Syllabus For

Master of Pharmacy
(M. Pharm)

(Two year full time course)

Pharmaceutical Biotechnology

Department of Pharmaceutical Sciences
Saurashtra University
Rajkot - 360 005

Saurashtra University - RAJKOT

Semester & Credit system

For Various Subject specialization of M. Pharm. Programme

M. Pharm. Semester – I

Sr. No.	Subject Code	Type of Subject	Subject	Teaching Scheme		
				Theory Hours/week	Practical Hours/week	**Credits**
1		Interdisciplinary-I	Modern Analytical Technique-I	3	-	**3**
2		Interdisciplinary-II	Practical –I(Modern Analytical Technique-I)	-	6	**3**
3		Core – I	Fundamentals of Biotechnology	6	-	**6**
4		Core – II	Practical - II (Fundamentals of Biotechnology)	-	12	**6**
5		Core – III	Advanced Biochemistry, Bioprecessing and Immunotechnology	4	-	**4**
6		Multidisciplinary - I	Elective – I **1.** Pharmaceutical Preformulation **2.** Pharmaceutical and Industrial Biotechnology **3.** Methods in Biological Evaluation of Drugs	4	-	**4**
					Total Credits	**26**

M. Pharm. Semester – II

Sr. No.	Subject Code	Type of Subject	Subject	Teaching Scheme		
				Theory Hours/week	Practical Hours/week	**Credits**
1		Interdisciplinary-III	Modern Analytical Technique-II	3	-	**3**
2		Interdisciplinary-IV	Practical-III (Modern Analytical Technique-II)	-	6	**3**
3		Core – IV	Proteins and Protein Formulations	6	-	**6**
4		Core – V	Practical - IV (Proteins and Protein Formulations)	-	12	**6**
5		Core – VI	Bioinformatics	4	-	**4**
6		Multidisciplinary - II	Elective – II 1. NDDS: Multidisciplinary and Regulatory Aspectrs 2. Analysis of Recombinant Proteins and Diagnostics 3. Quality Improvement Techniques in Drug Manufacturing	4	-	**4**
					Total Credits	**26**

M. Pharm. Semester – III

Sr. No.	Subject Code	Type of Subject	Subject	Teaching Scheme		
				Theory Hours/week	Practical Hours/week	**Credits**
1		Interdisciplinary-V	Research Methodology	4	-	**4**
2		Interdisciplinary-VI	Patent, Design of experiments and Biostatistics	4	-	**4**
3		Core – VII	Subject Specialization-V (Recombinant DNA Technology and Gene Therapy) (Core-VII)	6	-	**6**
4		Core – VIII	Practical – V (Subject Specialization-V) (Core-VIII) (Recombinant DNA Technology and Gene Therapy)	-	12	**6**
5		Core – IX	Seminar to Dissertation	4	-	**4**
					Total Credits	**24**

M. Pharm. Semester – IV

Sr. No.	Subject Code	Type of Subject	Subject	Teaching Scheme		
				Theory Hours/week	Practical Hours/week	**Credits**
1		Core- X to XII	Dissertation & Viva-Voice	-	-	**20**
					Total Credits	**20**

Total Credits: 96

SAURASHTRA UNIVERSITY SYLLABUS

M. Pharm. Semester-I

Interdisciplinary paper - I

Modern Analytical Techniques-I Theory

Subject code: 1612010002010100

(Three hours per week, 3 credits)

UNIT-I **(12 hours)**

UV-VISIBLE SPECTROSCOPY:

Brief review of electromagnetic spectrum and absorption of radiations. The chromophore concept, absorption law and limitations. Theory of electronic spectroscopy, absorption by organic molecules, choice of solvent and solvent effects. Applications of UV-Visible spectroscopy, Woodward –Fischer rules for calculating absorption maximum, interpretation of spectra, multi-component assay, difference spectra and derivative spectra.

INFRARED SPECTROPHOTOMETRY:

Introduction, basic principles, and sampling techniques, interpretation of spectra, applications in Pharmacy. FT-IR, Attenuated Total Reflectance (ATR), near infra red Spectroscopy (NIR) -theory and applications.

UNIT-II **(11 hours)**

ATOMIC ABSORPTION AND PLASMA EMISSION SPECTROSCOPY:

Principle, instrumentation, interferences and applications in Pharmacy.

REFERENCE STANDARDS

Reference standards source, preparation, characterization, usage, storage and records.

UNIT-III **(11 hours)**

NUCLEAR MAGNETIC RESONANCE SPECTROSCOPY

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

UNIT-IV **(11 hours)**

MASS SPECTROSCOPY

Basic principles and instrumentation, ion formation and types, fragmentation processes and fragmentation pattern, Chemical ionization mass spectroscopy (CIMS), Field Ionization Mass, Fast atom Bombardment MS (FAB-MS), Matrix assisted laser desorption/ ionization MS (MALDI-MS), Interpretation of spectra and application in pharmacy.

Books Recommended:

1. Instrumental Methods of Analysis - Scoog and West.
2. Spectrometric Identification of Organic Compounds - Silverstein et., al.
3. Instrumental Method of Analysis - Willard Dean & Merrit.
4. Text Book of Inorganic Chemistry — A.I. Vogel.
5. Pharmaceutical Chemistry Vol. I & Vol. II — Becket and Stanlake.
6. Pharmaceutical Chemistry Vol. I & Vol. II — L.G.Chatten.
7. Text Book of Pharmaceutical Analysis - K.A. Connors.
8. Pharmaceutical Analysis — Hiquchi, Bechmman, Hassan.
9. Methods of Drug Analysis — Gearien, Graboski.
10. Text Book of BioPharmaceutic Analysis — Robert Smith and James Stewart.
11. Pharmaceutical Analysis — Modern methods — Part A and B — Munson James. W.
12. Quantitative Analysis of Drugs — Garrot.
13. Quantitative Analysis of Drugs in Pharmaceutical Formulations — P. D. Sethi.
14. IP/BP/USP.
15. Application of Absorption Spectroscopy of Organic Compounds — Dyer.
16. Analytical Profiles of Drug Substances — Florey [Volume 13].
17. Spectroscopy of Organic Compound - P. 5. Kalsi, Wiely Eastern Ltd., New Delhi.
18. Absorption Spectroscopy of Organic Molecules — V. M. Parikh, Addision — Wesley Publishing Company, London.

SAURASHTRA UNIVERSITY M. PHARM. SYLLABUS
Semester – I
Modern Analytical Techniques-I, Interdisciplinary paper - II
Subject code: ----
Practical-I
(Six hours per week, 3 credits)

1. Use of colorimeter for analysis of Pharmacopoeial compounds and their formulations.
2. Use of Spectrophotometer for analysis for Pharmacopoeial compounds and their formulations.
3. Simultaneous estimation of combination formulations (minimum of 4 experiments)
    a. Vitamins
    b. Oral antidiabetics
    c. NSAIDs
    d. Antimicrobials
    e. Antihistamines
    f. Antihypertensive etc.
4. Effect of pH and solvent on UV Spectrum of certain drugs.
5. Experiments on flame photometry.
6. Use of fluorimeter for analysis of Pharmacopoieal compounds.
7. IR, NMR and Mass Spectroscopy – Interpretation of spectra & Structural elucidation
    a. (at least for 4 compounds each).
2. Any other relevant exercises based on theory.

SAURASHTRA UNIVERSITY M. PHARM. SYLLABUS

Semester – I (Pharmaceutical Biotechnology)

Subject of Specialization paper – I (Core Subject-I)

Fundamentals of Biotechnology Theory

Subject code: 1612020302010200

(Four hours per week, 6 credits)

Unit - I

1. Microbial biotechnology:

- Bacteria, actinomycetes, fungi, algae and viruses- structure, chemistry, morphology, nomenclature, general classification, molecular & genotypic taxonomy, cultural, physiological and reproductive features, methods of isolation, cultivation, and maintenance of pure cultures. Industrially important microo rganisms- examples and applications.
- Microbial pathology – identifying features of pathogenic bacteria, fungi and viruses, mechanism of microbial pathogenicity, etiology and pathology of common microbial diseases and currently recommended therapies for common bacterial, fungal & viral infections.

Unit - II

2. Molecular Biology :

- Structure of nucleus and chromosome, Nucleic acids and composition, Different structures of DNA, DNA packaging, C-value paradox, genomic organization in prokaryotes and Archaebacteria. Bacterial characteristics determined by plasmids, Molecular properties of plasmid, Plasmid stability, method for studying plasmids.
- Central dogma of molecular biology: Replication, Transcription and post-transcriptional/transcriptional controls, transcription factors.
- Gene regulation: Gene copy number, transcriptional control and translational control.

  RNA processing: Modification and Maturation, RNA splicing, RNA editing, RNA amplification. Control of diversity in protein synthesis through alternate RNA splicing mechanisms.

Unit - III

3. Cellular Biology:

- Cell structure & function- cell organelles, cytoskeleton & cell movements, basic aspects of cell regulation, bioenergetics and fuelling reactions of aerobics and anaerobics, secondary metabolism & its applications. Intracellular vesicular traffic, cell communication, cell cycle and apoptosis, mechanism of cell division. Cell junctions/adhesion and extra cellular matrix, germ cells and fertilization, histology – the life and death of cells in tissues.
- Cell Cycle and Cytoskeleton: Cell Division and its Regulation, G-Protein Coupled Receptors, Kinases, Nuclear receptors, Cytoskeleton & cell movements, Intermediate Filaments. Microtubules, Functional Role and Therapeutic Potential of Cytoskeleton.
- Apoptosis and Oncogenes: - Programmed Cell Death, Tumor cells, Proto-

oncogenes, oncogenic mutations, cell cycle & controls, carcinogens & repair.

- Differentiation and Developmental Biology : Fertilization, Events of Fertilization, In- Vitro Fertilization, Embryonic Germ Cells, Stem Cells and its Application

Unit - IV

4. Genomics :

- Basic understanding of genome and its structure & function- genome, difference between eukaryotic and prokaryotic genome, transcriptome, proteome, phylogenetics. : Genes in development, the dynamic genome; DNA in flux, Control of Prokaryotic gene expression. Studying mapping, sequencing human genome & understanding genome sequence, genetic disorders, Positional cloning, mutation, repair & recombination.
- Functional analysis of gene variation, Genotyping techniques, Single Nucleotide Polymorphism, Pharmacogenomic Management.

Books Recommended:

1. Microbiology : Pelczar
2. General microbiology by R.Y. Steiner
3. Essential and application of microbiology, ZUDYKANDAL
4. Actionomyocytes : Waxman S.A.
5. Genomes by T. A. Brown.
6. Molecular Cell Biology by Lodish.
7. Genes V And VI by Lewin Benjamin.
8. Biotechnology the biological principles by M. D. Trevan, S. Bofley.
9. Modern Biotechnology by Primrose.
10. Eukaryotic Gene Regulation by David Lachman.
11. Microbial genetics by David Friefelder.
12. Functional genomics-Methods & Applications by Brown.
13. Molecular cloning by Sambrooke.
14. Industrial Microbiology by LE Casida

SAURASHTRA UNIVERSITY M. PHARM. SYLLABUS

Semester – I (Pharmaceutical Biotechnology)

Subject of Specialization paper – I (Core Subject-II)

Fundamentals of Biotechnology Practical

Subject code: ----

(Four hours per week, 6 credits)

Practicals :

Laboratory examination including oral and practical examination in general course illustrative of theory section in the syllabus –

1. Basic Laboratory Procedure – Instrument Introduction and Handling, Maintenance, Aseptic condition maintenance, Sterilization, Microscopy, etc.
2. Basic Microbiology Practicals: Culturing and harvesting of microbes. Staining and identification. Maintenance.
3. Isolation of human DNA, quality assessment by spectrophotometer and gel electrophoresis, restriction digestion of DNA, and separation of DNA fragments by gel electrophoresis, staining of bands with ETH-Br, DNA visualization.
4. Isolation of RNA from microbial sources and estimation.

SAURASHTRA UNIVERSITY M. PHARM. SYLLABUS

Semester – I (Pharmaceutical Biotechnology) Subject of Specialization paper – II (Core Subject-III)

Advanced Biochemistry, Bioprocessing and Immunotechnology Theory

Subject code: 1612030302010300

(Three hours per week, 4 credits)

Unit – I

1. Biochemistry

- Brief introduction to carbohydrate metabolism and diseases related to carbohydrate metabolism: Diabetes mellitus, methyl keto urea, galactosmias glycogen storage disease, lactose intolerance and glucose tolerance test.
- Lipid metabolism: Oxidation of fatty acid, alpha, beta, gamma-oxidation and energetics, control of metabolism, essential fatty acids and ecosinoids, (prostaglandins, thromboxanes and leukotriene) phospholipids, sphingolipids clinical orientation of lipid metabolism. Disease related to lipid metabolism. Hyper lipidamiya, cholesterol metabolism, fatty liver and lipotropic factors, hypolipoproteinous atherosclerosis.
- Metabolism of ammonia and nitrogen containing monomers: Nitrogen balance, essential amino acid, transamination, deamination, conversion of amino acids to specialized product assimilation of ammonia urea cycle, metabolic disorders, formation of bile salts and pigment and clinical significance.
- Biological oxidation: Redox potential, energy rich compounds. The respiratory chain, mechanism and energetics of oxidative phoshosporylation, study of cytochromes, bioenergetics, production of ATP and its biological significance.

Unit - II

2. Enzymology :

- Introduction, classification, general properties of enzymes, sources of enzymes, extraction and purification, Enzyme kinetics, enzyme regulation, applications of enzymology: biological preparations/ analytical reagents, diagnostics, therapeutics, inborn errors of enzymes, of production of important enzymes (examples), Techniques of immobilization of enzymes and their applications in industry, Biosensor technology, Immobilized Enzyme engineering, Kinetics of immobilized enzymes.

Unit - III

3. Immunology:

- Cellular basis of Immune response, Immunity to Viruses, Bacteria and fungi, Immunodeficiency diseases, Immune system, cells-tissues-organs of immune system, immunological tolerance, immunity to virus, bacteria, fungi, protozoa, worms. Primary and secondary immuno deficiency, autoimmune diseases, cell migration, inflammation, cytokines and cytokine receptors, T cell receptors, MHC, antigen presentation, antibodies and cell cooperation in antibody response, Hypersensitivity TYPE I, II, II, IV, Hypersensitivity reactions, Vaccine technology: Immuno-diagnostics.

- Vaccine technology: conventional vaccines, novel methods for vaccine production, anti- idiotype vaccine, DNA vaccine, genetically engineered vaccine, iscoms, synthetic peptides, and immunodiagnostics
- Hybridoma techniques – fusion methods for myeloma cells and B-Lymphocytes, selection and screening techniques. Production and purification of monoclonal antibodies and their applications in clinical diagnosis, immunotherapy and pharmaceutical research.

Unit - IV

4. Fermentation technology:

- Fermenter design, aeration agitation, mass transfer in fermentation, Reactors of immobilized enzymes: design and application, theory of fermentation system, fermentation kinetics scale up, screening techniques of microorganisms, detailed study of few industrial important microbial metabolites, computerized control of fermentation process: system configuration, Scale up of fermentation processes: principles, theoretical considerations and techniques used, Product recovery, isolation and purification of fermentation products: filtration, solvent extraction, adsorption and partition, paper/gas/thin-layer and ion-exchange chromatography, electrophoresis and counter- current distribution, crystallization, turbidity analysis and cell yield determination, metabolic responses, enzymatic assays, bioautographic techniques, disintegration of cells for product recovery.
- Products of fermentation: Organic solvents (alcohol. Acetone, butane) Organic acids (citric acid, lactic and gluconic acid). Antibiotics (penicillin, streptomycin , tetracycline , erythromycin , griseofulvin, neomycin , cephalosporins , ergot alkaloids, vitamins (vitamin C), Amino acids: glutamic acid and lysine.

Books Recommended:

1. Immunology by Ivan Roitt, Jonathan Brostooff and David Male.
2. Immunology by Weir.
3. Biochemical Engineering by Steel.
4. Harper's Illustrated Biochemistry by Robert K. Murray.
5. The foundations of biochemistry by Lehninger.
6. Biochemistry by Jeremy M. Berg, 5th edition.
7. Principles of Biochemistry by Zubay.
8. Principles of Biochemistry by U. Satyanarayan.
9. Encyclopedia of Bioprocess technology: Fermentation,
10. Bioseparation by Michael C. Flickinger and Stephen W. Drew.
11. Microbiology: Pelczar.
12. Fermentation and biochemical engineering handbook: Henry C Vogel.

Multidisciplinary/ Elective Subject-I

SAURASHTRA UNIVERSITY M. PHARM SYLLABUS

Semester – I

Multidisciplinary / Elective paper - I

Pharmaceutical Preformulation Theory

Subject code: 1612040002010401

(Three hours per week, 4 credits)

UNIT – I

General Considerations, Spectroscopy and Assay development, dissociation, partitioning and Solubility of Pharmaceutical Solids, pKa, salts, solvents, $K_{o/w}$, drug design, phase solubility analysis, solubilisation, release, dissolution and permeation, chiral drug substances, characterization scheme.

UNIT – II

Solid state properties, crystal morphology, melting point and its analysis, microscopy and particle size analysis, laws of crystallography, habit, polymorphism, pseudomorphism, isomorphism, purity, solubility, hygroscopicity, study methods for evaluation of solid state.

UNIT - III

Dosage form consideration in preformulation, solid dosage form, solution formulations, evaluations and its regulatory considerations, stability testing.

UNIT – IV

Preformulation study, Stability aspect and PEGylation based stability of Biopharmaceutical drugs, Stability study of Phytomedicines

REFERENCES

1. Modern Pharmaceutics by G. Banker.
2. Physical Characterization of Pharmaceutical Solids by H. Brittain.
3. Polymorphism in Pharmaceutical Solids by H. Brittain.
4. Solid State Chemistry of Drugs by S.R. Byrn.
5. Chemical Stability of Pharmaceuticals by K.A. Connors.
6. Pharmaceutical Preformulation and Formulation by M. Gibson.
7. Solubility Behavior of Organic Compounds by D.J.W. Grant and T. Higuchi.
8. Remingtons "Pharmaceutical Sciences" 19th edition.
9. Pharmaceutical Preformulation by J. Wells.
10. Solubility and Solubilisation in Aqueous Media by S. Yalkowsky.
11. Pharmaceutics "The Science of Dosage form design" by Aulton.
12. Hand book of Preformulation by Sarfaraz K. Niazi.

SAURASHTRA UNIVERSITY M. PHARM. SYLLABUS
Semester – I
Multidisciplinary / Elective paper - I
Pharmaceutical and Industrial Biotechnology Theory
Subject code: 1612040002010403
(Three hours per week, 4 credits)
Theory: 4 hours/week (4 Credits)

Unit I

Industrial aspects: Stability studies of biotechnology derived products, Effects of various environmental /processing on stability of the formulation and techniques for stabilization of product against the same regulatory requirement related to stability testing with emphasis on matrixing bracketing techniques, Climatic zones

Unit II

Concept of biotech process validation, Cell lines culture process validation and characterization, Purification process for viral clearance, validation of recovery, Purification, Cleaning, Filtration, Issues of DNA vaccines and plasmid DNA vaccines

Unit III

Analytical methods in protein formulation: concentration, size, purity, surface charge, identity, structure/sepuence, shape, activity.

Unit IV

Industrial application of biotech products: industrial enzymes (examples), immobilization of enzymes, their applications in industry, Immobilized Enzyme engineering, Kinetics of immobilized enzymes, novel methods for enzyme and vaccine production.

READING MATERIAL

1. **Jens T. Cartensen and C. T. Rhodes**, Drug stability principle and practice, 3rd ed. Vol. 107, Marcel Dekker

2. **Rodney pealman, Y. John wang,** formulation characterization and stability of protein drugs, (1996)
3. **Eugene J. McNally, Jayne E. Hasted**, protein formulation and delivery 2nd Ed. Informa-healthcare.
4. **Sven frokjaer and lars hovgaard,** pharmaceutical formulation development of peptides and proteins (2000) Taylor and Franceis
5. **Sarfaraz K. Niazi**, Handbook of Preformularion (2007), Informa Healthcare

SAURASHTRA UNIVERSITY M. PHARM. SYLLABUS

Semester – I

Multidisciplinary / Elective paper - I

Methods in Biological Evaluation of Drugs Theory

Subject code: 1612040002010402

(Three hours per week, 4 credits)

Unit-1

A. Biological standardization, general principles, Scope and limitation of bio-assay, bioassay of some official drugs. **4**

B. Preclinical drug evaluation of its biological activity, potency and toxicity-Toxicity test in animals including acute, sub-acute and chronic toxicity, ED_{50} and LD_{50} determination, special toxicity test like teratogenecity and mutagenecity. Various guidelines for toxicity studies. Animal experiments assessing safety of packaging materials. **6**

C. Selected topics in screening of drugs: **2**

- **a.** Recent advances in Transgenic and Knockout animals
- **b.** Administration of Neuropeptides and Neurohormones by Intracerebroventricular (ICV) route in rats.
- **c.** Screening models for drug abuse like alcohol addiction, dependence and withdrawal syndrome.
- **d.** Biostatistics and calculation of doses in experimental pharmacology

Unit -2

A. Pyrogens: Sources, Chemistry and properties of bacterial pyrogens and endotoxins, Official pyrogen tests **2**

B. Microbiological assay of antibiotics and vitamins. **4**

C. Biological evaluation of drugs--Screening and evaluation (including principles of screening , development of models for diseases : In vivo models / In vitro models / cell line study) techniques of the following:

Unit -3

A. Parasympathomimetics, Parasympathetic blocking agents, Sympathomimetics, Sympathetic blocking agents, Ganglion stimulants and blockers, Neuromuscular stimulants and blockers. **8**

B. General and local Anesthetics, Sedatives and Hypnotics, Antiepileptics, Psychopharmacological agents, Analgesics, Anti-inflammatory agents, Anti-Parkinson's drugs, CNS Stimulants.

12

C. Cardiotonics, Anti-hypertensive drugs, Anti-arrhythmic drugs, Drugs used in Ischemic Heart Diseases, Drugs used in Atherosclerosis.

10

Unit -4

A. Drugs used in Peptic Ulcer, Respiratory disorders, Hormone and Endocrine disorders. Anti fertility agents and diuretics.

8

B. Various models for Cataract, glaucoma, inflammatory bowel disease

4

Books recommended (Latest Edition):

1. Screening methods in pharmacology (vol I & II)–R.A. Turner
2. Drug Discovery and Evaluation in Pharmacology assay: Vogel
3. Design and analysis of animal studies in pharmaceutical development, Chow, Shein, Ching.
4. Evaluation of Drug Activity: Pharmacometrics D.R. Laurence
5. Animal and Clinical pharmacologic Techniques in Drug Evaluation-Nodine and Siegler
6. Pharmacology and Toxicology- Kale S.R.
7. Fundamentals of experimental Pharmacology- Ghosh M.N.
8. Handbook of Experimental Pharmacology- Goyal R.K.
9. Handbook of Experimental Pharmacology- Kulkarni S.K.

M. Pharm. Semester-II

SAURASHTRA UNIVERSITY M. PHARM. SYLLABUS
Semester – II
Interdisciplinary paper - III
Modern Analytical Techniques-II Theory
Subject code: 1612010002020100
(Three hours per week, 3 credits)

UNIT-I

CHROMATOGRAPHIC TECHNIQUES: 15 Hours

1. Classification of chromatographic methods based on mechanism of separation.
2. Theories of chromatographic separation. Principles, elution techniques, instrumentation, derivatization and applications of gas chromatography,
3. HPLC and HPTLC. Principles, elution techniques, applications of ion exchange and ion pair chromatography, affinity chromatography, size exclusion chromatography, chiral chromatography, super fluid chromatography (SFC), GC-MS and LC-MS.

UNIT-II

THERMAL METHODS OF ANALYSIS : 5 Hours

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

UNIT-III

X-RAY DIFFRACTION METHODS : 4 Hours

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

OPTICAL ROTARY DISPERSION : 2 Hours

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

UNIT-IV

RADIO IMMUNO ASSAY : 4 Hours

1. Introduction, Principle, Theory and Methods in Radio Immuno Assay, Related Immuno Assay procedures and Applications of RIA Techniques. Enzyme immuno assay- ELISA and EMIT

ELECTROPHORESIS: 3 Hours

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

Books Recommended:

1. Instrumental Methods of Analysis - Scoog and West.
2. Spectrometric Identification of Organic Compounds - Silverstein et., al.
3. Instrumental Method of Analysis - Willard Dean & Merrit.
4. Text Book of Inorganic Chemistry — A.I. Vogel.
5. Pharmaceutical Chemistry Vol. I & Vol. II — Becket and Stanlake.
6. Pharmaceutical Chemistry Vol. I & Vol. II — L.G.Chatten.
7. Text Book of Pharmaceutical Analysis - K.A. Connors.
8. Pharmaceutical Analysis — Hiquchi, Bechmman, Hassan.
9. Methods of Drug Analysis — Gearien, Graboski.
10. Text Book of BioPharmaceutic Analysis — Robert Smith and James Stewart.
11. Pharmaceutical Analysis — Modern methods — Part A and B — Munson James. W.
12. Quantitative Analysis of Drugs — Garrot.
13. Quantitative Analysis of Drugs in Pharmaceutical Formulations — P. D. Sethi.
14. IP/BP/USP.
15. Application of Absorption Spectroscopy of Organic Compounds — Dyer.
16. Analytical Profiles of Drug Substances — Florey [Volume 13].
17. Spectroscopy of Organic Compound - P. 5. Kalsi, Wiely Eastern Ltd., New Delhi.
18. Absorption Spectroscopy of Organic Molecules — V. M. Parikh, Addision — Wesley
19. Publishing Company, London.

SAURASHTRA UNIVERSITY M. PHARM. SYLLABUS
Semester – II
Interdisciplinary paper - IV
Modern Analytical Techniques-II Practical
Subject code: ----
(Three hours per week, 3 credits)

1. Experiments on Electrophoresis.
2. Experiments of Chromatography.
    a) Thin Layer Chromatography.
    b) Paper Chromatography.
3. Experiments based on HPLC & GC.
4. Thermaograph – Interpretation of spectra (at least for 4 compounds each).
5. Any other relevant exercises based on theory.

SAURASHTRA UNIVERSITY M. PHARM. SYLLABUS
Semester – II (Pharmaceutical Biotechnology) Subject of Specialization paper – III (Core Subject-IV)
Proteins and Protein Formulations Theory
Subject code: 1612020302020200
(Four hours per week, 6 credits)

Unit I

Protein engineering: Concepts for protein engineering. Isolation and purification of proteins, Stability and activity based approaches of protein engineering, Chemical and Physical Considerations in Protein and Peptide Stability, Different methods for protein engineering, Site- directed mutagenesis, gene shuffling, and direct evolution

Unit II

Proteomics: Protein identification and characterization: Methods/strategies, protein identification, de novo protein characterization, Isotope labelling, N- and C-terminal tags.

2-Dimensional gel electrophoresis -methods (including IPGs), -resolution -reproducibility and image analysis -future developments

Unit III

Protein formulation: Different strategies used in the formulation of DNA and proteins, Analytical and biophysical parameters of proteins and DNA in pre-formulation, Liposomes, Nano-spears, Nano-particulate system, PEGilation, Biological Activity, Biophysical Characterization Techniques, Forced degradation studies of protein.

Unit IV

Methods of protein sequencing: mass spectrometry, Edman degradation, Tryptic and/or Chymotryptic Peptide Mapping.

READING MATERIAL

1. **H. Lodhish et. Al.** Molecular Cell Biology,. W. H. Freeman and Company
2. Protein Purification – Hand Book – 1998 Amersham pharmacia biotech
3. **Engelbert Buxbaum,** Fundamentals of Protein Structure and Function (2007), Springer Science
4. **Sheldon J. Park, Jennifer R. Cochran,** Protein Engineering and Design (2009), CRC press.
5. **Robert K. Skopes.** Protein purification, principle and practice (1993), springer link.
6. **David Whitford**, Proteins-Structure and Function (2005), John Wiley & Sons Ltd.
7. **James Swarbrick**, Protein Formulation and Delivery (2008) Informa

Healthcare USA, Inc.
8. **Rodney Pearlman, Y. John Wang** Formulation, Characterization, and Stability of Protein Drugs (2002), Kluwer Academic Publishers.

SAURASHTRA UNIVERSITY M. PHARM. SYLLABUS
Semester – II (Pharmaceutical Biotechnology) Subject of Specialization paper – III (Core Subject-IV)
Proteins and Protein Formulations
Subject code: -----
Practical (Four hours per week, 6 credits)

1. Protein Characterization
2. Cell biology
3. Enzyme biochemistry:
4. Recombinant DNA Technology
5. Protein formulations

SAURASHTRA UNIVERSITY M. PHARM. SYLLABUS

Semester – II (Pharmaceutical Biotechnology)

Subject of Specialization paper – IV (Core Subject-VI)

Bioinformatics Theory

Subject code: 1612030302020300

(Three hours per week, 4 credits)

Unit I

- **Bioinformatics basics:** Computers in biology and medicine Importance of Unix and Linux systems and its basic commands, database concepts, protein and nucleic acid databases. Structural data bases. Biological XML DTD's; Pattern matching algorithm basics.
- **Computational tools for DNA sequence analysis: GCG:** The Wisconsin package of sequence analysis programs, web-based interfaces for the GCG sequence analysis programs.
- **Databases and search tools:** Biological back ground for sequence analysis. Identification of protein sequence from DNA sequence. Searching of databases similar sequence. The NCBI; Publicly available tools, resources at EBI, resources on the web; Database mining tools.

Unit II

- **DNA sequence analysis:** The gene bank sequence database; Submitting DNA sequence to the databases and database searching, sequence alignment, pair wise alignment techniques, multiple sequence analysis, multiple sequence alignment; Flexible sequence similarity searching with the FAST3 program package, the use of CLUSTAL Wand CLUSTAL X for the multiple sequence alignment.
- **Submitting DNA protein sequence to databases:** Where and how to submit, SEQUIN, genome centres; Submitting aligned set of sequences, updates and internet resources.

Unit III

- **Protein Modeling:** Introduction; Force field methods; Energ, buried and exposed residues, side chains and neighbours; Fixed regions, hydrogen bonds, mapping properties onto surfaces; Fitting monomers, rms fit of conformers, assigning secondary structures; Sequence alignment-methods, evaluation, scoring; Protein completion, backbone construction and side chain addition; Small peptide methodology, software accessibility, building peptides; Protein displays; Substructure manipulations, annealing.
- **Peptidomimetics:** Introduction, classification; Conformationally restricted

peptides, design, pseudopeptides, peptidomimetics and transition state analogs; Biologically active template; Amino acid replacements; Peptidomimetics and rational drug design; CADD techniques in peptidomimetics; Development of non peptide peptidomimetics.

- **Protein Structure Prediction:** Protein folding and model generation; Secondary structure prediction, analyzing secondary structures; Protein loop searching, loop generating methods, loop analysis; Homology modeling, concepts of homology

  modeling, potential applications, description, methodology, homologous sequence identification; Align structures, align model sequence; Construction of variable and conserved regions, threading techniques, Topology fingerprint approach for prediction, evaluation of alternate models; Structure prediction on a mystery sequence, structure aided sequence techniques of structure prediction, structural profiles, alignment algorithms, mutation tables, prediction, validation, sequence based methods of structure prediction, prediction using inverse folding, fold prediction; Significance analysis, scoring techniques, sequence- sequence scoring.

Unit IV

- **Protein-Ligand Docking:** Introduction; Docking problems, methods for protein- ligand docking, validation studies and applications; Screening small molecule databases, docking of combinatorial libraries, input data, analyzing docking results, software accessibility; FlexiDock, creating input structures, ligand propositioning, binding pockets, flexible bonds, torsional space, genetic algorithm, scoring**.**
- **The virtual library:** Searching MEDLINE, Pubmed, current content, science citation index and current awareness services, electronic journals, grants, and funding information.

READING MATERIAL

1. **David W. Mount,** Bioinformatics Sequence and Genome Analysis, Second Edition – 2005, CBS Publishers and Distributors
2. **S. C. Rastogi et. al.** Bioinformatics- Concepts Skill and Applications, First Edition – 2003, CBS Publishers and Distributors
3. **T. E. Creighton**, Protein Structure and Molecular Properties, Second Edition-1993 W. H. Freeman and Company
4. **Andreas D. Baxevanis, B. F. Francis Ouellette,** Bioinformatics; A Practical Guide to the Analysis of Genes and Proteins, 2nd Edition. 2001 John Wiley & Sons, Inc.
5. **Arthur M. Lesk,** Introduction to Bioinformatics (2002), Oxford University Press.

6. **Shui Qing Ye.** Bioinformatics: A Practical Approach (2008), Chapman & Hall/CRC.
7. **David Posada,** Bioinformatics for DNA Sequence Analysis (2008), Humana press.

Multidisciplinary/ Elective Subject-II

SAURASHTRA UNIVERSITY M. PHARM. SYLLABUS
Semester – II
Multidisciplinary / Elective paper – II
NDDS: Multidisciplinary and Regulatory Aspects Theory
Subject code: 1612040002020401
(Four hours per week, 4 credits)

UNIT- I **20 hours**

Introduction to Particulate and Vesicular Drug Delivery System

1. Particulate Drug delivery (Microshpres, Microcapsules, Nanosheres, Nanocapusels, Polymeric beads, etc.)
2. Vesicular Drug delivery (Liposmes, Ethosomes, Neosomes, etc.)

UNIT- II **20 hours**

Introduction to Controlled Drug Delivery Systems

1. Transdermal Drug delivery
2. *Insitu* gelling systems
3. Introduction, formulation strategy, evaluation and advances in Gastro retentive, Intestinal and Colon targeted drug delivery system

UNIT- III **10 hours**

Recent advances in Liquid and Semisolid dosage forms

1. Liquid: Multiple Emulsions, Micro and Nano Emulsions, SEDDS, Nanosuspension
2. Semisolid: Ointments, Gels, Emulgels, Creams, Lotions

UNIT- IV **10 hours**

Herbal and naturally derived Products:

1. Formulation development aspects
2. Regulatory and Product stability consideration.

Books Recommended:

1. Remingtons "Pharmaceutical Sciences" 19th Edition.
2. Pharmaceutics "The Science of Dosage Form Design" by Michael Aulton
3. Pharmaceutical Dispensing by Husa
4. Dispensing Pharmacy by Cooper and Goons
5. Encyclopedia of Pharmaceutical Technology, Volumes: I-VI, 3rd Edition
6. www.fda.gov/RegulatoryInformation/Guidances
7. Drug stability (Principles and Practices) by Jens Carstensen
8. Stability of drugs and dosage forms by Yoskioka
9. Modern Pharmaceutics by G. S. Banker
10. Controlled drug delivery: Fundamentals and applications by Robinson
11. Microencapsulation 2nd Edition by Benita
12. Nanoparticulate Drug delivery systems by Thassu
13. Novel drug delivery systems by Chein
14. Pharmaceutical Dissolution Testing by Dressman
15. Active Pharmaceutical Ingredients: Development, Manufacturing, and Regulation, Second Edition by Stanley Nusim
16. Compliance Handbook for Pharmaceuticals, Medical Devices, and Biologics by Carmen medina
17. Herbal Supplements - Drug Interactions: Scientific and Regulatory Perspectives by Y.W. Francis Lam
18. FDA Regulatory Affairs: A Guide for Prescription Drugs, Medical Devices, and
19. Poucher's Perfumes, Cosmetics and Soaps by H. Butler
20. Nanotechnology in Drug Delivery (Biotechnology: Pharmaceutical Aspects) by Melgardt M. de Villiers
21. Targeted & Controlled Drug Delivery: Novel Carrier Systems by Vyas / Khar
22. Bioadhesive Drug Delivery Systems: Fundamentals, Novel Approaches, and
23. Development (Drugs and the Pharmaceutical Sciences) by Edith Mathiowitz
24. Microparticulate Systems for the Delivery of Proteins and Vaccines (Drugs and the
    Pharmaceutical Sciences) by Smadar Cohen
25. Herbal Drugs and Phytopharmaceuticals, Third Edition - Hardcover by Max Wichtl

SAURASHTRA UNIVERSITY M. PHARM SYLLABUS
Semester – II
Multidisciplinary / Elective paper – II
Analysis of Recombinant Proteins and Diagnostics Theory
Subject code: 1612040002020402
(Four hours per week, 4 credits)

A. Analysis:

Unit I **(20 Hours)**

- Total protein assay: Quantitative amino acids analysis, Folin-Lowry protein assay, BCA assay, UV spectrophotometry etc.
- Purity: Protein impurities, contaminants, electrophoretic analysis, HPLC based analysis, DNA content analysis, immunological assays for impurities, combined immunological and electrophoretic methods, host-cell impurities etc.

Unit II **(10 Hours)**

- Test procedures: ICH guidelines.
- Potency assays: In-vitro biochemical methods. cell-Iine derived assays, whole animal assays etc.

B. Diagnostics:

Unit III **(15 Hours)**

- Principles, methods and applications: Principles and methods of some clinically used diagnostic immunoassays, e.g., homogeneous immuno assays, fluorescence, chemiluminescence and bioluminescence enzyme immunoassays etc., immunosensors.

Unit IV **(15 Hours)**

- Principles, methods applications: DNA probe based diagnostics, sample preparation, hybridization, separation, detection, PCR-RFLP in paternity and forensic cases, SNP detection MALDI and DHPLC.
- Cancer diagnostics, human retroviral diseases specially AIDS. Role of enzymes in diagnostics.

READING MATERIAL

1. Practical Biochemistry: Principles and Techniques, Fifth Edition – 2005, K. Wilson and J. Walker
2. Experimental Biochemistry, Third Edition – 1999, R. L. Switzer and L. F. Garrity W. H. Freeman and Company
3. US Pharmacopeia Vol. 1-3 National Formulary 25, 2007 (Biotechnological drugs) The USP Convention
4. Indian Pharmacopoeia -2007 Vol. 1-3 (Biotechnology products) The IP Commission, Ghaziabad
5. Related review Articles

Semester – II
Multidisciplinary / Elective paper – II
Quality Improvement Techniques in Drug Manufacturing Theory
Subject code: 1612040002020403
(Four hours per week, 4 credits)

UNIT- I **(12 hours)**

International Organization for Standard – ISO, Grading, Documents specified by ISO like control of records, control of manufacturing, preventive maintenance, control of documents, corrective action, Internal audits etc and its relevance with Quality Drug Manufacturing

UNIT- II **(12 hours)**

Total Quality Management and Process steps of Total Quality Management (TQM) Statistical process control – SPC

UNIT- III **(12 hours)**

Six Sigma including concept of Defects Per Million Opportunities (DPMO), DMAIC process (Define, Measure, Analyze, Improve, and Control), DMADV process (Define, Measure, Analyze, Design, Verify) and DFSS (Design For Six Sigma)

UNIT- IV **(12 hours)**

Process and Analytical Technology – PAT, Failure Mode Effect Analysis – FMEA

UNIT- V **(12 hours)**

Lean manufacturing Malcolm Baldrige National Quality Award – MBNQA, European Foundation for Quality Management (EFQM) excellence model

M. Pharm. Semester-III

SAURASHTRA UNIVERSITY M. PHARM. SYLLABUS
Semester – III
Interdisciplinary paper - V
Research Methodology Theory
Subject code: 1612010002030100
(Three hours per week, 3 credits)

1. Research-Meaning, purpose, Types, (Educational, Clinical, Experimental, historical descriptive, Basic applied and Patent oriented Research) objective of research

2. Literature survey-Use of Library, books and journals-Medlines-Internet, Patent Search, and reprints of articles as a source for Literature survey

3. Selecting a problem and preparing Research proposals

4. Methods and tools use in research –
   A. Qualities studies, quantitative studies
   B. Simple data organization descriptive data analysis,
   C. Limitation & sources of Error
   D. Inquiries in form of Questionnaire, etc.,

5. Documentation-
   A. "How" of documentation
   B. Techniques of documentation
   C. Importance of documentation
   D. Use of computer packages in documentation

6. The Research Report Paper writing/ thesis writing
   Different parts of the Research paper
   A. Title –Title of project with authors name
   B. Abstract- Statement of the problem, Background list in brief and purpose and scope.
   C. Key Words.
   D. Methology-subject, apparatus, instrumentation & procedure.
   E. Results- tables, graphs, figures & statistical presentation
   F. Discussion support or non support of hypothesis, practical & theoretical Implications
   G. Conclusion
   H. Acknowledgements.

I. References
J. Errata
K. Importance of Spell check for entire project
L. Uses of footnotes

7. Presentation (especially for oral presentation)

8. Importance, types different skills, contained, format of model, introduction, Poster, Gestures, eye contact, facial, expressions, stage, fright, volume- pitch, speed, pause & language, Visual aids & seating, Questionnaire

9. Cost analysis of the project – cost incurred on raw materials- Procedure, instrumentations and clinical trials

10. Sources for procurement research grants – international agencies, Government and private bodies

11. Industrial-institution interaction- Industrial projects, their, feasibility reports. Interaction with industries

Recommended Books

1. Research In Education- John V. Best, John V. Kahn 7th edition
2. Presentation skills - Michael Hallon- Indian Society for Institute education
3. Practical Introduction o copyright.- Gavin Mcfarlane
4. Thesis projects in Science & Engineering – Richard M. Davis.
5. Scientist in legal Systems- Ann labor science
6. Thesis & Assignment – Jonathan Anderson
7. Writing a technical paper- Donald Menzel
8. Effective Business Report Writing –Leland Brown
9. Protection of industrial Property rights- P. Das & Gokul Das
10. Spelling for the millions- Edna Furmess
11. Preparation for publication – King Edward Hospital Fund for London
12. Information Technology – The Hindu speaks
13. Documentation – Genesis & Development 3792.
14. Manual for evaluation of industrial projects-United Nations
15. Manual for the preparation of industrial feasibility studies

SAURASHTRA UNIVERSITY M. PHARM. SYLLABUS
Semester – III
Interdisciplinary paper - VI
Patent, Design of experiments and Biostatistics
Subject code: 1612020002030200
(Three hours per week, 3 credits)

UNIT-I

1. Intellectual property, importance and types of intellectual property
2. Paris conventional, World Trade Organization, WIPO and GATT.
3. US Patent System and European Patent System

UNIT-II

The Indian Patents Act 1970 and Indian patents (Amendments) Act 2005 and issue related to Patents, Importance, parts of patent, type of patent, provisional application, Oppositions, Patent infringement, Patent search engines

UNIT-III

Biostatistics and Various statistical methods i.e. Null hypothesis, t- Test, Regression analysis, ANOVA, Chi-square, etc.

UNIT- IV

Optimization Techniques, Design of experiments, Factorial designs, Grid search technique, Response surface methodology, contour plots, etc.

SAURASHTRA UNIVERSITY M. PHARM. SYLLABUS
Semester – III (Pharmaceutical Biotechnology) Subject of Specialization paper – V (Core Subject-VII)
Recombinant DNA Technology and Gene Therapy Theory
Subject code: 1612030302030300
(Four hours per week, 6 credits)

Unit I

Recombinant DNA technology: Bacterial transformation, principles of DNA isolation, RNA isolation, southern, northern and western blot, DNA sequencing, cDNA synthesis; Gene cloning; Gene cloning vectors, prokaryotic vectors, shuttle vectors, expression vectors, mutagenesis; PCR, site directed and PCR mutagenesis

Unit II

Plant biotechnology and Animal biotechnology:

Plant transformation methods, genetic engineering in plants for virus resistance, pest resistance, delay of fruit ripening, production of antibodies.

Transformation of animal cells, baculo virus expression system, invitro fertilization, transgenic animals and animal cloning.

Unit III

Second generation molecules: Second generation molecules via site-specific gene alteration, second generation protein program design, examples of engineered proteins of therapeutic potential.

Unit IV

Gene therapy: Potential approach to gene therapy, somatic cell gene transfer, prospects and limitations, Application of gene delivery.

READING MATERIAL

1. **J. Sambrook et. al**. Molecular Cloning: A laboratory Manual, Cold Spring Harbor laboratory Press
2. **S. B. Primrose et. al.** Principles of Gene Manipulation, Blackwell Science
3. **P. K. Gupta,** Elements of Biotechnology, Rastogy Publishers
4. **A. J. F. Griffiths et. al.** An Introduction to Genetic Analysis, W. H. Freeman and Company
5. **Benjamin Lewin,** Gene IX, Jones and Bartlett Publishers
6. **Sandhya Mitra**, Genetic Engineering Principles and Practice -2007, Macmillan

India Ltd.
7. **Julia Lodge, Pete Lund & Steve Minchin,** Gene Cloning (2007), Taylor & Francis Group.
8. **E. J. Murray,** Methods in Molecular Biology, Vol. 7: Gene Transfer and Expression Protocols (1991), Humana press.
9. **R Tuan**, Methods m Molecular Biology, vol 62 Recombmant Gene Expression Protocols, Humana Press Inc.
10. **Susan Carson, Dominique Robertson,** Manipulation and Expression of Recombinant DNA-A Laboratory Manual 2nd ed (2006), Academic Press **Hubert Rehm,** Protein Biochemistry and Proteomics (2006), Elsevier academic press

SAURASHTRA UNIVERSITY M. PHARM. SYLLABUS

Semester – III (Pharmaceutical Biotechnology) Subject of Specialization paper – V (Core Subject-VII)

Recombinant DNA Technology and Gene Therapy

Subject code: -----

Practical (Four hours per week, 6 credits)

1. Cell biology
2. Enzyme biochemistry:
3. Recombinant DNA Technology
4. Gene delivery