Syllabus For

Master of Pharmacy
(M. Pharm)

(Two year full time course)

Pharmaceutics

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 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.

SAURASHTRA UNIVERSITY M. PHARM. SYLLABUS

Semester – I (Pharmaceutics)

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

Pharmaceutical Formulation, Development & Biopharmaceutics Theory

(Four hours per week, 6 credits)

Unit - I

1. Preformulation studies **8 hour**

(a) Physical, Chemical and Pharmaceutical factors influencing formulation

(b) Solid-state characterization: Crystallinity, hygroscopicity, Particle size and particle size distribution, compaction properties, distribution and measurement of forces within the powder mass undergoing compression, effect of particle size, moisture content, lubrication, etc on strength of tablet.

(c) Crystalline and polymorphism and its evaluation. Rationale for selecting the preferred polymorph/crystalline form

(d) General principles and applications of various characterization techniques viz: Differential thermal analysis Differential scanning calorimetry, X-Ray diffraction, FTIR in Preformulation study.

(e) Drug-excipient compatibility study

(f) Traces of organic volatile impurities (OVIs) and their regulatory limits (residual solvents).

(g) Preformulation studies of Biotechnological derived products and reference guidelines.

2. Stability Study **8 hour**

(a) Basic concept and objectives of stability study,

(b) Order of reaction and their applications in predicting shelf life and half life of pharmaceutical formulations,

(c) Importance of accelerated stability study,

(d) Effect of various environmental/ processing factors like light, pH, temperature, etc. on stability of the formulation and techniques for stabilization of product against the same.

(e) Regulatory requirements related to stability testing with emphasis on matrixing / bracketting techniques, climates zone, impurities in stability study, photostability testing, ICH guidelines, USFDA guidelines etc.

(f) Impurities in stability study.

(g) Applications of microcalorimetry in stability study.

Unit – II

1. Solubilization and solubilized system **8 hour**

(a) Theoretical aspects and applications.

(b) Techniques for improvement in drug solubilization for development of various dosage forms.

2. Dissolution study **8 hour**

(a) Importance, objectives, equipments,

(b) Biological classification system (BCS); its significance on dissolution study and application in dosage form development.
(c) Selection of dissolution media and conditions.
(d) Comparison of dissolution profile by model independent (similarity and dissimilarity factor) and dependent methods.
(e) Dissolution study for NDDSs.
(f) Modification in dissolution condition to mimic in-vivo conditions for oral dosage forms, Parenteral: depots, implants and ophthalmic dosage forms, Topical and targeted drug delivery systems.

Unit - III

1. Drug Absorption 8 hour

(a) Factors affecting drug absorption; i.e. Physicochemical, Physicality and Pharmaceutical.
(b) Method of studying bioavailability and bioequivalence.
(c) Transport across CACO 2 monolayers, Other Cell-lines to predict- Biological, Pharmaceutical and Analytical considerations

2. In-vitro In-vivo Correlation (IVIVC) 6 hour

(a) Methods of establishing IVIVC
(b) Factors affecting IVIVC

Unit - IV

1. Pharmacokinetic parameters 8 hour

(a) Basic concept and importance of biological half-life, volume of distribution, renal clearance, total body clearance, plasma protein binding, absorption rate constant, elimination rate constant.
(b) Analysis of blood and urine data, compartment models, kinetics of one and two compartment model.
(c) Non-Linear Pharmacokinetics.

2. Cosmetic, Dental and Herbal products 6 hour

(a) Formulation and evaluation of various cosmetic and dental products
(b) Formulation and evaluation of products containing herbal ingredients.

Book Recommended:

1. Remingtons “Pharmaceutical Sciences” 19th edition.
2. Lachman “The theory and Practice of Industrial Pharmacy” 3rd edition.
3. Pharmaceutics “The Science of Dosage form design” by Aulton
4. Pharmaceutical dispensing by Husa.
5. Modern pharmaceutics by G. S. Banker.
6. Encyclopedia of pharmaceutical technology Volumes: 1 to 19.
7. Pharmaceutical dissolution testing by Banaker.
8. United States Pharmacopeia.
9. Techniques of Solubilization of Drugs by Yalkowsky.

10. Drug stability (Principles and Practices) by Jens. T. Carstensen.
11. Stability of drug and dosage forms by Yoskioka.
12. Applied Biopharmaceutics and pharmacokinetics by Leon Shargel, 4th edition.
13. Pharmacokinetics by Welling and Tse.
14. Pharmacokinetics by Gibaldi and Perrier
15. Biopharmmaceutics and pharmacokinetics: An introduction by Notari.
16. Pharmacokinetics for pharmaceutical scientist by John Wagner.
17. Dissolution, Bioavailability and Bioequivalence by Abdul.
18. Clinical Pharmacokinetics, Concepts and applications by Rowland and Tozer.
19. Novel Cosmetic Drug Delivery Systems, by Magdassi and Touitou.
20. Cosmetics by Sagerin.
21. Perfumes, Cosmetics and Soaps by Poucher.

SAURASHTRA UNIVERSITY M. PHARM. SYLLABUS

Semester – I (Pharmaceutics)

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

Pharmaceutical Formulation, Development & Biopharmaceutics Practical

(Four hours per week, 6 credits)

1. To prepare, evaluate and supply microspheres.
2. To prepare, evaluate and supply Aspirin microspheres.
3. To prepare, evaluate and supply microcapsules.
4. To prepare, evaluate and supply Aspirin Effervescent Tablets.
5. To prepare, evaluate and supply Chewable Antacid Tablets.
6. To prepare, evaluate and supply Floating Tablets.
7. Direct Warm Spheronization.
8. To prepare and evaluate Suppositories.
9. To prepare, evaluate and supply Cold Cream.
10. To optimize the formula for vanishing cream and to evaluate it.
11. To prepare Toothpaste.
12. To optimize the formula for gel and to evaluate it.
13. To optimize the formula for Lather Shaving Cream and to evaluate it.
14. Tablet Coating (Dip Coating)
15. Preparation and evaluation of multiple emulsion.
16. To carry out pan coating of tablets.
17. Preparation and evaluation of Fast Dispersible Tablets.
18. Industrial Visit.

Any other practical related to the Theory portion of this syllabus.

SAURASHTRA UNIVERSITY M. PHARM. SYLLABUS

Semester – I (Pharmaceutics)

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

Industrial Pharmacy Theory

(Three hours per week, 4 credits)

Unit – I (20 hrs)

1 Pharmaceutical factory location: Selection, layout and planning. Utilitiy services, Service facilities, HVAC and personnel facilities.
2 Preparation of qualitative and quantitative departmental layout with equipments required for different dosage forms like Aerosols, Powders, Tablets, Hard and Soft gelatin capsules, Liquid and Semisolid preparations, Sterile products, Cosmetic products, Veterinary and Surgical products, NDDSs (Liposome, TDDS).

Unit – II (10 hrs)

1 Preparation of documents like batch manufacturing record, batch packing record, validation protocols.
2 Preparation of standard operative procedure (SOPs) for equipments and manufacturing or processing steps.

Unit – III (15 hrs)

1 Detailed study of the equipments required in the manufacture of different dosage forms as per Schedule-M.
2 GMP and its implementation

Unit – IV (15 hrs)

1 Production planning and materials control.
2 Pilot plant, scale up technique, SUPAC guidelines.
3 Validation master plan, change control and sampling plans.

References

1. Lachman “The theory and Practice of Industrial Pharmacy
2. Remingtons “Pharmaceutical Sciences”
3. Bentley’s Pharmaceutics.
4. Pilot plants model and scale-up methods, by Johnstone and Thring.
5. GMP practices for pharmaceutical –James Swarbrick.
6. How to practice GMPs by P.P.Sharma.
7. Chemical Engineering Plant Design by Vibrant.
8. Pharmaceutical Process Validation by Loftus and Nash.
9. Drug and Cosmetic Act 1940 and rules.

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
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/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

(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, 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

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

SAURASHTRA UNIVERSITY M. PHARM. SYLLABUS
Semester – II (Pharmaceutics)
Subject of Specialization paper – III (Core Subject-IV)
Novel Drug Delivery System Part-I Theory
(Four hours per week, 6 credits)

UNIT - I **(10 Hours)**

1. General methods of design and evaluation of controlled release products.
2. Extended release dosage forms – purpose, types, designs and evaluation.

UNIT – II **(20 Hours)**

Recent Innovations in Conventional Dosage Forms – including site specific and time release modulation.

1. Tablets: Osmotic, Colon target, Gastro-retentive, Buccal, Sublingual.
2. Capsules: Modified release, Peyer's patches targeted drug delivery system – lymphatic delivery. Delivery system targeted to small intestine, Rectal drug delivery system
3. Powders: Particle coating, Taste-masking.

UNIT – III **(20 Hours)**

1. Semi-solids: Ointments, Gels, Emulgels, Creams, Lotions, etc…
2. Parenteral: Controlled release systems, Depots, Injectable suspensions etc..
3. Liquids: Micro and Nano emulsions, Nanosuspensions, Rheologically modified systems, controlled release systems.

UNIT – IV **(10 Hours)**

1. Packaging components and its evaluation: factors affecting selection, Types and classification, Primary and secondary and regulatory aspects. Contribution in stability of the dosage forms.

SAURASHTRA UNIVERSITY M. PHARM. SYLLABUS
Semester – II (Pharmaceutics)
Subject of Specialization paper – III (Core Subject-V)
Novel Drug Delivery System Part-I Practical
(Four hours per week, 6 credits)

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

REFERENCE BOOKS

1. Joseph R. Robinson, "Sustained and Controlled Release Drug Delivery Systems", Drugs & Pharm. Sci. Series, Vol. 6 Marcel Inc.,N.Y.
2. Yie W. Chien, Novel Drug Delivery Systems, Drugs and Pharm. Sci. Series, Vol.14, Marcel Dekker Inc.N.Y.
3. J.R.Robinson and Vincent H.L. Lee, Controlled Drug Delivery, Drugs and Pharm. Sci. Series, Vol. 29, Marcel Dekker Inc. N.y.
4. **Remingtons** "Pharmaceutical Sciences" 19th edition.
5. **Lachman "**The theory and Practice of Industrial Pharmacy" 3 rd edition.
6. Pharmaceutics "The Science of Dosage form design" **by Aulton**
7. Pharmaceutical dispensing **by Husa**.
8. Modern pharmaceutics **by G. S. Banker.**
9. Encyclopedia of pharmaceutical technology Volumes: 1 to 19.
10. Pharmaceutical dissolution testing **by Banaker.**
11. United States Pharmacopeia.
12. Drug stability (Principles and Practices) **by Jens. T. Carstensen.**
13. J.N.Nixon, Microencapsulation, Drugs and Pharm. Sci. Series, Vol.3, Marcel Dekker Inc., N.Y.,
14. G. Jolles and R.H. Wooldridge, Drug Design – Faact of Fantasy? Academic Press,1984
15. J.R.Juliano, Drug Delivery Systems Oxford University Press, Oxford, 1980.
16. M.I.Gutcho, Microcapsules and Microencapsulation Techniques, Noyes Data Corporation, 1976.
17. E.B.Roche, Design of Biopharmaceutical properities through prodrug and analogs, Am. Pharm. Assoc. Academy of Pharm. Sci. 1977.
18. Lisbeth, llum & Stanley S. Davis. Polymers in controlled drug delivery wright Bristol (1987).

SAURASHTRA UNIVERSITY M. PHARM. SYLLABUS

Semester – II (Pharmaceutics)

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

Global Regulatory Requirements Theory

(Three hours per week, 4 credits)

UNIT - I **(10 Hours)**

1. Validation of Pharmaceutical Processes, equipments/apparatus, basic concept in analytical method development for dosage forms, Computer System validation, ERP and SAP systems.

UNIT - II **(10 Hours)**

2. Basics in Drug approval process with reference to: Orange book, Freedom of information, IIG, DMF, Historical aspects with various phases of drug development and approval.

UNIT - III **(20 Hours)**

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

UNIT - IV **(20 Hours)**

4. Brief and comparative introduction to various regulatory agencies: USFDA, MCA, TGA, MHRA, ANVISA, CTD, WHO, ICH, SUPAC etc.

References Books:

The guidance documents shall be procured from the website of the respective Government.

Multidisciplinary/ Elective Subject-II

SAURASHTRA UNIVERSITY M. PHARM. SYLLABUS
Semester – II
Multidisciplinary / Elective paper – II
NDDS: Multidisciplinary and Regulatory Aspectrs Theory
(Three 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
(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-Iine 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

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. 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

(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 (Pharmaceutics)
Subject of Specialization paper – V (Core Subject-VII)
Novel Drug Delivery System Part-II Theory
(Four hours per week, 6 credits)

UNIT-I

Vesicular Drug Delivery System: Neosomes, Liposomes, Phytosomes, Ethosomes etc.

Particulate drug delivery systems: Microspheres, Microcapsules, Nanospheres, Nanocapsules, Nanoparticles, Polymeric Beads etc.

UNIT-II

Transdermal/skin drug delivery systems: Principles of skin permeation, sorption promoters, pharmacokinetics of skin permeation, development and evaluation of transdermal devices, transdermal controlled release delivery.

Recent advancements in pressurized drug delivery system, Aerosols, etc.

UNIT-III

Protein/peptide drug delivery systems, enzyme, epithelial/endothelial barriers, pharmacokinetics, different routes of delivery, practical considerations.

Biodegradable Polymers and its application in Formulation design.

UNIT-IV

Dental cosmetics and periodontal drug delivery systems.

Buccal drug delivery systems: Muco-adhesion – principles and theory involved, muco-adhesive materials, selection and evaluation – types of muco-adhesive delivery systems like mouth dissolving and sublingual tablet, chewing gum, buccal patches – design and evaluation.

SAURASHTRA UNIVERSITY M. PHARM. SYLLABUS
Semester – III (Pharmaceutics)
Subject of Specialization paper – V (Core Subject-VIII)
Novel Drug Delivery System Part-II Practical
(Four hours per week, 6 credits)

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

REFERENCE BOOKS

1. J.N.Nixon, Microencapsulation, Drugs and Pharm. Sci. Series, Vol.3, Marcel Dekker Inc., N.Y.,
2. Joseph R. Robinson, "Sustained and Controlled Release Drug Delivery Systems", Drugs & Pharm. Sci. Series, Vol. 6 Marcel Inc.,N.Y.
3. Yie W. Chien, Novel Drug Delivery Systems, Drugs and Pharm. Sci. Series, Vol.14, Marcel Dekker Inc.N.Y.
4. M.I.Gutcho, Microcapsules and Microencapsulation Techniques, Noyes Data Corporation, 1976.
5. Lisbeth, llum & Stanley S. Davis. Polymers in controlled drug delivery wright Bristol (1987)
6. Pharmaceutical Biotechnology, Second edition- 2002, Ed. D. J. A. Cromelin and R. D. Sindelar Taylor and Francis group.
7. Gilbert S Banker, Christophex T Rhodes Modern Pharmaceutics, 4th edition-2008, Marcel Dekker.
8. S P Vyas and Roop K Khar Controlled Drug Delivery:concepts and advances. Vallabh Prakashan-2008.
9. Biomaterials science: An Introduction to Materials in Medicine, Buddy D. Ratner, Allan S. Hoffman Academic Press-1996.