serum/urine levels of different neurotransmitters/hormones in given animals.
- Simulation exercises on animals for the purpose of Reduction, Replacement and Refinement of Animal use
- Demonstration and execution of Animal Handling and Care Protocols based on CPCSEA guidelines on animal care and use.

MPHPCOL – 03

Pharmacology II

## THEORY

Lectures: 2 hrs / week

### Unit-I

#### 1. Non-Receptor Drug Action

Drugs acting through Ion channels, Enzyme Regulation

#### 2. Drug Therapy of Cardiovascular Disorders

Hypertension, Congestive heart failure, Angina, Arrhythmia, Hyperlipidemia, Shock, Myocardial ischemia.

#### 3. Diuretics

**4. Gastro-intestinal system** - Drugs used to treat ulcers, Emesis, diarrhoea, constipation, Irritable Bowel Syndrome (IBS), Zollinger – Ellison Syndrome (ZES), Gastroesophageal Reflux Disease (GERD)

**5. Autocoid Pharmacology**- Endogenous autocoids, their receptors, physiological, pharmacological and therapeutic implications

### UNIT II

## 6. Inflammation and Inflammatory Mediators

- Anti-inflammatory agents,
- Anti-gout agents
- Drugs with analgesic – antipyretic properties

## 7. Hematopoietics, Anticoagulants, Thrombolytics and Antiplatelets

## 8. Ion channel structure and pathogenic enzymes

COX

NOS

GABA-chloride complex

Sodium channels

Potassium channels

Chloride channels

Calcium channels

### PRACTICALS

(6 hrs/week)

1. Muscle relaxant
2. Diuretic
3. Anti-hypertensive
4. Anti-diarrhoeal
5. Anti-ulcer
6. CNS stimulation and depression
7. Anti-diabetic
8. Acute toxicity exercise as per OECD guidelines.
9. Ophthalmic activities like mydriasis, miosis, anti-glaucoma, reflexes and anaesthesia.

MPHPCOL – 04

Pharmacology III

### THEORY

Lectures: 2 hrs / week

#### UNIT - I

#### 1. Animal models for drug evaluation

Analgesic, Antipyretic, Anti-inflammatory, Local anesthetic, Antianxiety, Antidepressant, Anticonvulsant, Antiparkinsonism, Anti-Alzheimer's disease.

2. Basic principles and types of bioassays.

3. Introduction to biostatistics, parametric and non parametric tests.

4. **Clinical trials:** Phases of Clinical trials, design, documentation, presentation, interpretation and statistical analysis of clinical data.

#### UNIT - II

#### 5. Pharmacovigilance

Definition, scope, and epidemiology of adverse events, product recall and withdrawal of drugs with specific examples, and drug related deaths.

#### 6. Pharmacoeconomics

Principles, methods, and applications of pharmacoeconomics to pharmacotherapy and managed health care.

#### 7. Pharmacoepidemiology

Types, Methods, and factors affecting drug utilization, applications of pharmacoepidemiology in health care and rational use of drugs.

#### 8. Chronobiology

#### 9. Chiral Pharmacology

### PRACTICALS

(6 hrs/week)

1. Education, Research and Intervention exercises on Rational use of medicines (RUM)
2. Education, Research and Intervention exercises on Pharmaceutical care.
3. Effects of standard agonists.
4. Effects of standard antagonists.
5. Determination of  $pD_2$  Value.
6. Determination of  $pA_2$  Value.
7. Bioassay of Acetylcholine by Comparative, Graphical, Multiple Point (doses) Methods.
8. Bioassay of Serotonin by Comparative, Graphical, Multiple Point (doses) Methods.
9. Bioassay of Histamine by Comparative, Graphical, Multiple Point (doses) Methods.

# SEMESTER - 2

MPHPCOL – 05

Pharmacology IV

## THEORY

Lectures: 2 hrs / week

### Unit-I

1. Protein phosphorylation
2. Inositol phosphates
3. Protein phosphorylation
4. Kinase Recognition Sites
5. Diacylglycerol and Protein Kinase C

**6. Hormones as Drugs and their antagonists** – Growth Hormone, Somatostatin, Prolactin, Gonadotropins, Gonadotropin-releasing hormone, Thyroid Hormones, Estrogens, Progestins, Androgens, Adrenocorticotrophic hormone, Insulin, Glucagon, Parathyroid, Calcitonin

**7. Advances in Diuretics, ACE inhibitors, AT<sub>2</sub> antagonists.**

### Unit-II

8. Chemotherapy of infectious diseases:
9. Antibiotics: General principles  
Sulphonamides and co-trimoxazole,  
pencillins,  
cephalosporins,  
tetracyclines,  
chloramphenical,  
aminoglycosides,  
macrolides,  
quinolones.

## PRACTICALS

(6 hrs/week)

1. Diuretic
2. Anti-hypertensive
3. Anti-diabetic
4. Anti-microbial activity
5. Additional experiments based on topics from theory.

MPHPCOL – 06

Pharmacology V

## THEORY

Lectures: 2 hrs / week

### Unit-I

1. **Advances in the following:**
  - a. Antidiabetics
  - b. Antiasthmatics.
  - c. Drugs used in the treatment of Erectile dysfunction, STD, AIDS.
  - d. Hormone replacement therapy.
  - e. Growth factors,
2. **Programmed Cell Death (Apoptosis)**  
Molecular biology, physiological and pharmacological implications and therapeutic potentials of apoptosis.
3. Chemotherapy of tuberculosis, leprosy, fungal diseases, viral diseases, urinary tract infections and sexually transmitted diseases. Chemotherapy of malignancy and Immunosuppressive agents. Antineoplastic agents

### UNIT-II

#### 4. Recombinant DNA Technology

DNA structure and functions, Restriction Endo nucleases, plasmid cloning, cloning DNA sequences that encode eukaryotic proteins, vectors for cloning large pieces of DNA, genetic transformation.

#### 5. Molecular diagnostics

*in situ* hybridization procedure, PCR, Ligase chain reaction (LCR)

#### 6. Gene Therapy

Clinical application of gene therapy. Disease targets for gene therapy. Impact of human genome sequence on the discovery of newer pharmacological agents.

**PRACTICALS****(6 hrs/week)**

1. Estimation of SOD
2. Estimation of GSH
3. Estimation of Catalase
4. Estimation of NO
5. Estimation of MDA.
6. Estimation of ROS.
7. Isolation and estimation of protein.
8. Isolation and estimation of DNA from the given source (animal/plant).
9. To perform Electrophoretic shift assays of endogenous molecules and changes in their levels as per experimental designs adopted in the laboratory.
10. Evaluation of anti-diabetic agents

**MPHPCOL – 07****Pharmacology VI****THEORY****Lectures: 2 hrs / week****Unit-I**

1. Preclinical models employed in the screening of drugs belonging to following categories. Anti-hypertensive, anti-arrhythmic, Anti-diabetic, Anti-malarial, diuretics, stress, anti-diarrhoeal, anti-ulcer, antacid, learning-memory

**Unit-II**

2. Preclinical models employed in the screening of drugs belonging to following categories. Antifertility, Antipsychotic, Sedatives, Muscle relaxants.
3. Introduction to new approaches in drug discovery: High throughput screening, Pharmacogenomics, Proteonomics, Pharmacogenetics, Array technology.

**PRACTICALS****(6 hrs/week)**

1. Antihypertensive
2. Antidiabetic
3. Antipsychotic
4. Sedatives
5. Muscle relaxants
6. Determination of brain levels of different neurotransmitters/hormones in given animals as part of experimental designs mentioned above.
7. Isolation and estimation of DNA from the given source (animal/plant).
8. To perform Electrophoretic shift assays of endogenous molecules and changes in their levels as per experimental designs adopted in the laboratory.