Syllabus For

Master of Pharmacy
(M. Pharm)

(Four semester full time programme)

Quality Assurance

Department of Pharmaceutical Sciences
Saurashtra University
Rajkot - 360 005

Saurashtra University - RAJKOT

Semester & Credit system

For Various Subject specialization of M. Pharm. Programme

M. Pharm. Semester – I

Sr. No.	Subject Code	Type of Subject	Subject	Teaching Scheme		
				Theory Hours/week	Practical Hours/week	**Credits**
1		Interdisciplinary-I	Modern Analytical Technique-I	3	-	**3**
2		Interdisciplinary-II	Practical –I(Modern Analytical Technique-I)	-	6	**3**
3		Core – I	Biological Evaluations and Clinical Research	6	-	**6**
4		Core – II	Practical - II (Biological Evaluations and Clinical Research)	-	12	**6**
5		Core – III	Good Manufacturing and Good Laboratory Practice	4	-	**4**
6		Multidisciplinary - I	Elective – I **1.** Pharmaceutical Preformulation **2.** Pharmaceutical and Industrial Biotechnology **3.** Methods in Biological Evaluation of Drugs	4	-	**4**
					Total Credits	**26**

M. Pharm. Semester – II

Sr. No.	Subject Code	Type of Subject	Subject	Teaching Scheme		
				Theory Hours/week	Practical Hours/week	**Credits**
1		Interdisciplinary-III	Modern Analytical Technique-II	3	-	**3**
2		Interdisciplinary-IV	Practical-III (Modern Analytical Technique-II)	-	6	**3**
3		Core – IV	Modern Pharmaceutical Analysis	6	-	**6**
4		Core – V	Practical - IV (Modern Pharmaceutical Analysis)	-	12	**6**
5		Core – VI	Regulatory Affairs and New Drug Applications	4	-	**4**
6		Multidisciplinary - II	Elective – II 1. NDDS: Multidisciplinary and Regulatory Aspects 2. Analysis of Recombinant Proteins and Diagnostics 3. Quality Improvement Techniques in Drug Manufacturing	4	-	**4**
					Total Credits	**26**

M. Pharm. Semester – III

Sr. No.	Subject Code	Type of Subject	Subject	Teaching Scheme		
				Theory Hours/week	Practical Hours/week	**Credits**
1		Interdisciplinary-V	Research Methodology	4	-	**4**
2		Interdisciplinary-VI	Patent, Design of experiments and Biostatistics	4	-	**4**
3		Core – VII	Validation, product development and stability testing	6	-	**6**
4		Core – VIII	Practical – V (Subject Specialization - V)	-	12	**6**
5		Core – IX	Seminar to Dissertation	4	-	**4**
					Total Credits	**24**

M. Pharm. Semester – IV

Sr. No.	Subject Code	Type of Subject	Subject	Teaching Scheme		
				Theory Hours/week	Practical Hours/week	**Credits**
1		Core- X to XII	Dissertation & Viva-Voice	-	-	**20**
					Total Credits	**20**

Total Credits: 96

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

Modern Analytical Techniques-I , Interdisciplinary paper - II

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.

IR, NMR and Mass Spectroscopy – Interpretation of spectra & Structural elucidation (atleast for 4 compounds each).

7 . Any other relevant exercises based on theory.

M. Pharm. Semester-I
SAURASHTRA UNIVERSITY M. PHARM. SYLLABUS
Semester – I (Quality Assurance)
Subject of Specialization paper – I (Core Subject-I)
Biological Evaluations and Clinical Research (Theory)

(Six hours per week, 6 credits)

Unit-I

1. Application of analytical methods to product obtained through genetic engineering
2. Amino acid sequence analysis and Tryptic mapping
3. Ion exchange amino acid analysis and Isoelectric focusing

Unit-I

1. Analysis of Impurities in Active Pharmaceutical Ingredients and Pharmaceuticals
2. Biological classification system (BCS); its significance on dissolution study and application in dosage form development.

Unit-III

1. Good Clinical Practice
2. Development of Monograph

Unit-IV

1. Biological Standardization: General Principles, Quality Control Test, Scope & limitations of Bioassays. Bio- assays of some Official Drugs

Unit-V

1. Sterility Tests: Methodology & Interpretation
2. Pyrogens: Production, Chemistry Properties of Bacterial Pyrogens & Endotoxins, official Pyrogen tests

M. Pharm. Semester-I
SAURASHTRA UNIVERSITY M. PHARM. SYLLABUS
Semester – I (Quality Assurance)
Subject of Specialization paper – I (Core Subject-II)
Biological Evaluations and Clinical Research (Practical)

(Twelve hours per week, 6 credits)

PRACTICAL:

1. Oral and practical examination in general course illustrative of theory section
2. Statistical analysis include data acquisition, processing and retrievals
3. Practice in developing of analytical method of drug substances

M. Pharm. Semester-I
SAURASHTRA UNIVERSITY M. PHARM. SYLLABUS
Semester – I (Quality Assurance)
Subject of Specialization paper – II (Core Subject-III)
Good Manufacturing and Good Laboratory Practice

(Four hours per week, 4 credits)

Unit-I

1. Concepts of Philosophy of Quality assurance Good and Quality control as applied to the pharmaceutical industry
2. Quality Audit

Unit-II

1. Calibration of Equipment & Instruments
2. Qualification of equipments

Unit-III

1. Good Laboratory Practices
2. Water determination

Unit-IV

1. Philosophy of GMP, cGMP, Schedule–M and Rules governing the manufacture of medicine in India.

Unit-V

1. Application of ISO criteria to the production of different types of pharmaceutical products.
2. Total Quality Management

Multidisciplinary/ Elective Subject-I
SAURASHTRA UNIVERSITY M. PHARM. SYLLABUS
Semester – I
Multidisciplinary / Elective paper - I
Pharmaceutical Preformulation Theory
(Four hours per week, 4 credits)

UNIT – I

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

UNIT – II

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

UNIT - III

Dosage form consideration in preformulation, solid dosage form, solution formulations, emulsion, suspension, freeze dried products, topical, pulmonary, evaluations and its regulatory considerations, stability tastings, order of reaction, antioxidants, chelating agents, impurity, GMP related to bulk drugs and APIs.

UNIT – IV

Characterization of Biopharmaceutical drugs and Phytomedicines.

REFERENCES

1. Modern Pharmaceutics by G. Banker.
2. Physical Characterization of Pharmaceutical Solids by H. Brittain.
3. Polymorphism in Pharmaceutical Solids by H. Brittain.
4. Solid State Chemistry of Drugs by S.R. Byrn.
5. Chemical Stability of Pharmaceuticals by K.A. Connors.
6. Pharmaceutical Preformulation and Formulation by M. Gibson.

7. Solubility Behavior of Organic Compounds by D.J.W. Grant and T. Higuchi.
8. Remingtons “Pharmaceutical Sciences” 19th edition.
9. Pharmaceutical Preformulation by J. Wells.
10. Solubility and Solubilization in Aqueous Media by S. Yalkowsky.
11. Pharmaceutics “The Science of Dosage form design” by Aulton.
12. Hand book of Preformulation by Sarfaraz K. Niazi.

SAURASHTRA UNIVERSITY M. PHARM. SYLLABUS

Semester – I

Multidisciplinary / Elective paper - I

Pharmaceutical and Industrial Biotechnology Theory

(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/sepuence, shape, activity.

Unit IV

Industrial application of biotech products: industrial enzymes (examples), immobilization of enzymes, their applications in industry, Immobilized Enzyme engineering, Kinetics of immobilized enzymes, novel methods for enzyme and vaccine production.

READING MATERIAL

1. **Jens T. Cartensen and C. T. Rhodes**, Drug stability principle and practice, 3rd ed. Vol. 107, Marcel Dekker
2. **Rodney pealman, Y. John wang,** formulation characterization and stability of protein drugs, (1996)
3. **Eugene J. McNally, Jayne E. Hasted**, protein formulation and delivery 2nd Ed. Informa-healthcare.

4. **Sven frokjaer and lars hovgaard,** pharmaceutical formulation development of peptides and proteins (2000) Taylor and Franceis
5. **Sarfaraz K. Niazi**, Handbook of Preformularion (2007), Informa Healthcare

SAURASHTRA UNIVERSITY M. PHARM. SYLLABUS

Semester – I

Multidisciplinary / Elective paper - I

Methods in Biological Evaluation of Drugs Theory

(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 teratogenecity and mutagenecity. Various guidelines for toxicity studies. Animal experiments assessing safety of packaging materials. **6**

C. Selected topics in screening of drugs: **2**

- **a.** Recent advances in Transgenic and Knockout animals
- **b.** Administration of Neuropeptides and Neurohormones by Intracerebroventricular (ICV) route in rats.
- **c.** Screening models for drug abuse like alcohol addiction, dependence and withdrawal syndrome.
- **d.** Biostatistics and calculation of doses in experimental pharmacology

Unit -2

A. Pyrogens: Sources, Chemistry and properties of bacterial pyrogens and endotoxins, Official pyrogen tests **2**

B. Microbiological assay of antibiotics and vitamins. **4**

C. Biological evaluation of drugs--Screening and evaluation (including principles of screening , development of models for diseases : In vivo models / In vitro models / cell line study) techniques of the following:

Unit -3

A. Parasympathomimetics, Parasympathetic blocking agents, Sympathomimetics, Sympathetic blocking agents, Ganglion stimulants and blockers, Neuromuscular stimulants and blockers. **8**

B. General and local Anesthetics, Sedatives and Hypnotics, Antiepileptics, Psychopharmacological agents, Analgesics, Anti-inflammatory agents, Anti-Parkinson's drugs, CNS Stimulants. **12**

C. Cardiotonics, Anti-hypertensive drugs, Anti-arrhythmic drugs, Drugs used in Ischemic Heart Diseases, Drugs used in Atherosclerosis. **10**

Unit -4

A. Drugs used in Peptic Ulcer, Respiratory disorders, Hormone and Endocrine disorders. Anti fertility agents and diuretics. **8**

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

Books recommended (Latest Edition):

1. Screening methods in pharmacology (vol I & II)–R.A. Turner
2. Drug Discovery and Evaluation in Pharmacology assay: Vogel
3. Design and analysis of animal studies in pharmaceutical development, Chow, Shein, Ching.
4. Evaluation of Drug Activity: Pharmacometrics D.R. Laurence
5. Animal and Clinical pharmacologic Techniques in Drug Evaluation-Nodine and Siegler
6. Pharmacology and Toxicology- Kale S.R.
7. Fundamentals of experimental Pharmacology- Ghosh M.N.
8. Handbook of Experimental Pharmacology- Goyal R.K.
9. Handbook of Experimental Pharmacology- Kulkarni S.K.

M. Pharm. Semester-II

SAURASHTRA UNIVERSITY M. PHARM. SYLLABUS
Semester – II
Interdisciplinary paper - III
Modern Analytical Techniques-II Theory
(Three hours per week, 3 credits)

UNIT-I

CHROMATOGRAPHIC TECHNIQUES : 15 Hours

a) Classification of chromatographic methods based on mechanism of separation. Theories of
chromatographic separation.

b) Principles, elution techniques, instrumentation, derivatization and applications of gas chromatography, HPLC and HPTLC.

c) Principles, elution techniques, applications of ion exchange and ion pair chromatography, affinity
chromatography, size exclusion chromatography, chiral chromatography, super fluid chromatography (SFC), GC-MS and LC-MS.

UNIT-II

THERMAL METHODS OF ANALYSIS : 5 Hours

Theory, instrumentation and applications of Thermo Gravimetric Analysis (TGA), Differential Thermal Analysis (DTA), Differential Scanning Calorimetry (DSC) and Thermo Mechanical Analysis (TMA).

UNIT-III

X-RAY DIFFRACTION METHODS : 4 Hours

Introduction, generation of X-rays, X-ray diffraction, Bragg's law, X-ray powder diffraction, interpretation of diffraction patterns and applications.

OPTICAL ROTARY DISPERSION : 2 Hours

Principle, Plain curves, curves with cotton effect, octant rule and its applications with example, circular dichroism and its relation to ORD.

UNIT-IV

RADIO IMMUNO ASSAY : 4 Hours

Introduction, Principle, Theory and Methods in Radio Immuno Assay, Related Immuno Assay procedures and Applications of RIA Techniques. Enzyme immuno assay- ELISA and EMIT

ELECTROPHORESIS : 3 Hours

Theory and principles, classifications, instrumentation, moving boundary electrophoresis, Zone Electrophoresis (ZE), Isoelectric focusing (IEF) and applications.

Books Recommended:

1. Instrumental Methods of Analysis - Scoog and West.
2. Spectrometric Identification of Organic Compounds - Silverstein et., al.
3. Instrumental Method of Analysis - Willard Dean & Merrit.
4. Text Book of Inorganic Chemistry — A.I. Vogel.
5. Pharmaceutical Chemistry Vol. I & Vol. II — Becket and Stanlake.
6. Pharmaceutical Chemistry Vol. I & Vol. II — L.G.Chatten.
7. Text Book of Pharmaceutical Analysis - K.A. Connors.
8. Pharmaceutical Analysis — Hiquchi, Bechmman, Hassan.
9. Methods of Drug Analysis — Gearien, Graboski.
10. Text Book of BioPharmaceutic Analysis — Robert Smith and James Stewart.
11. Pharmaceutical Analysis — Modern methods — Part A and B — Munson James. W.
12. Quantitative Analysis of Drugs — Garrot.
13. Quantitative Analysis of Drugs in Pharmaceutical Formulations — P. D. Sethi.
14. IP/BP/USP.
15. Application of Absorption Spectroscopy of Organic Compounds — Dyer.
16. Analytical Profiles of Drug Substances — Florey [Volume 13].
17. Spectroscopy of Organic Compound - P. 5. Kalsi, Wiely Eastern Ltd., New Delhi.
18. Absorption Spectroscopy of Organic Molecules — V. M. Parikh, Addision — Wesley Publishing Company, London.

SAURASHTRA UNIVERSITY M. PHARM. SYLLABUS

Semester – II

Interdisciplinary paper - IV

Modern Analytical Techniques-II Practical

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

M. Pharm. Semester-II

SAURASHTRA UNIVERSITY M. PHARM. SYLLABUS

Semester – II (Quality Assurance)

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

Modern Pharmaceutical Analysis (Theory)

(Six hours per week, 6 credits)

Unit-I

1. Analysis of solid oral dosage form, Injectable dosage form, Drugs in biological fluids and Cosmetics
2. Testing of Packaging materials

Unit-II

1. Dissolution study: Importance, objectives, equipments,
2. Selection of dissolution medium and conditions,

Unit-III

1. Comparison of dissolution profile by similarity and dissimilarity factor
2. In-vivo and In- vitro Co-relation (IVIVC)

Unit-IV

1. Analytical Aspects of Preformulation study
2. Manufacturing process design and development in process controls of Tablets, Capsule, Liquid orals, Ophthalmic applications, Aerosols, Sterile parenterals and Scale up operations

Unit-V

1. Pharmacokinetic & Bioequivalence study
2. Requirement criteria for Bioequivalence study.
3. Study of special toxicities like Teratogenicity & Mutagenicity.

M. Pharm. Semester-II

SAURASHTRA UNIVERSITY M. PHARM. SYLLABUS

Semester – II (Quality Assurance)

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

Modern Pharmaceutical Analysis (Practical)

(Twelve hours per week, 6 credits)

1. Oral and practical examination in general course illustrative of theory section
2. Statistical analysis include data acquisition, processing and retrievals
3. Practice in analysis of solid oral dosage form, Injectable dosage form, Drugs in biological fluids and Cosmetics, Packaging material
4. Dissolution study, Comparison of dissolution profile by similarity and dissimilarity factor and IVIVC

SAURASHTRA UNIVERSITY M. PHARM. SYLLABUS

Semester – II (Quality Assurance)

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

Regulatory Affairs and New Drug Applications Theory

(Four hours per week, 4 credits)

Unit-I

1. Contract manufacturing
2. Certification and Licensing Procedures
3. Quality Safety and Legislation for Cosmetic and Herbal products

Unit-II

1. Site Master File
2. Drug Master File
3. Quality Control Documentation
4. Batch release documents and Retentions of records

Unit-III

1. Drug regulatory and accrediting agencies of world and their guidelines including USFDA, MCA, TGA, MHRA, ANVISA, CTD, WHO, ICH, SUPAC etc.
2. Common Technical Document (CTD)
3. Electronic version of the Common Technical Document (eCTD)

Unit-IV

1. IND, NDA, ANDA, Concept of para I to IV, exclusivity: Content, format and Application.

Unit-V

1. Regulatory aspects of Bulk drug, Pharmaceutical and Biotechnology derived product.
2. Recent amendments to Drug & Cosmetic Act and other relevant rules.
3. Relevant provisions of Consumer Protection Act, Environment Protection Act, Factory Act Regulatory aspects of Bulk drug, Pharmaceutical and Biotechnology derived product.
4. Recent amendments to Drug & Cosmetic Act and other relevant rules.
5. Relevant provisions of Consumer Protection Act, Environment Protection Act, Factory Act

Multidisciplinary/ Elective Subject-II

SAURASHTRA UNIVERSITY M. PHARM. SYLLABUS

Semester – II

Multidisciplinary / Elective paper – II

NDDS: Multidisciplinary and Regulatory Aspectrs Theory

(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 **(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, Vlumes: 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

(Four 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.

UnitIV

- 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

SAURASHTRA UNIVERSITY M. PHARM. SYLLABUS

Semester – II

Multidisciplinary / Elective paper – III

Quality Improvement Techniques in Drug Manufacturing Theory

(Four hours per week, 4 credits)

UNIT- I **(6 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 **(6 hours)**

Total Quality Management and Process steps of Total Quality Management (TQM)
Statistical process control – SPC

UNIT- III **(6 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 **(6 hours)**

Process and Analytical Technology – PAT
Failure Mode Effect Analysis – FMEA

UNIT- V **(6 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
(Four hours per week, 4 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. 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)
   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 Furmess
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

(Four hours per week, 4 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 and its applications in relation to subject specialization
Design of experiments, Factorial designs
Grid search technique, Response surface methodology, contour plots, etc. its application in pharmaceutical sciences.

SAURASHTRA UNIVERSITY M. PHARM. SYLLABUS

Semester – III (Quality Assurance)

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

Validation, product development and stability testing Theory

(Six hours per week, 6 credits)

Unit-I

1. Validation: Types, Scope, Objectives and Apllication
2. Validation of processes
   a. Non- sterile: Mixing, granulation, drying, compression, filtration, filling
   b. Sterile: Dry heat sterilization, autoclaving, membrane filtration, Gaseous sterilization and sterilization by radiation.

Unit-II

1. Validation of Personnel.
2. Validation of Computer
3. Validation of air handling equipment and facilities

Unit-III

1. Validation of water supply system
2. Cleaning Validation

Unit-IV

1. Basic concept and objectives of stability study,
2. Order of reaction and their application in predicting shelf life and half-life of pharmaceutical formulations
3. Importance of accelerated stability study,

Unit-V

1. Effect of various environmental/processing factors (i.e. light, pH, metal etc.,) on stability of the formulation
2. Regulatory requirement related to stability testing with emphasis on matrixing/bracketing technique, climatic zone, photo stability testing etc.,

SAURASHTRA UNIVERSITY M. PHARM. SYLLABUS

Semester – III (Quality Assurance)

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

Validation, product development and stability testing Practical

(Twelve hours per week, 6 credits)

PRACTICAL:

1. Oral and practical examination in general course illustrative of theory section
2. Statistical analysis include data acquisition, processing and retrievals
3. Practice in Preparing validation documents, SOPs
4. Validation of Analytical procedure
5. Calibration of Instruments
6. stability testing with emphasis on matrixing/bracketing technique, climatic zone, photo stability testing
7. Practical regarding water determination

Reference Books for Quality Assurance

1. Alfred Larry Branen-Antimicrobial in food- P Michael division publishing corporation
2. B.T.Loftus & R.A.Nash, "Pharmaceutical Process Validation", Drugs and Pharm Sci. Series, Vol. 23, Maarcel Dekker Inc., N.Y.
3. Brain & Turner-The practical evaluation of phytopharmaceutical by
4. British Pharmacopoeia
5. Burn, Finiey and Godwin : Biological Standardisation, 2nd Edition, Oxford University Press, London.
6. Controller of Publication, Govt. of India - Indian Pharmacopeia, Vol. I and II -1996.
7. D.C.Garratt “The quantitative analysis of drugs” 2nd edition.
8. Dr. A. Patani : The Drugs and Cosmetics Act 1940, Eastern Book Company, Lucknow
9. G.S, Banker & C.T.Rhodes, "Modern Pharmaceutics",, Vol. 7, Maracel Dekker Inc., N.Y.
10. Good Laboratory Practice Regulations, 2nd Edition, Sandy Weinberg, Vo. 69, Decker Series.
11. H. Willig, M.M.Tuckeman and W.S.Hitchings, "Good Manufacturing Practices for Pharmaceuticals", Drugs and Pharm. Sci. Series, Vol. 16, Marcel Dekker Inc.,
12. I Kerese-Method of protein analysis
13. Indian Pharmacopoeia
14. J T Cartenson- Drug stability- Principles and Practices, Marsel Deckker.
15. K Maitra, S K.Ghosh- A guide to Total Quality Management
16. M B Jacobs- The chemical analysis of foods and food products.
17. M E Swartz- Analytical method development & validation.
18. M J Pelezar- “Microbiology”
19. M M Rieger -Henry,s cosmeticology
20. P. Borc- Cosmetic analysis- selective methods and techniques

21. P. P. Sharma -How to practice GMPs
22. P.P.Sharma - Cosmetics Formulation, Manufacturing and Quality control.
23. Quality Assurance Guide by Organisation of Pharmaceutical products of India.
24. Quality Assurance of Pharmaceuticals – A compendium of guidelines and related materials – Vol. I – WHO Publications.
25. S G Ghosh-ISO 9000 and Total Quality Management
26. S SNielsen, “Introduction to the Chemical analysis of foods”.
27. S. Bolton, "Pharmaceutical Statistics: Practical & Clinical Applications", Drugs and Pharm. Sci. Series, Vol. 25, Marcel Dekker Inc., N.Y.
28. The International Pharmacopoeia Vol. 1,2,3,4 - 3rd Edition, General Methods of Analysis and Quality specification for Pharmaceutical Substances, Excipients and Dosage forms.
29. Tortora, Funke, Case- Microbiology- An introduction.
30. U.S. Pharmacopoeia
31. WHO Guide line for the quality control of herbal plant material.