THE TAMILNADU Dr. M.G.R. MEDICAL UNIVERSITY

CHENNAI-600 032

REGULATIONS AND SYLLABUS

M. PHARMACY DEGREE COURSE

2010-2011

THE TAMILNADU Dr. M.G.R. MEDICAL UNIVERSITY
CHENNAI – 600 032

M. PHARMACY COURSE

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THE TAMIL NADU Dr. M. G. R. MEDICAL UNIVERSITY,

CHENNAI-600 032.

REGULATIONS OF THE UNIVERSITY

In exercise of the powers conferred by section 44 of The Tamil Nadu Dr. M.G.R. Medical University, Chennai, Act, 1987 (Tamil Nadu Act 37 of 1987), The Standing Academic Board of The Tamil Nadu Dr. M.G.R. Medical University, Chennai hereby makes the following regulations.

SHORT TITLE AND COMMENCEMENT

These regulations shall be called "THE REGULATIONS FOR THE M.PHARMACY DEGREE COURSE OF THE TAMIL NADU Dr. M.G.R. MEDICAL UNIVERSITY, CHENNAI".

They shall come into force from the Academic Year 2006-2007 sessions.

The regulation and syllabi are subject to modifications by the Standing Academic Board from time to time.

REGULATIONS

1. ELIGIBILITY

Candidates for admission to first year of the Master of Pharmacy Post-Graduate Degree course shall be required to have passed the B.Pharmacy Degree of this University or any other University recognized as equivalent thereto by the authority of this University.

2. ELIGIBILITY CERTIFICATE:

The Candidates who has passed the qualifying examination as specified in Regulation No.1 above from any other Universities other than the Tamil Nadu Dr. M.G.R. Medical University, before seeking admission to any one of the affiliated institutions shall obtain an Eligibility Certificate from the University by remitting the prescribed fees along with application form, which shall be downloaded from the University web site www.tnmmu.ac.in.

3. PHYSICAL FITNESS CERTIFICATE:

Every candidate before admission to the course shall submit to the Principal of the Institution a Certificate of Medical Fitness from an authorized Medical Officer that the candidate is physically fit to undergo the academic course and does not suffer from any disability or contagious disease.

4. REGISTRATION:

A candidate admitted into Master of Pharmacy Post-Graduate Degree course in any one of the affiliated institutions of the Tamil Nadu Dr. M.G.R. Medical University, Chennai, shall submit the prescribed application form for registration duly filled along with prescribed fee and declaration in the format, as in Annexure to the Academic Officer of this University through the affiliated institution within 60 days from the cut-off date prescribed for Master of Pharmacy Post Graduate course for admission.

5. DURATION OF THE COURSE AND COURSE OF STUDY:

a) The period of certified study and training of the M.Pharmacy Post-Graduate degree course shall be Two academic years.

b) No exemption shall be given from this period of study and training for any other experience gained prior to the admission of the course.

6. CUT-OFF DATES FOR ADMISSION TO EXAMINATIONS:

The candidates admitted upto 31st May shall be registered to take up their First year examination after fulfillment of the regulations from 15th March of the next year.

All kinds of admissions shall be completed on or before 31st May of the academic year. There shall not be any admission after 31st May, even if seats are vacant.

7. COMMENCEMENT OF THE COURSE:

The Academic year for M.Pharmacy Course shall commence from the 1st May of the year of admission.

8. MEDIUM OF INSTRUCTION:

English shall be the medium of instruction for all the subjects of study for examination of the M.Pharmacy course.

9. WORKING DAYS IN AN ACADEMIC YEAR:

Each academic year shall consist of not less than 270 working days (inclusive of the University exam days).

10. ATTENDANCES REQUIRED FOR ADMISSION TO EXAMINATION:

a) No candidate shall be permitted to appear in any one of the parts of M.Pharmacy Course Examinations, unless he / she has attended the course in all the subjects for the prescribed period in an affiliated Institution recognized by this University and has produced the necessary certificate of study, attendance progress and satisfactory conduct, from the Head of the Institution.

b) A candidate is required to put in minimum of 90% attendance in both theory and practical separately in each subject before admission to the examination.

c) A candidate lacking in the prescribed attendance and progress in any one subject in theory and practical classes, wherever necessary in the first appearance shall not be permitted for admission to the entire examination.

11. CONDONATION FOR LACK OF ATTENDANCE:

There shall be no condonation of lack of attendance in Post-Graduate courses.

12. COMMENCEMENT OF EXAMINATION:

March 15th/September 15th

Theory examinations will not held on Saturdays and Sundays. If the date of commencement of the examination falls on public holiday, the next working day will be the date of commencement of examinations.

13. INTERNAL ASSESSMENT:

The Internal Assessment should consist of the following points for evaluation:-

i) Theory

ii) Practical / Clinical.

iii) Viva Voce.

The Internal Assessment of the candidate has to be assessed on the above points and a report has to be submitted by the Institution once in three months as detailed below:

i) First Internal Assessment – At the end of 3 months.

ii) Second Internal Assessment – At the end of 6 months.

iii) Third Internal Assessment – One month prior to the University examination.

The average of the Theory, Practical and Oral should be added and aggregate must be taken

and sent to the University as Internal Assessment Marks. In all the subjects obtaining minimum 50% of marks in Internal Assessment is mandatory to appear for the University Examinations.

14. REVALUATION / RETOTALLING OF ANSWER PAPER:

There shall be no revaluation of the answer papers of failed candidates in any Post-Graduate examination. However, the failed candidate shall apply for retotalling through their College / Institutions.

15. NUMBER OF APPEARANCE(S)

A Candidate registered for Two years M.Pharmacy Post-Graduate Degree course must qualify in the Examinations within four years of the date of his / her admission.

16. DURATION FOR COMPLETION OF THE COURSE OF STUDY:

The duration for the completion of the course shall be fixed as double the time of the course and the students have to pass within the said period otherwise they have to get fresh admission.

17. TRAINING IN OUTSIDE CENTRES:

The Head of the Post-Graduate Departments should make necessary arrangements for their Post-Graduate candidates to undergo training in various skills in other centres within outside the state if facilities are not available in their own institution or hospitals.

18. QUESTION PAPER PATTERN:

The existing Question Paper Pattern is modified in respect of all the subjects Pertaining to all Under Graduate/Post Graduate Degree Courses and to follow the uniform Question Paper Pattern as given below:

6 Question X 10 Marks

8 Question X 5 Marks

19. MARKS QUALIFYING FOR A PASS:

50% of marks in the University Theory examination.

50% of marks in the University Practical examination.

50% of marks in aggregate in Theory, Practical IA & Oral taken together.

50% of marks in aggregate in Dissertation, Seminar & Viva Voce taken together for the approval of the Dissertation.

20. SUBJECTS OF STUDY:

I YEAR

Common to All Branches

Paper-I Modern Pharmaceutical Analytical Techniques.

BRANCH I PHARMACEUTICS

Paper II Industrial Pharmacy.

Paper III Bio-Pharmaceutics and Pharmacokinetics.

Paper IV Advances in Drug Delivery System.

BRANCH II PHARMACEUTICAL CHEMISTRY

Paper II Advanced Organic Chemistry.

Paper III Advanced Medicinal Chemistry.

Paper IV Natural Products of Medicinal Interest.

BRANCH III PHARMACOGNOSY

Paper II Pharmacognosy.

Paper III Biogenesis and Chemistry of Natural Products.

Paper IV Phytochemistry and Biotechnology.

BRANCH IV PHARMACOLOGY

Paper II Pharmacology & Toxicology.

Paper III Biological Standardisation and Pharmacological Screening methods.

Paper IV Drug Design and Molecular Pharmacology.

BRANCH V PHARMACEUTICAL ANALYSIS

Paper II Pharmaceutical and Cosmetic Analysis.

Paper III Advanced Pharmaceutical Analysis.

Paper IV Quality Control & Quality Assurance.

BRANCH VI PHARMACEUTICAL BIOTECHNOLOGY

Paper II Pharmaceutical Aspects of Microbial and Cellular Biology.

Paper III Bio-process Technology.

Paper IV Advances in Pharmaceutical Biotechnology.

BRANCH VII PHARMACY PRACTICE

Paper II Pharmocotherapeutics. (including Pathophysiology)

Paper III Hospital & Community Pharmacy.

Paper IV Clinical Pharmacy.

BRANCH VIII PHYTOPHARMACY AND PHYTOMEDICINE

Paper II Advanced Pharmacognosy.

Paper III Herbal Drug Development and Standardization.

Paper IV Indian System of Medicines.

II YEAR

Seminar and Viva Voce on Dissertation.

21. SCHEME OF EXAMINATION

The Scheme of Examinations is as follows:-

COURSE OF STUDY/WEEK: Theory: 4 Hrs. Practicals: 4Hrs

EXAMINATION TIME DURATION: Theory: 3 Hrs. Practicals: 6Hrs.

Sl.No.	SUBJECT	SCHEME OF EXAMINATION							
		Theory			Practical		Univ Oral	Total	
		Univ Marks	I.A.	Univ. Marks	I.A.				
					Prac	Rec			
Paper I	**I year** **Common for all Branches** Modern Pharmaceutical Analytical Techniques	100	25	100	15	10	50	300	1 50
	Branch –I								
Paper II	Industrial Pharmacy	10	25	100	15	10	50	300	
Paper III	Bio-Pharmaceutics & Pharmacokinetics	100	25	100	15	10	50	300	
Paper IV	Advances in Drug Delivery System	100	25	100	15	10	50	300	
	Branch - II								
Paper II	Advanced Organic Chemistry	100	25	100	15	10	50	300	
Paper III	Advanced Medicinal Chemistry	100	25	100	15	10	50	300	
Paper IV	Natural Products of Medicinal Interest	100	25	100	15	10	50	300	
	Branch - III								
Paper II	Pharmacognosy	100	25	100	15	10	50	300	
Paper III	Biogenesis & Chemistry of Natural Products	100	25	100	15	10	50	300	
Paper IV	Phytochemistry & Biotechnology	100	25	100	15	10	50	300	

	Branch – IV							
Paper II	Pharmacology & Toxicology	100	25	100	15	10	50	300
Paper III	Biological Standardisation & Pharmacological Screening Methods	100	25	100	15	10	50	300
Paper IV	Drug Design & Molecular Pharmacology	100	25	100	15	10	50	300

	Branch-V							
Paper II	Pharmaceutical and Cosmetic Analysis	100	25	100	15	10	50	300
Paper III	Advanced Pharmaceutical Analysis	100	25	100	15	10	50	300
Paper IV	Quality Control & Quality Assurance	100	25	100	15	10	50	300
	Branch – VI							
Paper II	Pharmaceutical Aspects of Microbial and Cellular Biology	100	25	100	15	10	50	300
Paper III	Bio-process Technology	100	25	100	15	10	50	300
Paper IV	Advances in Pharmaceutical Biotechnology	100	25	100	15	10	50	300
	Branch –VII							
Paper II	Pharmaacotherapeutics	100	25	100	15	10	50	300
Paper III	Hospital & Community Pharmacy	100	25	100	15	10	50	300
Paper IV	Clinical Pharmacy	100	25	100	15	10	50	300

Branch –VIII

Paper II	Advanced Pharmacognosy	100	25	100	15	10	50	300
Paper III	Herbal Drug Development and Standardization	100	25	100	15	10	50	300
Paper IV	Indian Systems of Medicine	100	25	100	15	10	50	300
II Year	**Dissertation**	**Dissertation Evaluation**		**Seminar**		**Viva-Voce**		**Total**
		200		50		50		300

22. DISSERTATION & EVALUATION OF DISSERTATION:

a) The topic of the dissertation should be submitted within 3 months after the commencement of 2nd year. The candidate should also inform the name of the Guide for the dissertation to the University while submitting the dissertation topic.

b) If any changes in the dissertation topic, the same has to be informed within 6 months after commencement of 2nd year.

c) The dissertation should be submitted one month in advance to the II year M.Pharmacy examinations duly signed by the Professor of that branch and the same has to be forwarded to the Controller of Examinations through the Dean or Principal of the College.

d) A candidate who has completed I year M.Pharmacy with fulfillment of attendance criteria is eligible to take II year M.Pharmacy examinations.

e) If the candidate fails in the Writen / Practical Examination or fails to appear the 1st year examination, but his / her dissertation is approved, the approval of the dissertation shall be carried over to the subsequent examinations.

f) A guide can supervise a maximum of 3 students in an academic year.

23. DETAILS OF THE EXAMINATIONS

a) At the time of practical examination, each candidate shall submit to the examiner or examiners concerned his laboratory note books duly certified by his teachers as a bonafide record of work done by the concerned teachers and the marks sent to the University before the Examinations.

b) The candidates may be allowed at the discretion of the examiners to bring to the practical examinations in any of the subjects of the M.Pharmacy examination any book or books they choose.

24. RE-ADMISSION AFTER BREAK OF STUDY:

Re-admission shall be made as per the University Common Regulations duly condoning the break of study for all courses.

25. MIGRATION / TRANSFER OF CANDIDATES:

Request for Migration / Transfer of candidates during the course of study from one affiliated college to another affiliated college of this University or from another University

shall not be granted under any circumstances.

26. a) AWARD OF MEDALS AND PRIZES:

The University shall award at its Convocation Medals and Prizes to outstanding candidates as and when instituted by the donors as per the schedule prescribed for the award.

27. AUTHORITY TO ISSUE TRANSCRIPT:

The Controller of Examination shall be the Authority for issuing Transcript of marks after remitting the prescribed fee of Rs. 1000/- (Rupees one Thousand only) or the fee as may be prescribed from time to time.

ANNEXURE

DECLARATION

I
…….....

Son/Daughter of ……..

Residing at …….

and admitted to the I year of ……(Name of the course /

U.G./P.G.) at …….....(Name of the college)

do hereby solemnly affirm and sincerely state as follows:

I declare that I shall abide by the rules and regulations prescribed by the Tamil

Nadu Dr. M.G.R. Medical University, Chennai for the ……..(course)

including regulations for readmission after the break of study.

Date: Signature of the candidate

/Counter signed/

(**College / Institution date seal)** Dean / Principal / Director

REGISTRAR

/TRUE COPY/

ASSISTANT REGISTRAR.

M. PHARMACY I YEAR
COMMON TO ALL BRANCHES - PAPER – I
MODERN PHARMACEUTICAL ANALYTICAL TECHNIQUES

THEORY 75 Hours (3 hrs. /week)

1. UV-VISIBLE SPECTROSCOPY : 5 Hours.

Brief review of electromagnetic spectrum and absorption of radiations. The chromophore concept, absorption law and limitations. Theory of electronic spectroscopy, absorption by organic molecules, choice of solvent and solvent effects, modern instrumentation – design and working principle. Applications of UV-Visible spectroscopy (qualitative and quantitative analysis), Woodward – Fischer rules for calculating absorption maximum, Photometric titrations and its applications.

2. FLAME EMISSION SPECTROSCOPY AND ATOMIC ABSORPTION SPECTROSCOPY : 3 Hours.

Principle, instrumentation, interferences and applications in Pharmacy.

3. SPECTROFLUORIMETRY : 3 Hours.

Theory, instrumentation, advantages, relationship of chemical structure to fluorescence spectra, solvent effect, effect of acids and bases on fluorescence spectra, concentration effects, factors affecting fluorescence intensity, comparison of fluorescence and UV-Visible absorption methods and applications in Pharmacy.

4. INFRARED SPECTROPHOTOMETRY : 5 Hours.

Introduction, basic principles, vibrational frequency and factors influencing vibrational frequency, instrumentation and sampling techniques, interpretation of spectra, applications in Pharmacy. FT-IR-theory and applications, Attenuated Total Reflectance (ATR).

5. NUCLEAR MAGNETIC RESONANCE SPECTROSCOPY : 10 Hours.

Fundamental Principles and Theory, Instrumentation, solvents, chemical shift, and factors affecting chemical shift, spin-spin coupling, coupling constant, and factors influencing the value of coupling constant, spin-spin decoupling and shift reagents, proton exchange reactions, FT-NMR, 2D -NMR, NMDR, NOE, NOESY, COSY and applications in Pharmacy, interpretation of spectra, C13 NMR-Introduction, Natural abundance, C13 NMR Spectra and its structural applications.

6. ELECTRON SPIN RESONANCE SPECTROSCOPY : 2 Hours.

Theory and Principle, Limitations of ESR, choice of solvent, g-values, hyperfine splitting, instrumentation, difference between ESR & NMR and applications.

7. MASS SPECTROSCOPY : 8 Hours.

Basic principles and instrumentation, ion formation and types, fragmentation processes and fragmentation pattern, Chemical ionization mass spectroscopy (CIMS), Field Ionization Mass Spectrometry (FIMS), Fast Atom Bombardment MS (FAB MS), Matrix Assisted laser desorption / ionization MS (MALDI-MS), GC-MS, interpretation of spectra and applications in Pharmacy.

8. X-RAY DIFFRACTION METHODS : 4 Hours.

Introduction, generation of X-rays, X-ray diffraction, Bragg's law, X-ray powder diffraction, interpretation of diffraction patterns and applications.

9. OPTICAL ROTARY DISPERSION : 4 Hours.

Principle, Plain curves, curves with cotton effect, octant rule and its applications with example, circular dichroism and its relation to ORD.

10. THERMAL METHODS OF ANALYSIS : 3 Hours.

Theory, instrumentation and applications of Thermo Gravimetric Analysis (TGA), Differential Thermal Analysis (DTA), Differential Scanning Calorimetry (DSC) and Thermo Mechanical Analysis (TMA).

11. CHROMATOGRAPHIC TECHNIQUES : 13 Hours.

a) Classification of chromatographic methods based on mechanism of separation: paper chromatography, thin layer chromatography, ion exchange chromatography, column chromatography and affinity chromatography – techniques and applications.

b) Gas Chromatography : Theory and principle, column operation, instrumentation, derivatisation methods and applications in Pharmacy.

c) High Performance Liquid Chromatography : Principle, instrumentation, solvents used, elution techniques, RP-HPLC, Chiral HPLC, LC-MS and applications in Pharmacy.

d) HPTLC and Super Critical Fluid Chromatography (SFC) : Theory and Principle, instrumentation, elution techniques and pharmaceutical applications.

12. ELECTROPHORESIS : 3 Hours.

Theory and principles, classifications, instrumentation, moving boundary electrophoresis, Zone Electrophoresis (ZE), Isoelectric focusing (IEF) and applications.

13. RADIO IMMUNO ASSAY : 3 Hours.

Introduction, Principle, Theory and Methods in Radio Immuno Assay, Related Immuno Assay procedures and Applications of RIA Techniques.

14. STATISTICAL ANALYSIS : 5 Hours.

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.

15. TEACHING SKILLS, RESEARCH METHODOLOGY AND LITERATURE SOURCES. 4 Hours.

Fundamentals of teaching and learning, art and science of teaching. Thesis of writing and presentation of the work. Citation of references.

PRACTICALS

1. Use of colorimeter for analysis of Pharmacopoeial compounds and their formulations.

2. Use of Spectro photometer for analysis for Pharmacopoeial compounds and their formulations.

3. Simultaneous estimation of combination formulations (minimum of 2 experiments).

4. Effect of pH and solvent on UV Spectrum of certain drugs.

5. Use of fluorimeter for analysis of Pharmacopoieal compounds.

6. Experiments on Electrophoresis.

7. Experiments of Chromatography.

(a) Thin Layer Chromatography.

(b) Paper Chromatography.

1) Ascending Technique.

2) Descending Technique.

3) Circular Technique.

4) Two dimensional Paper Chromatography and TLC.

8. Experiments based on HPLC & GC.

9. IR, NMR and Mass Spectroscopy – Interpretation of spectra & Structural elucidation (atleast for 4 compounds each).

10. Use of flame emission spectroscopy for analysis of pharmacopeial compounds

11. Any other relevant exercises based on theory.

REFERENCES

1. Spectrometric identification of Organic Compounds, Robert. M. Silverstein et al, 7th Edition, 1981.

2. Fundamentals of Mathematical Statistics, S.C. Gupta and V.K. Kapoor.

3. Principles of Instrumental Analysis by Donglas A. Skoog, James, J. Leary, 4th Edition.

4. Pharmaceutical Analysis – Modern Methods – Part A, Part B, James W. Munson – 2001.

5. Vogel's Text Book of Quantitative Chemical Analysis, 6th Edition, 2004.

6. Chromatographic Analysis of Pharmaceuticals, John A. Adamovics, 2nd Edition.

7. Practical Pharmaceutical Chemistry, Part two, A. H. Beckett & J. B. Stenlake – 4th Edition.

8. Instrumental Methods of Chemical Analysis – B. K. Sharma - 9th Edition.

9. Instrumental Methods of Analysis – Hobert H. Willard, 7th Edition.

10. Organic Spectroscopy – William Kemp, 3rd Edition.

11. Techniques and Practice of Chromatography – Raymond P. W. Scott, Vol. 70.

12. Identification of Drugs and Pharmaceutical Formulations by Thin Layer Chromatography – P. D. Sethi, Dilip Charegaonkar, 2nd Edition.

13. HPTLC – Quantitative Analysis of Pharmaceutical Formulations – P. D. Sethi.

14. Liquid Chromatography – Mass Spectrometry, W. M. A. Niessen, J. Van Der Greef, Vol. 58.

15. Stereo Chemistry – Conformation and Mechanism by P. S. Kalsi, 2nd Edition.

16. Spectroscopy of Organic Compounds by P. S. Kalsi.

17. Organic Chemistry by I. L. Finar Vol. II – 5th Edition.

SYLLABUS FOR PHARMACEUTICS

BRANCH – I

General:-

After completing the post graduate pharmaceutics course, the student should be able to:

- Understand the concept and design of various pharmaceutical dosage forms.
- Formulate and evaluate various dosage forms.
- Optimize and validate various techniques in pharmaceutical formulations.
- Calculate pharmacokinetic parameters for a given data.
- Apply the principles of pharmacokinetics in new drug development as well as in the design of new formulations.
- Conduct bioavailability and bioequivalence studies.
- Understanding the concept, design and evaluation of various sustained and controlled release dosage forms.

SYLLABUS FOR PHARMACEUTICS
BRANCH – I
PAPER – II
INDUSTRIAL PHARMACY
THEORY 75 Hours(3 hrs./week)

1. PREFORMULATION: 8 Hours

Introduction, organoleptic properties, purity, particle size, shape, and surface area. Solubilisation, surfactants and its importance, temperature, pH, co-solvency; Techniques for the study of crystal properties and polymorphism. Physicochemical characteristics of new drug molecules with respect to different dosage forms.

2. COMPACTION AND COMPRESSION : 9 Hours.

Compaction of powders with particular reference to distribution and measurement of forces within the powder mass undergoing compression including- physics of tablet compression; Effect of particle size, moisture content, lubrication etc on strength of tablets.

3. PRODUCTION MANAGEMENT AND GMP CONSIDERATIONS: 9 Hours.

An Industrial account of production management, legal control, lay out of building, finance management, inventory management, material management, production planning and control, sales forecasting; ISO 9000 series, GMP considerations, Quality assurance, process control and process validation.

4. PATENT, INTELLECTUAL PROPERTY RIGHTS AND REGULATORY AFFAIRS: 5 Hours.

Definitions, Pharmaceutical aspects related to GATT, TRIPS, TRIMS & WTO.

5. OPTIMIZATION TECHNIQUES IN PHARMACEUTICAL FORMULATION AND PROCESSING: 5 Hours.

Concept of optimization, Optimization parameters, Classical optimization, Statistical design, and Optimization methods.

6. PILOT PLANT SCALE UP TECHNIQUES AND MANUFACTURING PROCESS: 15 Hours.

Significance of pilot plant scale up study and large scale manufacturing techniques (formula, equipment, process, stability and quality control) of some important dosage forms such as tablets, capsules, injections, liquid orals, semisolids, ophthalmic products, dry syrups, emulsions including multiple emulsions, multivitamin products.

7. STERILIZATION PROCESS : 7 Hours.

Sterilization of various injectables, implantable devices, blood products, and biotechnological products

8. STABILITY TESTING: 6 Hours.

Physicochemical and biological factors affecting stability of drugs, Methods to find out degradation pathways, Determination of shelf life by accelerated stability testing, Overages and ICH guidelines.

9. PACKAGING OF PHARMACEUTICALS: 7 Hours.

Desirable features and a detailed study of different types of Pharmaceutical containers and closures (Glass, Plastics and Rubber), including their merits and demerits; selection and evaluation of Pharmaceutical packaging materials.

10. INDUSTRIAL SAFETY: 4 Hours.

Industrial hazards due to fire accidents, mechanical and electrical equipments, Chemicals and pharmaceuticals; Monitoring and preventive systems (Safety measures).

PRACTICALS

1. Preformulation study of tablets.

2. Preparation and comparative evaluation with marketed products for antacid efficiency of neutralizing property of suspensions.

3. Formulation and evaluation of stability of reconstituted dry syrup of amoxycillin, ampicillin etc.

4. Accelerated stability studies on various formulations, with reference to:

    a. Temperature dependence.

    b. Effect of buffers.

5. Determination of the order of decomposition for drugs like Aspirin, Benzocaine, Acetanilide or any other three drugs.

6. Effect of hardness of the tablets on disintegration time.

7. Studying the stability of suspensions using the data on sedimentation volume and degree of flocculation.

8. Determination of the critical micellar concentration of various surfactants by drop weight method or any other suitable method.

9. Determination of the optimum concentration of the surfactant for solubilisation (eg.,) peppermint oil with tween 20.

10. Study on the effect of various excipients on the dissolution rate of tablets.

11. Determination of particle size and size distribution of selected drugs by microscopy, sieving, sedimentation (using Andreasen pipette) etc.

12. Determinations of flow properties of powders by Angle of repose and flow through an orifice with, and without glidants.

13. Sterility testing of commercially available injections like water for injection, Dextrose injection, Analgin injection.

14. Determination of stability of emulsions by studying the globule size.

15. Estimation of optimum concentration of the various glidants for the flow of granules using angle of repose.

16. Other formulations based on the theory topics.

REFERENCES

1. Theory and Practice of Industrial Pharmacy By Lachmann and Libermann.

2. Pharmaceutical dosage forms: Tablets Vol. 1-3 by Leon Lachmann.

3. Pharmaceutical Dosage forms: Disperse systems, Vol, 1-2; By Leon Lachmann.

4. Pharmaceutical Dosage forms: Parenteral medications Vol. 1-2; By Leon Lachmann.

5. Modern Pharmaceutics; By Gillbert and S. Banker.

6. Remington's Pharmaceutical Sciences.

7. Advances in Pharmaceutical Sciences Vol. 1-5; By H.S. Bean & A.H. Beckett.

8. Physical Pharmacy; By Alfred martin

9. Bentley's Textbook of Pharmaceutics – Rawbins.

10. Good manufacturing practices for Pharmaceuticals: A plan for total quality control, Second edition; By Sidney H. Willig.

11. Quality Assurance Guide; By Organization of Pharmaceutical producers of India.

12. Drug formulation manual; By D.P.S. Kohli and D.H.Shah. Eastern publishers, New Delhi.

13. How to practice GMPs; By P.P.Sharma. Vandhana Publications, Agra.

14. Pharmaceutical Process Validation; By Fra. R. Berry and Robert A. Nash.

15. Pharmaceutical Preformulations; By J.J. Wells.

16. Applied production and operations management; By Evans, Anderson, Sweeney and Williams.

SYLLABUS FOR PHARMACEUTICS
BRANCH – I
PAPER – III
BIOPHARMACEUTICS AND PHARMACOKINETICS

THEORY 75 Hours(3 hrs./week)

1. ABSORPTION OF DRUGS : 11 Hours.

Definition, Structure of cell membrane and composition, Gastrointestinal absorption – Mechanism, Factors affecting drug absorption: Biological, Physiological, Physico-Chemical and Pharmaceutical dosage form factors; Methods of determining absorption: Invitro and Invivo methods; Absorption of drugs from non-oral route.

2. DISTRIBUTION OF DRUGS: 11 Hours.

Definition, Distribution in blood and other fluids: cellular distribution, drug penetration to CNS, placental transfer of drugs and blood flow; Volume of distribution, Plasma protein binding: Drug distribution and drug effects, Drug binding in tissues.

3. BIOTRANSFORMATION OF DRUGS: 7 Hours.

Definition, Phase I and Phase II reactions and Factors affecting biotransformation.

4. EXCRETION OF DRUGS: 7 Hours.

Definition, Renal and non- renal excretion.

5. PHARMACOKINETICS: 15 Hours.

a) Definitions, Basic considerations - zero order and first order kinetics.

b) A detailed study of open one compartment model and open Two compartment model.

c) Non-compartmental methods-Area under first moment curve (AUMC),drug clearance, apparent volume of distribution, mean residence time (MRT) and its significance.

d) Concept of clearance- Organ clearance, Total clearance, Hepatic clearance and Renal clearance.

e) Non- linear Pharmacokinetics: Cause of non-linearity, Michaelis-menten equation, Estimation of Km and Vmax.

6. BIOAVAILABILITY & BIOEQUIVALENCE: 10 Hours.

Measurement of bioavailability- Pharmacokinetic methods and Pharmacodynamic methods. Biopharmaceutical classification system, In vitro in vivo correlation (IVIVC) models. Pharmacokinetic and pharmacodynamic modeling. Enhancment of Bioavailability, Designing and protocol of bioequivalence studies as per CDSCO, Schedule Y guidelines, GCP guidelines related to bioequivalence studies.

7. DOSAGE REGIMEN: 9 Hours.

Multiple dosing with respect to IV and oral route, concept of loading dose, maintenance dose and accumulation index, therapeutic drug monitoring.

8. PHARMACOKINETIC VARIABILITY: 5 Hours.

Body weight, Age, Sex, Genetic factors, Pharmacokinetic variabilities in disease states of Renal, Liver, Cardiovascular, Thyroid and Dosage adjustment in the above conditions. Drug- drug and drug- food interactions.

PRACTICALS

1. Improvement of dissolution characteristics of slightly soluble drugs by some methods.
2. Comparison of dissolution studies of two different marketed products.
3. Influence of polymorphism on solubility and dissolution.
4. Protein binding studies of a highly protein bound drug and poorly protein bound drug.
5. Extent of plasma-protein binding studies on the same drug.(i.e.highly and poorly protein bound drug) at different concentrations.
6. Bioavailability studies of some commonly used drugs.
7. Calculation ka, ke, t1/2, Cmax.
8. Calculation of bioavailability from the urinary excretion data for two drugs.
9. Calculation of AUC and bioequivalence from the given data for two drugs.
10. Invitro absorption studies.

REFERENCES

1. Biopharmaceutics and clinical Pharmacokinetics By Milo Gibaldi.

2. Remington's Pharmaceutical Sciences; By Mack publishing company, Pennsylvania.

3. Pharmacokinetics; By Milo Gibaldi, Donald Perrier; Marcel Dekker, Inc.

4. Handbook of clinical Pharmacokinetics; By Milo Gibaldi and Laurie Prescott by ADIS Health Science Press.

5. Biopharmaceutics and Pharmacokinetics; By Robert E. Notari.

6. Biopharmaceutics; By Swarbrick.

7. Biopharmaceutics and Pharmacokinetics- A Treatise; By D.M.Brahmankar and Sunil B.Jaiswal., Vallabh Prakashan Pitampura, Delhi.

8. Clinical Pharmacokinetics, Concepts and Applications; By Malcolm Rowland and Thomas N.Tozer. Lea and Febiger, Philadelphia, 1995.

9. Dissolution, Bioavailability and Bioequivalence; By Abdou.H.M., Mack Publishing Company, Pennsylvania, 1989.

10. Biopharmaceutics and Clinical Pharmacokinetics- An introduction; 4th edition, Revised and expanded By Robert. E. Notari, Marcel Dekker Inc, New York and Basel, 1987.

11. Encyclopedia of Pharmaceutical Technology, Vol 13, James Swarbrick, James. C.Boylan. Marcel Dekker Inc, New York, 1996.

SYLLABUS FOR PHARMACEUTICS
BRANCH – I
PAPER – IV
ADVANCES IN DRUG DELIVERY SYSTEM

THEORY 75 Hours(3 hrs./week)

1. SUSTAINED RELEASE DRUG DELIVERY SYSTEMS. (SRDDS): 10 Hours.

Introduction ; Rationale of SRDDS; Advantages and Disadvantages of SRDDS; Factors influencing the design and performances of SRDDS; Physicochemical properties of a drug influencing design and performance: a)Aqueous solubility, b)Partition coefficient and Molecular size, c)Drug Stability, d)Protein binding; Biological factors influencing design and performance of SRDDS: a)Absorption, b)Distribution, c)Metabolism, d)Duration of Action, e)Side effects, f)Margin of safety, g)Role of disease state; Selected routes of drug administration of SRDDS: a) Parenteral, b)Oral, c) Buccal/Sublingual, d)Rectal, e)Nasal, f)Pulmonary, g)Vaginal, h)Intrauterine, i)Transdermal, j)Ocular ; MICRO ENCAPSULATION TECHNIQUES - Different Micro- encapsulation processes, Advantages,
Disadvantages and Applications.

2. POLYMERS USED IN CONTROLLED DRUG DELIVERY SYSTEMS: 7 Hours.

Introduction, Polymer-classification, Applications for Polymers in formulation of controlled drug delivery systems, Biodegradable and Natural polymers.

3. CONCEPTS AND SYSTEM DESIGN FOR THE RATE – CONTROLLED DRUG DELIVERY: 8 Hours.

Introduction, Classification, Rate - programmed drug delivery systems, Activation - moduled drug delivery systems, Feed back - regulated drug delivery systems, *in vitro* and *in vivo* evaluation of controlled released drug delivery.

4. PARENTERAL CONTROLLED RELEASE DRUG DELIVERY SYSTEMS: 8 Hours.

Approaches for injectable controlled release formulations, Development of Injectable controlled - Release formulations: Long acting Penicillin preparations,Long acting Insulin preparations, Long acting Steroid preparations and Long acting Contraceptive preparations; Approaches and applications of Implantable
Drug Delivery Systems.

5. TRANSDERMAL DRUG DELIVERY SYSTEMS (TDDS): 7 Hours.

Permeation through skin, Factors affecting permeation, Basic components of TDDS, Formulation approaches used in development of TDDS and their evaluation, Permeation enhancers.

6. CONTROLLED RELEASE ORAL DRUG DELIVERY SYSTEMS: 9 Hours.

Introduction, Design and Development of oral controlled release drug administration: Dissolution controlled, Diffusion controlled (Reservoir devices, Matrix devices), Membrane permeation

controlled, Osmotic pressure controlled, Gel diffusion controlled, pH controlled, Ion - exchange controlled delivery systems; Prolongation of GI retention of oral drug delivery system.

7. MUCOADHESIVE DRUG DELIVERY SYSTEMS: 8 Hours.

Introduction, Buccal drug delivery system: Concepts, Advantages and Disadvantages, Structure of oral mucosa, Trans-mucosal permeability, Mucosal membrane modules, Permeability enhancers, invitro and invivo methods for buccal absorption; Buccal strips; Nasal Drug Delivery Systems: Introduction, Physiology of nose, Fundamentals of nasal absorption, Distribution of drug in the nasal cavity, Enhancement in absorption, invitro and invivo methods for determination of nasal absorption, Applications of Nasal Drug Delivery system; Pulmonary Drug Delivery System and its applications.

8. OCULAR DRUG DELIVERY SYSTEM: 8 Hours.

Formulation and evaluation of ocular controlled drug delivery systems, Ophthalmic inserts and insitu gels.

9. TARGETED DRUG DELIVERY SYSTEM: 10 Hours.

Concepts of targeting, Brief study on colon targeting and brain targeting. Preparation and use of drug carriers – cellular (resealed erythrocytes), vesicular (liposomes), and particulate (nanoparticles and microparticles & microspheres) carriers, immunoconjucates (monoclonal antibodies) and magnetic microspheres.

PRACTICALS

1. Preparation of albumin microspheres by heat stabilization technique and their particle size determination.
2. Preparation and evaluation of microcapsules by different microencapsulation techniques.
3. Study on diffusion of drugs through various polymer membranes.
4. Preparation of resealed erythrocytes, loading of various drugs and the study on the release pattern.
5. Study on In-vitro dissolution of various sustained release formulations of marketed products.
6. Preparation of various drug formulations by solid dispersion technique and their evaluation.
7. Preparation of matrix tablets using various polymers, like polyvinyl alcohol, polyvinyl pyrrolidone etc., and studying their release patterns.
8. Preparation of various polymer films, loading of drugs and studying the release pattern.
9. Film coating of drug pellets for granules with sodium CMC and the study on In vitro dissolution.

REFERENCES

1. Encyclopedia of controlled delivery; By Edith Mathiowitz, Published by Wiley Interscience Publication, John Wiley and sons, Inc, New York / Chichester / Weinheim.

2. Controlled and Novel Drug Delivery; By N.K.Jain, CBS Publishers and Distributors, New Delhi, First edition, 1997 (reprint in 2001).

3. Controlled Drug Delivery - Concepts and Advances; By S.P.Vyas and R.K.Khar, Vallabh Prakashan, New Delhi, First edition, 2002.

4. Remington's Pharmaceutical Sciences.

5. Novel drug delivery system; By Y.M.Chien, Marcel Dekker, Inc.

6. Controlled Drug Delivery - Fundamentals and Applications, 2nd edition; By Joseph R.Robinson and Vincent H.L.Lee.

7. Pharmaceutical Dosage forms, disperse system: Volume 1, By Herbert A.Libermann et.al, Marcel Dekker, Inc.

8. Pharmaceutical Dosage forms: Tablets Volume II, Herbert A.Libermann et.al, Marcer Dekker, Inc.

9. Bentley's Textbook of Pharmaceutics; By E.A.Rawlins, ELBS Publications.

10. Microencapsulation and Related Drug Process; By Patric B. Daisy.

SYLLABUS FOR PHARMACEUTICAL CHEMISTRY COURSE

BRANCH - II

General:-

After completing the post graduate pharmaceutical chemistry course, the student should be able to:

- Apply the recent techniques in drug development and synthesis
- Able to extend the concepts of retro synthetic analysis and the synthon approach and the analysis and synthesis of more complex organic structures.
- Able to extend the knowledge of heterocyclic compounds to multi rings and multi hetero atom systems.
- Understand the various kinds of chemical reactions and their stereochemistry.
- Review the approaches to new drug discovery, enzymes and receptors as targets using drug design and Computer Aided Drug Design
- Comprehend the structural elucidation of active principles isolated from natural products.
- Exploit the potential of natural products as leads for new pharmaceuticals.
- Provide competent postgraduates in pharmaceutical chemistry who can become research chemists for pharmaceutical companies, teaching / research in academics and personnel for regulatory agencies.

BRANCH II

PHARMACEUTICAL CHEMISTRY
ADVANCED ORGANIC CHEMISTRY

PAPER - II

THEORY 75 Hours (3 Hrs./week)

I. Basic concepts of Nano-Chemistry: 4 Hours

II. Techniques in drug development and synthesis will be dealt at advanced level. These include a deep knowledge of the following topics: 8 Hours

a) Chemical bonding (localized, delocalized and Bonding weaker than covalent)
b) Reaction intermediates (carbocations, carbanions, free radicals, carbenes and nitrenes)
c) Various types of mechanisms and methods of determining them.
d) Acids and Bases.
e) Effect of structure on Reactivity.

III. Detailed knowledge to be imparted in the following topics: 12 Hours.

a) Substitution reactions (aliphatic nucleophilic, aromatic electrophilic, aliphatic electrophilic, aromatic nucleophilic and free radical).
b) Addition reactions (both carbon-carbon and carbon-heteroatom multiple bonds).
c) Elimination reactions and Rearrangement reactions.
d) Oxidation – reduction reactions and the reagents used for such reactions.
e) Protection and deprotection of various groups.

IV. a) Chirality and the importance of chiral drugs. **6 Hours.**
b) Techniques for preparing chiral drugs (chirality pool, enzymatic transformation and asymmetric synthesis).

V. Synthetic methodologies for obtaining drugs: 8 Hours.

a) Disconnection approach.
b) Synthones for carbon-carbon bond formation.
c) Difunctional compounds.
d) Selective functional group interconversions (FGI).
e) Retrosynthetic analysis.

VI. Heterocyclic Chemistry: 8 Hours.

Synthetic approaches for attaching heterocyclic ring systems in drug molecules having five membered and six membered heteroaromatic rings and fused ring systems.

VII. Photochemical Reactions: 5 Hours.

Basic theory, orbital symmetry rules and their applications.

VIII. Catalysis: 5 Hours.

Introduction, phase transfer catalysis in anhydride, epoxide, ester, nitryl, sulphide formation, ester hydrolysis and reduction reaction.

IX. Pericyclic reactions: 5 Hours.

Mechanism, Types of pericyclic reactions – cyclo addition, electrocyclic reaction, sigmatropic rearrangement.

X. A study of the following reactions of synthetic importance: 10 Hours.

a) Mannich reaction.
b) Meerwin-Pondroff's reduction.
c) Oppenauer oxidation.
d) Beckmann rearrangement.
e) Grignard reaction.
f) Hoffman rearrangement.
g) Ozonolysis.
h) Reformatsky reaction.
i) Michael reaction.

XI. Introduction to combinatorial chemistry 4 Hours.

PRACTICALS

I. Synthesis of the following heterocyclic compounds
   a) Benzimidazole.
   b) Benzotriazole.
   c) Phenothiazine
   d) Oxadiazole.
   e) Thiadiazole.
   f) Isatin.

II. To perform the following reactions of synthetic importance
   a) Birch reduction.
   b) Clemmenson reduction.
   c) Meerwin-Pondroff's reduction.
   d) Grignard reaction.
   e) Oppenauer oxidation.
   f) Benzyllic acid rearrangement.
   g) Beckmann rearrangement.
   h) Photochemical reaction.

REFERENCES

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 & Anthony W. Czarnik

BRANCH II – PHARMACEUTICAL CHEMISTRY

ADVANCED MEDICINAL CHEMISTRY

PAPER-III

THEORY : **75 Hours (3 hrs./week)**

1. DRUG RECEPTOR INTERACTION 6 Hours.

- Types, Receptor and Ligand interactions.

2. QUANTITATIVE ANALYSIS OF STRUCTURE ACTIVITY RELATIONSHIP 7 Hours.

a) History and development of QSAR.
b) Drug receptor interactions.
c) Physicochemical parameters.
d) Hansch analysis, Fee Wilson analysis, relationship between them.
e) Statistical methods – regression analysis, partial least square analysis (PLS) and other multivariate statistical methods.
f) 3D QSAR approaches.

3. MOLECULAR MODELING IN DRUG DESIGN 6 Hours.

Molecular mechanics, quantum mechanics, known receptor sites, calculation of affinity, unknown receptors – pharmacophore models. Searching for similarity, molecular comparison, finding common pattern.

4. ANALOG DESIGN FROM LEAD MOLECULE 6 Hours.

Introduction, Bioisosteric replacement, rigid analogs, alteration of chain branching, changes in ring size, ring position isomers, design of stereo isomers and geometric isomers, fragments of a lead molecule, variation in inter atomic distance.

5. PRODRUG DESIGN . 6 Hours.

Introduction, chemical bond, gastro intestinal absorption, parenteral administration, distribution, transdermal absorption, pharmacokinetic and biopharmaceutical aspects, rationale of prodrug design and practical considerations.

6. APPROACHES TO THE RATIONAL DESIGN OF ENZYME INHIBITORS 6 Hours.

Enzyme inhibitors in medicine, Enzyme inhibitors in basic research, rational design of non covalently and covalently binding enzyme inhibitors.

7. GASTRIC PROTON PUMP INHIBITORS. 6 Hours.

Introduction, gastric acid secretion and its inhibitors, test assay for studying gastric acid inhibitors, irreversible gastric proton pump inhibitors.

8. AGENTS AFFECTING IMMUNE RESPONSE. 6 Hours.

Immune response, immuno suppressants, immuno stimulants.

9. MEDICINAL CHEMISTRY OF THE FOLLOWING GROUP OF DRUGS 12 Hours.

a) Antiviral agents and agents under development of HIV infection.
b) Antineoplastic agents.
c) Antihypertensive agents.
d) Prostaglandins, leukotrienes and other eicosanoids.

10. A STUDY OF THE MANUFACTURE OF THE FOLLOWING DRUGS 6 Hours.

a) Paracetamol.
b) Diphenhydramine.
c) Indomethacin.
d) Sulphamethoxazole.
e) Pheniramine maleate.

11. STEREOCHEMISTRY AND DRUG ACTION 8 Hours.

Realization that stereoselectivity is a pre-requisite for evolution. Role of chirality in selective and specific therapeutic agents. Case studies, Enantio selectivity in drug absorption, metabolism, distribution and elimination.

PRACTICALS

1. Synthesis of various barbiturates and determination of pKa value of barbiturates in relation to their biological activity.

2. Determination of partition co-efficient and calculation of values of a series of drugs like barbiturates.

3. Synthesis of local anaesthetic and evaluation of their biological activity.

4. Synthesis of some anticonvulsants (other than barbiturates) and their evaluation.

5. Synthesis of some anti-inflammatory agents and their evaluation.

6. Synthesis of any three drugs by applications of Friedel-Crafts/Mannich Base/Claissen reaction.

7. Synthesis of non-narcotic analgesics and evaluation in comparison to narcotic analgesics.

8. Suitable synthesis and the evaluation of drugs based on theory topics.

REFERENCES

1. A Biomedical basis – Medicinal chemistry by Thomas Nogrady.

2. Introduction to Quantitative Drug Design by Y.C. Martin.

3. Selective toxicity by Aldrein Albert.

4. Comprehensive Medicinal Chemistry – Corwin Hansch.

5. Medicinal Chemistry by Burger.Vol I, II, III, IV

6. Principles of Medicinal Chemistry by William Foye.

7. Drug Design Volumes by Ariens.

8. Principles of Drug Design by Smith.

9. Strategy of Drug Design by Brucell.

10. The Organic Chemistry of the Drug Design and Drug action by Richard B. Silverman.

11. Remington's Text book of Pharmaceutical Sciences.

12. Wilson and Gisvold's Text book of Organic Medicinal and Pharmaceutical Chemistry.

BRANCH II - PHARMACEUTICAL CHEMISTRY

NATURAL PRODUCTS OF MEDICINAL INTEREST

PAPER –IV

THEORY: 75 Hours (3 Hrs./week)

1. **Isolation, identification and application of** GLC, HPLC and counter current distribution to separation and analysis of plant constituents. Application of IR H1 NMR, MS, ORD and CD to structural studies of natural products. **8 Hours.**

2. **NATURAL PRODUCTS AS LEADS FOR NEW PHARMACEUTICALS** **7 Hours.**

   Cannabinoids, asperlicin, etoposide, teniposide, echinocandins, teprotide, khellin, cromoglycate, milbemycins.

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3. **The Natural products obtained by terrestrial and microbial sources by spectral data. Important members representing the following classes of natural products shall be discussed. 8 Hours.**

   a. **Alkaloids-** General introduction and classification, isolation and purification methods, general methods employed for determining the structure of alkaloids, constitution of morphine, reserpine and quinine.

   b. **Steroids-** General introduction, stereochemistry, nomenclature and structure elucidation of sterols (cholesterol), sapogenin (diosgenin) and cardiac glycosides. **9 Hours.**

   c. **Flavonoids -** Detailed chemical account of rutin and quercetin. **8 Hours**

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   d. **Triterpenoids –** A general chemical treatment and structural elucidation of terpenoids. **7 Hours.**

   e. **Coumarins –** General methods of isolation and purification and structural determination of Xanthotoxin and psoralene. **4 Hours.**

4. **STEROIDAL HORMONES : 4 Hours.**

   Steroid receptor, natural hormones and currently used synthetic derivatives, SAR, comparison of activity, transformation of phytosterols into steroidal drugs.

5. **ROLE OF RECOMBINANT DNA TECHNOLOGY AND DRUG DISCOVERY. 6 Hours.**

   Cloning DNA, expression of cloned DNA, manipulation of DNA sequence information new biological targets for drug developments, novel biotechnology derived pharmaceutical products. Antibody, antisense oligonucleotide therapy, gene therapy.

6. ß – LACTUM ANTIBIOTICS. 4 Hours.

Mechanism of action, penicillins, cephalosporins, nocardicins and monobactums, carbapenems and penems, ß-lactamase inhibitors and other ß-lactum agents.

7. NON ß -LACTUM ANTIBIOTICS. 4 Hours.

Amino glycosides, macrolides, lincomycin and polypeptide antibiotics.

8. AWARENESS OF THE ACTIVE CONSTITUENT OF CERTAIN CRUDE DRUGS USED IN INDIGENOUS SYSTEM. 6 Hours.

a. Diabetic therapy – Gymnema sylvestre, Salacia reticulate, Pterocarpus marsupiam, Swertia Chirata, Trigonella Foenum – graecum.
b. Liver dysfunction – phyllanthus niruri. c. Antitumor – curcuma longa Linn.

PRACTICALS

1. Estimation of elements such as Na, K and Ca.
2. Estimation of functional groups in organic compounds.
3. Isolation, characterization like melting point, mixed melting point, molecular weight determination, functional group analysis, co-chromatographic technique for identification of isolated compounds and interpretation of UV and IR data.
4. Some typical degradation reactions to be carried on selected plant constituents.

REFERENCES

1. Modern methods of plant analysis – Peech and M.V.Tracey.
2. Phytochemistry Voi. I and II by Miller, Jan Nostrant Rein Hld.
3. Recent advances in Phytochemistry Vol. I to IV – Scikel Runeckles.
4. Chemistry of natural products Vol I onwards IWPAC.
5. Natural Product Chemistry Nakanishi Gggolo.
6. Natural Product Chemistry "A laboratory guide" – Rapheal Khan.
7. The Alkaloid Chemistry and Physiology by THF Manske.
8. Introduction to molecular Phytochemistry – CHJ Wells, Chapmannstall.
9. Organic Chemistry of Natural Products Vol I and II by Gurdeep and Chatwal.
10. Organic Chemistry of Natural Products Vol I and II by O.P. Agarwal.
11. Organic Chemistry Vol I and II by I.L. Finar
12. Elements of Biotechnology by P.K. Gupta.
13. Pharmaceutical Biotechnology by S.P.Vyas and V.K.Dixit.
14. Biotechnology by Purohit and Mathoor.
15. Phytochemical methods of Harborne.
16. Burger's Medicinal Chemistry.

SYLLABUS FOR PHARMACOGNOSY
BRANCH – III

General:-

After completing the post graduate pharmacognosy course, the student should:

- Understand the plant physiology, plant biochemistry, general aspects of sources of natural products and cultivations of medicinal plants.
- Have knowledge on chemical plant analysis, methods of extraction, isolation, separation, identification and analysis of results.
- Provide information regarding of primary and secondary plant metabolism, study of techniques employed in the elucidation of biosynthetic pathways.
- Acquire knowledge on plant tissue culture and its applications
- Able to do extract, separate and isolate plant constituents and volatile oils.
- Able to perform different types of estimation of active constituents from natural products.
- Provide herbal drug information.
- Provide information regarding natural products in alternative system of medicine.
- Knowledge on poisonous and allergenic plants and their mode of toxicity.
- General methods of screening natural products.
- Teach confidently pharmacognosy and phytochemistry subjects at undergraduate and diploma programmes in pharmacy.

SYLLABUS FOR PHARMACOGNOSY
BRANCH – III
PAPER – II
PHARMACOGNOSY

Theory 75 Hours (3 hrs./week)

1. General aspects of sources of natural medicinal products **5 Hours.**

2. Marine Pharmacognosy and its applications. **3 Hours.**

3. General cultivation of medicinal plants, their merits and Demerits. **8 Hours.**

a. General aspects.
b. Factors involved.
c. Methods used to improve the Quality.
d. Pest control.

4. Cultivation of Rauwolfia, Digitalis, Senna, Clove, Cardamom, Plantago, Artemisia annua, Coleus forskoli, Aloe, Phyllanthus niruri. **9 Hours.**

5. Quality control of natural medicine products including organoleptic, microscopical, physical, chemical and biological evaluation of crude drugs. **10 Hours.**

6. An overview of poisonous plants and their mode of toxicity with special emphasis to indigenous poisonous plants. **2 Hours.**

7. Role of natural products in alternative system of medicine like Siddha, Ayurveda, Homoeopathy, Chinese medicine, Tribal medicines and Neutraceuticals. **4 Hours.**

8. Drug Improvement: **11 Hours.**

a. Growth regulators, classification and preparation of growth regulators, Mechanism of action of growth regulators of the following – Auxins, gibberllins, Cytokinins, Absicisic acid.

b. Mineral Supplements – macronutrients, micronutrients, their role in the drug improvement.

c. Role of natural pesticides – Preparation and uses.

9. a. The Principles, rationals and technology involved in the production of herbal formulation and herbal cosmetics.

b. Commercial significance of herbal formulations and Quality control evaluation of herbal formulations as per WHO guidelines. **10 Hours**

10. Aromatic plants: **13 Hours.**

a. Cultivation, industrial production and their application: 1) Patchouli 2) Geranium 3) Rosemary 4) Eucalyptus oil 5) Davana 6) Cardamom.

b. Modern methods of Extraction of Volatile oils.

1) Steam distillation 2) Carbondioxide extraction.3) Enfleurage method.

c. Standardisation of essential oils, detection of adulterants.

d. Synthesis and isolation of constituents of volatile oils.

e. Extraction of plant drugs by microwave assisted technique and its merits and Demerits.

PRACTICAL

1. Macroscopical and microscopical evaluation including Quantitative microscopy.

2. Physical, Chemical and Biological evaluation in Quality control of crude drugs.

3. a) Estimation of secondary metabolites like alkaloids, terpenoids and flavonoids by different methods.
(b) Estimation of plant phytoconstituents using modern methods like UV and HPTLC.

4. Extraction and isolation of volatile oils.(Given in chapter 10).

5. Extraction of plant phytoconstituents.
   a). Curcumin from Turmeric.
   b). Reserpine from Rauwolfia.
   c). Naringin from Grapes.
   d). Capsaicin from Capsicum.
   e). Myristicin from Nutmeg.

6. Demonstration of simple experiment to study the effect of plant growth regulators.

REFERENCES

1. Pharmacognosy by G.E. Trease, W.C. Evans, ELBS.
2. Pharmacognosy by Varro E.Tyler, Lynn. R.Brady, James E.Robbers.
3. Text Book of Pharmacognosy by T.E. Wallis, CBS Pub. Delhi.
4. Plant Physiology of Frank B.Salisburry, Cleon. W.Ross, CBS Pub. Delhi
5. Indian Medicinal Plants by Kirthikar, Basu.
6. Indian Meteria Medica by K.M. Nadkarni
7. The Essential Oils by Guenther. E.
8. Modern Toxicology vol.II by P.K.Gupta, D.k. Salunkhe
9. Proceeding of the seminar on scope of Aromatic plants & Processing Industries.
10. Pharmacographia Indica by W.Dymock.
11. A Hand Book of Common remedies in Siddha system of medicine- CCRIMH.
12. Clinical applications of the Ayurvedic remedies.
13. Baidyanth Book of Ayurvedic Knowledge.
14. Perfumery technology by Wallis, Billot.M.
15. Jenkin's quantitative pharmaceutical Chemistry by A.M.Knevell.
16. Phytochemical methods of chemical analysis by Harbone.
17. Pharmacoepial standards for Ayurvedic formulations –CCRAS, Delhi.
18. Practical Pharmacognosy by Dr.C.K.Kokate.
19. Practical Pharmacognosy by Dr.P.K.Lala.
20. Bibiliography on pharmacognosy of medicinal plants-Roma Mitra.
21. British Herbal Pharmacopoeia.
22. Essential oils and waxes: H.F.Linskens & J.F.Jackson.
23. The Ayurveda Encyclopedia – Swami Sada Shiva Tirtha.
24. Encyclopedia of Natural medicine – Michael Murray & Joseph. Pizzorno
25. Toxic plants and other Natural toxicants – Tom Garland & Catharine Barr.
26. Alternate medicine – Dr. K.B.Nangia
27. Ayurvedic Medicines – H.Panda.
28. Pharmacognosy and Pharmacobiotechnology – Ashutoshkar.
29. Foundations of Ayurveda – K.H.Krishnamurthy.

30. The complete German commision, E.Monographs-Blumenthal Buse, Gold bery, Gruenwald Hall.
31. The Ayurvedic system of medicine – K.N.Sengupta.
32. Arboriculture – Harris, Clark, Matheny.
33. Herbal cosmetics Hand book – H.Panda.
34. Homoeopathic pharmacy – Steven B.Kayne.
35. Dictionary of Indian Folk medicine and Ethnobotony – Dr.S.K.Jain.

SYLLABUS FOR PHARMACOGNOSY
BRANCH III
PAPER – III
BIOGENESIS & CHEMISTRY OF NATURAL PRODUCTS

THEORY 75 Hours (3 hrs./week)

1) Detailed study of plant physiology and plant Biochemistry, Study of techniques employed in the elucidation of Biosynthetic pathways and the study of important Biosynthetic pathways of plants like photosynthesis, Carbohydrate utilization, Aromatic Biosynthesis, Isoprenoid Biosynthesis with special importance to active principles. **5 Hours.**

2) A detailed study of the following classes of Natural products with special importance to occurrence, chemistry, Biosynthesis, isolation, purification and estimation by Physical, Chemical and Biological methods.

a) Polypeptide – Insulin, Vasopressin and Oxytocin. **5 Hours.**

b) Alkaloids- Atropine, Ergometrine, Reserpine and Vinblastine, morphine and its synthetic analogues. Hypercin, Ginkobiloba, Forskolin. **9 Hours.**

c) Steroids – Chemistry and stereochemistry of Cholesterol, Preparation and Chemistry of corticosteroids. **5 Hours.**

d) Glycosides – Cardiac glycosides like Digoxin, Scillaren-A, Ovabain and Peruvoside. **5 Hours.**

e) Antibiotics – Penicillin, semisynthetic penicillins and Tetracylclines. **8 Hours.**

f) Vitamins – Vitamin A, Folic acid, Vitamin-B12 and Vitamin C. **8 Hours.**

3) Industrial methods of isolation and estimation of the following natural products **10 Hours.**

a) Digoxin b) Sennosides c) Diosgenin
d) Hesperidin e) Tannic acid f) Pectin
g) Atropine h) Quinine i) Emetin
j) citric acid k) Forskolin

4) General methods of screening natural products for the following Biological activities and their structural activity **20 Hours.**

a) Anti-inflammatory Activity.
b) Hypoglycemic.
c) Diuretic.
d) Cardiac Activity.
e) Antiviral & Antibacterial Activity.
f) Antineoplastic Activity.
g) Psychopharmacological Activity.
h) Antifertility Activity.
i) Screening of Invitro Antioxidant Activity.
j) Antiulcer Activity.
k) Hepato protective Activity.

PRACTICALS

1. Isolation of piperine from pepper.
2. Estimation of piperine in pepper by UV, HPTLC, and HPLC Analysis.
3. Estimation of Total phenolic compounds from plant drugs.
4. Determination of Antioxidant potential of some plant drugs by DPPH and Nitric oxide methods.
5. UV and IR analysis of the following isolated phytochemicals and determination of their purity.
    a) Caffeine.
    b) Piperine.
    c) Quinine.
    d) Andrographolide.
    e) Curcumin.
6. Study on the Micro wave assisted extraction technique of plant drugs.
7. Analysis of extracts obtained from microwave assisted technique by modern techniques like UV, HPLC, HPTLC and comparison with the extracts obtained from conventional method.
8. Determination of total andrographolides from Kalmegh.
9. Determination of total bitters from the following plant drugs.
    a) Kalmegh.
    b) Eclipta alba.
    c) Picrorhiza.
    d) Tinospora cordifolia.
10. Estimation of total saponins from
    a) Bacopa monnieri.
    b) Tribulus terrestris.
11. Estimation of withanolides from Withania Somnifera.
12. HPTLC estimation of Gugulosterones in Guggul.
13. Estimation of Boswellic acid from Boswellia serrata by nonaqeous titration.
14. Estimation of Berberine from plant drugs by HPTLC.
15. Estimation of flavanoids in Liquorice.
16. Estimation of Glycyrrhizin in Liquorice by spectrophotometric method.

REFERENCES

1. Pharmacognosy by G.E. Trease, W.C. Evans, ELBS.
2. Pharmacognosy by Varro E.Tyler, Lynn. R.Brady, James E.Robbers.
3. Text Book of Pharmacognosy by T.E. Wallis, CBS Pub. Delhi.
4. Plant Physiology of Frank B.Salisburry, Cleon. W.Ross, CBS Pub. Delhi
5. Diosgenin and other steroid drug precursors by Asolkar,CSIR.
6. Antibiotics,Isolation&Seperationby Weinsted.M.I.Wagman,G.H.
7. Hormone Chemistry by W.R.Butt.
8. Quantitative analysis & Steroids by Gorog.S.
9. Steroids by Feiry & Feisher.
10. Alkaloids Chemical & Biological by S.W.Pelletier.
11. Biotechnology of Industrial antibiotics by E.vardemme.
12. Chromatography of Alkaloids by Vapoorte, Swendson.
13. Elements of chromatography by P.K.Lala.

14. Introduction to chromatography theory & Practicals by V.K. Srivastava, K.Kishore.
15. Principles of Biotechnology by Leininger.
16. Jenkins Quantitative Pharmacuetical Chemistry by A.N.Knevell.
17. Handbook of vitamins by L.J.Machlein.
18. Clerk's Isolation & Identification of drugs by A.C.Mottal.
19. Selected Topics in Exp-Pharmacology by Seth.V.K.
20. Burger's Medicinal Chemistry by wolff.M.I.
21. Wilson & Gisvolds Text Book of organic Medicinal and Pharmacuetical Chemistry by Deorge.R.F.
22. Phytochemical methods of chemical analysis by Harbone.
23. Organic chemistry vol.II by I.L.Finar.
24. The Essential oil by Gunther.E.
25. The use of Pharmacological techniques for the evaluation of natural products by B.N.DhavanR.C.Srimal. CDRI, Lucknow.
26. Physical methods in organic chemistry by J.C.P.Schwartz.
27. Techniques in organic chemistry by Weiss Creger.
28. Practical Pharmacognosy by Dr.C.K. Kokate.
29. Practical Pharmacognosy by Dr.P.K.Lala.
30. Herbal medicines – Janne Barnes, Linda. A.Anderson.
31. Chinese materia medica – Yaru – PingZhu.
32. Natural products from plants – Peter.B.Kanfman.
33. Selection, Preparation and pharmacological evaluation of plant material – M.Williamson, David T.Okpako, J.Evans.

34. SYLLABUS FOR PHARMACOGNOSY
BRANCH – III
PAPER – IV
PHYTOCHEMISTRY & BIOTECHNOLOGY

THEORY 75 Hours(3 hrs./week)

1) Phytochemistry : 11 Hours.

a. Introduction and general methods of phytochemical plant analysis, methods of extraction, isolation, separation, identification and analysis of results.

b. Microbiological conversions, aberrant synthesis in Higher plants.

2) Genetics and comparative phytochemistry in pharmacognosy. **3 Hours.**

3) Secondary plant metabolism : 10 Hours.

a. Primary and secondary metabolism.
b. The function of secondary metabolites.
c. The usefulness of secondary metabolites.
d. Secondary metabolites in chemosystematics.

4) Microchemical Analysis : 4 Hours.

A study of the elements of optical crystallography, using ordinary light microscope, the polarizing microscope and various microtechniques useful in the identification of crude drugs and their constituents.

5) Fermentation Chemistry: 17 Hours

a. A detailed account of fermentation technology with examples and applications.

b.The production aspects of Pharmaceutically and economically important substances by microorganisms :

i) Penicillin ii) Dextrose from starch
iii) Vitamin B 12 iv) Ergot alkaloids

c. Yeast and its use, production of single cell proteins.

d. Industrial fermentation and pharmaceutical effluents – its treatment and legal requirement.

6) Plant Tissue Culture: 20 Hours.

A detailed study of plant tissue culture and its application in pharmacognosy :

a. Introduction, History and development of plant tissue culture.
b. Laboratory requirements and general techniques.
c. Tissue culture media, nutrients and mineral supplements.
d. Callus culture.
e. Isolated culture and genetic manipulation of plant protoplasts.
f. Secondary product formation by cell suspension cultures.
g. Hairy root culture and its applications.
h. Biotransformation.
i. Plant tissue culture as a medium to study of secondary plant metabolism.

7) A chemical and spectral study of the constituents of Secondary phytometabolites. 10 Hours.

PRACTICALS

1) Preliminary phytochemical screening and detection of various plant constituents such as

a. Carbohydrates.
b. Alkaloids.
c. Anthraquinones.
d. Flavanoids.
e. Polyphenolic compounds.
f. Lipids.
g. Proteins and Aminoacids.

2) Preparation of extracts enriched with active principles and studying their Stability.
3) Phytochemical analysis of isolated plant constituents by UV, HPLC and HPTLC.
4) UV analysis of some crude drugs and phytochemicals for identification and detection of adulterants.
5) Analysis of medicinally used oils by various methods.
6) Estimation of cineole, Eugenol, Citral and other terpenoidal compounds by suitable methods.

REFERENCES

1. Pharmacognosy by G. E.Trease, W.C.Evans, ELBS.
2. Pharmacognosy by Varro E.Tyler, Lynn R.Brady, James E.Robbera.
3. Plant Physiology by Frank B.Salisburry, Cleon.W.Rose, CBS Pub. Delhi.
4. Antibiotics Isolation & Separation by M.L.Wenisten, G.H. Wagman.
5. Introduction to Biotechnology by Bullock, John.
6. Biotechnology of Higher plants by Gorden E. Russel
7. Modern Biotechnology by S.B. Primrose.
8. Plant cell culture – A practical approach by R.A. Dixon.
9. Plant cell culture technology by M.M. Yeoman.
10. Plant tissue culture by Dennis N.Butcher, David. S.Ingram.
11. Plant tissue culture by Pitman.
12. Plant tissue culture – theory & practice by S.S.Bhajwani, M.K.Razdan.
13. A Laboratory guide to Organic Natural Products by R.Ikan
14. Environmental Chemistry by Anil Kupur.D.
15. Basic gas chromatography by Menair, Bondhi.
16. Quantitative thin layer chromatography & its industrial application by Trieber.L.R.
17. Biotechnology of Industrial antibiotics by E.J.Vardamme.
18. Chromatography of alkaloids by Verpoorte Swendson.
19. Elements of chromatography by P.K.Lala.
20. Introduction to chromatography – theory & practice by V.K.Srivastava, K.Kishore.
21. Principles of Biotechnology by Leininger.
22. Handbook of Vitamins by L.S.Machlein.
23. Industrial Microbiology by L.E.Cassida.
24. Microbial Technology by Peppler, Perlman.
25. Burger's Medicinal Chemistry by M.I.Wollf.

26. Wilson and Gisvolds Text Book of Organic Medicinal and Pharmacuetical Chemistry by Deorge.R.F.
27. Phyto chemical methods of chemical analysis by Harbone.
28. Cytogenetics and evolution of plant Breedings by R.S.Shukla.
29. Introduction to organic laboratory techniques by Pavia Lampman.
30. Drug analysis by chromatography by Egon stahl0.
31. Secondary plant metabolism by Margaret L.Vikery, Brian Vikery.
32. Practical Pharmacognosy by Dr.C.K.Kokate.
33. Practical Pharmacognosy by Dr.P.K.Lala.
34. The review of Natural products – Ara Dermarderosia.
35. Phytochemical Dictionary – Jestorey. B.Harbone.FRS.
36. PDR for Herbal medicines.
37. Methods in plant tissue culture – U.Kumar.
38. Plant cell and tissue culture – Angela Stafford and Grahamwarren.
39. Phytochemicals – R.Bidlack, Tomaye, s.Meskin.
40. Propagating plants – Alan toogood.
41. Modern methods of plant analysis –High performance Liquid chromatography in plant science –H.F.Linskens and J.F.Jacksons.
42. Indian Herbal Pharmacopiea -Regional Research Laboratory.
43. Principles and practice of phytotherapy - Simon Mills & Kerry Bone.

SYLLABUS FOR M. PHARM PHARMACOLOGY
BRANCH – IV

General :-

After completing the post graduate pharmacology course, the student should be able to:

- Understand the effects of drug at molecular and cellular levels.
- Emphasize the applications of pharmacokinetics and pharmacodynamics to therapeutics.
- Recognize the mechanism of actions, pharmacology and toxicology of drugs in systemic pharmacology.
- Justify the drug interactions and adverse drug reactions.
- Maintain and breed laboratory animals.
- Acquire thorough knowledge on New Drug discovery processes including newer approaches like CADD, QSAR, combinatorial chemistry, proteomics, etc.
- Contribute to new drug development processes at preclinical and clinical levels.
- Comment of various regulations related to drug application filing processes.
- Acquire knowledge on the principles of toxicology and management of poisoning in clinical and forensic setup.
- Discuss the generation and role of free radicals in various diseases and the protective activity of antioxidants.
- Comment on gene expression, regulation and mapping and their applications.
- Teach confidently anatomy, physiology, health education and pharmacology subjects at under-graduate and diploma programmes in pharmacy.

SYLLABUS FOR M. PHARM PHARMACOLOGY
BRANCH – IV
PAPER – II PHARMACOLOGY AND TOXICOLOGY
THEORY

1. DRUG ABSORPTION: - 3 hours

Gastro intestinal, percutaneous and rectal absorption
Factors affecting drug absorption
Drugs and its characterization, problems encountered in absorption of drugs, proteins, high molecular weight substances, herbals etc in GIT.

2. DRUG DISTRIBUTION: - 3 hours

a. Plasma Protein binding – factors affecting plasma protein binding.
b. Tissue binding.
c. Transfer of drugs through biological barriers, their therapeutic implication in drug action with emphasis on drug transporters and mechanism of drug transport.
d. Significance of Vd; implications and *in vitro* methodologies.

3. ELIMINATION OF DRUGS: - 3 hours

a. Routes of elimination of drugs.
b. Concept of hepatic and renal clearance.
c. Biological half life.

4. BIOAVAILABILITY AND BIOEQUIVALENCE OF DRUG PRODUCTS: - 2 hours

Factors affecting bioavailability & importance of bioequivalence studies

5. BIOTRANSFORMATION OF DRUGS: - 4 hours

a. Phase-I and Phase-II metabolic reactions, microsomal and non-microsomal biotransformation reactions.
b. Drug metabolism in liver, kidney, intestine and placenta.
c. Drug metabolism in fetus, new born and aged.

6. FACTORS INFLUENCING DRUG METABOLISM: - 3 hours

a. Stereochemical, Physicochemical and biological factors.
b. Physiological and environmental factors, species, strain, sex, and age difference.
c. Pathological states.
d. Genetic factors – evaluation of pharmacogenetics, heritable factors recognized in the use of drugs.

7. PHARMACODYNAMICS: - 3 hours

a. General aspects of receptor pharmacology
b. Structural and functional aspects of receptors
c. Regulation of receptors, Classification and characterization of receptors
d. Drug – drug interactions, drug - food interactions

8. NEUROTRANSMISSION : - 3 hours

a. Definition and general properties of neurotransmission
b. General aspects and steps involved in neurotrasmision.
c. Concepts of excitatory and inhibitory neurotransmission
d. Role of neurotransmitters in various disorders
e. Neurohumoral transmission in autonomic nervous system and central nervous system.
f. Non-adrenergic non-cholinergic transmission (NANC).
g. Co-transmission

9. SYSTEMIC PHARMACOLOGY : - 33 hours

A detailed study of the mechanism of action, pharmacology and toxicology, drug interaction, rationale for drug combination and therapeutic uses of drugs used in

a. ANS- Parasympathomimetics and lytics, sympathomimetics and lytics, agents acting at neuromuscular junction and ganglia.
b. Local anesthetics.
c. CNS – General anesthetics, sedatives, hypnotics. Drugs used to treat anxiety, depression, psychosis, mania, epilepsy, neurodegenerative diseases, drug dependence and addiction.
d. CVS- Diuretics, anti ischemics antihypertensives, antiarrythmics, drugs for heart failure and dyslipidiemia.
e. Effect of drug on blood constituents.
f. Autocoid Pharmacology- A study of the mechanisms involved in the formation, release, pharmacological actions and possible physiological role of histamine, serotonin, kinins, prostaglandins, opioid autocoids and cyclic 3' – 5' AMP. Systemic pharmacology of drugs acting as agonists and antagonist to the autocoids.
g. Immunopharmacology- Cell and biochemical mediators involved in allergy, immunomodulation and inflammation. Classification of hypersentitivity reactions and diseases involved. Therapeutic agents for allergy, asthma, COPD and other immunological diseases with emphasis on immunomodulators.
h. GIT pharmacology- Antiulcer, prokinetics, antiemetics, antidiarrhoeal and drugs for constipation and irritable bowel syndrome.
i. Analgesics and anti-inflammatory agents.
j. Hormones and hormone antagonists.
k. Antibiotics & Chemotherapeutic agents.

10. FREE RADICALS PHARMACOLOGY - 3 hours

a. Generation of free radicals.
b. Role of free radicals in etiopatholgy of various diseases.
c. Protective activity of certain important antioxidants.

11. TOXICOLOGY - 5 hours

a. Principles of toxicology.
b. Abnormal action of drugs such as tolerance, addiction, habituation, idiosyncracy, allergy, hypersensitivity, antagonism, synergism, potentiation, tachyphylaxis.
c. Adverse drug reactions and its monitoring.
d. Heavy metals poisoning.

12. CLINICAL TRIALS - 5 hours

a. Clinical trials of drugs, design of clinical trials and testing of drugs in humans
b. Ethics in conduction of clinical trails
c. Protocol preparation
d. Regulatory bodies
e. Intellectual property rights

13. CLINICAL PHARMACOLOGY - 5 hours

a. Basics in clinical pharmacology.
b. Therapeutic drug monitoring:- Criteria for TDM, Specific examples: Digoxin, aminoglycosides & theophylline.

PRACTICALS

1. Experiments for studying the effects of the more important biogenic agents like histamine, acetylcholine, 5HT, oxytocin and their effect in the presence of antagonist on suitable isolated tissue preparations.
2. Estimation of PA_2 values of various antagonists under suitable isolated tissue preparations.
3. Experiments on CVS- Effect of various drugs on isolated heart preparations on various animal models under normal, arrhythmic and hypodynamic conditions.
4. Drugs acting on Gastro intestinal tract. To study the drug activity on oesophagal motility
5. Monitoring of drug concentration in saliva/urine /blood.
6. Drug absorption and elimination studies.
7. PK/PD modeling correlation studies on theoretical basis
8. Any other experiment based on the topics mentioned in theory.

REFERENCES

1. The Pharmacological basis of therapeutics – Goodman and Gilman's.
2. Pharmacotherapy – DiPiro.
3. Pharmacology – Katzung.
4. Fundamentals of experimental pharmacology by M.N.Ghosh.
5. Handbook of experimental pharmacology by S.K.Kulkarni.
6. Text book of *In vitro* practical pharmacology by IanKitchen.
7. Pharmacological experiments on intact preparations by Churchill Livingstone.
8. Hand book of clinical pharmacokinetics- Gibaldi and Prescott.
9. Principles of drug action by Goldstein, Amaow and Kalman.
10. Clinical pharmacology by Molmon and Morrelli.
11. Clinical trails and tribulations by Allen E. Cato.
12. Drug interactions by Ivan H. Stockley.
13. Text book of therapeutics- drug, disease and management by Herfindal and Gourley.

PAPER – III- BIOLOGICAL STANDARDIZATION & PHARMACOLOGICAL SCREENING METHODS

THEORY

1. LABORATORY ANIMALS - 8 hours

a. Commonly used laboratory, transgenic and other genetically prone animal models (viz., nude mice, SH rats, etc.).
b. Techniques of blood collection, anesthesia and euthanasia of experimental animals.
c. Maintenance and breeding of Laboratory animals.

2. PRINCIPLES OF BIOLOGICAL STANDARDIZATION: - 6 hours

a. Statistical treatment of model problems in evaluation of drugs.
b. Methods of biological assay, principles of biological assays with certain examples mentioned in monograph.
c. Statistical analysis of model problems using appropriate statistical analysis like one way ANOVA, two way ANOVA/ student 't' test

3. IMMUNOASSAY - 8 hours

a. General principles of immunoassay:
Theoretical basis, optimization of immunoassay, Heterogeneous immunoassay system Homogeneous immunoassay systems.
b. Production of Immunoassay reagents:
Introduction, receptors or binders, unlabelled ligands calibrators, Labelled ligands and receptors, separation techniques, buffers.
c. Immunoassay methods evaluation:
Protocol outline, objectives and preparation, evaluation of precision, standard tracer, sensitivity, evaluation of accuracy, antibody characteristics monitoring, reaction conditions, Clinical evaluation.

4. CELL CULTURE - 4 hours

Concepts of *in vitro* screening
Different cell lines (animal and human) used in screening techniques
Primary cultures
Protocols in the preparation and maintenance of cell lines

5. Organization of screening for the Pharmacological activity of new substances with emphasis on evaluation using possible animal models. - 38 hours

a. General Principles and Safety Pharmacology Procedures.
b. Cardiovascular pharmacology– Anti-hypertensives, anti-arrythmics, vasodilators and diuretics.
c. CNS pharmacology – behavioural and muscle co-ordination, CNS stimulants and depressants, anxiolytics, anti-epileptics and Nootropics.
d. Drugs for neurodegenerative diseases like Parkinsonism, Alzheimers, multiple sclerosis, etc.
e. Drugs acting on Autonomic Nervous system.
f. Respiratory pharmacology – Anti- asthmatics, COPD, Anti- allergic and mucoactives.

g. Reproductive pharmacology – Aphrodisiacs and anti-fertility agents.
h. Analgesics, anti-inflammatory and antipyretic agents.
i. Gastrointestinal drugs – Anti-ulcer, anti-emetic, anti-diarrhoeal and laxatives.
j. Anti-cancer agents.
k. Drugs for metabolic disorders like anti-diabetic, anti-hyperlipidemic, antiobesity, and hepatoprotective agents.
l. Models in drug absorption and metabolism.
m. Immunopharmacology - Specific (cell and humoral mediated) and non specific methods.
n. Screening of free radical scavenging activity.

6. ESSENTIALS OF TOXICOLOGY - 8 hours

a. Physicochemical, Biochemical and genetic basis of toxicity, principles of toxicokinectics, mutagenesis and carcinogenesis.
b. Guidelines and regulatory agencies – CPCSEA, OECD, FDA, ICH, WHO, etc.,
c. Behavioural, Inhalation, cellular and sub-cellular toxicity hypersensitivity and immune response, range finding tests.
d. Acute, sub-acute and chronic toxicity studies according to ICH and OECD guidelines.

7. Importance of alternative experimental models - 3 hours

Its advantages and disadvantages

PRACTICALS

1. Biological standardization of drugs like Histamine, Acetylcholine, 5 - HT.

2. Experiments on CNS. General screening methods of drugs acting on CNS
a. CNS stimulants and depressants.
b. Anxiogenics and anxiolytics.
c. Amnestics and Nootropics.
d. Anticonvulsants.
e. Analgesics.
f. Safety pharmacology.

3. Drugs acting on Gastrointestinal tract :
a. General screening methods for the anti ulcer activity, intestinal motility, and anti – diarrhoeals

4. Experiments on CVS:
General screening procedure of anti-arrhythmic agents, anti- hypertensives, anti –ischemics.

5. Experiments on Local anesthetics:
a. General methods for evaluating local anesthetic activity.

6. Experiments on General Pharmacology:
a. Enzyme induction activity.
b. Drug dependence & withdrawal effects.

7. Experiments on Diuretics:
a. General screening methods for evaluating the diuretic activity.
8. Screening procedure for antidiabetic drugs.

9. Experiments on Analgesic & Anti-inflammatory drugs :
a. General screening methods for the evaluation of Analgesics and Antiinflammatory agents (using both acute and chronic models for anti-inflammatory agents).

10. Experiments on Chemotherapy:
a. General methods for evaluating the Antimicrobial activities of chemotherapeutic agents.

11. Experiments on toxicology:
a. Oral & skin acute toxicity tests.

12. Estimation of biochemical and free radical scavengers.

REFERENCES

1. Biological standardization by J.H. Burn, D.J. Finney and L.G. Goodwin.
2. Indian Pharmacopoeia and other pharmacopoeias.
3. Screening methods in Pharmacology by Robert Turner, A.
4. Evaluation of drugs activities by Laurence and Bachrach.
5. Methods in Pharmacology by Arnold Schwartz.
6. Selected topics on the Experimental Pharmacology by Usha G. Kamat, Dadkar, N.K and Seth, U.K.
7. Fundamentals of experimental Pharmacology Ghosh, M.N.
8. Pharmacological experiment on intact preparations by Churchill Livingstone.
9. Drug Discovery and Evaluation by Vogel HG.
10. Animal models in toxicology by Shayne Cox Gad and Christopher P. Chengelis.
11. The UFAW Handbook on the care and management of laboratory animals by UFAW.
12. Principles and methods of toxicology by Hayes.
13. CRC Handbook of toxicology by Derelanko and Hollinger

PAPER – IV- DRUG DESIGN AND MOLECULAR PHARMACOLOGY
THEORY

1. A general treatment of the approaches to drug design: including the methods of variation, study of the use of biochemical and physiological information involving new drugs. **- 6 hours**

2. Drug Receptor theory: - 6 hours
Concept of receptors, theories of drug receptor interaction, forces involved in drug receptor interaction. Receptor polymorphism and dimerization and its importance in drug design.

3. Physiochemical properties in relation to biological action and drug design: - 10 hours
a. Complex of events between drug administration and drug action.
b. Solubility & partition coefficient.
c. Rational drug design.
d. Selected physiochemical properties like isosterism, steric behaviour, ionization, hydrogen bonding, chelation, oxidation- reduction potential, surface actions.

4. New approaches in drug discovery - 4 hours
a. Combinatorial chemistry
b. Pharmacogenomics
c. Proteomics
d. Array technology

5. Guidelines for drug and analog drug design: - 6 hours
a. Basic considerations of drug design, de- novo drug design, lead seeking methods, rational drug design.
b. Structural factors in drug design.
c. Prodrug concepts.

6. Principles of Computer aided drug design. - 6 hours

7. The quantitative analysis of structure activity relationships - 7 hours
a. Fundamentals of QSAR- objectives, expressions of biological activity.
b. QSAR parameters related to chemical structure, correlative methods and analysis of results.

8. Molecular pharmacology - 10 hours
a. Application of molecular pharmacology to drug design.
b. Introduction to cell structure and function.
c. Cell signaling, organization of signal transduction pathway and biosensors.
d. Protein structure prediction and molecular modeling.

9. Gene expression, regulation and gene mapping - 5 hours

10. Recombinant DNA technology: Principles, process and its application - 5 hours

11. Gene Therapy - 10 hours

a. Gene transfer technologies (viral and non viral vectors).
b. Clinical application of gene therapy.
c. Disease targets for gene therapy.
d. Pharmacodynamics, pharmacokinetics of peptide and protein drugs and immunogenicity of protein therapeutics.

PRACTICALS

1. Practicals related to physiochemical properties in relation to biological action including partition coefficient.
2. Cell cultures preparation and maintenance: Chick embryo fibroblast Lymphocyte culture.
3. Protein separation and isolation using gel electrophoresis.
4. DNA isolation, sequencing and PCR techniques.
5. Estimation of protein and nucleic acids.
6. RNA isolation from yeast.

REFERENCES

1. A guide to chemical basis of drug design by Alfred Burger (John Wiley & Sons).
2. Introduction to the principles of drug design by John Smith and Haywel Williams (Wright PSG).
3. Burgers Medicinal chemistry – The basis of Medicinal Chemistry by Manfred E. Wolff Part – 1 (John Wiley & Sons).
4. Computer assisted Drug Design by Edward. C. Olson (American Chemical Society- ACS symposium series 112).
5. Wilson & Giswold's text book of Organic, Medicinal and Pharmaceutical chemistry.
6. Goodman and Gilman's – The Pharmacological Basis of Therapeutics – 8th edition (Pergamon Press)
7. Medicinal Chemistry – The role of organic chemistry in drug research by S.M. Roberts and B.J. Price.
8. Principles of Medicinal chemistry by William Foye.
9. Vogel's text book of practical organic chemistry by Arthur I. Vogel (ELBS and Longman).
10. Current protocols in molecular biology by Frederick. M. Ausubel.
11. Human molecular genetics by Tomstracham & Andrew P. Read.
12. Bioinformatics: Genes, proteins & Computers by Christine Orengo.
13. The Cell – A molecular approach, Geoffrey M. Cooper.
14. Genetherapy, Therapeutic mechanism and strategies by NancySmyth, Templeton Danilo D. Lasic.

SYLLABUS FOR PHARMACEUTICAL ANALYSIS
BRANCH-V

Preamble and objectives

- The main objective of this course is to impart the knowledge on the current scenario of an analytical laboratory of a pharmaceutical industry.
- To produce competent experts in the field of analytical research through practical training in analytical instrumental techniques, calibration of common laboratory equipments & glass ware, and laboratory testing of raw materials and finished products as performed by a quality control laboratory.
- Students would be trained in troubleshooting, analytical instrument failure in compliance with regulatory requirements.
- Students are given hands-on training on method development, and validation requirements within pharmaceutical industry.
- Students are required to perform a wide variety of quality control activities which include, developing standard operating procedures to ensure compliance with GMP, GLP, and FDA, analyzing data and interpreting results.
- An exposure of cGLP and various guidelines enable the students to be skilled personnels who are marketable in pharmaceutical industry.

SYLLABUS FOR PHARMACEUTICAL ANALYSIS

BRANCH - V

PAPER – II

PHARMACEUTICAL AND COSMETIC ANALYSIS

THEORY 75 Hours(3 hrs./week)

A. PHARMACEUTICAL ANALYSIS:

1. Principle and procedures involved in following, including assays of official drugs in I.P by Non-aqueous Titration, Complexometric Titration, Gravimetric Methods, Diazotisation Titration, UV-Visible Method and HPLC . **12 Hours.**

2. A detailed study on related substances and impurities present in drugs and their effect on drug stability and therapeutic action. ICH guidelines for impurity and related substances determination in drugs. **6 Hours.**

3. (a) Identification and quantitative determination of preservatives, Antioxidants, colouring materials, emulsifiers and stabilizers in Pharmaceutical formulation.

(b) Quality control and in process Quality control of Tablets, Capsules, Liquid dosage forms - parenteral & sterile preparations, ointments, creams, suppositories and controlled release products. **8 Hours.**

4. Analysis of drugs from biological samples including, selection of biological sample, extraction of drugs by various methods as LLE, SPE and Membrane filtration. Factors affecting extraction of drugs. **5 Hours.**

5. Stability testing of formulation and shelf life prediction. ICH guidelines for stability studies of drugs. **6 Hours.**

6. Quality control of Radio Pharmaceuticals and radio chemical methods in analysis.

5 Hours.

B. COSMETIC ANALYSIS:

1. General method of analysis to determine the quality of raw materials used in cosmetic industry. **7 Hours.**

2. Sampling and analysis of various cosmetics in the finished forms such as Hair care products, Skin care products, Baby care products, Dental products, Personal hygiene products, Colour cosmetics, Ethnic products, Colour makeup preparation, Lipsticks, Hair setting lotions and Eye shadows. **20 Hours.**

3. Toxicity testing in cosmetics and Safety and Legislation of Cosmetic products

6 Hours.

PRACTICALS

1. Assay of Ibuprofen Tablet I.P., Tolbutamide Tablet I.P., Calcium Lactate and Ferrous Fumerate I.P.

2. Determination of Water in Sorbitol, Sodium Citrate & Ampicillin.

3. Determination of Total Chloride in Thiamine Chloride Hydrochloride.

4. Assay of Piperazine citrate as picrate derivative by Gravimetry.

5. Quality control Tests for Tablets, Capsules, Injections, Ointments and Suppositories.

6. Detection and Determination of Preservatives, Antioxidants and Colouring materials in Pharmaceuticals.

7. Determination of related substances in Albendazole, Amiloride, Metronidazole, Betamethazone, Carbamazepine, Diclofenac, Ephedrine, Ibuprofen, Paracetamol, Eucalyptus oil, Phenylbarbitone and Sulphafurazone as per I.P.

8. Based on topics covered in theory with emphasis on analysis of cosmetics and their adulteration with reference to Drugs and Cosmetic rules 1945.

9. Quality Control tests for some cosmetics. (e.g.,) Determination of SLS in Shampoo.

REFERENCES

1. Comprehensive Pharmacy Review 5th Edition by Leon Shargel, Alan H. Mutnick, Paul F. Souney, Larry N. Sawnson – 2004.
2. Applied Biopharmaceutics and Pharmacokinetics, 4th Edition by Leon Shargel / Andrew B.C., Yu – 1999.
3. A. H. Beckett and J. B. Stenlake Practical Pharmaceutical Chemistry, Part I and Part II, 4th Edition.
4. G. H. Jeffery, J. Basset, J. Mendham, R. C. Denny (Rev. by) Vogels Text Book of Quantitative Chemical Analysis, 5th Edition 1989, ELBS.
5. The Controller of Publications; New Delhi, Govt. of India, Indian Pharmacopoeia, Vol. I and Vol. II - 1996.
6. J. B. Wilkinson and R. J. Moore : Herry's Cosmeticology; Longman Scientific and Technical Publishers, Singapore.
7. P.D. Sethi; Quantitative Analysis of Drugs in Pharmaceutical Formulations, 3rd Edition - 1997,
8. ICH guideline for impurity determination and stability studies.
9. Practical HPLC method development by Lloyd R. Snyder, Joseph J. Kirkland, Joseph I. Glajch, John Wiley and Sons 2nd Edition – 1997.
10. Classification of cosmetics raw materials and adjuncts IS 3958 of Indian Standards Institution (BIS).
11. Cosmetic and toilet goods – methods of sampling IS 3958 of Indian Standards Institution (BIS).
12. Methods of sampling and test for various cosmetics as laid down by Indian Standard Institution (BIS).

SYLLABUS FOR PHARMACEUTICAL ANALYSIS

BRANCH - V

PAPER - III

ADVANCED PHARMACEUTICAL ANALYSIS

THEORY 75 Hours (3 hrs./week)

1. Introduction to product characterization for drug and product development, concept of Analytical Methods development. **5 Hours.**

2. Validation and calibration of various instruments used for drug analysis such as UV-Visible Spectrophotometer, IR Spectrophotometer, Spectrofluorimeter, HPLC, HPTLC and GC. **10 Hours.**

3. Principles and procedures involved in quantitative determination of following groups

(a) Hydroxyl, (b) Aldehyde, (c) Ketone, (d) Ester (e) Amine. **5 Hours.**

4. A detailed study of principle and procedures involved in various physicochemical methods of analysis including instrumental methods of analysis of Pharmaceutical dosage forms containing the following classes of drugs: **20 Hours.**

a. Sulphonamides.

b. Barbiturates – i.e., Barbituric acid derivatives and Xanthine derivatives.

c. Steroids such as Adrenocortical steroids, Progesterone, Androgens and Cholesterol.

d. Vitamins like Vitamin A, B1, B2, B12, C & E.

e. Antibiotics like Chloramphenicol, Erythromycin, Penicillin & Streptomycin.

f. Alkaloids of Cinchona, Ergot, Opium & Rauwolfia.

g. Glycosides such as Digitoxin, Digoxin & Strophanthin.

5. Elemental analysis such as determination of sodium, potassium, calcium, phosphorous, sulphur, chlorine, bromine and iodine. **6 Hours.**

6. Principles and procedures involved in the use of the following reagents in Pharmaceutical analysis : **10 Hours.**

a. N, 1-naphthyl ethylene diamine.

b. Para – dimethyl amino Benzaldehyde (PDAB).

c. 2, 6 – Dichloro quinone chlorimide.

d. 1, 2 – Naphtho quinone 4 – sulphonate.

e. 2, 3, 5 – Triphenyl Tetrazolium Salt.

f. Ninhydrin.

g. Folin – Ciocalteau reagent.

h. Para dimethyl amino cinnamaldehyde.

i. 3 – methyl 2 – benzothiazolinone hydrazone (MBTH).

j. 2, 4 – dinitro phenyl hydrazine.

7. Analysis of Drugs and Excipients in solid state – Particle size analysis, X-ray powder diffraction. **6 Hours.**

8. A detailed study of Principles and Procedures involved in the following Biological tests and assays : **13 Hours.**

Test for effectiveness of Antimicrobial preservatives, Adsorbed Diphtheria Vaccine, Adsorbed Diphtheria Antitoxin, Microbiological Assay of Cyanocobalamine, Microbiological Assay of Neomycin sulphate, Oxytocin, Tetanus Antitoxin, Rabies vaccine, Rabies Antiserum.

9. A detailed study of principles and procedures involved

a.BABE

b.TDM

c.LAL'S test.

PRACTICALS

1. Calibration and validation of UV-Visible, IR, Flourimeter, HPLC & HPTLC.

2. Assays of official compounds by fluorimetry : a) Quinine b) Codeine c) Thiamine and d) Riboflavin.

3. Determination of 'Sodium' in Sodium chloride injection.

4. Colorimetric estimation of Sulphacetamide in 'eye drops' using NED.

5. Assay of Reserpine injection IP.

6. Quantitative Analysis of drugs in the following 'Multicomponent dosage form' - Ibuprofen & Paracetamol Tablet, Paracetamol and Nimusulide Tablet, Ciprofloxacin and Tinidazole Tablet.

7. Quantitative Determination of following groups : a) Hydroxyl group b) Carbonyl group c) Amine.

8. Quantitative Colorimetric determination of suitable drugs using following reagents :

a) Paradimethyl Amino cinnamaldehyde b) MBTH c) F C reagent d) 2,6 dichloro quinone chlorimide e) Ninhydrin.

9. Assay of the following official formulations : a) Frusemide Tablet b) Metformin Tablet c) Chloroquine Tablet d) Chloramphenicol Capsule e) Digoxin Tablet.

10. Verification of Standards for a sample .

11.HPLC & HPTLC analysis of drugs.

REFERENCES

1. Vogel's : Text book of quantitative chemical analysis revised by G. H. Jeffery, J. Bassett, J. Mendham, R. C. Denney, 6th Edition, Pearson Education Publishers – New Delhi, 1989, India.3.

2. H. Beckett and Stenlake, Practical Pharmaceutical Chemistry, Vol. I and Vol. II, 4th Edition CBS Publishers, 1997, New Delhi.

3. K.A Connors : Text Book of Pharmaceutical Analysis, 3rd Edition, Wiley- inter Science Publication, 1999, New York.

4. Indian Pharmacopoeia, Vol. I & II, 1996, the Controller of Publications, Government of India.

5. John H. Kennedy, Principles of Analytical Chemistry, 2nd Edition, Saunders College Publishing, 1990, New York.

6. Higuchi, Bechmman and Hassan : Pharmaceutical Analysis, 2nd Edition, John Wiley and Sons, New York.

7. D. C. Garratt, The Quantitative Analysis of Drugs, CBS Publishers, 2001, New Delhi.

8. P. D. Sethi, Quantitative Analysis of Drugs in Pharmaceutical Formulation, 3rd Edition.

9. J. W. Munson, Pharmaceutical Analysis – Modern Methods, Part – A & B, 2001.

SYLLABUS FOR PHARMACEUTICAL ANALYSIS

BRANCH – V

PAPER – IV

QUALITY CONTROL AND QUALITY ASSURANCE

THEORY 75 Hours (3 hrs./week)

1. Concepts and Philosophy of TQM, GMP (orange guide) and ISO-9000. **5 Hours.**

2. Organisation and personnel, responsibilities, training, hygiene. **3 Hours.**

3. Premises : **4 Hours.**

Location, Design, Plan Layout, Construction, Maintenance and Sanitations. Environmental control, Sterile areas, control of contamination.

4. Equipments : **4 Hours.**

Selection, purchase specifications, maintenance, sterilization of an area (TP & STP)

5. Raw Materials : **3 Hours.**

Purchase specifications, Maintenance of stores, Selection of vendors, Controls on Raw materials.

6. Manufacture and controls on dosage forms : **5 Hours.**

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, sterilisation, membrane filtration etc. **4 Hours.**

8. Packaging and labeling controls, line clearance, reconciliation of labels; cartons and other packaging material; types and tests assuring quality of glass. Types of plastics used, permeation, leaching, sorption, chemical reactions, biological tests, modification of plastics by drugs; Different types of closures and closure liners; film wrapper; Blister packs, Bubble packs, shrink handling; foil / plastic pouches, bottle seals, tape seals, breakable seals and sealed tubes; Quality control of packaging material and filling equipment. **9 Hours.**

9. Quality control Laboratory : **7 Hours.**

Responsibilities, Good Laboratory Practices, Routine controls, Instruments, Protocols, Non-clinical testing, Controls on animal house, Application of Computers in Quality control laboratory.

10. Finished product release : **3 Hours.**

Quality review, Quality audits, Batch release document.

11. Warehousing : **2 Hours.**

Good warehousing practice, Materials, Managements.

12. Distribution : **3 Hours.**

Distribution of records, Handling of returned goods, Recovered materials and Reprocessing.

13. Complaints and Recalls : **2 hours.**

Evaluation of complaints, Recall procedures, Related records and documents.

14. Waste disposal, Scrap disposal procedure and records. **2 Hours.**

15. Regulatory aspects of Pharmaceuticals and Bulk drug Manufacturing, Regulatory drug analysis. **3 Hours.**

16. Loan License Auditing – Concepts, Auditing. **3 Hours.**

17. Recent Amendments to drugs and cosmetics act and other relevant rules, Consumer protection, Environmental protection act, Certification and Licensing procedure.

5 Hours.

18. WHO Certification, Globalisation of Drug Industry, Introduction to Export of Drugs and Import Policy **4 Hours.**

19. Patent regimen. **2 Hours.**

20. Regulatory affairs: FDA, UKMCA and TGA. **2 Hours.**

PRACTICALS

1. Calibration of volumetric glass wares.

2. Testing containers, closures, liners, glass, plastics used for packing.

3. Test of packaging materials, cartons, aluminium foils, strip packing, blister packing, ampoules, vials, etc.

4. Sterility testing of areas.

5. Testing of related substances and foreign substances in raw materials as per I.P.

6. Assay for the raw materials, calculated either on anhydrous or hydrous basis as per I.P.

7. Estimation of the Acid value, Iodine value, Ester value, Saponification value for the raw materials as per I.P.

8. Microbiological evaluation of waste water.

REFERENCES

1. Quality Assurance Guide by Organisation of Pharmaceutical products of India.

2. Good Laboratory Practice Regulations, 2nd Edition, Sandy Weinberg, Vo. 69, Decker Series.

3. Quality Assurance of Pharmaceuticals – A compendium of guidelines and related materials – Vol. I – WHO Publications.

4. A guide to Total Quality Management – Kaushik Maitra and Sedhan K.Ghosh.

5. How to practice GMPs – P. P. Sharma.

6. ISO 9000 and Total Quality Management – Sadhank. G. Ghosh.

7. The International Pharmacopoeia Vol. 1,2,3,4 - 3rd Edition, General Methods of Analysis and Quality specification for Pharmaceutical Substances, Excipients and Dosage forms.

8. Controller of Publication, Govt. of India - Indian Pharmacopeia, Vol. I and II - 1996. 9.
9. Burn, Finiey and Godwin : Biological Standardisation, 2nd Edition, Oxford University Press, London.

10. Dr. A. Patani : The Drugs and Cosmetics Act 1940, Eastern Book Company, Lucknow.

SYLLABUS FOR PHARMACEUTICAL BIOTECHNOLOGY
Branch – VI

General:-

After completing Post graduation in Pharmaceutical Biotechnology the student should be able to:

- Handle different types of microorganisms like Bacteria, Fungi and Viruses employing strict aseptic techniques including learning the safe modes of culture disposal.
- To identify pathogenic microbes based on microscopic, cultural, biochemical characteristics and using other advanced techniques including gene manipulation, isolation of DNA, sequencing and identification of resistance in clinical isolates.
- To identify, isolate, produce and characterize Pharmaceuticals like antibiotics, vitamins, amino acids, biopolymers, biosurfactants, enzymes etc. that is produced naturally by microbes.
- Screen natural and synthetic compounds for antimicrobial activity against bacteria, viruses and fungi including qualitative and quantitative studies like MIC & MBC determination, drug synergism and antagonism.
- Carry out official microbial techniques like antibiotic and vitamin assays, microbiology of food, water, air and microbial contamination (load) in pharmaceuticals & excipients, sterility testing of pharmaceuticals, quality control test for biopharmaceuticals.
- Employ concept of Immobilization of enzymes and whole cells and use them in bioconversions of pharmaceutical importance.
- Study the immunomodulating activity of pharmaceuticals using basic immunological techniques like estimation of cytokines, production of antibodies, T cell rosette formation, phagocytosis assay and cytotoxicity studies. Expertise in Immunodiagnostic tests like ELISA and other tests based on antigen - antibody reactions.
- Teach and practice confidently basic concepts and advance techniques of Pharmaceutical Biotechnology and apply them in the development of pharmacy.

SYLLABUS FOR PHARMACEUTICAL BIOTECHNOLOGY
BRANCH – VI
PHARMACEUTICAL-BIOTECHNOLOGY
PAPER – II
PHARMACEUTICAL ASPECTS OF MICROBIAL AND CELLULAR BIOLOGY

THEORY 75 Hours(3 Hrs./week)

1. Bacteria, Fungi and viruses: 16Hours
Structure, chemistry and Morphology, Cultural, physiological and Reproductive features, Methods of isolation, Cultivation and Maintenance, Nomenclature, General classification. Molecular and Genotype taxonomy. Industrially important microorganisms including Actinomycetes with examples and uses

2 8 Hours
(a) Basic aspects of cell regulation. (b) Bio-energetics and Metabolism- biochemical mechanisms of generating ATP; Fuelling reactions of aerobic and anaerobic organisms (c) Secondary metabolism and its applications.

3. Nucleic acids, the genetic code and protein synthesis 10 Hours
(a) Synthesis of DNA- polymerization of nucleotides into DNA-Basic chemical structure, replication and its role in protein synthesis. c) Synthesis of proteins- the roles of RNA in Translation (mRNA,tRNA rRNA).

4. Manipulating cells in culture 12 Hours
(a) Growth of micro organisms in culture pertaining to Bacteria: Principles of microbial nutrition: physical and chemical environment of microbial growth; Batch, continuous and synchronous cultures; Stability and degeneration of microbial cultures.(b) Growth of animal cells in culture; General procedures for cell culture; nutrient composition; primary established and transformed cell cultures; applications of cell culture in pharmaceutical industry and research.(c) Growth of viruses in culture; propagation and enumeration; application of above techniques for antiviral screening.

5. Microbial Genetics 15 Hours
(a)Genetic organization of prokaryotic and eukaryotic cells; mutagenesis and repair mechanisms; types of mutants; application of mutagenesis in strain improvement; gene mapping of plasmids – types, purification, transfer and applications, (b) Transformation, conjugation Tranduction. (c) Phage genetics- gene organization, phage mutation and lysogeny.

6. Immunology: 7 Hours
Cellular basis for immune response, immunity to viruses, bacteria and fungi, immuno-deficiency diseases, hypersensitivity reactions and auto-immune diseases. Immunisation-Active and Passive.

7.Microbial pathology and chemotherapy: 7 Hours

Identifying features of pathogenic bacteria, viruses and fungi, mechanism of microbial pathogenecity, etiology and pathology of common microbial diseases, currently recommended therapies for common bacterial, fungal and viral infection, mechanism of action of anti-microbial agents and possible sites for chemotherapy.

PRACTICALS

1. Fumigation of aseptic area and air sampling
2. Morphological study, isolation and characterization of some bacteria and fungi.
3. Methods of preservation of culture
4. Isolation and primary screening of streptomyces
5. Qualitative analysis of potable water
6. Estimation of microbial load in pharmaceutical excipients and materials as per official pharmacopoeia
7. Construction of UV survival curve and demonstration of dark repair mechanism
8. Preparation ad maintenance of primary cell culture and cell lines.
9. Enumeration of viruses by titration and plaque assay
10. Determination of cytotoxicity and screening for anti-viral activity of some natural and synthetic products.
11. Induction of mutation, isolation of antibiotic resistant and auxotropic mutants adopting replica plating technique.
12. Isolation of specialized transducing phage
13. Animal immunization – inoculation, breeding and antigen-antibody reactions by haemaggulutination – inhibition, neutralization and precipitin reactions.
14. Standardization of inoculum and estimation of MIC by serial dilution and gradient- plate technique.
15. Qualitative and quantitative analysis of anti-microbial agents by ditch plate method and extinction methods (RWC test).

16. Microbial sensitivity of some human pathogenic isolates against various antibiotics.

REFERENCES

1. General Microbiology:R.Y.Stainer.
2. Essentials and applications of microbiology: Judy Kandal
3. Microbiology:Pelczar,Reid and Chan
4. Genetics of Antibiotic producing Microorganisms: G.Sermonti
5. Microbial Genetics:David Freifelder
6. Topley & Wilson:Volumes I to IV
7. Genes V and VI: Lewin Benjamin
8. Virology: Fields
9. Animal cell culture: Ian Frshney
10. Immunology: Weir
11. Immunology: Ivan Roitt, Johnathan Bronstoff, David Male
12. Medical Microbiology: Mackie and McCartney.
13. The Actinomycetes: Waksman SA.

SYLLABUS FOR PHARMACEUTICAL BIOTECHNOLOGY
BRANCH-VI
PAPER – III
BIOPROCESS TECHNOLOGY

THEORY 75 Hours(3 hrs./week)

1. Basic principles in fermentation **8 Hours**
2. Isolation, screening and application of industrially important microbes- primary and secondary screening, maintenance of stock cultures, strain improvement for increased yield.

   6 Hours

3. **(**a)Detailed study of the design and operation of bioreactor, ancillary parts and functions; impeller design & agitation power requirements; on line measurement and control of dissolved oxygen,, carbon-di-oxide, temperature, pH and foam (b) types of reactors – CSTR, tower, air-lift, bubble-column, packed bed, hollow fiber-configuration and applications. **6 Hours**

4. Mass transfer-theory, diffusional resistance to oxygen transfer, oxygen requirements of micro organism, measurement of mass transfer coefficient and factors affecting them; effects of aeration and agitation on mass transfer, supply of air, air compressing, cleaning and sterilization of air, air sampling and testing standards for air purity. **6 Hours**

5. Rheological properties of fermentation systems and their importance in bio-processing. **4 Hours**

6. Fermentation kinetics: Reaction kinetics: Michaelis Menten constant and Monod equation-derivations for biomass estimation; Lineweaver-Burke plot. **4 Hours**

7. Cultivation systems-closed, semi-open and open systems; graphical plot representing the above systems; use of immobilized culture systems to prepare fine chemicals. **4 Hours**

8. Scale up of fermentation process-principles, theoretical considerations and techniques used; fermentation media. HTST sterilization-advantages and disadvantages, liquid sterilization techniques; Thermal death kinetics. **4 Hours**

9. Downstream processing: Theory, equipment design and operation, methods, filtration, solvent extraction, chromatographic separation, crystallization, turbidity analysis and cell yield determination metabolic response assay, enzymatic assay, bio-autography, techniques for disruption of cells for product recovery. **6 Hours**

10. Bioprocessing of the following industrially important microbial metabolites:

15 Hours

Organic solvent	: Alcohol
Organic acids	: Citric acid and lactic acid
Antibiotics	: Penicillin, Streptomycin, Griseofulvin, Cephalosporins, Amphotericin B, Rifampicin, Mitomycin-C.
Vitamins	: Vit - B12 and Riboflavin
Aminoacids	: Glutamic acid and Lysine
Nucleotides	: Cyclic AMP & GMP

11. Biosynthetic pathways for some secondary metabolites, microbial transformation of steroids and alkaloids.

6 Hours

12. Computer control of fermentation processes: System configuration and applications. **4 Hours**

13. Regulations governing the manufacturing of biological products **2 Hours**

PRACTICALS

1. Isolation and secondary screening of industrially important microorganisms.
2. Strain improvement (for increased yield) by stress inducers.
3. Preparation, calibration and standardization of a bioreactor.
4. Power calculations, KLa determinations and MTR calculations of a typical bioprocess.
5. Construction of growth curve and determination of specific growth rate and doubling time.
6. Biomass estimation by monitoring protein synthesis and sugar depletion.
7. Enzyme kinetic study
    a. Effect of metal ion concentration
    b. Effect of pH
    c. Effect of temperature
    d. Effect of varying substrate concentration
    e. Kinetic parameter calculations
8. Protein separation by aqueous two-phase partitioning.
9. Fermentation process of alcohol and wine production
10. Fermentation of vitamins and antibiotics.

11. Whole cell immobilization engineering
    a. Using various polymers
    b. Study of physical characteristics
    c. Comparison of efficacy of immobilized and free cells
12. Down stream processing
    a. Methods of cell disruption
    b. Typical isolation process for antibiotics
    c. Purification by chromatographic techniques
13. Microbiological assay of antibiotics
14. Thermal death kinetics of bacteria and its applications

REFERENCES

1. Industrial Microbiology: L.E. Casida
2. Industrial Microbiology: B.M. Miller and W. Litsky
3. Microbial Technology Vol I & II :H. Peppler
4. Industrial Biotechnology: Vedpal S Malik and Padma Sridhar
5. Biochemistry of Industrial Microorganisms, C Rainbow and AH Rose
6. Biochemical Engineering: F.C. Webb
7. Biochemical Engineering; R. Steel
8. Biochemical Engineering Fundamentals: Bailey and Ollis
9. Current protocols in molecular biology, Vol I & II:F.M Asubel, Wiley publishers.
10. Biotechnology of antibiotics and other bioactive microbial metabolites: Gianeario Lancini and Rolando Lorenzetti.
11. Biological reaction engineering: I J Dunn, E. Heinzle, J Ingham, J.E. Prensil.
12. Bioreactor design and product yield: Butterworth and Heinemann
13. Enzyme assays- a practical approach; Robert Eisenthal and Michael J Danson.
14. Fermentation and biochemical engineering handbook: Henry C Vogel
15. Principles of Fermentation technology – P.F.Stanbury

SYLLABUS FOR PHARMACEUTICAL BIOTECHNOLOGY
BRANCH-VI
PAPER - IV
ADVANCES IN PHARMACEUTICAL BIOTECHNOLOGY
THEORY 75 Hours(3 hrs./week)

1.Enzyme Technology **8 Hours**

a) Classification, general properties of enzymes, dynamics of enzymatic activity, sources of enzymes, extraction and purification: Applications pharmaceutical, therapeutic and clinical. Production of amyloglucosidase, glucose isomerase, amylase and trypsin.
b) Techniques of immobilisation of enzymes and their applications in the industry. Reactors for immobilized systems and perspective of enzyme engineering. **5 Hours**

2. Animal Biotechnology:

a) **Genetic engineering:** Techniques of gene manipulation, cloning strategies, procedures, cloning vectors expression vectors, recombinant selection and screening, expression in E.coli and yeast. **8 Hours**
b) Site directed mutagenesis, polymerase chain reaction, and analysis of DNA sequences. **6 Hours**
c) Gene library and cDNA **2 Hours**
d) Applications of the above technique in the production of **6 Hours**
   I- Regulatory proteins interferon, interleukins etc.
   II- Blood products-Erythropoietin
   III- Vaccines-Hepatitis-B,
   IV- Hormones-Insulin
e) Study on controlled and site specified delivery of therapeutic peptides and proteins through various routes of administration. **3 Hours**
f) Production of useful proteins in transgenic animals and gene therapy. **3 Hours**
g) Signal transduction, oncogenes and their proteins. **4 Hours**
h) The human genome project-a brief study. **4 Hours**
i) Human chromosome – Structure and classification; chromosomal abnormalities – Syndromes. **2 Hours**

3. Immuno Biotechnology

a) Hybridoma technology-fusion methods for myeloma cells and B-Lymphocytes, selection and screening techniques. Production and purification of monoclonal antibodies and their application in clinical diagnosis, immunotherapy and pharmaceutical research. **4 Hours**
b) Immuno-diagnosis of infectious diseases. **2 Hours**
c) Vaccinology – Immuno potentiation, adjuvants, living and non-living antigen, newer delivery systems and naked DNA vaccines. New and improved vaccines against Hepatitis-A, Malaria Typhoid, Experimental HIV-1 vaccines. **6 Hours**

4. Microbial biotechnology:

Biotransformation for the synthesis of chiral drugs and steroids. Biodegradation of xenobiotics, chemical and industrial wastes. Production of single-cell protein.**6 Hours**

5.Bio-informatics and Biostatistics:

Information theory and biology, redundancy. Networking: Network access, internet and E-mail servers, use of Databases in biology sequence databases for comparisons. **3 Hours**

6. Basic statistics:

Mean, median & mode standard deviation and standard errors, simple linear regression, basic of significance test, hypothesis test, levels of significance, student 't' 'chi' square and goodness of fit. **3 Hours**

PRACTICALS

1. Production of extra-cellular enzymes from microbial sources and downstream processing.
    a) Ammonium sulphate precipitation
    b) Dialysis
    c) Size exclusion chromatography
    d) Affinity chromatography
2. Estimation of some microbial enzyme and quantification in terms of total protein by Lowry method.
3. Isolation of plasmid DNA-Miniprep and estimation of DNA
4. Isolation of RNA from microbial sources and its estimation
5. DNA cloning with different expression vectors and agarose electrophoretic analysis.
6. Transformation techniques with different antibiotic resistance markers.
7. Southern blotting with radioactive and non-radioactive probes
8. Northern blotting technique
9. Qualitative analysis of proteins & Estimation of molecular weight of proteins by PAGE techniques
10. Enzyme-linked immunosorbant assay and western blotting techniques.
11. Hybridoma techniques: Fusion of myeloma and lymphocytes, screening methods and raising Monoclonal antibodies and purification.
12. Development of suitable delivery system for anti-tumour agents, newer vaccines and therapeutic proteins and peptides for site-specific delivery.

REFERENCES

1. Biotechnology-The biological principles: MD Trevan, S Boffey, KH Goulding and P.F. Stanbury.
2. Immobilization of cells and enzymes: Hosevear Kennady cabral & Bicker staff
3. Principles of Gene Manipulating: RW Old and S.B.Primrose.
4. Molecular Cell Biology: Harvey Lodish, David Baltimore, Arnold Berk, S Lawence Zipursky, Paul Matsudaira, James Darnell.
5. Modern Biotechnology: S.B Primrose
6. Immunology: Ivan Roitt, Jonathan Brostoff and David Male
7. Gene transfer and expression protocols-methods in Molecular Biology, vol. VII, Edit E.T. Murray
8. Current protocols in Molecular Biology, Vo1.I & II:F.M. Asubel, John wiley Publishers
9. Current protocols in cellular biology, Vo1.1 & II John wiley publishers.
10. Cell Biology, Vo1,II & III Edited by Julio E Celis.
11. Genetics in medicine, by James Scott Thomson, Margaret Wilson Thompson. Published by Saunders 1986.
12. Principles of human genetics; by Curt Stern, published by W.H. Freeman, 1960.

SYLLABUS FOR PHARMACY PRACTICE COURSE

BRANCH - VII

General :-

After completing the post graduate pharmacy practice course, the student should be able to:

- Understand the pathophysiology of specific diseases.
- Recognize the signs, symptoms and laboratory tests, abnormalities associated with each of the disease state.
- Able to suggest appropriate drug therapy with the knowledge of Biopharmaceutics and pharmacokinetics.
- Able to comment on drug interaction and adverse drug reaction.
- Able to suggest alternative therapy in such cases and also when therapy fails.
- Organize pharmacy services at hospitals.
- Provide healthcare services and patient counselling.
- Provide unbiased drug information to health care professionals.
- Teach confidently pathophysiology, pharmacy practice, clinical pharmacy and pharmacology subjects at undergraduate and diploma programmes in pharmacy.

SYLLABUS FOR PHARMACY PRACTICE

BRANCH – VII

PAPER II

PHARMACO THERAPEUTICS

THEORY 75 Hours(3 hrs./week)

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, Endocarditis, 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.**

Various types of Anaemia, Drug induced haematological disorders

5. Immunology **5 Hours.**

Immune disease – pathogenesis, mechanism of action of immunosuppressive agents.

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, Alzheimer's disease

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,Acne, Syphilis and Gonorrhoea.

13. Oncology **5 Hours.**

Basic principles of cancer chemotherapy with special emphasis on chemotherapeutic regimen in the management of cancer.

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.

TEXT BOOKS

1. Clinical Pharmacy and therapeutics- Roger and Walker, Churchill Livingstone publication.

2. Pharmacotherapy : A Patho-physiological approach- Joseph T. Dipiro et al. Appleton and Lange.

REFERENCE BOOKS

1. Pathologic basis of diseases-Robins SL, W.B.Saunders publication.

2. Pathology and therapeutics for pharmacists: a basis for clinical Pharmacy Practice.

Green and Harris, Chapman and Hall Publication.

3. Clinical Pharmacy and therapeutics- Eric T Herfindal, Williams and Wilkins Publication.

4. Applied Therapeutics: the clinical use of drugs. Lloyd Young and Koda-Kimble MA [ISBN 0-333-65881-7].

5. Avery's drug treatment, 4th Edn, 1997, Adis international Limited.

6. Relevant review articles from recent medical and pharmaceutical literature.

PRACTICALS

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) Degenerative joint disease – Temporal arthritis, Polymyalgia rheumatica etc., d) Systemic lupus erythmatosis.

4. Respiratory medicine

a) Asthma, b) Congestive obstructive airways disease (COAD), c) Acute respiratory failure, d) respiratory tract infections, e) Interstitial lung disease f) Respiratory aids.

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, h) Febrile

neutropenia.

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) Syndrome of inappropriate anti-diuretic hormone secretion e) Adrenal disorders.

14. Dermatology

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

15. Neurology

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.

Assignments:

The students are required to submit a minimum of three written assignments (1500 to 2000 words) selected from the topics on different disease conditions given to them. The students are required to discuss both the clinical and therapeutic aspects in the same.

TEXT BOOKS

1. Clinical Pharmacy and therapeutics- Roger and Walker, Churchill Livingstone publication.

2. Pharmacotherapy: A Patho-physiological approach - Joseph T. Dipiro et al. Appleton and Lange.

REFERENCE BOOKS

1. Pathologic basis of diseases-Robins SL, W.B. Saunders publication.

2. Pathology and therapeutics for pharmacists: a basis for clinical Pharmacy Practice. Green and Harris, Chapman and Hall Publication.

3. Clinical Pharmacy and therapeutics- Eric T. Herfindal, Williams and Wilkins Publication.

4. Applied Therapeutics: The clinical use of drugs. Lloyd Young and Koda-Kimble MA[ISBN 0-333- 65881 – 7].

5. Avery's drug treatment, 4th Edn, 1997, Adis international Limited.

6. Relevant review articles from recent medical and pharmaceutical literature.

JOURNALS

1. British Medical Journal.

2. New England Journal of Medicine.

3. Annals of Pharmacotherapy.

4. Lancet.

SYLLABUS FOR PHARMACY PRACTICE

BRANCH – VII

PAPER - III

HOSPITAL AND COMMUNITY PHARMACY

THEORY 75 Hours(3 hrs./week)

I. COMMUNITY PHARMACY 18 hours.

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. Patient information leaflets.

II. COMMUNICATION SKILLS 3 Hours.

Principal and elements of communication skills, non verbal communication in pharmacy, barriers in communication, listening skills, questioning skills, explaining skills and ethics in communication.

III. HOSPITAL PHARMACY 22 Hours.

1. The role of hospital pharmacy department and its relationship to other hospital departments and staff.

2. Pharmacy and Therapeutics Committee:

Selection of drugs, Hospital formulary development and management, Assessing drug efficacy, Assessing and managing drug safety, evaluating the cost of pharmaceuticals, identifying and addressing drug use problems including standard treatment guidelines.

Other hospital committees such as infection control committee and research & ethics committee.

3. Hospital pharmacy management

Staff (professional and non-professional), Materials (drugs, non-drugs, consumables), Financial (drug budget, cost centres, sources of revenue, revenue collection), Policy and Planning, Infrastructure requirements (building, furniture and fittings, specialised equipment, maintenance and repairs), Workload statistics.

4. Hospital Pharmacy Services

Purchasing, storage, stability and safety of drugs, drug distribution, Radiopharmaceuticals, IV additive services and total parentral nutrition.

IV. PHARMACOEPIDEMIOLOGY **5 Hours.**

 Definitions and scope.

 Methods [qualitative, quantitative and Meta-analysis models].

 System for monitoring drug effects.

 Advantages and disadvantages of pharmacoepidemiology.

V. PHARMACOECONOMICS **4 Hours.**

Definitions and scope, types of economic evaluation, cost models and cost

effectiveness analysis.

VI. PUBLIC HEALTH POLICY AND HEALTH CARE SYSTEM **2 Hours.**

VII. CONCEPT OF RATIONAL USE OF DRUGS **5 Hours.**

 Importance of rational drug use.

 Pharmacists role.

 Drug use indicators.

 Guidelines for rational prescribing.

VIII. EVIDENCE BASED MEDICINE **7 Hours.**

 Formulating clinical questions.

 Searching for the best evidence.

 Critical appraisal of the evidence.

 Applying evidence to patients.

 Evaluation.

IX. EDUCATION AND TRAINING 4 Hours.

Training of technical staff, training and continuing education for pharmacists, pharmacy students, medical staff and students, nursing staff and students, formal and informal meetings and lecturers, drug and therapeutics newsletter Ethical issues in biomedical research – Principles of ethics in biomedical research, good clinical practice [ICH GCP guidelines], Ethical committee [institutional review board], its constitution and functions, ethics of publication.

X. MEDICATION ERROR AND MEDICATION ADHERENCE 5 Hours.

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.

PRACTICALS

The student is expected to perform ABC and VED analysis on the given data on drugs used in the hospital, participate in activity session involving issues regarding pharmacy and therapeutic committee, prepare a model monograph for a drug formulary, critically analyse the given data on hospital pharmacy budget, work flow patterns etc., perform patient medication interview and counselling and present drug profiles one new drugs.

ASSIGNMENTS

The student is expected to perform the following and report.

 Comparison of prescription handling in two community pharmacies.

 Audit of OTC sales over a 24 hour period in a local community pharmacy].

 Role of community pharmacists in health education, family planning, first aid, smoking cessation screening programmes, immunisation, etc.

 Code of ethics for community pharmacies.

 Summary of the advice and recommendations which should be provided to the customers at a community pharmacy.

 Select a new drug, which has recently been marketed in India for the first time. Prepare a report for a hospital's Drug and Therapeutic Committee, and make a case either for or against the addition of this new drug on to the hospital's formulary. Issues, which you may need to cover, include the drug's pharmacology, its clinical use, the opinions of relevant hospital consultants and a cost comparison with existing therapies for the same condition for which the new drug is indicated.

 Examine and report on the drug distribution methods used in a local hospital .

 Examine and report on the purchase and inventory of drugs in a local hospital.

REFERENCES

1. Hospital Pharmacy - Hassan WE. Leac and Febiger publication.

2. Textbook of hospital pharmacy - Allwood MC and Blackwell.

3. Avery's Drug Treatment, 4th Edn, 1997, Adis international limited.

4. Evidence based medicine: How to practice and teach EBM. Sharon E Straus III Edition Churchill Livingston.

JOURNALS

1. Hospital Pharmacist, UK.

2. Indian Journal of Hospital Pharmacy.

SYLLABUS FOR PHARMACY PRACTICE

BRANCH – VII

PAPER – IV

CLINICAL PHARMACY

THEORY 75 Hours(3 hrs./week)

INTRODUCTION TO CLINICAL PHARMACY

• Definition, development and scope **1 Hour.**

PATIENT DATA ANALYSIS **16 Hours.**

• The patient's case history, its structure and use in evaluation of drug therapy, presentation of cases.

• Communication skills including patient medication history interview, patient counselling, teaching skills.

• Understanding common medical abbreviations and terminologies used in clinical practices.

• Haematological, Liver function, Renal function, Tests associated with cardiac disorders.

• Fluid and electrolyte balance, Common tests in urine, sputum, faeces, CSF.

• Sensitivity screening for common pathogenic micro-organisms, its significance, resistance in disease states and selection of appropriate anti-microbial regimens.

DRUGS & POISONS INFORMATION **11 Hours.**

• Introduction to information resources available.

• Systematic approach in answering drug information queries.

• Critical evaluation of drug information and literature.

• Preparation of written and verbal reports.

• Establishing a Drug Information Centre.

• Poisons information-organisation and information resources.

• Poisons management in drug dependence and drug abuse (opiates, cocaine, amphetamines, alcohols, benzodiazepines, barbiturates, tobacco). Role of emetics, anti-emetics and respiratory stimulants.

DAILY ACTIVITIES OF CLINICAL PHARMACISTS **16 Hours.**

• Drug therapy monitoring (Medication chart view, clinical review, TDM, pharmacist interventions).

• Ward round participation.

• Adverse drug reaction - Epidemiology, Classification, Risk factors, Monitoring and detecting adverse drug reactions, Assessing causality, Reporting adverse drug reactions.

• Pharmaceutical care.

• Drug utilisation evaluation (DUE) and review (DUR).

• Quality assurance of clinical pharmacy services.

NUTRITION **3 Hours.**

• Malnutrition and deficiency states.

• Enteral and parentral nutrition.

RESEARCH DESIGN AND CONDUCT OF CLINICAL TRIALS **12 Hours.**

• Research support including planning and execution of clinical trials.

• Guidelines for good clinical research practice and ethical requirements.

- GCP – ICH Guidelines

• Various phases of clinical trials.

• Categories of Phase IV studies.

• Monitoring and auditing of clinical trials.

• Design and execution of trials in different clinical settings.

CLINICAL PHARMACOKINETICS **16 Hours.**

• 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 paediatric patients.

• Therapeutic drug monitoring.

PRACTICALS

• The students should be trained in the following aspects of services provided at the hospital and should be assessed for their performance on the same. The students are required to submit a record of activities (1-5) performed, which includes the strategies used.

• Patient Medication Interviews (3).

• Answering Drug Information Queries (4).

• Patient Medication Counselling (3).

• Literature Evaluation (2).

• Therapeutic Drug Monitoring.

• Problem solving in Clinical Pharmacokinetics (2).

• Ward Round Participation.

• Medication order review (2).

• Detection and assessment of adverse drug reactions and their documentation (3).

Assignments:

The students are required to submit atleast three assignments selected from the topics given to them.

1. Drug information.

2. Patient medication history interview.

3. Patient medication counseling.

4. Problem solving in Clinical Pharmacokinetics.

5. Literature evaluation pertaining to Therapeutic drug monitoring.

6. Critical appraisal of recently published articles in the biomedical literature which deals with a drug or therapeutic issue.

7. Case studies related to laboratory investigations covering the topics dealt in theory class.

REFERENCES

1. Basic skills in interpreting laboratory data – Scott LT, American Society of Health System Pharmacists, Inc., USA.

2. Practice Standards and Definitions – The Society of Hospital Pharmacists of Australia, 1997.

3. Clinical Pharmacokinetics – Rowland and Tozer, Williams and Wilkins Publication.

4. Biopharmaceutics and Applied Pharmacokinetics – Leon Shargel, Prentice Hall publication.

5. Relevant review articles from recent medical and pharmaceutical literature.

JOURNALS

1. Pharmaceutical Journal. Royal Pharmaceutical Society, London.

2. Therapeutic Drug Monitoring.

3. European Journal of Clinical Pharmacology.

4. Indian Journal of Medical Research.

5. Journal of Pharmacy Practice and Research, Society of Hospital Pharmacists of Australia.

6. International Journal of Pharmacy Practice, UK.

7. Hospital Pharmacist, UK.

8. Indian Journal of Hospital Pharmacy.