**SRM COLLEGE OF PHARMACY**
**SRM UNIVERSITY**
**Branch – I: PHARMACEUTICAL BIOTECHNOLOGY**

**FIRST YEAR**

| S.No | Subject Code | Name of the Subject |
|---|---|---|
| 1 | R14MPA04 | Modern Analytical Techniques |
| 2 | R14MPB01 | Pharmaceutical Microbiology and Cell Biology |
| 3 | R14MPB02 | Microbial Fermentation and Bioprocess Technology |
| 4 | R14MPB03 | Genetic Engineering and Animal Cell Biotechnology |

**SECOND YEAR**

| S.No | Subject Code | Name of the Subject |
|---|---|---|
| 1 | R14MPB 21 | Thesis |

## FIRST YEAR

**R14MPB01 PHARMACEUTICAL MICROBIOLOGY AND CELL BIOLOGY**
**THEORY**
**75 Hours**

**UNIT-I: TAXONOMY OF ORGANISMS (6 hours)**
Classification of microorganisms concepts (Haeckel's and Whittaker's kingdom) taxonomical methods of studying microorganism microscopy light, phase, dark field, electron and laser optic system micrometry.

**UNIT-II: INTRODUCTION TO MICROORGANISM (7 hours)**
Structure, Organization & Reproduction and economic importance of bacteria, algae, fungi and plant virus and animal virus.

**UNIT-III: CELL STRUCTURE AND FUNCTION (7 hours)**
Cell structure and function of prokaryote sand eukaryotes – transduction, transformation, conjugation–metabolic pathways– ppp, TCA cycle bioenergetics (laws of thermodynamics) oxidation, reduction and electron carriers– photosynthesis.

**UNIT-IV: NUTRITIONAL REQUIREMENTS (10 hours)**
Nutritional requirements and nutritional grouping of microorganisms. Growth curve, synchronous culture, Continuous culture. Different methods of enumeration of microorganism–methods of preservation of microbes. Effects of physical and chemical factors on microbial growth control of microorganisms.

**UNIT V: MICROBIAL PATHOLOGY AND CHEMOTHERAPY (8 hours)**
Identifying features of pathogenic bacteria, fungi and viruses. Mechanism of microbial pathogenicity and possible sites for chemotherapy. Etiology and pathology of common microbial disease and their therapies–mechanism of action of antimicrobial agents.

**UNIT VI: THE MOLECULES OF LIFE (7 hours)**
Chromosomes –genomes – genes – mobile genetic elements. Central dogma of Molecular
Biology.

**UNIT VII: CONCEPTS OF GENE EXPRESSION AND REGULATION (8 hours)**

Transcription – basic mechanism and machinery – enzymes involved transcription in prokaryotes – transcription in eukaryotes – prokaryotic and eukaryotic transcription controls– post and co-transcriptional modifications. Translation – basic mechanism and machinery – enzymes involved – translation in prokaryotes – translation in eukaryotes – prokaryotic and eukaryotic translation controls – mRNA, rRNA, tRNA processing – post translational processing.

**UNIT VIII: OVERVIEW OF CELL CYCLE AND REGULATIONS *(CHECK POINTS)* (6hours)**

Cell division (mitosis and meiosis) – differentiation – growth and development – regulation –

Apoptosis (programmed cell death) Cell to cell signaling – signal transduction – cascade

pathways – cellular interactions in development.

**UNIT IX: CANCER BIOLOGY (7 hours)**

Cancer biology – onset of cancer (inherited and sporadic) – the multistage cancer development – mitogens – carcinogens –proto oncogenes – oncogenes – oncoproteins – transformation – immortalization – tumour suppressor genes – ras– rb – p53 – cancer therapy therapeutic applications of oncogenes and their products.

**UNIT X: MEMBRANE BIOLOGY (9 hours)**

Membrane biology – cell membranes – lipid bilayer – membrane proteins and design– functions of membranes – models transport across membranes – membrane structure, assembly and transport – ion channels and membrane potential –membrane transport proteins – carrier proteins and their functions.

**R14MPB01 PHARMACEUTICAL MICROBIOLOGY AND CELL BIOLOGY PRACTICAL 100 Hours**

1. Microscopic techniques – light microscopy hanging drop – phase contrast – to demonstrate spirochetes and other microbes' fluorescent microscopy antibody technique.
2. Staining technique- gram's staining, acid fast, spore, and capsule staining.
3. Morphological study, isolation and biochemical characterization of some bacteria.
4. Morphological identification of fungi.

5. Isolation and primary screening of actinomycetes.
6. Qualitative analysis of potable water.
7. Estimation of microbial load in pharmaceutical excipients and raw materials as per official pharmacopeia.
8. Enumeration of viruses by titration and plaque assay.
9. Standardization of inoculums and estimation of MIC by serial dilution and gradient plate technique.
10. Estimation of protein – by Lowry's method.
11. Estimation of protein – by Bradford method.
12. DNA Estimation (Diphenylamine method).
13. RNA Estimation (Orcinol method).

**TEXT BOOKS**

1. Microbiology – Concepts and Applications by Pelczar, 5th Edition, Tata Mcgraw- Hill Publishing Company Ltd.
2. Microbiology – Prescott,7th Edition, Mcgraw Hill Publishers,2003.
3. Text book of Microbiology – Ananthanarayan, 5th Edition, Orient Longman publishers,1996.

**REFERENCE BOOKS**

1. Essential of Diagnostic Microbiology –Rodgers, Delmer Publishers 1999.
2. Introduction to Microbiology J.I. Ingraham. 2nd Edition
3. Microbiology a Laboratory manual by J.G.Cappuccino and N.Sharman, 4th Edition Wesley Longman 1999.
4. Principle of Microbiology by Ronald M. Atlas., WCB Publishers 1997.
5. Handbooks of Microbiological Media, 2nd edition by R.M.Atlas, CR press 1977.
6. Molecular Biology of the Cell. Alberts (B),4th Edition. Et-Al Garland Science 2002.
7. Molecular biology by David Freifelder. 2nd Edition, Narosa Publishers, 1997.
8. Cell and Molecular Biology by Karp (G), 3rd Edition, John Wiley and Sons Publishers, 2002.
9. Methods in Microbiology: Microscopy and Staining by Desai (J.D). Emkay Publications 1995.

**R14MPB02 MICROBIAL FERMENTATION AND BIOPROCESS TECHNOLOGY**
**THEORY 75 Hours**

**UNIT – I: ENZYME NOMENCLATURE AND CLASSIFICATION (8 hours)**
Enzyme nomenclature and classification- general and IUB general properties of enzymes, factors influencing velocity of enzyme reaction – pH, temperature, substrate concentration, mechanism of enzyme action–lock and key model, koshland's induced mechanism. Energy of activation, progress curve of enzyme catalyzed reaction.

**UNIT - II: ENZYME MECHANISM (8 hours)**
Chemical nature and mechanism of enzyme catalysis– enzyme specificity ,active site of enzyme, mechanism of active site determination, acid base catalysis, covalent catalysis, structure and mechanism of action of representation enzymes like chymotrypsin and lysozyme, nucleophiles and electrophilic attack, and metal activated enzymes.

**UNIT – III: INDUSTRIAL USES OF ENZYME (9 hours)**
Industrial uses of enzyme, enzyme on solid support–methods of immobilization properties of immobilized enzymes, techniques and applications, biosensors, enzyme purification–source of enzyme, intra cellular localization, extraction, fractionation, criteria of purity, enzyme assay techniques– determination of total activity, specific activity–Spectrophotometry, Spectroflurimetry, electrode method.

**UNIT – IV: IMMOBILIZATION TECHNIQUES AND KINETICS (8 hours)**
Methods of cell and enzyme immobilization –electro static and external mass transfer effect on immobilization–applications of immobilized cells and enzymes.

**UNIT- V: INTRODUCTION OF ENUMERATION PROCESS (8 hours)**
History– The chronological development of the fermentation industry. Range of enumeration Process– Fermenters–design, operation and applications– Batch reactor, Fed batch reactor, Continuous reactor and alternative fermenter designs– animal and plant cell bioreactors.

**UNIT – VI: FERMENTATION KINETICS (8 hours)**
Microbial growth kinetics– mode of growth kinetics, unstructured and structured model of growth kinetics product formation kinetics, cell destruction kinetics. Computer control of fermentation processes: system configuration and applications.

**UNIT- VII: INDUSTRIALLY IMPORTANT MICROORGANISMS (7 hours)**

Isolation, preservation and improvement of industrially important microorganisms–inoculum development for industrial fermentations– media for industrial fermentation– (media formulation and media optimization)–recovery and purification of fermented products.

**UNIT – VIII: DOWNSTREAM PROCESSING (9 hours)**

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

**UNIT- IX: INDUSTRIAL MICROBIAL PROCESSES (8 hours)**

Production of Organic acid (Citric acid, Acetic acid and Lactic acid). Production of Antibiotic (Penicillin, Streptomycin, Griseofulvin, Cephalosporin etc.) Production of alcohol (ethanol), production of malt beverages (brewing)– Steroid fermentation–production of enzymes (amylases and proteolytic enzymes)– production of fermented dairy products–production of biopolymers–production of amino acids.

**UNIT - X: BIO TRANSFORMATION OF STEROIDS (8 hours)**

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

**R14MPB02 MICROBIAL FERMENTATION AND BIOPROCESS TECHNOLOGY PRACTICAL 100 Hours**

1. Isolation of industrially important microorganisms for microbial processes.
2. Determination of Thermal Death Point (tdp) and Thermal Death Time (tdt) of
3. Microorganism for design of a sterilizer.
4. Determination of growth curve of supplied microorganism and also determine
5. Substrate degradation profile (shake flask condition)
6. Compute specific growth rate (m), growth yield (yx/s) from the above experiment.
7. Comparative studies of ethanol production using different substrates.
8. Microbial production of citric acid using **Aspergillus *niger***.
9. Microbial production of antibiotics (penicillin).
10. Production and estimation of alkaline protease.
11. Fermentation of vitamins and antibiotics.
12. Immobilization of enzymes – different methods.
13. Separation of mononuclear cells from peripheral blood and its enumeration

by Trypan Blue exclusion method.

14. Isolation of T cells and B cells.

**TEXT BOOKS**


1. Industrial Microbiology. Patel.A.H, 2nd Edition Macmillan 2012.
2. Principles of fermentation technology by P.F.Stanbury and a Whittaker, Pergamon Press, 1984.
3. Industrial Microbiology by Casida .L.E, Wiley Eastern Ltd. New Age International Ltd 1997.
4. Microbial Technology Vol I & II by H.J.Peppler 2nd edition. Academic Press.


**REFERENCE BOOKS**


1. Principles of Fermentation Technology. 2nd Edition Stanburt P.F, Elsevier 1995.
2. Fermentation microbiology and Biotechnology by Mansi and CFA, Bryce (taylor and francis group).
3. Biochemical Engineering Fundamentals by James E.Bailey and David 2nd edition, MGraw Hill International Edition.
4. Biotransformations and Bioprocessess Doble (M) Marcel Dekker 2004.
5. Bioprocess Technology Kalaichelvan (P.T) Mjp Publishers 2007.
6. Pharmaceutical Biotechnology: Concepts and Applications by Walsh.G, John Wiley & Sons Publishers, 2007.
7. Biotechnology and Biopharmaceutical Manufacturing Processing by Avis.K.E, Vol.2, International Book Distributors, 1996.
8. Fundamentals of Enzymology. 3rd Edition Price (N.C) Oxford University Press 1999.

**R14MPB03 GENETIC ENGINEERING AND ANIMAL CELL BIOTECHNOLOGY**
**THEORY 75 Hours**

**UNIT - I: GENE CLONING (6 hours)**

Gene cloning: genetic engineering tools – nucleic acid manipulating enzymes, selectable markers, vectors used in rDNA technology. Cloning strategies – restriction digestion, ligation, transformation, selection and screening of recombinants.

**UNIT –II: BLOTTING AND NUCLEIC AND HYBRIDIZATION TECHNIQUES (7 hours)**

Molecular probes – types of probes and its construction – DNA probes, cDNA probes, riboprobes, synthetic oligonucleotide probes. Probe labeling – nick translation, end labeling and random primer labeling methods. Polymerase chain reaction and its variants. RFLP, RAPD and DNA fingerprinting.

**UNIT – III: DNA SEQUENCING (6 hours)**

DNA sequencing – Maxam and Gilbert sequencing. Sanger's dideoxy sequencing, Pyro sequencing. PCR based sequencing and hybridization sequencing. Site directed mutagenesis, DNA microarray, chromosome walking and jumping, synthetic DNA.

**UNIT- IV: CONSTRUCTION OF GENE LIBRARIES (5 hours)**

Construction of gene libraries – genomic and DNA libraries, gene mapping techniques, genome project.

**UNIT- V: APPLICATION OF RECOMBINANT DNA TECHNOLOGY (7 hours)**

Applications of recombinant DNA technology – in medicine – diagnosis and therapy gene targeting, gene therapy and antisense therapy, pharmaceutical products –vaccine, humulin, etc.

**UNIT –VI: HISTORY OF ANIMAL BIOTECHNOLOGY (7hours)**

History of animal biotechnology – basic principles of biotechnology as applicable to animal science-artificial insemination, pregnancy diagnosis, ***invitro*** fertilization-embryo transfer technology – transgenic animals.

**UNIT –VII: ANIMAL HEALTH (7 hours)**

Animal health – disease diagnosis, Hybridoma technique, application of probes for diagnosis of existing and emerging animal diseases.

Prophylaxis vaccines – oral vaccines – modern vaccines – DNA vaccines in

animal diseases – institute PCR diagnostic based methods – oral vaccines – enzyme in animal feed.

**UNIT- VIII: CELL CULTURE TECHNOLOGIES (10 hours)**

Cell culture technologies-setting up a new cell culture tab – adaptation of mammalian cells to growth in serum free media – viral evaluation of animal cell lines used in biotechnology – molecular methods optimizing gene expression in mammalian cells– cytogenic characterization of recombinant cells – cell evaluation protocols – cell counting and viability measurements – monitoring animal cell growth and productivity measurement of cell death in culture – hollow film technology.

**UNIT – IX: NUCLEAR MAGNETIC RESONANCE METHODS OF MONITORING CELL METABOLISM (10 hours)**

Nuclear magnetic resonance methods of monitoring cell metabolism – culturing animal cells in fluidized bed reactors – gpi – anchored fusion proteins – harvesting gri and cho red proteins from cho cells – hematopoietic cells for cellular and gene therapy.

**UNIT –X: BASIC ASSAY TECHNIQUE (10 hours)**

Basic assay techniques– cytotoxicity testing using cell lines – product evaluation protocols measuring the folding dynamics of recombinant proteins secreted from mammalian cells – control of proteolysis in cell culture –use of inhibitors and engineered cell lines.

**R14MPB03 GENETIC ENGINEERING AND ANIMAL CELL BIOTECHNOLOGY PRACTICAL 100 Hours**

1. Preparation of tissue culture medium and membrane filtration.
2. Preparation of single cell suspension from spleen and thymus cell counting and viability.
3. Trypsinization of monolayer and sub culturing.
4. Measurement of doubling time.
5. MTT and Sulpho Rhodamine B assay.
6. Lymphocyte proliferation assay.
7. Agarose gel electrophoresis – molecular size determination.
8. SDS polyacrylamide gel electrophoresis
9. Midi-scale preparation of plasmid DNA
10. Elution of DNA from agarose gel
11. Restriction enzyme digestion
12. Amplification of DNA (PCR)

**TEXT BOOKS:**

1. Principles Of Gene Manipulation And Genomies by Primrose (S.B), 7th Edition, Blackwell Publishing 2006.
2. Molecular biology and biotechnology, 3rd edition by M.Walker& E.B.Gingold, Panama Publishing Corporation, 1999.
3. Recombinant DNA, 2nd edition by J.D.Watson, M.Gillman, J.Witknowski and M.Zoller scientific American Books, NY, 1992.

**REFERENCES BOOKS**

1. Handbook of Pharmaceutical Biotechnology Gad (S.C), Edr Wiley Interscience 2007.
2. Pharmaceutical Biotechnology: Concepts and Applications by Walsh (G), John Wiley & Sons Publishers, 2007. Gene Cloning By T.A.Brown, 2001.
3. The human genome project – deciphering the blue print of heredity by Neciagrant cooper, University science books, 1994.
4. Animal cell biotechnology methods and protocols by Nigel Jenkins human a press, New Jersey. 1997.
5. Recombinant DNA and Biotechnology a guide for teachers. 2nd edition H.Kreuzer& Massey. Asm press, Washington, 2001.
6. Practical Biotechnology Gaud (R.S) Nirali Prakashan - Pune 2000.
7. Pharmaceutical Biotechnology., Crommelin (J.A), 2nd Edition Taylor And Francis 2002.
8. Genetic engineering of animals by A.Puhler vch publishers, Wienhem, FRG 1993.
9. Recombinant DNA by Watson. Scientific American books NW, 1992.

**SRM COLLEGE OF PHARMACY**
**SRM UNIVERSITY**
**Branch – II: PHARMACEUTICAL ANALYSIS**

**FIRST YEAR**

| S.No | Subject Code | Name of the Subject |
|---|---|---|
| 1 | R14MPA03 | Advanced Pharmaceutical Analytical Techniques |
| 2 | R14MPQ01 | Quality Control and Quality Assurance |
| 3 | R14MPA01 | Modern Pharmaceutical Analysis |
| 4 | R14MPA02 | Analysis of food, cosmetics and phytochemicals |

**SECOND YEAR**

| S.No | Subject Code | Name of the Subject |
|---|---|---|
| 1 | R14MPA21 | Thesis |

## FIRST YEAR

**R14MPA03 ADVANCED PHARMACEUTICAL ANALYTICAL TECHNIQUES**
(Common Paper for Branches – Pharmaceutical Analysis, Pharmaceutical Chemistry, Pharmacognosy and Pharmaceutical Quality Assurance)
**THEORY** **75 Hours**

**UNIT - I: PRINCIPLES OF OPTICAL INSTRUMENTS (7 hours)**
Brief review of electromagnetic spectrum and absorption of radiations, Light sources, Wavelength selection, dispersion, refraction, reflection, scattering of radiation, monochromators, prisms, diffraction grating, Sample containers, detector layouts of spectrometers.

**UNIT - II: UV –VISIBLE SPECTROSCOPY (8 hours)**
The Chromophore concept, absorption law and limitations, solvent effects, design and working principle of various components of modern UV-VIS instrument, Woodward and Fieser rules for calculating absorption maximum. Quantitative spectroscopic methods..

**UNIT- III: OTHER SPECTROSCOPY TECHNIQUES (7 hours)**
Spectrofluorimetry – Theory, Instrumentation, various factors affecting fluorescence intensity and applications in pharmacy. Flame emission and Atomic absorption spectroscopy- principle, Instrumentation, interferences and application. Inductively Coupled Plasma Mass Spectrometry-Introduction, principle, Instrumentation and applications. Optical Rotatory Dispersion- Principle, plain curves, Cotton effect, Circular Dichorism, Measurement of rotation Angle in ORD and its application.

**UNIT- IV: INFRARED SPECTROSCOPY (7 hours)**
Basic Principles modes of vibrations, different factors influencing vibrational frequencies, Hooke's law, Instrumentation of IR and FTIR, various sampling techniques including ATR. Characteristic group frequencies of organic molecules, qualitative interpretation of IR spectra of Organic compounds. Raman spectroscopy – Introduction, Instrumentation and applications.

**UNIT- V: NUCLEAR MAGNETIC RESONANCE SPECTROSCOPY (9 hours)**
Fundamental Principles of NMR – nuclear spin and magnetic resonance, Chemical shift and factors affecting chemical shift, Spin-spin coupling, coupling constant, geminal coupling, vicinal coupling and long range coupling. Proton exchange reactions, Nuclear Overhauser effect (NOE) and Double resonance Phenomena.

Brief outline of instrumentation, Introduction to 13C NMR spectroscopy and 2-DNMR techniques. Interpretation of NMR spectra of different organic compounds.

**UNIT- VI: MASS SPECTROMETRY (9 hours)**

Basic Principles and theory behind. Brief outline of instrumentation. Various ionization techniques – chemical ionization, electron impact ionization, fast atom bombardment, MALDI and other desorption techniques. Fragmentation rules including nitrogen rule, ring rule, Mclafferty rearrangement and meta stable ions. General fragmentation modes and fragmentation characteristics in relation to parent structure and functional group. Mass analysers – Quadrapole, time of flight and magnetic sector. Interpretation of Mass spectra of Organic compounds. Qualitative and Quantitative applications.

**UNIT- VII: X-RAY METHODS (7 hours)**

Radioactive sources, absorption of X-ray, X-ray instrumentation, X-ray detection and measurement, ionization methods for measurement of radiation, X-ray emission methods, X-ray diffraction methods, Bragg's law, sample preparation and applications.

**UNIT VIII: LIQUID CHROMATOGRAPHY (8 hours)**

Basic principles, details about different compounds used, normal and reverse phase packing materials including ion exchange and chiral (direct and indirect). Construction and working principles of all types of detectors used. Theories of HPLC and different parameters involved to improve the efficiency in separation. Pre-column and Post-column derivatization techniques. Quantitative methods – external standard, internal standard and standard addition. Bio analytical methods – Protein precipitation, Liquid Extraction and Solid Phase Extraction. Introduction to the hyphenated techniques – LC-MS and LC MS/ MS.

**UNIT- IX: (7 hours)**

**(i) Gas Chromatography**

Basic Principles, Plate theory, rate theory (Vandeemter Equation) Instrumentation, packed and open tubular columns, column efficiency parameters including Kovat's Retention Indices and McReynold's Number. Construction and working of detectors – FID, ECD and TCD. Derivatization methods like acylation alkylation and esterification. Hyphenated techniques – GC-MS – Working principle and applications in Pharmacy.

**(ii) Planar Chromatography and other techniques**

High Performance thin layer Chromatography – Basic principles, advantages over other techniques, selection of adsorbents and mobile phase, various steps

involved, Insitu densitometry and quantitative methods. Electrophoresis and Super critical fluid chromatography – Principles, Instrumentation and applications in pharmacy.

**UNIT -X: STATISTICS (6 hours)**

Introduction, significance of statistical methods, Normal distribution, measures of Central tendency – mean, median and mode, measures of variation – standard deviation, variance, standard error, Correlation and regression, tests for statistical significance – students "t" test, F test and Chi square test. Analysis of Variance (ANOVA) – one way and two way – Theory and problems related to above topics.

**R14MPA03 ADVANCED PHARMACEUTICAL ANALYTICAL TECHNIQUES PRACTICAL 100 Hours**

1. Use of Spectrophotometer for analysis of Pharmacopoeial compounds and their formulations.
2. Simultaneous estimation of combination formulation (minimum of 4 experiments)
3. Effect of pH and solvent on UV spectrum of certain drugs.
4. Use of fluorimeter for analysis of Pharmacopoeial compounds like Riboflavine, Quinine etc.
5. Use of flame photometer for analysis of Na+, K+, Ca++ in biological fluids and formulation.
6. Assay of Pharmaceutical compounds by using complexing reagents.
7. Work shop on Spectral interpretation of IR, NMR and Mass in identification of organic compounds.
8. Identification of compounds using paper by ascending and circular separation techniques.
9. Identification of compounds using TLC as separation technique.
10. Quantitative determination of compounds using HPLC.
11. Quantitative analysis of compounds using HPTLC.

**REFERENCE BOOKS**


1. Principles of Instrumental Analysis by Donglas A. Skoog, James, J.Leary, 4th Edition, Harocurt College Publishers.
2. Pharmaceutical Analysis - Modern Methods - Part A. Part B, James W.Munson-2001, International Medical Book Distributors, Mumbai.
3. Vogel'sText Book of Quantitative Chemical Analysis, 6th Edition, 2004, Pearson Education.

4. Practical Pharmaceutical Chemistry, Part two, A.H.Beckett & J.B. Stenlake - 4th Edition.
5. Instrumental Method of Chemical Analysis - B.K.Sharma - 9th Edition, Goel Publishing House, Meerut.
6. Application of absorption spectroscopy for organic compounds by John Dyer.
7. Quantitative Analysis of Drugs by D.C. Garrett, CBS Publishers, NewDelhi.
8. Spectrometric identification of organic compounds, Robert. M. Silverstein et al, 7th Edition, 1981, John Wiley & Sons Inc., Newyork.
9. Identification of Drugs and Pharmaceutical Formulations By Thin Layer Chromatography – P.D.Sethi, Dilip Charegaonkar, 2nd Edition, CBS Publishers
10. HPTLC – Quantitative Analysis of Pharmaceutical Formulations – P.D.Sethi, CBS Publishers, New Delhi.
11. Spectroscopy of organic compounds by P.S.Kalsi, New Age International Ltd Publisher.
12. Elementary Organic Spectroscopy by Y.R.Sharma, S.Chand & Company Ltd., New Delhi.
13. Practical HPLC method Development by Snyder, 2nd Edition, Wiley Interscience Publication, USA.
14. Instrumental methods of chemical analysis by chatwal and anand, Himalaya publication house, Mumbai
15. Fundamental of Biostatistics by Khan and Khanum, 3rd revised edition, Ukaaz publication, AP, India.

## R14MPA04 MODERN ANALYTICAL TECHNIQUES

(Common Paper for Branches - Pharmaceutics, Pharmacy Practice, Pharmacology and Pharmaceutical Biotechnology)

**THEORY** **75 Hours**

**UNIT- I: PRINCIPLES OF OPTICAL INSTRUMENTS**
**(7 Hours)**

Brief review of electromagnetic spectrum and absorption of radiations , Light sources, Wavelength selection, dispersion, refraction, reflection, scattering of radiation, monochromators, prisms, diffraction grating, Sample containers, detector layouts of spectrometers.

**UNIT -II: UV –VISIBLE SPECTROSCOPY ( 8 hours)**

The Chromophore concept, absorption law and limitations, solvent effects, design and working principle of various components of modern UV-VIS instrument, Woodward and Fieser rules for calculating absorption maximum. Quantitative spectroscopic methods.

**UNIT -III: OTHER SPECTROSCOPY TECHNIQUES (8 hours)**

Spectrofluorimetry – Theory, Instrumentation, various factors affecting fluorescence intensity and applications in pharmacy. Flame emission and Atomic absorption spectroscopy- principle, Instrumentation , interferences and application.

**UNIT –IV: INFRARED SPECTROSCOPY (7 hours)**

Basic Principles modes of vibrations, different factors influencing vibrational frequencies, Hooke's law, Instrumentation of IR and FTIR, various sampling techniques including ATR. Characteristic group frequencies of organic molecules, qualitative interpretation of IR spectra of Organic compounds.

**UNIT- V: NUCLEAR MAGNETIC RESONANCE SPECTROSCOPY AND MASS SPECTROSCOPY (8 hours)**

Fundamental Principles of NMR – nuclear spin and magnetic resonance. Chemical shift and factors affecting chemical shift. Spin-spin coupling and coupling constant.

Mass Spectroscopy – Basic Principles and theory behind. Brief outline of instrumentation. Fragmentation rules including nitrogen rule, ring rule, Mclafferty rearrangement and Meta stable ions. Qualitative and Quantitative applications.

**UNIT –VI: X-RAY METHODS (7 hours)**

Radioactive sources, absorption of X-rays, X-ray instrumentation, X-ray detection and measurement, ionization methods for measurement of radiation, X-ray emission methods, X-ray diffraction methods, Bragg's law, sample preparing and applications.

**UNIT- VII: INTRODUCTION TO CHROMATOGRAPHY (8 hours)**

**(i) Basics of Chromatography**

Classification of Chromatographic techniques, basic principles, paper chromatography – techniques and applications. Thin layer Chromatography – adsorbents used preparation of TLC plates, detecting agents and applications. Column Chromatography – Column packing, elution principles and applications.

**(ii) Liquid Chromatography**

Basic principles, details about different components used, normal and reverse phase packing materials including ion exchange and chiral (direct and indirect). Construction and working principles of all types of detectors used. Theories of HPLC and different parameters involved to improve the efficiency in separation. Quantitative methods – external standard, internal standard and standard addition.

**UNIT- VIII: GAS CHROMATOGRAPHY AND OTHER TECHNIQUES (8 hours)**

Basic Principles, rate theory (Vandeemter Equation) ,Instrumentation, packed and open tubular columns, column efficiency parameters including Kovat's Retention index and McReynold's Number. Construction and working of detectors. High Performance thin layer Chromatography – Basic principles, advantages over other techniques, selection of adsorbents and mobile phase, various steps involved, Insitu densitometry and quantitative methods. Super critical fluid chromatography – Principle, Instrumentation and applications in pharmacy.

**UNIT -IX: OTHER TECHNIQUES (7 hours)**

Thermal methods of analysis – Differential scanning calorimetry and Differential thermal analysis – principle, instrumentation and applications. Electrophoresis – paper and Gel – Principle, types, electrophoretic mobility, electro-osmotic mobility, Instrumentation and applications.

**UNIT -X: STATISTICS (7 hours)**

Introduction, significance of statistical methods, Normal distribution, measures of Central tendency – mean, median and mode, measures of variation – standard deviation, variance, standard error, Correlation and regression, tests for statistical significance – students "t" test, F test and Chi square test. Analysis of Variance (ANOVA) – one way and two way – Theory and problems related to above topics.

**R14MPA04 MODERN ANALYTICAL TECHNIQUES**

**PRACTICAL 100 Hours**

1. Use of Spectrophotometer for analysis for Pharmacopoeial compounds and their formulations.
2. Simultaneous estimation of combination formulation (minimum of 4 experiments).
3. Effect of pH and solvent on UV spectrum of certain drugs.
4. Identification of compounds using paper as separating techniques.
5. Quantitative determination of compounds using HPLC.
6. Experiments involving calculation of statistical parameters.
7. Identification of compounds using TLC as separation technique.
8. Use of fluorimeter for analysis of Pharmacopoeial compounds.
9. Use of flame photometer for analysis of Na+, K+ and Ca++ in biological fluids and in formulation.
10. Quantitative determination of compounds using HPTLC.
11. Spectral interpretation and identification of organic compounds by IR, NMR and Mass.

**REFERENCE BOOKS**


1. Principles of instrumental Analysis by Donglas A. Skoog, James, J.Leary, 4th Edition, Harcourt College Publishers.
2. Pharmaceutical Analysis – Modern Methods – Part A, Par B, James W.Munson-2001, International Medical Book Distributors, Mumbai.
3. Vogel's Text Book of Quantitative Chemical Analysis, 6h Edition, 2004, Pearson Education.
4. Practical Pharmaceutical Chemistry, Part two, A.H.Beckett & J.B. Sterlake – 4th Edition.
5. Instrumental Method of Chemical Analysis – B.K.Sharma – 9th Edition, Goel Publishing House, Meerut.
6. Spectrometric identification of organic compounds, Robert M.Silverstein et al, 7th Edition, 1981, John Wiley & Sons Inc. Newyork.
7. Identification of Drugs and Pharmaceutical Formulations by Thin Layer.
8. Chromatography – P.D.Sethi, Dilip Charegeonkar, 2nd Edition, CBS Publishers and Distributors, Delhi.
12. HPTLC – Quantitative Analysis of Pharmaceutical Formulations – P.D. Sethi, CBS Publishers, New Delhi.
13. Applications of absorption spectroscopy for organic compounds by John Dyer.
14. Quantitative Analysis of Drugs by D.C.Garrett, 2nd edition, CBS Publishers, New Delhi.

15. Instrumental methods of chemical analysis by chatwal and anand, Himalaya publication house, Mumbai
16. Fundamental of Biostatistics by Khan and Khanum, 3rd revised edition, Ukaaz publication, AP, India.

**R14MPQ01 QUALITY CONTROL AND QUALITY ASSURANCE**
**THEORY 75 Hours**

**UNIT – I: (7 hours)**
Definition - Quality control and Quality assurance, concept and philosophy of TQM, GMP, ICH, Brief study of Quality by design, six sigma concept, ISO 9000 & 14000, ICH common technical documents like Validation of Analytical Procedures [Q2 (R1)], Stability testing of new substances and products [Q1A (R2)], photostability testing of new drug substances and products (Q1B). Impurities in new drug substances [Q3A(R)], Impurities in new drug products [Q3B(R)].

**UNIT – II: (8 hours)**
**Organization and personnel responsibilities:** Training, hygiene and personal records, drug industry location, design, construction and plant lay out, maintenance, sanitation, environmental control, utilities and maintenance of sterile areas, control of contamination and Good Warehousing Practice.

**UNIT – III: (7 hours)**
**Equipments and raw materials**: Equipments selection, purchase specifications, maintenance, clean in place, purchase specifications and maintenance of stores for raw materials, selection of vendors.

**UNIT – IV: (7 hours)**
Quality control test for containers, closures and secondary packing materials

**UNIT- V: (7 hours)**
**Document maintenance in pharmaceutical industry**: Batch Formula Record, Master Formula Record, Quality audit reports and documents, quality reports, distribution records, Common Technical Document and Drug Master Files, Medical Devices, Electronic Common Technical Documentation, complaints and evaluation of complaints, Handling of return goods, recalling and waste disposal.

**UNIT –VI: (8 hours)**
**In process quality control and finished products quality control for following formulation in pharma industry**: tablets, capsules, ointments, suppositories, creams, parenterals, ophthalmic and surgical products.

**UNIT - VII: (7 hours)**
**Production controls**: Written procedures, change control, contamination control, sterile products, aseptic process control, packaging.

**Unit – VIII: (8 hours)**

**Manufacturing operations and controls**: Sanitation of manufacturing premises, mix-ups and cross contamination, processing of intermediates and bulk products, packaging operations, IPQC, release of finished product, process deviations, charge-in of components, time limitations on production, drug product inspection, expiration dating, calculation of yields, production record review.

**Unit – IX: (8 hours)**

Scope of GLP, Quality assurance unit, SOP, protocols for conduct of clinical & non clinical testing, control on animal house, report preparation and documentation.

**Unit – X: (8 hours)**

NABL certification and accreditation procedure, Patent regime and intellectual property rights.

**R14MPQ01 QUALITY CONTROL AND QUALITY ASSURANCE**

**PRACTICAL 100 Hours**

**Suggested practical experiments (at least 12 experiments to be conducted)**

1. in process quality control tests for tablets, capsules, parenterals and creams
2. Quality control tests for secondary packing materials
3. Assay of raw materials as per official monographs
4. Testing of related and foreign substances in drugs and raw materials
5. Planning and design of plant layouts.
6. Power point presentation (atleast 6)
   i. TQM
   ii. GMP
   iii. ICH
   iv. Study of Quality by design
   v. Six sigma concept
   vi. ISO 9000 & 14000

**REFERENCE BOOKS:**


1. Quality Assurance Guide by organization of Pharmaceutical Procedures of India, 3rd revised dition, Volume I & II, Mumbai, 1996.
2. Good Laboratory Practice Regulations, 2nd Edition, Sandy Weinberg Vol. 69, Marcel Dekker Series, 1995.
3. Quality Assurance of Pharmaceuticals- A compendium of Guide lines and related materials Vol I & II, 2nd edition, WHO Publications, 1999.

4. How to Practice GMP's – P P Sharma, Vandana Publications, Agra, 1991.
5. The International Pharmacopoeia – vol I, II, III, IV & V - General Methods of Analysis and Quality specification for Pharmaceutical Substances, Excepients and Dosage forms, 3rd edition, WHO, Geneva, 2005.
6. Good laboratory Practice Regulations – Allen F. Hirsch, Volume 38, Marcel Dekker Series, 1989.
7. ICH guidelines
8. ISO 9000 and total quality management
9. The drugs and cosmetics act 1940 – Deshpande, Nilesh Gandhi, 4th edition, Susmit Publishers, 2006.
10. QA Manual – D.H. Shah, 1st edition, Business Horizons, 2000.
11. Good Manufacturing Practices for Pharmaceuticals a plan for total quality control – Sidney H. Willig, Vol. 52, 3rd edition, Marcel Dekker Series.

**R14MPA01 MODERN PHARMACEUTICAL ANALYSIS**
**THEORY 75 Hours**

**UNIT- I: SPECTROSCOPIC & COLORIMETRIC ESTIMATION (8 hours)**

1. UV spectroscopic and Colorimetric estimation of functional groups such as
   a. Aldehyde and ketones
   b. Amines
   c. Hydroxyl
   d. Ester
2. Principles and Procedure involved in the ion pair extraction with acidic dyes as reagents in pharmaceutical analysis for analysis of various suitable Pharmaceutical examples

**UNIT -II: REAGENTS (7 Hours)**

Principles and Procedure involved in the use of following reagents in Pharmaceutical analysis for analysis of various suitable Pharmaceutical examples

1. Para Dimethyl Amino Benzaldehyde
2. Folin Ciocalteu Reagent
3. N-1 – Napthyl Ethylene diamine dihydrochloride
4. 3 – Methyl 2 – Benzo Thiazoline Hydrazone
5. 2, 6- Dichloro Quinone chlorimide
6. 2, 3 Dichloro 5, 6 Dicyano 1, 4 benzoquinone
7. 1, 2 Naphtho quinone – 4 – sulphonate

**UNIT -III: ANALYSIS OF PHARMACEUTICAL FORMULATIONS – I (8 Hours)**

Principles and Procedures involved in the analysis of Pharmaceutical formulation for following classes of drugs.

a) Vitamins such as Vitamin A, Vitamin K, Thiamine, Riboflavin, Pyridoxine, Folic acidand Vitamin C.
b) Analgesics and anti-inflammatory drugs such as Paracetamol, Ibuprofen, Aspirin, Diclofenac sodium and Chlozoxazone.

**UNIT –IV: ANALYSIS OF PHARMACEUTICAL FORMULATIONS – II (7 Hours)**

Principles and Procedures involved in the analysis of Pharmaceutical formulations for following classes of drugs:

A) Steroids such as Testosterone, Progesterone and Dexamethasone.
B) Cardiovascular drugs such as Atenolol, Atorvastatin, Frusemide and Diltiazem

**UNIT –V: ANALYSIS OF PHARMACEUTICAL FORMULATIONS – III (7 Hours)**

Principles and Procedures involved in the analysis of Pharmaceutical formulations for following classes of Antibiotics such as Amoxycillin, Ampicillin, Cephalexin, Ciprofloxacin, Erythromycin, Chloramphenicol, Tetracycline, Rifampicin and Ofloxacin.

**UNIT –VI: IMPURITIES (7 Hours)**

Impurity profiling, sources of impurities, preliminary evaluation of Impurities in Pharmaceuticals, Isolation and characterization of Impurities applications of various instruments in Impurity profiling.

**UNIT –VII: CASE STUDIES OF IMPURITIES (8 Hours)**

Case studies of impurities for drugs such as Metoprolol tartrate, Chlorthalidone, Terbutaline sulphate, Lovastatin, Zidovudine and Imipramine.

**UNIT –VIII: CALIBRATION OF ANALYTICAL INSTRUMENTS (8 Hours)**

Calibration of analytical instruments such as

a. Weighing balance
b. pH Meter
c. Ultra Violet – Visible Spectrophotometer
d. High Performance Liquid Chromatography
e. Infra Red Spectrophotometer
f. High Performance Thin Layer Chromatography
g. Gas Chromatography

**UNIT- IX: HYPHENATED TECHNIQUES (7 Hours)**

Hyphenated Techniques – LC-MS Theory – Ionization techniques, mass analyzers - applications in bioequivalence study, impurity profiling and herbal drug standardization, LCMS/MS – Basic principles and applications.

**UNIT –X: BIOLOGICAL TESTS AND ASSAYS (8 Hours)**

a. Adsorbed Tetanus vaccine
b. Adsorbed Diphtheria vaccine
c. Rabies vaccine
d. Tetanus Anti toxin
e. Oxytocin
f. Heparin sodium IP

**R14MPA01 MODERN PHARMACEUTICAL ANALYSIS**

**PRACTICAL 100 Hours**

1. Analysis of Pharmaceutical compounds with reagents such as
   a) Para Dimethyl amino benzaldehyde.
   b) Folinciocalteu Reagent
   c) N-1 – Napthyl Ethylene diamine dihydrochloride
   d) 3 – Methyl 2 – Benzo Thiazoline Hydrazone
   e) 2, 6 Dichloro Quinone chlorimide
2. Quantitative Determination of following groups:
   a) Hydroxyl group
   b) Carbonyl group
   c) Amine
3. Assay of various Pharmaceutical Formulations using A1%, 1cm values.
4. Assay of pharmaceutical compounds mentioned in theory by UV, Colorimetry and HPLC methods.
5. Determination of Impurities by TLC
   a) Para amino phenol in paracetamol
   b) Salicylic acid in Aspirin
   c) 4 – Isobutyl Phenyl Propionic acid in Ibuprofen.
6. Calibration of the following instruments
   a) Weighing balance
   b) pH meter.
   c) UV – Visible Spectrophotometer
   d) IR Spectrophotometer
7. Demonstration of HPLC and HPTLC Calibration

**REFERENCE BOOKS**


1. Vogel's, Text book of Quantitative chemical analysis revised by G.H. Jeffery, J.Bassett, J. Mendham, R.C.Denney 6th Edition, first Indian reprint 2002, Pearson Education Publishers New Delhi, India.
2. Practical Pharmaceutical Chemistry by A.H. Beckett and J.B Stenlake, part I and II, fourth edition, 1997, CBS Pubishers and Distributors, New Delhi.
3. Text Book of Pharmaceutical Analysis by K.A.Connors, 3d Edition, 2004, Wiley – inter Science Publication, Replica press, India.
4. Principles of Analytical Chemistry by John H. Kennedy, 2nd Edition, 1990, Saunders College Publishing, New York.
5. Pharmaceutical Analysis by Takeru Higuchi, Brochman and Hanssen, 2nd Ediiton, reprint 2000, CBS Publishers and Distributors, New Delhi.
6. The Quantitative Analysis of Drugs by D.C.Garratt, first Indian edition 2001, reprint 2003, CBS Publishers and Distributors, New Delhi.

7. Quantitative Analysis of Drugs in Pharmaceutical Formulations by P.D.Sehti, 3rd Edition, 1997, CBS Publishers and Distributors, New Delhi.
8. Remington's, The science and practice of pharmacy, 21st edition, Indian reprint 2006, Uppincott Williams and wilkins, USA.
9. Handbook of Isolation and characterization of Impurities in Pharmaceuticals by Satinder Ahuja, first Indian print 2005, Academic Press, Elsevier, New Delhi.
10. Impurities, Evaluation of Pharmaceuticals by SatinderAhuja, first Indian reprint 2006, Marcel Dekker, Replica Press India.
11. Clark's Analysis of Drugs and Poisons in Pharmaceuticals, body fluids and postmortem materials, Vol.I and II byAnthony C.Moffat, M.David Osselton and Brain Niddop, third edition 2004, Pharmaceutical Press, UK.
12. Indian Pharmacopoeia 2014, Volume I- IV, Edited by the Indian Pharmacopeia Commission, Ghaziabad.
13. Method Validation in Pharmaceutical Analysis, A guide to best practices by Joachim Ermer, John H Mc B Miller, edition 2004, Wiley VCH verlay Gm bH & CoKGaA.

**R14MPA02 ANALYSIS OF FOOD, COSMETICS AND PHYTOCHEMICALS**
**THEORY 75 Hours**

**UNIT – I: GENERAL METHODS OF ANALYSIS OF IMPORTANT CHEMICALCONSTITUENTS (6 Hours)**

General methods involved in the analysis of important chemical constituents of food such as proteins, carbohydrates and fats. Determination of physical constants, moisture, total solids, ash and crude fibre.

**UNIT – II: FOOD ADULTERATION (7 Hours)**

Analysis of pure foods and their common adulterants, prevention of food adulteration Act and Rules

**UNIT – III: ESTIMATION OF FOOD PRODUCTS (8 Hours)**

Analysis of Food products
Milk and milk products - cheese, ice cream, butter, Ghee
Carbohydrates foods - sugars, honey, starch.
Alcoholic beverges - Wine, Spirit, beer.
Non-alcoholic beverages - soft drinks, cocoa, coffee, tea.

**UNIT - IV: DETERMINATION OF FOOD ADDITIVES (8 Hours)**

Studies including detection and determination in food of different additives i.e. preservatives, antioxidants, colouring matter, emulsifiers, stabilizers and contaminants, i.e. toxic trace metals – tin, arsenic, cadmium, mercury, lead; pesticides, aflatoxin.
Physical, chemical and microbiological factors involved in deterioration of food quality and spoilage.

**UNIT – V: FOOD LAWS (9 Hours)**

A study of the prevention of food adulteration act and rules, fruit products order, vegetable oil product, products control order, A.G. Mark and ISI, BIS and EU guidelines. Water analysis – Physical, chemical and bacteriological analysis of water supplies and effluents with special reference to public health and food industries.

**UNIT - VI: ESTIMATION OF RAW MATERIALS USED IN COSMETIC (8 Hours)**

General methods involved in the analysis of important raw materials such as water, humectants, surfactants, Oils and fats.

**UNIT- VII: DETAILED STUDY ON QUALITY CONTROL TEST FOR FOLLOWING COSMETIC PRODUCTS (7 Hours)**

Tooth paste, Nail polish, Shampoo, Depilatories, Skin cream, Lipsticks, Hair dye and Soap.

**UNIT-VIII: STABILITY STUDIES FOR COSMETICS (7 Hours)**

Importance of stability testing on cosmetics. A detailed study on general preservation tests, photo stability test, aerosol stability test, accelerated stability test and stress testing.

**UNIT- IX: TOXICITY TESTS FOR COSMETICS (7 Hours)**

Importance of toxicity testing on cosmetics. Detailed study on various Skin irritation test – Draize test, oral toxicity limit test. Mucous membrane irritancy tests – eye irritancy test, oral mucosal irritation test. Sensitivity testing – Patch test (open and closed), prophetic patch test, photo patch test, test for volatile substances and sensitizing potentials. Toxicity tests for some specific cosmetic products – creams, depilatories, hair dyes, nail polish, lipsticks, hair and bath preparations.

**UNIT-X: QUALITY CONTROL OF HERBAL DRUGS (8 Hours)**

i. General method of extraction and identification of phytoconstituents like alkaloids, flavanoids, volatile oils and glycosides.
ii. Analytical principles and procedure involved in analysis of drugs containing phytoconstituents
    Alkaloids - Ephedrine, ergotamine
    Flavanoids - rutin, quercetin
    Volatile oils - mentha oil, eucalyptus oil
    Steroids - cholesterol, progesterone
    Glycosides - digitoxin, sennosides
iii. Application of HPLC and HPTLC in herbal analysis.

**R14MPA02 ANALYSIS OF FOOD, COSMETICS AND PHYTOCHEMICALS**
**PRACTICAL 100 Hours**

1. Determination of Acid value and Saponification value for oils.
2. Physical and chemical methods of water analysis.
3. Determination of caffeine in beverages.
4. Determination of Protein and chloride content in milk.
5. Estimation of Benzoic acid in soft drinks.
6. Estimation of titratable acidity in butter.
7. Analysis of Cheese.
8. Test for food adulterants.
9. Quality control test on tooth paste and nail polish.
10. Determination of Total fatty matter and pH of Skin cream.
11. Determination of pH of and volatile matter in Shampoo.
12. Quality control tests for Depilatories.
13. Estimation of combined alkali in soap.
14. Estimation of free caustic alkali in liquid soap.
15. Determination of moisture content in herbals.
16. Estimation of tannins in tea powder.
17. UV, Colorimetry, TLC and HPTLC methods of analysis for few phytoconstituents.
18. Extraction and qualitative tests for few important phytoconstituents.

**REFERENCE BOOKS:**


1. Introduction to Food Analysis by Suzanne Nielsen.
2. Food analysis of A.G. Woodman (Mc. Craw hill Co., London).
3. The chemical analysis of foods by David Pearson (J & A Churcuil).
4. Food adulteration by Jcob Thankamma (Macmillan Co. New Delhi).
5. Canned foods by J.G. Baumganter and A.C.Horson (J.A.Churchil Ltd. London)
6. The chemical analysis of food and food products by Marris B Jacobs (van Nostrand, New York).
7. Modern Food analysis by J.F. Hart H.J. Fischer.
8. Prevention of food adulteration act and rules (A Government of India Publication).
9. Aids to analysis of food and drugs by J.R. Nicholas.
10. Analysis of Fruit and Vegetable product by S. Ranganna.
11. Handbook of cosmetic analysis by P.P.Sharma.
12. Phytochemical methods – A guide to modern techniques of plant analysis, third edition – J.B. Harborne, Third edition, 2005, Springer (India) Pvt. Ltd, New Delhi.

13. Indian pharmacopoeia, Govt of India, Ministry of Health and family welfare, 1996, Published by The controller of publications, Delhi.

**SRM COLLEGE OF PHARMACY**
**SRM UNIVERSITY**
**Branch – III: PHARMACEUTICAL CHEMISTRY**

**FIRST YEAR**

| S.No | Subject Code | Name of the Subject |
|---|---|---|
| 1 | R14MPA03 | Advanced Pharmaceutical Analytical Techniques |
| 2 | R14MPC01 | Advanced Organic Chemistry |
| 3 | R14MPC02 | Medicinal Chemistry |
| 4 | R14MPC03 | Phytopharmacy |

**SECOND YEAR**

| S.No | Subject Code | Name of the Subject |
|---|---|---|
| 1 | R14MPC21 | Thesis |

**FIRST YEAR**

**R14MPC01 ADVANCED ORGANIC CHEMISTRY**

**THEORY 75 Hours**

**UNIT –I: NUCLEOPHILIC SUBSTITUTION REACTION (8 Hours)**

Aromatic Nucleophilic Substitution reaction; Mechanism, Substitution in hetero aromatic compounds Substitution via benzyne, Reactions of benzyne, SN1 reaction, Reactivity.

Aliphatic Nucleophilic Substitution reaction: Mechanism (unimolecular and bimolecular) factors affecting mechanism, Walden inversion, SN1 Mechanism, Participation of neighbouring group in nucleophilic substitution, Asymmetric synthesis.

**UNIT -II: AROMATIC ELECTROPHILIC SUBSTITUTION REACTION (8 Hours)**

Aromatic Electrophilic Substitution reaction; Mechanism, directive and rate controlling factor, Formation of C-C bond, C-N bond, C-S bond and C-X bond. Aliphatic Electrophilic Substitution reaction : Mechanism, Bimolecular SE and SE Reactivity, SE1, Reactions as hydrogen leaving group, halogen as leaving group, Carbon as leaving group.

**UNIT- III: FREE RADICAL AND NAME REACTIONS (8 Hours)**

Free Radical reactions: Structure, Preparation and stability of free radical, Free radical substitution reaction, Free radical addition reaction, Radical inhibitors, Gomberg reaction, Hunsdiecker reaction, Ullmann reaction, Barton reaction.

Name reaction: Biginelli pyrimidone synthesis, Bergmann cyclization, Jiffeneau-Demjanov reaction, Polonovski reaction, Mc Murry coupling, Michael addition, Mannich reaction, Diels –Alder reaction

**UNIT -IV: OXIDATION-REDUCTION & ELIMINATION REACTION (8 Hours)**

Oxidation-reduction reaction: Oxidation reduction mechanism, epoxidation, Diol formation, Catalytic hydrogenation and dehydrogenation, Etard reaction, Riley reaction, Oppenauer oxidation, Sommelet reaction, hydroboration, Metal-Hydride reduction (LiAlH4, NaBH4, MPV reduction, Birch reduction

Elimination reaction : Unimolecular and bimolecular elimination, Pyrolytic SYN elimination.

**UNIT -V: MOLECULAR REARRANGEMENTS (7 Hours)**

Molecular Rearrangements: Pinacol rearrangement, Benzilic acid rearrangement, Curtius rearrangement, Beckmann rearrangement, Schmidt rearrangement, Bayer-

Vlliger rearrangement, Dakin rearrangement, Wittig rearrangement, Stevens' rearrangement, Sommelet Hauser rearrangement.

**UNIT -VI: OPTICAL ISOMERISM (8 Hours)**

Optical activity and chirality, Elements of symmetry, Optical isomerism due to one asymmetric carbon, two or more unequal asymmetric carbon atom, Diastereomer, Racemic modification, Nature and formation of racemic modification, Resolution of racemic modification, Absolute and relative configuration, Atropisomerism-Biphenyl isomerism, Optical isomerism in Allenes, Alkylidene cycloalkane, Spirans, Stereo specific and stereo selective reactions.

**UNIT -VII: GEOMETRICAL ISOMERISM AND REAGENTS (7 Hours)**

Geometrical isomerism: Structural requirements, Nomenclature, Determination of configuration.

Reagents used in organic synthesis (Application):

i. Pyridinium chlorodichromate
ii. Chromium oxide
iii. Dicyclohexyl carbidoimide
iv. Grignard Reagent
v. N-Bromo succinimide.

**UNIT –VIII: (7 Hours)**

Conformational isomerism; Conformation of Ethane, Butane, Cyclohexane, Mono substituted and disubstitued cyclohexane. Synthesis and reactions of selected five membered hetereocyclic compounds: Thiazole, Imidazole, Triazole, Tetrazole, Oxadiazole.

**UNIT – IX: (7 Hours)**

Synthesis and reactions of heterocyclic compounds: Indole, Pyrimidine, Pyrazine, Quinoline, Isoquinoline, Pteridine, Thiadiazole

**UNIT X: – RETRO SYNTHESIS (7 Hours)**

Introduction, Disconnection approach, Terminology, One group disconnection, Two group disconnection, C-X disconnection, One group C-C disconnection Functional group inter- conversion. Applications of synthon approach to the synthesis of Propronolol, Chlorpromazine, Imipramine, Promethazine, Cyclizine and Epinephrine.

**R14MPC101 ADVANCED ORGANIC CHEMISTRY**

**PRACTICAL 100 Hours**

1. Synthesis of some suitable heterocyclic system (Quinoline, Indole, Phenothiazine etc.) and theoretical predication of spectral data.
2. Reaction based on theory like Clemmenson reduction, Mannich reaction, Beckmann rearrangement.
3. Determination of optical activity of sugar solution by polarimeter.
4. Construction of stereo models.
5. Determination of configuration of stereo molecules by theoretical approach.
6. Resolution of racemic mixture.
7. Work shop on Drug Stereo chemistry.
8. Any other exercise to substantiate theory.

**TEXT BOOKS**


1. Elementary Practical Organic Chemistry Part-I, II & III by A.I.Vogel, 2nd Eidtion, CBS Publishers, India 1987.
2. Text book of Organic Chemistry by Raj, K.Bansal, 3rd Edition, Newage International (P) Ltd. India1997.
3. Text book of Practical Organic Chemistry by A. L. Vogel, 5th Edition, Pearson Education Ltd. New Delhi, 2008
4. Organic Chemistry by Mc.Murray Thomson Pvt. Ltd. Brooks cole USA1992
5. Conformation and Mechanism by PS.Kalsi, 4h Edition, New Age International (P) Limited. India1994.


**REFERENCE BOOKS**


1. Quantitative chemical analysis by Vogels. 5th education. Longman scientific and technical, New York, 1989.
2. Organic Chemistry by Morrison and Boyd 6th Edition, Pearson Education Ltd.,New Delhi India 2008.
3. Advanced Organic Chemistry by Jerry March, 4th Edition Wiley Interscience Publication. India 2004
4. Stereochemistry of carbon compounds by E.L.Eliel, Tata McGraw Hill Publishing company. India1975.
5. Stereochemistry by Potopov, MIR Publishers, Moscow. 1979.
6. Organic Chemistry by I.L.Finar Vol. I & II, Pearson education, 6th Edition, 2002.
7. Stereo chemistry of organic compounds by D.Nasipuri 2nd Edition, New Age International (P) Limited, India 1994.

**R14MPC02 MEDICINAL CHEMISTRY**

**THEORY 75 Hours**

**UNIT – I: (8 Hours)**

Theoretical aspects of drug action: Route of administration, absorption, metabolism, distribution and excretion, physico chemical parameters in relation to biological activities like ionization, hydrogen bonding, chelation, partition coefficient, oxidation reduction potential and surface activity. Influence of optical isomerism on the pharmacokinetic, pharmacodynamic profile of chiral drugs. Conformational isomerism and biological action. Geometrical isomerism and biological action. Drug-Receptor interaction: Types of receptors, forces involved in drug-receptor interaction, theories of receptors. Receptor and the biological response, signal transduction, ligand gated ion channel, G-protein coupled receptors.

**UNIT – II (7 Hours)**

Metabolism: Introduction, pathways of metabolism, factors affecting drug metabolism. Pro drug: Utility of pro drug, prodrug design and carrier linked pro drug and Bio precursor, Applications.

**UNIT - III: (8 Hours)**

Drug Discovery and Development: Drug discovery without lead, random screening, non-random screeing, drug metabolism studies, clinical observations, Rational approach to lead discovery, drug development and lead modification. Approach to rational design of enzyme inhibitors and inactivates: Enzyme inhibitors, Mechanism of reversible and irreversible inhibitors, Transition state analogs, Potential of irreversible enzyme inhibitors. Affinity labeling agents, Mechanism based enzyme in activators, Examples of drugs as inhibitors like Lovastatin, Sulfonamide, Captopril, Vigabatrin, Floxuridine.

**UNIT – IV: (7 Hours)**

Prostaglandins and Leucotrienes: Bio-synthetic path ways. NSAID: Classification, Mechanism of action, SAR, synthesis of Tolmetin, Zomepirac, Diclofenac and, Aceclofenac, Ketoprofen and Piroxicam

**UNIT – V: (8 Hours)**

DNA – Interactive drugs: DNA intercalators, Alkylators and strand breakers

Antineoplastic agents: Classification, Mechanism of action and synthesis of Mechlorethamine, Cyclophosphamide, Carmustine, Procarbazine, Mercaptopurine, Thioguanine, Methotrexate, Letrazole, Tamoxifen, Carboplatin.

**UNIT -VI:** **(7 Hours)**

Quantitative Structure Activity Relationship (QSAR) : Physico chemical parameters, Electronic, Steric and lipophilic parameters. Methods used to correlate physio chemical parameters using biological activity, Hansch analysis, Denovo method, Topliss method, Cluster analysis, Computer based method of QSAR. Computer Aided Drug-Design (CADD) : Molecular modeling, Molecular graphics, Molecular dynamics, Quantum mechanics

**UNIT – VII:** **(7 Hours)**

Combinatorial Chemistry: Combinatorial libraries concepts, Solid phase synthesis, Solutions phase synthesis, Encoding methods, High throughput screening (HTPS), Applications. Medicinal Chemistry aspects of the following class of drugs in relation with Mechanisms, SAR (if any) and Synthesis of the following drugs mentioned. Antihypertensive agents: Clonidine, Atenolol, Labetolol, Minoxidil, Hydralazine Verapamil, Nifidipine, Amlodipine Captopril, Enalapril Lorsartan.

**UNIT – VIII:** **(7 Hours)**

Antiviral agents: Ganciclovir, Methisazone, Ribavirin, Didanosine, Lamivudine, Delaviridine.

Hyperlipidemic agents: Lovastatin, Clofibrate, Benzafibrate, Probucol

**UNIT – IX:** **(8 Hours)**

Cholinergic and Cholinergic blocking agents: Carbachol, Dicyclomine, Orphenadrine, Procyclidine, Ethoprazocin. Gastric proton pump inhibitors: Omeprazole, Lansoprazole.

**UNIT – X:** **(8 Hours)**

Tranquilizers: Chlorpromazine, Prochlorperazine, Haloperidol, Droperidol, Chlorothixene, Chlordiazepoxide, Diazepam.

Antisense therapeutic agents: Principle, Design and drug therapy.

**R14MPC02 MEDICINAL CHEMISTRY**

**PRACTICAL** **100 Hours**

1. Preparation of some Drugs or its intermediates.
2. Determination of partition coefficient and $\pi$ values.
3. Preparation of some heterocyclic nucleus.
4. Study of crystal behavior of synthesized compounds.
5. Techniques for developing chromatograms of synthesized compounds.
6. Determination of physic chemical parameters using free downloadable software's for medicinal important compounds.

7. Characterization of synthesized compounds by various techniques *viz* such as UV, IR and $^{1}H$ NMR.
8. Any other exercise to substantiate theory.

**TEXT BOOKS**

1. Text Book of Organic Medicinal and Pharmaceutical Chemistry, by Wilson and Griswold's wolters kluwer. 8th Edition India.2011
2. Medicinal Chemistry by Ashutoshkar, New Age International (P) Ltd., 2nd Ediiton, 2000.
3. Principles of Medicinal Chemistry by Kadam Vols. 1 & 2, Nirali prakash, 2003.

**REFERENCE BOOKS**

1. Wolff, "Burger's Medicinal Chemistry and Drug Discovery", Vols. 1-4, 6th edn, New York,(USA) Wiley-Interscience, 2003
2. Organic Chemistry by I.L.Finar Vol. I & II, Pearson education. India 6th Edition, 2002
3. Introduction to the Principles of Medicinal Chemistry by Smith, H.J. and Williams, H, John Wright & Sons, Bristol, 1983.
4. Principles of Medicinal Chemistry by Foye, W.O., Lemke, T.L. and Williams, D.A B.I. Waverly Pvt. Ltd., New Delhi, India 1995.
5. Orgnaic Chemistry of Drugs Synthesis by Daniel Lednicer, LesterA. Mitscher, Vol. 1-6, John Wiley and Sons, 1997.

**R14MPC03 PHYTOPHARMACY**

**THEORY 75 Hours**

**UNIT I: GENERAL METHODS (7 Hours)**

Methods of extraction, Methods of separation – Paper chromatography. Thin layer chromatography, Gas chromatography, High Performance Liquid chromatography, Methods of Identification – UV, IR, NMR and Mass, Qualitative tests for Natural products viz., Carbohydrates, Amino acids, Vitamins, Flavanoids and Steroids

**UNIT II: ALKALOIDS (8 Hours)**

Definition, Classification, Extraction, General properties, General methods for determining structure, Structural elucidation of Nicotine, Atropine, Papaverine, Morphine, Reserpine.

**UNIT III: TERPENOIDS (8 Hours)**

Introduction, General properties, Isolation, Isoprene Rule, Classification, General methods for determining the structure of Terpenoids, Wagner-Meerwin and Nametkin rearrangement. Structural elucidation of Citral, $\alpha$- Terpineol, Zingiberene and Abietic acid.

**UNIT IV: ANTIBIOTICS (7 Hours)**

Introduction, Classification, Isolation, Properties and Chemistry of Penicillin, Cephalosporins, Tetracycline, Nocardins and Monobactams, Clavulanic acid analogue, Carbapenams.

**UNIT V: STEROIDS & HORMONE (7 Hours)**

Steroids: Introduction, Nomenclature, Stereochemistry of Steroids. Sex Hormones: Androgens, Oestrogens, Progesterone, Artificial hormones and Adrenal cortex hormones & their derivatives. Plant Hormones: Auxins, Gibberellins and Cytokinins

**UNIT – VI: (8 Hours)**

Cardiac glycosides: Introduction, Classification and detailed chemistry of Digitalis, Strophanthus, Squil and Toad poisons. Blood Glucose Regulators: Introduction, Diabetes mellitus, Insulin preparation, Human insulin, storage and release of insulin.

**UNIT – VII** **(8 Hours)**

Flavones and Flavonoids : Introduction, Isolation, General Properties of Flavones, Structural Elucidation of Flavones, Flavanol, Quercetin, Inter relationship between Flavone, Isoflavone, Flavanol and Xanthone. Active Constituents (with structure) of crude drug likes Momordica charantia, Allum sativum, marmelos, Coccinia indica, Gymnema sylvestre, Trigonella Aegle – graeceum used in antidiabetic therapy in Indian System of Medicine.

**UNIT – VIII:** **(8 Hours)**

Vitamins: Introduction, Classification and structural elucidation of Vitamin A, Thiamine, Riboflavine, Folic acid, Pyridoxine and Ascorbic acid.

Screening and Review of Literature for the following activities. Analgesic, Antipyretic, Anti inflammatory, Anti-microbial, Antidiabetic, Hepatoprotective.

**UNIT – IX:** **(7 Hours)**

Nucleic acids: Introduction, Classification, Isolation, Composition and Constituents of nucleic acids, Sequence of DNA and RNA. Proteins: Introduction, Primary, Secondary and Tertiary structure of protein, Biosynthesis of Amino acids and peptides, Structural features of Oxytocin.

**UNIT -X: PURINES** **(7 Hours)**

Introduction, Classification, Biological importance. Chemistry of Uric acid, Xanthine, Caffeine, Theophylline and Theobromine and its inter-relationships, Structural elucidationof Uric acid and Caffeine.

**R14MPC03** **PHYTOPHARMACY**

**PRACTICAL** **100 Hours**

1. Isolation of natural product compounds from various plant sources.
2. Determination of Rf value of Amino acids using paper chromatography
3. Determination of R value of Mixture of Amino acids using paper chromatography.
4. TLC of some alkaloids
5. Estimation of elements and functional group of organic compounds
6. Some typical degradation reaction to be carried out on selected plant constitutents.
7. Assay of some important natural products.

**TEXT BOOKS:**

1. Pharmacognosy by Brady and Tyler. 8th edition lee and febiger Philadelphia 1970.
2. Clark's Isolation and Identification of Drugs by A.C.Mottal
3. Phytochemical methods, "A Guide to modern techniques of plant analysis" by J.B.
   Harbone, 3rd Edition, Springer (India) Pvt. Lt. 1998.

**REFERENCE BOOKS:**

1. Organic Chemistry by I.L.Finar Vol. I & II, Pearson education. India 6th Edition, 2002
2. Wolff (ed), "Burger's Medicinal Chemistry and Drug Discovery", Vol. 1-4 5th edn, New York, Wiley-Interscience, 1995.
3. Alkaloid Chemical and Biological perspective by S.William Pelletier Royal Society of Chemistry, perggamon (USA), 1983.
4. Pharmacognosy by Trease and Evans, 14th edition,
   Saunders Elsevier, India 2000
5. Indian Pharmacopoeia,
   1996.
6. British Pharmacopoeia 2001.
7. Burger's Medicinal Chemistry and Drugs Discovery" Vols.1-6, 6th Edition, John Wiley & Sons, Inc. New Jersey 2007.
8. Clarke's Analysis of Drugs and Poisons by Anthony.C. Moffat, 3rd Edition, Pharmaceutical Press 2004.

**SRM COLLEGE OF PHARMACY**
**SRM UNIVERSITY**
**Branch – IV: PHARMACEUTICS**

**FIRST YEAR**

| S.No | Subject Code | Name of the Subject |
|---|---|---|
| 1 | R14MPA04 | Modern Analytical Techniques |
| 2 | R14MPP01 | Biopharmaceutics and Pharmacokinetics |
| 3 | R14MPP02 | Advanced Drug Delivery System |
| 4 | R14MPP03 | Pharmaceutical Dosage Forms |

**SECOND YEAR**

| S.No | Subject Code | Name of the Subject |
|---|---|---|
| 1 | R14MPP 21 | Thesis |

## FIRST YEAR

### R14MPP01 BIOPHARMACEUTICS AND PHARMACOKINETICS

(Common Paper for Branches: Pharmaceutics & Pharmacy Practice)

**THEORY** **75 Hours**

**UNIT –I: ABSORPTION AND DISTRIBUTION (9 hours)**

Drug absorption and disposition, structure and properties of membrane composition - membrane potential - mechanism of drug transport, factors affecting absorption. Methods of determining absorption : *Invitro* and *Invivo* methods, Distribution - barriers of distribution - blood brain barrier - placental - volume of distribution - Protein binding.

**UNIT- II: METABOLISM AND EXCRETION (8 hours)**

Biotransformation - Endoplasmic recticulum and microsomal system - types of bio-transformation, Excretion - renal, biliary, faecal and alveolar. Clearance concept, organ clearance-extraction ratio - total clearance - renal clearance - hepatic clearance and elimination - other non renal clearances.

**UNIT -III: ONE COMPARTMENT MODELS (9 hours)**

Definitions, Basic considerations – Pharmacokinetics model - objective - zero order and first order processes–open one compartment model - intravenous and extravascular administration - pharmacokinetic parameters ( using blood level data and urinary excretion data) - rate constants- Ke, Ka (using Wagner-Nelson method, method of residuals), half life, Volume of distribution, AUC and other important pharmacokinetic parameters use of semi logarithmic plot.

**UNIT -IV: TWO COMPARTMENT MODEL AND MULTIPLE DOSING (6 hours)**

Intravascular and extravascular administration-pharmacokinetic parameter- use of Loo Reiglemann method and method of residuals. Multiple dosing- One compartment and two compartment models; Repetitive IV dosing, IV infusion, repetitive extravascular dosing. Continuous constant IV rate infusion, combination of IV injection and IV infusion - steady state concentration-Equations and calculations involved. Intravascular and extravascular administration-pharmacokinetic parameters.

**UNIT- V: NON-COMPARTMENT (8 hours)**

Non-compartmental methods – Area under first moment curve (AUMC) – drug clearance – apparent volume of distribution – mean residence time (MRT) and

significance Concept of clearance – Organ clearance – Total clearance – Renal clearance.

**UNIT -VI: NON-LINEAR PHARMACOKINETICS (6 hours)**

Concepts of Non-linear Pharmacokinetics – Causes and factors of non-linearity, testing of non linearity, Michaelis-Menton equation and its importance in non-linearity. Estimation of pharmacokinetic parameters.

**UNIT -VII: CLINICAL PHARMACOKINETICS (7 hours)**

Application of Pharmacokinetics principles in clinical situation - individualization of drug dosage regimen - therapeutic drug monitoring - design of dosage regimen. Calculation of loading and maintenance dose –with respect to IV and oral route. Dose adjustments in renal and hepatic impairment.

**UNIT -VIII: PHARMACOKINETIC VARIABILITY (8 hours)**

Pharmacokinetic variability - body weight, sex, obesity, age - Drug metabolism - plasma protein binding - renal excretion in new-born and children, sex, pregnancy and genetic factors – polymorphic acetylation and oxidation - Drug interaction.

**UNIT -IX: BIOAVAILABILITY AND BIOEQUIVALENCE (7 hours)**

Factors affecting bioavailability, measurement of bioavailability and bioequivalence - Pharmacokinetic and pharmacodynamic methods –– *Invitro Invivo* correlation (IVIVC) models –Design and protocol of bioequivalence studies as ,Schedule Y and GCP guidelines related to bioequivalence studies.

**UNIT -X: CLINICAL TRIALS AND THERAPEUTIC DRUG MONITORING (7 hours)**

Clinical trials - introduction - experimental designs - patient inclusion and exclusion criteria

protected preparation - analysis of data.Therapeutic drug monitoring- Hypothesis of individualization and optimization of drug therapy. Dosage prediction of digoxin, gentamicin and anticonvulsants.

**R14MPP01 BIOPHARMACEUTICS AND PHARMACOKINETICS PRACTICAL 100 Hours**

1. Improvement of dissolution characteristics of slightly soluble drugs by some methods.
2. Comparison of dissolution studies of two different marketed products.
3. Influence of polymorphism on solubility and dissolution.
4. Protein binding studies of highly protein bound drug and poorly protein bound

drug.

5. Extent of plasma-protein binding studies on the same drug (i.e. highly and poorly protein bound drug) at different concentrations.
6. Bioavailability studies of some commonly used drugs.
7. Calculation of bioavailability from the urinary excretion data for two drugs.
8. Calculation of Ka, Ke, t1/2, Cmax.
9. Calculation of AUC and bioequivalence from the given data for two drugs.
10. *Invitro* absorption studies-everted sac method.
11. Calculation of Doses - Loading and Maintenance doses.
12. Assessment of Kinetic, Parameters for oral administration one compartment model (Method of residuals).
13. Assessment of kinetic Parameters for IV bolus administration two compartment model, (Method of residuals)
14. Determination of Pharmacokinetic parameters for given plasma drug concentration (Cp) Vs Time data of a drug after oral administration.
15. Permeability studies using cell lines like CaCo -2 cells.

**TEXT BOOKS:**


1. D M Brahmankar and Sunil B Jaiswal, Biopharmaceutics and Pharmacokinetics - A treatise, 2nd Edn,Vallabh Prakashan Pitampura, Delhi.
2. Malcolm Rowland and Thomas N Tozer. Clinical Pharmacokinetics, Concept and Applications, Lea Febiger, 3rd Edn, Philadelphia 2002.
3. Robert E Notari, Biopharmaceutics and Clinical pharmacokinetics – An Introduction, 4th Edn, Marcel Dekker inc, New York and Basel, 1987.
4. Leon Shargel, Susanna Wu-pong, Andrew Yu and Yu AB, Applied Biopharmaceutics and Pharmcokinetics and Pharmacokinetics, 6th Edn, Appleton and Lange, Norwalk, CT, 1993.


**REFERENCE BOOKS:**


1. Milo Gibaldi, Donald Perrier, Pharmacokinetics, 2nd Edn, Marcel Dekker, inc.2006.
2. Milo Gibaldi and Laurie Prescott, Handbook of clinical Pharmacokinetics, ADIS Health Science Press, 1984.
3. James Swarbrick, Biopharmaceutics, Lea and Febiger, Philadelphia.
4. Abdou H M, Dissolution, Bioavailability and Bioequivalence; Mack Publishing Company, Pennsylvania, 1989.
5. James Swarbrick James, C Boylan, Encyclopedia Of Pharmaceutical Technology, vol 13, Marcel Dekker inc, New York, 1986.
6. Lippincott Williams and Willkins, Remington: The Science and Practice of

Pharmacy, 22nd Edn, Vol.I & II, Philadelphia 2000.
7. Gibaldi, Biopharmaceutics and Clinical Pharmacokinetics, 4th Edn, Lea and Febiger, Philadelphia 2005.
8. Wagner J G, Biopharmaceutics and Relevant Pharmacokinetics, 1st Edn, Drug Intelligence Publications, Washington D.C.1971.
9. Ritschel, Wolfgang A, Kearns Gregory L, Handbook of Basic Pharmacokinetics including clinical applications, Amer Pharmaceutical Assn (1999).
10. T Loftsson, Essential Pharmacokinetics, Academic Press, 1st Edn, (April 2015).
11. V.Venkateswarlu, Biopharmaceutics and Pharmacokinetics, Pharmamed Press 2010.

**R14MPP02 ADVANCED DRUG DELIVERY SYSTEM**

**THEORY 75 Hours**

**UNIT -I: SUSTAINED RELEASE DRUG DELIVERY SYSTEMS (8 hours)**

Introduction: rationale of SRDDS; advantages and disadvantages of SRDDS; factors influencing the design and performances of SRDDS; physicochemical properties of a drug suitable for SRDDS. Selected routes of drug administration of SRDDS: a) Parenteral, b)Oral, c) Buccal/Sublingual, d)Rectal, e)Nasal, f)Pulmonary, g)Vaginal, h) Intrauterine, i) Transdermal, j) Ocular, in-vitro evaluation .

**UNIT- II: POLYMERS (7hours)**

Introduction-classification-solution formation (principles and techniques) mechanism of biodegradation-chemical and biochemical degradation of polymers; - biodegradable and natural polymers-application of polymers in controlled drug delivery systems.

**UNIT -III: PRODRUGS AND MICROENCAPSULATION (8 hours)**

Prodrug concept - types - approaches - applications. Microencapsulation techniques - advantages and disadvantages - evaluations and applications.

**UNIT -IV: ORAL CONTROLLED RELEASE SYSTEMS (8 hours)**

Dissolution controlled-diffusion controlled-membrane permeation controlled-gel diffusion controlled-osmotic pressure controlled, pH controlled, ion exchange controlled systems. Introduction, classification, rate - programmed drug delivery systems, activation - moduled drug delivery systems, feedback - regulated drug delivery systems, in vitro and in vivo evaluation of controlled release drug delivery products.

**UNIT -V: GASTRO RETENTIVE DRUG DELIVERY SYSTEMS (7 hours)**

Introduction - advantages and disadvantages - approaches - floating drug delivery systems altered density systems - mucoadhesive systems-colon specific drug delivery systems: anatomy of colon-approaches-in-vitro evaluation of such systems.

**UNIT -VI: TRANSDERMAL DRUG DELIVERY SYSTEM (7 hours)**

Structure of skin - principles of skin permeation, factors affecting percutaneous absorption of drugs, sorption promoters, absorption enhancement by energy input – iontophoresis, sonophoresis and electroporation, pharmacokinetics of skin

permeation, in vitro evaluation – permeation enhancers – development and evaluation of transdermal devices.

**UNIT -VII: TRANSMUCOSAL DRUG DELIVERY SYSTEMS (8 hours)**
Buccal drug delivery-structure of oral mucosa-transmucosal permeability -in-vitro evaluation - buccal strips-nasal drug delivery-anatomy of nasal cavity - applications of nasal drug delivery systems - pulmonary drug delivery systems.

**UNIT -VIII: OCULAR DRUG DELIVERY SYSTEMS (7 hours)**
Absorption and disposition in eyes-methods to prolong ocular drug residence - ocular biodegradable polymers-ophthalmic inserts formulation and evaluation.

**UNIT- IX: PARENTERAL CONTROLLED DRUG DELIVERY SYSTEMS (7 hours)**
Injectable controlled release formulations, development of injectable controlled - release formulations:implants - inserts osmotically controlled systems - different devices and applications

**UNIT -X: TARGETED DRUG DELIVERY SYSTEMS (8 hours)**
Liposomes-microspheres-magnetic microspheres-cell carriers-resealed erythrocytes-monoclonal antibodies in drug delivery

**R14MPP02 ADVANCED DRUG DELIVERY SYSTEM**
**PRACTICAL 100 Hours**

1. *In-vitro* Dissolution test on a sustained release tablets of Diclofenac Sodium.
2. *In-vitro* Dissolution test on enteric coated tablets/pellets filled capsules.
3. Preparation and evaluation of sustained release matrix tablets.
    a. Ibuprofen.
    b. Nimesulide.
4. Preparation and evaluation of floating tablets of Ibuprofen.
5. Preparation and evaluation of fast dissolving tablets Paracetamol.
6. Preparation of Ocular drug delivery system.
7. Preparation and evaluation of Transdermal patches
    a. Diclofenac sodium
    b. Nimusulide
8. Preparation of albumin micro spheres of Diclofenac sodium.
9. Preparation of ferrous sulphate micro spheres.
10. Preparation of Colon specific drug delivery system.
11. Formulation of Mucoadhesive drug delivery system.

**TEXT BOOKS:**


1. Chein Y.W, Novel Drug Delivery System, 2nd Ed, Marcel Dekker, inc., New York 1992.
2. P. Vyas and R. K. Khar, Controlled Drug Delivery: Concepts and Advances. Ed.2 Vyas (S.P) Vallabh Prakashan, New Delhi 2012.
3. Robinson J.R. and Lee V.H. Controlled Drug Delivery system - Fundamentals and Applications 2nd Ed. Marcel dekker inc. New york 1995.
4. Donald L.Wise , Hand Book of Pharmaceutical Controlled Release Technology, Edn 1 Marcel Dekker, Inc, NewYork 2000.
5. Bandyopadh, Novel Drug Delivery System, Everest Publishing House Pune 2008.
6. Ijcoma F.Uchegbu, Andreas G. Schatztein, Polymers in Drug Delivery ,Taylor And Francis, Finland 2006.


**REFERENCE BOOKS:**


1. Banker G.S. and Rhodes C.T, Modern Pharmaceutics, 3rd Edn. Marcel Dekker inc,New York 1995.
2. Lippincott Williams & Willkins, Remington: The Science and Practice of Pharmacy 21th Edn, Vol.1 & 2, Philadelphia 2000.
3. Tyle p, Drug Delivery Devices, Fundamentals and Applications, Edn 2. Marcel Dekker, inc New York 1988.
4. N. K. Jain, Controlled and Novel Drug Delivery, CBS Publishers and Distributors, 1st edn, New Delhi 2001.
5. Joseph R. Robinson, Vincent H. L. Lee, Controlled Drug Delivery: Fundamentals And applications, edn 2nd, Informa Health Care 2009.
6. Encyclopedia of Pharmaceutical Technology, James Swarbrick, James C.Boylan, Edn 2nd, Vol – 1, 2 &3, Marcel Dekker, Inc NewYork 2002.
7. Raptael M. Otterbrite , Sung Wan Lin, Polymeric Drugs and Drug Delivery Systems.

**R14MPP03 PHARMACEUTICAL DOSAGE FORMS**
**THEORY 75 Hours**

**UNIT- I: PREFORMULATION STUDIES (7 hours)**
Introduction- characterization of new drug entity -organoleptic properties-purity-particle size-shape- crystal properties-polymorphism-partition coefficient, drug solubility, compatibility and stability studies. Incompatibilities- encountered in multi-component formulations-rationale of drug combinations. Biopharmaceutical classification system (BCS) and techniques to improve the solubility of class II and IV and permeability of class III and IV.

**UNIT -II: TABLETS, CAPSULES (10 hours)**
Compaction of powders-physics of tablet compression-effect of particle size – moisture content-lubricant on strength of tablets. Classification-formulation, manufacturing and evaluation of tablets-problems in manufacture and methods to rectify-quality control test. Capsules advantages and disadvantages-formulation and manufacturing of empty capsules-filling machines quality control tests. Soft gelatin capsules - formulation, manufacture and evaluation. Dissolution- different techniques and applications.

**UNIT -III: SCALE-UP AND MANUFACTURING (8 hours)**
Pilot-plant- scale-up techniques in manufacturing solids, liquids and semi-solids. Applications of scale-up principles. Identification of scale dependent and scale independent factors. Process analytical techniques (PAT) and continuous manufacturing.

**UNIT- IV: PACKAGING (7 hours)**
Packaging materials-desirable features-selection and evaluation-container and closures-container and product interaction-Pharmacopoeial specifications-tests and standards of packaging materials.

**UNIT-V: QUALITY ASSURANCE MANAGEMENT (7hours)**
Concept of GMP and cGMP-Schedule-M-Drugs and cosmetics Act-Quality audits-standard operating procedures-Documentation related to product development-Quality control - quality control documents complaints and recall records-retention of records.

**UNIT -VI: STERILE PRODUCTS** (**7 hours)**

Sterilization method - advantages and disadvantages-sterility testing-layout of manufacturing plant of parenteral products-formulation and manufacture of sterile products-quality control tests.

**UNIT –VII: STABILITY TESTING AND ICH GUIDELINES (7 hours**)

Stability testing of pharmaceutical products-physico-chemical factors affecting stability of drugs-degradation pathways-determination of shelf-life-overages. ICH guidelines-Overview on ICH guidelines from Q1-Q11.

**UNIT –VIII: PROCESS VALIDATION (7 hours)**

Introduction of validation - Process validation of solid dosage forms - liquid dosage forms - sterile dosage forms - raw materials - water system - cleaning process.

**UNIT -IX: QUALITY BY DESIGN AND OPTIMIZATION TECHNIQUES (7 hours)**

Quality by design concepts- QTTP, CQA, CMA, CPP, basic statistics, design of experiments and risk assessments. Optimization techniques using design of experiments (Design expert software).

**UNIT -X: INTELLECTUAL PROPERTY RIGHTS AND REGULATORY AFFAIRS**

**(8 hours)**

Patent system - definitions - intellectual property rights - patent system - pharmaceutical aspects related to GATT, TRIPS, TRIMS, WTO and FDA.

**R14MPP03 PHARMACEUTICAL DOSAGE FORMS PRACTICAL**

**100 Hours**

1. Preformulation study of tablets.
2. Determination of Critical Micellar Concentration of given surfactant.
3. Determination of particles size distribution of drugs by microscopy, sieving, sedimentation techniques.
4. Study of effect of glidants on angle of repose.
5. Study on the effect of various excipients on the dissolution rate of tablets.
6. Formulation and Evaluation oral Suspension
    a. Nimesulide
    b. Ibuprofen
7. Formulation and Evaluation of Tablets
    a. Paracetomol
    b. Diclofenac sodium

8. Filling of Hard gelatin capsules by hand filling and evaluation
    a. Ampicillin
    b. Amoxycillin
9. Preparation and Evaluation of Ampoules
    a. Calcium gluconate
    b. Ascorbic acid.
10. Formulation and Evaluation of Shampoo.
11. Formulation and Evaluation of Toothpaste
12. Formulation and Evaluation of Lipstick.
13. Formulation and Evaluation of Face powder
14. Evaluation of Glass container.
15. Evaluation of primary packaging materials.
16. Evaluation of secondary packaging materials;
17. Accelerated stability study with respect to temperature.

**TEXT BOOKS:**


1. Aulton M.E., Pharmaceutics - The Science of Dosage Form Design, 3rd (International Student Edn.) Churchill Livingstone, New York, 2007.
2. Liberman H Lachman I, Schwartz J ,Pharmaceutical Dosage Forms Tablets 2nd Edn, Vol.I, II and III, Marcel Dekker, New York 2005.
3. The Science and Practice of Pharmacy,21st Edn Vol.I & II, Lippincott Williams and Wilkins, Philadelphia, P.A. 2006.
4. Lachman L & Liberman H.A., The Theory and Practice of Industrial Pharmacy, 4th Edn., Vergese Publishing House, Mumbai, 2013.
5. Banker G.S. and Rhodes C.T. Modern Pharmaceutics, 4th Edn, Marcel Dekker Inc. New York, 2009.
6. Mahato , Pharmaceutical Dosage Forms and drug delivery, CRC Press 2007.
7. Loyd V Allen Jr , Howard C Ansel, Pharmaceutical Dosage Forms and Drug, Lippincott Williams and Wilkins 2011.


**REFERENCE BOOKS:**


1. Turco S and King R.E., Sterile Dosage Forms, 4th Edn Lea & Febiger, Philadelphia, 1994.
2. S.H.Willing, Good Manufacturing Practices for Pharmaceuticals: A plan for total quality control, 4TH Edn, Marcel Dekker Inc, NewYork 2001.
3. Quality Assurance Guide, Organisation of Pharmaceutical Products of India.
4. P.P.Sharma - How to practice GMPs, Vandhana Publication, Delhi.
5. Rawlins, Bentley's Text Book of Pharmaceutics, Edn 8, Elsevier, 2010.
6. E.J. Bauer, Pharmaceutical Packaging Hand Book, Informa Health Care, 2009.

**SRM COLLEGE OF PHARMACY**
**SRM UNIVERSITY**
**Branch – V: PHARMACOLOGY**

**FIRST YEAR**

| S.No | Subject Code | Name of the Subject |
|---|---|---|
| 1 | R14MPA 04 | Modern Analytical Techniques |
| 2 | R14MPL01 | General Pharmacology |
| 3 | R14MPL02 | Advanced Pharmacology |
| 4 | R14MPL03 | Drug Design and Molecular Modelling |

**SECOND YEAR**

| S.No | Subject Code | Name of the Subject |
|---|---|---|
| 1 | R14MPL 21 | Thesis |

## FIRST YEAR

**R14MPL01 GENERAL PHARMACOLOGY**

**THEORY 75 Hours**

**UNIT -I -PHARMACOKINETICS (10 hours)**

Route of Drug administration, Drug absorption and its mechanism, factors affecting drug absorption. Transport of drug across biological membrane, Plasma protein binding, Tissue storage, Redistribution, Volume of distribution. Bioavailability, Factors affecting Bioavailability, Bioequivalence and Importance of Bioequivalence studies. Phase - I and Phase - II metabolic reactions, Microsomal and Non-Microsomal biotansformation reactions, Enzyme Induction & Inhibition, Factors affecting drug metabolism. Models to study drug metabolism - *Invivo & Invitro* metabolism, First pass metabolism First order and zero order kinetics, Dose effect relationship, drug metabolism in fetus, new born and aged people. Route of Elimination of drugs, Concept of Hepatic and Renal clearance, Biological Half - Life.

**UNIT- II – PHARMACODYNAMICS (8 hours)**

General aspects of Receptor pharmacology, Structural and Functional aspects of Receptors - Drug Antagonism and Synergism, Receptor Classes, Receptor – Effector coupling theories, Signaling mechanism, Drug Action - Types, Receptor regulation, Spare receptors, Secondary messengers, Non-Receptor mediated drug action. Factors modifying Drug Action and Adverse Drug Reaction and its monitoring. Drug interaction - Introduction, Pharmacological basis of Drug Interaction, Drug -Drug interaction and Drug - Food interaction, Interactions - outside the body, at the site of absorption, during distribution, during metabolism, during excretion.

**UNIT -III NEUROHUMORAL TRANSMISSION (4 hours)**

General aspects and steps involved in Neurohumoral transmisison. Neurohumoral transmission in Autonomic nervous system Neurohumoral transmission in Central nervous system Non-Adrenergic and Non cholinergic transmission (NANC).

**UNIT -IV CLINICAL PHARMACOLOGY (5 hours)**

Introduction, Principles of Clinical Pharmacology, Fundamentals and Phases of Clinical trials, Designing of Clinical trials according to GCP, ICH & ICMR

guidelines, Therapeutic drug Monitoring with specific examples, Pharmacovigilance, Pharmacoeconomics.

**UNIT -V SYSTEMIC PHARMACOLOGY - I (10 hours)**

**Central Nervous System Drugs :** Sedative & Hypnotics,Anti seizure Drugs, Drugs used to treat anxiety, depression, psychosis, epilepsy, mania, Neurodegenerative disease. Opioid Analgesics & Antagonists, Non Steroidal Anti-Inflammatory Drugs.

**Cardio Vascular Drugs :** Drugs used in Congestive Heart Failure, Hypertension, Angina Pectoris, Myocardial Infarction & Cardiac Arrhythmia, Diuretics.

**Respiratory system acting drugs:** Drugs used in the treatment of Bronchiectasis, Status asthmaticus, COPD.

**UNIT -VI - SYSTEMIC PHARMACOLOGY – II (12 hours)**

**Autonomic Nervous System:** Parasympathomimetics and lytics, Sympathomimetics and lytics, Agents acting at Neuromuscular Junction and ganglia.

**Drugs acting on Gastro Intestinal Tract :** Drugs in gastro oesophageal reflux disease, Crohn's disease, Pancreatitis, liver cirrhosis, Antidiarrhoeal drugs and drugs for irritable bowel syndrome.

**Chemotherapy**-General aspects of Chemotherapy, Beta-lactam antibiotics. Tetracyclines & Chloramphenicol, Aminoglycosides, Fluoroquinolones, Chemotherapy of Tuberculosis, Leprosy, Antineoplastic agents.

**UNIT -VII –PATHOPHYSIOLOGY ( 8 hours)**

Principles involved in cell injury and adaptation, causes and pathogenesis of cell injury, intercellular alterations in lipids, proteins and carbohydrates, cellular atrophy and hypertrophy.

**UNIT VIII - IMMUNOPHARMACOLOGY AND ENDOCRINOLOGY (10 hours)**

Immunopharmacology - Cell and biochemical mediators involved in allergy, immunomodulation and inflammation. Classification of hypersensitivity reactions and diseases involved. Therapeutic agents for allergy, asthma, COPD and other immunological diseases with emphasis on immunomodulators. Hormones & Hormonal Antagonists - Pituitary Hormones, Pancreatic hormones, Anti-Diabetics Drugs, Adrenocortico steroids, Thyroid and Anti - Thyroid drugs, Parathyroid hormones, Hormonal contraceptives.

**UNIT -IX –TOXICOLOGY (5 hours)**

Principles of Toxicology, Abnormal actions of drugs such as Tolerance, Addiction, Dependence, Habituation, Allergy, Hypersensitivity, and Tachyphylaxis, Toxicokinetics.Heavy Metal Poisoning, Non-Metallic Environmental Toxicants, House hold poisons, Xenobiotics. Management of Poisoning and Regulatory Toxicology.

**UNIT-X – FREE RADICAL & CHRONOPHARMACOLOGY (5 hours)**

Generation of Free Radicals Role of Free Radicals in Etiopathology of various Diseases (Neurodegenerative disease, cardiac disease and diabetes) Protective activity of certain Important Antioxidants. Chronopharmacology

**R14MPL01 GENERAL PHARMACOLOGY**

**PRACTICAL 100 Hours**

1. Experiment to study different routes of dug administration.
2. Experiments for studying the effect of Acetycholine on suitable isolated tissue preparation.
3. Experiments for studying the effect of Acetycholine in the presence of agonist and antagonist on suitable isolated tissue preparation.
4. Experiments for studying the cumulative effect of Acetylcholine on suitable isolated tissue preparation.
5. Experiments on Enzyme induction and inhibition.
6. Experiment to study the Local Anesthetic effect of drug
7. Experiments for studying the effect of Histamine, 5 - Hydroxytryptamine, Oxytocin on suitable isolated tissue preparation.
8. Estimation of PA2 values of various antagonists under suitable isolated tissue preparation.
9. Experiments for studying the effect of various drugs on isolated heart preparations using various animal models under normal hypo dynamic condition.
10. Experiments to study the drug activity on oesophageal motility.
11. Experiments to study the activity of diuretic drugs.
12. General method to study the effect of antimicrobial drugs.

**TEXT BOOKS**


1. Experimental pharmacology – Vogels.
2. Gibaldi and Prescott, Handbook of clinical Pharmacokinetics, 4th edition, New York: ADIS Health Science Press, (1983)
3. Goldstein, Amaow and Kalmain, Principles of Drug Actions, Hoeber Medical Division, Harper & Row (1969)
4. Sujatha Devi (J), Experimental Pharmacology For Undergraduates & Postgraduates, JPB; First edition (2013)
5. Pharmacology and Therapeutics - K.D. Tripathi, 7th edition, Jaypee Brothers
6. Pharmacology and Therapeutics – Satoskar, 19th edition, Popular Prakashan P.ltd.
7. General Pharmacology – H L Sharma and K K Sharma, 2nd edition, Paras Medical Publishers, New Delhi
8. Gaur (S) And Srivastava (B), Experimental Pharmacology, New Central Book Agency (P) Ltd.
9. Rang and Dale - Pharmacology. 7th Edition, churuchill livingstone, Elsevier Ltd.
10. Turner (P), Volans (G.N), Recent Advances In Clinical Pharmacology And Toxicology. 1st Edition
11. Goyal (R.K), Practicals In Pharmacology 6th edition.
12. Atkinson (A.J), Et-Al, Principles Of Clinical Pharmacology 3rd edition, Academic Press; 3 edition (October 2, 2012)
13. Foreman (J.C), Edrs., Et-Al, Textbook Of Receptor Pharmacology 3rd edition, T Johansen & AJ Gibb (London:CRC Press)
14. Katzung (B.G), Basic And Clinical Pharmacology 11th edition, McGraw Hill Education; 12th edition (1 February 2012)


**REFERENCE BOOKS**


1. Rataboli (P.V), Clinical Pharmacology And Rational Therapeutics 2nd edition, Ane Books India (2011)
2. Bennett (P.N), Brown (M.J), Clinical Pharmacology 11th edition, Churchill Livingstone
3. Grahame-Smith (D.G), Aronson (J.K), Oxford Text Book Of Clinical Pharmacology And Drug Therapy 2nd edition, Oxford University Press; 2nd Revised edition(1 November 1992)
4. Lemmer (B), Edr, Chronopharmacology: Cellular And Biochemical Interactions, Marcel Dekker, New York
5. Edmunds (M.W), Introduction to Clinical Pharmacology , Mosby; 7 th edition (February 9, 2012)

6. Tomlin (M), Edr, Pharmacology & Pharmacokinetics : A Basic Reader, Springer-Verlag London
7. Pharmacology - An introduction to Drugs - Michael C. Gerald.
8. Handbook of Experimental Pharmacology - S.K.Kulkarni, 4th edition, Vallabh Prakash
9. Textbook of Invitro practical pharmacology - Ian Kitchen, Year Book Medical Pub (June 1984)
10. Pharmacological experiments on intact preparation - Churchill Livingstone.
11. Principles of Toxicology – Seth, CRC Press
12. Pharmacotherapy – Dipiro, McGraw Hill Education; 9 th edition (1 February 2014)
13. The Pharmacological basis of therapeutics–Goodman and Gilman's, McGraw-Hill Education / Medical; 12 th edition (January 10, 2011)
14. Clinical trials and tribulations - Allen E. Cato, Dekker, 1988
15. Drug Interactions - Ivan H. Stockley, Pharmaceutical Press; 7th Revised edition edition (13 October 2005)

**R14MPL02 ADVANCED PHARMACOLOGY**
**THEORY 75 Hours**

**UNIT -I - INTRODUCTION TO LABORATORY ANIMALS AND ETHICAL REQUIREMENTS (7 hours)**

Handling, breeding and care of laboratory animals. Blood collection techniques, Drug administration techniques, Anaesthesia and euthanasia of experimental animals. Concept of transgenic animals, knockout mice, nude mice, SHAY Rats and other genetically prone animal models. Importance and need of animal models in pharmacology, advantages and disadvantages. Knowledge of CPCSEA Proforma for performing animal studies.

**UNIT- II - PRECLINICAL EVALUATION OF DRUGS *(INVIVO, INVITRO, EXVIVO,INSITU, INSILICO* METHODS) (9 hours)**

Organization of a preclinical evaluation programme and safety assessment tests (BLIND SCREENING) ANS Pharmacology: Screening of Neuromuscular blockers, skeletal muscle relaxants,cholinergics and Anticholinergics, Adrenergics, Anti adrenergics, Local anaesthetics. Analgesics, Anti-inflammatory agents, Anti pyretics. Drugs for Antihyperlipidemic, Anti-obesity, Anti-diabetics and Hepatoprotectives.

**UNIT -III - TOXICOLOGICAL SCREENING ( 8 hours)**

Physico-chemical, Biochemical and genetic basis of toxicity principles of toxicokinetics and toxicodynamics - Mutagenicity, Carcinogenicity, Teratogenicity. Behavioural toxicity, Inhalational Toxicity, Cellular, Sub cellular toxicity, Dermatotoxicity, Photo-toxicity. Acute, Subacute and chronic toxicity studies, Range finding test.

**UNIT- IV –PRECLINICAL EVALUATION OF DRUGS – I (10 hours)**

**CNS Pharmacology :** Screening of psychopharmacological agents, CNS stimulants and depressants, Antiepileptics models for status epilepticus, antiparkinsonian drugs, analeptics, sedative and hypnotics, nootropics, Alzheimer's, Multiple sclerosis.

**Respiratory Pharmacology :** Screening of Bronchodilators, Anti-asthmatics, Mast cell stabilizers, Anti-allergics, Muco-actives.

**Gastrointestinal Pharmacology:**Anti-ulcer, Anti secretory, Antiemetics,Antidiarrhoeals, laxatives.

**UNIT -V - PRECLINICAL EVALUATION OF DRUGS - II (8 hours)**

**CVS Pharmacology :** Screening of cardiotonics, Anti-arrhythmic,Antihypertensives, Vasodilators and Diuretics.

**UNIT -VI - PRECLINICAL EVALUATION OF DRUGS -III (10 hours)**

Immunomodulators Antidiabetic, anticancer, hepatoprotevtive, Wound healing, Atherosclerosis, Obesity, Antihyperlipidemics, Anti-thyroid, antifibrinolytics, haematinics screening.

**UNIT -VII – IMMUNOASSAY (7 hours)**

Principles of immunoassay, optimization, homogenous and heterogeneous systems, immunoassay reagents, labelled and unlabelled ligands, buffer separation techniques.

Precision, accuracy, evaluation and protocols for immunoassay. Radio Immuno Assays of insulin, digoxin.

**UNIT –VII REPRODUCTIVE PHARMACOLOGY (5 hours)**

Screening models of Fertility Agents, Anti Fertility Agents, Aphrodisiacs.

**UNIT -IX - REGULATORY PHARMACOLOGY (6 hours)**

Protocol preparation for safety assessment of new Drugs. Knowledge of planning, performing, analyzing, Document & monitoring of toxicities.

Guidelines and regulatory agencies to conduct the toxicity studies (OECD, FDA, WHO, ICH, FDA guidelines).

**UNIT -X- ADVANCES IN DRUG DEVELOPMENT PROCESS (5 hours)**

Proteonomics, G-proteins, Combinational chemistry Cell lines, Patch clamp techniques, Computational Biology - Blotting techniques and Array Technology

**R14MPL02 ADVANCED PHARMACOLOGY**

**PRACTICAL 100 Hours**

1. Handling of Experimental animals, Standard Feeding and Drug administration techniques and Intra-cerebro ventricular injeciton collection of Blood samples.
2. Techniques of Euthanasia, Anesthesia, Canulation of Veins, arteries and trachea working of Physiographs, Recording BP and ECG, Preparation of Vaginal smears and Examination, Normal Biochemical reference values in Experimental animals.
3. Bioassays of Histamine / Ach-using guinea pig ileum and Rat colon preparations.

4. Bioassay of oxytocin using Rat uterus.
5. Bioassay of serotonin using Rat fundus strip.
6. Oral and Skin acute toxicity tests.
7. Screening of Antiulcer, Anti Inflammatory, Psychotropic, Cardio tonics, Antiarrhythmic, Diuretics, Vasodilators, Antimicrobials, Invitro-Antioxidants.
8. Neuropharmacological screening.
9. Bioassay of various agonists using Three and Four point bio-assay methods.
10. Estimation of Drug concentrations in Body fluids.
11. Estimation of Antioxidants and Lipid peroxidation level using tissue homogenates.
12. *Invitro* methods in pharmacological screening.
13. Experiments for studying the effect of various drugs on tracheal and anococcygeous muscle.

**TEXT BOOKS**


1. Burn J.H. Practical pharmacology, Blackwell scientific, Oxford, Blackwell Scientific Publications [1952], London
2. Nodine siegler, Animal and clinical pharmacological techniques in drug evaluation, Chicago, Yearbook Medical Publishers [©1964].
3. Pharmacological experiment on intact preparations by Churchill Livingston.
4. The UFAW Handbook on the care and management of laboratory animals by UFAW.
5. CRC Handbok of toxicology by Derelanko and Holinger, CRC Press; 3rd edition (March 7, 2014)
6. Jaju B.P. Pharmacology, A Practical Exercise Book, Jaypee Bros. Medical Pub., 1989
7. Toxicology - Frank Lu.
8. Ghosh M.N.Fundamental of Experimental Pharmacology, 5th edition, Scientific book agency. Calcutta.
9. Lawrence, D.R. and Bacharch, A.L. Evaluation of Drug Activities,Pharmacometrics, Academic Press, *Academic Press* Inc. Ltd., Berkeley
10. Kulkarni, S.K. Handbook of Experimental Pharmacology, 4th edition, Vallabh Prakashan, Delhi


**REFERENCE BOOKS**


1. Drug discovery and evaluation, pharmacological assays by H. Gerhard Vogel.
2. Experimental Pharmacology, Sharma & Sharma, Paras Medical Publishers, New Delhi

3. Donald J. Ecobichon, The Basis of Toxicity Testing, CRC Press; 2nd edition (August 11, 1997)
4. Shayne. C.Gad, Safety Pharmacology in Pharmaceutical Development – Approval and Post Marketing Surveillance, CRC Press; 2nd edition (10 May 2012)
5. John .H. Duffus, Douglas M Templeton and Monica Nordberg, Concepts in Toxicology, RCS Publishing
6. John. M. Frazier, Invitro Toxicity Testing – Application and Safety Evaluation, CRC Press.
7. Kale, Practical Pharmacology and Toxicology, Nirali Prakashan, 07-Jul-2008
8. Turner, Screening Method in Pharmacology, Vol – I & II, Academic Press, 1965
9. Daniel. P. Stiter, Abba. I. Terr, Medical Immunology, Appleton & Lange; 9th edition (April 9, 1997)
10. Bioassay Techniques for Drug Development by Atta-ur-Rahman, Iqbal choudhary and William Thomsen, CRC Press; 1st edition (September 14, 2001)

**Journals**

a. Indian Journal of Pharmacology.
b. Indian Journal of Physiology and Pharmacology.
c. Indian Journal of Experimental Biology.
d. Pharmacological research

**R14MPL03 DRUG DESIGN AND MOLECULAR MODELLING**
**THEORY 75 Hours**

**UNIT -I - DRUG DISCOVERY AND DEVELOPMENT - I (8 Hours)**
Lead discovery, Lead modification, de-Nova drug design Structural modification (Homological, chain branching, structural chain transformation, Bio-isosterism)
***Pre-Clinical drug development***-Techniques in drug development including High Throughput Screening, Orphan drugs, Pharmacogenomics.

**UNIT- II - DRUG DISCOVERY AND DEVELOPMENT – II (6 Hours)**
Drug development Programme - Pharmacokinetic and Pharmacodynamic approaches. Guidelines to introduce a new drug in US and INDIA (IND, NDA & FDA requirements and schedule Y and its amendments) Bio ethics committee (Role & Function.)

**UNIT -III - PHYSIOCHEMICAL PROPERTIES IN RELATION TO BIOLOGICAL ACTION AND DRUG DESIGN (7 Hours)**
Complex of events between drug administration and drug action.
Partition - coefficient
Solubility
Isosterism and Steric behavior
Ionisation and Hydrogen bonding
Chelation and Surface action.
Oxidation - reduction potential
Rational drug design
Pro-drug concept

**UNIT -IV - DRUG RECEPTOR THEORY (7 Hours)**
Concept of receptors , Theory and Forces involved in drug receptor interaction. Receptor polymorphism and dimerization and its significance in drug design. Structure of receptors - Ligand gated ion channel, G-protein coupled receptors, tyrosine kinase enzyme coupled receptors and steroid receptors.

**UNIT -V - MOLECULAR MODELING (8 Hours)**

Computer aided drug design - Principles and Application

QSAR-Fundamentals of QSAR (Objectives, expression of biological activity) QSAR parameters related to chemical structure, correlative methods and analysis of results.

**UNIT -VI - CHIRAL PHARMACOLOGY (6 Hours)**

Influence of chirality's on the pharmacodynamic, pharmacokinetic and toxicological profile of chiral drugs.Influence of geometric isomerism on drugs with suitable examples. VSFDA (CDER) regulatory affairs on racemic drugs.

**UNIT -VII - STRUCTURAL ACTIVITY RELATIONSHIP (9 Hours)**

Structural activity relationship of Phenothiazines, Opioids, Barbiturates, Benzodiazepines, Sulfonamides, Anti-neoplastic agents, Cardiac glycosides, Broad spectrum antibiotics, Beta lactam antibiotics, aminoglycosides.

**UNIT -VIII - IMMUNO PHARMACOLOGY (9 Hours)**

General features of immune system, Cells of immune system, T & B lymphocytes,macrophages and cytokines. Auto immune diseases - primary immuno deficiency and Acquired immuno deficiency diseases. Immunological tolerance, Immunological deficiency syndrome.

**UNIT -IX - MOLECULAR PHARMACOLOGY (7 Hours)**

Introduction to cell structure & function Cell signaling, Organization of signal transduction pathway and bio sensors. Protein structure prediction and molecular modeling. Applications of Molecular Pharmacology.

**UNIT-X - GENE THERAPY AND RECOMBINANT DNA TECHNOLOGY (8 Hours)**

Gene expression, regulation and gene mapping, Recombinant DNA technology: Principles, process and its application.Gene therapy Gene transfer technology, Disease targets for gene therapy, Clinical application of gene therapy.

**R14MPL03 DRUG DESIGN AND MOLECULAR MODELING**

**PRACTICAL 100 Hours**

1. Practical related to physiochemical properties in relation to biological action.
   a. Partition coefficient
   b. Pka
   c. Solubility

d. Bioisosterism
e. Pro-drug concept

2. Protein separation and isolation using gel electrophoresis.
3. Estimation of Protein and nucleic acids.
4. DNA isolation, Sequencing and PCR Techniques.
5. Screening of Synthesized Phenytoin, Diazepam, Chlorpromazine.
6. RNA isolation from Yeast.
7. Cell culture preparation and maintenance: Chick embryo fibroblast, lymphocyte culture.

**TEXT BOOKS**


1. Principles of Medicinal Chemistry by William Foye.
2. Vogel's text book of practical organic chemistry y Arthur I. Vogel (ELBS andLongman) Fifth Edition.
3. A guide to chemical basis of drug design by Alfred Burger (John Wiley &Sons) Third Edition.
4. Introduction to the principles of drug design by John Smith and Haywel Williams (Wright PSG) Third Edition.
5. Burgers Medicinal chemistry - The basis of Medicinal Chemistry by Manfred E. Wolff Part - 1 (John Wiley & Sons) Fifth Edition.
6. Computer assisted Drug Design by Edward. C. Olson (American Chemical Society – ACS symposium series 112).
7. Wilson & Giswold's Text book of Organic, Medicinal and Pharmaceutical Chemistry.
8. Goodman and Gilman's - The Pharmacological Basis of Therapeutics - 8$^{th}$edition (Pergamon Press) Mc Graw Hill Publishers.
9. Medicinal Chemistry - The role of organic chemistry in drug research by S.M. Roberts and B.J. Price.


**REFERENCE BOOKS**


1. Current protocols in molecular biology by Frederick. M. Ausubel. (Academicedition)
2. Human molecular genetics by Tomstracham & Andrw P. Read.
3. Bioinformatics: Genes, proteins & Computers by Christine Orengo.
4. The Cell - A molecular approach, Geoffrey M. Cooper.
5. Genetherapy, Therapeutic mechanism and strategies by Nancy Smyth, Templeton.
6. Biopharmaceuticals: Biochemistry & Biotechnology by Gary Walsh 1998 Wiley and Sons (1998).

7. Recombinant DNA, second edition by James D.Watson, Michael Gilman,JanWitowski, Mark Zoller, Scientific American Books, Newyork 1996 Fifth Edition.

**SRM COLLEGE OF PHARMACY**
**SRM UNIVERSITY**
**BRANCH - VI - PHARMACOGNOSY**

| S.No | Subject Code | Name of the Subject |
|---|---|---|
| 1 | R14MPA03 | Advanced Pharmaceutical Analytical Techniques |
| 2 | R14MPG01 | Advanced Pharmacognosy & Phytochemistry |
| 3 | R14MPG02 | Medicinal Plant Cultivation & Biotechnology |
| 4 | R14MPG03 | Herbal Drug Design |

**SECOND YEAR**

| S.No | Subject Code | Name of the Subject |
|---|---|---|
| 1 | R14MPG 21 | Thesis |

## FIRST YEAR

## R14MPG 01 - ADVANCED PHARMACOGNOSY & PHYTOCHEMISTRY

**THEORY** **75 Hours**

**UNIT –I: PLANTS AS SOURCE OF MEDICINE (8 hours)**

Survey of Plant derived modern drugs and their sources. Drug development from Plants – a Flowchart. Principles and procedures involved in collection; identification, phytochemical screening of medicinal plants of research interest. Good Practices fot Medicinal plant and herbal raw material identification and authentication. Sources of information on medicinal plants.

**UNIT -II: MARINE PHARMACOGNOSY (7 hours)**

Present status and future perspectives, introduction, chemistry and therapeutic applications of marine toxins and marine biomedicines falling under the class of Anti-cancer, Cardio active, Anti-microbial and Anti-inflammatory compounds.

**UNIT –III: AGRO PRODUCTS (7 hours)**

Industrial production and application of agro products of economically significant such as Corn oil, Soya bean, Spirulina, Papain, Pectin, Starch, Citric acid and Casein.

**UNIT –IV: NATURAL PRODUCTS (7 hours)**

Study of herbal products like natural sweeteners, natural colorants, taste enhancers, Pharmaceutical exicipients, food supplements and herbal pesticides. Study of Information retrieval methods of natural products and Herbal data base.

**UNIT -V: ADULTERATION & ITS DETECTION (8 hours)**

Introduction to adulteration and different methods of drug adulteration. Detection of drug adulteration by microscopical, physical, chemical and biological methods. Contamination of plant drugs, classification of contaminants and Need for their detection. Detection and estimation of Arsenic and Heavy Metals – Cadmium and Lead. Determination of Pesticide residues. Microbial contamination, microbial load/counts etc.

**UNIT -VI: BIOGENESIS & BIOSYNTHESIS (9 hours)**

Biosynthesis of tropane and indole alkaloids, steroidal glycosides and terpenoids. Microbiological conversion, aberrant synthesis in higher plants. Investigation of biogenetic pathways in plants - Tracer technique, isolated organs, tissue and cells, grafting techniques and mutant strains.

**UNIT -VII: CHEMISTRY OF ALKALOIDS, GLYCOSIDES, TERPERNOIDS (8 hours)**

Chemistry of following classes of secondary metabolites, their biogenesis and methods of extraction and estimation of Alkaloids - Atropine, Quinine, Caffeine, Hypericin, Gingkobiloba and Forskolin. Glycosides - Cardiac glycosides like Digoxin, Scillarin A. Ouabain and Peruvoside. Terpenoids - Isoprene rules, Menthol, Camphor, Artemisinin and Eugenol.

**UNIT -VIII: TRADITIONAL SYSTEM OF MEDICINE (7 Hours)**

Review of Traditional System of Medicine (TSM). Role of Natural products in Alternative System of Medicines like Ayurveda, Siddha, Unani, Chinse, Homeopathy and Tribal Medicine. Study of different dosage forms and methods of preparation in TSM. Standardization of Ayurvedic, Siddha Dosage forms and associated problems.

**UNIT -IX: NATURAL PRODUCTS AS LEAD COMPOUNDS FOR DRUG DISCOVERY (7 Hours)**

Introduction to natural products as leads to design new drugs for CNS, Anticancer, Antidiabetic and Cardiovascular drugs. Reverse pharmacology process for drug development from natural leads. High throughoutput screening (HTS), Ethnomedicine approach for drug discovery, Role of Complementary Alternative Medical (CAM) systems for search of new drugs.

**UNIT -X: PHARMACOVIGILANCE FOR HERBAL DRUGS (7 Hours)**

- WHO Guidelines on safety monitoring of herbal medicines in pharmacovigilance systems. Safety monitoring of herbal medicines.
- Interaction of herbs with other herbs, food and allopathic drugs (Herb- drug Interaction, Herb-Herb Interaction, Herb- Food Interaction) with suitable examples.

**R14MPG01 ADVANCED PHARMACOGNOSY & PHYTOCHEMISTRY**

**PRACTICAL** **100 Hours**

1. Fieldwork of medicinal and aromatic plants.
2. Exercises involving Quantitative microscopy
3. Evaluation of crude drugs by physical and chemical methods.
4. Isolation and identification of agro products mentioned in the theory.
5. Preparation and standardization of any Ayurvedic and Siddha dosage forms.
6. Preliminary phytochemical screening for natural compounds mentioned in theory.
7. Quantitative estimation of phytoconstituents mentioned in theory.
8. Isolation and estimation of phytoconstituents mentioned in theory.
9. Identification of phytoconstitutents by chromatographic and special analysis.
10. Analysis of fixed oils.

**TEXT BOOKS**


1. G.E. Trease, W.C. Evans, Pharmacognosy, ELBS.
2. Varro E.Tyler, Lynn. R.Brady, James E.Robbers, Pharmacognosy.
3. T.E. Wallis, Text Book of Pharmacognosy, CBS Pub. Delhi.
4. Ashutoshkar, Pharmacognosy and Pharmacobiotechnology
5. Khandelwal, K.R, Practical Pharmacognosy, 7th Ed., Nirali Prakashan, Pune2000.


**REFERENCE BOOKS**


1. Frank B.Salisburry, Cleon. W.Ross, Plant Physiology,f, CBS Pub. Delhi.
2. Dean F. Martin & George Padilla, Marine Pharmacognosy.
3. A Hand Book of Common remedies in Siddha system of medicine - CCRIMH.
4. Baidyanth, Book of Ayurvedic Knowledge.
5. Pharmacopeial standards for Ayurvedic formulations - CCRAS, Delhi.
6. British Herbal Pharmacopoeia.
7. Swami Sada Shiva Tirtha, The Ayurveda Encyclopedia.
8. H.Panda, Ayurvedic Medicines
9. K.N.Sengupta, The Ayurvedic system of medicine
10. Steven B.Kayne, Homoeopathic Pharmacy.
11. Dr.S.K.Jain, Dictionary of Indian Folk medicine and Ethnobotony.
12. Iyengar M.A and Naik S.G.K. Anatomy of crude drugs.
13. Brain K.R. and Turner T.D, The Practical evaluation of Phytopharmaceuticals.
14. P.K.Lala, Elements of Chromatography
15. Varpoorte Swendson, Chromatography of Alkaloids.

16. Egon Stahl, Drug Analysis by Chromatography.
17. Paul J. Schewer, Chemistry of Marine Natual Products.
18. P. Pushpangadam, Ulf Nyman, V George, Glimpses of Indian Ethano Pharmacology Tropical Botanic Garden & Research Institute, 1995.
19. General Guidelines for Methodologies on Research and Evaluation of Traditional Medicine WHO/EDM/TRM/2000.
20. WHO guidelines on safety monitoring of herbal medicines in pharmacovigilance systems WHO 2004
21. Kaviraj nagendra and Nath Sengupta, The Ayurvedic system of medicine, 2 volumes, 1998

**R14MPG02 MEDICINAL PLANT CULTIVATION & BIOTECHNOLOGY**
**THEORY 75 Hours**

**UNIT -I: MEDICINAL BOTANY & SYSTEMIC CLASSIFICATION (7 Hours)**
A taxonomic approach to the study of medicinal plants. Plant cytology, plant histology and plant organology. Morphological, microscopical and cytomorphological examination of crude drugs. Classification of crude drugs with special reference to Serotaxonomy and Chemotaxonomy. A brief study on chemotaxonomy of alkaloids, glycosides and terpenoids.

**UNIT -II: PRODUCTION AND MANAGEMENT OF COMMERCIALLY USEFUL PLANTS (9 Hours)**
Commercial scale cultivation of medicinal and aromatic plants; General understanding of good agricultural and collection practices (GACP). National and international trade in medicinal and aromatic plants. Export potential of phytopharmaceuticals. Disease management of medicinal and aromatic plants. Weed and pest control. Study of natural pesticides.Profile for commercial cultivation technology and post harvest care of following medicinal and aromatic plants - Ashwagandha, Guggul, Senna, Isapgol, Piper, Lemon Grass, Amla, Ginkgo. In situ conservation of medicinal plants. Mutation breeding.

**UNIT -III: METABOLITE PROFILING (8 Hours)**
Rational and concepts of metabolite profiling and fingerprinting in assessing the efficacy, quality of phytomedicines and in general to plant drug analysis. Role of Molecular markers in herbal drug quality assurance and associated pitfalls. A brief review of modern extraction methods and sample-preparation techniques for the standardization and analysis of herbal medicinal products.

**UNIT -IV: MEDICINAL & AROMATIC PLANTS (7 Hours)**
Cultivation methods developed in India for the following plants of economical significance: a) Medicinal plants: Senna, Digitalis, Vinca, Opium, Taxus, Aloe, Aswagandha, and Coleus. b) Aromatic plants : Cultivation and production of Patchuoli oil, Geranium, Rosemary, Lavender, Eucalyptus, Artemisia, Cardamom, Mentha Export potential of medicinal and aromatic plants in India.

**UNIT -V: HYPHENATED ANALYTICAL TECHNOLOGIES (6 Hours)**
Application of various analytical tools (including Hyphenated analytical technologies [HAT]) in metabolite fingerprinting and profiling of plant drugs and its derivative products in assessing their quality and efficacy. Some typical case

studies (at least 3) from scientific publications illustrating the current and modern approaches to plant drug quality assurance.

**UNIT- VI : PLANT TISSUE CULTURE (7 Hours)**

Introduciton, history and development, laboratory requirements, nutrients, culture media, general techniques, types of culture and its application in herbal drug development. Production of some important secondary metabolites like Ajmalicine, Shikonin, Artemisin, Cinnamic acids, Flavonoids, Anthraquinones.

**UNIT -VII: ENZYME BIOTECHNOLOGY (7 Hours)**

Introduction, general methods of extraction and purification of enzymes, Applications of enzyme in pharmaceutical industry, a detailed study on plant cell immobilization, a special note on papain, bromelin, streptrokinase, uronase and pectin.

**UNIT -VIII: FERMENTATION TECHNOLOGY (8 Hours)**

Introduction, design of fermentors, its operation and functions, yeast and its use, production of single cell proteins, production of some important compounds by fermentation technology like penicillin, dextrose from starch & cellulose substrates, vitamin B12 and ergot alkaloids.

**UNIT -IX: PLANT GENOMICS (9 Hours)**

Introduction to genetics and molecular biology - Structural, molecular and chromosomal organization of cell, cytogenetics, cell cycle, mitosis and meiosis, genetic code and gene mutation, genetic engineering, genetic mapping and molecular maps of plant genomes.

**Gene Transfer :** Using vectors of Agro bacterium, Ti, Ri, Co-integrative and intermediate plasmid, DNA mediated gene transfer techniques, electroporation, micro projection, micro and macro injection, liposomes, ultrasonication and localization of transferred gene in genetically modified plants. Transgenic Plants: Applications of transgenic plant: Resistance to insects, herbicides, fungus and virus and physiological stress.

**UNIT -X: MOLECULAR BIOLOGY (7 Hours)**

Definition and a brief description of some common terms used in biotechnology, Different types of DNA and RNA, Replication, Transcription and Translation, immunology and immunomodulators. Plant Bio-diversity and Bioinformatics in plant drug discovery. Microbiological assays of antibiotics and vitamins. Genetically engineered edible vaccines, gene splitting and antibiotics in biotechnology.

**R14MPG02 MEDICINAL PLANT CULTIVATION & BIOTECHNOLOGY**

**PRACTICAL 100 Hours**

1. Selection, authentication and herbarium preparation of medicinal and aromatic plants. Morphological, microscopical and powder analysis of crude drugs mentioned in theory.
2. Microscopical study using Microtome and preparation of permanent slides.
3. Exercises involving determination of leaf constants and linear measurements of crude drugs mentioned in theory.
4. Extraction and isolation of Volatile oil mentioned in the theory.
5. Technique for cell immobilization of bioactive compound.
6. Isolation and identification of plant enzyme.
7. Determination of enzyme activities.
8. Screening of antibacterial activity of any plant extract.
9. Isolation of DNA from plant materials.

**TEXT BOOKS**


1. G.E. Trease, W.C. Evans Pharmacognosy, ELBS.
2. Varro E.Tyler, Lynn, R.Brady, James E.Robbers Pharmacognosy.
3. T.E. Wallis, Text Book of Pharmacognosy, CBS Pub. Delhi.
4. J.M. Walker & E.D. Gingo, Molecular biology & Biotechnology
5. S.B. Primrose, Modern Biotechnology.
6. L.E.Casida, Industrial Microbiology
7. S.P.Vyas & V.K.Dixit, Pharmaceutical Biotechnology.
8. P.K.Gupta Elements of Biotechnology.


**REFERENCE BOOKS**


1. Kirthikar, Basu, Indian Medicinal Plants
2. K.M.Nadkarni, Indian Materia Medica.
3. Guenther. E , The Essential Oils.
4. Proceeding of the seminar on scope of Aromatic plants and Processing Industries.
5. Tom Garland & Catharine Barr, Toxic plants and other Natural toxicants.
6. Dr.S.K.Jain, Dictionary of Indian Folk medicine and Ethnobotony.
7. Smith P.M. The Chemotoxonomy of plants.
8. Shriramu and Farooqi, Cultivation of medicinal plants
9. Atal C.K. and Kapoor BM., Cultivation and utilization of medicinal plants.
10. David R.Murray Advanced methods in plant breeding & biotechnology.
11. Atal & Kapoor, Cultivation & Utilization of aromatics plants, RPOL, Jammu.
12. R.A.Dixon, Plant cell culture - A practical approach.

13. M.M.Yeomen, Plant cell culture technology.
14. S.S.Bhojwani, M.K.Razdan, Plant tissue culture - Theory & Practice.
15. Jeffery. W. Pollard & John, M.Walker Plant cell & tissue culture.
16. E.J.Vandamme Biotechnology of Industrial antibiotics.
17. Lehninger Principles of Biotechnology.
18. Alan too good, Propagating plants.
19. David. F.A. George, M.M Essentials of Molecular biology.
20. Jack G.C Biotechnology theory and technique.
21. Purohit & Matherr Biotechnology.
22. A.G.Salle, Introduction to microbiology.
23. Trehan, Introduction to biotechnology.

**R14MPG03 HERBAL DRUG DESIGN**
**THEORY 75 Hours**

**UNIT -I: HERBAL DRUG ANALYSIS (8 Hours)**
Introduction and general methods of herbal drug analysis involving methods of extraction, isolation, separation, identification and analysis of natural products with special importance to Super critical fluid extraction, chromatographic techniques, micro wave assisted extraction, electrophoresis. A brief study on finger printing techniques.

**UNIT -II: HERBAL FORMULATION (7 Hours)**
Types of Modern herbal dosage forms and Dosage forms in traditional systems of medicine such as Ayurveda and Siddha. Methods involved in monoherbal and polyherbal formulations with their merits and demerits. Excipients used in herbal formulation. Formulation of powders, granules, capsules, tablets; liquid formulations, gels, creams, ointments and other dosage forms. Evaluation of different dosage forms. Stability studies of herbal formulations.

**UNIT -III: STABILITY STUDIES (8 Hours)**
Stability studies on herbal formulations. Study of biological markers and its role in quality control of herbal products. Current status of regulatory affairs for herbal formulations and ICH guildelines.

**UNIT- IV: PHYTO PHARMACEUTICALS (7 Hours)**
1. Nutraceuticals : Health foods, food supplements, dietary fibers, anti-oxidants, prebiotics and probiotics.
2. Cosmeceuticals: Introduction, current trend and future perspectives of cosmeceuticals. Different cosmeceutical agents of natural origin and their role in cosmetics.

**UNIT- V: HERBAL BASED INDUSTRIES**
**(8 Hours)**
Introduction to Herbal drug industries and its role in the nation's economy. Introduction and a brief study on herbal based industries such as OTC consisting of plant extracts and galenicals, Essential oil industry, Phytopharmaceuticals, Natural health product industry, Cosemeceutical industry.

**UNIT -VI: BOTANICALS (8 Hours)**
Scale up process, industrial production and standardisation of plant extracts of Tinospora cordifolia, Curcuma longa, Solanum xanthocarpum, Ocimum sanctum,

Adathoda vasica, Embelica officinalis, Centella asiatica, Melia azadirachta, Withania somnifera, Bosewellia serrata.

**UNIT -VII: PHYTOTHERAPY (8 Hours)**

General methods of screening of natural products for the following biological activities: (a) In vivo studies : Anti-infammatory activity, Hypoglycemic, Diuretic, Cardiac activity, Anti-neoplastic activity, Psychopharmacological activity, Anti-fertility, Anti-ulcer activity, Hepato protective activity, Immuno modulatory activity. (b) In vitro studies; Anti-oxidant activity, Anti-viral Activity, Anti-cancer, Anti-inflammatory actiivty. (c) Clinical trials and guidelines for Investigational New Drug Application (IND)

**UNIT –VIII: TOXICOLOGY (7 Hours)**

Introduction and methods of toxicological evaluation of herbal drugs. A study on toxicity of herbal drugs and extracts with reference to various guidelines such as ICH, OECD and WHO guidelines. A brief study on herbal interactions (herb-herb, herb-drug and herb-food interactions). Acute, sub acute, and chronic toxicological studies and calculation of median lethal dosage for drugs.

**UNIT -IX: HERBAL DRUG STANDARDIZATION (7 Hours)**

Factors affecting Variability and Quality in herbal raw material and the need for standardization. Problems and prospects of standardization of Herbal Medicinal Products. Physical, chemical, Spectral and Chromatographic Parameters in Standardization. Role of Bio-markers in herbal drug standardization.

**UNIT -X: HERBAL COSMETICS (7 Hours)**

Raw materials of herbal origin and their uses in cosmetics: oil, waxes, gums, colors, perfumes, protective agents, bleaching agents, preservatives, antioxidants and other ancillary agents. Formulation and standardization of herbal cosmetics like skin care preparations, deodorants, anti perspirants and hair care preparations. Regulatory aspects of safety as per BIS standards (Bureau of Indian Standards)

**R14MPG03 HERBAL DRUG DESIGN**

**PRACTICAL 100 Hours**

1. Exercises involving comparison microwave assisted extraction with conventional methods.
2. Exercises involving application of chromatographic and spectral analysis of herbal drugs.

3. Preparation and standardization of herbal formulation.
4. Screening of anti-oxidants by DPPH and nitric acid methods.
5. Visit to herbal based industry.
6. Preparation and standardization of botanicals mentioned in the theory.
7. Experiments for biological screening of herbal drugs by in vivo methods.
8. Preparation and standardization of any herbal cosmetics mentioned in theory.
9. Experiments for biological screening of herbal drugs by in vitro methods.
10. Exercises involving analysis of raw materials and finished products.

**TEXT BOOKS**


1. G.E. Trease, W.C.Evans, Pharmacognosy, ELBS.
2. T.E.Wallis, Text Book of Pharmacognosy, CBS Pub., Delhi.
3. P.K.Lala, Elements of chromatography
4. V.K.Srivastava, K.Kishore, Introduction to chromatography theory & Practicals.
5. A.C.Mottal, Clerk's Isolation & Identification of drugs.
6. S.S.Agarwal & M.Paridhavi, Herbal Drug Technology.
7. Kalia, Industrial Pharmacognosy.
8. R.Ikan, A Laboratory guide to Organic Natural Products.


**REFERENCE BOOKS**


1. J.B.Harbone, Phytochemical methods.
2. J.C.P.Schwartz, Physical methods in organic chemistry.
3. Peter.B.Kanfman, Natural products from plants.
4. Wallis, Billot.M, Perfumery technology.
5. Pulok. K. Mukerjee Quality control of Herbal Drugs.
6. R.D. Chaudhari, Herbal Drug Industry, Eastern Publishers, New Delhi 1996.
7. H.Panda, Herbal cosmetics Hand Book.
8. V.Raipal, Standardization of Botanicals Vol. I & II.
9. Seth. V.K, Selected Topics in Experimental Pharmacology.
10. B.N.Dhavan R.C.Srimal, CDRI, Lucknow, The use of Pharmacological techniques for the evaluation of natural products by.
11. Janne Barnes, linda, A.Anderson, Herbal medicines.
12. M.Williamson, David T.Okpako, J.Evans Selection, Preparation and pharmacological evaluation of plant material.
13. P.K.Gupta, D.K. Salunkhe, Modern Toxicology, Vol.II .
14. Gupta, Drug Screening Methods
15. WHO guide lines - Quality control of Crude drugs.
16. Various journals related to spices, perfumes, food and nutrition

**SRM COLLEGE OF PHARMACY**
**SRM UNIVERSITY**
**Branch – VII: PHARMACY PRACTICE**

**FIRST YEAR**

| S.No | Subject Code | Name of the Subject |
|---|---|---|
| 1 | R14MPA04 | Modern Analytical Techniques |
| 2 | R14MPP01 | Biopharmaceutics and Pharmacokinetics |
| 3 | R14MPR01 | Pharmacotherapeutics |
| 4 | R14MPR02 | Hospital, Clinical, Community Pharmacy and Clinical Research |

**SECOND YEAR**

| S.No | Subject Code | Name of the Subject |
|---|---|---|
| 1 | R14MPR 21 | Thesis |

## FIRST YEAR

**R14MPR01 PHARMACOTHERAPEUTICS**

**THEORY 75 Hours**

Pathophysiology and Pharmacotherapy of diseases associated with following systems/ diseases.

**UNIT -I: CARDIOVASCULAR SYSTEM (8 hours)**

Hypertension, Congestive cardiac failure, Ischemic Heart disease, Myocardial infarction, Arrhythmias, Hyperlipedemia..

**UNIT -II: RESPIRATORY SYSTEM & GASTROINTESTINAL SYSTEM (9 hours)**

Asthma, Chronic obstructive airway disease, Drug induced pulmonary diseases Peptic ulcer diseases, inflammatory bowel diseases, Hepatitis, GERD

**UNIT -III: SKIN AND SEXUALLY TRANSMITTED AND INFECTIOUS DISEASE (12 hours)**

Psoriasis, Eczema and scabies, Syphillis and Gonorrhea, Meningitis, Respiratory tract infections Pneumonia, Bacterial endocarditis, Septicaemia, Otitis media, Urinary tract infections, Tuberculosis, Leprosy, HIV and opportunistic infections

**UNIT -IV: HEMATOLOGICAL DISEASES & RENAL SYSTEM (8 hours)**

Anemia, Deep vein thrombosis, Acute renal failure, chronic renal failure, renal dialysis and transplantation

**UNIT -V: RHEUMATIC DISEASES & PAIN MANAGEMENT (7 hours)**

Rheumatoid arthritis, Osteoarthritis, Gout, Systemic lupus erythematosus, Pain pathways, Analgesics and NSAIDs, Neuralgias

**UNIT -VI: GENERAL PRESCRIBING GUIDELINES (5 hours)**

Pediatrics patients, Geriatric patients, Pregnancy and breast feeding

**UNIT -VII: ENDOCRINE SYSTEM (7 hours)**

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

**UNIT -VIII: NERVOUS SYSTEM & PSYCHIATRIC DISORDERS (11 hours)**

Epilepsy, Parkinson's disease, Stroke and transient ischemic attacks, Headache, Schizophrenia, Depression, Anxiety & Sleep disorders, OCD

**UNIT -IX: ONCOLOGY (5 hours)**

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

**UNIT -X: OPHTHALMOLOGY (3 hours)**

Glaucoma, Eye infections, Cataract

**R14MPR01 PHARMACOTHERAPEUTICS PRACTICAL 100 Hours**

The students are required to be posted to various clinical wards for their exposure with therapeutic management and other clinical aspects. They are expected to have experience and do a tutorial as well as case presentation in the following clinical conditions. The list of clinical cases presented should include follow-up of the clinical cases mentioned below from the day of admission till discharge and presented in the SOAP (Subjective, Objective, Assessment and Plan)/ FARM formats. The cases may be selected from the following diseases:

Hypertension, Heart failure, Myocardial infarction, coronary heart disease, asthma, Chronic obstructive pulmonary disease, anemia, Osteoarthritis, Rheumatoid arthritis, Gout, Peptic ulcer, GERD, Hyperlipidemia, Neuralgia, psoriasis, Hepatitis, Diabetes type 1, diabetes type 2, Hypothyroidism, hyperthyroidism, acute renal failure, chronic renal failure, schizophrenia, depression, anxiety, epilepsy, Parkinson's disease, stroke, Infectious disease (any 5)

Identify and report drug interactions/ Adverse drug reactions/ Medications errors from patients medication records in the prescribed format.

**REFERENCES:**


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.

## R14MPR02 HOSPITAL, CLINICAL, COMMUNITY PHARMACY AND CLINICAL RESEARCH

**THEORY** **75 Hours**

**UNIT -I: HOSPITAL PHARMACY** **(6 hours)**

The role of hospital pharmacy department, Roles & responsibilities of hospital pharmacist. Hospital Formulary system.

**UNIT -II: HOSPITAL PHARMACY SERVICES** **(9 hours)**

Inventory control Definition, various methods of Inventory Control ABC, VED, EOQ, Lead time, safety stock. Evaluation of hospital pharmacy services

**UNIT – III:** **(9 hours)**

Drug distribution in the hospital i) Individual prescription method ii) Floor stock method iii) Unit dose drug distribution method d) Distribution of Narcotic and other controlled substances, Pharmacy and Therapeutics Committee, infection control committee and research & ethics committee.

**UNIT – IV: CLINICAL PHARMACY** **(8 hours)**

Definitions, development and scope of clinical pharmacy. Introduction to daily activities of a clinical pharmacist

- Pharmaceutical calculations
- Pharmaceutical care
- Ward round participation
- Drug therapy monitoring (medication chart review, clinical review, pharmacist interventions)
- Medication history interview
- Medication errors
- Medication adherence
- Adverse drug reaction reporting and its management
- Drug interactions
- Drug utilization evaluation (DUE) and review (DUR)

**UNIT -V: DRUG & POISON INFORMATION** **(6 hours)**

- Introduction of Drug Information and Drug Information resources
- Systematic approach in answering Drug Information queries
- Critical evaluation of drug information and literature
- Poisons information – organization & information resources
- Rational Drug use ( Definition, Essential Drug concept & Role of pharmacist in rational drug use)

**UNIT -VI: PHARMACOEPIDEMIOLOGY AND PHARMACOECONOMICS (6 hours)**

Definitions and scope, Methods (Sources of data, study design, drug utilization studies, Metaanalysis), Advantages and disadvantages of pharmacoepidemiologyDefinitions and scope, methods of pharmacoeconomic evaluation,

**UNIT -VII: COMMUNITY PHARMACY (6 hours)**

Introduction to the concept of community pharmacy – its activities and professional responsibilities, community pharmacy layout and design, Patient counseling, Over the counter (OTC) sales, code of ethics, community pharmacy licenses, registers and document to be maintained

**NIT -VIII: CLINICAL RESEARCH (9 hours)**

Introduction to Clinical Research
Introduction, Definition and terminology used in clinical trials
Drug development process
Various phases of clinical trial.
Methods of post marketing surveillance
Designing of clinical study documents : Protocol, Informed consent Process

**UNIT -IX: ROLE AND RESPONSIBILITIES OF CLINICAL TRIAL PERSONNEL AS PER ICH GCP (11 hours)**

Sponsor
Investigators
Clinical research associate
Auditors
Contract research coordinators
Regulatory authority

**UNIT- X: ETHICS AND GUIDELINES IN BIOMEDICAL RESEARCH (5 hours)**

Ethical Issues in Biomedical Research – Principles of ethics in biomedical research, Ethical committee (Institutional review board), its constitution and functions

**R14MPR02 HOSPITAL, CLINICAL, COMMUNITY PHARMACY AND CLINICAL RESEARCH**

**PRACTICAL** **100 Hours**

The students are required to be posted in ward rounds, case studies related to laboratory investigations covering the topics dealt in theory class. In addition students are required to perform different services related to the topic mentioned below in the prescribed format.

**Hospital and community pharmacy services:**

Evaluation of pharmacy services
Present drug profiles on new drug
Prepare a model monograph for drug formulary
Various inventory management techniques
Manufacture of parenteral and powder formulation.

**Clinical pharmacy services:**

Answering drug information queries
Patient medical history interview
Patient medication history interview
Patient counseling
Medication order review
Detection and assessment of adverse drug reaction and their documentation.

**REFERENCES**


1. Basic skills in interpreting laboratory data – Scott LT, American Society of Health System Pharmacists, Inc., USA.
2. Practice Standards and Definitions – The Society of Hospital Pharmacists of Australia, 1997.
3. Clinical Pharmacokinetics – Rowland and Tozer, Williams and Wilkins Publication.
4. Biopharmaceutics and Applied Pharmacokinetics – Leon Shargel, Prentice Hall publication.
5. Relevant review articles from recent medical and pharmaceutical literature.


**JOURNALS**


1. Pharmaceutical Journal. Royal Pharmaceutical Society, London.
2. Therapeutic Drug Monitoring.
3. European Journal of Clinical Pharmacology.
4. Indian Journal of Medical Research.

5. Journal of Pharmacy Practice and Research, Society of Hospital Pharmacists of Australia.
6. International Journal of Pharmacy Practice
7. Hospital Pharmacist,
8. Indian Journal of Hospital Pharmacy.

**SRM COLLEGE OF PHARMACY**
**SRM UNIVERSITY**
**Branch – VIII: PHARMACEUTICAL REGULATORY AFFAIRS**

**FIRST YEAR**

| S.No | Subject Code | Name of the Subject |
|---|---|---|
| 1 | R14MPY01 | Pharmaceutical Quality Management |
| 2 | R14MPY02 | Pharmaceutical Regulations in India |
| 3 | R14MPY03 | International Drug Regulatory Affairs – I |
| 4 | R14MPY04 | International Drug Regulatory Affairs – II |

**SECOND YEAR**

| S.No | Subject Code | Name of the Subject |
|---|---|---|
| 1 | R14MPY21 | Thesis |

## FIRST YEAR

**R14MPY01 PHARMACEUTICAL QUALITY MANAGEMENT**
**THEORY 75 Hours**

**UNIT – I: CGMP OF PHARMACEUTICAL MANUFACTURING PROCESS (8 hours)**
Evolution and Principles of cGMP, Schedule-M, WHO-GMP requirements, European Union (EU) and United States Food and Drug Administration (USFDA) guidelines on Pharmaceutical manufacturing.

**UNIT – II: PACKAGING AND LABELING OF DOSAGE FORMS (8 hours)**
Rule 96 of D&C Act 1940, Annex 13 of EU, Packing and labeling requirements of various regulated and nonregulated markets for Solids, Liquid Orals, Parenterals and Semisolids, introduction to data loggers.

**UNIT – III: DOCUMENTATION IN PHARMACEUTICAL INDUSTRY – I (8 hours)**
Exploratory Product Development Brief (EPDB) for Drug substance and Drug product, Product Development Plan (PDP), Product Development Report (PDR), Master Formula Record, Batch Manufacturing Record and its calculations.

**UNIT – IV: DOCUMENTATION IN PHARMACEUTICAL INDUSTRY – II (8 hours)**
Batch Reconciliation, Batch Packaging Records, Print pack specifications, Distribution records, Certificate of Analysis (CoA), Site Master File and Drug Master Files (DMF).

**UNIT – V: VALIDATION (8 hours)**
Types of Validation, Statistical Process Control (SPC), Types of Qualification, Validation master plan (VMP), Analytical Method Validation. Validation of utilities, [Compressed air, steam, water systems, Heat Ventilation and Air conditioning (HVAC)], Cleaning Validation, Validation facilities in Sterile and Non-Sterile area.

**UNIT – VI: QUALITY MANAGEMENT (8 hours)**
Concept of Quality, Total Quality Management, Quality by design, Six Sigma concept, Out of Specifications (OOS), Change control

**UNIT – VI: AUDITS AND RISK MANAGEMENT (7 hours)**
Types of Audits, Auditors, Auditing strategies and preparation of audits, Auditing/inspection of manufacturing facilities by regulatory agencies. Conducting and Handling of audits, Timelines for audits /inspection, Pre approval inspections, Corrective and Preventive action (CAPA), Risk Management.

**UNIT – VIII: HARMONIZATION OF REGULATORY REQUIREMENTS (7 hours )**

The International Conference on Harmonization (ICH) process, ICH guidelines to establish quality, safety and efficacy of drug substances and products. Pharmacopoeias, harmonization of pharmacopoeial standards and stability testing, WHO guidelines.

**UNIT – IX: ISO (6 hours)**

The International Organization for Standardization (ISO) 9000 series of quality systems standards, ISO 14000.

**UNIT – X: (7 hours)**

NABL certification and accreditation procedure, GLP - Scope of GLP, Quality assurance unit, SOP, protocols for conduct of clinical & non clinical testing, control on animal house, report preparation and documentation.

**R14MPY01 PHARMACEUTICAL QUALITY MANAGEMENT PRACTICAL 100 Hours**

Twenty Assignments to be carried out and submitted on the fore mentioned theoretical aspects like

1. Validation of equipments like HPLC, Dissolution, UV spectrophotometer, tablet press
2. Documentation for in process and finished products Quality control tests for Solid, liquid, Semisolid and Sterile preparations.
3. Preparation of SOPs, Analytical reports (Stability and validation)
4. Protocol preparation for documentation of various types of records (BMR, MFR, DR)
5. Labeling comparison between brand, generics and trademark
6. Power point presentation:
    i. Auditing strategies and preparation of audits,
    ii. Auditing/inspection of manufacturing facilities by regulatory agencies.
    iii. Pre approval inspections,
    iv. Corrective and Preventive action (CAPA), Risk Management
    v. NABL certification and accreditation procedure,
    vi. GLP - Scope of GLP, Quality assurance unit,
    vii. SOP,
    viii. protocols for conduct of clinical & non clinical testing,
    ix. control on animal house,

x. report preparation and documentation

**REFERENCE BOOKS**


1. Good Manufacturing Practice Rationale and compliance by John Sharp.
2. Pharmaceutical master validation plan: The ultimate guide to FDA, GMP and GLP Compliance by Syed Imitiaz Haider.
3. Pharmaceutical dosage forms: Parenterals Vol-2, II Edition, by Kenneth EA and Leon Lachman.
4. Packaging and Pharmaceuticals and health care products by H.Lockhart, Frank A. Paine.
5. Establishing a CGMP laboratory audit system- A Practical guide by David M. Bliesner.
6. J.F.Hanlon: Hand book of package engineering: Mac-Grawhill Company.
7. Good manufacturing practices: A plan total quality control: S.H.Wilhing, M.M. Tuckerman, S.Hitchings, Marcel Deckker, Inc.Newyork.
8. Pharmaceutical Process Validation, 3rd Edition, Edited by Robert Nash and Alfred Wachter, Marcel Dekker.
9. Good Manufacturing Practices for Pharmaceuticals: A Plan for Total Quality Control from Manufacturer to Consumer, Sidney J. Willig, Marcel Dekker, 5th Ed.
10. Validation of Pharmaceutical Processes: Sterile Products, Frederick J. Carlton (Ed.) and James Agalloco (Ed.), Marcel Dekker, 2nd Ed.
11. Validation Standard Operating Procedures: A Step by Step Guide for Achieving Compliance in the Pharmaceutical, Medical Device, and Biotech Industries, Syed Imtiaz Haider
12. Pharmaceutical Equipment Validation: The Ultimate Qualification Handbook, Phillip A. Cloud, Interpharm Press.
13. Pharmaceutical Quality Assurance by Manohar A. Potdhar, 2nd edition, Nirali Prakashan.

**R14MPY02 PHARMACEUTICAL REGULATIONS IN INDIA**
**THEORY 75 Hours**

**UNIT – I: (7 hours)**
**Laws and Acts:** An introduction of following laws with regard to drug product design, manufacture and distribution in India (with latest amendments):
a. Drugs and Cosmetics Act 1940 and its rules 1945
b. National Pharmaceutical Pricing Authority (NPPA)

**UNIT – II: (7 hours)**
Intellectual property rights - Indian patent Act and its rules, Law of Copyright and Designs, Law of Trademark and Geographical indications, Patent Procedure in India

**UNIT – III: (7 hours)**
**Guidelines for drug testing in animals**
Animal testing: Rationale for conducting studies, CPCSEA Guidelines for laboratory animal facility.

**UNIT – IV: (8 hours)**
**Guidelines for drug testing in humans**
Human testing: ICMR guidelines (Transfer of human biological material for research commercial purpose, Good clinical laboratory practices, stem cell research and therapy, international collaboration for research, ethical guidelines for human participants), IRB / IEC structure and function, Pharmacovigilancerequirements – ADR Reporting.

**UNIT – V: (9 hours)**
**CDSCO (Central Drug Standard Control Organization):** Organization, Responsibilities, and Registration Procedures for approval of drug products. Approval procedures (clinical trials), timelines for approval, CDSCO guidelines (Approval of Clinical trials, Indian Common Technical Document, Serious Adverse Events Reporting, Indian GCP)

**UNIT – VI: (7 hours)**
**Registration Requirements:** Forms, Clinical Trial Registration, Test License, Commercial Import License, Sale License, Manufacture License, Certificate of Pharmaceutical Product (CoPP)

**UNIT - VII: (7 hours)**

**Submission Regulations:** PSUR, Trial material, registration samples, stability data requirements, license renewal, post approval changes & reporting categories

**UNIT - VIII:** **(8 hours)**

**BA/ BE:** Bioavailability and Bioequivalence Requirements, BCS classification of drugs, Documentation Requirements for Bioequivalence study for export applications, CDSCO Guidelines for Bioavailability and Bioequivalence studies.

**UNIT - IX:** **(7 hours)**

**Regulatory requirements:** For import and product registration of New Drugs, DCGI & RCGM requirements, Generics, Medical Devices, Biologics, Herbals, Cosmetics & Fixed Dose Combinations, Export of drugs, traditional drugs, narcotics etc.

**UNIT – X:** **(8 hours)**

**FSSAI (Food Safety Standards Authority of India):** Introduction, Approval process and registration requirements for nutraceuticals.

**R14MPY02 PHARMACEUTICAL REGULATIONS IN INDIA**

**PRACTICAL** **100 Hours**

to be carried out and submitted on the forementioned theoretical aspects like following and powerpoint presentation

1. Preparation of clinical trial protocol for registering trial in India
2. Registration for conducting BA/ BE studies in India
3. Import of medical devices into India
4. Import of drugs for research and developmental activities
5. Preparation of regulatory dossier as per Indian CTD format
6. Registering for different Intellectual Property Rights in India
7. Registration of a facility for conducting animal studies
8. Preparation of Product Safety Update Report (PSUR) for an approved product
9. GMP Audit Requirements as per CDSCO
10. Preparation and documentation for Indian Patent application

**REFERENCE BOOKS:**


1. Manual of Patent Practice & Procedure, 3rd Edition, by The Patent Office of India.
2. Patent Failure How Judges, Bureaucrats, and Lawyers put innovators at risk by James Bessen and Michael J. Meurer.
3. Principles and Practice of Clinical Trial Medicine by Richard Chin and Bruce Y.Lee.
4. Ethical Guidelines for Biomedical Research on Human Participants by Indian Council of Medical Research New delhi 2006.
5. CPCSEA Guidelines for Laboratory Animal Facility by Committee for the purpose of control and supervision on experiments on animals (CPCSEA).
6. ICH E6 Guideline " Good Clinical Practice" by ICH Harmonised Tripartite.
7. Guidance for Industry on Submission of Clinical Trial Application for Evaluating Safety and Efficacy by CDSCO (Central Drug Standard Control Organisation).
8. Guidance for Industry on Requirement of Chemical & Pharmaceutical Information including Stability Study Data before approval of clinical trials / BE studies by CDSCO.
9. Guidelines for Import and Manufacture of Medical Devices by CDSCO.
10. Guidelines from official website of FSSAI (Food Safety Standards Authority of India).
11. Encyclopedia of Biopharmaceutical Statistics 2nd Edition, Edited by Shein-Chung Chow.
12. Guidelines from official website of CDSCO

**R14MPY03 INTERNATIONAL DRUG REGULATORY AFFAIRS - I**
**THEORY 75 Hours**

**UNIT – I: DRUG PRODUCT DEVELOPMENT (7 hours)**
New Drug Discovery and development, Concept of generics, Generic drug product development, *in vitro* and *in vivo* drug product performance, BA/BE studies and CRO, IB, CMC, Genotoxic impurities.

**UNIT – II: REGULATORY SUBMISSIONS (7 hours)**
Common Technical Document (CTD), eCTD

**UNIT – III: REGULATIONS ON CLINICAL TRIALS - I (7 hours)**
Developing clinical trial protocols, Institutional Review Board/ Independent Ethics committee-formation and working procedures, Informed consent process and procedures, Health Insurance Portability and Accountability Act (HIPAA) - A new requirement to clinical study process, GCP obligations of Investigators, sponsors & Monitors,

**UNIT – IV: REGULATIONS ON CLINICAL TRIALS - II (7 hours)**
Importance of Quality Assurance in clinical trials, Managing and Monitoring clinical trials, European clinical trials (CT) directives- implementation and update., Pharmacovigilance-safety monitoring in clinical trials.

**UNIT – V: REGULATORY REQUIREMENTS FOR VARIOUS MARKETS (7 hours)**
PIC guidelines and mutual recognition system for audits and compliance

**UNIT – VI: (8 hours)**
Organization and structure of FDA. Federal register and CFR, History and evolution of FDC act, Hatch Waxman act, Regulatory Approval Process for IND, NDA, ANDA.

**UNIT – VII: (7 hours)**
Regulatory requirements for Orphan drugs and Combination Products, SUPAC & PMS. Changes to an approved NDA / ANDA.

**UNIT – VIII: EUROPEAN UNION (9 hours)**
Organization of EMA & Marketing Authorization procedures in EU (CP, DCP, MRP, NP). Eudralex directives for human medicines, Variations & extensions, IMPD. Requirements for BA/BE studies, Compliance of European Pharmacopoeia (CEP)/ Certificate of Suitability (CoS).

**UNIT – IX: MEDICAL DEVICES (8 hours)**

Regulatory approval process for Medical Devices and In vitro Diagnostics in US and EU. CE certification, ISO standards for Medical devices and In vitro diagnostics. GHTF/ IMDRF

**UNIT – X: (8 hours)**

Product approval process: For Biologics, Biotechnology products (biosimilars), Herbals, and Nutraceuticals in US & EU.

**R14MPY03 INTERNATIONAL DRUG REGULATORY AFFAIRS - I**

**PRACTICAL 100 Hours**

Twenty Assignments to be carried out and submitted on the aforementioned theoretical aspects like following and power point presentation

1. Preparation of checklist for registration of IND as per ICH CTD format.
2. Preparation of checklist for registration of NDA as per ICH CTD format.
3. Preparation of checklist for registration of ANDA as per ICH CTD format.
4. Case studies on response with scientific rationale to USFDA Warning Letter.
5. Patent challenge / non infringement (Para IV) case studies.
6. Preparation of Periodic Safety Update Report (PSUR).
7. Comparison study of DMF system in US and EU.
8. Preparation of an IMPD for EU submission.
9. Preparation of Clinical Trial Application (CTA) for EU submission.
10. Comparison study of marketing authorization procedures in EU.
11. Checklist for registration of prescription medicines (Category I & II applications) for TGA.
12. Checklist for submission of Category III applications (Post approval changes) for TGA.
13. Preparation of submission checklist for Class I, II and III medical devices.
14. Preparation of submission checklist for registration of OTC products.
15. Preparation of submission checklist for registration of Herbal products.
16. Comparison of Clinical Trial Application Requirements of US, EU and Japan of a dosage form.

**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. F, Wayne L. Pines and Gary H. Slatko.
13. Preparation and Maintenance of the IND Application in eCTD Format By William K.S.
14. Medical Device Development: A Regulatory Overview By Jonathan S. Kahan.
15. Medical Product Regulatory Affairs: Pharmaceuticals, Diagnostics, Medical Devices ByJohn J. Tobin and Gary Walsh.
16. Country Specific Guidelines from official websites.

**R14MPY04 INTERNATIONAL DRUG REGULATORY AFFAIRS - II**
**THEORY 75 Hours**

**UNIT – I: (7 hours)**
Emerging Markets: Regulatory Requirements for generic drug registration, new drugs and post approval requirements in BRICS countries (Brazil, Russia, India, China, South Africa) and Egypt.

**UNIT – II: (8 hours)**
Regulatory pre-requisites related to Marketing authorization requirements for generics in CIS countries (Common Wealth Independent States). i.e. Armenia, Azerbaijan, Belarus, Kazakhstan, Ukraine and Uzbekistan.

**UNIT – III: (7 hours)**
Regulatory pre-requisites for post approval requirements in CIS (Commonwealth Independent States) countries i.e. Armenia, Azerbaijan, Belarus, Kazakhstan, Ukraine and Uzbekistan.

**UNIT – IV:**
**(8 hours)**
Regulatory pre-requisites related to Marketing authorization requirements for generics in GCC (Gulf Cooperation Council) for Arab states i.e Saudi Arabia, Bahrain, Kuwait, Oman, Qatar, UAE and Yemen.

**UNIT – V: (7 hours)**
Regulatory pre-requisites for post approval requirements in GCC (Gulf Cooperation Council) for Arab states i.e Saudi Arabia, Bahrain, Kuwait, Oman, Qatar, UAE and Yemen.

**Unit – VI: (8 hours)**
Regulatory requirements for registration of new drug approval in LATAM Countries i.e. Argentina, Chile, Mexico, Costa Rica, Columbia, Peru.

**UNIT – VII: (7 hours)**
Regulatory Requirements for generics and post approval requirements in LATAM countries i.e. Argentina, Chile, Mexico, Costa Rica, Columbia, Peru.

**UNIT – VIII: (8 hours)**

Regulatory requirements for registration new drug approval in ASEAN (Association of Southeast Asian Nations) member Countries - Brunei, Malaysia, Singapore, Thailand and Vietnam.

**UNIT – IX: (8 hours)**

ACTD, Regulatory requirements for generics and post approval requirements in ASEAN (Association of Southeast Asian Nations) member countries i.e. Brunei, Malaysia, Singapore, Thailand and Vietnam.

**Unit – X: (7 hours)**

Japan, Canada, Australia & UK: Organization of the regulatory body, Drug approval process and types of registration applications.

**R14MPY04 INTERNATIONAL DRUG REGULATORY AFFAIRS – II**

**PRACTICAL 100 Hours**

Twenty Assignments to be carried out and submitted on the aforementioned theoretical aspects like following and power point presentation

1. Registration requirement comparison study in emerging markets (BRICS)
2. Registration requirement comparison study in CIS countries
3. Registration requirement comparison study in ASEAN countries
4. Registration requirement comparison study in LATAM countries
5. Registration requirement comparison study in GCC countries
6. Study of DMF system in Japan.

**REFERENCE BOOKS:**


1. Roadmap to an ASEAN economic community Edited by Denis Hew.ISEAS Publications, Singapore 2005, ISBN981-230-347-2
2. ASEAN, Rodolfo C. Severino, ISEAS Publications, Singapore 2005, ISBN 978-981- 230-750-7
3. Building a Future With Brics: The Next Decade for Offshoring, Mark Kobayashi- Hillary, Springer
4. Outsourcing to India: The Offshore Advantage, Mark Kobayashi-Hillary, Springer
5. Trade performance and Regional Integration of the CIS Countries, Lev Freinkman, The world Bank, Washington, DC, ISBN: 0-8212-5896-0.
6. Global Pharmaceutical Policy: Ensuring Medicines for Tomorrow's World By Frederick M. Abbott, Graham Dukes, Maurice Nelson Graham Dukes.
7. The Gulf Cooperation Council: A Rising Power and Lessons for ASEAN by Linda

Low and Lorraine Carlos Salazar (Nov 22, 2010).
8. Desert Dreams. The Quest for Arab Integration from the Arab Revolt to the Gulf Cooperation Council by Justin Dargin (Feb 15, 2012).
9. Doing Business in the Asean Countries, Balbir Bhasin, Business Expert Press ISBN:13:978-1-60649-108-9.
10. Realizing the ASEAN Economic Community: A Comprehensive Assessment, Michael G Plummer (Editor), Chia Siow Yue (Editor), Instute of South east asian studies, Singapore.
11. The Future of Pharma, Brian Smith, Grower publishing ltd England, ISBN-10: 1409430316 | ISBN-13: 978-1409430315.
12. Investing in BRIC Countries: Evaluating Risk and Governance in Brazil, Russia, India, and China, Svetlana Borodina (Author), Oleg Shvyrkov, Mc - Graw- Hill Inc. USA, ISBN:978-0-07-166406-6
13. Understanding Emerging Markets: Building Business Bric by Brick, Stefano Pelle, Response Books, New Delhi, ISBN:10:0-7619-3557-6.
14. http://www.pharmweb.net/pwmirror/pwk/pharmwebk.html.
15. http://www.ijptonline.com/wp-content/uploads/2010/06/Useful-Websites-links.pdf.
16. http://www.who.int/medicines/areas/quality_safety/regulation_legislation/ListMRAWebsites.pdf

**SRM COLLEGE OF PHARMACY**
**SRM UNIVERSITY**
**Branch – IX: PHARMACEUTICAL QUALITY ASSURANCE**

**FIRST YEAR**

| S.No | Subject Code | Name of the Subject |
|---|---|---|
| 1 | R14MPA03 | Advanced Pharmaceutical Analytical Techniques |
| 2 | R14MPQ01 | Quality Control and Quality Assurance |
| 3 | R14MPQ02 | Pharmaceutical Validation |
| 4 | R14MPQ03 | Pharmaceutical Technology and Quality Management |

**SECOND YEAR**

| S.No | Subject Code | Name of the Subject |
|---|---|---|
| 1 | R14MPQ 21 | Thesis |

## FIRST YEAR

**R14MPQ01 QUALITY CONTROL AND QUALITY ASSURANCE**
**THEORY 75 Hours**

**UNIT – I: (7 hours)**
Definition - Quality control and Quality assurance, concept and philosophy of TQM, GMP, ICH, Brief study of Quality by design, six sigma concept, ISO 9000 & 14000, ICH common technical documents like Validation of Analytical Procedures [Q2 (R1)], Stability testing of new substances and products [Q1A (R2)], photostability testing of new drug substances and products (Q1B). Impurities in new drug substances [Q3A(R)], Impurities in new drug products [Q3B(R)].

**UNIT – II: (8 hours)**
**Organization and personnel responsibilities:** Training, hygiene and personal records, drug industry location, design, construction and plant lay out, maintenance, sanitation, environmental control, utilities and maintenance of sterile areas, control of contamination and Good Warehousing Practice.

**UNIT – III: EQUIPMENTS AND RAW MATERIALS**: **(7 hours)**
Equipments selection, purchase specifications, maintenance, clean in place, purchase specifications and maintenance of stores for raw materials, selection of vendors.

**UNIT – IV: (6 hours)**
Quality control test for containers, closures and secondary packing materials

**UNIT -V: DOCUMENT MAINTENANCE IN PHARMACEUTICAL INDUSTRY(7 hours)**
Batch Formula Record, Master Formula Record, Quality audit reports and documents, quality reports, distribution records, Common Technical Document and Drug Master Files, Medical Devices, Electronic Common Technical Documentation, complaints and evaluation of complaints, Handling of return goods, recalling and waste disposal.

**UNIT VI IN PROCESS QUALITY CONTROL AND FINISHED PRODUCTS QUALITY CONTROL FOR FOLLOWING FORMULATION IN PHARMA INDUSTRY**: **(8 hours)**
Tablets, capsules, ointments, suppositories, creams, parenterals, ophthalmic and surgical products.

**UNIT – VII: PRODUCTION CONTROLS**: **(7 hours)**
Written procedures, change control, contamination control, sterile products, aseptic process control, packaging.

**UNIT – VIII: MANUFACTURING OPERATIONS AND CONTROLS**: **(7 hours)**
Sanitation of manufacturing premises, mix-ups and cross contamination, processing of intermediates and bulk products, packaging operations, IPQC, release of finished product, process deviations, charge-in of components, time limitations on production, drug product inspection, expiration dating, calculation of yields, production record review.

**UNIT – IX:** **(8 hours)**
Scope of GLP, Quality assurance unit, SOP, protocols for conduct of clinical & non clinical testing, control on animal house, report preparation and documentation.

**UNIT – X** **(7 hours)**
NABL certification and accreditation procedure, Patent regime and intellectual property rights.

**R14MPQ01 QUALITY CONTROL AND QUALITY ASSURANCE PRACTICAL** **100 Hours**

**Suggested practical experiments (at least 12 experiments to be conducted)**

1. In process quality control tests for tablets, capsules, parenterals and creams
2. Quality control tests for secondary packing materials
3. Assay of raw materials as per official monographs
4. Testing of related and foreign substances in drugs and raw materials
5. Planning and design of plant layouts.
6. Power point presentation (at least 6)
    i. TQM
    ii. GMP
    iii. ICH
    iv. study of Quality by design
    v. six sigma concept
    vi. ISO 9000 & 14000

**REFERENCE BOOKS:**


1. Quality Assurance Guide by organization of Pharmaceutical Procedures of India, 3rd revised dition, Volume I & II, Mumbai, 1996.
2. Good Laboratory Practice Regulations, 2nd Edition, Sandy Weinberg Vol. 69, Marcel Dekker Series, 1995.
3. Quality Assurance of Pharmaceuticals- A compedium of Guide lines and Related materials Vol I & II, 2nd edition, WHO Publications, 1999.
4. How to Practice GMP's – P P Sharma, Vandana Publications, Agra, 1991.
5. The International Pharmacopoeia – vol I, II, III, IV & V - General Methods of Analysis and Quality specification for Pharmaceutical Substances, Excepients and Dosage forms, 3rd edition, WHO, Geneva, 2005.
6. Good laboratory Practice Regulations – Allen F. Hirsch, Volume 38, Marcel Dekker Series, 1989.
7. ICH guidelines
8. ISO 9000 and total quality management
9. The drugs and cosmetics act 1940 – Deshpande, Nilesh Gandhi, 4th edition, Susmit Publishers, 2006.
10. QA Manual – D.H. Shah, 1st edition, Business Horizons, 2000.
11. Good Manufacturing Practices for Pharmaceuticals a plan for total quality control – Sidney H. Willig, Vol. 52, 3rd edition, Marcel Dekker Series.

**R14MPQ02 PHARMACEUTICAL VALIDATION**

**THEORY** **75 Hours**

**UNIT – I:** **(7 hours)**

**Introduction to Pharmaceutical Validation - I:** Definition, Manufacturing Process Model, scope of Validation, Advantage of Validation, Organization for Validation, Validation Master plan,

**UNIT – II:** **(8 hours)**

**Introduction to Pharmaceutical Validation - II:** Types of validation, Design Qualification, Installation Qualification, Operational Qualification & Performance Qualification of facilities. A Review of Prospective, Concurrent, Retrospective Validation & Revalidation including the use of Statistical Process Control (SPC).

**UNIT – III:** **(10 hours)**

Planning & Managing a Validation Program including Change Control, Scale-Up and Post-Approval Changes (SUPAC), Pre Approval Inspections (PAI) & Technology Transfer Issues.

**UNIT – IV:** **(8 hours)**

**Validation of equipment – I:** Dry Powder Mixers, Fluid Bed and Tray dryers, Tablet Compression (Machine), Dry Heat Sterilization/Tunnels, Autoclaves, Membrane filtration, Capsule filling machines,

**UNIT – V:** **(7 hours)**

**Validation of equipment – II:** Validation of Integrated lines by media fill test. Vendor Certification, Utilities Validation - Pharmaceutical Water System & pure steam, HVAC system, Compressed air.

**UNIT – VI:** **(10 hours)**

**Process Validation:** Prospective, concurrent, retrospective & revalidation, Process validation of following formulations - Coated tablets, Capsules, Ointment/Creams, Liquid Orals. Computer System Validation. Validation of security measures for electronic data processing.

**UNIT – VII:** **(10 hours)**

Analytical method validation, Validation of facilities in Sterile and Non-Sterile plant

**UNIT – VIII:** **(6 hours)**

**Cleaning Validation:** Cleaning of Equipment, Cleaning of Facilities

**UNIT – IX:** **(5 hours)**

**General principles for validation of analytical instruments:** U.V./Visible spectrophotometer, FTIR, DSC, GC, HPLC, HPTLC, LC-MS.

**UNIT – X:** **(4 hours)**

**Validation of laboratory equipments:** Hardness tester, Friability test apparatus, tap density tester, Disintegration tester, Dissolution test apparatus

**REFERENCE BOOKS:**


1. B. T. Loftus & R. A. Nash, "Pharmaceutical Process Validation", Drugs and Pharm Sci. Series, Vol. 129, 3rd Ed., Marcel Dekker Inc., N.Y.
2. The Theory & Practice of Industrial Pharmacy, 3rd edition, Leon Lachman, Herbert A. Lieberman, Joseph. L. Karig, Varghese Publishing House, Bombay.
3. Validation Master plan by Terveeks or Deeks, Davis Harwood International publishing.
4. Validation of Aseptic Pharmaceutical Processes, 2nd Edition, by Carleton & Agalloco, (Marcel Dekker).
5. Michael Levin, Pharmaceutical Process Scale-Up", Drugs and Pharm. Sci. Series, Vol. 157,2nd Ed., Marcel Dekker Inc., N.Y.
6. Validation Standard Operating Procedures: A Step by Step Guide for Achieving Compliance in the Pharmaceutical, Medical Device, and Biotech Industries, Syed Imtiaz Haider.
7. Pharmaceutical Equipment Validation: The Ultimate Qualification Handbook, Phillip A. Cloud, Interpharm Press.
8. Validation of Pharmaceutical Processes: Sterile Products, Frederick J. Carlton (Ed.) and James Agalloco (Ed.), Marcel Dekker, 2nd Ed.
9. Analytical Method validation and Instrument Performance Verification by Churg Chan, Heiman Lam, Y.C. Lee, Yue. Zhang, Wiley Interscience.


**R14MPQ02 PHARMACEUTICAL VALIDATION**

**PRACTICAL**

**100 Hours**

1. Validation of following equipment
    a. Autoclave
    b. Hot air oven
    c. Powder Mixer (Dry)
    d. Tablet Compression Machine
2. Validation of analytical methods

3. Validation of a processing area
4. Validation of at least two analytical instruments
5. Cleaning validation of one equipment
6. Validation of at least two laboratory equipment
7. Power point presentation
    i. Manufacturing Process Model, Scope of Validation, Advantage of Validation,
    ii. Organization for Validation,
    iii. Validation Master plan,
    iv. Design Qualification, Installation Qualification, Operational Qualification & Performance Qualification of facilities. A Review of Prospective, Concurrent, Retrospective Validation & Revalidation including the use of Statistical Process Control (SPC)

**R14MPQ03 PHARMACEUTICAL TECHNOLOGY AND QUALITY MANAGEMENT**
**THEORY** **75 Hours**

**UNIT – I: PREFORMULATION STUDIES (8 hours)**
Introduction, organoleptic properties, purity, impurity profiles, particle size, shape and surface area. Solubility, Methods to improve solubility of Drugs: Surfactants & its importance, co-solvency. Techniques for the study of Crystal properties and polymorphism. Preformulation protocol, Preformulation stability studies.

**UNIT – II: ASEPTIC TECHNOLOGY AND STERILE FORMULATIONS (7 hours)**
Sterile Facility Design requirements (Air, water, Personnel and utilities) Facility Qualifications, Personnel Qualification - Gowning, Building Management system (GAMP – 5). Media Fills – 3 consecutive successful media fills – acceptance criteria. Investigation of Media fills failure.

**UNIT – III: ASEPTIC TECHNOLOGY AND STERILE FORMULATIONS (8 hours)**
Sterile area maintenance – Equipment upkeep, Preventive Maintenance Schedules and Management of various sterile area equipments (Washing and sterilization, sterile Filling, Rubber Bung placement, Flip off seal placement, Labelling and secondary packaging to Final packing operations involved in sterile preparation) Daily operation management of sterile equipment of autoclave- leak test, steam penetration study for clothing and porous load. Chemical Indicators and Biological Indicators and determination of Cold spots in the autoclave. Load selection criteria for autoclaves. Steam quality testing methods and Limits. Aseptic Filtration technique – Filter selection and compatibility, Qualification of Filter, Bubble point testing. Documentation – Batch Manufacturing Record, Batch Packing Record, Sterilization data sheet (retention of Washing equipment data and autoclave, Dry Heat Sterilizer or Tunnel thermographs).

**UNIT – IV: INDUSTRIAL HAZARDS, SAFETY, POLLUTION CONTROL AND EFFLUENT TREATMENT (12 hours)**
Introduction, Factory act and rules, fundamentals of accident prevention, elements of safety programme and safety management, electrical hazards, chemicals hazards and management of over exposure to chemicals, Gas hazards and handling of gases, dust explosion and its control, Fire prevention and control, Physicochemical measurements of effluents, BOD, COD, Determination of some contaminants, Effluent treatment procedure, treatment of some characteristic effluent.

**UNIT – V: CGMP OF PHARMACEUTICAL MANUFACTURING (8 hours)**
Evolution and Principles of cGMP, Schedule-M, WHO-GMP requirements, European Union (EU) and United States Food and Drug Administration (USFDA) guidelines on Pharmaceutical manufacturing. URS, FAT, DQ, SAT, IQ, OQ, PQ of machines and equipment. Clean room standards for 130 different countries and names.

**UNIT – VI: PRINCIPLES OF DRUG DISCOVERY AND DEVELOPMENT (10 hours)**
Introduction, Clinical research process. Development and informational content for Investigational New Drugs Application (IND), New Drug Application (NDA), Abbreviated New Drug Application (ANDA), Supplemental New Drug Application (SNDA), Scale Up Post approval changes (SUPAC) and Bulk active chemical Post approval changes (BACPAC), Post marketing surveillance

**UNIT – VII: QUALITY EVALUATION AND BATCH RELEASE (7 hours)**
Change Control, Deviation-(planned and unplanned), Corrective Action and Preventive Action (CAPA), Handling of nonconformance, Vendor evaluation process, Out of specification (OOS), batch reconciliation and finished goods release, Market recalls & Market complaints.

**UNIT – VIII: (6 hours)**
Conducting and Handling of internal/Domestic/International Regulatory Audits/ Customer specific audits /Pre approval inspections, Annual product reviews, Standard operating procedures – general guidelines

**UNIT – IX: (5hours)**
Stability testing guidelines: ICH and WHO guidelines, Photostability studies

**UNIT – X: QUALITY RISK MANAGEMENT (4 hours)**
Introduction, risk assessment, risk control, risk review, risk management tools, HACCP, risk ranking and filtering

**R14MPQ03PHARMACEUTICAL TECHNOLOGY AND QUALITY MANAGEMENT PRACTICAL 100 Hours**

1. To study the effect of pH on the solubility of drugs, (1 experiment)
2. Accelerated stability of drugs in solution dosage forms (1 experiment)
3. Effect of pH on the stability of drugs in solution at elevated temperature (1 experiment)
4. Improved solubility of drugs using surfactant systems (1 experiment)
5. Improved solubility of drugs using co-solvency method (1 experiment)

6. Comparative study of marketed products solid, semisolid and parenteral (3 experiments)
7. GMP in three different formulations (Tablets, liquid orals and semi solids) (2 experiments each) presentation.
8. Power point presentation
   i. Standard operating procedures- for analytical instrumentation
   ii. Standard operating procedures- for operating pharmaceutical machinery
   iii. Standard operating procedures- cleaning process
   iv. risk assessment and risk control
   v. risk management tools
   vi. HACC
   vii. risk ranking and filtering

**REFERENCE BOOKS**


1. Lachman L Liberman Theory and practice of industrial pharmacy by 3 rd edition
2. Sidney H Willing, Murray M, Tuckerman. Williams Hitchings IV, Good manufacturing of pharmaceuticals (A Plan for total quality control) 3rd Edition.Bhalani publishing house Mumbai.
3. Tablets Vol. I, II, III by Leon Lachman, Herbert A. Liberman, Joseph B. Schwartz, 2nd Edn. (1989) Marcel Dekker Inc. New York.
4. Text book of Bio- Pharmaceutics and clinical Pharmacokinetics by Milo Gibaldi, 3rd Edn, Lea & Febriger, Philadelphia.
5. Dissolution, Bioavailability and Bio-Equivalence by Abdou H.M, Mack Publishing company, Eastern Pennsylvania.
6. Remingtons Pharmaceutical Sciences, by Alfonso & Gennaro, 19th Edn.(1995)OO2C Lippincott; Williams and Wilkins A Wolters Kluwer Company, Philadelphia.
7. The Pharmaceutical Sciences; the Pharma Path way 'Pure and applied Pharmacy' by D. A Sawant, Pragathi Books Pvt Ltd.
8. The process of new drug discovery and development. I and II Edition by Charles G. Smith, James T and O. Donnell.