KERALA UNIVERSITY OF HEALTH SCIENCES

FACULTY OF PHARMACY

REGULATIONS AND SYLLABUS

MASTER OF PHARMACY COURSE (M PHARM)

2011 ADMISSION ONWARDS

OBJECTIVES-MASTER OF PHARMACY COURSE

1. To generate Pharmacy Post Graduates with profound knowledge in various branches of Pharmaceutical Sciences to meet with the rapidly increasing demands put forward by-
    - Pharmaceutical Manufacturing
    - Pharmaceutical Research & Development
    - Pharmacological research including preclinical & clinical studies.
    - Herbal Drug Research
    - Pharmaceutical & Herbal Drug Analysis
    - Clinical Toxicology & Toxicological Analysis

2. To discover the potential to become faculty in Pharmaceutical Sciences with unmatched quality and excellence, so as to educate the future pharmacy generation (Undergraduate, Post graduate, and Doctoral)

REGULATIONS RELATING TO MASTER OF PHARMACY DEGREE (M.Pharm) COURSE AND EXAMINATION

These regulations may be called the regulations relating to the Master of Pharmacy degree course and examinations

1. Eligiblity for admission

A candidate who has passed the B.Pharm degree examination of Kerala University of Health Sciences or an examination equivalent thereto of any other university recognized by Kerala University of Health Sciences with not less than a total of 55% marks for the B.Pharm degree examination shall be eligible for admission to M.Pharm degree course. The candidate should have undergone B.Pharm degree course in an institution approved by AICTE and the PCI.

2. Specialisations in M Pharm courses

The following branches are available in M.Pharm course:

Branch - A	Pharmaceutical Analysis
Branch - B	Pharmaceutical Chemistry
Branch - C	Pharmacognosy and Phytochemistry
Branch - D	Pharmaceutics
Branch - E	Pharmacology
Branch - F	Pharmacy practice

3. DURATION OF THE COURSE:

The academic duration of M Pharm course is two years (24 months). Only candidates who have registered for all subjects of M.Pharm Part-I examination shall be eligible for admission to M Pharm Part-II course. The thesis of M Pharm Part II is to be submitted on completion of 24 months.

4. EXAMINATION:

There shall be one annual examination at the end of the first academic year called M Pharm Part-1 examination. There shall also be a supplementary examination of

M Pharm Part I after 3 months.

M Parm Part II examination shall consist of a thesis evaluation in any one of the following branches.

Branch -A	Pharmaceutical Analysis
Branch -B	Pharmaceutical Chemistry
Branch -C	Pharmacognosy and Phytochemistry
Branch -D	Pharmaceutics
Branch -E	Pharmacology
Branch -F	Pharmacy Practice

5. COURSE OF STUDY & ATTENDANCE:

a) M.Pharm Part-1 course of study consists of two subjects namely *one compulsory* and *one optional.*

The compulsory subject consist of two papers- a theory paper (Code No: MCS-I) and a practical paper (Code No: MCS-II). MCS- I and MCS- II shall be compulsory for students of all branches

The optional subject consists of four theory papers (Paper I, Paper II, Paper III and Paper IV) and one practical of the respective branch of study. (See Table-A)

Candidates who have attended a minimum of 80% of the theory and practical classes separately in each prescribed subject shall be permitted to appear for the M Pharm Part I examination.

Condonation of shortage of attendance (10%) shall be vested with a committee constituted by the Principal/Head of the respective college, with the Principal/Head as the Chairman and 5 members (Senior teachers) in the Committee. The benefit of condonation will be available only to the students of M Pharm Part I course.

b) M P harm part-II course of study consists of a thesis written on the basis of regular research during the second year by the candidate. A certificate by the supervising teacher (guide) stating that the candidate has worked under him/her during the M Pharm Part-II course and has satisfactorily conducted the two seminars during this period shall be attached along with the thesis. Certificate from the co-guide, if any, is also necessary. Head of the institution shall forward the list of candidates, names of supervising teachers and the title of the thesis work to the university within three months from the commencement of the M Pharm Part -2 course. The candidate shall be eligible to submit their thesis only after passing M-Pharm Part-1 examination. The number of candidates for a supervising teacher (guide) shall not exceed *four*.

Students of Pharmacy Practice have to undergo clerkship programme in various clinical departments during the first 3 months of M Pharm Part II.

All M Pharm Part II students have to present ***two*** seminars relevant to their subject specialization including recent advances before submission of thesis.

TABLE-A

CODE NO:	TITLE		THEORY hrs/week	PRACTICAL hrs/week
	COMPULSORY SUBJECT			
MCS-I	Modern Analytical and Research Methods		2	
MCS-II	Modern Analytical and Research Methods **Practical**			4
	OPTIONAL SUBJECT			
BRANCH A	**PHARMACEUTICAL ANALYSIS**			
MPH .A-I	Analytical Techniques and Instrumentation	Paper I	3	
MPH .A-II	Advanced Pharmaceutical Analysis	Paper II	3	
MPH .A-III	Quality Assurance	Paper III	3	
MPH .A-IV	Clinical Chemistry and Toxicological Analysis	Paper IV	3	
MPH.A-V	Pharmaceutical Analysis **Practical**			18
BRANCH B	**PHARMACEUTICAL CHEMISTRY**			
MPH.B-I	Drug Design	Paper I	3	
MPH.B-II	Advanced Medicinal Chemistry	Paper II	3	
MPH.B-III	Advanced Organic Chemistry	Paper III	3	
MPH. B-IV	Chemistry of Natural Products	Paper IV	3	
MPH.B-V	Pharmaceutical Chemistry **Practical**			18
BRANCH C	**PHARMACOGNOSY & PHYTOCHEMISTRY**			
MPH.C-I	Phytochemistry	Paper I	3	
MPH.C-II	Cultivation and Collection of Drugs	Paper II	3	
MPH.C-III	Applied Pharmacognosy	Paper III	3	
MPH.C-IV	Medicinal Plant Biotechnology	Paper IV	3	
MPH.C-V	Pharmacognosy and Phytochemistry **Practical**			18
BRANCH D	**PHARMACEUTICS**			
MPH.D-I	Formulation Technology	Paper I	3	

MPH.D-II MPH.D-III MPH.D-IV MPH-D-V	Biopharmaceutics and Pharmacokinetics Industrial Microbiology and Biotechnology Industrial Pharmacy Pharmaceutics **Practical**	Paper II Paper III Paper IV	3 3 3	 18
BRANCH E	**PHARMACOLOGY**			
MPH.E-I	Pharmacological Screening Methods and Clinical Evaluation	Paper I	3	
MPH.E-II	Biochemical & Molecular Pharmacology	Paper II	3	
MPH.E-III	Recent Advances in Pharmacology	Paper III	3	
MPH.E-IV	Clinical Pharmacology and Toxicology	Paper IV	3	
MPH.E-V	Pharmacology **Practical**			18
BRANCH F	**PHARMACY PRACTICE**			
MPH.F-I	Clinical Pharmacy Practice	Paper I	3	
MPH.F-II	Pathophysiology and Pharmacotherapeutics	Paper II	3	
MPH.F-III	Clinical Toxicology and Pharmacokinetics	Paper III	3	
MPH.F-IV	Hospital and Community Pharmacy and Drug Store Management	Paper IV	3	
MPH.F-V	Pharmacy Practice **Practical**			18

6. SCHEME OF EXAMINATION:

I. M.Pharm Part I Examination.:-

(A) Sessional Examination:

i.Theory: The sessional marks for the compulsory subjects and for each optional subject are 50; out of which 40 marks is awarded for Sessional examination of 1½hr duration. 10 marks are assigned for seminars conducted for each subject. Seminars are evaluated on the basis of coverage of topic, use of audio visual aids, and confidence in the topic and defense performances.

There shall be 3 sessional examinations in each of the five papers of M.Pharm part I during an academic year and aggregate of best two is computed out of 40. There shall be three seminars in each paper and aggregate of best two performances in seminar is computed out of 10.

ii.Practical:

Compulsory subject: The sessional marks for the compulsory subject are 50, of which 40 is awarded for daily assessment and 10 marks for practical sessional examination.

Optional subject: The total marks for optional subject is 200. 40 marks will be awarded for daily assessment in each set of practicals mentioned in the syllabus (40x4=160). 40 marks is awarded for *one* practical examination conducted towards the end of the academic year.

The daily assessment is done on the basis of following criteria.

-Assembly of equipments
-Use of instruments
-Manipulative skills
-Precision and Accuracy
-Cleanliness
-Interpretation of data and results
-Preparation of protocols, case presentation, case study analysis
-Record maintenance
(Whichever applies)

(B) University Examination:

i) Theory : There shall be 5 theory papers each of 3 hr duration carrying 100 marks.

ii) Practical: - There shall be practical examination for the compulsory subject (MCS-II) of 8 hrs duration including Viva voce. The marks for the practical examination are out of 100, which is distributed as follows.

Synopsis……	20
1 major experiment……	40
1 minor experiment……..	25
1 minor experiment (Spectral Analysis)……	15
**Total…….. **	**100**

Viva-voce…….. 50

The practical examination of the 4 optional subject is conducted as one examination of 16 hrs duration spread over 2 days including Viva-voce. The mark out of 300 for the examination is distributed as follows.

Synopsis……	50
2 major experiments (75 marks each)……..	150
2 minor experiments (50 marks each)……..	100
**Total…….. **	**300**

Viva-voce……. 50

The marks awarded for the M Pharm Part-I examinations will be as follows

(Table-B)

Subject	Theory				Practical					Total
	Duration	Exam	Sessional	Total	Duration	Exam	Sessional	Viva Voce	Total	
Modern Analytical Technique (Common)	3 hrs	100	50	150	8 hrs Including viva voce	100	50	50	200	350
Optional subject					16 hrs spread over *two* days					
Paper I	3hrs	100	50	150	including viva					
Paper II	3hrs	100	50	150	voce					
Paper III	3hrs	100	50	150		300	200	50	550	1150
PaperIV	3hrs	100	50	150						
TOTAL = 1500										

(C)Evaluation system:

Evaluation system for M.Pharm Part I is Centralized Double valuation by examiners from outside state and within state. The average of marks of the two examinations is taken as the mark of the theory paper. If there is a variation in marks of 15% or more among the two valuing examiners, a third valuation is done for the paper and the average of aggregate of the two nearest will be counted. M.Pharm Part I practical and Oral examination shall be evaluated jointly by the examiners appointed by the University.

(D) Pass Minimum and Re-appearance in the case of Failure (M Pharm Part-I) :

i) For passing the examination a candidate shall be required to obtain 50% marks in each theory paper and in each practical examination and overall aggregate of 50% marks including sessional marks in each theory paper and in the case of practical examination including viva-voce and sessional marks.
ii) If a candidate fails in any of the theory papers or practical examination of compulsory subjects or optional subjects he/she has to appear again in the compulsory subject or in all the optional subjects including the theory and practical as the case may be.

II.**M.Pharm Part II Examination:-**

(A*) Submission of thesis and Distribution of marks:*

M.Pharm Part II Examination consists of evaluation of thesis, seminar on the thesis topic and oral examination. Three copies of the thesis duly certified by the supervising teacher shall be submitted to the University by the candidate either in printed or type written form through the Head of the institution before the last date prescribed by the University. Marks for the M.Pharm Part II shall be allotted as follows.

Thesis	-	300
Oral	-	100
Seminar	-	100
Total	**-**	**500**

(B)Evaluation system:

The thesis, seminar and viva-voce shall be evaluated jointly by one external examiner and one internal examiner appointed by the University. The internal examiner shall be the supervising teacher of the candidate. The candidates have to present the dissertation work using audio-visual aids with a duration of about 30 minutes, which is followed by a viva voce.

(C)Rejection of thesis and resubmission

The thesis may be rejected if the examiners evaluate the work as not satisfactory and or the total mark awarded is less than 50%. If the thesis is rejected by any one of the examiners, the reasons for rejecting and the methods of rectifying the defects shall be intimated to the University by the examiner. And the candidate shall be intimated accordingly through the University, giving valid reasons for such rejections and suggestions regarding the methods of rectifying the defects in the thesis. The candidate, whose thesis has been rejected, shall be given three months time from the date of such communication to resubmit the thesis in the revised form as suggested by the examiners. In case one fails to resubmit the thesis in the revised form as suggested by examiners within the said three months, he/she shall be allowed to submit the thesis only along with the next regular batch.

III .**Grand total, Class and Award of Rank:**

The grand total of marks for M Pharm examination (M Pharm Part I + M Pharm Part II) is 2000.

Class and Rank shall be declared on the basis of the aggregate of marks in M.Pharm Part I and Part II examinations (only for those candidates who pass in the first attempt).

Rank is awarded for individual branches.

First Class means the aggregate is 60% or more.

Second Class means the aggregate is less than 60%

M PHARM SYLLABUS

MCS I -MODERN ANALYTICAL AND RESEARCH METHODS
(Compulsory to all branches of M. Pharm course)

THEORY [2hrs/week]

1. UV-VISIBLE SPECTROSCOPY

Brief review of electromagnetic spectrum, UV-Visible range, energy, wave length and colour relationship. The chromophore concept, absorption laws and limitations. Instrumentation, choice of solvents, application of UV absorption spectroscopy in pharmacy.

2. INFRA RED SPECTROSCOPY

Theory, brief outline of classical IR and FTIR, instrumentation and interpretation of spectra. Sample preparation for spectroscopy. Qualitative interpretation of IR spectra and application in pharmacy.

3. NUCLEAR MAGNETIC RESONANCE SPECTROSCOPY

Fundamental principles of NMR, Chemical shift, concept, isotopic nuclei, reference standards, Proton Magnetic spectra and their interpretation. Brief outline of instrumentation. Application of signal splitting and coupling constant data to interpretation of spectra. Decoupling and shift reagent method. Brief outline of principles of FT-NMR with reference to ^{13}C NMR. Nuclear overhauser effect, ^{13}C NMR spectra, their presentation, characteristics, interpretation, examples and applications.

4. MASS SPECTROSCOPY

Basics principles and brief outline of instrumentation; Ion formation and types; molecular ion, Meta stable ions, fragmentation processes. Fragmentation patterns and fragmentation characteristics in relation to parent structure and functional groups. Relative abundance of isotopes and their contribution to characteristic peaks. Mass spectrum, its characteristics, presentation and interpretation, chemical ionization, Mass spectrometry GC-MS, other recent advances in MS; Fast atom bombardment mass spectrometry.

5. CHROMATOGRAPHIC TECHNIQUES

Classification of chromatographic methods based on the mechanism of separation; Paper chromatography, techniques and application. Thin layer chromatography, comparison to paper chromatography and HPLC, adsorbents for TLC, preparation techniques, mobile phase selection, reversed phase TLC, High performance TLC, detection methods, quantitative methods in TLC.

6. GAS CHROMATOGRAPHY

Instrumentation, packed open tubular columns, Column efficiency parameters, Resolution, liquid stationary phases. Derivatisation methods of GC including acylation, perflouroacylation, alkylation and esterification. Detectors -FID, ECD, TCD, NPD. Examples of GC application in pharmaceutical analysis. Hyphenation of GC with other instruments.

7. LIQUID CHROMATOGRAPHY

Comparison of GC and HPLC. Instrumentation in HPLC; analytical, preparative microbore columns, normal and reversed phase packing material. Reversed phase HPLC, column selection, and mobile phase selection, efficiency parameters, resolution; detectors in HPLC - refractive index, photometric, electrometric and other detectors. HPLC instrumentation and applications.

8. FLUORIMETRY

Theory; fluorescence and chemical structure, factors affecting fluorescence intensity, Fluorescent immunoassay, Fluorescence polarization immunoassay; Instrumentation and application in pharmacy.

9. X-RAY DIFFRACTION METHODS

Introduction; generation of X-Ray, elementary crystallography, Miller's Indices, X-Ray diffraction, Bragg's law, X-Ray powder diffraction, X-Ray powder diffractometer. Interpretation of X-Ray powder diffraction data.

10. ATOMIC ABSORPTION SPECTROPHOTOMETER

Theory and instrumentation, elementary analysis and its application in pharmacy.

11. STASTISTICAL ANALYSIS

Introduction, significance of statistical methods, normal distribution, probability, degree of freedom, standard deviation, correlation, variance, accuracy, precision, classification of errors, reliability of results ,confidence interval, Test for statistical significance; students T-TEST, F-test, Chi-square test, correlation and regression

MCS-II – MODERN ANALYTICAL AND RESEARCH METHODS

PRACTICALS [4hrs/week]

1. Use of UV-Visible Spectrometer in the analysis of Pharmacopoeial compounds and their formulation.

2. Use of spectroflourimeter in the analysis of Pharmacopoeial compounds.
3. Use of Flame photometer for the analysis of sodium, potassium, calcium and lithium in body fluids.
4. Experiments in chromatography; TLC, Paper chromatography (ascending, descending and circular techniques).
5. Identification of drugs using UV-Visible scanning spectrophotometry.
6. Quantitative analysis using HPLC.
7. Qualitative analysis of drugs using IR Spectrophotometry.
8. Clinical toxicological analysis.

REFERENCES

1. Spectrophotometry Identification of Organic Compounds by R.M.Silverstein et al.
2. Organic Spectroscopy by William Kemp.
3. Pharmaceutical Analysis Modern methods [Part A, Part B] by James W. Munson.
4. Instrumental Methods of Analysis by Donglas A. Skoog, James J. Leary.
5. Instrumental Methods of Analysis by Willard et al.
6. Application of Absorption Spectroscopy of Organic Compounds by John Dyer.
7. Vogel's Text book of Quantitative Chemical Analysis.
8. Chromatographic Analysis of Pharmaceuticals by John A. Admovics.
9. Practical Pharmaceutical Chemistry by A.H.Beckett, J.B.Stenlake.
10. Techniques and Practice of Chromatography Raymound P.W.Scott.
11. Quantitative Analysis of Drugs by D.C.Garetth.
12. Quantitative Analysis by Jenkins.
13. Isolation and Identification of Drugs by Clark.
14. Fundamentals of Mathematical Statistics by S.C.Gupta, V.K.Kapoor.

BRANCH- A - PHARMACEUTICAL ANALYSIS

MPH.A-I (PAPER I)
ANALYTICAL TECHNIQUES & INSTRUMENTATION

THEORY [3hrs/week]

1. UV-VISIBLE SPECTROSCOPY

Brief review of the Electromagnetic spectrum and absorption of radiations. The chromophore concept, absorption laws, limitations. Theory of electronic spectroscopy, absorption by organic molecules, choice of solvents, solvent effects. Application of UV-Visible spectroscopy [qualitative and quantitative analysis]. Woodward –Fischer rules for calculating absorption maxima. Photometric titration and its applications. Modern instrumentation - design and working principle.

2. INFRA-RED SPECTROSCOPY

Theory of IR Spectroscopy. Mechanical model of stretching vibrations, quantum treatment of vibrations. Nature of IR radiations, Interaction of IR radiation with organic molecules. Molecular IR spectrum. Brief outline of classical IR instrumentation and interpretation of spectra. Sample preparation for spectroscopy. Influence of substituents, ring size, hydrogen bonding, vibrational coupling and field effects on frequency. Quantitative methods, Recent advances in IR spectroscopy including FT-IR, ATR [Attenuated Total Reflectance], NIR etc., their instrumentation and application.

3. NUCLEAR MAGNETIC RESONANCE SPECTROSCOPY

Fundamental principles of NMR, Classic and quantum description of NMR, Chemical shift concept, isotopic nuclei, reference standards, Proton magnetic spectra, their characterization, presentation, terms used in describing spectra and their interpretation. Brief outline of instrumentation. Signal multiplicity phenomena in high resolution PMR. Spin-spin coupling. Application of signal splitting coupling constant data to interpretation of spectra. Decoupling and shift reagent method. Brief outline of principles of FT-NMR with reference to C^{13}NMR. Spin-spin and spin-lattice relaxation phenomena. Free induction decay proton noise decoupling, signal average in time domain and frequency domain signals. Nuclear Overhauser effect. C^{13}NMR spectra their presentation, characteristics, interpretations examples and applications.

Brief indication of application of magnetic resonance spectral data of other nuclei by modern NMR instruments, Introduction to 2D-NMR techniques. Use of NOE, DEPT, NMDR, NOESY, COSY, HMBC, and FAB; Structure elucidation of selected molecules. ESR- Principles, correlation with PMR and application like MRI in diagnosis.

4. MASS SPECTROMETRY

Basic principles and instrumentation, ion sources, chemical ionization, fast atom bombardment, electron impact, desorption sources, MALDI, electron spray ionization, sample inlet systems, mass analysers and detectors. Ion formation and types, molecular ion, meta stable ion, fragmentation processes, fragmentation patterns and fragmentation characteristics in relation to parent structure and functional groups. Relative abundances of isotopes, and their contribution to characteristic peaks. Mass spectrum, its characteristic presentation and interpretation. Other recent advances in MS including FT instruments. Hyphenation of MS with other analytical instruments. Fast atom bombardment Mass spectroscopy, LC-MS technique for isomeric purity determination and chiral analysis.

5. CHROMATOGRAPHIC TECHNIQUES

Classification of chromatographic methods of based on mechanism of separation. Paper chromatography, techniques and applications. Thin layer chromatography, comparison to paper chromatography and HPLC, adsorbents for TLC, preparation techniques, mobile phase selection, reversed phase TLC, High performance TLC detection methods, quantitative methods in TLC. Programmed multiple development techniques, Immobilised stationary phase chromatography, Super critical fluid chromatography extraction principles, instrumentation and applications. Capillary electrophoresis and Capillary electro chromatography, gel electrophoresis and solid phase extraction chromatography.

6. GAS CHROMATOGRAPHY

Instrumentation; packed open tubular column. Column efficiency parameters, the Van Deemter equation, Resolution, liquid stationary phase. Derivatisation methods of GC including acylation perfluroacylation, alkylation and esterification. Detectors FID, ECD, TCD, NPD. A critical comparison of sensitivity, selectivity and field of application of these detectors. Examples of GC application in pharmaceutical analysis. Hyphenation with other instruments.

7. LIQUID CHROMATOGRAPHY

Comparison of GC and HPLC. Instrumentation in HPLC, analytical, preparative and micro bore columns, normal and reversed phase packing material. Reverse phase HPLC, column selection, mobile phase selection, efficiency parameters, resolution, various detectors in HPLC like refractive index, photometric and electrochemical. Comparison of sensitivity, selectivity and field of application of these detectors; HPLC instrumentation and application.

8. LUMINESCENCE SPECTROSCOPY

Theory of fluorescence and phosphorescence. Chemical structure and fluorescence, factors affecting intensity. Instruments for measuring fluorescence and phosphorescence. Application of photo luminescent methods in pharmacy and biology. Chemiluminescence theory, instrumentation and application. Fluorescent Immunoassay; Fluorescent polarization immunoassay. Instrumentation and application in pharmacy.

9. X-RAY DIFFRACTION METHODS:

Introduction, generation of X-Rays, elementary crystallography, Miller indices, X-Ray diffraction, Bragg's law, X-Ray powder diffraction , X-Ray powder diffractometer, Interpretation of powder diffraction data.

10. LASER SPECTROSCOPY

Introduction, principle, theory, instrumentation and application.

11. ATOMIC ABSORPTION SPECTROPHOTOMETRY

Theory and instrumentation and application in pharmacy.

12. THERMAL METHODS OF ANALYSIS

Theory of thermogravimetric analysis, differential thermal analysis, differential scanning calorimetry and thermo mechanical analysis.

MPH.A-II (PAPER II)

ADVANCED PHARMACEUTICAL ANALYSIS

THEORY [3hrs/week]

1. A detailed study of principles and techniques involved in the analysis of pharmaceutical formulation containing antibiotics, steroid, hormones, vitamins, barbiturates and sulpha drugs.
2. General methods of quality control of the following as per Indian Pharmacopoeia.
   i. Tablets ii. Capsules iii. Liquid orals iv. Parenterals v. External preparation.
3. A detailed study on the extractive procedures and the estimation of drugs in multidrug formulation.
4. Use of colorimeter, flame photometer, spectrophotometer, spectroflourimeter, AAS, HPLC, and HPTLC in the analysis of drugs and pharmaceuticals. Knowledge of sample preparation for each of the instrument.
5. A detailed study on immunological assays, ELISA, Immunoblotting, Immunofluorescence, Immunoaffinity, Radioimmunoassay, and Radiotracer techniques and the use of these techniques in Pharmaceutical analysis.

6. Principles and procedures involved in the use of the following reagents in pharmaceutical analysis.

   1. 2, 6, dichloroquinone chloride.
   2. 1, 2 naphthaquinone-4-sulphonate.
   3. 3-methyl-1,-2 benzothiazoline hydrazine hydrochloride [MBTH]
   4. Folin Ciocalteau Reagent.
   5. p-dimethyl amino benzaldehyde [PDAB]
   6. p-dimethyl amino cinnamaldehyde [PDMAC]
   7. 2, 3, 5,-triphenyl tetrazolium salt.
   8. N, 1-naphthyl ethylene diamine.
   9. 2, 4,-dinitro phenyl hydrazine.
   10. Ninhydrin reagent.

7. Analysis of drugs originating from genetic engineering, vaccines, sera and toxoids.

8. Validation and calibration of various instruments used for drug analysis such as UV-Visible spectrophotometer, IR spectrophotometer, spectroflourimeter, HPLC, HPTLC, and GC.

9. Quality control of radio pharmaceuticals and radio chemical methods of analysis.

10. Identification and quantitative determination of preservatives, antioxidants, colouring materials, emulsifiers, and stabilizers in pharmaceutical formulation.

11. Microbiological assay of vitamins, antibiotics and LAL test.
12. General method of analysis of chemical constituents of food, determination of physical constants, identification of common adulterants, water analysis including pesticides residue in water.

13. Analysis of various types of raw materials used in cosmetics. Analysis of cosmetics in finished form such as skin care products, baby care products, dental products, personal hygiene products, colour cosmetics and ethnic products.

Indian Standard Specification [ISI] laid down for sampling and testing various cosmetics in the finished form by the Bureau of Indian Standards. Toxicity testing in cosmetics Legislation of cosmetic products.

13. WHO guidelines for the assessment of quality, safety and efficacy of herbal drugs, protocols and procedures for systematic evaluation and standardization of herbal drugs.
    Finger print profiles using HPTLC.

14. Analysis of drugs and excipients in solid state, particle size analysis, X-Ray powder diffraction.

MPH.A-III (PAPER III)

QUALITY ASSURANCE

THEORY [3hrs/week]

1. Concept of TQM, GLP, GMP, ISO 9000, ISO 14000, NABL and ISO 18000. Concept of validation, types of validations, protocols for process validation, validation of equipments and procedures.
2. Organisation and personnel, responsibilities, training and hygiene.
3. Premises:
   Location, design, plan, layout, construction, maintenance and sanitations, environmental control, sterile areas, control of contamination.
4. Equipments
   Selection, purchase specification, maintainance, sterilization of an area [TPand STP]

5. Raw materials
   Purchase specification, maintenance of stores, selection of vendors, controls on raw materials.

6. Manufacture of and control on dosage forms, manufacturing documents, master formula, batch formula records, standard operating procedure, Quality audits of manufacturing processes and facilities.

7. Standard operating procedures for various operations like cleaning, filling, drying, compression, coating, disinfection, sterilization, membrane filtration etc.

8. Packing and labeling controls, line clearance, reconcillation of labels, cartons and other packing material, types and tests assuring quality of glass, types of plastics used, permeation, leaching, sorption, chemical reaction, biological tests, modification of plastics by drugs, different types of closure and closure liners, film wrappers, blister packs, bubble packs, shrink handling, foil/plastic pouches, bottle seals, tape seals,

breakable seals and sealed tubes. Quality control of packing material and filling equipment.

9. Quality control laboratory

Responsibility, good manufacturing practice, routine controls, instruments, protocols, non clinical testing, controls in animal house, application of computer in Quality control laboratory.

10. Protocols of analysis, preparation of analytical report and documentation. Data generation and storage, quality control documentation, retention samples, record quality audits, stability testing, and determination of shelf life.

11. Finished products.

Quality review, quality audit, batch release documentation.

12. Warehousing.

Good warehousing practice, material management.

13. Distribution

Distribution of records, handling of returned goods, recovered materials and reprocessing.

14. Complaints and recalls.

Evaluation of complaints, recall procedures, related records and documents.

15. Waste disposal, scrap disposal, procedure and records.

16. WHO Certification, globalization of Drug industry, Introduction to Export of drugs and Import policy, Patent regime.

MPH.A-IV (PAPER IV)

CLINICAL CHEMISTRY AND TOXICOLOGICAL ANALYSIS

THEORY (3hrs/week)

1. Toxicological

Principles of toxicological analysis, identification of common poisons, identification of toxic syndrome, correlation of clinical symptoms and poisoning. Knowledge of the metabolic pathways of common poisons and antidotes available for them. Knowledge on methodology of specimen collection and processing-handling of specimen for testing.

2. Emergency toxicology

Screening procedure –Spot tests and the use of TLC, GC and HPTLC in the identification of poisons. Qualitative tests for commonly encountered poisons. Determination of toxic substances in biological matrices. A through knowledge on the

analytical procedures for the quantification of Phenobarbitone, Phenytoin, Paracetamol, Salicylic acid, Methanol, Ethanol, Lithium, Pseudo cholinesterase activity etc.

3. Therapeutic Drug Monitoring

A detailed discussion on the methods of estimation of drugs implicated in TDM such as Phenobarbitone , Phenytoin, Valproic acid, Carbamazepine , Ethosuximide, Digoxin, Lidocaine, Quinidine, Procainamide, Lithium, Methotrexate, Cyclosporine, Theophylline, and Antidepressants.

4. Normal levels of biochemical constituents

Clinical correlation and significance of abnormal values. Qualitative and quantitative determination of blood glucose, serum protein, SGOT,SGPT, serum bilirubin, serum alkaline phosphatase and other enzymes, serum cholesterol, serum creatinine, ketone bodies and serum electrolytes.

5. A detailed discussion on DOPE tests and methods for the estimation of anabolic steroids and drugs of abuse in blood/urine.

MPH.A-V
PHARMACEUTICAL ANALYSIS PRACTICALS
[18 hrs/week]

a)Analytical Techniques and instrumentation:

1. Calibration and validation of UV-Visible, IR spectrophotometer, spectroflourimeter, HPLC, HPTLC.
2. UV-Visible spectrum scanning of drugs like Paracetamol, Ibuprofen, Diazepam, Phenobarbitone etc. Absorption and correlation of structures.
3. Optimisation of analytical techniques.
4. IR Spectrophotometric techniques including sample preparation.
5. Workshop on structural elucidation of at least 10 unknown compounds based on UV, IR, Mass and NMR spectral data.
6. Study of the Quenching effect in fluorimetry.

b) Advanced Pharmaceutical Analysis:

1. Use of spectrophotometer for the analysis of Pharmacopoeial compounds and their formulation.
2. Assay of official compounds by fluorimetry: Quinine, Codeine, Thaimine, and Riboflavin.
3. Quantitative analysis of drugs in multicomponent dosage forms.
4. Quantitative determination of the following groups: hydroxyl, carbonyl, and amino groups.
5. HPLC & HPTLC analysis of drugs.
6. Quality control test for tablets, capsules, injections, ointments and suppositories.
7. Detection and determination of preservatives, antioxidants and colouring materials in pharmaceuticals.
8. Microbiological assay of antibiotics and vitamins.
9. Immunological assays.
10. Quality control of some cosmetics.

11. Determination of pesticide residue in food and water.
12. Sterility testing of areas
13. Microbiological evaluation of waste water.
14. Monograph analysis of Pharmacopoeial compounds used as raw materials

c) Quality Assurance:

1. Development of analytical profiles for newer drugs.
2. Calibration of glass wares. Testing of containers, closures, liners, glass, plastics used for packing. Testing of packing material, cartons, aluminium foils, strip packing, blister packing, ampoules, vials, etc.
3. Preparation of process protocols, SOP etc.
4. Familiarization of softwares pertaining to ISO and GLP.

d)Clinical Chemistry and Toxicological Analysis:

1. Screening of commonly encountered poisons in biological fluids.
2. Estimation of drugs implicated in TDM.
3. Toxicological analysis of biological fluids (qualitative and quantitative)
4. DOPE Tests.

BOOKS RECOMMENDED:

1. Spectrophotometric identification of Organic Compounds, Robert M. Silverstein et al.
2. Principles of Instrumental Analysis by Donglas A. Skoog, James J. Leary.
3. Pharmaceutical Analysis-Modern Methods by James W. Munson.
4. Vogel's Text Book of Quantitative Chemical Analysis.
5. Instrumental Methods of Analysis- Hobert H.Willard.
6. Chromatographic Analysis of Pharmaceuticals, John A. Adamovics.
7. Practical Pharmaceutical Chemistry-A.H.Beckett& J.B.Stenlake.
8. Organic Spectroscopy- William Kemp.
9. Techniques and practice of Chromatography - Raymond P.W.Scott.
10. Application of Absorption Spectroscopy of Organic compounds by John Dyer.
11. Identification of Drugs and Pharmaceutical Formulations-P.D.Sethi.
12. HPTLC-Quantitative Analysis of Pharmaceutical Formulations-P.D.Sethi.
13. Quantitative Analysis of Drugs and Pharmaceutical Formulations-P.D.Sethi.
14. Liquid Chromatography-Mass Spectrometry, W.M.A. Niessen, J.Van der Greef.
15. Organic Chemistry by I.L. Finar.
16. Comprehensive Pharmacy Review by Leon Shargel, Alan H. Mutnick, Paul F. Souney, Larry N. Sawnson.
17. Applied Biopharmaceutics and Pharmacokinetics by Leon Shargel et al.
18. Indian Pharmacopoeia
19. Practical HPLC method development by Lloyd R. Snyder et al.
20. Herry's Cosmeticology-J.B.Wilkinson and R.J. Moore.
21. Indian Standard Institution.(BIS).
22. Text Book of Pharmaceutical Analysis-K.A. Connors.
23. Quantitative Analysis of Drugs – D.C. Garreth.

BRANCH B- PHARMACEUTICAL CHEMISTRY

MPH.B-I (Paper-I)

DRUG DESIGN

Theory (3 hrs/wk)

1. Introduction to drug design and discovery. Conventional methods of drug design: Lead, discovery of lead, lead optimization, objective of lead optimization, pharmacophoric identification and analog approach of drug designing.
2. Structure activity relationships in drug design. Qualitative versus quantitative approaches, advantages and disadvantages; Random screening, nonrandom screening, drug metabolism studies, clinical observations, rational approaches to lead discovery; Homologation, chain branching, ring-chain transformations, bioisosterism; Insights into molecular recognition phenomenon; Structure based drug design, ligand based drug design.
3. Molecular modeling, energy minimization, geometry optimization, conformational analysis, global conformational minima determination; Automated methods of conformational search; Advantages and limitations of available software; Molecular graphics; Computer methodologies behind molecular modeling..
4. QSAR: Electronic effects; Hammett equation, Lipophilicity effects; Hansch equation, Steric Effects; Taft Equation; Experimental and theoretical approaches for the determination of physico-chemical parameters. 3D QSAR approach, generation of 3D coordinates, conversion of 2D structures in to 3D form.
5. Molecular docking and dynamics: Rigid docking, flexible docking, manual docking; autodocking, receptor mapping, pharmacophore matching, deNovo design. Docking softwares, Monte Carlo algorithms and simulations, genetic algorithms, and molecular dynamics and free energy calculations.
6. Drug target binding force, energy components for intermolecular non-covalent interactions. Examples of drug-receptor interactions. Drug receptors (Non catalytic) Concept of receptors and receptor theories, molecular biology of receptors, protein coupled receptors, ion channel linked receptors, nuclear receptors, transcription factors, receptor binding assays. Drug receptors (Catalytic) Enzyme inhibitors, enzyme inhibitors in medicines, rational design of non-covalent binding enzyme inhibitors. Rational design of covalent binding enzyme inhibitors. Mechanism based enzyme

inhibitors.

7. Recombinant DNA technology in medicinal chemistry, protein engineering and site directed mutagenesis, genetically engineered drugs, enzymes as drug targets, receptors as drug targets.
8. Analog design. Bioisosterism in drug design, rigid analogs, alteration in chain length, branching, ring size, alteration in stereochemistry, fragmentation of a lead molecule. Peptidomimetics in drug design, use of peptidomimetics in peptide design, cyclisation of peptides, constrained amino acids, amide bond isosters. Topliss decision tree analysis.
9. Oligonucleotide therapeutics, oligonucleotides as drugs, interaction with nuclic acids, modification of bases, sugars and back bone, antisense oligonucleotides.
10. Drug metabolism- Phase-I & Phase-II metabolic reactions. Introduction to drug design on the basis of metabolic pathways. Prodrug and metabolite considerations in prodrug design: Aims of prodrug designing. Types of prodrugs, fundamental groups involved in prodrug designing. Bioprecurser prodrugs.
11. Combinatorial Chemistry. Introduction, Solid Phase Synthesis, Liquid Phase Synthesis, Methods of Parallel and Mixed Combinatorial Synthesis, Deconvolution and High Throughput Screening, library synthesis on resin beads, peptide synthesis, parallel synthesis, tea bag method, pin method.
12. Informatics methods in drug design: Bioinformatics, cheminformatics, genomics, proteomics, chemogenomics, pharmainformatics; ADME databases, chemical biochemical and pharmaceutical databases; Drug design techniques using these databases.

MPH .B-II (PAPER II)
ADVANCED MEDICINAL CHEMISTRY

Theory(3hrs/wk)

A detailed study of classification, chemistry, mechanism of action, SAR, Synthetic approach, uses and recent advances of the following classes of drugs:

1. Antiviral agents including Anti- HIV agents.
2. Antineoplastic agents
3. Antihypertensive agents
4. Prostagandins, Leukotrienes and other Eicosanoids.
5. Antihyperlipidemic agents.
6. Central Nervous system depressants including Anxiolytics, Anticonvulsants, Sedative and Hypnotics, Antidepressants, Antipsychotics.
7. Gastrointestinal agents including drugs used in Peptic Ulcer.
8. Diuretics
9. Immunosuppressant and immunostimulants
10. H1- receptor antagonists.
11. Steroidal anti-inflammatory agents.
12. Newer Macrolide antibiotics, Cephalosporins and Fluoroquinoline antibacterials.
13. Anti Parkinsonism agents and agents for Alzheimer's disease

14. Adrenergic drugs.
15. Anticholinergic drugs
16. Gene Therapy in cancer and other chronic disease
17. Radiosensitizers and radioprotective agents.

MPH-B-III (PAPER-III)
ADVANCED ORGANIC CHEMISTRY

Theory (3 hrs/week)

1. Bonding and electron distribution: Localized and delocalized bonding (including aromaticity), heterocyclic rings exhibiting aromaticity. Bonding weaker than covalent: hydrogen bonding, addition complex, electron donor-acceptor complexes, crown ethers, inclusion compounds and clathrate compound, acids and bases and effect of structure on their reactivity.
2. Introduction to stereo chemistry: Chiral compounds, molecules with cone chiral center, molecules with a chiral axis, molecules with a chiral plane of symmetry, molecules with two or more chiral centers, characterization of enantiomers by chiroptical methods.
3. Asymmetric synthesis- Chiral induction, factors controlling selectivity, chiral reagents, catalyst and solvents (include industrially used); kinetic resolution, double asymmetric induction, acyclic diastereo selection, asymmetric amplification. Asymmetric synthesis of amino acids and betalactams.
4. Chemistry of electron sources: general ranking of electron sources, nonbonding electrons, electron rich sigma bond, electron rich pi-bonds and simple pi-bonds, aromatic rings.
5. Electron acceptors: general ranking of electron acceptors, electron deficient species, weak single bonds, polarized multiple bond, mechanisms and methods of determining; thermodynamic and kinetic requirement for reaction– methods of determining reaction mechanism.
6. Stability and reactivity of reaction intermediates, ion stability, solvation and media effect. Ranking of stability and trends (structure, lone pair stabilization, pi-bond stabilization, hyper conjugation).

   Ranking of electron donor groups.Ranking of electron withdrawing groups .

Δ pka rule.

7. Study of mechanism and reactivity, stereochemistry of the following organic reactions.

   Aliphatic nucleophilic and electrophilic substitutions. Aromatic electrophilic and nucleophilic substitutions. Free radicle substitution. Addition to carbon-carbon and carbon- hetero multiple bond

Elimination reactions.

Rearrangements involving carbon to carbon, carbon to nitrogen, carbon to oxygen, nitrogen to carbon, oxygen to carbon.

8. Principles of synthetic planning, logic centered molecular synthesis; dislocation, synthetic tree, synthons, logical imposition of boundary conditions, directed associated approach. Structure functionality relationship; functionality and unsaturation levels. Polar reactivity analysis; control elements, consonant and dissonant circuits. Protocol for synthetic design. Retrosynthesis.
9. Photochemistry: Exited state and ground state, Franck and Condon principles, Jablonski diagram, singlet and triplet state photo sensitization, forbidden transitions, types of excitations, photolytic cleavage, the fate of excited molecules, physical and chemical processes, determination of photochemical mechanisms.
10. Generation, fate and biological significance of electron deficient species, carbocations, carbenes ,carbanions, free radicals, nitrenium ions and nitrenes.

Mechanisms (include stereochemistry) of oxidation- reduction reactions-Birch reduction, Meerwin Pondroff's reduction, Oppeneaur Oxidation, Wolf Kishner reduction and catalytic hydrogenation.

11. Alkylation: enolates: regio and stereo selective enolate generation, "O" versus "C"-alkylation, effects of solvents, counter cation and electrophiles, symbiotic effects. Thermodynamically and kinetically controlled enolate formation. Enamines and metallo- enamines: Regioselective in generation, applications in controlling the selectivity of alkylation.
12. Catalysis: Introduction, phase transfer catalysis in anhydride, epoxide, ester, nitryl, sulphide formation, ester hydrolysis and reduction reaction.

MPH.B-IV (PAPER IV)
CHEMISTRY OF NATURAL PRODUCTS
Theory (3hrs/wk)

1. General methods of isolation and separation of plant constituents, qualitative reactions for the detection of plant constituents. Applications of GLC,HPLC, HPTLC and Counter current distribution to separation and analysis of plant constituents. Application of IR, H^1 NMR, C^{13} NMR, ESR, Mass spectroscopy in the structural determination of natural products.
2. Alkaloids: - Introduction, chemical classification, General isolation and purification methods, Constitution of morphine, reserpine and quinine.
3. Steroids:- Introduction, nomenclature, stereochemistry, structural elucidation of cholesterol, ergosterol, diosgenin and cardiac glycosides. Synthesis of Progesterone from diosgenin.
4. Flavinoids:- Chemistry of Rutin and quercetin.
5. Terpenoids:- Classification, general structural elucidation of terpenoids. Constitution of citral,α-terpineol, camphor and abietic acid.
6. Coumarins :- Structural determination of Xanthotoxins and Psoralene.
7. Carotenoids:- Chemistry of carotenes, conversion of beta carotene to vitamin A, constitution of vitamin A.
8. Herbal drugs:- Introduction and evaluation of herbal drugs for antidiabetic, hepatoprotective, diuretic, antidiarrheal, antiulcer, wound healing, cardiovascular,

anti- inflammatory, analgesic, antipyretic, antifertility, antioxidant, antiviral and antitumour properties. Identification of biomarkers and fingerprinting of herbal drugs.
9. Chemistry of natural products having cosmetic value.
10. Marine natural products with therapeutic potential.
11. Isolation and characterization of important neutraceuticals
12. WHO guidelines for evaluation of safety and efficacy of herbal medicines.
13. Role of natural products in new drug development.
14. Role of Recombinant DNA technology.

MPH.B-V
PHARMACEUTICAL CHEMISTRY PRACTICALS
(18 HRS/WK)

a)Drug Design:
1. Protein sequence analysis
2. Molecular graphics
3. Evaluation of protein structure
4. Small molecule generation
5. Molecular docking
6. Workshop on QSAR
7. Workshop on organic synthesis, proposing different routes and reaction conditions.

b)Advanced Medicinal Chemistry:
1. Experiments based on biological evaluation of drugs.
2. Identification and estimation of the drug metabolites in biological fluids.
3. Synthesis and Characterization of drug / organic compounds involving more than two steps.
4. Controlled synthesis of stereoisomers of selected (any two).
5. Physiochemical activity studies of some selected medicinal and their chemical modifications(two sets of experiments).
6. Synthesis of the following heterocyclic compounds

a) Benzimidazole.
b) Benzotriazole.
c) 2,3 diphenylquinoxaline.
d) Oxadiazole.
e) Thiadiazole.
f) Isatin.

c)Advanced Organic Chemistry:
1. Workshop on spectral interpretation of selected compounds using UV, IR, NMR and Mass spectra
2. To perform the following reactions of synthetic importance

a) Birch reduction.
b) Clemmenson reduction.
c) Meerwin-Pondroff's reduction.

d) Grignard reaction.
e) Oppeneaur oxidation.
f) Benzyllic acid rearrangement.
g) Beckmann rearrangement.
h) Photochemical reaction.

d)Chemistry of Natural Products:

1. Isolation of active principles from natural sources like alkaloids, terpenes, steroids,

Eg :- Piperine from Black pepper
-Citral from lemongrass oil.
-Asiaticoside from Centella asiatica.
-Beta- sitosterol from Sida acuta.
Conversion of Diosgenin to progesterone.

2. Isolation and characterization of active principles including neutraceuticals from natural sources including UV,IR and NMR spectroscopic analysis and TLC

Eg: Eugenol from clove
Curcumin from turmeric
Hesperidine from orange peel
Embelin from Embelica ribes
Pectin from orange peel
Epicatechin from Cahew kernel outer covering
Borswellic acid from Borswellia Serrata.

3. Workshop on various strategies to new lead identification and optimization from natural products.
4. Degradation reaction of following products and the identification of degraded intermediates by micro TLC and qualitative tests
Eg: (a) Atropine (b) Caffeine (c) Ephedrine.

BOOKS RECOMMENDED:

1. "Advanced Organic chemistry, Reaction mechanisms and structure", J. march, John Wiley and sons, N.Y.
2. "Mechanism and structure in organic chemistry", E.S.Gould, Hold Rinchart and Winston,NewYork.
3. "The Organic Chemistry of Drug Design and Action" R.B.Silverman, Academic press Inc., San Diego, 1992.
4. "Chitotechnology" R.A. Steldon, Marcell Dekker Inc., Newyork 1993.
5. "Asymmetric synthesis", R.A. Aitken and S.M.Kilengi, Ed., Blackie Academic and professional London, 1992.
6. "Organic Chemistry" Clayden, Greeves, Warren and Woihers., Oxford University Press 2001.
7. "Organic Chemistry" Vol I and II. I.L. Finar. ELBS, Sixth ed., 1995.
8. A guide to mechanisms in Organic Chemistry – Peterskyes (Orient Longman, New Delhi).

9. Reactive intermediates in organic chemistry – Tandom and Gowel.
10. Molecular reaction and Photochemistry – C.H. Depuy and O.L.Chapman.
11. Combinational Chemistry – Synthesis and applications – Stephen R. Wilson &
12. Anthony W. Czarn
ik Heterocyclic Chemistry:Vol.I,II, III: R. R. Gupta, M. Kumar and M. Gupta.
13. Heterocyclic Chemistry: Joules and Mills.
14. Modern heterocyclic Chemistry: L. A. Paquette (Benjamin).
15. Organic Chemistry: Jonathan Clayden.
16. Organic Chemistry Volume II I. L. Finar
17 Burger's Medicinal Chemistry
18. Modern Methods of Plant Analysis- Peech and Tracey.
19. Phytochemistry Volume I and II by Miller.
20. Chemistry of Natural Products by S. V. Bhat.
21. Trease and Evans, Pharmacognosy, 15th Edition.
22. Recent Advances in Phaytochemistry Volume I to IV
23. Natural Product Chemistry- Nakanishi Gggolo.
24. Organic Chemistry of Natural Products- Volume I and II by Chatwall
25. Organic chemistry of Natural Products Volume I and II by O. P. Agarwal.
26. Text book of Burger's Medicinal Chemistry and drug Discovery-Volume I to IV
27. Textbook of Organic and Pharmaceutical Chemistry- Wilson and Gisvold
28. Text book of Medicinal Chemistry- W. A. Foye
29. The Organic Chemistry of Drug Synthesis by Lediuieer, Volume I to V
30. Remington's Pharmaceutical Sciences- 20th Edition.
31. Indian Pharmacopoeia 2007, Volume I to III.
32. Burger: Medicinal Chemistry)John Wiley & Sons N. Y.)
33. Foye: Principles of Medicinal Chemistry (Varghese & Co.)
34. Ledinicer: Organic Drug synthesis Vol. 1,2,3,4 (John Wiley & Sons N.Y.)
35. Ariens: Medicinal Chemistry Series
36. Ellis and West: Progress in Medicinal Chemistry Series
37. Butterworther: Progress in Medicinal Chemistry Series
38. Wilson and Gisvold's: Text book of Medicinal Chemistry (J.B. Lippincoff cam)
39. Stuart Warren: Organic Synthesis – The Disconnection Approach (John Wiley & Sons)
40. Comprehensive Medicinal Chemistry – Series – I-VI (Academic Press)
41. Schueler, Chemobiodynamic and Drug Design
42. Martin, Y., QSAR, 1978
43. Hansch, Principles of Med. Chem.
44. Kubiny's, QSAR
45. Holtje. Sippl., Rognan and Folkers, Molecular Modeling.
46. P.K. Larsen, Tommy and U.Madsen, textbook of Drug Design and Discovery.
47. T.J. Perun and C.L. Propst, Computer Aided Drug.

BRANCH C- PHARMACOGNOSYAND PHYTOCHEMISTRY

MPH-C-I (PAPER-I)

PHYTOCHEMISTRY

Theory 3 hrs/wk

1) Biogenetic pathways for the production and chemistry of the following Phytopharmaceuticals
    - Alkaloids – tropane, indole, quinoline, isoquinoline,phenanthrene, alkaloidal amines
    - Glycosides- Anthraquinone, saponins, cardiac glycosides
    - Steroids
    - Flavanoids
2) Study of chemistry of natural products using analytical techniques like UV, NMR,MS, OR . Significance of chemotaxonomical studies with special reference to therapeutically important plant products.
3) Variability in drug constituents – a review of effects of indigenous and exogenous factors.
4) Methods of extraction isolation , purification and estimation of the following plant constituents-
    a) Tropane alkaloids
    b) Indole alkaloids- ergot, rauwoifia, nux vomica
       Anthraquinone glycosides
    c) Cardiac glycosides
    d) Flavanoids
    e) Ginsenosides
    f) Artemisinin
    g) Taxol
5) Sources, chemistry and pharmacological actions of terpenoids and carotenoids
6) Chemistry of proteins and peptides, methods of separation and analysis
7) Natural products as leads for new drugs. Approaches to discovery and development of natural products as potential
   new drugs, selection and optimization of lead compoundsfor further development
8) Different methods of extraction of phytochemicals and preparation of extracts. Separation and isolation techniques for
   Phytochemicals
9) Neutraceuticals , herbal cosmetics and phytoestrogens - sources, chemistry and uses
10) SAR of phytochemicals with examples , introduction to docking studies

MPH-C-II (PAPER-II)

CULTIVATION AND PROCESSING OF DRUGS

Theory 3 hrs/wk

1. Biodiversity conservation. Endangered species of plants.
2. Plant breeding and Germ plasm conservation
3. Extrinsic factors affecting yield and quality of constituents – altitude, light, temperature, moisture, irrigation, rainfall. Intrinsic factors affecting cultivation
4. Soil management, classification of soils
5. Fertilizers, manures, biofertilizers
6. Plant growth regulators
7. Mineral supplements- micro and macronutrients
8. Crop quality improving methods – chemodemes, hybridization,, mutation, polyploidy
9. WHO guidelines on good agricultural practices for medicinal plants
10. Problems and recent trends in pest management. Biopesticides, pheromones, juveline hormones
11. Commercial cultivation of the following plants with reference to Indian conditions –
    Senna, Clove, Cardomom, Cinchona, Vanilla, Saffron, Ashwagandha

MPH-C-III(PAPER-III)

APPLIED PHARMACOGNOSY

Theory 3 hrs/wk

1) Different methods of standardization of crude drugs including organoleptic , microscopical, physical and chemical methods, quantitative microscopy, biological screening, DNA finger printing.
2) Application of chromatographic and spectroscopic methods of standardization for quality control and assay of crude drugs and herbal formulations.
3) Emerging plant drugs- study of hepatoprotective , antifertility, antimalarial, anti inflammatory, antimicrobial, anticancer, antidiabetic, immunomodulatory, and adaptogenic activity , effects on CNS, CVS and GIT of herbal drugs.
4) Drugs and pharmaceuticals from marine sources- sources, extraction, constituents, description and uses.
5) WHO guidelines for herbal drugs including standards for pesticide residues and aflatoxins.
6) Development of herbal formulations .Problems encountered in the manufacture of herbal formulations. GMP for herbal drug formulations.
7) Plant products and high thoroughput screening.
8) Adverse effects of herbal drugs.
9) A review of current status of medicinal plants in alternative system of medicines and general standards for Ayurvedic formulations

10) Determination of shelf life of herbal formulations, development of evaluation methods, use of markers in herbal drug
Standardization
11) Patents for phytochemicals and herbal formulations
12) Herb drug interactions
13) Introduction to preparation and uses of phytosomes

MPH-C-IV (PAPER-IV)

MEDICINAL PLANT BIOTECHNOLOGY

Theory 3 hrs/wk

1.Introduction to genetics and molecular biology.Cytogenetics, genetic code and gene mutation, genetic engineering, genetic mapping, molecular maps of plant genomes, uses of PCR in gene mapping, plant chromosome analysis
2.Principles of plant genetics, genetic factors affecting plants and their constituents, gene mutation and selection, transgenic medicinal plants, gene transfer methods and applications of transgenic plants.
3.Gene recombination and basis of plant breeding, DNA recombinant technology
Use of DNA markers and DNA hybridisation
4.A detailed study of plant tissue culture and its application in pharmacognosy, laboratory requirements and general techniques , tissue culture media.
Callus culture, meristem culture, organ culture, anther and microspore culture, liquid cell suspension culture, pollen culture, protoplast fusion, hairy root culture, immobilized plant cell culture, immobilization techniques and synthetic seeds
5.Secondary metabolism in tissue cultures with emphasis on production of medicinal agents and its impact on pharmacy. Screening and selection of high yielding cell lines.
6.Effect of cultural practices, precursors and elicitors on production of biomedicinals.
7.Biotransformation, bioreactors for pilot and large scale cultures of plant cells. Cellular totipotency, cryopreservation and retention of biosynthetic potential in cell cultures.
8.Applications of fermentation technology, Industrial fermentation

MPH-C-V
PHARMACOGNOSYAND PHYTOCHEMISTRY PRACTICALS
(18 hrs/wk)

a)Phytochemistry:
1.Extraction of phytochemicals from fresh and dried plants
2.Isolation and purification of constituents
3.Spectral studies of phytochemicals
4.Chromatographic studies of plant extracts
5.Estimation of constituents and official herbal preparations by different analytical techniques

6.Extraction of volatile constituents

b) Cultivation and Processing of Drugs:

1.Experiments on cultivation of medicinal plants
2.Use of fertilizers and manures in cultivation
3.Effect of plant growth regulators on the yield and quality of constituents
4.Collection and preservation of locally available medicinal plants

c)Applied Pharmacognosy:

1.Preparation of herbal formulations including cosmetics
2.Evaluation of traditional herbal formulations
3.Standardisation of herbal formulations using various analytical techniques
4.Simple in vitro screening of extracts and formulations for biological activity

d) Medicinal and Plant Biotechnology:

1. Experiments in plant tissue culture using different media
2. Different methods of sterilization of explants
3. Simple experiments in fermentation
4. Observation of different stages of cell division

Books Recommended:

1. Evans, W.C., Trease and Evans Pharmacognosy, W.B., Saunders & co. London.
2. Jean Bruneton, Pharmacognosy and Phytochemistry of medicinal plants Techniques and Documentation, Lavoiser, 1995.
3. Wickery, M.L., Secondary Plant Metabolism, MC Millan Press, London.
4. Introduction to Alkaloids, A Biogentic Approach, Willy, New York.
5. Vinod D. Rangari, Pharmacognosy and Phytochemistry, Career publication, Nashik.
6. Tyler, E., Brady, R., Pharmacognosy, Philadelphia P.A., U.S.A.
7. Kaufmann, Natural Products from Plants, CRS Press, New York.
8. Nakanishi K., Chemistry of Natural Products, Kodausha Book Publishing Company, Osaka (Japan).
9. Swain, T., Chemical Plant Taxonomy, Academic Press, London.
10. Harborne, J.B., Phytochemical Methods, Chaparan & Hall, London.
11. Sim, S.K., Medicinal Plant Guidelines, University of Toronto Press.
12. Sim, S.K., Medicinal Plant Alkaloids, University of Toronto press.
13. Cordell, G.A., The Alkaloids - Chemistry and Pharmacognosy, Academic Press, London.
14. Raphael, Ikan, Natural products, A Laboratory Guide, Academic Press, INC.
15. Finar, I.L., Oraganic Chemistry, Stereochemistry and the Chemistry of Natural Products, U.S.A.
16. Silverstein, Spectrometric Identification of Organic Compounds, John Willy & Sons INC, New York.
17. Agarwal, O.P., Chemistry of Organic Natural Products, Krishna Prakashan Media (P) Ltd., Meerut, India.
18. Mohammed Ali, Pharmacognosy and Phytochemistry, Vol. I, II, CBS Publication & Distributors, New Delhi.
19. Kalia, A.N., Textbook of Industrial Pharmacognosy.

20. Jarald, E.E., Jarald, S.E., Textbook of Pharmacognosy and Phytochemistry.
21. Encyclopedia of Chemical Technology, The Inter Science Encyclopedia, New York.
22. Dewick, Medicinal Natural Products, A Biosynthetic Approach.
23. Atal, C.K., Kapur, B.M., Cultivation and Utilization of Medicinal and Aromatic Plants, R.R.L. Jammu.
24. Farooqui, A.A., Sreeramu, B.S., Cultivation of Medicinal and Aromatic Plants University press, 2001.
25. Yoganasimhan, S.N., Medicinal Plants of India, 1st Edition, Interlive Publishing Pvt. Ltd.
26. Medicinal and Aromatic Plant abstracts (MAPA) CSIR, New Delhi..
27. Wallis, T.E., Text Book of Pharmacognosy.
28. Indian Herbal Pharmacopoeia.
29. Bruneton Jean, Pharmacognosy and Phytochemistry of Medicinal Plants.
30. Kaufmann, Natural Products from Plants, CRC Press, New York.
31. Butler, M., Poucher's Perfumes, Cosmetics and Soaps.
32. Panda, Herbal Soaps and Detergents.
33. Vimladevi, Text Book of Cosmetics.
34. D'Amelio, Botanicals, A Phytocosmetic Desk reference
35. Practical Pharmacognosy Dr. C.K.Kokate
36. Agarwal, S.s. and Paridhavi.M, Herbal Drug Technology, Orient Longman Pvt Ltd, Hyderabad.

BRANCH-D- PHARMACEUTICS

MPH.D-I (PAPER- I)
FORMULATION TECHNOLOGY

Theory (3hrs/wk)

1 Formulation, Design , manufacturing and quality control of solid dosage forms.
2 Design and formulation of sustained release tablets - Factors affecting drug release, coating technologies.
3 Formulation of parenteral products - Formulation and manufacture of small volume and large volume parenterals, containers and their evaluation.
4 Manufacture and quality control of liquid dosage forms: oral and topical.
5 Controlled release drug delivery system Concept, drug properties relevant to controlled release- formulation, mechanism, microencapsulation, oral and parenteral dosage forms and their evaluation. *In vitro- in vivo* correlation.
6 Controlled drug delivery modules
   a) Insulin pump, ocusert , osmotic pump system, modules for GIT, implants, IUD system,
   b) Transdermal drug delivery system, Nasal drug delivery systems
7 Colloidal drug delivery system – microemulsion, Liposomes, Nano particles. Formulation, evaluation and their applications. Gene delivery and protein

drug delivery.

8 Drug Targeting – concept, different approaches – use of physical, chemical and biological methods.

9 Pharmaceutical Inhalation Aerosols – Targeting to lungs – chemical and biochemical consideration, mechanism, Design and development of inhalation drug delivery systems, Aerosol filling equipments. A detailed study of aerosol containers and evaluation of aerosols.

10 Pharmaceutical process validation- regulatory basis for process validation, prospective process validation, retrospective validation, validation of solid dosage forms, Transdermal process validation.

11 Cosmetic technology- Formulation and evaluation of cosmetics applied to skin, face and hair.

MPH.D-II (PAPER- II)
BIOPHARMACEUTICS AND PHARMACOKINETICS
Theory (3hrs/week)

1) Overview of fundamental principles in biopharmaceutics and pharmacokinetics. Biopharmaceutical classification system.

2) Compartment models – one compartment open, multi compartment open, nonlinear kinetics – multiple dosing, physiological models, loading and maintenance dose, dosing time interval. Wagner-Nelson and Loo-Reigelman methods. Mean residence Time.
3) Effects of rate determining parameters on controlled release of drugs. Polymer solubility, solution solubility, partition coefficient, polymer diffusivity, thickness of hydrodynamic diffusion layer, Drug loading dose, surface area.
4) Clinical Pharmacokinetics-Applications of Pharmacokinetic data in dose adjustment and individualization of therapy
5) Bio-availability studies – bioavailability of single dose and multiple dose administrations, comparative bioavailability studies and analysis.
6) Biopharmaceutics of injectable medications; physico chemical and physiological factors affecting drug absorption, application of pharmacokinetics to biopharmaceutic investigations, pharmacokinetic models.
7) An overview of the software relevant to pharmacokinetic studies.

MPH. D-III (PAPER – III)
INDUSTRIAL MICROBIOLOGY AND BIOTECHNOLOGY
Theory 3 hrs/week

1) Gene expression and recombinant DNA technology-an overview. DNA sequencing, Genome sequencing, DNA hybridization, PCR technology. Gene therapy.
2) Genomics and proteomics, Transgenic animal and plant technology, tissue engineering.
3) Chemistry of antigens, vaccines-production, standardization and storage. Modern vaccine technologies. Monoclonal antibody based pharmaceuticals. Interferons and Interleukins.
4) Fermentation Technology– Design & Operation of Industrial fermentor– Development of industrial micro organisms. Advances in Screening, batch culture, continuous culture and kinetics, precursors, inducers, repressors. Manufacture of pharmaceutical products by fermentation- antibiotics, vitamins, Industrial alcohol, citric acid, lactic acid.
5) Enzyme production. Study of important enzymes and industrial applications. Enzyme engineering.
6) Biotechnology products – detailed study of production of Humulin, Humatrop, activase , Hepatitis –B Vaccine, proteases and other biotechnology products. Storage and handling of biotechnology products. Economic considerations in Medical Biotechnology.
7) Aseptic process validation.
8) Recent advances in Diagnostic techniques in clinical microbiology, serological reactions, immunoassays. Emerging infectious diseases. Drug Resistance.

MPH. D-IV (PAPER- IV)
INDUSTRIAL PHARMACY
(Theory 3hrs/week)

1) Characterisation of raw materials. Excipient compatibility.
2) Preformulation studies – introduction, organoleptic properties, Particle size, particle shape, surface area , solubility dissolution, parameters affecting absorption, Stability. Polymorphism – crystal properties
3) Polymer science and application – Introduction and definitions, types of polymers, Pharmaceutical applications, polymers as thickening agents, viscosity, solvent selection, fabrication technologies.
4) Optimization techniques in Pharmaceutics, formulation and processing – Optimization parameters
5) Statistical design of formulations and other applications-factorial design, ANOVA, Student's 't' test, Similarity factor, Central composite design.
6) Stability of drugs, effect of temp, humidity, light and pH, stability studies-stability loss, overage and shelf life – design for short term and long term stability studies of dosage forms, statistical considerations.
7) Production Management and Documentation : Documentation – relevance and importance, statutory requirement and procedure for documentation, Schedule U, critical examination of documents. ISO 9000 series, Label control. Intellectual Property Rights. Total quality management and productivity, guide to pharmaceutical manufacturing facilities, materials management and cost control.

8) Regulatory requirements as per ICH, WHO and FDA guidelines. Clinical trials and Schedule Y.

9) Patent laws, NDA & ANDA- general considerations, specific requirements, content and format.

10) cGMP : definition, Schedule M, cGMP in manufacturing, processing, packaging and holding of drugs, control of components, containers and closures, production and process controls, packaging and labeling controls, premises, design, construction, maintenance, equipment, ware-housing.

11) Pilot Plant Scale Up Techniques: Significance of pilot plant scaleup phase from laboratory procedures to routine production procedures. Discussion on important parameters such as formula and equipment, product uniformity and stability. Raw materials and process, physical layouts, personnel requirements and reporting responsibilities.

12) Production Planning, Scheduling and Forecasting : capacity (Plant, machine, human resource) assessment, production rate changes, inventory management, costing of product and cost controls, planning product mix, plant site selection, layout and organization of pharmaceutical industries.

13) Industrial Safety: Industrial hazards due to fire, accidents, mechanical and electrical equipments, chemical and pharmaceuticals. Monitoring and prevention systems (safety measures).

14) Effluent Testing and Treatment.

MPH. D-V
PHARMACEUTICS PRACTICALS

(18 HRS/WEEK)

a)Formulation Technology:

1. Study of effect of various new type of binding agents on the properties of tablets
2. Formulation and evaluation of semi-solid dosage forms using different bases
3. Formulation and comparative evaluation of coated and uncoated tablets(marketed) of various categories. Similarity factor.
4. Formulation and evaluation of stability of reconstituted dry syrups of amoxicillin, ampicillin etc.
5. Product development and protocol preparation for
   a. Liquid antacid preparation.
   b. Multivitamin tablet/capsule
   c. Skin ointments / creams.
   d. Injection containing antibiotics.
   e. Sustained release preparations
6. Preparation of albumin microspheres and their particles size characterization
7. Preparation of matrix tablets using various polymers and studying their release pattern.
8. Preparation and evaluation of microcapsules by different microencapsulation techniques
9. Preparation and evaluation of wax embedded microspheres
10. Preparation and evaluation of Reservoir type devices (eg.) PEG Ethylcellulose in

chloroform/dichloromethane as the coating material

b) Biopharmaceutics and Pharmacokinetics:

1. Study on the diffusion of drugs through various polymer membranes.
2. Preparation and study on the *in-vitro* dissolution of various sustained action products and comparison with marketed products.
3. Preparation of various polymer films, containing different drugs and studying the film characteristics and release patterns.
4. Sudy of *in-vitro* one compartment and two compartment models.
5. Diffusion study of drugs using natural/artificial membranes and various diffusion media.
6. Study of Transdermal delivery of drugs from various dosage forms and use of absorption enhancers.
7. Determination of pharmacokinetic parameters using given data of plasma level/urine level - time profile. Wagner-Nelson, Loo Reigelmann methods, MRT, Loading and Maintenance doses, dosing interval.
8. *In- vivo* bio availability /bio equivalence studies using animal models.
9. Study of effects of parameters on controlled release of drugs.
10. Study of IVIVC.
11. Characterisation of polymers- Solubility, Acidity/Alkalinity, loss on drying, UV/Visible spectroscopy, FTIR,XRPD, DSC.

c) Industrial microbiology and Biotechnology:

1. Validation of sterilization procedures
2. Fermentation studies.
3. Evaluation of disinfectants.
4. Screening, Isolation and identification of pharmaceutically significant microorganisms.
5. Evaluation of Antibiotics and susceptibility testing of isolated organisms.
6. Microbial assay of antibiotics and vitamins.
7. Antigen-Antibody reactions.

c) Industrial Pharmacy:

1. Accelerated stability studies on formulations and drugs with respect to temperature, moisture & light.
2. Determination of rate and order of decomposition of drugs like aspirin, vitamins.
3. Evaluation of packaging materials like glass, plastic and rubber
4. Effluent treatment testing.
5. Study on characterization of raw materials flow and consolidation properties, True density, Bulk density, compressibility, particle size, surface area.
6. Study on optimization techniques, factorial design, Response surface methods, Central composite design, Box Behenken design.

BOOKS RECOMMENDED:

1. Physical Pharmacy 4th edition Alfred Martin
2. Pharmaceutical inhalation Aerosol Technology edited by Anthony J Hickey
3. Controlled Drug delivery Fundamentals & application edited by : Joseph R Robinson Vincent H L Lee
4. Good Manufacturing Practice for Pharmaceuticals A Plan for Total Quality Control Sidney H Wolley, Murray M Tuckerman, Wollian S Hitchings
5. Physical Pharmaceutics: E.Shotton and K.Ridgway
6. Statistical design and analysis in Pharmaceutical Sciences Sherin – Chung
7. Statistics in the Pharmaceutical Industry by C.Ralph Bunche, Jin-Yeong J Sang
8. Prescott, Harley & Klein's Microbiology
9. Biopharmaceuticals- Biochemistry and Biotechnology by G.Welsh
10. Text book of Microbiology by R. Anantha Narayanan and C.K Panicker.
11. Bernard T.L .And Robert A. Narth Pharmaceutical Process Validation, Volume 23, Marcel Dekker.
12. O Kayser R H Muller "Pharmaceutical Biotechnology"
13. Industrial Microbiology by Prescott S.C. and Dunn G.S
14. Industrial Microbiology by L E Casida
15. Pharmaceutical Microbiology by Hugo W.B and Russell A.D
16. S S Purohit "Biotechnology: Fundamentals & Applications."
17. Gennaro AR, Remington: The Science and Practice of Pharmacy, 20th Edn., Vol. I & II Lippincott Williams & Willkings, Philadelphia, PA, 2000.
18. Banker G S and Rhodes C T, Modern Pharmaceutics, 3rd Edn., Marcel Dekker, Inc., New York, 1995.
19. Lachman L, et al, Pharmaceutical Dosage Forms: Parenteral Medication, 2nd Edn., Vol I & II, Marcel Dekker, New York, 1992.
20. Lachman L, et al, Pharmaceutical Dosage Fors: Tablets, 2nd Edn., Vol I, II & III Marcel Dekker, New York, 1992
21. Turco S and King R E, Sterile Dosage Forms , 3rd Edn., Lea & Febiger, Phladelphia, 1987.
22. Aulton M E., Pharmaceutics – The Science of Dosage Form Design, 1st (International student) Edn., Churchill Livingstone, New York, 1996.
23. Wiseman A, Handbook of Enzyme Biotechnology, 2nd Edn., Ellis Horwood Ltd., New York, 1985.
24. Theory and Practice of Industrial Pharmacy by Liberman and Lachman
25. Gibaldi M, Bio-Pharmaceutics and Clinical Pharmacokinetics, 4th edn., Lea and Febiger, Philadelphia 1991.
26. Notari R E., Bio-Pharmaceutics and Clinical Pharmacokinetics, 4th Edn. Marcel Dekker, Inc., New York 1987.
27. Lachman l & Liberman H A, The Theory and Practice of Industrial Pharmacy 3rd Edn, Vergese Publishing House, Mumbai, 1991.
28. Swarbrick J, Current concept in Pharmaceutical Science: Bio-Pharmaceutics, Lea & Febiger, Philadelphia, 1970.
29. Wagner J G, Bio-Pharmaceutics and relevant Pharmacokinetics, Drug Intelligence Publications, Washington DC 1971.

30. Rowland M and Tozer TN, Clinical Pharmacokinetics concepts and applications, 3rd Edn., Lea & Febiger, Philadelphia, 1995.
31. Shargel L and Yu AB, Applied Bio-Pharmaceutics and Pharmacokinetics, Appleton & Lange, Norwalk, CT, 1993.
32. Ansel HC. Allen, Jr. LV et al, Pharmaceutical Dosage forms and Drug Delivery Systems 7th Edn., Lippincott Williams & Wilkins, Philadelphia, PA, 2000.
33. Chien Y W, Novel Drug Delivery Systems, 2nd Edn., Marcel Dekker, Inc., New York, 1992.
34. Tyle P, Drug Delivery Devices, Fundamentals and Applications, Marcel dekker, Inc., New York 1988.
35. Sharma PP, How to Practice GMP, 1st Edn., New Delhi, 1998.
36. ISO Standards, Bureau of Indian Standard, New Delhi**.**
37. Rodney J Y Ho, Milo Gibaldi "Biotechnology & Biopharmaceuticals"
38. **All Indexed National and International journals.**

BRANCH –E PHARMACOLOGY

MPH- E-I (PAPER-I)
PHARMACOLOGICAL SCREENING METHODS AND DRUG DEVELOPMENT

3hrs/wk

1.Principles of experimental pharmacology

Different laboratory animals in pharmacological research , routes of drug administration to laboratory animals and collections of biological samples, breeding of laboratory animals, euthanasia. CPCSEA guidelines for laboratory animal facility and animal welfare requirements,limitation of animal testing

2. Principles of toxicity evaluations. Different aspects of acute, chronic and special toxicity studies.

LD_{50}, ED50, TD50, IC50 determination.

ICH Ethics and animal experimentation., recommendations, guidelines and regulatory agencies- CPCSEA, OECD, FDA, FHSA, EPA, EEC, WHO. OECD guidelines for toxicity evaluations .In vitro screens for specific toxicities.

3.Bioassays-Basic principles of bioassay, experimental models and designs employed in biological standardization, official bioassays, boiassays of Antihaemophillic fraction, Heparin Sodium,Diphtheria anti toxin, Anti rabies vaccine.

4.Microbial assay of antibiotics. Screening for antimicrobial activity.

5.Receptor- radio ligand binding assays: general principles and techniques of radio ligand binding assys ,specific assay design for adrenoreceptors ,dopamine receptors,histamine receptors GABA and benzodiazepine receptors , Principle and methods of ELISA, FPIA, Apoenzyme Reactivation Immunoassay.

6 Evaluation of kinetics of new drugs. Bioavailability studies.models

7. Screening of new drugs for pharmacological activities. Principles and techniques used in screening. Transgenic animals, genetically modified animal models

8. Pharmacological models employed in the screening of new drugs belonging to the following categories (invivo & in vitro models):Analgesics and drugs used in Arthritis and neuropathic pain, Antiinflammatory agents ,antiipsychotics, Anxiolytics, Antidepressants , Nootropics, Antiparkinsonian agents, Antiepileptics, Local anaesthetics , Skeletal muscle relaxants and neuromuscular blockers

Drugs Drugs affecting memory, Drugs for Alzheimer's disease, Antiatherosclerotic agents,, Antihypertensive agents, Antianginal agents, Antiarrhythmic agents and agents used in sudden cardiac death, Drugs for myocardial infarction, Drugs in cardiac failure and cardiac myopathies, Antiplatelet and thromolytic agent, Antimigraine agents, Anticancer agents, Antidiabetics, Antiulcer agents, Antiasthmatic agents, Antiemetics, Drugs affecting reproductive system, Antifertility agents , Diuretics, Drugs used in inflammatory bowel disease, Hepato protective agents, Antiobesity agents, Drugs used in erectile dysfunction, Antiviral agents, Antimalarial agents, Dermatological agents and experimental models in skin pharmacologyIn vitro and invivo evaluation of drigs influencing immune system., Biochemical estimation of free radical scavengers.

9.Biostatistics. & Research methodology- Selection of study groups,Study designs and variables,Blinding, confounding and randomization, Various statistical methods.

Methods of collection of data, classifications and graphical representation of data. Binomial and normal probability distribution. Polygon, histogram, measure of central tendency. Significance of statistical methods, probability, degree of freedom, measures of variation - Standard deviation, Standard error. Sampling, sample size and power.

Statistical inference and hypothesis. Tests for statistical significance: student t-test ,Chi-square test, confidence level, Null hypothesis.

Linear regression and correlation. Analysis of Variance (one way and two way).

Factorial designs (including fraction factorial design). Theory of probability, Permutation and Combination , Ratios, Percentage and Proportion. Two way ANOVA and Multiple comparison procedures.

Non-parametric tests, Experimental design in clinical trials, Statistical quality control, Validation, Optimization techniques and Screening design. Correlation and regression, least square method, significance of coefficient of correlation, nonlinear regression.

Bioassays-calculations of doses response relationships, LD_{50}, ED_{50}, probit analysis.

Applications of software for statistical calculation viz. SPSS, foxtron. EPI Info, SAS

Application of computers in Pharmaceutical research.

10. Concept of total quality management, requirements of GMP, GLP, GCP, Regulatory requirements of drugs and Pharmaceutical (USFD-NDA/ ANDA)

Documentation and Maintenance of records.

Intellectual property rights patents, Trademarks, Copyrights, Patents Act..

11.Alternatives to screening procedures

Cell culture and cell line techniques

Types, sourcing maintenance, propagation and preservation of cell lines, Design and equipment for the cell culture laboratory,quality control considerations. Applications of cell culture and good cell banking practices.

Patch clamp techniques, different in vitro models

12. Drug discovery : strategies and approaches employed in drug discovery,basic concept of combinatorial chemistry, High throughput screening, lead selection & optimization. Insilico systems for assessing toxicity and pharmacokinetics. Docking-a brief description,Transgenic animal models in the development of new drugs
13 Genomics: Impact of human genome sequence on the discovery of newer pharmacological agents, basic concepts and applications of bioinformatics and proteomics in drug discovery.

MPH.E-II (PAPER-II)
BIOCHEMICAL & MOLECULAR PHARMACOLOGY
3hrs/wk

1. Biochemical mechanisms of cell injury, reactive oxygen species, oxidoreductive stress, antioxidant defense mechanisms.
2. Biochemical mechanisms of acute and chronic inflammation, apotosis and necrosis, mediators of inflammation.
3. Programmed celldeath(Apotosis) : physiological and pharmacological implications and therapeutic potentials of apotosis.
4. Endogenous bioactive molecules:
a. **Cytokines and Chemokines**: Classification, physiology, pharmacology, pathological and therapeutic implications of various cytokines and chemokines.
b. **Cell adhesion molecules and Matrix proteins**: Biology of cell adhesion molecules and matrix proteins , their rol in various disease processes, and potential target ssites to develop newer agents. Glycoproteins11b/IIIa receptor antagonists and anti-integrin therapy.
c. **Growth factors** : Biology and therapeutic potentials of various growth factors. Pharmacology of Erb B receptors, cardiac and vascular remodeling.
d. **Biology of vascular endothelium**: Biology of EDRF, EDCF, and EDHF , pharmacology of endothelins and nitric oxide . Clinical implications of endothelial dysfunctions.
e. **Neuropeptides**: Biological functions, pharmacological implications, and their antagonists and therapeutic potentials of the following neuropeptides:.Neuropeptide Y Calcitonin gene-related peptide(CGRP),.Substance P,.Cholecytokinin
f. **Transport proteins**: Classification and biology of ATP binding cassette (ABC) transport super family. Multidrug resistance (mdr) proteins, Cystic fibrosis transmembrane regulator (CFTR
g. **Neurosteroids**
h.Arachidonic acid metabolites, cox-2 regulators and their role in inflammation
i. Atrial peptides
j. Oxygen intermediates, antioxidants and their therapeutic implications.
4.Chronobiology and Chiral biology : Basic concepts and clinical potentials of chronobiology and chiral configuration.
5.Drug metabolism: Distribution of drug metabolizing enzymes, phaseI metabolizing enzymes enzymes- cytochrome P450, other oxidative enzymes, enzymes in phase II reactions.

6. Biochemical pathway of drug metabolism, factors influencing drug metabolism
7. Introduction to pharmacogenetics and pharmacogenomics, chrono pharmacology.
8. **Molecular biology:** Cell and its components, plasma membrane its structure and functions, The nucleus, cell growth and division, molecular organisation and behaviour of the genome. Cell motility and excitation, cell differentation. Molecular basis of mutations. Biology and pathophysiology of cancer, diabetes, Thalessemia, cystic fibrosis, Hemophilia & other diseases-Physiological manifestations and symptoms..
9. **MOLECULAR GENETICS:** Introduction to genetics, structure of DNA, DNA replication and transcription, enzymes involved in replication, isolation of DNA, RNA, etc. Gene sequencing and mutation.Plymerase Chain Reaction and analysis of DNA sequences.
10. **GENE REGULATION AND EXPRESSION:** Regulation of gene activity in prokaryotes and eukaryotes. Principles of regulation, E. coil lactose system, tryptophan operon, autoregulation, feed back inhibition, gene family, gene amplification, regulation of trancsription and processing, translational control, gene rearrangement.
11. **TECHNIQUES OF GENE ANALYSIS:** Southern blotting, Northern and Western blotting, gene probes.
12. **GENETIC DISORDERS:** Single gene disorders and molecular pathology, molecular genetics and common diseases. autoimmune diseases, cancer, cardiovascular diseases, nervous disorder.
13. **GENE THERAPY:** Current methods of treatment of genetic disorders.

Future trends in treatment of genetic disorders, Gene replacement or corrective therapy, Targeting aspects. Viral and non-viral gene therapy. Gene therapy of genetic disorders like cystic fibrosis, Thalassaemia, Neuroblastoma, Hepatitis, AIDS, Diabetes. Hemophilia Band SCID

14. **GENETIC ENGINEERING:** Introduction, mutagenisis, cutting and rejoining. Polymerase chain reaction Isolation and amplification of genes, gene expression and general introduction to genomics.
15. **Genetic recombination:** Transfer of characters, genetic recombination, phage crosses, gene transfer Mechanisms, plasmids, insertion of phage chromosomes, transduction, transformation.
16. **Gene cloning:** Cloning vectors, cloning techniques, cloning strategies, Cloning of eukaryote gene

Therapeutic protein expression, Transgenic animals, engineered gene expression, second generation protein program design, examples of engineered proteins of therapeutic potential. Applications of recombinant DNA technology.

17. **Immunotoxins**: Biology, pharmacology, therapeutic potentials of immunotoxins.
10. Molecular biology of aging, theories of aging
11. Molecular basis of mutations- biology and genesis of diabetes, thalassemia, cystic fibrosis, hemophilia, and cancer, types of cancer and carcinogenesis

MPH –E-III (PAPER-III)
RECENT ADVANCES IN PHARMACOLOGY
(3hrs/wk)

1.Molecular mechanisms of drug action, Receptor occupancy , drug receptor interaction, forces binding the drug to the receptors, targets for drug binding, kinetics and quantitative aspects of drug receptor interactions, drug antagonism, stereo selectivity of drug action.

Cellular signaling systems including G proteins, phosphatidyl inositolCyclic nucleotides, Calcium and calcium binding proteins, phospholipase.

2. Neurohumoral transmission in CNS & ANS

3Pharmacology of receptors: Classifications, cellular signaling systems, and pharmacology of agonist and antagonist and modulators of the following receptor types:

Excitatory amino acid receptors, Kinin receptors. Purinoreceptors

GABA and benzodiazepine receptors, Neurosteroid receptors

Cannabinoid receptors, Melatonin receptors

Adrenergic receptors, Cholinergic receptors

4. Ion channel and their modulators: Classification and biology of potassium, calcium, and chloride channels , pharmacology of their modulators.

5. Novel target sites: Physiological functions, pharmacological implications and therapeutic potential of following target sites:

(a) Rho kinase
(b) Phosphoinositide 3-kinase
(c) Akt (protein kinase)
(d) Caspase
(e) Poly(ADP-ribose)polymerase(PARP)
(f) Peroxisome proliferators activator receptors
(g) AMP activated protein kinases
(h) Protein kinases
(i) Phosphodiesterases

6. **Nucleic acid therapies**: Basic concepts and clinical potentials of gene therapy, oligonucleotide therapy, aptamer therapy and ribozyme therapy.

7. Stem cell therapeutics: Biology of stem cell and their potentials in various disorders.

8. Ethical issues: Ethical issues related to stem cells, human cloning, genetic counseling, foeticide, and surrogated parenthood.

9. Gene therapy- Gene transfer technologies (viral and non-viral vectors), clinical applications of gene therapy, disease targets for gene therapy.

Pharmacokinetics and pharmacodynamics of peptides and protein drugs.

Immunogenecity of protein drugs.

10.Immunopharmacology: a)Basic principles- cells of immune system, specific and non specific immunity, antigens, antigen- antibody binding immunoglobulins, humoral immune response, cellular immune response, control of immune response, complement system.

b) Pharmacological aspects of clinical conditions involving immunological mechanisms- Hypersensitivity, delayed hypersensitivity, immunomodulators, current concept in the therapy and research of drugs for AIDS, Tissue transplantation (immunosuppressants and immunoenhancers), cancer, vaccines and sera, anti fertility drugs and vaccines, drug allergy

c) Immunomodulatorsa of indigenous origin (plants)

d) Fc Receptors: Introduction, structure and function of antibodies, confirmation of antibodies, Fc8R family, Proteins, transcripts and genes: Gene, structure and actions of high affinity. Fc receptor for immunoglobulin E. binding factors. E . Fc - receptor mediated killing.

Fc – receptor on T and B lymphocytes, Immunoglobulin binding factors

11. Free radicals and therapeutic agents- generation of free radicals, role of free radicals in etiology of various diseases, protective activity of certain important anti oxidants.
12. Nutraceuticals- Concept, regulatory requirements and clinical uses
12. Recent developments in chemotherapeutic agents: mechanism of action, mechanism of anti microbial resistance,
13. Anti sense agents.

MPH. E-IV(PAPER 1V)
CLINICAL PHARMACOLOGY AND TOXICOLOGY

3hrs/wk

1 a) Definition and scope of clinical pharmacology

b) Clinical pharmacokinetics : Pharmacokinetic parameters and their estimation, physiological determinants of drug clearance. Organ extraction and models of hepatic clearance. Estimation and determinants of bioavailability. Multiple dosing. Calculation of loading and maintenance doses.

Estimation of serum concentration of digoxin, theophylline, gentamycin, lithium, phenytoin, cyclosporine,creatinine clearance estimation.

Dose adjustments in renal failure, hepatic failure,hepatic dysfunction,geriatric and pediatric patients.

c) Drug development process: Clinical trials, definition,types of clinical trial,choice of patients,exclusion criteria,inclusion criteria,ethical and legal aspects of clinical trials, methods of randomization,size,documentation monitoring and management of clinical trial, clinical trial registry of India, phase 1,phase 11, phase 111 and phase 1V studies, design, safety evaluation, guidelines as per ICMR, WHO and Drugs control authorities, preparation of IND/NDAs, post marketing surveillance of drugs, statistical designs in clinical trials, data analysis techniques and presentation skills.

Clinical research :Types of research designs based on control methods-(Experimental, Quasiexperimental, and Observational methods). Time Sequences (Prospective and Retrospective), Sampling methods (Cohort study, case Control study and cross sectional study), Institutional review board, Helsinki declaration , Clinical trial registry of India. Management of Clinical trials- Role and responsibilities of Stakeholders of clinical trials (FDA, CRO, Sponsor, Physicians, Nurses, Health professionals, Hospitals, Patient), monitoring of clinical trials, Publications of clinical trials

II. a) Basic principles of drug therapy and prescription, Pharmacokinetics and pharmacodynamic monitroring in special situations such as paediatric , geriatric, pregnancy etc.

b) Pharmaco-epidemiology and pharmacoeconomics, essential drug list, rational drug use, national drug policy.

III. Pathophysiology and pharmacotherapy of : Arrhythmia, Hypertension including hypertension in pregnancy, Congestive heart failure, Asthma, Acid peptic disease, Rheumatoid arthritis, Dementia and Alzheimer's disease, Leukemia and Lymphomas, Respiratory tract infections, Tuberculosis, Diabetes, Osteoporosis, Epilepsy, Parkinson's

disease, Unipolar and bipolar disorders, Anxiety, Psychosis, Acute renal failure, Chronic renal failure, End stage renal disease, Hepatitis A,B,C, Jaundice, Fatty liver, Liver cirrhosis.

1V. TOXICOLOGY:

a) General principles of toxicology, definition and scope of toxicology, factors influencing toxicity, evaluation of safety, biotransformation and toxicokinetics, toxicogenomics.
b) ADR and ADR monitoring and management, yellow card system.
c) Target organ toxicity, neuronal and behavioural toxicity, kidney,pulmonary,hepatic, cutaneous, ototoxicity, haematotoxicity, mutagenicity, carcinogenicity, reproductive toxicity.
d) Evaluation of toxicity and management of different poisoning: general principles, antidotes, gut decontamination, elimination enhancement, of :.Paracetamol, benzodiazepines, barbiturates, iron preparations, organophosphorous compounds, carbamates, organochloroinsecticides, methanol, ethanol, pyrethroids, heavy metals, household chemicals.hydrocarbons,PEG, radiation poisoningsnake venoms, plant poisons- odollam, mushroom, general measures of food poisoning

MPH. E-V
PHARMACOLOGY PRACTICALS
18hrs/wk

a) Pharmacological Screening methods and Drug Development:

1. Animal handling and techniques as per CPSCEA guidelines
   i. Breeding data, Housing, Maintenance, Animal feeds
   ii.Study of basic animal techniques, injection og drugs, collection of blood samples, feeding of animals
   iii.Techniques of euthanasia,
   iv.Anaesthesia in animals
   v.Sacrificing animals
2. Evaluation/ Screening of drugs for the following activity .(use different models) Hypnotic activity, Locomotor activity, Anti-psychotic activity, Muscle relaxant activity, Analgesic activity, Anti-inflammatory activity, Anti-convulsant activity, Anti-anxiety activity (Four different models),Anti-parkinsonoan activity, Anti-dementia- Learning & Memory, Anti-diabetic activity, Diuretic activity, Anti- ulcer, intestinal motility, anti-diarrhoeal activity, Local anaesthetic activity, Anti-histaminic activity, Anti-pyretic activity, Anti-fertility activity.
3. Evaluation of anti-microbial activity,& Anti biotic assays
4. Recording of blood pressure and respiration in anaesthetized animals.
5. Any other activity using newer animal models.

b) Biochemical and Molecular Pharmacology:

1. Anti-oxidant/ free radical scavengers estimation in blood, saliva, tissue homogenates in normal, after drug challenge, and in diseased.
2. Renal function test- nephrotoxic drugs/ diseased
3. Liver function test- hepatotoxic drugs/ diseased.

4. Measurements of inflammatory mediators- inflammation and effect of anti inflammatory drugs
5. Evaluation of anti-inflammatory activity – HRBC method
6. Pharmacokinetic studies:
   i. Bioavailability and Bioequivalent studies.
   ii. Intestinal absorption studies- simple sac method, everted sac method
   iii. Drug metabolism- induction and inhibition studies
   iv. Drug distribution, protein binding studies
   v.Drug excretion studies.
7. Cell cultures preparation and maintenance:
   Chick embryo fibroblast Lymphocyte culture.
8. Protein separation and isolation using gel electrophoresis.
9. DNA isolation, sequencing and PCR techniques.
11. Estimation of protein and nucleic acids.
12. RNA isolation from yeast.
13. Mutagenicity testing using mouse bone marrow micronucleus test.
14. *In vitro* cell cultures and toxicity testings
15. *In vitro* cell cultures and drug evaluation for various activities

c) Recent Advances in Pharmacology:

1. Physiological salt solution, preparation , maintenance,modifications
2. Preparation of drug solutions and storage
3. Biological standardization of drugs like Histamine, Acetylcholine, 5 - HT., Oxytocin, DTC
4. Experiments for studying the effects of Histamine ,Aacetyl Choline, 5HT, adrenaline and noradrenaline alone and in the presence of antagonist on suitable isolated tissue preparations.
5.Cumulative Dose response curve- guinea pig tracheal chain
6. Estimation of PA2 values of various antagonists under suitable isolated tissue preparations
7. Drug potentiation and drug antagonism(competitive & non-competitive) –using isolated tissue preparations
8. Effect of Calcium channel blockers- isolated tissue preparations.
9. Phrenic nerve diaphragm of rat- Effect of of drugs on neuro muscular junction
10.Experiments on CVS:
   a. General screening procedure of vasodilators
   b. Effect of various drugs on isolated heart preparations on various animal models under normal, arrhythmic and hypo dynamic conditions.
11 Experiments on toxicology :
   a. Acute toxicity tests.
   b. Determination of LD50, ED50
   c. Subacute and chronic toxicity tests
   d. Gross behavioural studies
   e. Pyrogen testing
12. Record of blood pressure and respiration of anaesthetized animals(dog, rat) and identification of unknown drug based on response.
13. Computer Assisted Learning- Designing programmes for various experiments,

Computer based illustration and data presentation.

d)Clinical Pharmacology and Toxicology:

1. Case studies analysis on - Diabetes mellitus, Bronchial asthma, COPD, MI, CAD, Hypertension , Epilepsy, RA, Peptic ulcer, Infectious diseases like AIDS, Tuberculosis, Pneumonia, UTI.
2. Toxicology: Case studies on poisoning, and management of various categories of poisonings
3. Patient counseling on cases of DM, Hypertension, Asthma, CAD, Peptic ulcer, Tuberculosis. And other diseases mentioned in the theory
4. Preparation of Drug Information Sheet (WHO criteria)
5.. Exercises on drug information queries
6.. Exercises on Drug interactions and managements- case history
7. Preparation of protocol for human experiment/ clinical trials
8. Preparation of 'Informed Consent Form' for human experiments
9. Synopsis writing of research papers.
10. Preparation of Drug Reviews.
11. Evaluation of fixed dose combinations and Rational Drug Therapy.

. **BOOKS RECOMMENDED:**

1. Genetics. Of Antibiotics Producing Micro organisms: GSermonti
2. Principles of Gene Manipulation: RW Old and S B Primrose
3. Genes V and VI: Lewin Benjamin
4. Biochemical Engineering: F CWebb.
5. Biochemical Engineering: R Steel
6. Immunoassays - Daniel W Chan and Marie T Perlstein
7. Pharmaceutical Biotechnology, S. P. Vyas and V. K. Dixit
8. Gene Transfer and Expression Protocols - Methods in molecular biology, Vol VII, E T Murray
9. Current Protocols in Molecular Biology, Vol. I and II: F M Asubel, JohnWiley Publishers
10. Current Protocols in Cellular Biology, Vol. I and II, JohnWiley Publishers.
11. Biological Reaction Engineering: I J Dunn, E Heinzle, J Ingham, J E Prenosil
12. The Pharmacological basis of therapeutics – Goodman and Gilman's.
13. Pharmacotherapy – DiPiro.
14. Pharmacology – Katzung.
15. Fundamentals of experimental pharmacology by M.N.Ghosh.
16. Handbook of experimental pharmacology by S.K.Kulkarni.
17. Text book of In vitro practical pharmacology by IanKitchen.
18. Pharmacological experiments on intact preparations by Churchill Livingstone.
19. Hand book of clinical pharmacokinetics- Gibaldi and Prescott.
20. Principles of drug action by Goldstein, Amaow and Kalman.
21. Clinical pharmacology by Molmon and Morrelli.
22. Clinical trails and tribulations by Allen E. Cato.
23. Drug interactions by Ivan H. Stockley.
24. Text book of therapeutics- drug, disease and management by Herfindal and Gourley.

25. Biological standardization by J.H. Burn, D.J. Finney and L.G. Goodwin.
26. Indian Pharmacopoeia and other pharmacopoeias.
27. Screening methods in Pharmacology by Robert Turner, A.
28. Evaluation of drugs activities by Laurence and Bachrach.
29. Methods in Pharmacology by Arnold Schwartz.
30. Selected topics on the Experimental Pharmacology by Usha G. Kamat, Dadkar, N.K and Seth, U.K.
31. Fundamentals of experimental Pharmacology Ghosh, M.N.
32. Pharmacological experiment on intact preparations by Churchill Livingstone.
33. Drug Discovery and Evaluation by Vogel HG.
34. Animal models in toxicology by Shayne Cox Gad and Christopher P. Chengelis.
35. The UFAW Handbook on the care and management of laboratory animals by UFAW.
36. Principles and methods of toxicology by Hayes.
37. CRC Handbook of toxicology by Derelanko and Hollinger
38. Current protocols in molecular biology by Frederick. M. Ausubel.
39. Human molecular genetics by Tomstracham & Andrew P. Read.
40. Bioinformatics: Genes, proteins & Computers by Christine Orengo.
41. The Cell – A molecular approach, Geoffrey M. Cooper.
42. Genetherapy, Therapeutic mechanism and strategies by NancySmyth, Templeton Danilo D. Lasic.

BRANCH F - PHARMACY PRACTICE

MPH- F-I (PAPER – I)
CLINICAL PHARMACY PRACTICE

THEORY (3 HRS/WK)

1. Definition, development and scope of clinical pharmacy

2. Introduction to daily activities of a clinical pharmacist

- Pharmaceutical care: concepts and its implementation.
- Ward round participation
- Drug therapy monitoring (medication chart review, clinical review, pharmacist interventions)
- Medication history
- Drug information and poison information
- Adverse drug reaction management
- Drug utilization evaluation (DUE) and review (DUR)
- Quality assurance of clinical pharmacy services
- Therapeutic drug Monitoring (TDM)

3. Patient data analysis

- The patient's case history, its structure and use in evaluation of drug therapy
- Understanding common medical abbreviations and terminologies used in clinical practices.

• Patient Counseling; Compliance, non – compliance, Factors affecting compliance.

• Communication: Introduction, Importance of communication skills, Model of communication, Barriers to communication, verbal communication skills, non-verbal communication, patient interviewing and written communication including patient counseling techniques, medication history interview, presentation of cases.

4. Clinical laboratory tests used in the evaluation of disease states, and interpretation of Test results

• Haematological tests, Liver function, Renal function, Thyroid function tests
• Tests associated with cardiac disorders, Fluid and electrolyte balance
• Microbiological culture sensitivity tests, Pulmonary Function Tests
• Common tests in Urine, sputum, feces & CSF.
• Sensitivity screening for common pathogenic microorganisms: - Its significance, resistance in disease states, and selection of appropriate anti-microbial regimens.

5. Drug & Poison information

• Introduction to drug information and Drug Information resources
• Systematic approach in answering DI queries
• Critical evaluation of drug information and literature
• Preparation of written and verbal reports
• Quality assurance of Drug information services.
• Drug Information Bulletin (DIB).
• Notes and patient package inserts.
• Establishing a Drug Information Centre
• Poisons information- organization & information resources

7. Medication error and medication adherence

Categories and causes of medication error, tools to measure the performance of the medication use process, categories of medication non-adherence, role of pharmacist in medication error and medication adherence.

8. Pharmacoepidemiology

• Definitions and scope,
• Methods [Sources of data, study design, drug utilization studies, Meta analysis]
• Social, cultural and economic factors influencing drug use
• Systems for monitoring drug effects
• Advantages and disadvantages of Pharmacoepidemiology

9. Pharmacoeconomics: Definition and scope, types of economic evaluation, cost models and cost effectiveness Analysis

10. Public health policy: WHO, national & state level.

11. Concept of essential drugs & Rational use of Drugs: Importance of rational drug use, Pharmacist role, Drug use indicators, Guidelines for rational prescribing.

12. Evidence Based Medicine:

Formulating clinical questions, searching for the evidence, Critical appraisal of the evidence, Applying evidence to patients & Evaluation.

13. **Drug Interactions**:

Introduction, types, mechanisms, Drug-drug, drug-disease, drug-food & drug-laboratory test interactions.

14. Adverse Drug Reactions:

Epidemiology, Classification, Risk factors, monitoring, detection & reporting of ADRs.

MPH -F-II (PAPER – II).
CLINICAL RESEARCH & CLINICAL PHARMACOKINETICS
(THEORY) 3hrs/wk

A. CLINICAL RESEARCH

1. Introduction to clinical Trial

History, terminologies, types of clinical research, phases of clinical research, role of clinical trial in new drug developments

2. Regularly affairs in clinical trials

IND, NDA, ANDA- Parts and contents, Safety monitory boards, FDA in various countries including India

3. Ethical issues in clinical trials

Principal, responsible conduct, supervision of ethics, (Informed Consent, Institutional Review Board (Role responsibility, members and auditing), Protection of participants, The Nuremberg Code, The Declaration of Helsinki, The Belmont Report

4. Clinical trial design :. Planning and execution of clinical trials

- Various Phases of clinical trials
- Bioavailability and Bioequivalence studies
- Randomization techniques (Simple randomization, restricted randomization, blocking method and stratification)
- Types of research designs based on Controlling Method (Experimental, Quasi experimental, and Observational methods) Time Sequences (Prospective and Retrospective), Sampling methods (Cohort study, case Control study and cross sectional study)
- Health outcome measures (Clinical & Physiological, Humanistic and Economic).

5. Clinical trial protocol Development

Required Documentation including Investigator's Brochure, Case Report Forms, Serious Adverse Event (SAE) Reports, Laboratory Certification, data collection and quality control of data, closing out of clinical trial

6. Good Clinical Practice

Concept, importance, and GCP guidelines including ICH ,Schedule Y (CDSCO regulations) EMEA, MHRA, and USFDA guidelines in the conduct of clinical trials]

7. Management of Clinical trials)

Role and responsibilities of Stakeholders of clinical trials (FDA, CRO, Sponsor, Physicians, Nurses, Health professionals, Hospitals, Patient), monitoring of clinical trials, Publications of clinical trials

8. Bioavailability, bioequivalence and Therapeutic Drug Monitoring

Concept, organization, advantages, special issues, applications, bioequivalence

9. Data analysis issues in Clinical Trials

Monitoring of data, computer applications, statistical tests used, interpretation, survival analysis, sub-group analysis, Quality control of clinical trials

B. CLINICAL PHARMACOKINETICS Clinical Pharmacokinetic models

- Physiological determinants of drug clearance and volumes of distribution
- Renal and non-renal clearance
- Organ extraction and models of hepatic clearance
- Estimation and determinants of bioavailability
- Multiple dosing
- Calculation of loading and maintenance doses
- Dose adjustment in renal failure, hepatic dysfunction, geriatric and pediatric patients
- Therapeutic Drug Monitoring (General aspects).

C. TOXICOLOGY A).General principles of toxicology, definition and scope of toxicology, factors nfluencing toxicity, biotransformation and toxicokinetics. Target organ toxicity, neuronal and behavioura toxicity, kidney, pulmonary, hepatic & cutaneous toxicity, ototoxicity, haematotoxicity, mutagenicity, carcinogenicity, reproductive toxicity.

B). Toxic manifestations of commonly used drugs and poisonous substances including snake bites. Evaluation toxicity and management of different poisoning. Paracetamol, Benzodiazepines, Barbiturates, Iron preparations, Organophosphorous compounds, Carbamates, Organochloro insecticides, Methanol, Ethanol, Pyrethroids, Heavy metals, Household chemicals.

C). Material toxicology with respect to commonly used hospital requisites including surgicals, IV sets, blood bags etc.

D). CLINICAL APPLICATION OF STATISTICAL ANALYSIS

- Basic concepts of biomedical statistics
- Descriptive and Differential statistics
- Statistical tests-Parametric & Non-parametric
- Sample size calculation
- Confidence intervals
- Test of significance Statistical Analysis – Introduction, Significance of statistical methods, normaldistribution, probability, degree of freedom, standard deviation, correlation, variance, accuracy, precision, classification of errors, reliability of results, confidence interval, test for statistical significance – Students T test, F test, Chisquare test, Correlation and regression.

MPH -F –III (Paper – III)
HOSPITAL & COMMUNITY PHARMACY AND DRUG STORE MANAGEMENT

THEORY (-3 HRS/WK)

A. HOSPITAL PHARMACY

1. **Hospital:** Evolution, Introduction, Scope, Classification, Objectives, Functions & Organization. Health delivery system in India. The role of the hospital pharmacy department and its relationship to other hospital departments and staff.
2. **Hospital Pharmacy:** Introduction, various committees on Hospital Pharmacy(national & International), Scope, Objectives, Functions & Organization. Location, layout, flow chart of material and men. Requirements and abilities required for Hospital Pharmacists. The role of the hospital pharmacist and their relationship to other hospital departments and staff.
3. **Drug distribution :**Purchasing, Warehousing (storage conditions, expiry date control, recycling of drugs, stocktaking, drug recalls), Drug distribution methods, Ward Pharmacy, Satellite Pharmacy & Bed side Pharmacy, Specific requirements for inpatients, outpatients, Casualty/Emergency, Operation Theatres, ICU/CCU, Drugs of dependence, Hospital waste management. Dispensing of controlled drugs.
4. **Hospital drug policy:** Drug Committees, Pharmacy & Therapeutics committee, Pharmacy and Therapeutics Committee: Selection of drugs, Hospital formulary development and management, Assessing drug efficacy, Assessing and managing drug safety, Adverse drug reaction monitoring and management, evaluating the cost of pharmaceuticals, identifying and addressing drug use problems including standard treatment guidelines (STG"s). Other hospital committees such as infection control committee, antibiotic policy committee and research & ethics committee. Role of Pharmacist in Hospital Committees.
5. **Central Sterile Supply Department:** Central sterile supply unit and their management: Types of materials used for sterilization, Sterilization equipments and techniques, procedurem application of surgical dressings used in OT and other equipments used in Hopital (Cotton, Bandage, Adhesive taps, IV sets, B. G sets, Ryles tube, Catheters, and syringes).
6. **Surgical Supplies**
   An account of surgical dressing like primary would dressings, adsorbents bandages, adhesive tapes, protective, sutures and suture materials (method of preparation are to be avoided).
7. **Hospital pharmacy management**
   Staff (professional and non-professional), Materials (drugs, non-drugs, consumables), Financial (drug budget, cost centers, sources of revenue, revenue collection), Policy and planning, Infrastructure requirements (building, furniture and fittings, specialized equipment, maintenance and repairs), Workload statistics.
8. **Drug Procurement and Warehousing**

Introduction, Procurement procedures for various materials used in Hospitals.

9. Inventory control

Introduction, Objectives & Principles, Control procedures, Organisation of drug store, types of materials stocked, levels of inventory and categorization of stores. Storage conditions & store management.

10. Hospital Manufacturing

Sterile and non-sterile production, including total parenteral nutrition, Cytotoxics, Radio-pharmaceuticals(Radio isotope committee, role of Pharmacist in isotope and no isotope pharmacy), IV additive service, Pre-packing and labeling, quality control. Controlled drugs dispensing: (Narcotics & other hazardous substances) procedures for dispensing and maintenance of records and disposal of expiry drugs.

11. Pharmacovigilance: Definition, collection of data, reporting, assessment of Post marketing surveillance, periodic safety update reports, Risk-benefit assessment. Population Pharmacokinetics.

12. Applications of computer in Hospital Pharmacist .

B. COMMUNITY PHARMACY

1. Introduction to the concept of community pharmacy - its activities and professional responsibilities.
2. The role of the community pharmacy and its relationship to other local health care providers.
3. Prescribed medication order - interpretation and legal requirements.
4. Patient counselling in community pharmacy.
5. Over the counter (OTC) sales.
6. Health education and community pharmacy: Family planning, first aid, communicable disease prevention, smoking cessation, screening programs.
7. Services to Nursing homes/clinics.
8. Community Pharmacy management : Financial, material and staff management, infrastructure requirements, drug information resources, computers in community pharmacy.
9. Code of ethics for community pharmacists.
10. Polypharmacy and its implications.

MPH –F-IV (PAPER IV)
PHARMACOTHERAPEUTICS

THEORY (3 HRS/WK)

Pathophysiology and applied therapeutics of diseases associated with following System/diseases with special reference to the drugs of choice.

1. Cardiovascular system 9 Hours.

Hypertension, Congestive cardiac failure, Ischaemic heart disease (Angina, Myocardial infarction), Arrhythmias, Hyperlipidaemias, Thromboembolic disorders, Cardiac arrest – resuscitation.

2. Respiratory system 5 Hours.

Pulmonary function tests, Asthma, Chronic obstructive airways disease, Drug induced pulmonary diseases. Hydrogen ion hemostasis and blood gases

3. Renal system 6 Hours.

Diuretic therapy, Potassium depletion, Hyperkaelemia, Alkalosis, Acute renal failure, Chronic renal failure, Dialysis, Renal replacement therapy, End-stage renal disease, Drug induced renal diseases.

4. Haematological diseases 5 Hours.

Blood and body fluids, Complications of blood transfusion and blood substitutes, Anaemia, Drug induced haematological disorders

5. Immunology 5 Hours.

Immune disease – pathogenesis, mechanism of action of drugs, Glucocorticoids – anti-inflammatory, anti-allergic and immunosuppressive actions in tissue as well as organ transplantation, Vaccines – management of primary immunodeficiencies

6. Endocrine system 5 Hours.

Diabetes, Thyroid diseases, Oral contraceptives, Hormone replacement therapy, Osteoporosis.

7. Nervous system 4 Hours.

Epilepsy, Parkinson's disease, Stroke and transient ischaemic attacks, Headache, Migraine.

8. Psychiatric disorders 4 Hours.

Schizophrenia, Depression, Anxiety disorders, Sleep disorders.

9. Gastrointestinal system 4 Hours.

Ulcer diseases, inflammatory bowel diseases, Hepatitis, Jaundice, Diarrhoea and Constipation.

10. Bone and joint Disorders 4 Hours.

Osteoporosis, rheumatoid arthritis, osteoarthritis, gout, Paget's disease of bones.

11.Infectious diseases 10 Hours.

Meningitis, Respiratory tract infections, Gastroenteritis, Pneumonia, Bacterial endocarditis, Septicaemia, Otitis media, Urinary tract infections, Tuberculosis, Leprosy, Protozoal infections and helmenthiasis, HIV and opportunistic infections, Fungal infections.

12.Skin and sexually transmitted diseases 2 Hours.

Psoriasis, Eczema and scabies, Syphilis, Chancroid, Gonorrhoea

13.Oncology 5 Hours.

Cell cycle, General principles of cancer chemotherapy, Commonly used cytotoxic drugs, Chemotherapy of lung cancer, breast cancer, head and neck cancer, prostate cancer, Cervical cancer, colorectal cancer, haematological malignancies.

14.Ophthalmology 1 Hour.

Glaucoma, Eye infections.

15.Pain management 4 hours.

Pathophysiology of inflammation and repair, Pain pathways, Analgesics and NSAIDs, Opiates, Local anaesthetics, Neuralgia, Muscle relaxants.

16.General Prescribing Guidelines for :- 2 Hours.

Paediatric patients.
Geriatric patients.
Pregnancy & Breast feeding.
Antibiotics & parenterals.

MPH –F-V
PHARMACY PRACTICE PRACTICAL
18hrs/wk

a)Clinical Pharmacy:

Patient medication history interview, answering drug information questions, patient medication counseling, participation in ward rounds. Case studies related to laboratory investigations covering the topics dealt in theory class.

1. Answering drug information questions (Any four)
   (Queries related to Dosage, administration, Contraindications, Adverse drug reactions, drug use in pregnancy and lactation, drug profile, efficacy and safety)
2. Patient medication counseling (Any three)
3. Case studies related to laboratory investigations (Any four) LFT, Hematology, Thyroid, Renal, Cardiac enzymes.
4. Patient medication history interview (Any two)
5. Medication order Review (Any five)
6. Detection and assessment of adverse drug reactions and their documentation (Any five)

b) Clinical research and clinical pharmacokinetics:

1. Toxicological analysis and management
2. Preparation of protocol for different clinical studies.
3. Designing of informed consent process
4. Clinical data monitoring
5. Designing of CRF
6. Dosage adjustment in geriatrics, pediatrics, hepatic failure, renal failure & heart failure cases.

c) Hospital & Community Pharmacy and Drug store management :

1. Preparation and evaluation of any two commonly used transfusions fluids in a Hospital
2. Preparation of extemporaneous medication (Minimum four)
3. Quality evaluation of sutures

a) Polyglactin 910 (b) Poliglecaprone 25 (c) Polydioxanone (d) Surgical cat gut chromic

4. Sterilization of surgical instruments
5. Evaluation of surgical dressings
6. Indent preparation of Hospital Pharmacy
7. Preparation of Inventory for Drugs and Surgical, based on ABC and VED Analysis
8. Familiarization of Hospital equipments
9. Preparation of emergency drug list
10. Prescription analysis in community pharmacy setup
11. Preparation of patients leaf lets for commonly used drugs in community pharmacy

d) Pharmacotherapeutics:

The students are required to be posted to various clinical wards for their exposure with therapeutic management and other clinical aspects. They are expected to have experience and do a tutorial as well as case presentation in the following clinical conditions. The students have to make at least 10 case presentations covering most common diseases found in the hospital to which the college is attached. The student should also submit a record of the cases presented. The list of clinical cases presented should include follow-up of the clinical cases mentioned below from the day of admission till discharge and presented in the SOAP (Subjective, Objective, Assessment and Plan) format. The cases may be selected from the following diseases:

1. Cardiology

a) Arrhythmias, b) Ischaemic heart disease, c) Congestive heart failure, d) Myocardial Infarction, e) Hypertension, f) Thrombo-embolic disease, g) Endocarditis.

2. Gastroenterology

a) Diarrhoea, Constipation, b) Acid peptic disease, c) Hepatic diseases - Hepatitis, Cirrhosis & Drug induced hepatic disorders, d) Oesophageal reflux, e) Helicobacter pylori induced gastric disorders.

3. Rheumatology

a) Rheumatoid arthritis, b) Gout, c)) Systemic lupus erythmatosis.

4. Respiratory medicine

a) Asthma, b) Congestive obstructive airways disease (COAD c)) respiratory tract infections, e)

5. Surgery

a) Prophylactic Antibiotics, b) Anticoagulants - Heparin, Warfarin, c) Thrombolytics, d) Adjunctive therapy, e) Pre-operative medications, f)Analgesia.

6. Geriatric Medicine

a) Postural hypotension, b) Dementia & delirium, c) Compliance assessment.

7. Paediatrics

a) Acute otitis media, b) Tonsillitis, c) Paediatric asthma, d) Paediatric gastroenteritis, e) Colic, f) Immunisation, g) Attention deficit disorder

8. Oncology

a) Breast Cancer, b) Lung cancer - Small cell, Non small cell, c) Gastric cancer, d) Colon cancer, e) Genitourinary tract cancer - Bladder, Prostate, Testicular, f) Skin cancer, g) Radiation therapy h) Adjunctive therapy - Anti-emetics, Mouth care, Nutrition, Extravasations, Pain control, Blood products, i) Colony stimulating factors, j)Infectious disease in immuno-compromised patients, k) Hypercalcemia l) Cerebral oedema m) Malignant effusions.

9. Renal

a) Acute renal failure, b) Chronic renal failure, c) Drug induced renal disease.

10. Haematology

a) Leukaemias, b) Lymphomas - Hodgkin's, Non-Hodgkin's, c) Multiple myeloma, d) Anaemia, e) Bleeding disorders.

11. Infectious Disease

a) Respiratory tract infections b) Tuberculosis c) Urinary tract infections,

d) Joint and borne infections, e) Skin and Soft tissue infections.

12. Critical Care

a) Haemodynamic monitoring , b) Parenteral & enteral nutrition,
c) Pharmacotherapy of ventilated patients, d) Shock - Septic, Cardiogenic.

13. Endocrinology

a) Diabetes, b) Osteoporosis, c) Thyroid disorders, d) Adrenal disorders.

14. Dermatology

a) Psoriasis, b) Dermatitis, c) Drug induced skin disorders.

15. a) Convulsive disorder b) Parkinson 's disease, c) Neuro-degenerative disorders, d) Stroke, e) TIAs.

16. Psychiatry

a) Uni-polar and bipolar disorders, b) Anxiety, c) Psychosis, d) Alcohol abuse, e) Drug abuse.

17. Ophthalmology

a) Ocular infections, b) Conjunctivitis, c) Glaucoma d)Post-operative management.

BOOKS RECOMMENDED:

1. Hospital Pharmacy - Hassan WE. Lec and Febiger publication.
2. Textbook of hospital pharmacy - Allwood MC and Blackwell.
3. Avery's Drug Treatment, 4th Edn, 1997, Adis International Limited.
4. Remington Pharmaceutical Sciences.
5. WHO Guidelines for the procurement of various materials.
5. Relevant review articles from recent medical and pharmaceutical literature.
6. Charaka Samhita, Sushrut Samhita, Sharangardhar Samhita, Ayurvedic formulary of India.
7. Pharmacopocial standards for Ayurvedic drugs C.C.A.R.A., New delhi
8. Hospital Pharmacist, U.K.
9. Indian Journal of Hospital Pharmacy.
10. Clinical Pharmacokinetics – concepts and applications Malcom Rowland & Thomas N tozer
11. Biopharmaceutics and Applied Pharmacokinetics - Leon Shargel , Prentice Hall publication
12. Text book of Pharmacy Practice By G. Parthasarathi.
13. Biopharmaceutics and Clinical Pharmacokinetics: - Milo Gibaldi.
14. Remington Pharmaceutical Sciences,
15. Relevant review articles from recent medical and pharmaceutical literature.
16. WHO Guidelines for ICH – GCP.
17. Basic skills in interpreting laboratory data - Scott LT, American Society of Health System Pharmacists Inc.
18. Practice Standards and Definitions - The Society of Hospital Pharmacists of Australia., 1997

19. Clinical Pharmacokinetics - Rowland and Tozer, Williams and Wilkins Publication.
20. Relevant review articles from recent medical and Pharmaceutical literature.
21. Pharmaceutical Journal. Royal Pharmaceutical Society, London
22. Journal of Pharmacy Practice and Research, Society of Hospital Pharmacists of Australia
. International Journal of Pharmacy Practice, United Kingdom
23. Hospital Pharmacist, UK
24. Indian Journal of Hospital Pharmacy.
25. Clinical Pharmacy and therapeutics- Roger and Walker, Churchill Livingstone publication.
26. Pharmacotherapy : A Patho-physiological approach- Joseph T. Dipiro et al. Appleton and Lange.
27 Pathologic basis of diseases-Robins SL, W.B.Saunders publication.
28. Pathology and therapeutics for pharmacists: a basis for clinical Pharmacy Practice.
29 Green and Harris, Chapman and Hall Publication.
30 Clinical Pharmacy and therapeutics- Eric Herfindal, Williams and Wilkins Publication.
31. Applied Therapeutics: the clinical use of drugs. Lloyd Young and Koda-Kimble MA [ISBN 0-333-65881-7].
32. Avery's drug treatment, 4th Edn, 1997, Adis international Limited.
33.. Relevant review articles from recent medical and pharmaceutical literature.
34. Clinical Pharmacy and therapeutics- Roger and Walker, Churchill Livingstone publication.
35. Pharmacotherapy: A Patho-physiological approach - Joseph T. Dipiro et al. Appleton and Lange.
36. Pathologic basis of diseases-Robins SL, W.B. Saunders publication.
37. Pathology and therapeutics for pharmacists: a basis for clinical Pharmacy Practice.
Green and Harris, Chapman and Hall Publication.
38. Clinical Pharmacy and therapeutics- Eric T. Herfindal, Williams and Wilkins Publication.
39. Applied Therapeutics: The clinical use of drugs. Lloyd Young and Koda-Kimble MA[ISBN 0-333- 65881 – 7].
40. Avery's drug treatment, 4th Edn, 1997, Adis international Limited.
41. Relevant review articles from recent medical and pharmaceutical literature.
42. British Medical Journal.
43. New England Journal of Medicine.
44. Annals of Pharmacotherapy.
45. Lancet.
