

1. PHARMACEUTICAL ANALYSIS AND QUALITY ASSURANCE

FIRST SEMESTER

Course Nos. 1101, 2101, 3101, 4101, 5101, 6101, 7101, 8101, 9101, 10101 and 11101

Course Nos. 1101 BIostatistics (THEORY)

(Common paper for all specialisations)

LEARNING OBJECTIVES:

Learning this subject must help the student

1. To perform easily the calculations involved in all the statistical procedures, to properly understand all the concepts involved in testing of hypothesis and experimental design.
2. To apply the knowledge gained through this subject in the design, data collection and analysis involved in his/her research project in second year M.Pharm.
3. To interpret properly the experimental data in an industry or research setting in his/her future career and to take decisions in a more scientific manner.

UNIT I Introduction to biostatistics and applications of biostatistics in pharmaceutical and medical research. Tests of significance: Testing hypotheses- principle and applications of Z, t test and F tests. **8 hours**

UNIT II Analysis of Variance: 1-way, 2-way and 3-way classification. **8 hours**

UNIT III Non-parametric tests: Chi square test, sign test, Wilcoxon signed rank test, Wilcoxon rank sum test, Kruskal Wallis test, run test and median tests. **8 hours**

UNIT IV Design of Experiments: Principles of randomization, replication and local control; CRD, RBD, LSD - their applications and analysis of data. **8 hours**

UNIT V Factorial Experiments-Principles and applications; Use of software such as design expert and origin in the design of experiment **8 hours**

UNIT VI Probit analysis-Dose-effect relationships, calculation of LD₅₀, ED₅₀ **8 hours**

UNIT VII Regression and correlation: Method of least squares, Correlation Coefficient, rank correlation and multiple regression. **8 hours**

UNIT VIII Optimization Techniques: Basic principles and advantages of optimization, Optimization using factorial design, the simplex lattice and sequential optimization. **8 hours**

REFERENCE BOOKS

1. Statistics (Theory, Methods & Application) by D.C. Sancheti and V.K. Kapoor ; Sultan Chand & Sons; Educational Publishers, New Delhi
2. Comprehensive Statistical Methods by P.N. Arora, Sumeeth Arora and S.Arora;S.Chand Publication
3. Biostatistics- An Introductory Text by Avram Goldstein; The Macmillan Company, New York
4. Pharmaceutical Statistics Practical and Clinical Applications by Stanford Bolton, Charles Bon; Marcel Dekker Inc.

Course No. 1102 ADVANCED PHARMACEUTICAL ANALYSIS I (THEORY)

LEARNING OBJECTIVES:

This subject is aimed

1. To train students in advanced qualitative and quantitative aspects of different spectroscopic methods and separation techniques.
2. After learning this subject the student must be able to apply these concepts in various steps like sample preparation, routine quality control analysis, development and validation of analytical methods useful in pharmaceutical industry.

UNIT I

UV-Visible & Derivative Spectroscopy

Brief review of electromagnetic spectrum, UV-Visible range, Energy wavelength-colour relationships. Interaction of electro - magnetic radiation (UV-Vis) and matter and its effects, Chromophores and their interaction with EMR, Woodward-Fischer rule, Absorption spectra of organic compounds and complexes illustrating the phenomenon and its utilization in qualitative and quantitative studies of drugs, Beer-Lambert's law, Shifts and their interpretation (including solvent effects). Principles, Instrumentation- including sources, monochromators, detectors, preparation of calibration curves and pharmaceutical applications including assay of official compounds and formulations used in the structure determination, Multicomponent analysis, Derivative spectroscopy. Source of errors and their corrections and validation of spectrophotometric methods. Pharmaceutical Applications

Infrared Spectroscopy

Nature of Infra-red radiation, Molecular or infra-red spectra, origin of infra red spectra, vibrational energies of diatomic molecules, Interaction of IR radiation with organic molecules and effects on bonds, Brief outline of classical IR instrumentation and interpretation of spectra, including sample preparation for spectroscopy, qualitative interpretation of IR Spectra, influence of substituent's, ring size, hydrogen bonding, vibrational coupling and field effect on frequency, quantitative methods, FT-IR and applications. Recent advances in IR Spectroscopy (FT-NIR), Interpretation of IR spectra- Characteristic group frequencies of organic molecules. Pharmaceutical Applications.

9 hours

UNIT II

Fluorimetry and Phosphorimetry

Concept of Fluorescence and Phosphorescence, factors effecting Fluorescence and Phosphorescence. Quenching-Internal conversion and external conversion, relation between intensity of fluorescence and concentration, calculation of results and measurement of fluorescence, filter fluorometers, spectrofluorometers, principles, instrumentation and applications; electro-chemiluminescence, resonant ionization and laser-enhanced ionization

Atomic Emission Spectroscopy and Plasma Emission Spectroscopy

Introduction, theory of signal generation-Atomic spectra, Molecular Spectra, continuum, instrumentation-atomic emission source-Inductively Coupled Plasma (ICP), Direct Current Plasma (DCP), Microwave Induced Plasma (MIP) and capacitively coupled microwave plasma (CMP, Optical System and detectors) Pharmaceutical Applications.

7 hours

UNIT III

H¹ NMR and C¹³ NMR Spectroscopy

Nuclear spin and magnetic moment, nuclear magnetic- resonance-origin of NMR spectra, theory of NMR spectroscopy, Nuclear resonance: saturation-relaxation process in NMR, Flipping –origin of signal, factors effecting -chemical shift and spin spin splitting. Double resonance-spin spin decoupling and nuclear overhauser effect (NOE). One dimensional and two dimensional NMR spectroscopy- comparisons between one dimensional and two dimensional NMR, C¹³ NMR-natural abundance of C¹³, resolution and multiplicity FT mode, RF mode, uses of proton coupled, decoupled and off resonance decoupling techniques, deuterium substitution, chemical equivalence in peak assignment, chemical shift. Effect of

substitution on chemical shifts, position of alkanes, alkenes, alkynes and benzene spin coupling and $c^{13}\text{-H}^1$ coupling – other techniques like COSY, HETCOR, NOESY TOCSY AND ROESY. Interpretation of NMR Data. Pharmaceutical applications.

Electron Spin Resonance Spectroscopy

Introduction, factor affecting g-value, limitations of ESR, Difference between ESR and NMR, Instrumentation, electron nucleus coupling or electron nucleus interaction. Hyperfine interactions- isotopic and anisotropic coupling constants. Spin Hamiltonian, Electronic structure and hyperfine splitting-spin densities and McConnell relationship. triplet states-Zero field splitting and Kramer's degeneracy. Choice of solvents, sensitivity, quantitative analysis, applications of ESR-Study of free radicals, determination of reaction rates and mechanisms by ESR, structural determination by ESR, study of inorganic compounds, transition elements by ESR and pharmaceutical Applications. **7 hours**

UNIT IV

Mass Spectroscopy

Basic principles and instrumentation (components and their significance). Ionization techniques (FAB, MALDI, SELDI, APCI, APPI, ESI and DART). Mass analyzers [Quadrupole, Ion Trap, FT-ICR, TOF and tandem mass (MS-MS)]. High resolution mass spectroscopy. Concepts of interpretation of mass spectra: Mass spectrum, molecular ion, metastable ions, fragmentation patterns α fission, β fission. Mac Lafferty rearrangement, Retro Diels Alder rearrangement. Pharmaceutical applications.

Hyphenated techniques of Mass Spectroscopy

Hyphenated techniques-GC-MS/MS, LC-MS/MS- including recent advances in MS, fast atom bombardment mass spectroscopy; Pharmaceutical Applications.

8 hours

UNIT V

High performance liquid chromatography and Derivative methods

Theoretical principles involved in HPLC, discussion of typical equipment including pumps, columns, injection systems, detectors, packing materials and solvent systems, pharmaceutical applications, advantages and disadvantages. Precolumn and post column derivatization, detection methods, reagents for coloured and UV absorbing derivatives, reagents for UV/Visible detection, fluorimetric detection, fluorescent derivatives, electrochemical

derivatives, chiral derivatization reagents. Introduction to UPLC and pharmaceutical applications

7 hours

UNIT VI

Gas chromatography

Basic principles, instrumentation, columns, detectors, Van Deemter equation, Kovats retention index and HETP and temperature programming, qualitative and quantitative applications in Pharmacy, combination of GLC with other methods, advantages and disadvantages. Derivatization techniques – acylation, silylation, alkylation and esterification. Introduction to head space GC and pharmaceutical applications.

Super critical fluid chromatography

Introduction, theory, important properties of supercritical fluids, fluid extraction solvents, Categorization of SFC, instrumentation and pharmaceutical applications.

7 hours

UNIT VII

Ion Exchange Chromatography

Introduction, principle, theory, Cationic and Anionic exchange Columns, Instrumentation, Pharmaceutical Applications.

Vapour phase chromatography Introduction, theory, instrumentation, factors effecting the elution time and resolution power, Applications in pharmaceutical industries

Affinity chromatography Introduction, matrix, spacer arm, ligand binding, elution, ligand coupling, pre-activated matrices. Purification steps, media selection of media and buffers, sample preparation Purification of specific groups of molecules, components of an affinity medium, designing affinity media using pre-activated matrices. Sample preparation- fractional precipitation, ammonium sulphate precipitation, resolubilization of protein precipitates, buffer exchange and desalting, sample stability, sample clarification. Pharmaceutical applications.

7 hours

UNIT VIII

Optical Rotatory dispersion and Circular Dichroism: Basic principles, Instrumentation and pharmaceutical applications of ORD and CD spectroscopy

X-ray Diffraction: Bragg's Equation, concept of crystal and x-rays, Basics of crystallography, production of X-rays, instrumentation and pharmaceutical applications of XRD.

Thermal methods of analysis: Basic principles, instrumentation and pharmaceutical applications of DTA (Differential thermal analysis), DSC (Differential scanning calorimetry), TGA (Thermogravimetric analysis).

8 hours

REFERENCE BOOKS:

1. Marvin C. McMaster, "LC/MS: A practical user's guide", John Wiley and Sons, 2005
2. Marvin C. McMaster, "GC/MS: A practical user's guide", Second edition, John Wiley and Sons, 2008.
3. ManMohan Srivastava , "High performance thin layer chromatography", Springer, 2011.
4. Silverstein RM, Webster FX. Spectrometric identification of organic compounds. 6th ed., John Wiley & Sons (Asia) Pvt, Ltd., Singapore, 2005
5. Donald L. Pavia, Gary M. Lampman, George S. Kriz and James A. Vyvyan, "Introduction to spectroscopy", Fourth edition, Cengage Learning, 2009.
6. Skoog, D.A., "Principles of Instrumental Analysis", 3rd Edition, Saunders College Publishing, 1985
7. Willard, H.H., Merritt. L.L., Dean J.A., and Settle, F.A., "Instrumental Methods of Analysis", 7th Edition, CBS Publishers, 2004.
8. Wim Kok., "Capillary Electrophoresis : Instrumentation and Operation" Vol.51, Stefanie Hoffmann, 2000.

Course No. 1103 ADVANCED PHARMACEUTICAL ANALYSIS I (PRACTICAL)

1. Determination of λ max, (KMnO₄ and methylene blue solutions)
2. Assay of sulphadiazine tablets by Visible Spectrophotometry.
3. Assay of sulphadiazine tablets by UV spectrophotometry.
4. Demonstration experiments in IR spectrophotometry including interpretation of given spectra.
5. Fluorimetric estimation of quinine sulphate in formulations.
6. Fluorimetric estimation of riboflavin in formulations.
7. Flame photometric estimation of sodium ions.
8. Flame photometric estimation of potassium ions Losartan Potassium.

9. Separation of plant materials by column chromatography.
10. Separation and identification of flavonoids/sulphonamides by paper chromatography.
11. Separation and identification of sulphonamides by paper chromatography.
12. Separation and identification of amino acids by TLC methods.
13. Separation and identification of barbiturates by TLC methods.
14. Demonstration experiments in HPLC.
15. Demonstration experiments in GLC.

**Course No. 1104 VALIDATION OF INSTRUMENTAL METHODS OF ANALYSIS
(THEORY)**

LEARNING OBJECTIVES:

1. After learning this subject student should understand the scope and functional importance of documentation and validation in pharmaceutical field.
2. The student must be able to apply these concepts in various steps like development and validation of new analytical method, calibrations, validation of equipment, cleaning, sterilization and utilities; use of validation in pharmaceutical industry.

UNIT I Validation

- a. Introduction, history, definition
- b. Types of validation, prospective validation, retrospective validation, concurrent validation, revalidation
- c. Validation Master Plan **8 hours**

UNIT II Process Validation of Solid Dosage forms

- a. Process validation of low dose tablet manufacturing process
- b. Uniformity of blend (US FDA guideline) for tablets subjected to content uniformity test as per USP
- c. Process validation of compression machine giving details of control charts **8 hours**

UNIT III Sterilization Validation

- a. Process validation of terminally sterilized product. Validation of sterilization process including heat distribution, heat penetration studies, and sterility assurance level.
- b. Process validation of aseptically filled product with special emphasis on media fill test. **8 hours**

UNIT IV Cleaning Validation

- a. Validation of cleaning process.
- b. Elements of validation protocol.
- c. Determination of acceptable limits for cleaning process.
- d. Factors to consider in setting the limits.
- e. Numerical calculation of limits.

7 hours

UNIT V Utilities Validation

- a. Validation of water system- for production of demineralised (DM) water, distilled water
- b. Validation of Air handling Units- classification of environment (class 100, 10,000, 1,00,000)
- c. Performance qualification & parameter of cleanliness such as no. of airborne particles, microbes filter integrity test of HEPA filter, air velocity, air flow pattern, no. of air changes, pressure differentials etc.

8 hours

UNIT VI Analytical Method Validation

- a. Recommendation of ICH guideline- Definition of accuracy, precision, linearity, LOD, LOQ, range, robustness, ruggedness, specificity, system suitability test.
- b. USP requirement of analytical validation- different category of assays.
- c. Stability indicating methods.
- d. Bio analytical method validation

7 hours

UNIT VII Instruments calibration

- a. Analytical balance calibration.
- b. Calibration of weight box.
- c. Calibration of UV-spectrophotometer.
- d. Calibration of IR spectrophotometer.
- e. Calibration of HPLC system.
- f. Calibration of Gas Chromatography instrument.
- g. Performance check of HPLC/GC column.
- h. Out of Calibration.

8 hours

UNIT VIII Equipment Validation

- a. Definition of DQ, IQ, OQ, PQ
- b. Comparison of different types of liquid filling machines (vacuum / volumetric)
- c. Process capability of filling machines

d. Performance qualification of bottle washing/ ampoules washing machines - challenge test. **6 hours**

REFERENCE BOOKS:

1. R. Nash and Wachter, "Pharmaceutical Process Validation". Volume 129, Latest Edition. Marcel Dekker Inc., New York
2. K.L. Williams, "Microbial Contamination Control in Parenteral Manufacturing". Latest Edition. Marcel Dekker Inc., New York
3. Guidance for Industry, Sterile Drug Products Produced by Aseptic Processing — Current Good Manufacturing Practice-USFDA
4. J.T. Carstensen, C.T. Rhodes, "Drug stability: principles & Practices". Latest Edition. Marcel Dekker Inc., New York
5. www.ich.org – Q7 a guideline
6. www.fda.org
7. United State Pharmacopoeia
8. US-FDA guideline for bio-analytical studies. Dekker Inc., New York
9. It is strongly recommended that some standard book/s be used for practicals. The choice of book/s is left to the concerned teachers

**Course No. 1105 VALIDATION OF INSTRUMENTAL METHODS OF ANALYSIS
(PRACTICAL)**

LIST OF LABORATORY EXPERIMENTS:

1. Calibration of pH meter
2. Calibration of UV spectrophotometer
3. Calibration of HPLC instrument
4. Calibration of IR spectrophotometer
5. Demonstration and calibration of GC, Spectrofluorimeter, LC-MS wherever possible.

Course No.1106 Comprehensive Viva

PHARMACEUTICAL ANALYSIS AND QUALITY ASSURANCE
SECOND SEMESTER

Course Nos. 1207, 2207, 3207, 4207, 5207,6207,7207,8207,9207,10207 and 11207

Course No. 1207 MODERN ANALYTICAL TECHNIQUES (THEORY)

(Common paper for all specializations)

LEARNING OBJECTIVES:

1. This subject should train the students in advanced qualitative and quantitative aspects of different spectroscopic methods, thermal methods and separation techniques.
2. The student must be able to apply these concepts in various steps like sample preparation, characterization of excipients, structural analysis, routine quality control analysis, development and validation of analytical methods useful in pharmaceutical industry.

UNIT I UV SPECTROSCOPY

Theory – Beer and Lambert's law and its limitations – energy levels and selection rules, Woodward-Fieser, Fieser-Kuhn and Nelson rules – Influence of substituent, ring size and strain on spectral characteristics – solvent effects, stereochemical effects – Non-conjugated interactions, spectral correlation with structure – Applications of UV spectroscopy. **7 hours**

UNIT II INFRA RED SPECTROSCOPY

Molecular spectra – Origin of IR spectra – Harmonic oscillator model – Electronic band spectra – Pre-dissociation spectra – Vibrations coupling – Instrumentation – Fourier transform spectrometer – Dispersive instruments – Non-dispersive instruments – Mid-infrared absorption spectrometry – Factors influencing vibrational frequencies – Spectral regions in IR – Environmental effects – Applications of IR spectroscopy. **8 hours**

UNIT III HIGH PRESSURE LIQUID CHROMATOGRAPHY

Theory of chromatography – Principle – Instrumentation – column efficiency (theoretical plates), HETP, selectivity, resolution – tailing and fronting – Applications and recent trends in chromatography. **8 hours**

UNIT IV GAS LIQUID CHROMATOGRAPHY

Gas chromatography – Basic principle, instrumentation – selection of liquid stationary phases – Derivatization in GC – GC detectors – Applications. **7 hours**

UNIT V NUCLEAR MAGNETIC RESONANCE SPECTROSCOPY

Theory of NMR – Magnetic properties of nuclei and the spin number – Chemical equivalence – chemical shift – shielding and deshielding – Spin-Spin coupling, pascal's triangle, coupling constant – decoupling– local diamagnetic shielding – magnetic anisotropy, nuclear overhauser effect–Applications. **8 hours**

UNIT VI MASS SPECTROMETRY

Principle – reactions inside the mass spectrometer – resolution – principle of measuring of ion currents – electron impact – chemical ionization – Instrumentation and ionization methods(FAB, ESI, MALDI, FID, etc) – Plasma desorption mass spectrometry –fragmentation –rearrangements –Applications of mass spectrometry. **8 hours**

UNIT VII X RAY AND ELECTRON SPECTROSCOPY

X-ray diffraction – Bragg's law – Diffraction of X-rays – production and detection of X-rays – sample preparation – identification of powder diffraction patterns – quantitative analysis – principle, instrumentation and applications of XRD, SEM and TEM. **7 hours**

UNIT VIII THERMAL ANALYSIS

Theory – Instrumentation of TGA, DTA and DSC and its role in the characterization of drugs and excipients. **7 hours**

REFERENCE BOOKS:

1. Skoog DA, Holler FJ, Crouch SR. Principles of instrumental analysis. 6th ed., Baba Barkha Nath printers, Haryana, 2007
2. Silverstein RM, Webster FX. Spectrometric identification of organic compounds. 6th ed., John Wiley & Sons (Asia) Pvt, Ltd., Singapore, 2005
3. Willard HR, Merritt LL, Dean JA, Settle FA. Instrumental methods of analysis, 7th ed., CBS Publishers & distributors, New Delhi, 1986
4. Ewing GW. Instrumental methods of chemical analysis, 5th ed., McGraw Hill Book Company, New York, 1985
5. Schirmer RE. Modern methods of pharmaceutical analysis, Vol. I & II, 2nd ed., CRC Press, Florida, 2000
6. Whoston C. X-ray methods, John Wiley & Sons, New York, 1987
7. Lee DC, Webb M. Pharmaceutical Analysis, Blackwell publishing, Australia, 2004
8. Gurdeep R. Chatwal, Instrumental Methods of Chemical Analysis, Himalaya Publishing House, 2006.

Course Nos. 1208, 2208, 3208, 4208, 5208,6208,7208,8208,9208,10208 and 11208

**Course No. 1208 QUALITY ASSURANCE AND DRUG REGULATORY AFFAIRS
(THEORY)**

(Common paper for all specializations)

LEARNING OBJECTIVES:

On learning this subject the student must

1. Understand the concepts and procedures involved in quality assurance, GMP, and validation.
2. Be thorough in the drug development process and the drug registration process in India and in the United States of America.

UNIT I The concepts of quality assurance, GMP, TQM- Principles and objectives, process control, sources and control of quality variation, statistical quality control, in process quality control, dosage forms control, specifications.

8 hours

UNIT II GMP- A study of Schedule M of Drugs and Cosmetics Act, WHO specifications, US FDA guidelines. The study shall include special emphasis on premises, personnel, sanitation, equipment, manufacturing operations and documentation.

8 hours

UNIT III Validation: Types of validation, protocol for process validation, cleaning validation, validation of air handling, validation of equipment and facilities in sterile and non-sterile areas. Analytical method validation

8 hours

UNIT IV Ware housing for materials and products; complaints and recalls- evaluation of complaints and recall procedures; finished product release-Quality review-Quality audits- Handling of returned goods, recovered materials and reprocessing.

8 hours

UNIT V Documentation related to Product Development, standard operating procedures, standard test procedures, cleaning methods, quality control documents, batch release document, distribution records, complaints and recalls records, retention of records.

4 hours

UNIT VI Drug Regulatory Affairs: A study of the Drugs and Cosmetics Act with relevance to new drug development and approval; Part 10A of the Act Schedule Y and the Appendices I, II,

III, IV and V. Intellectual Property Rights, Patents, and non-infringing patents. Guidelines for Bioavailability and Bioequivalence studies as per Central Drugs Standard Control Organization (CDCSO, Govt. of India).

12 hours

UNIT VII New Drug Approval Process – Investigational New Drug (IND)- New Drug Application (NDA) – Abbreviated New Drug Applications (ANDA), Hatch-Waxman Act.

4 hours

UNIT VIII ICH for technical requirements for registration of biopharmaceuticals for human use- History and constitution of ICH, ICH guidelines relating to quality, safety, efficacy and multi disciplinary topics and detailed study of

Q1-Stability testing of new drug substances and products

Q3- Impurities in new drug substances and new drug products

S3- Toxicokinetics and Pharmacokinetics

S7- Pharmacology studies

12 hours

REFERENCE BOOKS:

1. Leon Lachman, H. A. Lieberman & J. L. Kanig : “The Theory and Practice of Industrial Pharmacy”, 3rd edition, Varghese Publishing House, Bombay, 1991.
2. Quality Assurance of Pharmaceuticals Vol. I and Vol. II published by Pharma book syndicate.
3. Lachman/Lieberman’s The Theory and Practice of Industrial Pharmacy, Fourth Edition, Editors, Roop K khar, SP Vyas, Farhan J Ahmad and Gaurav K Jain, CBS Publishers and Distributors Pvt. Ltd.
4. Pharmaceutical Product development by N. K. Jain, CBS Publishers and distributors Pvt. Ltd.
5. Law relating to Drugs & Cosmetics by Vijay Malik, Eastern Book Company.

Course No.1209 BIO-ANALYTICAL METHODS (THEORY)

LEARNING OBJECTIVES:

This course is aimed

1. To train students in qualitative and quantitative analysis of drugs and endogenous substances in biological samples.
2. To acquaint the student about the applications of bio-analytical methods in pharmacokinetics, toxicokinetics and bioequivalence.

The student must be able to apply these concepts in various steps like bioassays of drugs, clinical trials, therapeutic drug monitoring, and routine quality control analysis in pharmaceutical industry.

UNIT I PRINCIPLES OF BIOLOGICAL STANDARDIZATION

Methods of biological assay, Principles of biological assays with certain examples as per IP and BP. Development of new bioassay methods. Alternatives to animal screening procedures: Cell-Line, Patch-Clamp Techniques, In-Vitro Models, molecular biology techniques. Principles of toxicity evaluations, ED50, LD50 and TD values. Regulations for laboratory animal care and ethical requirements: Organization of screening. International guidelines (ICH recommendations).

8 hours

UNIT II BIOASSAYS

Statistical methods in biological assays, Antibiotics-microbiological assays, Test for freedom from undue Toxicity, test for pyrogens, Determination of potency of diphtheria antitoxin, Determination of potency of Gas – Gangrene antitoxin (oedematiens), Determination of potency of Gas – Gangrene antitoxin (Septicum), Determination of potency of Gas – Gangrene antitoxin (perfringens), Determination of potency of tetanus antitoxin, Biological assay of Plague vaccine, , Biological assay of old tuberculin, test for potency of vaccine Lymph, Determination of ABO group and of RH group.

8 hours

UNIT III BIOASSAYS

Biological assay of cobra and viper venoms, Biological assay of chorionic Gonadotrophin, Biological assay of Serum Gonadotrophin, Biological assay of corticotrophin, Biological assay of insulin, The Mouse Method, Biological assay of protamine Zinc insulin,

Biological assay of posterior pituitary injection, Biological assay of Adrenaline, Biological assay of heparin sodium. **7 hours**

UNIT IV HUMAN DRUG METABOLISM

Phase-I metabolic reactions- cytochrome P450 enzyme system, Non-microsomal oxidation, Reduction, Hydrolysis, Phase-II metabolic reactions (conjugation)- Glucuronidation, Glutathione conjugation, Acetylation, Sulphation, methylation, Amino acid conjugation. Biomimetic model systems in the drug metabolism studies- Synthetic porphyrins, The Fenton-reaction, electrochemical oxidation Experimental setups for the investigation of Phase-I and II reactions. **7 hours**

UNIT V HUMAN DRUG METABOLISM

In vitro and ex vivo techniques in the drug metabolism studies, Supersomes, Human Liver Microsomal, Cytosolic and S9 fractions (HLM, HLC, HLS9), Immobilized Enzyme Reactors (IMER), Liver cell lines, HepG2 cell line, Transgenic cell lines, Hepatocytes, Liver slices, isolated perfused liver, Integrated discrete Multiple Organ Co-culture system (IdMOC). **8 hours**

UNIT VI BIOAVAILABILITY AND BIOEQUIVALENCE

Bioequivalence and its determination, study design for the assessment of bioavailability and bioequivalence, factors influencing bioavailability and bioequivalence. Correlation of in vitro dissolution & in vivo bioavailability. Statistical concepts in estimation of bioavailability and bioequivalence. **8 hours**

UNIT VII SAMPLE PREPARATION TECHNIQUES

Protein precipitation, Liquid-Liquid extractions, Solid-Liquid extraction, Hybrid extraction techniques. Solvents used for extraction procedures, Identification of drug metabolites in biological fluids using qualitative spectroscopic and chromatographic techniques. **7 hours**

UNIT VIII IDENTIFICATION OF DRUG METABOLITES IN BIOLOGICAL FLUIDS

Objectives of metabolite isolation – Bioavailability of drug metabolites – Principles of isolation of metabolites – Influence of Biological matrix in isolation – Principles of Metabolite identification – Use of Tandem mass spectrometry (MS-MS) in metabolite identification –

Isotopically labeled compounds in metabolite identification – Practical aspects for the identification of metabolites by mass spectrometry. **7 hours**

REFERENCE BOOKS:

1. H. G. Vogel: “Drug Discovery and Evaluation-Pharmacological Assays”, 2nd edition, Springer Verlag, Berlin, Germany, 2002.
2. Robert A. Turner: “Screening Methods in Pharmacology”
3. M. N. Ghosh: “Fundamentals of Experimental Pharmacology”, 2nd edition, Scientific Book Agency, Calcutta, India, 1984.
4. D. R. Laurence and A.L. Bacharach: “Evaluation of Drug Activities: Pharmacometrics”, Vol. 1, Academic Press, London, U.K., 1964.
5. David R. Gross: “Animal Models in Cardiovascular Research”, 2nd edition, Kluwer Academic Publishers, London, U.K., 1994.
6. A handbook of Bioanalysis and Drug metabolism by Gary Evans
7. Shargel, L., Wu-Pong, S. and Yu, B.C.A., “Applied Biopharmaceutics and Pharmacokinetics” 5th Edition, McGraw-Hill, 2004.
8. Gibaldi. M. and Perrier, D., “Pharmacokinetics”, 2nd Edition, Marcel Dekker Inc., 1982.
9. Pharmacopoeia of India, 3rd edition, volume –II, 1985.
10. Pharmacopoeia of India, 2nd edition, 1996, appendix XXXV.
11. Modern analytical techniques in the pharmaceutical- and bioanalysis by Dr. Istvan Bak.

Course No.1210 ADVANCED PHARMACEUTICAL ANALYSIS II (THEORY)

LEARNING OBJECTIVES:

The subject is aimed

1. To train students in advanced qualitative and quantitative analytical principles of sampling techniques, colorimetric reagents, quality control of excipients & packaging materials, stability tests and impurity profiling.
2. The student must be able to apply these concepts in various steps like stability testing of raw materials & finished drug products, sample preparation, routine quality control analysis and characterization of impurities in active pharmaceutical ingredients and pharmaceutical drug products in pharmaceutical industry.

UNIT I Analysis of Drugs in Dosage Forms

A detailed study of principles and procedure involved in various physicochemical methods of analysis including instrumental methods, (biological and microbiological methods to be completely excluded) of pharmaceutical preparations and dosage forms include in the Indian pharmacopoeia containing the following class of drugs.

- | | | |
|------------------------|--------------------------|----------------|
| a) Anti Malarial drugs | b) Anti Neoplastic Drugs | |
| c) Antibiotics | d) Anti viral drugs | 9 hours |

UNIT II Analysis of Drugs in Dosage Forms

A detailed study of principles and procedure involved in various physicochemical methods of analysis including instrumental methods, (biological and microbiological methods to be completely excluded) of pharmaceutical preparations and dosage forms include in the Indian pharmacopoeia containing the following class of drugs.

- | | | |
|--------------------------|-----------------|----------------|
| a) Steroidal Hormones | b) Vitamins | |
| c) Anti tubercular drugs | d) Sulfonamides | 6 hours |

UNIT III Analysis of Drugs in Dosage Forms

A detailed study of principles and procedure involved in various physicochemical methods of analysis including instrumental methods, (biological and microbiological methods to be completely excluded) of pharmaceutical preparations and dosage forms include in the Indian pharmacopoeia containing the following class of drugs.

- | | | |
|----------------------------|--------------|----------------|
| a) Adrenergic drugs | b) Diuretics | |
| c) Anti hypertensive drugs | | 6 hours |

UNIT IV Analysis of Drugs in Dosage Forms

A detailed study of principles and procedure involved in various physicochemical methods of analysis including instrumental methods, (biological and microbiological methods to be completely excluded) of pharmaceutical preparations and dosage forms include in the Indian pharmacopoeia containing the following class of drugs.

- a) Drugs acting on CNS (Local anesthetics, Sedatives and hypnotics, Anti depressants, Anti psychotics)
- b) Analgesics and Anti Pyretics **6 hours**

UNIT V Reagents and Functional Group Based Analysis of Active Pharmaceutical Ingredients (API)

Principles and procedures involved in quantitative determination of the following functional groups

- a) Hydroxy b) Aldehyde c) Ketone d) Amine
- e) Methoxyl f) Ester g) Carboxyl

Analytical principles, procedures and applications involved in the use of the following reagents.

- a) MBTH (3-methyl-2-benzothiazoline hydrazone).
- b) Folin – Ciocalteu (FC) reagent.
- c) 2,6- Dichloroquinone chlorimide.
- d) 2,3,5- Triphenyl tetrazolium salt.
- e) 1,2- naphtho quinone -4- sulfonate.
- f) Bratton-Marshall reagent.
- g) *p*-Dimethyl amino cinnamaldehyde (PDAC) reagent. **8 hours**

UNIT VI Quality Control Tests of Pharmaceutical Dosage forms

- a) Tablets b) Capsules c) Parentrals d) Liquid orals e) Ointments **7 hours**

UNIT VII Quality Control of Excipients & Packaging Materials

Tests related to excipients such as bulk density, tapped density, particle size distribution, pH, moisture content, viscosity (dynamic), gelling temperature, swelling temperature, loss on drying, residue on ignition, conductivity, congealing range, readily carbonizable substances and readily oxidizable substances, melting point and melting range. Excipients of interest, disintegrating agents, binders, emulsifiers, viscosity modifiers and preservatives including preservative challenge test.

Containers and Closures: Glass light transmission, chemical resistance – glass containers, powdered glass test, water attack test. Biological tests – plastics and other polymers: physicochemical tests – plastics, polyethylene containers, single unit containers and unit dose containers for non sterile solids and liquid dosage forms, customized patient medication packages, containers – permeation, metal containers, and rubber closures.

8 hours

UNIT VIII

Stability Testing

Solid state drug stability, accelerated stability studies, physical degradation of pharmaceutical products, prolonging the shelf life, effect of packaging materials on dosage form on stability, ICH guidelines- ICH basic principles, stability testing of new drug substance and formulations, photostability testing, Containers. WHO stability guidelines. Forced Degradation.

Impurity Profiling

Sources of impurities and their effect on drug stability and therapeutic action – Determination of impurities in bulk drugs: Isolation, characterization, and analytical methods – Formulation related impurities: Isolation, characterization, and analytical methods. ICH and WHO guidelines for impurity and related substances in the drugs.

10 hours

REFERENCE BOOKS:

1. Hiaguchi T, Brochmann E, Hanssen H, Hanseen H. Pharmaceutical analysis, CBS publishers & distributors, New Delhi, 2004.
2. Rowe RC, Sheskey PJ, Owen SC. Handbook of Pharmaceutical excipients. 5th ed., Pharmaceutical press, Britain, 2006.
3. Lachman L, Lieberman HA, Kanig JL. The theory and practice of industrial pharmacy, 3rd ed., Varghese Publishers, Mumbai 1987.
4. Ahuja S, Alsante KM. Handbook of isolation and characterization of impurities in pharmaceuticals. Academic press, California, 2003.
5. Sethi PD. Quantitative analysis of drugs in pharmaceutical formulations, 3rd ed., CBS publishers & distributors, New Delhi, 2008.
6. Beckett AH, Stenlake JB. Practical pharmaceutical chemistry, Part I & II. 4th ed., CBS publishers & distributors, New Delhi, 2004.
7. Remington: The science and practice of pharmacy. 21st ed., vol. I & II, Lippincott Williams & Wilkins, New Delhi, 2005.

8. Indian Pharmacopoeia. Controller of Publication. Delhi, 2007.
9. British Pharmacopoeia. British Pharmacopoeia Commission Office, London, 2008.
10. United States Pharmacopoeia. United States Pharmacopoeial Convention, Inc, USA, 2006.
11. Methods of Drug Analysis by Gearin and Grobowski
12. Text book of Pharm Analysis by K.A.Connors.(John wiley
13. Spectroscopy by Silverstein.
14. Pharmaceutical Analysis-Modern Methods by J.W.Munson(Marcel Dekker)
15. Pharmaceutical chemistry by L.G.Chatten(Marcel Dekker)

Course No. 1211 ADVANCED PHARMACEUTICAL ANALYSIS II (PRACTICAL)

1. Utility of MBTH reagent for the assay of Aldehyde drugs.
2. Utility of FC reagent for the assay of phenolic and amine drugs
3. Utility of DCQC reagent for the assay of phenolic drugs
4. Utility of 2,3,5, tri phenyl tetrazolium salt for the assay of drugs
5. Utility of 1,2- naphtho quinone -4- sulfonate for the assay of amine drugs
6. Utility of BM reagent for the assay Primary aromatic amine drugs
7. Utility of PDAB and PDAC reagent for the assay of amine drugs.
8. Assay of Antibiotics
9. Assay of Vitamin
10. Assay of steroids
11. Assay of Sulfonamides
12. Assay of Adrenergic drugs
13. Assay of Diuretics
14. Assay of Anti neoplastic drug
15. Assay of Barbiturates
16. Assay of Antipyretic and analgesics
17. Assay of Antiviral drugs
18. Assay of Anti hypertensive drugs
19. Stability indicating assay method of any one drug.

Course No. 1212 comprehensive viva

THIRD SEMESTER

Course No. 1313 Seminar on the objectives and work plan of the proposed project to be completed within one month from the commencement of the project.

Course No. 1314 Mid-term project review at the end of third semester.

Course No. 1315 Seminar on the selected topic

FOURTH SEMESTER

Course No. 1416 Thesis evaluation

Course No. 1417 Thesis viva-voce

2. PHARMACEUTICAL CHEMISTRY

FIRST SEMESTER

Course No.2101 BIOSTATISTICS (THEORY)

(Common paper for all specializations)

Course No.2102 PHARMACEUTICAL CHEMISTRY – I (ADVANCED ORGANIC CHEMISTRY) (THEORY)

LEARNING OBJECTIVES:

1. Basic concepts of organic chemistry to be dealt at advanced level: A thorough understanding on atomic and bond properties and their contribution towards inter and intra molecular interaction extrapolated to drug receptor and other biological interaction. Physicochemical properties.
2. Stereochemistry: A clear concept on chirality in organic compounds, identification of chiral centre, nomenclature and biological significance. Importance of chirality in bioactivity of drug molecules
3. Mechanism of Organic Reactions: Mechanistic study of organic reactions, including various types of substitution and addition reactions. A thorough study on Named reactions and their modifications, applicability in medicinal chemistry.
4. Reagents and their synthetic applications: An understanding of specialty reagents used for synthetic applications, synthesis, stability, storage and their applicability.
5. Retrosynthetic analysis: a thorough understanding on the disconnection approach and design of synthesis for a simple target compound using chemical logic.

UNIT I Basic concepts of organic chemistry to be dealt at advanced level: Inductive effect, Mesomeric effect, hyperconjugation, Dipole moments, carbocations, carbanions, free radicals and carbenes and steric effects. **5 hours**

UNIT II Stereochemistry: Optical isomerism: optical activity and chirality, structural features necessary for optical activity including biphenyls, allenes. Determination of configuration (Absolute and Relative) in compounds containing one chiral center and more chiral centres, Racemic modification, methods of resolution.

Cis-trans isomerism: Cis-trans isomerism resulting from double bonds, monocyclic compounds, fused and bridged ring systems.

Conformational analysis: Conformations in open chain, six membered and other rings, steric strain in small rings, unsaturated rings and unavoidable crowding.

8 hours

UNIT III Asymmetric synthesis: Absolute and partial asymmetric synthesis, Chiral induction, factors controlling facial selectivity, chiral reagents, catalysis and solvents, double asymmetric induction, asymmetric synthesis of amino acids.

7 hours

UNIT IV Mechanism of Organic Reactions: Mechanism of free radical addition, substitution, electrophilic addition and substitution, mechanism of nucleophilic addition and substitution (S_N1 , S_N2 including participation of neighboring groups) with suitable examples.

7 hours

UNIT V Molecular rearrangements: Pinacol-pinacolone rearrangements, trans-annular rearrangements, benzilic acid rearrangements, rearrangements due to electron deficient nitrogen atoms-Hofmann reaction, Schmidt reaction and Beckmann rearrangement.

7 hours

UNIT-VI Name reactions: Michael addition, Mannich reaction, Bayer-Villiger oxidation, Oppenauer oxidation and their applications in organic synthesis.

7 hours

UNIT-VII Reagents and their synthetic applications:

Methods of preparation, physical and chemical properties and important synthetic applications of the following reagents.

10. Lithium aluminium hydride and Sodium borohydride.

11. N-Bromosuccinimide

12. Lead tetraacetate

13. Diazomethane

14. Sodium in liquid ammonia

7 hours

UNIT-VIII Retrosynthetic analysis:

Introduction to: (i) Retrosynthetic analysis and designing of the synthesis. (ii) Grounding of organic Chemistry for understanding retrosynthesis. (iii) Disconnection approach: An introduction to synthons, synthetic equivalents, disconnection approach, functional group interconversions, importance of order of events in organic synthesis, one and two group C-X disconnections, selective organic transformations chemoselectivity, regioselectivity, stereoselectivity, enantioselectivity.

7 hours

Course No. 2103 PHARMACEUTICAL CHEMISTRY - I (ADVANCED ORGANIC CHEMISTRY) (PRACTICAL)

LEARNING OBJECTIVES:

Qualitative analysis of unknown organic compounds:

1. Design of methodology for effective separation of various binary mixtures. Identification of unknown organic compound using chemical tests and effective deductive logic.
2. Synthesis of compounds in single step or multi step. Reaction monitoring, maintenance of reaction conditions including inert environment. Yield calculations for multistep synthesis. Purification and identification of product.

A) Preparation of the following compounds

1. Benzanilide from Benzophenone (Beckmann Rearrangement)
2. 2-Phenylindole from Acetophenone (Fisher's indole synthesis)
3. Cinnamic acid from Benzaldehyde (Perkins reaction).
4. 2,5, dihydroxy acetophenone from hydroquinone (Frie's rearrangement)
5. Diethyl fumarate from maleic acid (Conversion of cis isomer to trans isomer)
6. Benzilic acid from benzil (Benzilic acid rearrangement)
7. Nitrosoinethyl urea from acetamide
8. Biphenic acid from anthranilic acid.

B) Qualitative analysis of binary organic mixtures (At least 6)

REFERENCE BOOKS:

1. Text book of organic chemistry by I.L.Finar Vol.1 & 11.
2. Advanced organic chemistry-reactions, mechanisms & structures-Jerry March (Wiley Eastern, New Delhi)
3. Reactions mechanisms in Organic chemistry-S. Mukhatjee & S.P. Singh (Mc Millan India Ltd., New Delhi).
4. A guide book to mechanisms in organic chemistry-peter sykes(Oriental longmann, New Delhi).
5. Structure and mechanisms inorganic chemistry-C.Kingold (Cornell University press, Newyork.)
6. Structure and mechanisms inorganic chemistry-jerry March.
7. Designing Organic Synthesis: S. Warren, Wiley.

Course No. 2104 PHARMACEUTICAL CHEMISTRY – II (NATURAL PRODUCTS OF MEDICINAL INTEREST) (THEORY)

LEARNING OBJECTIVES: An over view of role of natural products research in drug discovery. Methodical approach followed for structure elucidation of various natural products and their applicability in identification of new natural product. Role of spectral and chromatographic methods in natural products research.

(Natural Products of Medicinal Interest)

UNIT-I: General methods of isolation and separation of plant constituents. Qualitative tests employed for the detection of plant constituents. Application of GLC, HPLC and HPTLC techniques of separation and analysis of natural products. **8 hours**

UNIT-II: Application of IR, ¹H NMR MS, CR1) and C.D. to structural studies of natural products. **7 hours**

UNIT-III: Study of biogenesis: the acetate hypothesis. isoprene rule, biogenetic hypothesis relating to alkaloids. **5 hours**

Methods of isolation, purification, structure elucidation, structural features involving synthetic, degradative and spectroscopic methods, to be discussed for the following natural products.

UNIT-IV: Alkaloids: Atropine, ergometrine, reserpine, vinbiastin and vincristin.

Steroids: Cholesterol, Ergosterol, Ergocalciferols, cardiac steroids (Digoxin, Ouabain, Scillarin A and Pervuoside), corticosteroids, synthesis of cortisone

Antibiotics: Structural features and uses of cephalosporins, rifampicin and tetracyclines.

7 hours

UNIT-V: Vitamins: Vitamin A, folic acid and Vitamin B12.

7 hours

Salient structural features of polypeptides and proteins: Insulin, oxytocin and Vasopressin.

UNIT-VI: Chemistry of nucleotides, co-enzymes and prostaglandins.

7 hours

UNIT-VII: Chemistry of natural products of recent origin-podophyllotoxin and its derivatives, camptothecin and its derivatives, taxol, artemisinin.

7 hours

UNIT-VIII: Marine natural products with therapeutic potential.

7 hours

Course No. 2105 PHARMACEUTICAL CHEMISTRY (PRACTICAL)

LEARNING OBJECTIVES:

Isolation of natural products from various resources. Importance of planning, solvent and other conditions needed for extraction. Usage of chromatographic, chemical and spectral methods for identification of isolated natural product.

1. Isolation, purification and characterization of some of the following natural products using different chromatographic techniques
 - a. Piperine from black pepper
 - b. Caffeine from tea powder
 - c. Curcumin from turmeric
 - d. Sennosides from *Senna*
 - e. Anthraquinone glycosides from Rhubarb
 - f. Hesperidine from orange peel
 - g. Rutin from *Bauhinia tomentosa*
 - h. Embellin from *Embelia ribes*
 - i. Pectin from orange peel
 - j. Strychnine and Brucine from *Strychnos nuxvomica*
 - k. Diosgenin from *Dioscorea* tubers
2. Degradation reactions and identification of degradation products of some of the above natural products.

REFERENCE BOOKS:

1. Text book of organic chemistry IL Finar
2. Text book of medicinal chemistry Wilson & Gijvold.

Course No. 2106 Comprehensive Viva

PHARMACEUTICAL CHEMISTRY
SECOND SEMESTER

Course No. 2207 MODERN ANALYTICAL TECHNIQUES (THEORY)

(Common paper for all specializations)

Course No. 2208 QUALITY ASSURANCE AND DRUG REGULATORY AFFAIRS (THEORY)

(Common paper for all specializations)

Course No. 2209 ADVANCED MEDICINAL CHEMISTRY (THEORY)

LEARNING OBJECTIVES:

1. A comprehensive idea on drug design process. Role of various physicochemical properties of drug molecule and their application in drug optimization studies. ADME properties of drug molecules are to be dealt with the help of case studies.
2. A comprehensive idea on structure based and ligand based drug design methodologies including latest developments are to be studied. Role of green chemistry and role of environment friendly medicinal chemistry is to be stressed upon.

UNIT I Influence of physicochemical properties on biological activity: partition coefficient, hydrogen bonding, surface activity, redox potential, chelation, enantiomerism, geometrical isomerism and conformational isomerism. **7 hours**

UNIT II Factors affecting absorption of drugs: Mechanism of drug absorption, physicochemical, biological and dosage form factors influencing absorption. **Drug distribution:** volume of distribution, protein binding **Excretion of drugs:** Renal and non-renal excretion concept of clearance and kinetics. **7 hours**

UNIT III Drug biotransformations: Phase I (oxidative, reductive and hydrolytic) reactions and role of Cytochrome P450, Phase II (conjugative) reactions; factors affecting biotransformations. **6 hours**

UNIT IV Prodrugs and soft drugs: Objectives of prodrug design, strategies of designing prodrugs. **7 hours**

UNIT V Drug receptors and receptor theories of drug action. Types of receptors, Protein coupled receptors, ion-channel linked receptors, nuclear receptors, dose-response relationships. **7 hours**

UNIT VI Drug target binding forces: energy components of non-covalent interactions. Thermodynamics of association in gas phase and solvation effects. **7 hours**

UNIT VII Introductory treatment of modern drug discovery concepts and technologies. Principles of combinatorial chemistry and high throughput screening.

7 hours

UNITV III Computer Aided drug design; Quantitative structure — activity relationships, Hansch analysis, Free-wilson analysis, 3D-QSAR approaches, comparative molecular field analysis. **Structure based drug design:** Role of x-ray crystallography and NMR spectroscopy in drug discovery, Principles of computational chemistry techniques and their role in drug discovery, Molecular modeling in drug design. Virtual screening. Bioinformatics and its applications in drug discovery.

7 hours

REFERENCE BOOKS:

1. Comprehensive Medicinal chemistry-Corwin & I-Ianch.
2. Medicinal Chemistry by Burger.
3. Principles of medicinal chemistry by William Foye.
4. Microwaves in Organic Synthesis by A.Loupy
5. Green Chemistry an Introductory Text by Lancaster, M.; Royal Society of Chemistry, Cambridge, UK
6. Drug Design – Cutting Edge Approaches by Darren R.Flower

Course No. 2210 PHARMACEUTICAL CHEMISTRY – III (BULK DRUGS AND SYNTHETICS) (THEORY)

LEARNING OBJECTIVES:

1. An over view of bulk drug industry, scale-up technology and environmental issues including effluent disposal. A comprehensive idea on medicinal chemistry of various classes of drugs.
2. Focus must be on pathogenesis, identification of drug target, SAR and synthesis of important members of a drug class with the help of case studies.

UNIT I Development and scale up of processes for the manufacture of new pharmaceuticals factors which effect synthetic route selection, optimization of synthetic route, important factors involved in scale up to pilot plant, pilot plant equipment, Effluent disposal; Crystallization and polymorphism.

7 hours

UNIT II Green chemistry: Principles of green chemistry, atom economy, green chemical processes. Microwave synthesis: Introduction, principle and synthetic applications.

7 hours

UNIT III Aspects of the commercial production of the following bulk drugs with emphasis the reaction sequence and flow sheets.

Para amino salicylic acid; INH, Phenytoin, phenobarbitone, chlorpheniramine, diethylcarbamazine citrate, diazepam, propranolol, clotrimazole, dapsone.

Classification, mode of action, structure — activity relations and synthesis of important members of the following groups of drugs. **7 hours**

UNIT IV Antineoplastic agents. Drugs affecting immune response; Immunostimulators, immunosuppressants. **7 hours**

UNIT V Anti viral and anti HIV drugs. **6 hours**

UNIT VI Anti ulcer drugs. Anabolic and contraceptive steroids. **7 hours**

UNIT VII Antihypertensives. Anti hyperlipidemic agents. **7 hours**

UNIT VIII Drugs for the treatment of neurodegenerative disorders like parkinsonism, Alzheimers disease, Antipsychotics and Anti depressants. **7 hours**

REFERENCE BOOKS:

1. Organic chemistry of synthetic drugs- lednicher.
2. Remingtons pharmaceutical sciences.
3. Wilson & Gisvold- text Book of Medicinal chemistry.
4. William-o-Foye- Principles of Medicinal chemistry.
5. Medicinal chemistry & Drug discovery by Burger.
6. Introduction of chemical Engg. by badger & Banchero.

Course No. 2211 PHARMACEUTICAL CHEMISTRY - III (BULK DRUGS AND SYNTHETICS) (PRACTICAL)

LEARNING OBJECTIVES:

1. Synthesis of compounds via multistep methods. Design of synthesis using retrosynthetic methodology. Introduction of alternate energy sources for synthesis including microwave. An overview on calculation of various physicochemical constants for organic compounds is to be provided.
2. An introduction to computational tools and their role in drug design and discovery using free tools available online taking any protein target (like cyclooxygenase) as an example. A clear understanding on drug design protocols is to be provided.
3. Synthesis purification and identification of the following synthetic drugs and intermediates Phenytoin, 7-hydroxy- 4-methylcoumarin, Benzocain, Phenothiazine. INH, 2,3 Diphenyl

quinoxalinc, 2 -Mercapto 4,5 ,diphenyl imidazole. 6-Methyl uraci I, Saccharine sodium, Benzofuran.

4. Determination of n-octanol/water partition coefficient (log P) of parent and substituted molecules (Eg. Benzoie acid and p-chloro benzoic acid) and calculation of Hansch hydrophobic constant (IT) from the above log p values
5. Determination Pka of substituted and parent molecules and calculation of the Hammett constant of the substituent.
6. Structure based drug design: i) preparation of compound library ii) obtaining protein structure from online databases (www.pdb.org) iii) identification and defining receptor site iv) virtual screening v) analysis of docking result (score and pose) and identification of lead molecule. Vi) structure modification and lead optimization

Course No. 2212Comprehensive Viva

THIRD SEMESTER

Course No. 2313Seminar on the objectives and work plan of the proposed project to be completed within one month from the commencement of the project.

Course No. 2314Mid-term project review at the end of third semester.

Course No. 2315Seminar on the selected topic.

FOURTH SEMESTER

Course No. 2416 Thesis evaluation.

Course No. 2417Thesis viva-voce.

3. PHARMACEUTICAL TECHNOLOGY

FIRST SEMESTER

Course No. 3101 BIOSTATISTICS (THEORY)

(Common paper for all specializations)

Course No. 3102 BIOPHARMACEUTICS AND PHARMACOKINETICS (THEORY)

LEARNING OBJECTIVES:

1. The course will help the student in understanding the various factors that contribute towards the bioavailability of a drug.
2. The student would gain knowledge on topics like drug interactions and pharmacokinetics. The student would be able to correlate *in vitro* and *in vivo* data and design experimental models for bioavailability studies.

UNIT I Drug Absorption, Distribution, Biotransformation and Excretion: Absorption of drugs, Significance of metabolisms involved in the absorption and bio transformation of drugs. Effects of Physico-Chemical, Pharmaceutical and Biological Factors on absorption, distribution, metabolism and excretion. Renal and Non renal Excretion Concept of clearance. **10 hours**

UNIT II Bioavailability and Bioequivalence of Drug Products: Factors-Assessment-Experimental designs and protocol for bioavailability and bioequivalence studies as per CDSCO, Schedule Y guidelines and GCP guidelines, *in-vitro and in-vivo* correlation of bioavailability, methods to enhance bioavailability. Statistical considerations in comparative bioavailability studies. **8 hours**

UNIT III Drug Interactions: Interaction of drugs with food, Classification of food drug interactions, models for estimation of pharmacokinetic parameters in food drug interaction studies. Effect of alcohol, smoking on drugs. Drug-Drug Interactions: factors contributing to drug interactions, Mechanisms of drug interactions with emphasis on pharmacokinetic interactions. **8 hours**

UNIT IV Pharmacokinetics: Basic consideration, pharmacokinetic models, Pharmacokinetic Parameters, Compartment modeling: One compartment model- IV bolus, IV infusion, Extra-vascular; MultiCompartmentmodels; Twocompartmentmodel- IV bolus, IV infusion, Extra-vascular. Application of pharmacokinetics in new drug development and designing of dosage forms and novel drug delivery systems. Kinetics of multiple dosing-dosage regimens-

loading and maintenance doses of sustained release and continuous blood levels. Concepts of software used in the pharmacokinetic analysis Win Nonlin[®] and Kinetica.

10 hours

UNIT V Non-linear and Clinical Pharmacokinetics: Concepts of linear and non-linear pharmacokinetics, Michaelis - Menten Kinetics characteristics. Basic kinetic parameters, possible causes of non-induction, non-linear binding, non-linearity of pharmacological responses.

7 hours

UNIT VI Time Dependent Pharmacokinetics: Introduction, classification, physiologically induced time dependency, Chromo pharmacokinetics.

6 hours

UNIT VII Non Compartmental Analysis based on Statistical Moment Theory Statistical Moments, Bioavailability, Clearance, half-life, Absorption kinetics, Apparent volume of distribution, fraction metabolites, Predicting Steady State Concentrations, Predicting time to steady state.

7 hours

UNIT VIII Clinical Pharmacokinetics: Altered Kinetics in Paediatrics, Geriatrics, Kinetics in GI, Liver, Cardiac, Renal and Pulmonary Disease State.

7 hours

REFERENCE BOOKS:

1. Pharmacokinetics, Milo Gibaldi, 2nd Ed.
2. Applied Biopharmaceutics and Pharmacokinetics, Leon Shargel, 5th Ed.
3. Biopharmaceutics and Clinical Pharmacokinetics, Robert E. Notari, 4th Ed.
4. Modern Pharmaceutics, Gilbert S. Banker, Christopher T. Rhodes, 4th Ed.
5. Clinical Pharmacokinetics and Pharmacodynamics – Concepts and Applications, Malcolm Rowland and Thomas N. Tozer, 4th Ed.
6. Drug Disposition and Pharmacokinetics, Stephen H. Curry, 3rd Ed.
7. Current concepts in the Pharmaceutical Sciences-Biopharmaceutics, James Swarbrick
8. Current concepts in the Pharmaceutical Sciences-Dosage Form Design and Bioavailability, James Swarbrick

Course No. 3103 BIOPHARMACEUTICS AND PHARMACOKINETICS (PRACTICAL)

1. Effect of particle size on the drug dissolution using drugs like aspirin, salicylic acid, nitrofurantoin
2. Effect of surfactant on the drug dissolution using drugs like sulfamethoxazole, nefidipine.
3. Effect of ointment base on drug diffusion using agar plate method and diffusion membrane.

4. Determination of protein binding effect on drugs by using dialysis sac method using protein bound drugs.
5. Improvement in the dissolution of drugs by solid dispersion, cyclodextrin complexation etc.
6. To study the effect of sink condition on dissolution of drugs using discriminatory dissolution medium
7. To study the effect of permeation enhancers on drug diffusion using Franz-diffusion cell using suitable biomembranes.
8. Calculation of pharmacokinetic parameters using reported data.
9. Calculation of bioavailability and bioequivalence from the given data using different approaches.
10. In vitro-in vivo correlations using experimental data.
11. Preparation of experimental protocols for carrying out pharmacokinetic, pharmacodynamic, bioavailability and bioequivalence studies using suitable experimental designs for the given data.

Course No.3104 ADVANCED PHYSICAL PHARMACEUTICS (THEORY)

LEARNING OBJECTIVES:

On learning this subject, the student must understand

1. The concepts of solubility, solubilization, dissolution, compression, granulation, stability, stability testing, polymers and biodegradable polymers.
2. The student must be able to apply these concepts in preparing dosage forms that have enhanced dissolution and bioavailability, and in performing operations like tablet compression, stability testing and polymer characterization, required in the industry.

UNIT I Solubilisation of drugs in aqueous media:

Solubility, ideal solubility, activity coefficient, Hildebrand solubility approach, solubility parameter, estimating solubility and dissolution rate, apparent solubility enhancement from different solid phases, pH control, salt formation, buffers, cosolvents, dependence of solubilisation on solute properties, dependence of solubilisation on cosolvent properties, multiple cosolvents, surfactants, complexation, self-association and stacking complexation, inclusion complexes, combination of pH and complexation. **8 hours**

UNIT II Solubilising excipients in pharmaceutical formulations:

Introduction, oral formulations (water soluble organic solvents, surfactants, water insoluble organic solvents, water insoluble solids, cyclodextrins, microemulsion oral formulations); injectable formulations (water soluble organic solvents, surfactants, cyclodextrins, phospholipids, emulsions), oily injectable formulations and transdermal formulations.

8 hours

UNIT III Granulation and tablet characteristics: Granule formation and structure, particle size measurement and interpretation, shape determination, surface area, densities and packings, granule strength and friability, electrostatic properties, flow properties, ease of consolidation and mechanisms; control of tablet characteristics, such as , size and shape, tablet thickness, hardness, friability, disintegration, weight variation and content uniformity.

8 hours

UNIT IV Compression: properties of tablets influenced by compression (elastic deformation, plastic deformation, brittle fracture, micro squashing, density and porosity, hardness and strength, specific surface, disintegration, dissolution); measurement of compressional force, energy expenditure, transmission of force. Consolidation, role of moisture, compression and consolidation under high loads, effect of friction, force distribution, development of radial force die wall lubrication, Heckle plots, energy involved in compaction, force-displacement curves, instrumentation of tablet machines, single station presses, multistation presses and signal processing.

8 hours

UNIT V Stability: physical, chemical and microbiological stability, quantitation of rate of degradation (zero order kinetics, first order kinetics, shelf life calculation), factors influencing reaction rate (temperature, pH, ionic strength, dielectric constant), methods of stabilizing dosage forms.

8 hours

UNIT VI Stability testing: ICH guidelines for stability testing, selection of batches and container closure systems, matrixing and bracketing design, storage conditions and testing frequency, climatic zones concept, stability testing in different stages of drug product life cycle, specific stability tests for various dosage forms. Photo stability studies, expiration dating, overages calculation.

8 hours

UNIT VII Polymers: Definitions, molecular weight averages, determination of molecular weight from solution viscosity, polymers as thickening agents, polymers in solutions, preparing

polymer solutions, thermodynamics of polymer solutions, gel formation, coacervation and microencapsulation, Pharmaceutical application of polymers.

8 hours

UNIT VIII Hydrogels (over view, synthesis, structure and properties, swelling ratio and water content, use in drug delivery, mucoadhesive hydrogels, sensitivity to pH changes, Polyethylene oxides), lipids(physical and chemical properties, applications in drug delivery), Biodegradable polymers as drug carriers (overview, factors affecting selection of polymer, factors affecting drug release, degradation mechanisms, polyesters, polyanhydrides).

8 hours

REFERENCE BOOKS:

1. Encyclopedia of Pharmaceutical Technology, edited by James Swarbrick, Third Edition, Informa Healthcare publishers.
2. Pharmaceutical Dosage Forms, Tablets, Volume II, edited by Herbert A. Lieberman and Leon Lachman; Marcel Dekker, Inc.
3. The Theory and Practice of Industrial Pharmacy, Fourth Edition, edited by R. P. Khar, S. P. Vyas, Farhan J. Ahmad, Gaurav K. Jain; CBS Publishers and Distributors Pvt. Ltd.
4. Martin's Physical Pharmacy and Pharmaceutical Sciences, Fifth Edition, edited by Patrick J. Sinko, BI Publications Pvt. Ltd.

Course No. 3105 ADVANCED PHYSICAL PHARMACEUTICS (PRACTICAL)

1. Stability studies on commercial tablets containing drugs like aspirin over two months at room temperature, 37°C and 45°C.
2. Stability studies on suspensions containing drugs like aspirin over 20 days at room temperature, 37°C and 45°C.
3. Determination of molecular weight by viscosity method, by Mark- Houwink equation for gelatin, methyl cellulose and polyvinyl alcohol.
4. Effect of temperature on the decomposition of bromophenol blue at three temperatures and two pH values
5. Effect of pH on the decomposition of aspirin.
6. Preparation of granules, drying by conventional dryer and fluidized bed dryer and comparing the granules by their flow properties.

7. Preparation of tablets by two different sets of granules with different flow properties; and finding the effect of variability in flow rate of granules on the weight variation of resultant tablets using drugs like Metronidazole.
8. Drawing the coacervation curve on a three component system graph (gelatin, sodium sulphate and water) for gelatin, sodium sulphate system.
9. Determination of bloom strength of gelatin.
10. Preparation of liquid paraffin emulsion in a colloid mill; determining the effect of duration of milling (up to 10 minutes), on the heat developed in the emulsion (temperature) and on the extent of micronization (globule size analysis).
11. Visiting a pharmaceutical industry and observing the modern equipment used in production and quality control.
12. Carrying out accelerated stability studies of disperse systems using freeze thaw technique and centrifugation techniques and prediction of shelf life.

Course No. 3106 Comprehensive viva

PHARMACEUTICAL TECHNOLOGY

SECOND SEMESTER

Course No. 3207 MODERN ANALYTICAL TECHNIQUES (THEORY)

(Common paper for all specializations)

Course No. 3208 QUALITY ASSURANCE AND DRUG REGULATORY AFFAIRS (THEORY)(Common paper for all specializations)

Course No. 3209 NOVEL DRUG DELIVERY SYSTEMS (THEORY)

LEARNING OBJECTIVES:

On learning this subject, the student will understand the concepts in parenteral controlled release and will be able to design sustained or controlled or novel drug delivery systems

UNIT I Introduction to Parenteral Drug Delivery: Basic requirements of Parenteral Controlled release products; release profiles and biofate of intravenously administered systems and intramuscularly administered systems. **4 hours**

UNIT II Targeted Drug Delivery: Concepts of Targeting, Rationale of Drug Targeting, Carriers, Passive Targeting, Inverse Targeting, Active Targeting, First, Second, and Third order Targeting, Ligand Mediated Targeting, Physical Targeting, Dual Targeting, Double Targeting, Combination Targeting and problems associated with Targeted Delivery Systems. **4 hours**

UNIT III Targeting to the Brain, Targeting to the tumour and Targeting to the colon. **4 hours**

UNIT IV Sustained release formulations (encapsulated slow release granules, tableted slow release granulations, matrix tablets, drug complexes, ion activated systems, pH independent systems, altered density systems, colonic release systems). **8 hours**

UNIT V Controlled release formulations (osmotic pressure activated systems, hydrodynamic pressure activated systems, hydrodynamically balanced systems, the synchron system, the Penn kinetic system and bio adhesive system); *In vitro* and *in vivo* product evaluation and testing. **10 hours**

UNIT VI Design and Evaluation of Novel drug delivery systems: Ocuserts, transdermal drug delivery systems, *In situ* gelling systems, stimuli-sensitive “smart” polymers as drug delivery systems, glucose-responsive insulin delivery, polymer drug conjugates. **10 hours**

UNIT VII Novel carriers for controlled targeted drug delivery: Liposomes, Niosomes, Ethosomes, Transferosomes, Virosomes, polymeric nanoparticles, solid lipid nanoparticles, inorganic nanoparticles. **10 hours**

UNIT VIII Supra molecular systems, micelles/reverse micelles, lipoproteins, liquid crystals, resealed erythrocytes, carbon nanotubes, self-emulsifying drug delivery systems, Aquasomes, DQA somes, nanosuspension, nanocapsules. **10 hours**

REFERENCE BOOKS:

1. Targeted and Controlled Drug Delivery, Novel Carrier Systems by S. P. Vyas and R. K. Khar, CBS Publishers and Distributors Pvt. Ltd, First Edition 2012.
2. Lachman/Lieberman’s The Theory and Practice of Industrial Pharmacy, Fourth Edition, Editors: Roop K Khar, S P Vyas, Farhan J Ahmed, and Gaurav K Jain, CBS Publishers and Distributors Pvt Ltd, 2013.

Course No.3210: PRODUCT FORMULATION AND DEVELOPMENT (THEORY)

LEARNING OBJECTIVES:

The course gives a foundation on

1. Pre-formulation aspects involved in product development.

2. The student will be able to carry out the functions in the production division of a pharmaceutical industry by understanding the production, scale up techniques, quality control and packaging aspects of large scale manufacture of different dosage forms like oral liquids, tablets, capsules, parenterals etc.

UNIT I Pharmaceutical Product Development: Introduction to product development. Goals of preformulation, preformulation drug characterization in a structured program for different dosage forms. Influence of the parameters like intrinsic solubility, dissociation constant (pK_a), salts, solvents, partition coefficient, dissolution, polymorphism, particle size, shape and surface area, bulk density, flowability, hygroscopicity, stability indicating assays, and stability.

10 hours

Formulation Development of the following dosage forms:

UNIT II Oral Liquids: Monophasic Systems, Solutions: Vehicles, Additives Used in Formulation of Solutions, Oral Solution Products, Equipment, and Compounding, Filling of Liquids.

Biphasic Systems: Suspensions: Formulation and Manufacture of Suspension, Evaluation of Stability.

Emulsions: Microemulsions, Multiple Emulsions, Nanoemulsions Theories of Emulsification, Preparation of Emulsion, Equipment's Used for Emulsification, Stability, evaluation of Emulsions and their applications in drug delivery.

8 hours

UNIT III Tablets: Types of Tablets, Components of a Tablets, Excipients, Granulation Methods, Mechanisms and Equipment, Processing Problems of Tablets, working of tablet Machines.

Tablet Coating: Comparison of different coating techniques procedures. Problems involved in each coating and trouble shooting. Equipment used for sugar coating, film coating, aqueous film coating, compression coating, enteric coating. Novel Drug Delivery. Technologies: Mouth Dissolving Tablets (Orasolv, Durasolv and Zydis Oral Fast Dissolving Dosage Forms), Oral Controlled Release Drug Delivery Systems, Osmotically Controlled release dosage forms, Nanocrystal Technology, IDD Formulations, Self-Repairing Tablets, Effervescent Tablets, Dissocubes.

10 hours

UNIT IV Capsules and Microencapsulation: Types of gelatin and excipients used in the preparation of soft and hard gelatin capsules. Related advantages of soft and hard gelatin

capsules. Methods and equipment involved in the manufacturing of soft and hard gelatin capsules. Powder Filling, Choice of Excipients, Non Powder Filling, Storage, packaging and Stability Considerations of hard gelatin capsules. Micro encapsulation: Methods and Applications of Microencapsulation. **10 hours**

UNIT V Parenteral Products: Routes of administration, categories of Parenteral Products based on volume, formulation additives, development of Parenteral Products, Important parameters for Parenterals development, manufacturing of Parenterals, Quality Control requirements for Parenterals. **7 hours**

UNIT VI Ophthalmic Products: Absorption of drugs in the Eye, product development of ophthalmic products, general safety considerations, conventional ophthalmic dosage forms, Packaging and Storage, approaches for efficient drug delivery. Ophthalmic implants and shunts, Inserts, Non erodible ocular inserts, Erodible Ocular inserts, Contact lens, recent development of contact lenses (bandage lenses, therapeutic contact lenses in drug delivery, Silicone hydrogel based lenses), Collagen Shields and Implants, An anophthalmos and orbital implants, glaucoma shunts, particulate based drug carriers. **6 hours**

UNIT VII Topical Products: Structure of skin, Mechanisms of skin penetration, Percutaneous Absorption, Design of topical drug products (Gels, Liquid-Preparations, powders, Ointments), Novel Drug Delivery Systems for topical Drug Delivery (Micro emulsion, liposome, Transferons, Ethosomes, Hydrogels), Evaluation of topical dosage forms. Rectal Products: Advantages, Rectal preparations. **6 hours**

UNIT VIII Pharmaceutical Packaging: Packaging Materials, Glass, Plastic, Metals, Rubber, Evaluation of Packaging materials. Special problems of container product interactions, pharmacopoeial specifications tests and standards for packaging materials. **6 hours**

REFERENCE BOOKS:

1. Lachmen/Liberman - Theory and Practice of Industrial Pharmacy, Roop K. Khar, S.P. Vyas, Farhan J. Ahmad, Gaurav K. Jain, 4th Ed.
2. Pharmaceutical Dosage Forms and Drug Delivery Systems, Loyd V. Allen Jr., Nicholas B. Popovich, Howard C. Ansel, 9th Ed.

3. Aulton's Pharmaceutics – The Design and Manufacture of Medicines, Michael E. Aulton, 3rd Ed.
4. Remington – The Science and Practice of Pharmacy, 20th Ed.
5. Encyclopedia of Pharmaceutical Technology, James Swarbrick, 3rd Ed.
6. Pharmaceutical Dosage Forms – Tablets Vol 1 to 3, A. Liberman, Leon Lachman and Joseph B. Schwartz
7. Pharmaceutical Dosage Forms – Disperse Systems Vol 1 to 3, H.A. Liberman, Martin, M.R. and Gilbert S. Banker.
8. Pharmaceutical Dosage Forms – Parenteral Medication Vol 1 & 2, Kenneth E. Avis and H.A. Libermann.

Course No. 3211 PRODUCT FORMULATION AND DEVELOPMENT (PRACTICAL)

1. Preformulation studies of drugs like aspirin, sulfamethoxazole, nefidipine etc. using different excipients as per ICH guidelines.
2. Preparation and evaluation of matrix controlled drug delivery systems using suitable drugs like theophylline, diclofenac, aceclofenac.
3. Formulation and evaluation of oral disintegrating tablets using suitable drugs.
4. Formulation and evaluation of transdermal patches
5. Preparation and evaluation of microcapsules using techniques like coacervation-phase separation, ionic gelation method.
6. Formulation of dry syrup and its evaluation.
7. Formulation and evaluation of gastric floating drug delivery system
8. Comparison of different gels using diclofenac/aceclofenac like drugs
9. Formulation of liposomes and their characterization using microscopy.
10. Formulation and evaluation of suspensions containing suitable drugs.
11. Studies on effect of emulsifying agents on the stability of emulsion.

Course No. 3212 Comprehensive Viva

THIRD SEMESTER

Course No.3313 Seminar on the objectives and work plan of the proposed project to be completed within one month from the commencement of the project.

Course No.3314 Mid-term project review at the end of third semester.

Course No.3315 Seminar on the selected topic.

FOURTH SEMESTER

Course No.3416 Thesis evaluation.

Course No.3417 Thesis viva-voce.

4. PHARMACEUTICAL BIOTECHNOLOGY

FIRST SEMESTER

Course No. 4101 BIOSTATISTICS (THEORY)

(Common paper for all specializations)

Course No. 4102 MOLECULAR BIOTECHNOLOGY & GENETICS OF INDUSTRIAL MICROORGANISMS (THEORY)

LEARNING OBJECTIVES:

At the end of the course, the student is expected to gain the knowledge in

1. Nucleic acids, their role in gene expression & technologies for control of gene expression
2. Strain improvement techniques
3. Types and biological characterization of animal cell lines
4. Principles of rapid microbiological methods and its advantage over conventional methods
5. Different approaches to microbial taxonomy
6. Theory, advantages and limitations of microbial growth kinetics in batch and continuous culture
7. Isolation and identification of industrially important microorganisms and
8. Secondary metabolism and its importance in the production of bioactive metabolites.

UNIT I Gene expression – DNA replication, transcription and translation. Techniques of gene manipulation, cloning strategies, procedures, cloning vectors, expression vectors, recombinant selection and screening. **8 hours**

UNIT II DNA transfer and sources – cDNA, DNA libraries, synthetic DNA. Specific DNA techniques- DNA sequencing, genome sequencing, DNA hybridization, PCR technology. **7 hours**

UNIT III Molecular Diagnostics: Immunological diagnostic procedures – ELISA, Monoclonal antibodies – selection and identification of hybrid cells. DNA diagnostic systems : hybridization probes, DNA finger printing. **5 hours**

UNIT IV Animal Cell culture: Laboratory requirement of animal cell culture, principles of animal cell culture, establishment and maintenance of cell lines, cell type and biological characterization. Introduction to stem cell biology. **5 hours**

UNIT V The structure and chemistry of virus, prokaryotic and eukaryotic cell. The significance of viruses in fermentation industry. **3 hours**

Mechanism of action of mutagens such as UV & γ -rays, HNO_2 and nitosoguanidine (NTG) . Strain improvement of industrially important microorganisms (bacteria, actinomycetes and fungi): Mutation, recombination, regulation and other genetic methods. **7 hours**

UNIT VI Principles of Microbial taxonomy: New approaches to taxonomy – numerical taxonomy, genetic homology, 16s rRNA sequencing, immunological reaction and phage typing. **5 hours**

UNIT VII Rapid microbiological methods for isolation, detection and characterization of microorganisms – Growth based, artifact based, nucleic acid based and viability based methods. **5 hours**

UNIT VIII Methods for isolation, cultivation and maintenance of industrially important bacteria, actinomycetes, and fungi. Microbial growth and its kinetics: Batch and continuous culture, synchronous growth. Stability and degeneration of microbial cultures on repeated transfer. Secondary metabolism: Its importance in fermentation industry. **10 hours**

REFERENCE BOOKS:

1. General Microbiology by Stanier, R.Y et al.
2. Molecular Biotechnology – Principles and Applications of Recombinant DNA by Bernard R.Glick, Jack J. Pasternak. Third Edition 2003 ASM Press.
3. Microbial Limit and Bioburden Tests – Validation Approaches and Global Requirements by Lucia Clontz, Second edition 2009 CRC Press.
4. Microbiology – Principles and Explorations by Jacquelyn G.Black, 6th Edition, John Wiley & Sons Publications.
5. Principles of Gene Manipulation – An Introduction to Genetic Engineering by R.W.Old & S. B. Primrose, 5th Edition 2003,Blackell Science Publications.
6. Molecular Cell Biology by Harvey Lodish et.al 6th Edition 2005, W.H. Freeman and Company, New York.

7. Culture of Animal Cells – A Manual of Basic Technique and Specialized Applications by R. Ian Freshney 6th Edition, Willey-Blackwell.
8. Molecular Biology and Biotechnology by John M. Walker and Ralph Rapley 4th Edition, 2000 Published by Royal Society of Chemistry.
9. Principles of Fermentation Technology by Peter F. Stanbury, A. Whitaker and S.J. Hall , 2nd Edition 1995, published by Butterworth – Heinemann Ltd., Oxford
10. Biotechnology : A Text book of Industrial Microbiology by Wulf Crueger and Anneliese Cruger, 2nd Edition 1989, Panima Publishing Corportation.
11. Pharmaceutical Biotechnology by Daan J.A Crommelin and Robert D. Sindelar, 2nd Edition 2002, published by Taylor & Francis, New York.

Course. No. 4103 MOLECULAR BIOTECHNOLOGY & GENETICS OF INDUSTRIAL MICROORGANISMS (PRACTICAL)

(Practicals based on theory)

Course No. 4104 BIOPROCESS TECHNOLOGY (THEORY)

LEARNING OBJECTIVES:

At the end of the course the student is expected to gain knowledge in

1. Development and optimization of fermentation medium
2. Fermentation process development and optimization
3. Production of specific bioactive metabolites on large scale
4. Production of specific biopharmaceuticals on large scale
5. Economic considerations in the production of above products and their safety regulations
6. Types & importance of microbial transformations

UNIT I An Introduction to fermentation processes: The range of fermentation processes – Microbial biomass, enzymes, metabolites, recombinant products and transformation processes.

2 hours

UNIT II Screening techniques, stock cultures, fermentation media and medium optimization, detection and assays of fermentation products. The development of inocula for industrial fermentations.

6 hours

UNIT III Microbial synthesis of the following commercial products:

- a. Organic acids: Citric and lactic acids

b. Beer : Types of beers , elements of brewing process.

c. Amino acids: Glutamic acid and lysine

d. Nucleotide: Cyclic 5'GMP

7 hours

UNIT IV Microbial transformations: Types, procedures for biotransformation, applications and economically important transformations. Microbial polysaccharides: Dextran, Pullulan

5 hours

UNIT V Fermentative production of the following bioactive metabolites :

a. Antibiotics: Cephalosporins, semi-synthetic penicillins, erythromycin, amphotericin and antitumor antibiotics

b. Enzymes: Streptokinase and amylase

7 hours

UNIT VI Prebiotics : Inulin, fructooligosaccharides; Probiotics *Bifidobacterium* and *Lactobacillus* Biosurfactants: Glycolipids and Rhamnolipids

6 hours

UNIT VII Production of the following Biopharmaceuticals by rDNA technology

15 hours

a. Interferons

b. Erythropoietin

c. Granulocyte colony stimulating factor (G-CSF)

d. Human Growth hormone (hGH)

e. Genetically improved live and subunit vaccines.

UNIT VIII

Economic considerations in Pharmaceutical biotechnology : Introduction, the value of a new medical technology, an overview of economic analysis for new technologies, pharmacoeconomics. Biosafety and regulation of biotechproducts.

7 hours

References (List of Text books):

1. Industrial Microbiology by Prescott & Dunn 4th Edition, Macmillan Publishers.
2. Industrial microbiology by L.E. Casida Jr.
3. Biotechnology : A Text book of Industrial Microbiology by Wulf Crueger and Anneliese Cruger, 2nd Edition, Panima Publishing Corporation.
4. Principles of Fermentation Technology by Peter F. Stanbury, A. Whitaker and S.J. Hall , 2nd Edition 1995, published by Butterworth – Heinemann Ltd., Oxford

5. Molecular Biotechnology – Principles and Applications of Recombinant DNA by Bernard R.Glick, Jack J. Pasternak. Third Edition ASM Press.
6. Pharmaceutical Biotechnology by Daan J.A Crommelin and Robert D. Sindelar, 2nd Edition, published by Taylor & Francis, New York.
7. Modern Industrial Microbiology and Biotechnology by Nduka Okafor, Science Publishers, USA.

Course No. 4105 BIOPROCESS TECHNOLOGY (PRACTICAL)

(Practicals based on theory)

Course No. 4106 Comprehensive viva

PHARMACEUTICAL BIOTECHNOLOGY

SECOND SEMESTER

Course No. 4207 MODERN ANALYTICAL TECHNIQUES (THEORY)

(Common paper for all specializations)

Course No. 4208 QUALITY ASSURANCE AND DRUG REGULATORY AFFAIRS (THEORY) (Common paper for all specializations)

Course No. 4209 ADVANCED PHARMACEUTICAL BIOTECHNOLOGY (THEORY)

LEARNING OBJECTIVES:

At the end of the course the student is expected to gain knowledge in

- a. Recent developments and techniques of enzyme engineering
- b. Applications of gene manipulation
- c. Formulation development of biopharmaceuticals
- d. Concepts of pharmacogenomics, proteomics, bioinformatics and biosimilars
- e. Production and applications of monoclonal antibodies and
- f. Formulation development of subunit and dna vaccines.

UNIT I Immobilized enzyme engineering: Concept of immobilization, detail study of methods of immobilization, immobilized enzyme kinetics. Types, design and operation of immobilized enzyme reactors. Problems in using immobilized biocatalysts; medical, analytical and other applications of immobilized enzymes. **5 hours**

UNIT II Computer applications in bioprocess control: General applications, specific applications: Data logging, data analysis, process modeling, process control and optimization. System configuration. **4 hours**

UNIT III Applications of gene manipulation: Gene therapy – *Ex vivo*, *in vivo* gene therapy; potential target diseases for gene therapy- inherited disorders and cancer. Gene transfer methods – viral and non-viral methods. Concept of antisense and ribozyme technology. A brief study of Human genome project and its applications. **7 hours**

UNIT IV Biophysical and biochemical analysis of recombinant proteins: Protein structure, folding and stability. Analytical techniques: Blotting techniques, immune assays, electrophoresis, chromatography and mass spectroscopy. Introduction to proteomics. **6 hours**

UNIT V Formulation of biotech products including biopharmaceutical considerations: Microbiological considerations, excipients used in parenteral formulations of biotech products, shelf life of protein based pharmaceuticals. Delivery of proteins: Routes of administration and absorption enhancement, approaches for rate controlled and target site specific delivery by parenteral route. Introduction to pharmacokinetics and pharmacodynamics of peptide and protein drugs. **9 hours**

UNIT VI Pharmacogenomics : Genetic mapping of human chromosomes - genetic polymorphism, restriction fragment length polymorphism, short tandem repeat polymorphism. Bioinformatics: Introduction, databases – sequence, genome, enzyme and literature databases; sequence analysis and other nucleic acid sequence analysis; protein structure and mapping; Bioinformatics sites and centers. Biosimilars : Introduction, existing biosimilars, emerging biosimilars, development of biosimilars, comparison of bioequivalency/biosimilarity, regulatory requirements, interchangeability of biosimilar. **12 hours**

UNIT VII Immunobiotechnology: Antibody structure and antigen recognition, general procedure for the production of monoclonal antibodies(hybridoma technique), development of monoclonal antibodies as therapeutics – murine, chimeric, humanized and human antibodies with examples. Autoimmunity. **6 hours**

UNIT VIII Vaccines: Immunological principles, attenuated, killed, subunit and DNA vaccines. Pharmaceutical considerations – production, formulation, characterization and storage. **6 hours**

REFERNCEBOOKS:

1. Pharmaceutical Biotechnology by Daan J.A Crommelin and Robert D. Sindelar, 2nd Edition 2002, published by Taylor & Francis, New York.
2. Selected topics in enzyme engineering by Wingard Jr. L. B.
3. Immobilized enzymes by Messing
4. Fermentation Microbiology and Biotechnology by Mansi El-Mansi and Charlie Bryce, published by Taylor & Francis, New York.

5. Principles of Gene Manipulation – An Introduction to Genetic Engineering by R.W.Old & S. B. Primrose, 5th Edition 2003, Blackell Science Publications.
6. Molecular Biotechnology – Principles and Applications of Recombinant DNA by Bernard R.Glick, Jack J. Pasternak. Third Edition 2003 ASM Press.
7. Molecular Biology and Biotechnology by John M. Walker and Ralph Rapley 4th Edition 2000, Published by Royal Society of Chemistry.

Course No. 4210 BIOCHEMICAL ENGINEERING (THEORY)

LEARNING OBJECTIVES:

At the end of the course the student is expected to gain knowledge in

1. Design and operation of fermenter and its ancillary fittings, measurement of bioprocess parameters, maintaining the aseptic condition and containment levels during operation of the fermenter.
2. Theory of mass transport phenomena in bioprocess systems and various methods for the measurement of volumetric mass transfer coefficient.
3. Kinetics of thermal sterilization, various methods used and their usage & limitations in a fermentation process.
4. Fermentation process kinetics in batch and continuous process.
5. Theory and practice of different unit operations used in the recovery of a fermentative product and its identification in culture broth by different methods.
6. Concept of scale up process.

UNIT I Detailed study of design and operation of different types of bioreactors, ancillary fittings like sampling point, aseptic transfer of spore suspension, transfer of inoculum from seed tank to bioreactor; impeller design and agitator power requirements. **5 hours**

UNIT II Achievement and maintenance of aseptic conditions, containment requirements for different groups of microorganisms. Measurement and control of dissolved oxygen, CO₂, temperature, pH, and foam. **4 hours**

UNIT III Transport phenomena in bioprocess systems: Effects of aeration and agitation; Gas – liquid mass transfer in cellular systems – basic mass transfer concepts, rates of metabolic oxygen utilization; Determination of oxygen transfer rates – measurement of K_La using gas-liquid reactions and factors affecting K_La value. **8 hours**

UNIT IV Sterilization of medium, fermenter, air and other added material: Kinetics of sterilization, Del factor, thermal death times, inactivation of bacterial spores, continuous sterilization and batch sterilization – merits and limitations, the design of continuous and batch sterilization processes. HTST sterilization and its limitations. **5 hours**

UNIT V Sterilization of the fermenter. Sterilization of air by filtration through fibrous filters and modern filters like pleated membrane, fixed pore filters.
Rheology of fermentation systems and its importance in fermenter operation. **5 hours**

UNIT VI Fermentation process kinetics: Reaction kinetics – Monod equation, Michaelis-Menten constant, Lineweaver - Burk plot; Kinetics of continuous fermentation, advantages and limitations. **5 hours**

UNIT VII Theory of single and two stage continuous fermentation systems, applications. Kinetics of fed-batch culture systems. Scale up of fermentation processes: Principles, theoretical considerations and techniques used. **5 hours**

UNIT VIII Biotech product recovery operations: Theory, equipment, design, operation and applications of the following in recovery process – filtration, centrifugation, liquid-liquid extraction, two phase aqueous extraction, precipitation, chromatography techniques, membrane processes, drying, freeze drying and crystallization. Turbidity analysis and cell yield determinations, metabolic response assays, enzymatic assays; Bioautographic technique and disintegration of cells. **18 hours**

REFERENCEBOOKS:

1. Biochemical engineering by F.C. Webb
2. Biochemical Engineering fundamentals by J.E. Bailey and D.F. Ollis 2nd Edition 1986
3. Biochemical Engineering by R.Steel
4. Principles of Fermentation Technology by Peter F. Stanbury, A.Whitaker and S.J. Hall , 2nd Edition 1995, published by Butterworth – Heinemann Ltd., Oxford
5. Pharmaceutical Biotechnology by Daan J.A Crommelin and Robert D. Sindelar, 2nd Edition, published by Taylor & Francis, New York.
6. Fermentation Microbiology and Biotechnology by Mansi El-Mansi and Charlie Bryce, published by Taylor & Francis, New York.

7. Fermentation and biochemical engineering hand book by Henry C Vogel.

Course No. 4211 BIOCHEMICAL ENGINEERING (PRACTICAL)

(Practicals based on theory)

Course No. 4212 Comprehensive Viva

THIRD SEMESTER

Course No 4313 Seminar on the objectives and work plan of the proposed project to be completed within one month from the commencement of the project.

Course No 4314 Mid-term project review at the end of third semester.

Course No 4315 Seminar on the selected topic.

FOURTH SEMESTER

Course No 4416 Thesis evaluations.

Course No 4417 Thesis viva-voce.

5. PHARMACOLOGY

FIRST SEMESTER

Course No. 5101 BIOSTATISTICS (THEORY)

(Common paper for all specializations)

Course No. 5102 PHARMACOKINETICS AND DRUG METABOLISM (THEORY)

LEARNING OBJECTIVES:

1. To impart the knowledge on the mechanisms of drug transport across the biological membranes
2. To train the students about how the protein binding / tissue binding influence the distribution of the drugs.
3. To train the students about how the drugs gets metabolized in order to eliminate from the body.
4. How drugs or metabolites gets excreted by various routes of excretion from the body.
5. To impart the knowledge on the clinical applications of pharmacokinetics of the drug molecules and the maintenance on the drug concentration levels in the blood.

UNIT I Absorption

- a. Transfer of drugs through biological membranes (including Blood Brain Barrier, Placental Barrier)
- b. Factors affecting drug absorption, Role of P-glycoprotein in drug absorption
- c. Gastrointestinal, Percutaneous and Rectal absorption

UNIT II Absorption Kinetics

- a. Absorption Kinetics, Wagner Nelson & Loo Riegelman methods
- b. *In Vitro* methods of drug absorption (PAMPA and CACO2 models)

UNIT III Distribution

- a. Plasma protein binding, factors affecting plasma protein binding
- b. Kinetics of protein binding, Tissue binding, Volume of distribution

UNIT IV Metabolism

- a. Microsomal & Non microsomal biotransformations of drugs (Liver, kidney and intestine)
- b. First pass effect
- c. Human Cytochrome P 450 enzymes, Substrates, inducers and inhibitors of CYP enzymes

- d. *In Vitro* methods of drug metabolism (Liver microsomes, Liver S9 fraction & Hepatocytes)

UNIT V Factors Affecting Metabolism

- a. Physiological, Pathological factors affecting drug metabolism
- b. Genetic factors influencing drug metabolism

UNIT VI Excretion

- a. Excretion of drugs by various routes
- b. Factors affecting excretion of drugs
- c. Enterohepatic recirculation
- d. Significance of elimination rate constant and elimination half life

UNIT VII Clinical Pharmacokinetics

- a. Basic concepts of clinical pharmacokinetics
- b. Therapeutic drug monitoring
- c. Population pharmacokinetics
- d. Pharmacokinetic and Pharmacodynamic modeling (PK/PD modeling)

UNIT VIII Drug Interactions

- a. Drug interactions and their clinical significance
- b. Prediction of drug interactions and their management

REFERENCE BOOKS

1. Applied Biopharmaceutics & Pharmacokinetics, Leon Shargel , Andrew Yu, Susanna Wu-Pong ,Mc Graw Hill Publishing Company.
2. Biopharmaceutics & Pharmacokinetics A Treatise, D M Brahmkar, Sunil B Jaiswal, Vallabh Publications Prakashan.
3. Biopharmaceutics and Clinical Pharmacokinetics ,
4. Milo Gibaldi, Publisher: Lea & Febiger
5. Biopharmaceutics and pharmacokinetics: An introduction by Robert E Notari , Publisher: M. Dekker.

Course No. 5103 PHARMACOKINETICS AND DRUG METABOLISM (PRACTICAL)

(Practicals based on theory)

RECOMMENDED BOOKS:

1. Biopharmaceutics and Pharmacokinetics an introduction by Robert E. Notari.
2. Drug metabolism by Bernard Testa and Peter Jenner.

3. Selected chapters from: Principles of drug action by Goldstein, Aranow and Kalman.
4. Drug interaction edited by D.G. Grahme – Smith.
5. Remington's Pharmaceutical Sciences.
6. Goodman and Gillman's The Pharmacological basis of therapeutics 10th edition.

Course No. 5104 SYSTEMIC PHARMACOLOGY (THEORY)

LEARNING OBJECTIVES:

1. To have knowledge on physiological role of autonomic nervous system, pharmacology of sympathetic, parasympathetic mimetics and lytics with relevance to their clinical applications.
2. Functional organization of the CNS, its synaptic transmitters (neurotransmitters) and their role in the CNS. Understanding of all drugs with CNS effects act on specific receptors that modulate synaptic transmission.
3. Basic understanding of algesia, pyrexia, inflammation, cancer and immunity, and understanding the pharmacology of the drugs.
4. To study the pathophysiological aspects of CVS & renal systems and its implication in health problems and understanding the pharmacology of the drugs.
5. To understand the molecular targets of anti-microbial drugs, identification of new targets and pharmacology of chemo-therapeutic drugs.
6. To study and understanding the physiological role of endocrine glands and their pathophysiological state on health and the pharmacology of drugs used.
7. Basic knowledge on coagulation, thrombus and platelet aggregation and pharmacology of drugs used in the above pathological conditions.

UNIT I Introduction

Basic principles of Pharmacology. Mechanisms of drug action, Receptor proteins, Types of Receptor proteins and their Molecular structure, Targets for G-Protein coupled receptors, Protein phosphorylation and Kinase cascade mechanisms, Cellular aspects- Excitation, contraction and Secretion.

UNIT II Pharmacology of Autonomic Nervous System:

- a. Physiology of autonomic nervous system
- b. Muscarinic receptor agonists and antagonists
- c. Anticholinesterase agents
- d. Adrenergic agonists and antagonists

- e. Agents acting at neuromuscular junction and autonomic ganglia.

UNIT III Drugs acting on Central Nervous System:

- a. Neurotransmission in central nervous system
- b. Anti epileptics
- c. CNS stimulants
- d. Anti psychotics
- e. Antidepressants
- f. Hypnotics and Sedatives
- g. Opioid analgesics
- h. Drug addiction and Drug Abuse

UNIT IV

Analgesic, Antipyretic and Anti-inflammatory agents, Antineoplastic agents, Immunosuppressants and immunostimulants.

UNIT V Drugs affecting Cardiovascular and Renal functions:

- a. Cardiotonics
- b. Anti-arrhythmics
- c. Anti-hypertensives
- d. Anti-anginals
- e. Anti-hyperlipidemic drugs
- f. Diuretics

UNIT VI Pharmacology of Chemotherapeutic and Anti- microbial agents:

- a. General considerations of antimicrobial therapy
- b. Sulfonamides, trimethoprim, quinolones, other related agents
- c. Penicillins, Cephalosporins, and other beta lactam antibiotics
- d. Aminoglycosides
- e. Protein synthesis inhibitors and miscellaneous anti-bacterial agents
- f. Anti-fungal agents
- g. Antiviral agents
- h. Chemotherapy of Tuberculosis , Leprosy and malaria
- i. Chemotherapy of Protozoal infections

UNIT VII Hormones and their antagonists:

- a. Pituitary hormones and their hypothalamic releasing factors
- b. Thyroid and anti-thyroid drugs

- c. Endocrine pancreas; Pharmacotherapy of Diabetes Mellitus
- d. Estrogens and progestins
- e. Androgens

UNIT VIII Drugs acting on the Blood and Blood-Forming Organs:

- a. Hematopoietic agents: Growth factors, minerals and vitamins
- b. Blood coagulation and anti-coagulant, thrombolytic and anti-platelet drugs.

RECOMMENDED BOOKS:

1. Pharmacology and Pharmacotherapeutics revised 18th edition by R.S. Satoskar, S.D Bhandarker and S.S. Ainapure.
2. Goodman and Gilman's The Pharmacological basis of therapeutics 10th edition.
3. Pharmacology 5th edition by M.M. Rang and H.D. Dale.
4. Basic and clinical pharmacology 8th edition edited by Bertram G. Katzung. Susan B. Masters and Anthony J.Trevor.

Course No.5105 Systematic Pharmacology (Practical)

(Practicals based on theory)

Course No.5106 Comprehensive Viva

**PHARMACOLOGY
SECOND SEMESTER**

Course No. 5207 MODERN ANALYTICAL TECHNIQUES (THEORY)

(Common paper for all specializations)

Course No. 5208 QUALITY ASSURANCE AND DRUG REGULATORY AFFAIRS

(THEORY) (Common paper for all specializations)

Course No. 5209 ADVANCED PHARMACOLOGY (THEORY)

LEARNING OBJECTIVES:

1. To have knowledge on cellular signaling, neurotransmitters and their receptors.
2. To have knowledge on cell communication, signaling through G-Proteins, enzymes and other signaling pathways.
3. To gain knowledge on mechanisms involved in the formation, release, possible physiological role, pharmacological actions, agonists, antagonists and therapeutic potentials of neuropeptides.

4. To acquire knowledge on autocooids and peptides, and their pharmacology.
5. To understand the role of transporter proteins.
6. To know principles of clinical pharmacology and knowledge on clinical trials.
7. To have knowledge on stem cells and their therapeutic potentials.
8. To understand the nature and role of free radicals in biological systems in health and disease.

UNIT I

Molecular Pharmacology:

Pharmacology of receptors: Classification, Cellular signaling systems, and pharmacology of agonists and antagonists of the following receptors

1. Excitatory amino acid receptors
2. Purinoreceptors
3. GABA and Glycine receptors
4. Neurosteroid receptors
5. Cannabinoid receptors
6. Melatonin receptors
7. Adrenergic receptors
8. Cholinergic receptors
9. Dopaminergic receptors
10. Serotonergic receptors

UNIT II

Signaling mechanisms: Physiological function, pharmacological implications and therapeutic potential of the following target sites:

1. Phosphoinositide 3-kinase (P13K)
2. MAP kinase
3. Akt (Protein Kinase B)
4. Caspases
5. Peroxisome proliferator activator receptors (PPAR) – α and γ
6. Protein kinases
7. Phosphodiesterases

UNIT III

Neuropeptides:

1. Calcitonin gene related peptides (CGRP)
2. Neuropeptide Y
3. c-AMP
4. Substance P
5. Cholecystokinin

UNIT IV

Endogenous Mediators:

- | | |
|----------------------|-------------------|
| 1. Histamine | 2. Prostaglandins |
| 3. Leucotrienes | 4. Kinins |
| 5. Opioids | 6. Nitric oxide |
| 7. EDRF, EDCF & EDHF | 8. 5-HT |

UNIT V

Transporter Proteins: Classification and biology of ATP binding cassette (ABC) transporter superfamily.

Multidrug resistance (MDR) proteins

Cystic fibrosis trans-membrane regulator (CFTR)

UNIT VI

Principles of clinical pharmacology and designs for testing of drugs in humans. Clinical Trials- Phases I,II,III,IV.

UNIT VII

Stem Cells: Basic concepts and therapeutic applications in medicine.

UNIT VIII

Free radicals, their biological role, Endogenous anti-oxidant systems and their role in tissue protection.

RECOMMENDED BOOKS:

1. Goodman and Gilman's The Pharmacological basis of therapeutics 10th edition
2. Pharmacology 5th edition by M.M. Rang and H.D. Dale.
3. Basic and clinical pharmacology 8th edition edited by Bertram G. Katzung, Susan B.Masters and Anthony J.Trevor.
4. Clinical pharmacology by Molmon and Morelli.
5. Free radicals by Michael Brooks

(Source:<http://www.waterstones.com/wat/images/special/pdf/9781847654496.pdf>)

6. Free radical mechanisms of tissue injury by Mary Treinen Moslen Charles V Smith (Source: http://books.google.co.in/books/about/FreeRadical_Mechanisms_of_Tissue_Injury.html?W0kztp7vmkC&redir_esc=y)
7. Stem cells by Paul Knoepfler (source : Amazon.com)
8. Stem cells : A Very short introduction by Jonathan Slack (Source: Amazon.com)

Course No. 5210 BIOASSAYS AND PHARMACOLOGICAL SCREENING METHODS (THEORY)

LEARNING OBJECTIVES:

1. To learn about handling of animals, anaesthetics used, regulation for care and use of laboratory animals, strategies and approaches employed in drug discovery.
2. Knowledge on bio-assays, their importance, its application in the present context. Principles and procedures of bio-assays of IP.
3. Knowledge on simple, blind and programmed screening, screening of compounds or drugs from various origins for establishing defined pharmacological activity etc.
4. Calculation of LD₅₀, ED₅₀ and knowledge on acute, sub-acute and chronic toxicity studies.

UNIT I

Principles of Experimental Pharmacology and Drug Discovery:

Common laboratory animals in pharmacological research, Limitations of animal tests, Alternatives to animal use, Anesthetics used in laboratory animals, Some standard techniques used in handling laboratory animals, Euthanasia of experimental animals. Regulation for the care and use of laboratory animals.

Strategies and approaches employed in drug discovery. Basic concepts of combinatorial chemistry, High throughput screening, Cell lines and their applications in drug discovery. Transgenic animal models in the development of new drugs.

UNIT II

Principles of Biological Standardization: Statistical treatment of model problems in the biological evaluation of drugs. Methods used in the bioassays for antibiotics and microbiological assays. Bioassay for diphtheria antitoxin; Tetanus; Cholera vaccine; Posterior pituitary extract; Adrenalin; Heparin; Digitalis; d-Tubocurarine. Test for pyrogens.

UNIT III

Bioassay methods for Autocoids, Development of new bioassay methods. Assays using special designs for experiments to eliminate known source of variation. Toxicity tests, Determination of

LD₅₀, Acute, Sub acute, and Chronic toxicity studies- Tests for freedom from undue toxicity of drugs.

UNIT IV

Basic principles of screening and types- Simple, Blind and Programmed screening. Need for isolated tissues in pharmacological evaluation of drugs.

UNIT V

Organization for Screening of Pharmacological activity and Evaluation of new substances

CVS:

1. Diuretics
2. Anti-hypertensives
3. Anti-anginal agents
4. Anti-arrhythmic agents and agents used in sudden cardiac failure
5. Drugs used in cardio myopathies
6. Drugs used in hyperlipidemia and atherosclerosis
7. Anti-infarct agents

UNIT VI

CNS:

1. Anti-epileptics
2. Anti-Parkinsonian agents
3. Anti-migraine agents
4. Anti-anxiety agents and drugs used in mood and sleep disorders
5. Antipsychotics
6. Drugs affecting memory
7. Drugs used in Alzheimer's disease

UNIT VII

1. Local Anesthetics
2. Skeletal muscle relaxants and neuromuscular blockers
3. Anti-ulcer agents
4. Hepatoprotective agents

UNIT VIII

Others:

1. Anti-diabetic agents
2. Analgesics and drugs used in arthritis and Neuropathic pain
3. Anti-inflammatory agents

4. Anti-asthmatic agents

REFERENCE BOOKS:

1. H.G. Vogel (ed), Drug Discovery and Evaluation- Pharmacological Assays, 2nd Edition, Springer verlag, Berlin, Germany, 2002.
2. Screening Methods in Pharmacology by Robert A. Turner.
3. D.R. Laurence and A.L. Bacharach (Eds), Evaluation of Drug activities: Pharmacometrics, Volume I and II, Academic Press, London, U.K, 1964.
4. Biological Standardization by J.H. Burn, D.J. Finney and L.G. Goodwin.
5. Pharmacopoeias: IP, BP, USP
6. M.N. Ghosh, Fundamentals of Experimental Pharmacology, 2nd Edition, Scientific Book Agency, Calcutta, India, 1985.
7. Methods in Pharmacology by Swarbrick.

Course No. 5211 BIOASSAYS AND PHARMACOLOGICAL SCREENING METHODS (PRACTICAL) (Practicals based on Theory)

RECOMMENDED BOOKS:

1. Biological standardization by J.H. Burn, D.J. Finney and L.G. Goodwin.
2. Pharmacopoeias: IP, BP, USP.
3. Screening methods in Pharmacology by Robert A. Turner.
4. Evaluation of drug activities by Laurance and Bachrach.
5. Drug evaluation 6th edition by Vogel.
6. Methods in Pharmacology by Swarbrick.

Course No. 5212: Comprehensive viva

THIRD SEMESTER

Course No. 5313 Seminar on the objectives and work plan of the proposed project to be completed within one month from the commencement of the project.

Course No. 5314 Mid-term project review at the end of third semester.

Course No. 5315 Seminar on the selected topic.

FOURTH SEMESTER

Course No. 5416 Thesis evaluation.

Course No. 5417 Thesis viva-voce.

6. PHARMACOGNOSY AND PHYTOCHEMISTRY

FIRST SEMESTER

Course No. 6101 BIOSTATISTICS (THEORY)

(Common paper for all specialisations)

Course No. 6102 ADVANCED PHARMACOGNOSY AND PHYTOCHEMISTRY (THEORY)

LEARNING OBJECTIVES:

1. To train students in Medicinal Plants Cultivation, Preliminary Phytochemical Study of some phytoconstituents & Structural Elucidations.
2. To acquaint students about the Marine Pharmacognosy / Applications of Spectroscopy & Chromatography.
3. To give latest updates in this area.

UNIT I Medicinal Plants Cultivation

- (a) General aspects involved in the cultivation of medicinal plants.
- (b) Factors involved in production of crude drugs
 - (i) Exogenous
 - (ii) Mineral supplements
 - (iii) Nutrients
 - (iv) Growth regulators and inhibitors
- (c) Pest/weed control. Study of pesticide and weedicides with special importance to natural origin.

UNIT II Systematic methods of cultivation and post harvest technology for medicinal plants cultivated in India.

Senna, Vinca, Ispagula, Opium, Acorus, Garcinia, Lemon grass, Aswagandha

UNIT III Detailed phytochemical study of the following class of phytoconstituents.

- (a) Phospholipids - Biosynthesis of lipids, palmitic acid, prostaglandins
- (b) Terpenes and Triterpenoids - Camphor, Menthol, Artemisinin, Forskolin, Taxol, Azadirachta
- (c) Resins and related compounds - Cannabis, Ginger, Myrrh, Benzoin
- (d) Plant phenols - Phenyl propanoids, Capsaicin, Podophyllotoxin, Rutin, Tannins, Gossypin

UNIT IV Phytochemical study of the following class of phytoconstituents

- (a) Alkaloids - Nicotine, Atropine, Quinine, Emetine, Morphine, Reserpine, Caffeine
- (b) Glycosides - Anthraquinone glycosides, Cardiac glycosides, Saponin Glycosides
- (c) Steroids - Cholesterol, Vitamin A&D Diosgenin

UNIT V Structure elucidation of important phytoconstituents belonging to different groups.

- (a) Alkaloids : Nicotine, Atropine, Morphine, Caffeine
- (b) Glycosides : Digitoxin
- (c) Steroids : Cholesterol
- (d) Terpenes : Camphor, Menthol, Cineole

UNIT VI Marine Pharmacognosy

- (a) Study of important bioactive agents including chemistry and uses.
- (b) Definition, present status and classification of important bioactive agents from Marine Source.

UNIT VII Applications of UV, IR, ¹HNMR, ¹³CNMR and Mass Spectroscopy in the structural elucidation of Natural products.

UNIT VIII Chromatographic applications (TLC, PC, HPLC, HPTLC, GLC) in the isolation, separation and purification of Natural products

Course No. 6103 ADVANCED PHARMACOGNOSY AND PHYTOCHEMISTRY (PRACTICAL)

- I. Isolation, separation, purification and identification of important phytoconstituents
 - a) Starch from potatoes
 - b) Myristicin from nutmeg
 - c) Eugenol from clove
 - d) Curcumin from turmeric
 - e) Sennosides from senna
 - f) Glycyrrhizin from glycyrrhiza
 - g) Caffeine from tea
- II. Quantitative microscopy
- III. Spectral interpretation (UV, IR, NMR and Mass)

REFERENCE BOOKS:

1. Organic Chemistry of Natural Products, Vol. 1 & 2. Gurdeep R. Chatwal.
2. I.L. Finar: Organic Chemistry – Vol. I & II.
3. Pharmacognosy – G.E. Tease and W.C. Evans.
4. Pharmacognosy – Tyler, Brady, Robbers
5. Modern Methods of Plant Analysis – Peech & M.V. Tracey, Vol. I to VII.
6. Phytochemistry – Vol. I to IV Miller Jan Nostrant Renhold.
7. Recent Advances in Phytochemistry – Vol. 1 to 4 Scikel Runeckles – Appleton Century Crofts.
8. Chemistry of Natural Products – Vol. 1 onwards IWPAC.
9. Natural Products – Chemistry Nakanishi Golo
10. Natural Products – A Laboratory Guide, Raphaelkhan
11. The Essential Oils – Ernest Guenther – Robbert E. Kreiger 1)
The Alkaloids Chemistry & Physiology – Vols. R.H.F. Manske
12. Introduction to Molecular Phytochemistry – Paul J. Schewer 1973.
13. Chemistry of Marine Natural Products – Paul J. Schewer 1973.
14. Marine Pharmacognosy Ed. By Dean F. Martin & George Padilla.
15. Marine Natural Products – Vol. I to IV.
16. Comparative Phytochemistry edited by T. Swain.
17. Chemical Plant Taxonomy edited by T. Swain
18. Cultivation of Medicinal Plants by C.K. Atal & B.M. Kapoor.
19. Cultivation and Utilisation of Aromatic Plants by C.K. Atal and B.M. Kapoor.
20. Plant Propagation Principles and Practices – Hertmann Kester
21. Ayurvedic Formulary of India, Government of India.
22. Glimpses of Indian Ethano-pharmacology by V.V. Pushpangadan.

Course No. 6104 INDUSTRIAL PHARMOCOGNOSY (THEORY)

LEARNING OBJECTIVES:

1. To impart training in Isolation and estimation of some phytoconstituents, Applications of HPLC & HPTLC in Natural Products.
2. To introduce the concept of quality control of phytochemicals, Herbal Formulations & their Standardization.
3. To give latest updates in this area.

UNIT I General methods of isolation, purification, identification and estimation of phytoconstituents. Morphine, quinine, emetine, sennosides, volatile oils.

UNIT II Commerce and quality control methods of crude drugs.

UNIT III Different methods (including industrial) for the isolation and estimation of the following phytopharmaceuticals.

- (a) Starch, (b) Caffeine, (c) Atropine, (d) Taxol, (e) Vinca alkaloids,
- (f) Withaferin, (g) Ergometrine, (h) Morphine

UNIT IV Applications of HPLC and HPTLC in the isolation, separation and identification of natural products.

- (a) Vasicine, (b) Bacopside (c) Solasodine, (d) Lupeol

UNIT V Herbal based industries.

Study of infrastructure, regulatory requirements, research, patents and scope.

UNIT VI Study of herbal extracts

- (a) Processing, (b) Plant and equipment, (c) Project profile

UNIT VII Study of the following herbal extracts for processing and standardisation

- (a) *Withania somnifera*, (b) *Ocimum sanctum*,
- (c) *Adathoda vasica* (d) *Centella asiatica*,
- (e) *Melia azadirachta*

UNIT VIII Study of herbal formulations and their standardisation.

Course No. 6105 INDUSTRIAL PHARMOCOGNOSY (PRACTICAL)

- I. Chromatography of various classes of Phytoconstituents (PC, TLC, Column)
- II. Evaluation of crude drugs
 - (a) Extractive values
 - (b) Moisture content
 - (c) Ash values
 - (d) Volatile oil content
 - (e) Percentage of active constituents
- III. Spectroscopic analysis of plant constituents.
- IV. Monographic analysis of crude drugs mentioned in IP.
- V. Standardisation of herbal formulations.

REFERENCE BOOKS:

1. Pharmacognosy by G.E. Trease, W.c. Evans, ELBS.
2. Pharmacognosy by Varro E. Iylor, Lynn R. Brody, James E. Robberts, K.M. Varghese Co., Mumbai.
3. Text book of Pharmacognosy by T.E. Wallis, CBS Pub., Delhi.
4. Diosgenin and other Steroid Drug Precursors by Asolkar, CSIR.
5. Steroids by Feiry and Feisher.
6. Alkaloids Chemical and Biological by S.W. Pelletier.
7. Chromatography of Alkaloides by Vapoorte, Swendson.
8. Elements of Chromatography by P.K. Lala.
9. Jenkins Quantitative Pharmaceutical Chemistry by A.N. Knewell.
10. Clarke's Isolation and Identification o Drugs by A.C. Mottal.
11. Selected Topics in Exp-Pharmacology by Seth V.K.
12. Phytochemical Methods of Chemical Analysis by Harborne.
13. Organic Chemistry Vol. II by I.L. finar.
14. The Use of Pharmacological Techniques for the Evaluation of Natural Products by B.N. Dhavan, R.c. Srimal, CDRI, Lucknow.
15. Herbal Drugs Industry by R.D. Chaudhri.
16. Herbal Pharmacopoeia.
17. HPLC Methods of Drug Analysis by Mantu K. Ghosh.

Course No. 6106 Comprehensive Viva.

PHARMACOGNOSY AND PHYTOCHEMISTRY SECOND SEMESTER

Course No. 6207 MODERN ANALYTICAL TECHNIQUES (THEORY) (Common paper for all specializations)

Course No. 6208 QUALITY ASSURANCE AND DRUG REGULATORY AFFAIRS (THEORY) (Common paper for all specializations)

Course No. 6209 BIOLOGICAL EVALUATION OF NATURAL PRODUCTS (THEORY)

LEARNING OBJECTIVES:

1. To impart advanced level knowledge in Screening of new substances for pharmacological activity

2. To give training in Biological Evaluation of Various Natural Products.
3. To give latest knowledge in the developing / thrust areas in the subject.

UNIT I Principles involved in the screening of new substances for Pharmacological activity.

UNIT II Organisation of screening. Blind Screening and Programmed Screening

UNIT III A study of the following category of drugs and screening methods for the respective activities.

Analgesic, Antipyretic, Antinflammatory, Cardiotonic, Anti-arrhythmic, CNS stimulant and Depressant drugs.

UNIT IV Study of following drugs and screening methods:

Anticonvulsant, Tranquilliser, Musclerelaxant , Anti-histaminic and Autonomic.

UNIT V Different Screening methods for following activities:

Anti-ulcer, Antidiabetic, Anti-hypertensive.

UNIT VI Detailed study about Acute, sub-acute and chronic toxicity tests.

Tests for undue toxicity of drugs.

UNIT VII Testing of compounds for their anti-microbial activity.

UNIT VIII Study of following drugs and screening methods

Anti-hepatoprotective, Anti-cancer, Anti-HIV, Anti-fertility.

REFERNCE BOOKS:

- 1) Quality Control methods of Herbal Drugs by Pulok.V.Mukherjee.
- 2) Pharmacological Screening Methods by Turner

Course No. 6210: HERBAL DRUG TECHNOLOGY & FORMULATIONS DEVELOPMENT (THEORY)

LEARNING OBJECTIVES:

1. To impart advanced level knowledge in Tissue Culture, Production of secondary metabolites & phytopharmaceuticals, Herbal Cosmetic preparation and Standardization.
2. To acquaint students about Mutation, Hybridization, Biogenesis, Oleoresins.
3. To give latest knowledge in the developing / thrust areas in the subject.

UNIT I Tissue culture

- (a) Culture methods, (b) Organogenesis and embryogenesis,
- (c) Micropropagation, (d) Haploid culture, (e) Synthetic seeds,
- (f) Immobilisation

UNIT II Production of secondary metabolites:

Strategies, use of precursors, growth regulators and elicitors, batch culture and continuous culture, applications of new culture methods, hairy root culture, biotransformation, production of secondary metabolites, taxol, ajmalicine, artemicin.

UNIT III Mutation, hybridization, polyplady of medicinal plants and their applications.

UNIT IV Biogenesis of penicillin, streptomycin and tetracyclines.

UNIT V Manufacturing of phytopharmaceuticals

- (a) Strychnine, (b) Brucine, (c) Emetine, (d) Quinine, (e) Morphine,
(f) Cocaine, (g) Atropine, (h) Tannic acid, (I) Lemongrass oil,
(j) Sandalwood oil, (k) Clove oil, (l) Eucalyptus oil.

UNIT VI Oleoresins: capsicum, pepper, ginger, turmeric.

UNIT VII Herbal cosmetics: Study of the cosmetic preparation including methods of preparation and standardisation.

- (a) Shampoos, (b) Hair conditioners, (c) Hair dye, (d) Skincare products

UNIT-VIII Tracer techniques

Course No.6211 HERBAL DRUG TECHNOLOGY & FORMULATIONS DEVELOPMENT (PRACTICAL)

1. Isolation of Brucine and Strychnine from Nux vomica.
2. Isolation of Quinine from Cinchona stems.
3. Extraction of Oleoresins from Capsicum,Pepper,Ginger and Turmeric.
4. Extraction of volatile oils from Cloves,Eucalyptus and Lemon grass.
5. Introduction to Tissue culture techniques- Preparation of Culture Media,Development of suspension and callus culture.
6. Preparation of Herbal Shampoos.
7. Preparation of Skin care ointments using herbal medicines.
8. Introduction to Gene isolation with special reference to RNA & DNA

REFERENCE BOOKS:

1. Indian Herbal Pharmacopoeia Vol I & II
2. British Herbal Pharmacopoeia
3. Herbal drug Industry by R.D. Chaudhri
4. Quality control methods of Herbal drugs by Pulok V. Mukherjee.
5. Herbal Medicinal Products by Frauke Gaedcke & Barbana Steinhoff

6. Herbal Drug Technology by S. S. Agrawal & M. Paridhav
7. Plant Tissue Culture: Techniques and Experiments by Roberta H. Smith
8. Herbal Drugs and Phytopharmaceuticals, Third Edition by Max Wichtl

Course No. 6212 Comprehensive viva

THIRD SEMESTER

Course No. 6313 Seminar on the objectives and work plan of the proposed project to be completed within one month from the commencement of the project.

Course No. 6314 Mid-term project review at the end of third semester.

Course No. 6315 Seminar on the selected topic.

FOURTH SEMESTER

Course No. 6416 Thesis evaluation.

Course No. 6417 Thesis viva-voce.

7. PHARMACEUTICAL MANAGEMENT AND REGULATORY AFFAIRS

FIRST SEMESTER

Course No. 7101 BIOSTATISTICS (THEORY)

(Common paper for all specializations)

Course No. 7102 PHARMACEUTICAL ORGANIZATION AND PRODUCTION MANAGEMENT (THEORY)

LEARNING OBJECTIVES:

Through this course a thorough understanding about various facets of

1. Business development and organization like budgeting, entrepreneurship and management of personnel will be possible.
2. Understanding of an organization, operational management automation requirements are also explained. **75 hours**

UNIT I Meaning and Evolution of Management; Planning, Organizing, Staffing, Directing, Co-Ordinating, Reporting & Budgeting(POSDCORB),functions of management with reference to pharmaceutical management. Introduction to budgeting, budgetary control, types of budgets, entrepreneurship development, types of entrepreneurs & characteristics of entrepreneurs.

8 hours

UNIT II Understanding Organization: Types of organization structures; line, line & staff & matrix organizational structure. Resistance to change; Authority& Responsibility; Organizational conflicts, Organizational Communication system. Theory –X, Theory –Y and theory-Z. Motivational Aspects, Maslow’s hierarchy of needs, Hedge Berg two factor theory, group dynamics.

8 hours

UNIT III Personnel management: Recruitment & selection, training & development, compensation, transfer, promotion, demotion policies, job evaluation, performance appraisal, industrial relations, grievance handling, stress management. Handling strikes, gheraos, arbitration and negotiations, enforcement of discipline, lay off and discharge.

9 hours

UNIT IV Role of personnel manager: Professional Mangers; Tasks, responsibilities and skills needed. Leadership; Styles and managing change. Decision Making; Types, procedures, evaluation and selection of alternatives, decision making under various situations. Management information and decision support systems and time management. Rewards and incentives, interpersonal skills, significance of communication, its processes, measures for effective communication, conflict management. -Stress management. **9 hours**

UNIT V Operational Management: Nature and scope of production management: Types of manufacturing systems – batch production and selection: Process planning: Aggregate planning and Master production scheduling: Project management – project planning, scheduling Program Evaluation Review Technique (PERT) and Critical Path Method (CPM) use. **8 hours**

UNIT VI Materials Management: An introduction to materials management. Material requirement Purchase management, Inventory control, Material handling: Vendor selection Make or buy decision Negotiation: Cost – reduction techniques – Standardization codification and variety reduction: waste management: Value analysis. **9 hours**

UNIT VII Formulation and Production Management: Locating production and service facilities - layout planning and analysis. Material handling for various pharmaceutical products, service facilities and preventive maintenance in pharmaceutical companies-group and individual replacement. Introduction to automation requirements: supervisory control and data acquisition (SCADA) and programmable logic controller (PLC) based process controls. **9 hours**

UNIT VIII Introduction to accounting, book keeping, Systems of accounting, journal, ledger, trial balance and final accounts. Study of computer based systems for accounting with examples. **8 hours**

REFERENCE BOOKS:

1. The theory and practice of Industrial Pharmacy Leon Lachman, Ph.D., Lachamn Consultant Services, Inc. Garden City, New York. Herbert A. Lieberman, Ph.D., H.H. Lieberman Associates Inc. Consultant Services, Livingston, New Jersey, Joseph L. Kanig, Ph.D, Kanig Consulting and Research Associates, Inc Ridgefield Connecticut. Third Edition (Indian Edition) Varghese Publishing House, Hind Rajasthan Building, Dadar Bombay 400017.1987.
2. Pharmaceutical Dosage Forms and Drug Delivery Systems Fifth Edition Howard C. Ansel, Ph.D., Professor and Dean, College of Pharmacy, The University of Georgia. Nicholas G. Popovich , Ph.d., Professor, School of Pharmacy and Pharmaceutical Sciences, Purdue University. Published by Lea & Febiger, Philadelphia, London. 1990.
3. Selected Topics in Industrial Pharmacy, Dr. N. Udupa, 1992, II Edition Varghese Publishing House, Bombay.
4. Admn. E.E. and Ebert RJ: Production and Operations Management, 6th Edition, New Delhi, Prentice Hall of India 1995.

5. Chunawalla and Patel: Production and Operations Management, Himalaya Publishing House.
6. Gopalakrishnan.P and Sudarshan M Hand Book Materials Management New Delhi Prentice Hall of India. 1994.
7. Dutta A.K. Integrated Materials Management New Delhi PHI1986.
8. Buffa E.S. and Sareen: Modern Production Management, New York, John Wiley 2002.
9. Koonz, Weihrich and Aryasri: "Principles of Management", Tata Mc Graw Hill.
10. Daft : "The Era of Management ",Cengage Learning, New Delhi.
11. K.Aswathappa: "Organizational Behavior – Text, Cases and games", Himalaya Publishing House, New Delhi,2008,
12. Aswathappa K: "Production and Operation Management", Himalaya Publishing House, Mumbai.
13. R.Panneerselvam:"Productions and operations Management",PHI Learning private limited,New Delhi,2009.
14. Modern Pharmaceutics, Second Edition, Revised & Expand (Volume40) Edited by Gilbert S. Banker, University of Minnesota, Minneapolis, Minnesota; Chistopher T. Rhodes, University of Rhode Island, Kingston, 1990 Marcel Dekker Inc., 270 Madison Avenue, New York 10016.
15. GMP for Pharmaceuticals forth edition by S. Willing, J. Stocker Marcel Decker series 1997.
16. I.P., B.P., U.S.P. International Pharmacopoeia.

JOURNALS:

Journals related to National and International status to cover the syllabus.

Course No. 7103 PHARMACEUTICAL ORGANIZATION AND PRODUCTION MANAGEMENT (PRACTICAL)

1. Organization/ Business case presentations.
2. Survey of market research to collect information regarding management of a given disease and/or disorder.
3. Group discussions and case studies based on theory.
4. Layouts for production of API and Pharmaceutical formulations (Tablets, capsules, ophthalmic, parenteral and other formulations)

5. Preparation of trial balance, preparation of final accounts, inventory measurement methods

Course No. 7104: INDIAN DRUG REGULATORY AFFAIRS (THEORY)

LEARNING OBJECTIVES:

This course is aimed at giving all the required information regarding

1. The regulatory bodies in India, patenting and intellectual property rights.
2. Information regarding good clinical practices and WHO certification is also covered in the course.

UNIT I A study of regulatory aspects that affect drug product design, manufacture and distribution in India with special emphasis on the detailed study of the following Acts / Laws (with latest amendments)

- Package commodities act
- Competition council of India
- Right to information act
- National Pharmaceutical Pricing Authority (NPPA) – Power to fix the maximum sale prices of bulk drugs specified in the First Schedule, calculation of retail price of formulation, power to revise price of bulk drugs and formulations, display of prices of non-scheduled formulations and price list thereof. Study of different forms to be used for submission of these approvals. **8 hours**

UNIT II Introduction to IPRs : Intellectual property (IP) versus conventional property. Introduction to 8 different IP mechanisms – patents, industrial designs, and layout designs, plant varieties, geographical indications, copyright, trademark, trade secrets; their characteristics, properties. usefulness of patents for researchers. Factors affecting choice of IP protection; penalties for violation / infringement. IPRs vs. Regulatory affairs- similarities and differences.

Patenting in India : Development of IP law in India. Patent legislation and introduction to current IP laws in India. Amendments in Indian Patent laws and their significance; Requirement for patenting- novelty, inventive step (non obviousness) and industrial application (utility). Patent specification & claims, patent infringement. Procedure for filing patent in India- provisional, complete, divisional, additional and conventional patent applications; forms and fee. Prior art search and sources of patent information – free and paid databases. Patent analysis and land-scaping. Patent Search Maps. Infringement analysis. Concepts of Patent writing in India. Patent cooperation treaty (PCT) route of filing for International patents. **8 hours**

UNIT III Schedule M, M1, M2 & U general requirements and special provisions, DCGA & Central Drugs Standard Control Organization (CDSCO) regulatory requirements and other legal provisions related to production of Active Pharmaceutical Ingredients (APIs), other raw materials (including packaging materials) used in drugs & cosmetics.

Schedule M, M1, M2 & U general requirements and special provisions, DCGA & Central Drugs Standard Control Organization (CDSCO) regulatory requirements and other legal provisions related to production aspects of various drugs & cosmetic formulations (solid, parenteral and semi solid preparations).

Pilot plant scale- up techniques: Pharmaceutical pilot plant, pilot plant design, case studies for above preparations. Basic requirements for design of product, facility, equipment selection and personnel. **9 hours**

UNIT IV Schedule M, M1, M2 & U general requirements and special provisions DCGA & Central Drugs Standard Control Organization (CDSCO) regulatory requirements and other legal provisions related to quality control & quality assurance aspects of various drugs & cosmetic formulations (solid, parenteral and semi solid preparations). **9 hours**

UNIT V General requirements and special provisions, DCGA & Central Drugs Standard Control Organization (CDSCO) regulatory requirements and other legal provisions related to marketing of various drugs & cosmetic formulations (solid, parenteral and semi solid preparation). Introduction to uniform code of marketing practices for the Indian pharmaceutical industry (UCPMP). **8 hours**

UNIT VI Indian Good Clinical Practices guidelines: National regulatory requirements for pharmaceutical development regarding clinical research practices. Current issues in GCP; standards for design, conduct, performance, monitoring, auditing, recording, analysis, and reporting of clinical trials. Schedule Y of Indian Drugs and Cosmetics Act 1940, Role of Regulatory affairs in Developing clinical trial protocols, Clinical phase, Preclinical Phase, Manufacturing phase and Marketing Phase. **9 hours**

UNIT VII Hierarchy and working flow of DCGA in India. Regulations and documentation related to manufacturing, cleaning methods, retention samples and records, quality control, batch release documents, distribution records, complaints and recalls. **9 hours**

UNIT VIII WHO certification, Trademarks and copyrights. National Accreditation Board for testing and Calibration Laboratory (NABL) certification and accreditation procedure. The International Organization for Standardization (ISO) 9000 series of quality systems standards, ISO 14000. **8 hours**

REFERENCE BOOKS:

1. Drugs and Cosmetics Act, 1940 and its rules, published by Ministry of health and family welfare, Government of India.
2. Pharmaceutical Jurisprudence, G.K. Jani.
3. The Pharmaceutical Regulatory Process, 2nd ed. – Ira R. Berry, Robert P. Martin
4. Medical Product Regulatory Affairs: Pharmaceutical, Diagnostics, Medical Devices – John J. Tobin and Gary Walsh.
5. FDA Regulatory Affairs: A Guide for Prescription Drugs, Medical Devices and Biologics, 2nd ed. – Douglas J. Pisano and David S. Mantus
6. Good Drug Regulatory Practices: a Regulatory Affairs Quality Manual (Good Drug Development Series) – Helene I. Dumitriu.
7. Pharmaceutical Patent Law – John R. Thomas.
8. Original laws published by Govt. of India.
9. Text Book of Forensic Pharmacy by Mithal B. M.; Vallabh Prakashan, New Delhi.
10. Laws of Drugs in India by Hussain.
11. Text Book of Forensic Pharmacy by Jain N. K.; Vallabh Prakashan, New Delhi.

Course No.7105 INDIAN DRUG REGULATORY AFFAIRS (PRACTICAL)

1. Testing of glass, rubber, plastic & metal packaging materials and preparing document for submission for approval.
2. Stability testing of an API, a pharmaceutical excipient, pharmaceutical dosage forms (solid, parenteral & semi solid) as per regulatory requirements and preparing required documents for submission
3. Quality control testing of finished product (solid, parenteral & semi solid dosage forms) as per Indian Pharmacopoeial requirements and preparing required documents for submission.
4. Patent writing for a given modification in the composition of a dosage form (minimum of 2 protocols).
5. Preparation of documents for submitting a patent file through Patent cooperation treaty (PCT) route.
6. Preparation of Dossiers to be submitted to the CDSCO/DCGA for a solid/parenteral/ semi solid dosage forms.

Course No.7106 Comprehensive Viva

PHARMACEUTICAL MANAGEMENT AND REGULATORY AFFAIRS
SECOND SEMESTER

Course No.7207 MODERN ANALYTICAL TECHNIQUES (THEORY)

(Common paper for all specializations)

Course No. 7208 QUALITY ASSURANCE AND DRUG REGULATORY AFFAIRS

(THEORY) (Common paper for all specializations)

Course no.7209 PHARMACEUTICAL MANAGEMENT SCIENCE (THEORY)

75 hours

LEARNING OBJECTIVES:

Through this course a thorough understanding about various facets of

1. Business development and organization like budgeting, entrepreneurship and management of personnel will be possible.
2. Understanding of an organization, operational management automation requirements are also explained.

UNIT I History, growth of Indian Pharmaceutical Industry. Global scenario of Indian pharmaceutical Industry and pharmaceutical market past and present. **8 hours**

UNIT II Pharmaceutical marketing : Introduction of pharmaceutical marketing, evolution of marketing concept; production oriented, sales oriented, promotion oriented and consumer oriented modern concept); market segmentation; concept of marketing mix, role of 7 P's (product, price, promotion, place, physical evidence, process, people) in pharmaceutical marketing management, corporate planning & strategy, pharmaceutical industrial marketing management. pharmaceutical marketing environment. E-Pharma marketing. **8 hours**

UNIT III Supply Chain Management : Scientific purchasing, quality control, problems of productivity, stores organization, location of stores, receiving, inspection of materials, issue from the store, control of stores and stocks, store accounting and records. ABC analysis, VED (Vital, Essential, Desirable), Fast moving, Dormant moving & Obsolete (FDO), Economic Order Quantity (EOQ). **9 hours**

UNIT IV Product design planning: Selection of product, new product development and product differentiation, pricing, promotion.

Marketing research: definition and importance, Pharmaceutical marketing research techniques, marketing information systems, pharmaceutical market research area.

9 hours

UNIT V Management of Industrial Relations: Industrial disputes, settlement of disputes through various routes such as bargaining, etc.

Legal Environment of Business: Need for government regulations; financial regulations, Equity market & SEBI, BIFR, FEMA and others, Contract Act and Sale of Goods Act, Company Act, Corporate tax laws -Direct and Indirect. **8 hours**

UNIT VI Market demands and sales forecasting: major concepts in the demand measurement, estimating current demands, geo-demographic analysis, estimating industry sales, market share and future demand, sales forecasting. Social and legal and ethical issue of pharma marketing, International Federation of Pharmaceutical Manufacturers & Associations (IFPMA) code of pharmaceutical marketing practices, pharma guidelines for Direct-to-consumer advertising (DTC advertising) and Organization of Pharmaceutical Producers of India (OPPI) guidelines for Pharmaceutical marketing in India. **8 hours**

UNIT VII Strategic marketing : SWOT Analysis, GAP Analysis, Porter's five-force model, Ansoffs Matrix. Role of customer in marketing, importance of consumer behavior, customer relationship management (CRM). Nature of international marketing, evaluating international marketing, develop international marketing objectives, Formulate product marketing strategies, market entry and overseas distribution system, pricing. **9 hours**

UNIT VIII Functions of finance management; performance evaluation through ratio analysis & funds flow statement; project preparation, other ethical aspects of Pharmaceutical promotion and advertisement. Effect of Competition Council of India (CCI) on Pharma industry. **9 hours**

REFERENCE BOOKS:

1. Phillip Kotler: "Marketing Management", 11/e, Pearson Publishers, New Delhi, 2003
2. K Aswathappa: "Human Resource and Personnel Management", Tata McGraw Hill, New Delhi, 2007.
3. Aswathappa K: "Production and Operation Management", Himalaya Publishing House, Mumbai.
4. I.M Pandey: "Financial Management", 9/e, Vikas Publishing, 2004
5. Rajan Saxena: "Marketing Management, 2/edition, Tata McGraw Hill, New Delhi, 2008.
6. Shashi K Gupta & Sharma, Financial Management, Kalyani Publishers
7. Buffa, Production and Operations management
8. Business Environment, Francis Cherunilam, Himalaya Publications

Course No. 7210 INTERNATIONAL DRUG REGULATORY ASPECTS (THEORY)

LEARNING OBJECTIVES:

This course covers all the regulatory aspects in

1. Product design including generic product designing. It covers the international drug regulatory aspects in its entirety right from the product approvals to stability testing, quality evaluation and batch release.
2. Regulations put on excipients used in the formulation development.

UNIT I Generic drug product development: Introduction, Hatch-Waxman update, Drug product performance- in vitro, Abbreviated New Drug Application (ANDA) Regulatory Approval Process, paragraph IV drug product application. Bioequivalence and drug product assessment- in vivo, scale- up, post approval changes, post marketing surveillance, outsourcing Bioavailability and Bioequivalence studies to Contract Research organizations. Formats for marketing authorization submission to WHO, USFDA, EU. Data privacy Protection, Pharmaceutical Labeling, Advertising and Promotion, Risk Management in regulatory affairs.

9 hours

UNIT II Regulatory requirements for product approvals: Active Pharmaceutical Ingredients, Biologics, novel therapies, special categories [Over - the - counter (OTC) products, herbal medicines and Homeopathics]. Obtaining New Drug Application (NDA), ways and means of US Registration for foreign drugs, Chemistry, Manufacturing and controls (CMC), Post approval Regulatory affairs, Regulation for combination products (Controlled release systems), medical devices, Environmental concerns and regulations. 21 Code of Federal Regulations (CFR) Part 11 and LIMS (Laboratory Information Management System). **8 hours**

UNIT III FDA Approval indications and other considerations: Data procession for Global submission, Text and Tabular exposition- Common Technical Document (CTD)/ electronic Common Technical Document (eCTD) format, working with contract research organization (CRO), industry and FDA liaison, role of European Commission Competent Authorities and Notified Bodies and USFDA authorities. **9 hours**

UNIT IV Nonclinical drug development: Global submission of Investigational New Drug application (IND), New Drug application (NDA), Abbreviated New Drug Application (ANDA), Investigational medicinal product Dossier (IMPD) & Investigator Brochure (IB), new product applications for global pharmaceutical product approvals, US NDA vs. Global CTD Formats, ANDA & Supplemental Abbreviated New Drug Application (SNDA), CTD and eCTD for registration of pharmaceuticals for Human use, combination products & controlled release systems. **8 hours**

UNIT V Centralized procedure for marketing authorization: legal basis – scope. Procedure for submission of application – preauthorization, inspections (GMP inspection) – pre authorization inspection (GCP inspection) – Scientific evaluation of the application – CPMP (Committee for Proprietary Medicinal Products) opinion and follow up action. **8 hours**

UNIT VI Harmonization of regulatory requirements- The International Conference on Harmonization (ICH) process, guidelines to establish quality, safety and efficacy (carcinogenicity studies - need for carcinogenicity studies of pharmaceuticals and testing for carcinogenicity of pharmaceuticals, Genotoxicity- a standard battery for Genotoxicity testing of pharmaceuticals) of drug substances and products. Study of ICH common technical documents, harmonization of pharmacopoeial standards. Health Insurance Portability and Accountability Act of 1996 (HIPAA)- A new requirement to clinical study process, Code of Federal Regulations (CFR)/ International Conference on Harmonization (ICH) / EU GCP obligations of Investigators, sponsors & monitors. **9 hours**

UNIT VII Stability Testing of New Drug Substances and Products Stability Testing: Photo-stability testing of new drug substances and products, stability testing for new dosage forms, bracketing and matrixing designs for stability testing of new drug substances and products. Evaluation of stability data, impurities in new drug substances, impurities in new drug products, guidelines for residual solvents. **8 hours**

UNIT VIII Quality evaluation and batch release: change control, deviation-(planned and unplanned), corrective action and preventive action (CAPA), Handling of non-conformance, vendor evaluation process, out of specification (OOS), batch reconciliation and finished goods release, market recalls & market complaints.

Joint International Pharmaceutical Excipients Council (IPEC) – Pharmaceutical Quality Group (PQG) Good Manufacturing Practices guidelines for pharmaceutical excipients. **8 hours**

REFERENCE BOOKS :

1. Generic Drug Product Development, Solid Oral Dosage forms, Leon Shargel and Isader Kaufer, Marcel Dekker series, Vol.143
2. The Pharmaceutical Regulatory Process, Edited by Ira R. Berry Marcel Dekker Series, Vol.144
3. The Pharmaceutical Regulatory Process, Second Edition, Edited by Ira R. Berry and Robert P. Martin, Drugs and the Pharmaceutical Sciences, Vol.185 Informa Health care Publishers.
4. New Drug Approval Process: Accelerating Global Registrations By Richard A Guarino, MD, 5th edition, Drugs and the Pharmaceutical Sciences, Vol.190.

5. Guidebook for drug regulatory submissions / Sandy Weinberg. By John Wiley & Sons. Inc.
6. FDA regulatory affairs: a guide for prescription drugs, medical devices, and biologics /edited by Douglas J. Pisano, David Mantus.
7. Clinical Trials and Human Research: A Practical Guide to Regulatory Compliance by Fay A. Rozovsky and Rodney K. Adams
8. HIPAA and Human Subjects Research: A Question and Answer Reference Guide by Mark Barnes, JD, LLM and Jennifer Kulynych, JD, PhD
9. Principles and Practices of Clinical Research, Second Edition Edited by John I. Gallin and Frederick P. Ognibene
10. Drugs: From Discovery to Approval, Second Edition by Rick Ng
11. New Drug Development: A Regulatory Overview, Eighth Edition by Mark Mathieu
12. Pharmaceutical Risk Management By Jeffrey E. Fetterman, Wayne L. Pines and Gary H. Slatko
13. Preparation and Maintenance of the IND Application in eCTD Format By William K. Sietsema
14. Medical Device Development: A Regulatory Overview by Jonathan S. Kahan
15. Medical Product Regulatory Affairs: Pharmaceuticals, Diagnostics, Medical Devices by John J. Tobin and Gary Walsh

Course No.7211 INTERNATIONAL DRUG REGULATORY ASPECTS (PRACTICAL)

1. The general stages of drug development from R & D to marketing.
2. List the various types of manufacturer – FDA interactions that can occur during the drug development process.
3. Requirements for registration of ANDA as per ICH CTD/eCTD format.
4. Preparation of documents required for paragraph IV drug product application.
5. The general process by which new molecular entities (NMEs) are identified through pharmaceutical approaches.
6. Types of IND applications and structures of each type.
7. Requirements to complete an IND application and IND review process.
8. Requirements for a new drug application (NDA) & NDA submission process.
9. FDA’s review of submitted NDA application/FDA’s requirements for changes to an approved NDA
10. Clinical trial protocol preparation / clinical data requirements for approval of controlled release NDA

11. Post NDA approval responsibilities of a sponsor.
12. General study of ICH guidelines with special reference to ICH Q7, Q8, Q9 and Q10
13. Compliance requirements for bioavailability & bioequivalence studies.
14. Patent challenge/ non infringement case studies.
15. Qualification of disintegration test apparatus/friability test apparatus/dissolution test apparatus
16. Qualification of UV-Vis spectrophotometer.
17. Comparison of D & C Act with that of other regulations such as USFDA, UKMCA, EDQM, South Africa MCC, Brazilian ANVISA, Australian TGA

Course No.7212 Comprehensive Viva

THIRD SEMESTER

Course No. 7313 Seminar on the objectives and work plan of the proposed project to be completed within one month from the commencement of the project.

Course No. 7314 Mid-term project review at the end of third semester.

Course No. 7315 Seminar on the selected topic.

FOURTH SEMESTER

Course No. 7416 Thesis evaluation.

Course No. 7417 Thesis viva-voce.

8. PHARMACEUTICAL ANALYSIS AND QUALITY CONTROL

FIRST SEMESTER

Course No. 8101 BIOSTATISTICS (THEORY)

(Common paper for all specializations)

Course No. 8102 ADVANCED PHARMACEUTICAL ANALYSIS I (THEORY) (Paper common with Pharmaceutical Analysis and Quality Assurance)

Course No. 8103 ADVANCED PHARMACEUTICAL ANALYSIS I (PRACTICAL) (Paper common with Pharmaceutical Analysis and Quality Assurance)

Course No. 8104 QUALITY CONTROL OF PHARMACEUTICALS (THEORY)

LEARNING OBJECTIVES:

1. To train students in advanced qualitative and quantitative analytical techniques in
1. Sampling, quality control of excipients, in process quality control and analysis of herbal products.
2. The student must be able to apply these concepts in various steps like analysis of raw materials & finished drug products, sample preparation, routine quality control and different phases of validation in quality control lab or pharmaceutical industry.

UNIT I Sample collection and Preparation for Analysis

Importance of sampling techniques – Sampling techniques – Random, stratified, systematic, cluster, for quality control – Sample preparation – Separating analyte from interferants – Extraction – Automated extraction – Solid phase extraction – Solid phase micro extraction – Super critical fluid extraction and microwave assisted extraction. **7 hours**

UNIT II In Process Quality Control

In process control during component manufacture – Solid dosage forms – Liquid dosage forms – Semi solid dosage forms – Inhalations – Sterile solutions – Novel drug delivery systems – Various IP, BP, USP Methods. **8 hours**

UNIT III Process Analytical Technology (PAT)

Implementation of process analytical technologies in the industrial settings – Generalized process analytical works – PAT applications – Chemometrics – Online applications in pharmaceutical industries. **7 hours**

UNIT IV Performance Evaluation Methods

In vitro dissolution studies for solid dosage forms – In vitro drug dissolution testing models – method interpretation of dissolution data – Bioavailability studies and bioavailability testing

protocol and procedures – In vivo methods of evaluation and statistical treatment – In vitro invivo correlation (F2 Factor) – Various in-vitro and in- vivo models. **7 hours**

UNIT V Quality Control of following

- a. Liquid Oral Dosage Forms& Parenterals
- b. Tests related to excipients such as bulk density, tapped density, particle size distribution, pH, moisture content, viscosity (dynamic), gelling temperature, swelling temperature, loss on drying, residue on ignition, conductivity, congealing range, readily carbonizable substances and readily oxidizable substances, melting point and melting range.
- c. Types And Tests assuring Quality Of Glass **8 hours**

UNIT VI Herbal Products Analysis

Study of method procedure, drugs of formulations standard requirements of herbal medicines, traditional and folk remedies, preparation & their quality, safety and efficacy assessment & use for acceptance by FDA. **8 hours**

UNIT VII Biological Standardization

Biological Standardization: General Principles, Scope & limitations of Bioassays. Bio- assays of some Official Drugs. Pyrogen - chemistry and properties of bacterial pyrogens and endotoxins.

Mechanisms of action of pyrogens. Pharmaceutical aspects, pyrogen test of IP compared to that of BP & USP. Interpretation of data, Comparison of LAL and other pyrogen tests.

Analysis of drugs from biological samples including, selection of biological sample, extraction of drugs by various methods as LLE, SPE and Membrane filtration. Microbiological Limit Tests, Tests for effectiveness of antimicrobial preservatives . **8 hours**

UNIT VIII Bioassays

Detailed study of principles & procedures involved in bio assay of.

- (a) Heparin, insulin, posterior pituitary
- (b) Diphtheria, typhoid

Principles and Procedures involved in Biological tests of the following.

- (i) Living contaminants in vaccines.
- (ii) Histamine like substances
- (iii) Determine of toxic elements **7 hours**

REFERENCE BOOKS:

1. Brewer, R. F., "Design of Experiments for Process Improvement and Quality Assurance", Narora Publishing House, 1996.
2. Sethi, P.D., "Quantitative Analysis of Drugs in Pharmaceutical Formulations", 3rd Edition, C.B.S. Publishers and Distributors, 2003.
3. Bakeev, K.A., "Process Analytical Technology", Blackwell Publishers, 2006
4. Indian and British Pharmacopoeia

Course no. 8105 QUALITY CONTROL OF PHARMACEUTICALS (PRACTICAL)

(Practicals based on Theory)

Course No. 8106 Comprehensive viva

PHARMACEUTICAL ANALYSIS AND QUALITY CONTROL SECOND SEMESTER

Course No.8207 MODERN ANALYTICAL TECHNIQUES (THEORY)

(Common paper for all specializations)

Course No. 8208 QUALITY ASSURANCE AND DRUG REGULATORY AFFAIRS (THEORY)(Common paper for all specializations)

Course no. 8209 VALIDATION OF INSTRUMENTAL METHODS OF ANALYSIS (THEORY)

LEARNING OBJECTIVES:

Learning this subject should make student understand the scope and functional importance of

1. Documentation and validation in pharmaceutical field.
2. The student must be able to apply these concepts in various steps like development and validation of new analytical method, validation of equipment, cleaning validation, and utilities validation useful in pharmaceutical industry.

UNIT I Validation

- a. Introduction, history, definition,
- b. Types of validation, prospective validation, retrospective validation, concurrent validation, revalidation,
- c. Validation Master Plan

8 hours

UNIT II Process Validation of Solid Dosage forms

- a. Process validation of low dose tablet manufacturing process
- b. Uniformity of blend (US FDA guideline) for tablets subjected to content uniformity test as per USP
- c. Process validation of compression machine giving details of control charts.

8 hours

UNIT III Sterilization Validation

- a. Process validation of terminally sterilized product. Validation of sterilization process including heat distribution, heat penetration
- b. studies, and sterility assurance level
- c. Process validation of aseptically filled product with special emphasis on media fill test.

8 hours

UNIT IV Cleaning Validation

- a. Validation of cleaning process.
- b. Elements of validation protocol.
- b. Determination of acceptable limits for cleaning process.
- c. Factors to consider in setting the limits.
- d. Numerical calculation of limits.

7 hours

UNIT V Utilities Validation

- a. Validation of water system- for production of DM water, distilled water
- b. Validation of Air handling Units- classification of environment (class 100, 10,000, 1,00,000)
- c. Performance qualification & parameter of cleanliness such as no. of airborne particles, microbes filter integrity test of HEPA filter, air velocity, air flow pattern, no. of air changes, pressure differentials etc.

8 hours

UNIT VI Analytical Method Validation

- a. Recommendation of ICH guideline- Definition of accuracy, precision, linearity, LOD, LOQ, range, robustness, ruggedness, specificity, system suitability test.
- b. USP requirement of analytical validation- different category of assays.
- b. Stability indicating methods.
- c. Bio analytical method validation

7 hours

UNIT VII Instruments calibration

- a. Analytical balance calibration.
- b. Calibration of weight box.

- b. Calibration of UV-spectrophotometer.
- c. Calibration of IR spectrophotometer.
- d. Calibration of HPLC system.
- e. Calibration of Gas Chromatography instrument.
- f. Performance check of HPLC/GC column.
- g. Out of Calibration.

8 hours

UNIT VIII Equipment Validation

- a. Definition of DQ, IQ, OQ, PQ.
- b. Comparison of different types of liquid filling machines (vacuum / volumetric),
- c. process capability of filling machines,
- d. Performance qualification of bottle washing/ ampoules washing machines - challenge test.

6 hours

REFERENCE BOOKS:

1. R. Nash and Wachter, "Pharmaceutical Process Validation". Volume 129, Latest Edition. Marcel Dekker Inc., New York.
2. K.L. Williams, "Microbial Contamination Control in Parenteral Manufacturing". Latest Edition. Marcel Dekker Inc., New York.
3. Guidance for Industry, Sterile Drug Products Produced by Aseptic Processing — Current Good Manufacturing Practice-USFDA.
4. J.T. Carstensen, C.T. Rhodes, "Drug stability: principles & Practices". Latest Edition. Marcel Dekker Inc., New York
5. www.ich.org – Q7 a guideline
6. www.fda.org
7. United State Pharmacopoeia
8. US-FDA guideline for bio analytical studies. Dekker Inc., New York
9. It is strongly recommended that some standard book/s be used for practicals. The choice of book/s is left to the concerned teachers.

Course No. 8210 ADVANCED PHARMACEUTICAL ANALYSIS II (THEORY)

(Paper common with Pharmaceutical Analysis and Quality Assurance)

Course No. 8211 ADVANCED PHARMACEUTICAL ANALYSIS II (PRACTICAL)

(Paper common with Pharmaceutical Analysis and Quality Assurance)

Course No. 8212 comprehensive viva

THIRD SEMESTER

Course No. 8313 Seminar on the objectives and work plan of the proposed project to be completed within one month from the commencement of the project.

Course No. 8314 Mid-term project review at the end of third semester.

Course No. 8315 Seminar on the selected topic

FOURTH SEMESTER

Course No. 8416 Thesis evaluation

Course No. 8417 Thesis viva-voce

9. PHARMACEUTICS

FIRST SEMESTER

Course No. 9101 BIOSTATISTICS (THEORY)

(Common paper for all specialisations)

Course No. 9102 BIOPHARMACEUTICS AND PHARMACOKINETICS

(THEORY)(Paper common with Pharmaceutical Technology and Industrial Pharmacy)

Course No. 9103 BIOPHARMACEUTICS AND PHARMACOKINETICS

(PRACTICAL)(Paper common with Pharmaceutical Technology and Industrial Pharmacy)

Course No. 9104 ADVANCED PHYSICAL PHARMACEUTICS (THEORY)

(Paper common with Pharmaceutical Technology)

Course No. 9105 ADVANCED PHYSICAL PHARMACEUTICS (PRACTICAL) (Paper

common with Pharmaceutical Technology)

Course No. 9106 Comprehensive Viva

PHARMACEUTICS

SECOND SEMESTER

Course No. 9207 MODERN ANALYTICAL TECHNIQUES (THEORY)

(Common paper for all specializations)

Course No. 9208 QUALITY ASSURANCE AND DRUG REGULATORY AFFAIRS

(THEORY)

(Common paper for all specializations)

Course No. 9209 INDUSTRIAL PHARMACY II (THEORY)

(Paper common with Industrial Pharmacy)

Course No. 9210 NOVEL DRUG DELIVERY SYSTEMS (THEORY)

(Paper common with Pharmaceutical Technology and Industrial Pharmacy)

Course No. 9211 NOVEL DRUG DELIVERY SYSTEMS (PRACTICAL)

(Paper common with Industrial Pharmacy)

Course No. 9212 Comprehensive Viva

THIRD SEMESTER

Course No. 9313 Seminar on the objectives and work plan of the proposed project to be completed within one month from the commencement of the project.

Course No. 9314 Mid-term project review at the end of third semester.

Course No. 9315 Seminar on the selected topic

FOURTH SEMESTER

Course No. 9416 Thesis evaluation

Course No. 9417 Thesis viva-voce

10. INDUSTRIAL PHARMACY

FIRST SEMSTER

Course No. 10101 BIostatistics(THEORY)

(Common paper for all specializations)

Course No. 10102 BIOPHARMACEUTICS AND PHARMACOKINETICS

(THEORY)(Paper common with Pharmaceutical Technology and Pharmaceutics)

Course No. 10103 BIOPHARMACEUTICS AND PHARMACOKINETICS

(PRACTICAL) (Paper common with Pharmaceutical Technology and Pharmaceutics)

Course No. 10104 INDUSTRIAL PHARMACY I (THEORY)

LEARNING OBJECTIVES:

This course gives a complete knowledge on

1. Formulation designing of various dosage forms like solid dosage forms, powder dosage forms, liquid dosage forms, semi-solid dosage forms, parenterals and aerosols.
2. The student will have a thorough understanding on the concepts of formulation design right from the stage of preformulation to scale – up.

UNIT I Pre-formulation studies:

- a) Goals of preformulation, preformulation parameters, Methodology, Solid state, Properties, Solubility and Partition coefficient, Solubility, Drug excipient Compatibility.
- b) Excipients used in pharmaceutical dosage forms:
- c) Properties and selection criteria for various excipients like surfactant, viscosity Promoters, diluents, coating materials, plasticizers, preservatives, flavors and Colours.

Industrial unit operations relating to the manufacture of the following dosage forms:

UNIT II Solid dosage forms: Improved production techniques for tablets: New materials, process, equipments improvements, high shear mixers, compression machines, coating machines, coating techniques in tablet technology for product development , physics of tablet compression, computerization for in process quality control of tablets, types of tablets and their manufacture. Formulations, production and evaluation of hard and soft gelatin capsules.

UNIT III Powder dosage forms: Formulation development and manufacture of powder dosage form for internal and external use including inhalation dosage forms.

UNIT IV Liquid and Semi-solid dosage forms: Recent advances in formulation aspects and manufacturing of monophasic dosage forms. Recent advances in formulation aspects and manufacturing of suspensions, dry syrups and semi-solid dosage forms.

UNIT V Parenteral dosage forms: Advances in materials and production techniques, filling machines, sterilizers and aseptic processing. Manufacturing of small and large volume parenterals and quality control.

UNIT VI Aerosols: Advances in propellants, metered dose inhaler designs, dry powder inhalers, selection of containers and formulation aspects in aerosol formulation, Manufacture and quality control.

UNIT VII Aseptic processing operation: Introduction, contamination control, microbial environmental monitoring, microbiological testing of water, Microbiological air testing, characterization of aseptic process, media and incubation condition, theoretical evaluation of aseptic operations.

UNIT VIII Plant Design: Design of manufacturing facility as per current good manufacturing practices for the bulk production of the above mentioned dosage forms

REFERENCE BOOKS:

1. Encyclopedia of Pharmaceutical Technology, edited by James Swarbrick, Third Edition, Informa Healthcare publishers.
2. Pharmaceutical Dosage Forms, Tablets, Volume I and II, edited by Herbert A. Lieberman and Leon Lachman; Marcel Dekker, Inc.
3. The Theory and Practice of Industrial Pharmacy, Fourth Edition, edited by Roop k Khar, S P Vyas, Farhan J Ahmad, Gaurav K Jain; CBS Publishers and Distributors Pvt. Ltd.
4. The Theory and Practice of Industrial Pharmacy, Leon Lachman, H.A. Lieberman & J.L. Kanig; Varghese publishing House, Bombay.
5. Pharmaceutical Product Development, N.K. Jain, CBS Publishers and Distributors Pvt. Ltd.
6. Law relating to Drugs & Cosmetics by Vijay Malik, Eastern Book Company.

Course No.10105 INDUSTRIAL PHARMACY I (PRACTICAL)

(Practicals based on Theory)

1. Preformulation studies of drugs like aspirin, sulfamethoxazole, nefidipine etc. using different excipients as per ICH guidelines.
2. Formulation and evaluation of oral disintegrating tablets using suitable drugs.
3. Preparation and evaluation of microcapsules using techniques like coacervation-phase separation, ionic gelation method.
4. Formulation of dry syrup and its evaluation.
5. Comparison of different gels using diclofenac/aceclofenac like drugs

6. Formulation and evaluation of suspensions containing suitable drugs.
7. Studies on effect of emulsifying agents on the stability of emulsion
8. Visiting a pharmaceutical industry and observing the modern equipment used in production and quality

Course No. 10106 Comprehensive Viva

INDUSTRIAL PHARMACY SECOND SEMESTER

Course No. 10207 MODERNANALYTICAL TECHNIQUES (THEORY)

(Common paper for all specializations)

**Course No. 10208 QUALITY ASSURANCE AND DRUG REGULATORY AFFAIRS
(THEORY)**(Common paper for all specializations)

Course No. 10209 INDUSTRIAL PHARMACY II (THEORY)

LEARNING OBJECTIVE:

This is an industry oriented course with information regarding the various aspects of

1. Equipment handling like working, validation and maintenance.
2. The student would understand the production, planning, control and documentation involved in an industry. Pharma promotion management and human resource development will also be covered in this course

UNIT I Pharmaceutical Equipment: Installation, Validation, Maintenance and working of the following:

Tablet Machines: Rotary tablet, Multi punch Coating Equipment : Pans, fluidized bed Dryers: Freeze, spray, fluidized bed and tray dryer Granulators: Rapid mixer, extruder-spheronizer Mixers/Milling: Planetary, double cone, triple roller mill, colloidal mill Filters: Plate and frame press, membrane filters, air filtration system (Laminar flow) and Aseptic Room Sterilization: Autoclave Homogenizers and High Pressure Homogenizer.

UNIT II Pilot Plant Scale-up techniques: Significance, Pilot study of some important dosage forms like tablets, capsules, sustained release dosage forms and liquid orals. Discussion of parameters like formula, equipment, product uniformity, raw material processing, physical layouts, personal requirements and reporting responsibilities.

UNIT III Quality Control: Process controls involved in manufacturing process of pharmaceutical dosage forms, statistical quality control charts and their applications in process control. Testing program and methods for testing quality of pharmaceutical dosage forms.

UNIT IV Stability studies: Introduction to ICH guidelines and ICH stability protocols for different pharmaceutical dosage forms.

UNIT V Industrial Safety: Industrial hazards due to fire accidents, mechanical and electrical equipment, chemicals and pharmaceuticals. Monitoring and prevention systems and maintenance of accident records.

UNIT VI Applications of optimization techniques: Optimization parameters, statistical design and techniques in product development and evaluation. Production optimization and its importance.

UNIT VII Production, Planning, Control and documentation: Production scheduling, forecasting, Vendor development, Capacity assessment, Production management, Production organization, Productivity, guide to manufacturing facilities of tablets, liquid orals and capsules.

UNIT VIII Pharma Promotion Management and Human resource development: Strategic issues in Pharma marketing, consumer behaviour in pharmaceuticals, market research, sales management, Brand management, supply chain management. Personnel training, job specification, job enlargement, labour welfare and training. Business leadership.

REFERENCE BOOKS:

1. Leon Lachman, H. A. Lieberman & J. L. Kanig : “The Theory and Practice of Industrial Pharmacy”, 3rd edition, Varghese Publishing House, Bombay, 1991.
2. Lachman/Lieberman’s The Theory and Practice of Industrial Pharmacy, Fourth Edition, Editors, Roop K khar, SP Vyas, Farhan J Ahmad and Gaurav K Jain, CBS Publishers and Distributors Pvt. Ltd.
3. Pharmaceutical Product development by N. K. Jain, CBS Publishers and distributors Pvt. Ltd.
4. Pharmaceutical Statistics Practical and Clinical Applications by Stanford Bolton, Charles Bon; Marcel Dekker Inc.
5. Pharmaceutical Production And Management by C.V.S.Subrahmanyam, Vallabh Prakasan Publishers
6. Pharmaceutical Dosage Forms, Tablets, Volume I and II, edited by Herbert A. Lieberman and Leon Lachman; Marcel Dekker, Inc.

Course No.10210NOVEL DRUG DELIVERY SYSTEMS (THEORY)

(Paper common with Pharmaceutical Technology and Pharmaceutics)

Course No.10211 NOVEL DRUG DELIVERY SYSTEMS (PRACTICAL)

1. Preparation and evaluation of microcapsules with different polymeric coats
2. Preparation and evaluation of slow release granules
3. Preparation and evaluation of matrix tablets using different polymers
4. Preparation and evaluation of gastro retentive systems
5. Preparation and evaluation of transdermal patches
6. Preparation and evaluation of liposomes
7. Preparation and evaluation of mucoadhesive systems
8. Study of marketed novel drug delivery products

Course No.10212Comprehensive Viva

THIRD SEMESTER

Course No. 10313 Seminar on the objectives and work plan of the proposed project to be completed within one month from the commencement of the project.

Course No. 10314 Mid-term project review at the end of third semester.

Course No. 10315 Seminar on the selected topic

FOURTH SEMESTER

Course No. 10416 Thesis evaluation

Course No. 10417 Thesis viva-voce

11. PHARMACY PRACTICE

FIRST SEMESTER

Course No. 11101 BIostatistics (THEORY)

(Common paper for all specializations)

Course No. 11102 PHARMACO THERAPEUTICS I (THEORY)

LEARNING OBJECTIVES:

1. 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.
2. The students have to make at least 10 case presentations covering most of the common diseases found in the hospital to which the college is attached. The student should also submit a record of the cases presented.
3. The list of clinical cases should include follow up of the clinical cases mentioned below from the day of admission till discharge and present in the SOAP (Subjective, Objective, Assessment and Plan) format. The cases may be selected from the following diseases.

UNIT I Cardiovascular system: Hypertension, Congestive cardiac failure, Ischaemic heart disease (Angina, Myocardial infarction), Arrhythmias, Hyperlipidaemias, Endocarditis, Thromboembolic disorders, Cardiac arrest – resuscitation. **9 hours**

UNIT II Respiratory system: Pulmonary function tests, Asthma, Chronic obstructive airways disease, Drug induced pulmonary diseases. Hydrogen ion hemostasis and blood gases. **7 hours**

UNIT III Renal system :Diuretic therapy, Potassium depletion, Hyperkalemia, Alkalosis, Acute renal failure, Chronic renal failure, Dialysis, Renal replacement therapy, End-stage renal disease, Drug induced renal diseases. **6 hours**

UNIT IV Haematological diseases : Blood and body fluids, Complications of blood transfusion and blood substitutes, Anaemia, Drug induced haematological disorders. **7 hours**

UNIT V Immunology : Immune disease – pathogenesis, mechanism of action of drugs, Glucocorticoids – anti-inflammatory, anti-allergic and immunosuppressive actions in tissue as well as organ transplantation, Vaccines – management of primary immunodeficiencies. **9 hours**

UNIT VI Endocrine system: Diabetes, Thyroid diseases, Oral contraceptives, Hormone replacement therapy, Osteoporosis. **10 hours**

UNIT VII Nervous system: Epilepsy, Parkinson's disease, Stroke and transient ischaemic attacks, Headache, Migraine. **9 hours**

UNIT VIII Psychiatric disorders: Schizophrenia, Depression, Anxiety disorders, Sleep disorders. **10 hours**

REFERENCE 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.
3. Pathologic basis of diseases-Robins SL, W.B.Saunders publication.
4. Pathology and therapeutics for pharmacists: A basis for clinical Pharmacy Practice. Green and Harris, Chapman and Hall Publication.
5. Clinical Pharmacy and therapeutics- Eric T.Herfindal, Williams and Wilkins Publication.
6. Applied Therapeutics: the clinical use of drugs. Lloyd Young and Koda-Kimble MA [ISBN 0-333-65881-7].
7. Avery's drug treatment, 4th Edn, 1997, Adis international Limited.
8. 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.

Course No. 11103 PHARMACO THERAPEUTICS I (PRACTICAL)

LEARNING OBJEVTIVES:

1. 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.
2. The students have to make at least 10 case presentations covering most of the common diseases found in the hospital to which the college is attached. The student should also submit a record of the cases presented.
3. The list of clinical cases should include follow up of the clinical cases mentioned below from the day of admission till discharge and present in the SOAP (Subjective, Objective, Assessment and Plan) format. The cases may be selected from the following diseases.

1. Cardiovascular diseases

- a) Cardiac arrhythmias b) Ischemic heart disease c) Congestive heart failure
- d) Myocardial infarction e) Hypertension f) Thromboembolic disorders
- g) Endocarditis

2. Respiratory Disorders

- a) Asthma b) COPD c) Acute respiratory failure d) Respiratory tract infections
- e) Interstitial lung disease f) Respiratory supporting aids

3. Surgery

- a) Prophylactic antibiotics b) Anticoagulants c) Thrombolytics
- d) Adjunctive therapy e) Pre-operative medication f) Analgesics

4. Renal diseases

- a) Acute renal failure b) Chronic renal failure c) Drug induced renal diseases

5. Hematological disorders

- a) Leukemia's b) Lymphomas c) Multiple myelomas
- d) Anemia's e) Bleeding disorders

6. Critical Care

- a) Hemodynamic monitoring b) Parenteral and enteral nutrition
- c) Pharmacotherapy of ventilated patients d) Shock management

7. Endocrinology

- a) Diabetes Mellitus b) Diabetes Insipidus c) Osteoporosis
- d) Thyroid disorders e) Adrenal Disorders

8. Neurodegenerative disorders

- a) Epilepsy b) Parkinson's disease c) Stroke d) Transient ischemic attacks

9. Psychiatric disorders

- a) Psychosis b) Depression c) Anxiety d) Alcohol abuse e) Drug abuse

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

4. Pathology and therapeutics for pharmacists: A basis for clinical Pharmacy Practice. Green and Harris, Chapman and Hall Publication.
5. Clinical Pharmacy and therapeutics- Eric T. Herfindal, Williams and Wilkins Publication.
6. Applied Therapeutics: the clinical use of drugs. Lloyd Young and Koda-Kimble MA [ISBN 0-333-65881-7].
7. Avery's drug treatment, 4th Edn, 1997, Adis international Limited.
8. 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.

Course No. 11104 CLINICAL PHARMACY (THEORY)

LEARNING OBJECTIVE:

Upon completion of the subject student shall be able to (Know, do, appreciate) –

1. Monitor drug therapy of patient through medication chart review and clinical review.
2. Obtain medication history interview and counsel the patients
3. Identify and resolve drug related problems
4. Detect, assess and monitor adverse drug reaction
5. Interpret selected laboratory results (as monitoring parameters in therapeutics) of specific disease states
6. Retrieve, analyze, interpret and formulate drug or medicine information.

UNIT I Introduction to Clinical Pharmacy Definition, development and scope

Patient Data Analysis

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 counseling, teaching skills, Understanding common medical abbreviations and terminologies used in clinical practices.

UNIT II Interpretation of laboratory data

Hematological, 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, Enteral and Parenteral nutrition.

UNIT III Drugs & Poisons Information

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.

UNIT IV Daily Activities of Clinical Pharmacists

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 utilization evaluation (DUE) and review (DUR), Quality assurance of clinical pharmacy services.

UNIT V Pharmacoepidemiology

Origin and evaluation of Pharmacoepidemiology need for pharmacoepidemiology, aims and applications. Methods [qualitative, quantitative and Meta-analysis models].System for monitoring drug effects, Advantages and disadvantages of Pharmacoepidemiology.

UNIT VI Research Design and Conduct of Clinical Trials

Research support including planning and execution of clinical trials, Guidelines for good clinical research practice and ethical requirements, 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.

UNIT VII Clinical Pharmacokinetics

Clinical pharmacokinetic models, Physiological determinants of drug clearance and volumes of distribution, Renal and non-renal clearance, Organ extraction and models of hepatic clearance, Estimation and determinants of bioavailability, Multiple dosing, Calculation of loading and maintenance doses, Dose adjustment in renal failure, hepatic dysfunction, geriatric and pediatric patients, Therapeutic drug monitoring.

UNIT VIII Pharmacoeconomics

Definition, history, needs of pharmacoeconomic evaluations, Role in formulary management decisions, Pharmacoeconomic evaluation, Outcome assessment and types of evaluation Includes theoretical aspects of various methods and practical study of various methods with the help of case studies for individual methods: Cost – minimization, cost- benefit, cost – effectiveness, cost utility.

Course No. 11105 CLINICAL PHARMACY (PRACTICAL)

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.

- a. Patient Medication Interviews (3).
- b. Answering Drug Information Queries (4).
- c. Patient Medication Counseling (3).
- d. Literature Evaluation (2).
- e. Therapeutic Drug Monitoring.
- f. Problem solving in Clinical Pharmacokinetics (2).
- g. Ward Round Participation.
- h. Medication order review (2).
- i. Detection and assessment of adverse drug reactions and their documentation (3).

REFERENCE BOOKS:

1. Basic skills in interpreting laboratory data – Scott LT, American Society of Health System Pharmacists, Inc., USA.
2. A Textbook Of Clinical Pharmacy Practice ,Essential Concepts And Skills, by G. Parthasarathi, Karin Nyfort - Hansen, Milap C Nahata, Orient Longman Publishers
3. Clinical Pharmacy And Pharmacotherapeutics by K.Ravishankar, G.V.N. Kiranmayi., PharmaMed Press Publication
4. Practice Standards and Definitions – The Society of Hospital Pharmacists of Australia, 1997.
5. Clinical Pharmacokinetics – Rowland and Tozer, Williams and Wilkins Publication.
6. Biopharmaceutics and Applied Pharmacokinetics –Leon Shargel, Prentice Hall publication.
7. 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.

Course No. 11106 Comprehensive Viva

PHARMACY PRACTICE SECOND SEMESTER

Course No. 11207 MODERNANALYTICAL TECHNIQUES (THEORY)

(Common paper for all specializations)

Course No. 11208 QUALITY ASSURANCE AND DRUG REGULATORY AFFAIRS (THEORY)(Common paper for all specializations)

Course No. 11209 PHARMACO THERAPEUTICS II(THEORY)

LEARNING OBJECTIVES:

Upon completion of the subject student shall be able to–

1. Know the pathophysiology of Gastrointestinal, Bone and joint disorders, Infectious diseases, Skin disorders, STDs, Oncological disorders, Ophthalmic disorders, Pain management, General Prescribing guidelines and the rationale for drug therapy .
2. Know the therapeutic approach to management of these diseases
3. Know the controversies in drug therapy
4. Know the importance of preparation of individualized therapeutic plans based on diagnosis and
5. Appreciate the needs to identify the patient-specific parameters relevant in initiating drug therapy, and monitoring therapy (including alternatives, time-course of clinical and laboratory indices of therapeutic response and adverse effects).

UNIT I Gastrointestinal system

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

UNIT II Bone and joint Disorders

Osteoporosis, Rheumatoid arthritis, Osteoarthritis, Gout, Paget's disease of bones.

UNIT III Infectious diseases

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

UNIT IV Skin and sexually transmitted diseases

Psoriasis, Eczema and scabies, Syphilis and Gonorrhoea.

UNIT V Oncology

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

UNIT VI Ophthalmology

Glaucoma, Eye infections

UNIT VII Pain management

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

UNIT VIII General Prescribing Guidelines for

Pediatric patients, Geriatric patients, Pregnancy & Breast feeding.

REFERENCE BOOKS:

1. Clinical Pharmacy and Therapeutics - Roger and Walker, Churchill Livingstone publication.
2. Pharmacotherapy: A Pathophysiologic Approach - Joseph T. Dipiro et al. Appleton & Lange.
3. Pathologic basis of disease - Robins SL, W.B.Saunders publication.
4. Pathology and therapeutics for Pharmacists: A Basis for Clinical Pharmacy Practice – Greenand Harris, Chapman and Hall publication.
5. Clinical Pharmacy and Therapeutics - Eric T. Herfindal, Williams and Wilkins Publication.
6. Applied Therapeutics: The clinical Use of Drugs. Lloyd Young and Koda-Kimble MA
7. Avery's Drug Treatment, 4th Edn, 1997, Adis International Limited.
8. Relevant review articles from recent medical and pharmaceutical literature.

Course No.11210 HOSPITAL AND COMMUNITY PHARMACY (THEORY)

LEARNING OBJECTIVES:

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

1. Know various drug distribution methods

2. Know the professional practice management skills in hospital pharmacies
3. Provide unbiased drug information to the doctors
4. Know the manufacturing practices of various formulations in hospital set up
5. Appreciate the practice based research methods
6. Appreciate the stores management and inventory control
7. Know pharmaceutical care services
8. Know the business and professional practice management skills in community pharmacies
9. Do patient counselling & provide health screening services to public in community pharmacy
10. Respond to minor ailments and provide appropriate medication;
11. Show empathy and sympathy to patients and
12. Appreciate the concept of Rational drug therapy.

UNIT I Hospital Pharmacy

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

UNIT II Hospital Pharmacy Management

Staff (professional and non-professional), Materials (drugs, non-drugs, consumables), Financial (drug budget, cost centers, sources of revenue, revenue collection), Policy and Planning, Infrastructure requirements (building, furniture and fittings, specialized equipment, maintenance and repairs), Workload statistics, Hospital Pharmacy Services Purchasing, storage, stability and safety of drugs, drug distribution, Radiopharmaceuticals, IV additive services and total Parenteral nutrition.

UNIT III Communication Skills

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

UNIT IV Community Pharmacy

Introduction to the concept of community pharmacy - its activities and professional responsibilities, the role of the community pharmacy and its relationship to other local health care providers, Prescribed medication order - interpretation and legal requirements, Over the

counter (OTC) sales, Health education and community pharmacy: Family planning, first aid, communicable disease prevention, smoking cessation, screening programs, Services to Nursing homes/clinics

UNIT V Community Pharmacy Management

Financial, material and staff management, infrastructure requirements, drug information resources, computers in community pharmacy, Code of ethics for community pharmacists, Polypharmacy and its implications.

UNIT VI Concept of Rational Use of Drugs & Evidence Based Medicine

Importance of rational drug use, Pharmacists role, Drug use indicators, Guidelines for rational prescribing, Public Health Policy and Health Care System, Formulating clinical questions, searching for the best evidence, Critical appraisal of the evidence, Applying evidence to patients, Evaluation.

UNIT VII Education and Training

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.

UNIT VIII Medication Error and Medication Adherence

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

REFERENCE BOOKS:

1. Health Education and Community Pharmacy by N.S.Parmar.
2. WHO consultative group report.c. Drug store & Business management by Mohammed Ali & Jyoti.
3. Handbook of Pharmacy – Health care.Edt. Robin J Harman. The Pharmaceutical press.
4. Comprehensive Pharmacy Review – Edt. Leon Shargel. Lippincott Williams & Wilkins.
5. Hospital Pharmacy - Hassan WE. Lec and Febiger publication.
6. Textbook of Hospital Pharmacy - Allwood MC and Blackwell.
7. Avery's Drug Treatment, 4th Edn, 1997, Adis international limited.
8. 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

Course No.11211 PHARMACO THERAPEUTICS AND HOSPITAL AND COMMUNITY PHARMACY (PRACTICAL)

LEARNING OBJECTIVES:

1. 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.
2. The students have to make at least 10 case presentations covering most of the 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 should include follow up of the clinical cases mentioned below from the day of admission till discharge and present in the SOAP (Subjective, Objective, Assessment and Plan) format. The cases may be selected from the following diseases.

1. Gastrointestinal system

- a) Diarrhea and constipation
- b) Peptic ulcer
- c) Hepatitis, Cirrhosis, Drug induced hepatic disorders
- d) Esophagol reflux disease

2. Bone and joint Disorders

- a) Rheumatoid arthritis
- b) Osteoarthritis
- c) Gout
- d) Systemic lupus erythematosis.

3. Infectious diseases

- a) Respiratory tract infections
- b) Tuberculosis
- c) Urinary tract infections
- d) Joint and bone infections
- e) Skin and soft tissue infections

4. Skin disorders

- a) Psoriasis
- b) Dermatitis
- c) Drug induced skin disorders

5. Oncology

- a) Breast cancer
- b) Small cell and non small cell lung cancer
- c) Gastric cancer
- d) Colon cancer
- e) Bladder prostate, testicular, cervical cancer
- f) Skin cancer
- g) Radiation therapy
- h) Palliative care

6. Ophthalmology

- a) Ocular infections
- b) Glaucoma
- c) Post operative management

7. Geriatric care

- a) Postural hypotension
- b) Dementia and delirium, Compliance assessment

8. Pediatric care

- a) Acute otitis media b) Tonsillitis c) Pediatric asthma d) Pediatric gastroenteritis d) Immunization e) ADHD f) Febrile neutropenia

9. Prenatal care (Pregnancy)

- a) Hypertension b) Diabetes mellitus c) Depression d) Epilepsy

REFERENCE 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.
3. Pathologic basis of diseases-Robins SL, W.B.Saunders publication.
4. Pathology and therapeutics for pharmacists: A basis for clinical Pharmacy Practice.Green and Harris, Chapman and Hall Publication.
5. Clinical Pharmacy and therapeutics- Eric Herfindal, Williams and Wilkins Publication.
6. Applied Therapeutics: the clinical use of drugs. Lloyd Young and Koda-Kimble MA [ISBN 0-333-65881-7].
7. Avery's drug treatment, 4th Edn, 1997, Adis international Limited.
8. 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.

Course No.11212 Comprehensive Viva

THIRD SEMESTER

Course No. 11313 Seminar on the objectives and work plan of the proposed project to be completed within one month from the commencement of the project.

Course No. 11314 Mid-term project review at the end of third semester.

Course No. 11315 Seminar on the selected topic

FOURTH SEMESTER

Course No. 11416 Thesis evaluation

Course No. 11417 Thesis viva-voce3