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
Saurashtra University - RAJKOT

Semester & Credit system

For Various Subject specialization of M. Pharm. Programme

M. Pharm. Semester – I

<table>
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<th>Sr. No.</th>
<th>Subject Code</th>
<th>Type of Subject</th>
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<th>Teaching Scheme</th>
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Total Credits 26
## M. Pharm. Semester – II

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<td>2. Analysis of Recombinant Proteins and Diagnostics</td>
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# M. Pharm. Semester – III

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<td><strong>Total Credits</strong></td>
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*Note: The table represents the teaching scheme for M. Pharm. Semester – III, including the subject codes, type of subjects, and the teaching hours and credits for each.*
### M. Pharm. Semester – IV

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<tr>
<th>Sr. No.</th>
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**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:

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

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.
3. Instrumental Method of Analysis - Willard Dean & Merrit.
14. IP/BP/USP.
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).
8. Any other relevant exercises based on theory.
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, Terpenoids, Steroids and Resinous substances.

UNIT - V
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)

PRACTICAL’S:

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.
4. IUPAC - Chemistry of Natural Products - International symposium.
5. Zechmeister - Progress in the Chemistry of Organic Natural Products.
7. Wagner - Wolf- New Natural Products and Plant Drugs with Pharmacological, Biological or Therapeutic Activity
12. Backett - Stenlake - Practical Pharmaceutical Chemistry,
15. Greenbury - Metabolic Pathways.
16. Margaret - Brain - Secondary Plant Metabolism.
17. Wagner - Horhammer - Pharmacognosy and Phytochemistry
19. Lehninger - Principles of Biochemistry,
22. Rosenthaler - The Chemical Investigation of Plants.
SAURASHTRA UNIVERSITY M. PHARM. SYLLABUS
Semester – I (Pharmacognosy)
Subject of Specialization paper – II (Core Subject-III)
Natural Products
Subject code: 1612030102010300
Theory (Three hours per week, 4 credits)

1. Chemotaxonomy, significance in classification of medicinal plants, distribution of chemo taxonomical groups of constituents in plants.

2. Comparative photochemistry, 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 (adrenoceptors, opiate, benzodiazepine, ion channels, 5-HT, dopamine, adenosine, muscarinic, histamine, ATPase , GABA), cytotoxicity tests; bioassay- guided fractionations.


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

Subject code: 1612040002010401

(Three hours per week, 4 credits)

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

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

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

UNIT – IV
Preformulation study, Stability aspect and PEGylation based stability of Biopharmaceutical drugs, Stability study of Phytomedicines
REFERENCES

1. Modern Pharmaceutics by G. Banker.
10. Solubility and Solubilisation 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
(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
SAURASHTRA UNIVERSITY M. PHARM. SYLLABUS
Semester – I
Multidisciplinary / Elective paper - I
Methods in Biological Evaluation of Drugs Theory
Subject code: 1612040002010402
(Three hours per week, 4 credits)

UNIT-1
A. Biological standardization, general principles, Scope and limitation of bio-
analytical 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 2
   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.
UNIT -4
A. Drugs used in Peptic Ulcer, Respiratory disorders, Hormone and Endocrine disorders. 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.
1. Experiments on Electrophoresis.
2. Experiments of Chromatography.
   a) Thin Layer Chromatography.
   b) Paper Chromatography.
3. Experiments based on HPLC & GC.
4. Thermograph – Interpretation of spectra (at least 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
Subject code: 1612020102020200
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, Asiaticisides, Atropine, Solasodine, Bacoposide, Caffeine, Cubebol, Citral, Curcumin, Digitoxin, Diosgenin, Embelin, Emmetine, Ergometrine, Eugenol, Gingerol, Gycerrhentinic acid, Hesperidine, Kukkosides, Piperine, Plumbagin, Quinine, Quinidine, Recinolic acid, Sennosides, Taxol, Vinca alkoloids, Withaferin, etc. in extract / formulations.

Unit – II

3.0 Profiles for commercial cultivation technology and post harvest care of Ashwagandha, Belladona, Guggul, Papaya, Dioscorea, Isapgol, Umbelliferous fruits, Ginger, Turmeric, Aloe, 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.
5. HE Street Plant Tissue and Cell Culture, Blackwell Scientific Publication.
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.
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
   Subject code: ----
(Four hours per week, 6 credits)

PRACTICALS:
Laboratory examination including oral and practical examination in general course illustrative of theory section in the syllabus.
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
Subject code: 1612030102020300
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.
6.1 Genetic transformation methods, Hairy root cultures and their applications.

Unit - IV
6.2 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:

3. An introduction to plant tissue culture by M. K. Razdan.
4. Breeding field crops by John. M. P and David A. S.
6. Experiments in plant tissue culture by John H. D and Lorin W. R.
8. Plant cell and tissue culture by Jeffrey W. Pollard and John M. Walker.
10. Plant tissue culture by Street.
12. Biotechnology by Purohit and Mathur.
13. Biotechnological applications to tissue culture by Shargool.
15. Introduction to biotechnology by Bullock John.
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.
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
Subject code: 1612040002020401
(Four hours per week, 4 credits)

UNIT- I  20 hours

Introduction to Particulate and Vesicular Drug Delivery System
1. Particulate Drug delivery (Microshpres, Microcapsules, Nanospheres, Nanocapsules, Polymeric beads, etc.)
2. Vesicular Drug delivery (Liposomes, Ethosomes, Neosomes, etc.)

UNIT- II  20 hours

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

UNIT- III  10 hours

Recent advances in Liquid and Semisolid dosage forms
1. Liquid: Multiple Emulsions, Micro and Nano Emulsions, SEDDS, Nanosuspension
2. Semisolid: Ointments, Gels, Emulgels, Creams, Lotions

UNIT- IV  10 hours

Herbal and naturally derived Products:
1. Formulation development aspects
2. Regulatory and Product stability consideration.
Books Recommended:
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. Controlled drug delivery: Fundamentals and applications by Robinson
11. Microencapsulation 2nd Edition by Benita
12. Nanoparticulate Drug delivery systems by Thassu
13. Novel drug delivery systems by Chein
14. Pharmaceutical Dissolution Testing by Dressman
16. Compliance Handbook for Pharmaceuticals, Medical Devices, and Biologics by Carmen medina
17. Herbal Supplements - Drug Interactions: Scientific and Regulatory Perspectives by Y.W. Francis Lam
18. FDA Regulatory Affairs: A Guide for Prescription Drugs, Medical Devices, and Poucher's Perfumes, Cosmetics and Soaps by H. Butler
19. Nanotechnology in Drug Delivery (Biotechnology: Pharmaceutical Aspects) by Melgardt M. de Villiers
20. Targeted & Controlled Drug Delivery: Novel Carrier Systems by Vyas / Khar
22. Microparticulate Systems for the Delivery of Proteins and Vaccines (Drugs and the Pharmaceutical Sciences) by Smadar Cohen
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

4. Indian Pharmacopoeia -2007 Vol. 1-3 (Biotechnology products) The IP Commission, Ghaziabad
5. Related review Articles
Semester – II
Multidisciplinary / Elective paper – II
Quality Improvement Techniques in Drug Manufacturing Theory
Subject code: 1612040002020403
(Four hours per week, 4 credits)

Objectives of the course
1. To explore the students to various principles of improvement of quality manufacturing in pharmaceuticals.

Students learning outcomes
1. To get familiar with total quality management, PAT and various other principals which are the current concepts in manufacturing of pharmaceuticals.

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, EuropeanFoundation 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. 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)

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
UNIT-I

1. Intellectual property, importance and types of intellectual property
2. Paris conventional, 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 - 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 herbs / 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 Neutraceuticals:
5.1 Herbal Neutraceuticals 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.
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
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
23. Standardization of Botanicals –Testing and Extraction methods of Medicinal Herbs Dr. V. Rajpal Vol-I& II
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)

PRACTICAL’S:

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.