



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

(Four semester full time programme)

Pharmacology

Revised Syllabus effective from July 2012

**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	Cellular and Molecular Pharmacology	6	-	6
4		Core – II	Practical - II (Cellular and Molecular Pharmacology)	-	12	6
5		Core – III	Advances in Pharmacology	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	Pharmacometrics and Methods of biological evaluation of drugs	6	-	6
4		Core – V	Practical - IV (Pharmacometrics and Methods of biological evaluation of drugs)	-	12	6
5		Core – VI	Pharmacotherapeutics	4	-	4
6		Multidisciplinary - II	Elective – II 1. NDDS: Multidisciplinary and Regulatory Aspects 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 (Clinical Pharmacy and Practice) (Core-VII)	6	-	6
4		Core – VIII	Practical – V (Subject Specialization-V) (Core-VIII) (Clinical Pharmacy and Practice)	-	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, Addison — 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 Pharmacopoeial 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 (Pharmacology)

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

Cellular and Molecular Pharmacology (Theory)

Subject code: 1612020402010200

(Six hours per week, 6 credits)

Unit-I

1.1 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

14

1.2 Gene expression, pharmacogenomics, (SR) proteomics, techniques involved in studying receptor dynamics. PCR, (KG) Northern blot, Southern blot and Western blot. Protein purification. Mono, polyclonal antibodies

4

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

3

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

2

3.3. Pharmacology of purines and peptides.

2

3.4. Role of Cytokines, Prostaglandins, TNF-, Bradykinins, Leucotrienes, PAF, Interferons and Adhesion molecules in various immunological and Inflammatory disorders.

2

Unit-IV

Monoclonal Antibodies: Scope and limitation of monoclonal antibodies, formation and selection of hybrid cells, identification of specific antibody producing hybrid cell lines. Applications of monoclonal antibodies in clinical, treatment, and biomedical research.

4

Monoclonal antibodies as therapeutic agents, preventing rejection of transplanted organs, treatment of bacterial blood infections. Chemically linked monoclonal antibodies, human monoclonal antibodies, and hybrid human-mouse monoclonal antibodies **5**

Unit-V

5.1. Cellular and molecular pharmacology of apoptosis and necrosis **3**

5.2 Stem Cell Therapeutics: Biology of stem cells and their potentials in various disorders **4**

5.3. Gene therapy **3**

SAURASHTRA UNIVERSITY M. PHARM. SYLLABUS

Semester – I (Pharmacology)

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

Practical-II

Subject code: ----

(Twelve 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

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

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 – Churchill 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)

Subject code: 1612030402010300

(Four hours per week, 4 credits)

Recent advances in pharmacology of the following:

Unit-I

1.1 Pharmacology of receptors: Classification, cellular signaling systems, and pharmacology of agonists and antagonists of the following receptor types:

(b) Purinoreceptors, Endothelin receptors, Cannabinoid receptors, Melatonin receptors, Farnesoid receptors

Unit-II

2.1. Novel Target Sites: Physiological functions, pharmacological implications, and therapeutic potential of the following target sites:

Rho kinase (ROCK), Phosphoinositide 3-kinase (PI3K), Akt (Protein kinase B), Caspases, Poly (ADP-ribose) polymerase (PARP), Peroxisome proliferator activator receptors (PPAR), AMP activated protein kinases, Protein kinases, Phosphodiesterases, Urotensin, Apelin, Sirtuins,

2.2 Neuropeptides: Biological functions, pharmacological implications, their agonists and antagonists, and therapeutic potentials of the following neuropeptides:

Neuropeptide Y, Calcitonin gene-related peptide (CGRP), Substance P, Cholecystokinin

Unit-III

3.1. Immunopharmacological agents: Immunostimulants, Immunosuppressant

Unit IV

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

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

Unit V

5.1. Antimicrobial and Antineoplastic agents : Introduction to infectious disease, general Principles of Chemotherapy and management of infectious disease, Sulphonamides & Co-trimoxazole, Penicillins, Cephalosporins, Aminoglycosides, Tetracycline & Chloramphenicol,

5.2 Types of cancers ,their management with Anti- Cancer agents and radiation therapy.

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 – Churchill 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

Subject code: 1612040002010401

(Four 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

Subject code: 1612040002010403

(Four hours per 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

Subject code: 1612040002010402

(Four 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**

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.** Antiepileptics, Psychopharmacological agents, Analgesics, Anti-inflammatory agents, Anti-Parkinson's drugs,. **8**
- B.** Cardiotonics, Anti-hypertensive drugs, Anti-arrhythmic drugs, Drugs used in Ischemic Heart Diseases, Drugs used in Atherosclerosis. **12**
- 10**

Unit -4

A. Drugs used in Peptic Ulcer, asthma, and diabetes Diabetes . Anti fertility agents and diuretics. **8**

B. Various models for Cataract, glaucoma, inflammatory bowel disease **4**

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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, Addison — 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. Thermoograph – Interpretation of spectra (at least 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)

Subject code: 16120204020200

(Six hours per week, 6 credits)

Unit-I

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 e.g. OECD guidelines.

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-II

2.1. Antiepileptics, Psychopharmacological agents, Analgesics, Anti-inflammatory agents, Anti- Parkinson's drugs, Neuroprotectives

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

Unit-III

3.1. Drugs used in Peptic Ulcer, Asthma, Diabetes, Osteoporosis

3.2 Various models for Cataract, glaucoma, inflammatory bowel disease

3.3 Screening models for Anti-cancer drugs

SAURASHTRA UNIVERSITY M. PHARM. SYLLABUS

Semester – II (Pharmacology)

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

Practicals-IV

Subject code: ----

(Twelve hours per week, 6 credits)

Unit-I

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

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 pylorusligated 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)

Subject code: 1612030402020300

(Four hours per week, 4 credits)

Theory

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:

Unit I

1.1 Drug Therapy of Cardiovascular Disorders:

Pathophysiology and drug therapy of congestive cardiac failure, hypertension, cardiac arrhythmias, Angina, hyperlipidemia and atherosclerosis, Thromboembolic disorders

1.2. Drug Therapy of Endocrine Disorders:

Pathophysiology and drug therapy of diabetes mellitus, Thyroid and parathyroid disorders, infertility.

Unit II

2.1. Drug Therapy of Neurological Disorders:

Pathophysiology and drug therapy of epilepsy, Parkinson's disease, migraine.

2.1. Drug Therapy of Psychiatric Disorders:

Pathophysiology and drug therapy of anxiety, schizophrenia, Alzheimer's disease, mood and sleep disorders, and memory.

Unit III

3.1 . Drug Therapy of Inflammatory Disorders:

Biology of inflammation, pathophysiology and drug therapy of osteoarthritis, rheumatoid arthritis, and gout.

3.2 Drug Therapy of Respiratory Diseases:

Pathophysiology and drug therapy of asthma and COPD

3.3 Drug Therapy of Gastrointestinal Diseases:

Pathophysiology and drug therapy of peptic ulcers, emesis and inflammatory bowel disease.

Unit IV

4.1. Drug Therapy of Metabolic and Sexual Disorders:

Pathophysiology and drug therapy of obesity and erectile dysfunction

4.2. Drug Therapy of Infectious Diseases:

Pathophysiology and drug therapy of tuberculosis, leprosy, HIV and related opportunistic infections, malaria, amoebiasis, and helminth infection

4.3 Drug Therapy of Liver disorders

Liver cirrhosis, Hepatitis, Jaundice

Unit V

5.1 Miscellaneous

Anaemia, BPH, Renal failure, Glaucoma, Transplantation science

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

Subject code: 1612040002020401

(Four 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
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-line 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.

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 Furrness
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 (Pharmacology)

Subject of Specialization paper – V (Core Subject-VII)

Clinical Pharmacy and Practice Theory

Subject code: 1612030402030300

(Six hours per week, 6 credits)

Unit 1

Clinical development of drug

Introduction to clinical trials, various phases of clinical trials, IND applications, ANDA, NDA, Investigator Brochure Ethical guidelines in clinical research, Inform consent process, Composition, responsibility, procedures of IRB/IEC Role and responsibility of clinical trials personals as per ICH GCP guidelines.

Unit 2

Clinical Pharmacy Practice

Concept of essential and Rational Drug use. General principles of clinical pharmacokinetics General principle of clinical toxicology Drug induced diseases, adverse drug reaction; their monitoring and reporting (Pharmacovigilance)

Unit 3

Drug interaction- Prescription monitoring, documentation and other methods for minimizing clinically relevant drug interaction. Therapeutic drug monitoring and dosage adjustment in renal and hepatic disorders Drug treatment for special category of patients: pediatric and Geriatric consideration for drug treatment, drug treatment for pregnancy and lactation.

Unit 4

Racial, ethnic and gender differences in response to drug (Pharmacogenetics) Principles of Pharmacoepidemiology, and Pharmacoeconomics Interpretation of clinical laboratory test: Hematological, pathological and Biochemical investigations as markers of Disease/organ damage and their impact on drug therapy decision.

Unit 5

Basis of principles of diagnosis and treatment of human poisoning. Clinical feature of common poisoning and Antidotes in the management of poisoning. Phosphorus, Halogens, Organophosphorus, chlorinated hydrocarbons, arsenic, lead, iron, Dhatura , hemlock, cannabis, LSD, muscaline & cocaine, strychnine, curare, Barbiturate, Alcohol, quinine, digitalis, carbon monoxide, , opium & its derivatives

SAURASHTRA UNIVERSITY M. PHARM. SYLLABUS
Semester – III (Pharmacology)

Subject of Specialization paper – V (Core Subject-VIII)

Practical-V

Subject code: ----

(Twelve hours per week, 6 credits)

1. Practical scenario on essentiality concept and skill for clinical pharmacy practice (2 cases each)
2. Rational drug use and essential drug concept
3. Medication adherence
4. Interpreting laboratory data –biochemistry and hematology
5. Interpreting laboratory data –infectious disease
6. Patient Counseling
7. Ward round participation
8. Therapeutic drug monitoring
9. Drug therapy review
10. Drug Interaction
11. Adverse drug reaction
12. Geriatric pharmacy practice
13. Pediatric pharmacy practice
14. Pharmacy practice for pregnant women
15. Evaluation of drug formulation (based on essentiality and rationality-50 formulations):
16. Illustrated Examples
17. Rational drug therapy for nutritional anemia
18. Rational drug therapy for Cough
19. Rational drug therapy for diarrhea
20. Prescription audit (10)
21. Protocol preparation for submission to IRB

Books recommended (Latest Edition):

1. Central Drugs Standard Control Organization. Good Clinical Practices-Guidelines for
2. Clinical Trials on Pharmaceutical Products in India. New Delhi: Ministry of Health; 2001.
3. International Conference on Harmonization of Technical requirements for registration of Pharmaceuticals for human use. ICH Harmonized Tripartite Guideline. Guideline for Good Clinical Practice.E6; May 1996.
4. Ethical Guidelines for Biomedical Research on Human Subjects 2000. Indian Council of Medical Research, New Delhi.

5. Textbook of Clinical Trials edited by David Machin, Simon Day and Sylvan Green, March 2005, John Wiley and Sons.
6. Principles of Clinical Research edited by Giovanna di Ignazio, Di Giovanna and Haynes.
7. Clinical Pharmacy and Therapeutics Roger walker and Clive Edwards,Churchill Livingstone Edinburgh
8. Davidson's Principle and Practice of Medicine, EDs Christopher, Haslett, Edwin R.Chilvers.
9. Harrison's Principles of Internal medicine- Vol 1 and 2 Braunwald, Eugene & Others.
10. Textbook of Therapeutics Drug Disease Management- Eric T.Herfindal and Dick R.Gourley.
11. Comprehensive Pharmacy Review- Shargel Leon
12. Melmon and Morrells Clinical Pharmacology 4th Edition – S George Carrythers
13. A textbook of Clinical pharmacy practice- Parthasarathi G.