



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

(Two year full time course)

Pharmacognosy – Herbal Drug Technology

**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 (Pharmacognosy)

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

Advance Pharmacognosy Theory

(Four hours per week, 6 credits)

Unit – I

- 1.1 General Introduction to Pharmacognosy and its importance in herbal drug industry.
- 1.2 The classification and vegetable drug with special reference to chemotaxonomy.
- 2.1 WHO Guidelines for cultivation and collection of Herbal Drugs.
- 2.2 Factors affecting cultivation of crop including Plant Growth Regulators.
- 2.3 Influence of Mutation, Polyploidy, Hybridization in chemo demes.
- 2.4 Insecticides & pesticides of herbal origin and their suitable utilization.

Unit - II

- 3.1 Application of microscopy in evaluation – T.S./L.S./Surface views of Plant drugs.
- 3.2 Use of microtome and preparation of histological slides.
- 3.3 Determination of various diagnostic features of identification of different organs as per different herbal pharmacopoeias. Determination of Numerical values.

Unit - III

- 4.1 Detailed studies on phytochemical screening methods including TLC & HPTLC fingerprinting.
- 4.2 Application of Supercritical Fluid Extraction techniques in phytochemical screening.

Unit - IV

- 5 Commercial sources, method of isolation and separation, chemical properties, characterization (excluding synthesis) and therapeutic uses of some medicinally important class of Plant Phenolics, Alkaloids, Glycosides, Terpenoides, Steroids and Resinous substances.

Unit - V

- 6 Review of recent literature along with methods used for bio screening of Antiallergic, Anticancer, Antidiabetic, Antihepatotoxic, Anti-inflammatory agents, Immunomodulator, Cardiovascular, Respiratory, Psychotropic and Neurotropic, Analgesic, Antipyretic, Anti-obesity, Anti-atherosclerotic of herbal origin.

SAURASHTRA UNIVERSITY M. PHARM. SYLLABUS

Semester – I (Pharmacognosy)

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

Advance Pharmacognosy Practical

(Four hours per week, 6 credits)

Practicals:

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

The industrial visit and in national/ international conferences is also required to attend during the course.

Books Recommended:

1. Manske- The Alkaloid- Chemistry and Physiology.
2. Sim - Medicinal Plant Glycosides.
3. Sim - Medicinal Plant Alkaloids.
4. IUPAC - Chemistry of Natural Products - International symposium.
5. Zechmeister - Progress in the Chemistry of Organic Natural Products.
6. Reinhold - Liwschitz - Progress in Phytochemistry.

7. Wagner - Wolf- New Natural Products and Plant Drugs with Pharmacological, Biological or Therapeutic Activity
8. Finar- Organic Chemistry.
9. Peach - Tracey - Modern Methods of Plant Analysis.
10. Geissman - Modern Methods of Plant Analysis.
11. Garatt - The Quantitative Analysis of Drugs.
12. Backett - Stenlake - Practical Pharmaceutical Chemistry,
13. Arthur-Symposium on Phytochemistry.
14. Pridham - Swain - Biosynthetic Pathways in Higher Plants.
15. Greenbury - Metabolic Pathways.
16. Margaret - Brain - Secondary Plant Metabolism.
17. Wagner - Horhammer - Pharmacognosy and Phytochemistry
18. Harborne - Comparative Biochemistry of Flavonoids.
19. Lehninger - Principles of Biochemistry,
20. Bonner - Plant Biochemistry.
21. Harborne - Phytochemical Methods.
22. Rosenthaler - The Chemical Investigation of Plants.
23. Cheronis - Organic Functional Group Analysis.
24. Nakanishi -Natural Products Chemistry, Vol. 1 & Vol. 2

SAURASHTRA UNIVERSITY M. PHARM. SYLLABUS

Semester – I (Pharmacognosy)

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

Natural Products Theory

(Three hours per week, 4 credits)

1. Chemotaxonomy , significance in classification of medicinal plants,distribution of chemotaxonomical groups of constituents in plants.
2. Comparative phytochemistry, Phytochemical classification of plants,relationship between phytochemistry and taxonomy, variations, novel and unpredicted compounds.
3. Phytomics and metabolomics.
4. Plantibodies (immunoglobins) from plants.
5. Edible dyes,plant sweeteners,perfumery and cosmetic agents.
6. Bioactivity :Activity versus toxicity, rapid screening methods, correlation between enzyme inhibition and pharmacological activity, general screening of enzyme, inhibitors, radio ligand receptors binding assays (adrenoreceptors, opiate, benzodiazepine, ion channels, 5-HT, dopamine, adenosine, muscarinic, histamine, ATPase, GABA), cytotoxicity tests; bioassay-guided fractionations.
7. Dietary anti-oxidants in disease prevention.
8. Dereplication for natural products: Concept of dereplication, importance of dereplication, development of dereplication protocols with examples.

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

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..

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

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, Addision — 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 (Pharmacognosy)

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

Industrial Pharmacognosy Theory

(Four hours per week, 6 credits)

Unit - I

- 1.0 GMP and other regulatory and safety requirements as per amendments made from time to time in the schedules of Drug and Cosmetic Act and Rules for Herbal, Ayurvedic and other Drug of traditional origin.
- 2.1 Plant and equipment, processing and project profile of herbal extracts.
- 2.2 Recent Methods (UV, HPLC, HPTLC, etc.) of assay of Andrographolide, Amarogenin, Asiaticosides, Atropine, Solasodine, Bacoposide, Caffeine, Cubebol, Citral, Curcumin, Digitoxin, Diosgenin, Embelin, Emetine, Ergometrine, Eugenol, Gingerol, Gycerrhetic acid, Hesperidine, Kutkosides, Piperine, Plumbagin, Quinine, Quinidine, Recinolic acid, Sennosides, Taxol, Vinca alkaloids, Withaferin, etc. in extract / formulations.

Unit – II

- 3.0 Profiles for commercial cultivation technology and post harvest care of Ashwagandha, Belladonna, Guggul, Papaya, Dioscorea, Isapgol, Umbelliferous fruits, Ginger, Turmeric, Aloes, Digitalis, Vinca, Ephedra, Senna, Guar, Peppermint, Colchicum, Lemongrass, Piper spp.

Unit - III

- 4.1 General principles of formulation including physico-chemical properties like pH, solubility, distribution coefficient etc.
- 4.2 Methods of preparation of different conventional solid and liquid dosage forms incorporating herbal extracts.
- 5.1 Basic principles of treatment in Ayurvedic System of medicine.
- 5.2 Salient features of the techniques of preparation and standardization of some of the important class of formulation as per Ayurvedic Pharmacopoeia and texts.

Unit – IV

- 5.1 Pharmaceutical aids: Profile for manufacture and commerce of Papain, Pectin, Pharmaceutical gums, Starch, Absorbent cotton and Gelatin.
- 5.2 **Marine natural products:** Introduction, chemistry and biology of marine natural products
Marine toxins, marine biomedicinals falling under the class of cardiovascular, anticancer, antimicrobial, antiinflammatory and antibiotic drugs

Books Recommended:

1. Ramstad - Modern Pharmacognosy.
2. Biotechnical Applications.
3. Handa S.S. & Kaul. K.L. Supplement to cultivation & utilization of medicinal plants.
4. Gamborg, O.L. and Wetter, L.R., Plant Tissue Culture Methods, National Research Council of Canada, Saskatchewan.
5. HE Street Plant Tissue and Cell Culture, Blackwell Scientific Publication.
6. P.Prave, U.Fause, W. Sittig, and D.A. Sukatsch; Fundamentals of Biotechnology, VCH Publisher.
7. Alan T Bull, Howard Dalton and Murray Mao-Young, Comprehensive Biotechnology. The

principles, Application & Regulation of Biotechnology in Industry, Agriculture & Medicine; Vol. 1 to 4

8. Medicinal plants: Alkaloids and Glycosides By Toronto
9. CSIR- Cultivation and Utilization of Medicinal Plants
10. CSIR - Wealth of India, Raw Materials
11. Paul J. Schewer Chemistry of Marine Natural Products.
12. Dean F. Martin & George Padilla Marine Pharmacognosy.
13. Marine Natural Products-Vol.I to IV.
14. T. Swain Comparative Phytochemistry.
15. T. Swain Chemical Plant Taxonomy.
16. C.K. Atal & B.M. Kapoor Cultivation of Medicinal Plants.
17. C.K. Atal & B.M.Kapoor Cultivation and Utilization of Aromatic Plants

SAURASHTRA UNIVERSITY M. PHARM. SYLLABUS
Semester – II (Pharmacognosy)
Subject of Specialization paper – III (Core Subject-V)
Industrial Pharmacognosy Practical
(Four hours per week, 6 credits)

Practicals:

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

The industrial visit and in national/ international conferences is also required to attend during the course.

SAURASHTRA UNIVERSITY M. PHARM. SYLLABUS

Semester – II (Pharmacognosy)

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

Medicinal Plant Biotechnology Theory

(Three hours per week, 4 credits)

Unit - I

- 1.0 Historical perspectives, prospects for development of plant biotechnology as source of medicinal agents. Applications in pharmacy and allied fields.
- 2.0 Types, techniques, nutritional requirements and growth of plant tissue cultures. Organogenesis and embryogenesis. Protoplast fusion and cultures, artificial seeds, micropropagation of medicinal and aromatic plants. Genetic stability of tissue cultures.

Unit - II

- 3.1 Secondary metabolism in tissue cultures with emphasis on production of medicinal agents and its impact in pharmacy. Screening and selection of high yielding cell lines. Effect of cultural practices, precursors and elicitors on production of biomedicinals.
- 3.2 Plant finger print analysis: Methods used in gene identification, localization and sequencing of genes. Application of PCR to plant genome analysis
- 4.0 Biotransformation, bioreactors, industrially potential tissue culture systems for pilot and large scale cultures of plant cells, cellular totipotency, cryopreservation and retention of biosynthetic potential in cell cultures.

Unit - III

- 5.0 Immobilized plant cell culture systems, immobilization techniques, effect of immobilization on secondary metabolism and realization of chemosynthetic potential in immobilized cells.
- 6.0 Genetic transformation methods, Hairy root cultures and their applications.

Unit - IV

- 6.1 Basic metabolic pathways and techniques employed in elucidation of biosynthetic pathway. Biogenesis of tropane, quionoline, Imidazole, Isoquinoline and Indole alkaloids; Sterols, Anthraquinone and Saponin glycosides; Flavanoids; and Isoprenoid compounds of pharmaceutical significance.

Books Recommended:

1. Elements in biotechnology by P. K. Gupta.
2. Molecular biology and biotechnology by J. M. Walker and E. D. Gingold.
3. An introduction to plant tissue culture by M. K. Razdan.
4. Breeding field crops by John. M. P and David A. S.
5. Advanced methods in plant breeding and biotechnology by David. R. Murray.
6. Experiments in plant tissue culture by John H. D and Lorin W. R.
7. Pharmaceutical biotechnology by S. P. Vyas and V. K. Dixit.
8. Plant cell and tissue culture by Jeffrey W. Pollard and John M. Walker.
9. Plant tissue culture by Dixon.
10. Plant tissue culture by Street.

11. Pharmacognosy by G. E. Trease and W. C. Evans.
12. Biotechnology by Purohit and Mathur.
13. Biotechnological applications to tissue culture by Shargool.
14. Pharmacognosy by Varro E. Tyler, Lynn R. Brady and James E. Robberdt.
15. Introduction to biotechnology by Bullock John.
16. Biotechnology of higher plants by Gordon E. Russel.
17. Antibiotics isolation and separation by M. L. Wenisten and G. H. Wagman.
18. Plant cell culture technology by M. M. Yeoman.
19. Plant tissue culture by Dennis N. Butcher and David .S. Ingram.
20. Plant tissue culture by Pitman.
21. Plant tissue culture – Theory and practice by S. S. Bhajwani and M. K. Razdan.
22. Secondary plant metabolism by Margaret L. Vikery and Brian Vikery.
23. Plant tissue culture by W. E. George.

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 Q5E 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.

SAURASHTRA UNIVERSITY M. PHARM. SYLLABUS

Semester – III (Pharmacognosy)

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

Herbal Drug Technology Theory

(Four hours per week, 6 credits)

Unit - I

1.0 Introduction:

- 1.1 Role of natural products in herbal medicine
- 1.2 General status and importance of herbal medicine
- 1.3 Safety of herbals / herbal pharmacovigilance
- 1.4 W.H.O. policy on herbal medicine

2.0 Herbs as raw materials:

- 2.1 Definition of herb, herbal medicine, herbal medicinal product, herbal drug preparation
- 2.2 Source of Herbs
- 2.3 Selection, identification and authentication of herbal materials drying and processing of herbal raw material

Unit – II

3.0 Extraction of Herbal Materials :

- 3.1 Choice of solvent for extraction
- 3.2 Methods used for extraction and principles involved in extraction.

4.0 Standardization of herbal formulation & herbal extracts:

- 4.1 Standardization of herbal extracts as per WHO and cGMP guidelines
- 4.2 Physical, chemical, spectral and toxicological standardization, qualitative and quantitative estimations exemplified by the method of preparation of at least two standardized extracts.
- 4.3 Stability studies for extracts.
- 4.4 Predictable chemical and galenical changes

Unit - III

5.0 Nutraceuticals:

- 5.1 Herbal Nutraceuticals as new source of medicine.
- 5.2 concept of nutritional requirements at different age, sex and in different conditions like normal, diseases, pregnancy etc.. Different types of additives used. Analysis of these nutritional and other ingredients in ethical and non-ethical foods.

Unit – IV

6.0 Herbal product development :

- 6.1 Cosmetics – Information on ingredients used in various products such as creams, powders, lotions, hair products, nail polishes, lipsticks, depilatories, toiletries etc. and their analysis. The sources and description of raw materials of herbal origin used like fixed oils, waxes, gums, hydrophilic colloids, colours, perfumes, protective agents, bleaching agents, preservatives, antioxidants and other ancillary agents.
- 6.2 Methods involved in monoherbal and polyherbal formulations with their merits and demerits.
- 6.3 Compatibility studies and Stability studies
- 6.4 Bioavailability & pharmacokinetic aspects for herbal drugs with examples of well known documented, clinically used herbal drugs
- 6.5 Phytoequivalence & pharmaceutical equivalence
- 6.6 Quality control of finished herbal medicinal products.

Books Recommended:

1. Pharmacognosy by G.E.Trease, W.C. Evans, ELBS.
2. Pharmacognosy by Varro E. Tylor, Lynn R. Brody, James E. Robberts, K.M. Varghese Co. Mumbai.
3. Textbook of Pharmacognosy by T.E. Wallis, CBS Pub. Delhi.
4. Clark's Isolation & Identification of Drugs by A.C. Mottal
5. Introduction to chromatography theory and practical by V.K. Srivastava, K.Kishore
6. Elements of chromatography by P.K.Lala
7. Chromatography of Alkaloids by Vapoorte, Swendson
8. Drug Analysis by Chromatography- Egon Stahl
9. Quantitative Analysis & Steroids by Gorog S.
10. Phytochemical Methods of chemical Analysis By Harborne
11. Pharmacopical standards for Ayurvedic formulations –CCRAS Delhi
12. Quantitative Thin Layer Chromatography and its Industrial applications by Trieber LR
13. HPTLC- Quantitative Analysis of Pharmaceutical Formulations by P.D. Sethi.
14. Plant drug Analysis by Hildebert Wagner
15. Indian Herbal Pharmacopoeia Vol I & II
16. British Herbal Pharmacopoeia
17. Herbal drug Industry by R.D. Chaudhri
18. Indian Pharmacopoeia
19. The complete German commission E monographs- Blumenthal, Busse, Goldberg, Greenwald, hall, Klein, Riggins & Rister
20. Quality control methods of Herbal drugs by Pulok V. Mukherjee.
21. HPLC Methods of drug analysis by Mantu K.Ghosh.
22. Practical Evaluation of Phytopharmaceuticals K.R. Brain, T.D. Turner.
23. Standardization of Botanicals –Testing and Extraction methods of Medicinal Herbs Dr. V. Rajpal Vol-I& II
24. Dispensing for Pharmaceuticals students by S.J.Carter.
25. Theory and Practice of Industrial Pharmacy by Lachman, Libermann,Kanig
26. General Pharmacy by J.W.Cooper & Coline Gunn
27. Tutorial Pharmacy By S.J. Carter
28. Cosmeceuticals –Drugs Vs cosmetics by Peter Elsner & Howard D. Maibach
29. Harry's cosmeticology
30. Herbal Medicinal Products- Frauke Gaedcke & Barbana Steinhoff
31. Plants in cosmetics Vol I & II- Prof. Robert Anton, Dr. Franco Patni & Prof.Vittorio Silano
32. Research guideline for evaluating the safety & efficacy of herbal medicines WHO Publication (ISBN)
33. Pharmaceutics - The Science of Dosage form design - Aulton
34. Quality Control Methods for Medicinal Plant Materials- WHO
35. CMPC Guidelines

SAURASHTRA UNIVERSITY M. PHARM. SYLLABUS

Semester – III (Pharmacognosy)

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

Herbal Drug Technology Practical

(Four hours per week, 6 credits)

Practicals:

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

The industrial visit and in national/ international conferences is also required to attend during the course.