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

<table>
<thead>
<tr>
<th>Sr. No.</th>
<th>Subject Code</th>
<th>Type of Subject</th>
<th>Subject</th>
<th>Teaching Scheme</th>
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<td>Theory Hours/week</td>
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<td>3</td>
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<td>Cellular and Molecular Pharmacology</td>
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<td>Practical - II (Cellular and Molecular Pharmacology)</td>
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<td>5</td>
<td>Core – III</td>
<td>Advances in Pharmacology</td>
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<td>Elective – I</td>
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1. Pharmaceutical Preformulation
2. Pharmaceutical and Industrial Biotechnology
3. Methods in Biological Evaluation of Drugs

| Total Credits | 26 |
# M. Pharm. Semester – II

<table>
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<td>Pharmacometrics and Methods of biological evaluation of drugs</td>
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<td>Core – V</td>
<td>Practical - IV (Pharmacometrics and Methods of biological evaluation of drugs)</td>
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| 1. NDDS: Multidisciplinary and Regulatory Aspects  |
| 2. Analysis of Recombinant Proteins and Diagnostics  |
| 3. Quality Improvement Techniques in Drug Manufacturing |

| Total Credits | 26 |
# M. Pharm. Semester – III

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<td>Patent, Design of experiments and Biostatistics</td>
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<td>Core – IX</td>
<td>Seminar to Dissertation</td>
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**Total Credits**: 24
M. Pharm. Semester – IV

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<td>Dissertation &amp; Viva-Voice</td>
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<td>Total Credits</td>
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**Total Credits: 96**
UNIT-I (12 hours)

UV-VISIBLE SPECTROSCOPY:

INFRARED SPECTROPHOTOMETRY:
Introduction, basic principles, and sampling techniques, interpretation of spectra, applications in Pharmacy. FT-IR, Attenuated Total Reflectance (ATR), near infrared 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

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, 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.
3. Instrumental Method of Analysis - Willard Dean & Merrit.
14. IP/BP/USP.
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 (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

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 – 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
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, Fernesoid 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 & Chloramphanicol,
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 – 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
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.
10. Solubility and Solubilization in Aqueous Media by S. Yalkowsky.
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
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, ED$_{50}$ and LD$_{50}$ determination, special toxicity test like teratogenicity and mutagenecity. Various guidelines for toxicity studies. Animal experiments assessing safety of packaging materials. 6
C. Selected topics in screening of drugs:
   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. 12
B. 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, asthma, and diabetes Diabetes. Anti fertility agents and diuretics.

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

**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.
3. Instrumental Method of Analysis - Willard Dean & Merrit.
14. IP/BP/USP.
18. Absorption Spectroscopy of Organic Molecules — V. M. Parikh, Addision — Wesley
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. Thermoanograph – Interpretation of spectra (at least for 4 compounds each).
5. Any other relevant exercises based on theory.
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, ED$_{50}$ and LD$_{50}$ determination, special toxicity test like teratogenecity and mutagenecity. 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 plusmaze 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.
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
8. Lewis’s Pharmacology – James Crossland – Churchil Livingston
9. Modern Pharmacology with Clinical Applications- Craig, Charles R.
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 (Microshpres, Microcapsules, Nanosheres, Nanocapusels, Polymeric beads, etc.)
- Vesicular Drug delivery (Liposmes, Ethosomes, Neosomes, etc.)
- Insitu 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)
Biotechnoligical Products:
- Formulation development aspects for biotechnological products
- Delivery aspects for biotechnologically derived products (Recombinat DNA, Recombinat proteins, Gene delivery, Enzymes, Hormones, etc.)
- Product stabilization aspects with consideration of ICH QE5 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, crud 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

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:
3. Pharmaceutical Dispensing by Husa
4. Dispensing Pharmacy by Cooper and Goons
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
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
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
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
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

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

   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
5. Scientist in legal Systems- Ann labor science
7. Writing a technical paper- Donald Menzel
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
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 convention, World Trade Organization, WIPO and GATT.

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.
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, Datura, 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):

8. Davidson’s Principle and Practice of Medicine, EDs Christopher, Haslett, Edwin R.Chilvers.
11. Comprehensive Pharmacy Review- Shargel Leon
13. A textbook of Clinical pharmacy practice- Parthasarhi G.