



**Revised Syllabus For  
Master of Pharmacy  
(M. Pharm)  
(Two year full time course)**

**Pharmaceutics**

**Effective from June' 2014**

**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
<b>Total Credits</b>						<b>26</b>

## 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	-	<b>3</b>
2		Interdisciplinary-IV	Practical-III (Modern Analytical Technique-II)	-	6	<b>3</b>
3		Core – IV	Modern Pharmaceutical Analysis	6	-	<b>6</b>
4		Core – V	Practical - IV (Modern Pharmaceutical Analysis)	-	12	<b>6</b>
5		Core – VI	Regulatory Affairs and New Drug Applications	4	-	<b>4</b>
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	-	<b>4</b>
<b>Total Credits</b>						<b>26</b>

## 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	-	<b>4</b>
2		Interdisciplinary-VI	Patent, Design of experiments and Biostatistics	4	-	<b>4</b>
3		Core – VII	Validation, product development and stability testing	6	-	<b>6</b>
4		Core – VIII	Practical – V (Subject Specialization - V)	-	12	<b>6</b>
5		Core – IX	Seminar to Dissertation	4	-	<b>4</b>
<b>Total Credits</b>						<b>24</b>

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	-	-	<b>20</b>
<b>Total Credits</b>						<b>20</b>

**Total Credits: 96**

# SAURASHTRA UNIVERSITY SYLLABUS

## M. Pharm. Semester-I

### Interdisciplinary paper - I

#### Modern Analytical Techniques-I Theory

(Three hours per week, 3 credits)

#### **OBJECTIVE OF THE COURSE:**

To make students familiar with the principles of modern analytical techniques and its application in pharmacy.

#### **STUDENT LEARNING OUTCOMES/OBJECTIVES:**

At the end of the course, the student will be able to understand the fundamental concept of modern analytical techniques, which is important for qualitative as well as quantitative analysis of drug substances and drug product. Moreover, several aspects of the interpretations of the various spectroscopic data will be taught.

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#### **UNIT-I**

(12 hours)

#### **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**

(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 Pharmacy, interpretation of spectra. C13 NMR-Introduction, Natural abundance, C13 NMR Spectra and its structural applications.

### **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.
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, Addison — 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 Pharmacopoeial compounds.
7. IR, NMR and Mass Spectroscopy – Interpretation of spectra & Structural elucidation (at least for 4 compounds each).
8. 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 (Six hours per week, 6 credits)

#### Objectives of the course

1. To get acquainted with preformulation, method of preparation, evaluation and application of various pharmaceutical mechanisms and theory in formulation development with global stability requirements
2. To Study the absorption, distribution, metabolism and excretion of drugs
3. The overall study of biopharmaceutics and pharmacokinetics will help in design of drug delivery system and development of pharmaceutical formulations

#### Students learning outcomes

1. Students will be able to predict the effects of various physicochemical, biochemical, physiological and pathological processes on the kinetics and extent of drug absorption, distribution and elimination.
  2. Knowledge of various preformulation parameters in drug development
  3. Gaining knowledge of various mechanisms and theories to be understood before formulating any product
  4. Knowledge of Global stability requirement
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#### UNIT-I

##### *Preformulation*

**15 hours**

##### 1. **Introduction**

Detailed study of physical, chemical and pharmaceutical parameters influencing formulation of drugs

##### 2. **Polymorphism in pharmaceutical solids**

Application of phase rule to the characterization of polymorphic systems, structural aspect of polymorphism, hydrates and solvates, generation of polymorphs, amorphous solids, methods for the characterization of polymorphs and solvates, effect of polymorphism on solubility and dissolution rate, effect of pharmaceutical processing on drug polymorphs and solvates.

##### 3. **Introduction to excipients for Pharmaceutical formulations**

Factors affecting the selection (including safety considerations), drug-excipients and excipients- package interactions and compatibility, Study of newer excipients

like cyclodextrin, ion exchange resins, film coating materials, superdisintegrants, directly compressible vehicles, surfactants, thickeners. Co-processed excipients

#### 4. **Residual solvents**

OVI along with their regulatory limits. Brief about method of its determination

### ***Stability Study***

**12 hours**

1. Basic concept and objectives of stability study,
2. Kinetic principles applied for stability evaluation and their applications in predicting shelf life and half life of pharmaceutical formulations. Importance of accelerated stability study
3. 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.
4. Regulatory requirements related to stability testing with emphasis on matrixing / bracketing techniques, climates zone, impurities in stability study, photostability testing, etc.
5. ICH guidelines (Q1A (R2), Q1B, Q1C, Q1D, Q1E, Q1F, Q5C), USFDA guidelines
6. stability evaluation of disperse systems
7. Impurities in stability study.

## **UNIT-II**

### ***Drug Dissolution and Diffusion Phenomena***

**12 hours**

1. Drug diffusion: steady state diffusion, diffusion principles in biological systems, thermodynamics of diffusion, Fick's Law of diffusion.
2. Theory of dissolution, factors influencing dissolution, interpretation of dissolution rate data, Comparison of dissolution profile by model independent (similarity and dissimilarity factor) and dependent methods.
3. Biopharmaceutical classification system (BCS), its significance in context of dissolution study and dosage form development.
4. Selection of dissolution media.
5. Pharmacopoeial & Non-Pharmacopoeial dissolution testing devises, Automation in dissolution testing,
6. Dissolution of immediate release and modified release dosage forms

***Dissolution enhancement by complexation and solid dispersion*** **10 hours**

1. Classification, types, application product development, merits-demerits
2. Various methods/techniques of preparations,
3. Host – guest relationship,
4. methods of analysis ( Phase solubility study & characterization)

**UNIT III**

***ADME Characteristics of drug*** **12 hours**

**1. Drug Absorption**

General consideration, absorption / drug transport mechanisms, role of sorption promoters, factors affecting absorption, absorption of drug through routes other than oral. Methods to determine absorption of drugs including *in-vitro*, *in-situ*, *in-vivo* and cell line (Caco – 2) study.

**2. Drug Distribution**

Factors affecting drug distribution, protein & tissue binding, Apparent volume of drug distribution

**3. Drug Metabolism (Biotransformation)**

Biotransformation, factors affecting biotransformation, Phase I & Phase-II reactions.

**4. Drug Excretion**

Glomerular filtration, tubular secretion, tubular reabsorption, Factors affecting drug excretion.

- 5. BCS and BDDCS:** Introduction, History, Classification, Significance, Biowaivers, Case studies and correlation with Regulatory bodies.

***Pharmacokinetics Models*** **12 hours**

**1. One compartment open model**

I.V. bolus administration, I.V. infusion, Extra vascular administration

**2. Two compartment open model**

I.V. bolus administration, I.V. infusion, Extra vascular administration

**3. Non-linear Pharmacokinetics**

Causes of non-linearity, estimation of various parameters and bioavailability of drugs that follow non-linear kinetics

***Pharmacokinetics Parameters*** **12 hours**

Absorption rate constant, elimination rate constant, biological half life, % drug metabolized, apparent volume of distribution, excretion rate constant, Clearance

(including the concept of renal & non-renal clearance), Kinetics of protein binding and other Pharmacokinetic parameters

***In vitro-In vivo Correlation (IVIVC)***

**5 hours**

Concept, Methods of establishing IVIVC, Factors affecting IVIVC, Application of IVIVC for biowaivers of immediate release dosage forms.

**Book Recommended**

1. Remingtons “Pharmaceutical Sciences” 19<sup>th</sup> edition.
2. Lachman “The theory and Practice of Industrial Pharmacy” 3<sup>rd</sup> edition.
3. Pharmaceutics “The Science of Dosage form design” by Aulton Pharmaceutical dispensing by Husa.
4. Physical Characterization of Pharmaceutical Solids, H. G. Brittain, Marcel Dekker, NY.
5. Pharmaceutical Dosage Forms : tablets, Lieberman H. A. and Leon Lachman, Marcel Dekker, New York
6. Oral lipid based formulations; D.J. Hauss, Informa Healthcare, New York
7. Polymorphism in Pharmaceutucial solids: H.G. Brittain, Marcel Dekker, New York
8. Modern pharmaceutics by G. S. Banker.
9. Encyclopedia of Pharmaceutical Technology, James Swarbrick and C. Boylan, Marcel Dekker Inc, New York.
10. Pharmaceutical dissolution testing, U.V. Banaker, Marcel Dekker, Inc., New York.
11. Pharmaceutical Dissolution Testing, Jennifer J. Dressman, Johannes Kramer
12. The United States Pharmacopoeia-35 (NF-30), 2012, United State of Pharmacopeal convention, INC, 12601 Twinbrook Parkway, Rockville, MD 20852.
13. Techniques of Solubilization of Drugs by Yalkowsky.
14. Drug stability (Principles and Practices) by Jens. T. Carstensen.
15. Stability of drug and dosage forms by Yoskioka.
16. Applied Biopharmaceutics and pharmacokinetics by Leon Shargel, 4<sup>th</sup> edition.
17. Pharmacokinetics by Welling and Tse.
18. Pharmacokinetics, M Gibaldi, Marcel Dekker, Inc., New York.
19. Textbook of Biopharmaceutics & Pharmacokinetics, Javed Ali, R. K. Khar and Alka Ahuja, Birla Publication, Delhi.
20. Handbook of Preformulations, S. K. Niazi, Informa Healthcare, New York.
21. Pharmaceutical Preformulations & Formulation, edited by Marks Gibson, Interpharm/CRC, Boca Raton, Florida, USA.
22. Biopharmaceutics & Pharmacokinetics, Venkateshwarlu, India
23. Relevant articles from Journals

24. Textbook Of Biopharmaceutics & Pharmacokinetics Concepts & Applications by Cvs Subrahmanyam,
25. Biopharmaceutics and pharmacokinetics: An introduction by Notari.
26. Pharmacokinetics for pharmaceutical scientist by John Wagner.
27. Dissolution, Bioavailability and Bioequivalence by Abdul.
28. Clinical Pharmacokinetics, Concepts and applications by Rowland and Tozer.
29. Drug absorption studies: in situ, in vitro and in silico models, By Carsten Ehrhardt, Kwang-Jin Kim, 2008.
30. Biopharmaceutics and Pharmacokinetics- A Treatise, D.M. Brahmankar and Sunil B. Jaiswal, Vallabh Prakashan Pitampura, Delhi.
31. [www.oecd.org](http://www.oecd.org)
32. <http://www.ich.org>

**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. Laboratory examination including oral and practical examination in general course illustrative of theory section in the syllabus
2. Visit to Pharmaceutical industries/Pharmaceutical Instrument manufacturing units/Govt. laboratories/Indian Pharmaceutical Congress and other conferences/workshops/seminars for gaining practical knowledge
3. Visit to Pharmaceutical exhibitions /industrial exhibitions /Pharmaceutical machinery exhibitions, etc

# **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)**

#### **Objectives of the course**

1. To provide knowledge of plant design and layout of various pharmaceutical dosage forms
2. To make aware with the various types of documentations in pharmaceutical industry
3. To highlight various provisions of GMP

#### **Students learning outcomes**

1. The basic understanding acquired by the student at the end of the course shall help him/her to understand various structural and documentary requirements in the pharmaceutical industry.
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#### **Unit – I**

**(20 hrs)**

- 1 Pharmaceutical factory location: Selection, layout and planning. Utility services, Service facilities, HVAC and personnel facilities.
- 2 Preparation of qualitative and quantitative departmental layout with equipments required for different dosage forms like Powders, Tablets, Hard and Soft gelatine capsules, Liquid and Semisolid preparations, Sterile products, Cosmetic products.

#### **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 like Tablets, Capsules and Injectable as per Schedule-M.
2. Good Manufacturing Practices (GMP)  
Introduction to Current Good Manufacturing Practices  
The History of GMP's, GMP Definitions

Provisions of GMP with respect to followings

- Building & facilities
- Personnel & Sanitation
- Equipment
- Raw Material Testing
- Manufacturing Control
- Packaging and labelling control
- Quality Control
- Finished Product Testing
- Warehousing & Distribution
- Records & Reports
- Complaints and recalls
- Waste disposal, scrap disposal procedures

#### **Unit – IV**

**(15 hrs)**

##### 1 Production planning and Inventory control

Methods for market forecasting, role of market forecasting in production planning, role of production planning in inventory management, Methods of inventory management

##### 2 Pilot plant, scale up technique for tablets, capsules and liquid orals.

##### 3 Validation master plan

#### **References**

1. Lachman “The theory and Practice of Industrial Pharmacy
2. Remington: The Science and Practice of Pharmacy , Gennaro A R, 20<sup>th</sup> Edition, Vol: I & II, Lippincott Williams &Wilkins, Philadelphia, USA
1. Bentley’s Pharmaceutics.
2. Pilot plants model and scale-up methods, by Johnstone and Thring.
3. GMP practices for pharmaceutical –James Swarbrick.
4. Applied production and operations management; By Evans, Anderson, Sweeney and Williams
5. How to practice GMPs by P.P. Sharma.
6. Chemical Engineering Plant Design by Vibrant.
7. Pharmaceutical Process Validation by Loftus and Nash.
8. Drug and Cosmetic Act 1940 and rules.
9. Pharmaceutical Production and management by C.V.S. Subrahmanyam, Vallabh Prakashan
10. Good manufacturing practices for Pharmaceuticals: A plan for total quality control, Second edition; By Sidney H. Willig
11. From Bench to Pilot plant: Process research in the pharmaceutical industries, Mehdi Nafissi, John a Ragan, Keith M Devries
12. Pharmaceutical production facilities: design and applications. Cole, Graham.



13. Pharmaceutical Regulatory Affairs by C.V.S. Subrahmanyam, Vallabh Prakashan, New Delhi.
14. Industrial Pharmacy by C.V.S. Subrahmanyam, Vallabh Prakashan, New Delhi.
15. Guidelines on cGMP & Quality of Pharmaceutical Products, S. Iyer, D.K. Publication, Mumbai.
16. Validation in Pharmaceutical Industry (Concept, Approaches & Guidelines), P.P. Sharma, Vandhana Publications, New Delhi
17. Relevant articles from journals

# Multidisciplinary/ Elective Subject-I

## SAURASHTRA UNIVERSITY M. PHARM SYLLABUS

### Semester – I

#### Multidisciplinary / Elective paper - I Pharmaceutical Preformulation Theory (Three hours per week, 4 credits)

#### Objectives of the course

1. To explain the importance and fundamentals of preformulation studies in pharmaceutical R & D.
2. To explain various mechanisms interfering the formulation development

#### Students learning outcomes

1. At the end of this course, students will be acquiring the understanding of various parameters which is to be taken care and tested before formulating any product in the pharmaceutical industry.

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#### 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, 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.
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 Solubilisation 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/sequence, shape, activity.

#### **Unit IV**

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

#### **READING MATERIAL**

1. **Jens T. Cartensen and C. T. Rhodes**, Drug stability principle and practice, 3<sup>rd</sup> 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 2<sup>nd</sup> 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<sub>50</sub> and LD<sub>50</sub> determination, special toxicity test like teratogenicity and mutagenicity. Various guidelines for toxicity studies. Animal experiments assessing safety of packaging materials. **6**
- C.** Selected topics in screening of drugs: **2**
- a.** Recent advances in Transgenic and Knockout animals
  - b.** Administration of Neuropeptides and Neurohormones by Intracerebroventricular (ICV) route in rats.
  - c.** Screening models for drug abuse like alcohol addiction, dependence and withdrawal syndrome.
  - d.** Biostatistics and calculation of doses in experimental pharmacology

#### Unit -2

- A.** Pyrogens: Sources, Chemistry and properties of bacterial pyrogens and endotoxins, Official pyrogen tests **2**
- B.** Microbiological assay of antibiotics and vitamins. **4**
- C.** Biological evaluation of drugs--Screening and evaluation ( including principles of screening , development of models for diseases : In vivo models / In vitro models / cell line study ) techniques of the following:

#### Unit -3

- A.** Parasympathomimetics, Parasympathetic blocking agents, Sympathomimetics, Sympathetic blocking agents, Ganglion stimulants and blockers, Neuromuscular stimulants and blockers. **8**
- B.** General and local Anesthetics, Sedatives and Hypnotics, Antiepileptics, Psychopharmacological agents, Analgesics, Anti-inflammatory agents, Anti-Parkinson's drugs, CNS Stimulants. **12**

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

**Unit -4**

- A.**Drugs used in Peptic Ulcer, Respiratory disorders, Hormone and Endocrine disorders. Anti fertility agents and diuretics. **8**
- B.** Various models for Cataract, glaucoma, inflammatory bowel disease **4**

**Books recommended (Latest Edition):**

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

## **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)**

#### **Objectives of the course**

1. To make students familiar with the principles of modern analytical techniques and its application in pharmacy

#### **Students learning outcomes**

1. At the end of the course, the student will be able to understand the fundamental concept of modern analytical techniques, which is important for qualitative as well as quantitative analysis of drug substances and drug product.
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#### **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**

1. 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**

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.
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, Addison — Wesley
19. 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. Thermoograph – Interpretation of spectra (at least for 4 compounds each).
5. Any other relevant exercises based on theory.

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

**Objectives of the course**

1. To get acquainted with approaches, formulations, technologies, and systems of New Drug Delivery Systems for transporting a pharmaceutical compound in the body as needed to safely achieve its desired therapeutic effect
2. Basic understanding of Novel Drug delivery technologies which modify drug release profile, absorption, distribution and elimination for the benefit of improving product efficacy and safety, as well as patient convenience and compliance.

**Students learning outcomes**

1. Students can select research based project in subsequent semesters for specific type of delivery systems.
  2. The knowledge gained by the students during the study of this course can also help them in handling of NDDS related research projects in Pharma industry
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**UNIT - I**

**15 Hours**

***General methods of design and evaluation of controlled release drug delivery system (CDDS)***

1. Basics of CDDS and its need, Computation of desired release rate and dose for CRDDS, Types of rate controlled drug delivery systems, Effect of system parameters on Controlled drug delivery system i.e. Polymer Solubility, Solution solubility, pKa, Polymer diffusivity, solution diffusivity, Thickness of polymer layers, Thickness of diffusion layer, Drug loading, Surface area, etc.
2. Evaluation of Controlled Drug Delivery Systems

**UNIT – II**

**40 Hours**

***Oral Mucosal, Buccal and periodontal Drug Delivery System***

1. Introduction to Mucoadhesion and periodontitis, Theory and Principal, Rational, Criteria for selection of drug and polymers/excipients with their properties, merits and demerits, formulations and evaluations, manufacturing techniques,
2. Sublingual tablets, mouth dissolving tablets, various buccal tablet systems, buccal patches, oral powder jet system, Periochip, Medicated Chewing Gum, Ora Vescent technology
3. Various targeted Controlled Drug delivery systems for periodontal deceases

### ***Gastro-retentive Drug Delivery System***

1. Introduction to Gastro-retentive Drug Delivery, Theory and Principal, Rational, Criteria for selection of drug and polymers/excipients with their properties, merits and demerits, formulations and evaluations, manufacturing techniques, Recent innovations

### ***Intestinal and Colon targeted Drug Delivery Systems***

1. Introduction to intestinal and colon targeted drug delivery, Theory and Principal, Rational, Criteria for selection of drug and polymers/excipients with their properties, merits and demerits, formulations and evaluations, manufacturing techniques,
2. Time dependent-Pulsatile drug delivery, Immediate and Time-delayed release technology, Egalet technology, Enterion capsule technology, etc.
3. Peyer's patches targeted drug delivery system – lymphatic delivery

### ***Ocular Drug Delivery Systems***

1. Introduction to ophthalmic drug delivery, Excipients, Formulation considerations, Novel Ophthalmic products (Non erodible ocular inserts, Erodible ocular inserts, intraocular irrigation solution, intraocular injection, Intravitreal injection & implants), Recent advances.

## **UNIT – III**

**15 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**

**15 Hours**

### ***Various Innovations in Oral Controlled Drug Delivery Systems***

1. TIMERx, MASRx and COSRx, Procise, Ring Cap, Smatrix, TheriForm, Accudep, Modified osmotically controlled systems, THREE FORM, Meltrex, Dissocubes, IDD, Liquid filled and Sealed Hard Gelatin Capsule Technology, Zydis, Orosolve and Durasolve, etc.

## **UNIT-V**

**5 Hours**

### ***Packaging components and its evaluation***

1. Factors affecting selection, Types and classification, Primary and secondary and regulatory aspects. Contribution in stability of the dosage forms.

## **Books Recommended**

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" 19<sup>th</sup> 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, Ilum & Stanley S. Davis. Polymers in controlled drug delivery wright Bristol(1987)

**Subject of Specialization paper – III**  
**Novel Drug Delivery System Part-I**  
**Practical (Four hours per week, 6 credits)**

1. Laboratory examination including oral and practical examination in general course illustrative of theory section in the syllabus
2. Visit to Pharmaceutical industries/Pharmaceutical Instrument manufacturing units/Govt. laboratories/Indian Pharmaceutical Congress and other conferences/workshops/seminars for gaining practical knowledge
3. Visit to Pharmaceutical exhibitions /industrial exhibitions /Pharmaceutical machinery exhibitions, etc

# SAURASHTRA UNIVERSITY M. PHARM. SYLLABUS

## Semester – II

### Subject of Specialization paper - IV

### Global Regulatory Requirements

### Theory

(Four hours per week, 6 credits)

#### Objectives of the course

1. To explore the regulatory provisions with respect to clinical trials, Investigational New Drug Application, New Drug Application, ANDA, market authorization of medicines, inspection of Pharmaceutical manufactures and product registration.
2. To explore practical aspects repeated to patenting

#### Students learning outcomes

1. To get familiar with regulatory aspects related to Research & Development as well as manufacturing and marketing of Pharmaceutical Products
  2. To get familiar with ICH guidelines w.r.t. Quality topics.
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#### 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, CDSCO etc.

#### References Books:

1. Pharmaceutical Production and management by C.V.S. Subrahmanyam, Vallabh Prakashan
2. Good manufacturing practices for Pharmaceuticals: A plan for total quality control, Second edition; By Sidney H. Willig

3. The guidance documents shall be procured from the website of the respective Government.
4. Pharmaceutical Regulatory Affairs by C.V.S. Subrahmanyam, Vallabh Prakashan, New Delhi.
5. Validation in Pharmaceutical Industry (Concept, Approaches & Guidelines), P.P. Sharma, Vandhana Publications, New Delhi
6. Relevant articles from journals



## Multidisciplinary/ Elective Subject-II

### SAURASHTRA UNIVERSITY M. PHARM. SYLLABUS

#### Semester – II

#### Multidisciplinary / Elective paper – II

#### NDDS: Multidisciplinary and Regulatory Aspects Theory (Four hours per week, 4 credits)

#### Objectives of the course

1. To explore the students other than Pharmaceutics with respect to Novel drug development systems, recent advances in CDDS, various formulation parameters and targeting to various organs
2. To explore practical aspects of novel drug delivery

#### Students learning outcomes

1. To get familiar with manufacturing novel formulations and its requirements.
  2. To get familiar the role of various excipients and its mechanism to formulate desired drug delivery system.
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#### UNIT- I

20 hours

##### *Introduction to Particulate and Vesicular Drug Delivery System*

1. Particulate Drug delivery (Microspheres, 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. *In situ* 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:**

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](http://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
15. Active Pharmaceutical Ingredients: Development, Manufacturing, and Regulation, Second Edition by Stanley Nusim
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
19. Poucher's Perfumes, Cosmetics and Soaps by H. Butler
20. Nanotechnology in Drug Delivery (Biotechnology: Pharmaceutical Aspects) by Melgardt M. de Villiers
21. Targeted & Controlled Drug Delivery: Novel Carrier Systems by Vyas / Khar
22. Bioadhesive Drug Delivery Systems: Fundamentals, Novel Approaches, and
23. Development (Drugs and the Pharmaceutical Sciences) by Edith Mathiowitz
24. Microparticulate Systems for the Delivery of Proteins and Vaccines (Drugs and the Pharmaceutical Sciences) by Smadar Cohen
25. 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)**

**Objectives of the course**

1. To explore the students other than Pharmaceutics with respect to protein analysis, its assay techniques, various diagnostic techniques and immune assays
2. To explore practical aspects of diagnostic methods in protein analysis

**Students learning outcomes**

1. To get familiar with various potency assays and its procedures as per the regulatory guidelines.
  2. To get familiar the role of various enzymes and its mechanism in diagnostic techniques.
- 

**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**

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

**Semester – II**  
**Multidisciplinary / Elective paper – II**  
**Quality Improvement Techniques in Drug Manufacturing Theory**  
**(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.
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**UNIT- I**

**(12 hours)**

International Organization for Standard – ISO, Grading, Documents specified by ISO like control of records, control of manufacturing, preventive maintenance, control of documents, corrective action, Internal audits etc and its relevance with Quality Drug Manufacturing

**UNIT- II**

**(12 hours)**

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

**UNIT- III**

**(12 hours)**

Six Sigma including concept of Defects Per Million Opportunities (DPMO), DMAIC process (Define, Measure, Analyze, Improve, and Control), DMADV process (Define, Measure, Analyze, Design, Verify) and DFSS (Design For Six Sigma)

**UNIT- IV**

**(12 hours)**

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

**UNIT- V**

**(12 hours)**

Lean manufacturing Malcolm Baldrige National Quality Award – MBNQA, European Foundation for Quality Management (EFQM) excellence model

# **M. Pharm. Semester-III**

## **SAURASHTRA UNIVERSITY M. PHARM. SYLLABUS**

### **Semester – III**

#### **Interdisciplinary paper - V**

#### **Research Methodology Theory**

**(Three hours per week, 3 credits)**

#### **Objectives of the course**

1. To make students familiar with various established methods used in pharmaceutical research.

#### **Students learning outcomes**

1. At the end of the course, the student will be able to understand the hierarchy of continue research by proper fundamental methodology
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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
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)
- 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
- 4. Thesis projects in Science & Engineering – Richard M. Davis.
- 5. Scientist in legal Systems- Ann labor science
- 6. Thesis & Assignment – Jonathan Anderson
- 7. Writing a technical paper- Donald Menzel
- 8. Effective Business Report Writing –Leland Brown
- 9. Protection of industrial Property rights- P. Das & Gokul Das
- 10. Spelling for the millions- Edna Furrness
- 11. Preparation for publication – King Edward Hospital Fund for London
- 12. Information Technology – The Hindu speaks
- 13. Documentation – Genesis & Development 3792.
- 14. Manual for evaluation of industrial projects-United Nations
- 15. Manual for the preparation of industrial feasibility studies

# **SAURASHTRA UNIVERSITY M. PHARM. SYLLABUS**

## **Semester – III**

### **Interdisciplinary paper - VI**

#### **Patent, Design of experiments and Biostatistics**

**(Three hours per week, 3 credits)**

#### **Objectives of the course**

1. To give idea to the students regarding various patent issues related to pharmaceutical products as well as regulatory bodies and their work
2. To acquaint students with various Statistical Techniques used to draw conclusions in Experimental Research.
3. To emphasize the use of these Techniques to address the problems and issues arising in the discipline of Pharmacy and to find their solutions using Statistical Software

#### **Students learning outcomes**

1. Students will be able to identify, analyze and solve problems related to biostatistics using statistical software.
- 

#### **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 issues 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-VII)**  
**Novel Drug Delivery System Part-II Theory**  
**(Six hours per week, 6 credits)**

**Objectives of the course**

1. To provide knowledge of drug targeting with advanced dosage forms
2. To get acquainted with formulation, methods of preparation, evaluation and applications of New Drug Delivery Systems
3. To get information of various patented technologies in dosage for development

**Students learning outcomes**

16. Students can select research based project in subsequent semesters for specific type of delivery systems.
  17. The knowledge gained by the students during the study of this course can also help them in handling of NDDS related research projects in Pharma industry
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**UNIT - I**

**15 Hours**

***Vesicular and Particulate Drug Delivery Systems***

1. Introduction, Theory and Principal, Rational, Criteria for selection of drug and polymers/excipients with their properties, merits and demerits, formulations and evaluations, manufacturing techniques, recent advances in
  - Neosomes, Liposomes, Phytosomes, Ethosomes
  - Microspheres and capsules, Nanospheres and capsules, beads, magnetically modulated microparticles, etc for sustained and targeted drug delivery

**UNIT – II**

**40 Hours**

***Dermal and Transdermal Drug Delivery System***

1. 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
2. Recent advancements in pressurized drug delivery system, Aerosols, etc.

**UNIT – III**

**15 Hours**

***Protein and Peptides Drug Delivery Systems***

1. Protein/peptide drug delivery systems, enzyme, epithelial/endothelial barriers, pharmacokinetics, different routes of delivery, practical considerations.
2. Biodegradable Polymers and its application in Formulation design

## UNIT – IV

15 Hours

### *Injectable and Implants as a Drug Delivery Systems*

1. Introduction, Theory and Principal, Rational, Criteria for selection of drug and polymers/excipients with their properties, merits and demerits, formulations and evaluations, manufacturing techniques, recent advances such as Alzamer depot bioerodable polymer technology, Atrigel drug delivery system, DUROS implant, ProLease Technology, SAIB technology, Stealth technology, DepoFoam, Medipad Delivery system, etc.

## UNIT-V

5 Hours

### *Nasal, Vaginal and Pulmonary Drug Delivery System*

1. Introduction, Theory and Principal, Rational, Criteria for selection of drug and polymers/excipients with their properties, merits and demerits, formulations and evaluations, manufacturing techniques, recent advances

### **Books Recommended**

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" 19<sup>th</sup> 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, Ilum & Stanley S. Davis. Polymers in controlled drug delivery wright Bristol(1987)
19. Pharmaceutical Biotechnology, Second edition- 2002, Ed. D. J. A. Cromelin and R. D. Sindelar Taylor and Francis group.
20. Gilbert S Banker, Christophex T Rhodes Modern Pharmaceutics, 4th edition- 2008, Marcel Dekker
21. S P Vyas and Roop K Khar Controlled Drug Delivery:concepts and advances. Vallabh Prakashan-2008.
22. Biomaterials science: An Introduction to Materials in Medicine, Buddy D. Ratner, Allan S. Hoffman Academic Press-1996.
23. Michael J. Rathbone, Jonathan Hadgraft and Michael S. Roberts. Modified – Release Drug Delivery Technology, Marcel Dekker, Inc.-2002.

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

1. Laboratory examination including oral and practical examination in general course illustrative of theory section in the syllabus
2. Visit to Pharmaceutical industries/Pharmaceutical Instrument manufacturing units/Govt. laboratories/Indian Pharmaceutical Congress and other conferences/workshops/seminars for gaining practical knowledge
3. Visit to Pharmaceutical exhibitions /industrial exhibitions /Pharmaceutical machinery exhibitions, etc