



**Syllabus For
Master of Pharmacy
(M. Pharm)**

(Two year full time course)

Pharmacology

**Department of Pharmaceutical Sciences
Saurashtra University
Rajkot - 360 005**

M. Pharm. Semester-I

SAURASHTRA UNIVERSITY M. PHARM. SYLLABUS

Semester – I

Interdisciplinary paper - I

Modern Analytical Techniques-I Theory

(Three hours per week, 3 credits)

UNIT-I

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

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

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

MASS SPECTROSCOPY

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

Interdisciplinary paper - II

Modern Analytical Techniques-I Practical

(Three hours per week, 3 credits)

1. Use of colorimeter for analysis of Pharmacopoeial compounds and their formulations.
2. Use of Spectro photometer for analysis for Pharmacopoeial compounds and their formulations.
3. Simultaneous estimation of combination formulations (minimum of 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 Pharmacopoeial compounds.
IR, NMR and Mass Spectroscopy – Interpretation of spectra & Structural elucidation (atleast for 4 compounds each).
- 7 . Any other relevant exercises based on theory.

SAURASHTRA UNIVERSITY M. PHARM. SYLLABUS

Semester – I (Pharmacology)

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

Cellular and Molecular Pharmacology (Theory)

(Four hours per week, 6 credits)

Theory

Unit-I

1.1 Molecular structure of biological membrane and, transport mechanism across the cell membrane **3**

1.2 Molecular biology of receptor system: structure, receptor pharmacology, signal transduction mechanism and termination of receptor activity, regulation of receptor, their involvement in various biological processes including diseases resulting from receptor malfunction and their role in pharmacotherapeutics. Radio ligand binding studies. Theories of drug receptor interaction. Dose response relationship, potency and efficacy and different types of antagonisms **15**

Unit-II

2.1 Classification of cholinergic and adrenergic receptors, their signal transduction mechanism, agonists and antagonists **4**

2.2 NMDA, GABA, Glycine, Serotonin, Dopamine, Histamine and Endothelin (ET) receptors, their classification, signal transduction mechanism, agonists and antagonists **10**

Unit-III

3.1. Pharmacology of sodium, calcium and potassium channels and their modulators **5**

3.2. The role of nitric oxide in various physiological functions and its importance in pharmacotherapy of disorders like hypertension, angina and erectile dysfunction. **4**

Unit-IV

4.1. Pharmacology of purines and peptides. **3**

4.2. Role of Cytokines, Prostaglandins, TNF- α , Bradykinins, Leucotrienes, PAF, Interferons and Adhesion molecules in various immunological and inflammatory disorders. **6**

Unit-V

5.1. Cellular and molecular pharmacology of apoptosis and necrosis, stress induced expression of genes and their role in neurochemistry of aging and anti-aging drugs. (With special emphasis on CNS) **7**

5.2. Gene therapy **3**

SAURASHTRA UNIVERSITY M. PHARM. SYLLABUS
Semester – I (Pharmacology)
Subject of Specialization paper – I (Core Subject-II)
Cellular and Molecular Pharmacology (Practical)
(Four hours per week, 6 credits)

Practical

Unit-I

1.1 Introduction to experimental animals, ethics in pharmacological experiments, CPCSEA Guidelines

1.2. Methods for euthanasia, anesthesia, dosing (i.v., oral, i.p., s.c., i.m.) and blood collection by various techniques

Unit-II

2.1 To study the effects of various agonists (pD₂) and antagonist (pA₂) using isolated preparations (rat ileum, guinea pig ileum, rat fundus strip, rat anococcygeus muscle, rat vas deference, rat uterus, guinea pig taenia coli, rat/guinea pig heart, guinea pig tracheal chain, rat aortic strip)

2.2. To study the effects of calcium channel blockers on responses of various agonists on rat/guinea pig ileum

Unit-III

3.1To study the effect of various drugs on rat blood pressure by invasive/non invasive techniques

Books recommended (Latest Edition):

- 1.** Pharmacological Basis of Therapeutics-Goodman and Gilman
- 2.** Pharmacology-Rang and Dale
- 3.** Basic and Clinical Pharmacology – Bertam G. Katzung
- 4.** Principles of Pharmacology – Paul L. Munson
- 5.** Lewis's Pharmacology – James Crossland – Churchil Livingstone
- 6.** Review of Medical Physiology – Ganong William F.
- 7.** Fundamentals of Experimental Pharmacology- Ghosh M.N.
- 8.** Basic and Clinical Immunology- Peakman, Mark
- 9.** Handbook of Experimental Pharmacology- Goyal R.K.
- 10.** Handbook of Experimental Pharmacology- Kulkarni S.K.
- 11.** Pharmacology and Toxicology- Kale S.R.

SAURASHTRA UNIVERSITY M. PHARM. SYLLABUS
Semester – I (Pharmacology)
Subject of Specialization paper – II (Core Subject-III)
Advances in Pharmacology (Theory)
(Three hours per week, 4 credits)

Recent advances in pharmacology of the following:

Unit-I

1.1 Drugs acting on the peripheral nervous system: Sympathomimetics, Sympatholytics, Parasympathomimetics, Parasympatholytics, Ganglion blockers & Stimulants, Neuromuscular blockers. **15**

1.2. Autacoids : Eicosanoids, Polypeptides, Histamine, 5-HT **7**

Unit-II

2.1. Antimicrobial and Antineoplastic agents : Introduction to infectious disease, general Principles of Chemotherapy and management of infectious disease, Sulphonamides & Co-trimoxazole, Penicillins, Cephalosporins, Macrolide antibiotics, Aminoglycosides, Quinolones, Tetracycline & Chloramphenicol, Chemotherapy of Tuberculosis & Leprosy, Antifungal agents, Anti-viral agents, Anti-protozoal agents, Anthelmintics, Chemotherapy of Sexually Transmitted Disease (STD), Types of cancers ,their management with Anti- Cancer agents and radiation therapy. **30**

Unit-III

3.1. Immunopharmacological agents:
Immunostimulants, Immunosuppressant **8**

Books recommended (Latest Edition):

- 1.** Pharmacological basis of Therapeutics-Goodman and Gilman
- 2.** Pharmacology-Rang and Dale
- 3.** Principles of Pharmacology – Paul L. Munson
- 4.** Lewis’s Pharmacology – James Crossland – Churchil Livingstone
- 5.** Modern Pharmacology with clinical applications- Craig, Charles R.
- 6.** Lippincott’s illustrated reviews of Pharmacology- Mycek Mary J.
- 7.** Goth’s Medical Pharmacology- Wesley G. Clark
- 8.** Principles of pharmacology.--H. L. Sharma
- 9.** Essentials of medical pharmacology --K. D. Tripathi

Multidisciplinary/ Elective Subject-I

SAURASHTRA UNIVERSITY M. PHARM. SYLLABUS

Semester – I

Multidisciplinary / Elective paper - I Pharmaceutical Preformulation Theory (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, solubilization, 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, emulsion, suspension, freeze dried products, topical, pulmonary, evaluations and its regulatory considerations, stability tastings, order of reaction, antioxidants, chelating agents, impurity, GMP related to bulk drugs and APIs.

UNIT – IV

Characterization of Biopharmaceutical drugs and 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 Solubilization 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
(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/sequence, 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

(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, ED₅₀ and LD₅₀ determination, special toxicity test like teratogenicity and mutagenicity. 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

(Three hours per week, 3 credits)

UNIT-I

CHROMATOGRAPHIC TECHNIQUES : 15 Hours

- a) Classification of chromatographic methods based on mechanism of separation. Theories of chromatographic separation.
- b) Principles, elution techniques, instrumentation, derivatization and applications of gas chromatography, HPLC and HPTLC.
- c) 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

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

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

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

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

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, Addison — Wesley Publishing Company, London.

SAURASHTRA UNIVERSITY M. PHARM. SYLLABUS

Semester – II

Interdisciplinary paper - IV

Modern Analytical Techniques-II Practical

(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. Thermoanalytical – Interpretation of spectra (atleast for 4 compounds each).
5. Any other relevant exercises based on theory.

SAURASHTRA UNIVERSITY M. PHARM. SYLLABUS

Semester – II (Pharmacology)

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

Pharmacometrics and Methods of biological evaluation of drugs (Theory) (Four hours per week, 6 credits)

Unit-I

1.1 Biological standardization, general principles, Scope and limitation of bioassay, bioassay of some official drugs.

1.2. Preclinical drug evaluation of its biological activity, potency and toxicity-Toxicity test in animals including acute, sub-acute and chronic toxicity, ED50 and LD50 determination, special toxicity test like teratogenicity and mutagenicity. Various guidelines for toxicity studies. Animal experiments assessing safety of packaging materials.

Unit-II

2.1. Pyrogens: Sources, Chemistry and properties of bacterial pyrogens and endotoxins, Official pyrogen tests

2.2. Microbiological assay of antibiotics and vitamins.

Unit-III

3.1. 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:

3.2. Parasympathomimetics, Parasympathetic blocking agents, Sympathomimetics, Sympathetic blocking agents, Ganglion stimulants and blockers, Neuromuscular stimulants and blockers.

Unit-IV

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

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

Unit-V

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

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

SAURASHTRA UNIVERSITY M. PHARM. SYLLABUS
Semester – II (Pharmacology)
Subject of Specialization paper – III (Core Subject-II)
Pharmacometrics and Methods of biological evaluation of drugs (Practicals)
(Four hours per week, 6 credits)

Unit-I

1.1. Bioassays of drugs: Bioassay of agonists (Graphical, Matching, 3 Point, 4 point method) and Bioassay of antagonists using various isolated preparations.

1.2. Toxicity studies

1.3. Evaluation of drugs based on theory syllabus.

Illustrative examples

Unit-II

2.1 Evaluation of the antiepileptic activity of drug using maximum electro convulsive shock seizures (M. E. S.) and chemical induced convulsions methods.

2.2. Determination of the time required for induction and recovery from anesthesia for various volatile general anesthetics.

2.3 Evaluation of the effect of pentobarbitone sodium and diazepam in mice.

2.4. Evaluation of the effect of various tranquilizers and sedatives on motor co-ordination by rota rod test in mice.

2.5. Evaluation of the effects of drugs on spontaneous motor activity and to evaluate their nature as CNS stimulants or depressants.

Unit-III Evaluation of drugs based on theory syllabus.

Illustrative examples

3.1. Evaluation of the antiparkinsonian activity of drugs by pheno-thiazine induced catatonia.

3.2. Evaluation of the effect of psychotropic drugs on condition avoidance response.

3.3. Evaluation of the compulsive behavior (stereotypy) induced by apomorphine and its modification by chlorpromazine in mice.

3.4. Evaluation of anxiolytic (antianxiety) effect of diazepam in mice using elevated plus maze apparatus.

3.5. Study the effect of caffeine in human volunteers.

3.6. Evaluation of the effect of cimetidine in drug induced gastric (peptic) and duodenal ulcers and hyper secretion of gastric acid in rats.

Unit-IV Evaluation of drugs based on theory syllabus.

Illustrative examples 11. Evaluation of the antisecretory and ulcer protective effect of cimetidine in pylorus ligated rats.

4.1. Evaluation of the analgesic potency of drug by thermal method.

4.2. Evaluation of analgesic effect of morphine in mice using hot plate method.

4.3. Evaluation of the analgesic effect of drugs by acetic acid induced writhing method in mice.

4.4. Evaluation of the anti-inflammatory property of indomethacin against carrageenan induced acute paw oedema in rats.

4.5. Evaluation of the effects of various drugs (diuretics) on the output of the urine in rats.

References Books: (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.

SAURASHTRA UNIVERSITY M. PHARM. SYLLABUS

Semester – II (Pharmacology)

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

Pharmacotherapeutics (Theory)

(Three hours per week, 4 credits)

Theory

Unit-I

1.1 Important disorders/conditions (etiology, pathophysiology, complications, diagnosis, Prognosis), their control and management with special emphasis on pharmacology of drugs (mechanism of action, ADME, therapeutics use, and adverse effects, toxicities and possible drug interaction) of the following:

1.2 Central Nervous system: Neurodegenerative Disorders (Parkinson's disease, Alzheimer's disease, Huntington's chorea, Spasticity), behavioral disorder-

(Anxiety, Insomnia, Depression and Mania), Psychoses, Epilepsy, Migraine

1.3. Cardiovascular and hemopoietic system ; Hypertension, Acute Coronary Syndrome, Angina Pectoris, Atherosclerosis, Congestive Heart Failure, Arrhythmias, Thromboembolic disorder, Anaemia

Unit-II

2.1. Endocrine system : Disorders of thyroid gland and Parathyroid gland, Diabetes, Adrenocortical dysfunction

2.2. Gastro-intestinal System :Peptic Ulcer, Inflammatory Bowel Disease, Vomiting, Achlorhydria, Constipation, Diarrhea, Liver diseases

Unit-III

3.1. Respiratory system: Bronchial Asthma, Chronic Obstructive Pulmonary Disease (COPD), Allergic Rhinitis, Common cold & Cough, Cystic fibrosis

3.2. Urogenital system: Renal Failure, Infertility, Benign Prostatic Hypertrophy, dysmenorrhea, Menopause

3.3. Disorders of eye: Glaucoma

References Books: (Latest Edition):

1. Principles of Pharmacology –The Pathophysiologic Basic –Golan David E.

2. Pharmacological Basis of Therapeutics-Goodman and Gilman

3. Pharmacology-Rang and Dale

4. Essentials of Pharmacotherapeutics-F.S. Barar

5. Principles of Pharmacology – Paul L. Munson

6. Pharmacology and Pharmacotherapeutics-R.S.Satoskar

7. Pharmacotherapy- A Pathophysiological Approach-Joseph T. Dipiro.

8. Lewis's Pharmacology – James Crossland – Churchil Livingston

9. Modern Pharmacology with Clinical Applications- Craig, Charles R.

10. Principles of Pharmacology--H. L. Sharma

Multidisciplinary/ Elective Subject-II

SAURASHTRA UNIVERSITY M. PHARM. SYLLABUS

Semester – II

Multidisciplinary / Elective paper – II

NDDS: Multidisciplinary and Regulatory Aspects Theory

(Three hours per week, 4 credits)

UNIT- I

(6 hours)

Introduction and overview of Novel Drug Delivery Systems (NDDSs)

- Particulate Drug delivery (Microspheres, Microcapsules, Nanospheres, Nanocapsules, Polymeric beads, etc.)
- Vesicular Drug delivery (Liposomes, Ethosomes, Neosomes, etc.)
- In situ gelling systems
- Transdermal Drug delivery
- Microemulsion, Nanoemulsion, Self emulsifying systems, Nanosuspension, etc.
- Targeted Drug delivery
- Liquid and Semisolid preparations
- Sterile products, Cosmetic products and Aerosolized systems.

UNIT- II

(6 hours)

Consideration of various regulations in product development

- Organic volatile impurities
- Trace impurities
- API and product stability
- Product registration

UNIT- III

(6 hours)

Biotechnological Products:

- Formulation development aspects for biotechnological products
- Delivery aspects for biotechnologically derived products (Recombinant DNA, Recombinant proteins, Gene delivery, Enzymes, Hormones, etc.)
- Product stabilization aspects with consideration of ICH Q5 Section.
- Regulatory considerations with consideration of global regulatory guidelines.

UNIT- IV

(6 hours)

Herbal and naturally derived Products:

- Formulation development aspects
- Delivery aspects for herbal and naturally derived medicinal products (Herbal extracts, crude extracts, incorporation of product performance enhancers, etc.)
- Product stabilization aspects with consideration of ICH guideline.
- Regulatory considerations with consideration of global regulatory guidelines.

UNIT- V

(6 hours)

Synthetic and Semisynthetic medicines

- Formulation development aspects
- Delivery aspects for Synthetic and Semisynthetic medicines.
- Product stabilization aspects with consideration of ICH guideline.
- Regulatory considerations with consideration of global regulatory guidelines.

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. Biodegradable polymers as drug delivery systems by Cahsin
11. Biopolymers for medical and pharmaceutical applications, Volumes: I-II by Alexander Steinbüchel
12. Controlled drug delivery: Fundamentals and applications by Robinson
13. Microencapsulation 2nd Edition by Benita
14. Nanoparticulate Drug delivery systems by Thassu
15. Novel drug delivery systems by Chein
16. Pharmaceutical Dissolution Testing by Dressman
17. Protein biotechnology: isolation, characterization, and stabilization By Felix Franks
18. Active Pharmaceutical Ingredients: Development, Manufacturing, and Regulation, Second Edition by Stanley Nusim
19. Compliance Handbook for Pharmaceuticals, Medical Devices, and Biologics by Carmen Medina
20. Herbal Supplements - Drug Interactions: Scientific and Regulatory Perspectives by Y.W. Francis Lam
21. Textbook of Complementary and Alternative Medicine by Chun-su Yuan
22. FDA Regulatory Affairs: A Guide for Prescription Drugs, Medical Devices, and Biologics by Douglas J. Pisano
23. Cell Technology for Cell Products (ESACT Proceedings) by Rodney Smith
24. Poucher's Perfumes, Cosmetics and Soaps by H. Butler
25. Nanotechnology in Drug Delivery (Biotechnology: Pharmaceutical Aspects) by Melgardt M. de Villiers

26. Antigen Delivery Systems: Immunological and Technological Issues (Drug Targeting and Delivery) by Bruno Gander
27. Targeted & Controlled Drug Delivery: Novel Carrier Systems by Vyas / Khar
28. Bioadhesive Drug Delivery Systems: Fundamentals, Novel Approaches, and Development (Drugs and the Pharmaceutical Sciences) by Edith Mathiowitz
29. Pharmaceutical Gene Delivery Systems (Drugs and the Pharmaceutical Sciences) by Alain Rolland
30. Microparticulate Systems for the Delivery of Proteins and Vaccines (Drugs and the Pharmaceutical Sciences) by Smadar Cohen
31. Protein Formulation and Delivery (Drugs and the Pharmaceutical Sciences) by Eugene J. McNally
32. 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
(Three hours per week, 4 credits)

A. Analysis:

Unit I

- **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

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

B. Diagnostics:

Unit III

- 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

- 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

M. Pharm. Semester-III

SAURASHTRA UNIVERSITY M. PHARM. SYLLABUS

Semester – III

Interdisciplinary paper - V

Research Methodology Theory

(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-
 - “How” of documentation
 - Techniques of documentation
 - Importance of documentation
 - 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. Methodology-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)
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
8. Cost analysis of the project – cost incurred on raw materials- Procedure, instrumentations and clinical trials.
9. Sources for procurement research grants – international agencies, Government and private bodies,
10. 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
2. Practical Introduction o copyright.- Gavin Mcfarlane
3. Thesis projects in Science & Engineering – Richard M. Davis.
4. Scientist in legal Systems- Ann labor science
5. Thesis & Assignment – Jonathan Anderson
6. Writing a technical paper- Donald Menzel
7. Effective Business Report Writing –Leland Brown
8. Protection of industrial Property rights- P. Das & Gokul Das
9. Spelling for the millions- Edna Furness
10. Preparation for publication – King Edward Hospital Fund for London
11. Information Technology – The Hindu speaks
12. Documentation – Genesis & Development 3792.
13. Manual for evaluation of industrial projects-United Nations
14. Manual for the preparation of industrial feasibility studies

SAURASHTRA UNIVERSITY M. PHARM. SYLLABUS

Semester – III

Interdisciplinary paper - VI

Patent, Design of experiments and Biostatistics

(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.