Syllabus For

Master of Pharmacy
(M. Pharm)

EFFECTIVE FROM JULY 2011

(Four semester full time programme)

Pharmaceutical Drug Regulatory Affairs

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	cGMP and Doccumentation	6	-	**6**
4		Core – II	Practical – II (cGMP and Doccumentation	-	12	**6**
5		Core – III	Quality management system	4	-	**4**
6		Multidisciplinary - I	Elective – I **1.** Pharmaceutical Preformulation **2.** Pharmaceutical and Industrial Biotechnology **3.** Methods in Biological Evaluation of Drugs	4	-	**4**
					Total Credits	**26**

M. Pharm. Semester – II

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

M. Pharm. Semester – III

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

M. Pharm. Semester – IV

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

Total Credits: 96

M. Pharm. Semester-I

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

UNIT- I

UV-VISIBLE SPECTROSCOPY :

Brief review of electromagnetic spectrum and absorption of radiations. The chromophore concept, absorption law and limitations. Theory of electronic spectroscopy, absorption by organic molecules, choice of solvent and solvent effects. Applications of UV-Visible spectroscopy, Woodward –Fischer rules for calculating absorption maximum, interpretation of spectra, multi-component assay, difference spectra and derivative spectra.

INFRARED SPECTROPHOTOMETRY :

Introduction, basic principles, and sampling techniques, interpretation of spectra, applications in Pharmacy. FT-IR, Attenuated Total Reflectance (ATR), Near infra red Spectroscopy (NIR) -theory and applications.

UNIT- II

ATOMIC ABSORPTION AND PLASMA EMISSION SPECTROSCOPY:

Principle, instrumentation, interferences and applications in Pharmacy.

REFERENCE STANDARDS

Reference standards source, preparation, characterization, usage, storage and records.

UNIT- III

NUCLEAR MAGNETIC RESONANCE SPECTROSCOPY

Fundamental Principles and Theory, Instrumentation, solvents, chemical shift, and factors affecting chemical shift, spin-spin coupling, coupling constant, and factors influencing the value of coupling constant, spin-spin decoupling, proton exchange reactions, simplification of complex spectra, FTNMR, 2D -NMR and applications in Pharmacy, interpretation of spectra. C13 NMR-Introduction, Natural abundance, C13 NMR Spectra and its structural applications.

UNIT- IV

MASS SPECTROSCOPY

Basic principles and instrumentation, ion formation and types, fragmentation processes and fragmentation pattern, Chemical ionization mass spectroscopy (CIMS), Field Ionization Mass Spectrometry (FIMS), Fast Atom Bombardment MS (FAB MS), Matrix Assisted laser desorption / ionization MS (MALDI-MS), interpretation of spectra and applications in Pharmacy.

Books Recommended:

1. Instrumental Methods of Analysis - Scoog and West.
2. Spectrometric Identification of Organic Compounds - Silverstein et., al.
3. Instrumental Method of Analysis - Willard Dean & Merrit.
4. Text Book of Inorganic Chemistry — A.I. Vogel.

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

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SAURASHTRA UNIVERSITY M. PHARM. SYLLABUS

Semester – I

Interdisciplinary paper – II

Modern Analytical Techniques-I Practical-I

(Six 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
(Pharmaceutical Drug Regulatory Affairs)
Subject of Specialization paper – I (Core Subject-I)

cGMP and Documentation

(Six hours per week, 6 credits)

THEORY

UNIT - I

1 cGMP of Pharmaceutical manufacturing · Evolution and Principles of cGMP, Schedule-M, WHO-GMP requirements, European Union (EU) and United States Food and Drug Administration (USFDA) guidelines on Pharmaceutical manufacturing. **15 Hrs**

2 Organization and personnel responsibilities, training, hygiene and personal records, drug industry location, design, construction and plant lay out, maintenance, sanitation, environmental control, utilities and maintenance of sterile areas, control of contamination and Good Warehousing Practice. **10 Hrs**

UNIT - II

3 Packaging of Dosage Forms: cGMP complied packaging and documentation Labeling requirements of various regulated and nonregulated markets for Tablets, Capsules, Liquid Orals, Parenterals/ Injectables, and Semisolids. **06 Hrs**

4 Equipments selection & purchase specifications, maintenance, clean in place, purchase specifications and maintenance of stores for raw materials. **06 Hrs**

UNIT - III

5 In process quality control and finished products quality control for following formulation in pharma industry: tablets, capsules, ointments, suppositories, creams, parenterals, ophthalmic and surgical products. **10 Hrs**

6 Documentation in pharmaceutical industry: Batch Formula Record, Master Formula Record, Distribution records. Common Technical Document and Drug Master Files., Medical Devices, Electronic Common Technical Documentation **10 Hrs**

UNIT - IV

7 An introductory study of following laws with regard to drug product design, manufacture and distribution in India (**with latest amendments**) : **10 Hrs**

a. Drugs and Cosmetics Act 1940 and its rules 1945
b. National Pharmaceutical Pricing Authority (NPPA)
c. The Environmental Protection Act-1986 & Occupational Safety and Health Administration (OSHA)
d. Consumer Protection Act-1986
e. Factories Act-1948 and Pollution control Act-1989
f. Law of Contracts (Indian contract Act-1872)
g. Monopolistic & Restrictive Trade Practices Act-1969

8 Drug discovery and development process: Principles of Drug discovery and development. Clinical research process. Development and informational content for Investigational New Drugs Application (IND), New Drug Application (NDA), Abbreviated New Drug Application (ANDA), Supplemental New Drug Application (SNDA), Scale Up Post approval changes (SUPAC) and Bulk active chemical Post approval changes (BACPAC). Post marketing surveillance, Current Biopharmaceutical regulations and in particular related to Cell Therapy and regenerative medicine. **08 Hrs**

RECOMMENDED BOOKS

1. Good Manufacturing Practice Rationale and compliance by John Sharp
2. Pharmaceutical master validation plan: The ultimate guide to FDA, GMP and GLP Compliance by Syed Imitiaz Haider
3. Pharmaceutical dosage forms: Parenterals Vol-2, II Edition, by Kenneth EA and Leon Lachman
4. Packaging and Pharmaceuticals and health care products by H. Lockhart, Frank A. Paine
5. The process of new drug discovery and development. I and II Edition by Charles G. Smith, James T and O. Donnell.
6. Establishing a CGMP laboratory audit system- A Practical guide by David M. Bliesner.
7. J.F.Hanlon: Hand book of package engineering :Mac-Grawhill company
8. Good manufacturing practices: A plan total quality control: S.H.Wilhing, M.M. Tuckerman, S.Hitchings, Marcel Deckker, Inc. Yew york.
9. Cell therapy, CGMP, Facilities and Manufacturing, Springer

SAURASHTRA UNIVERSITY M. PHARM. SYLLABUS
Semester – I
(Pharmaceutical Drug Regulatory Affairs)
Subject of Specialization paper – II (Core Subject-II)
cGMP and Documentation Practical - II
(Twelve hours per week, 6 credits)

PRACTICALS : (75 Hrs)

Twenty Assignments to be carried out and submitted on the aforementioned theoretical aspects like

1. **Documentation** for in process and finished products Quality control tests for Solid, Semisolid and Sterile preparations.
2. **Protocol** preparation for purchase of manufacturing equipments and raw materials.
3. **Protocol** preparation for documentation of various types of records (BFR, MFR, DR, etc.)
4. **Labeling** comparison between brand & generics. (Review of Promotion Materials)

SAURASHTRA UNIVERSITY M. PHARM. SYLLABUS
Semester – I
(Pharmaceutical Drug Regulatory Affairs)
Subject of Specialization paper – III (Core Subject-III)
Quality Management systems
(Twelve hours per week, 6 credits)

THEORY

UNIT - I

1. Concept of Quality, Total Quality Management. Quality by design, six sigma concept

2. Auditors, Auditing strategies and preparation of audits, Quality audit & audit check lists and Auditing of manufacturing facilities by International regulatory agencies. Conducting and Handling of internal/Domestic/International Regulatory Audits/ Customer specific audits /Pre approval inspections

UNIT - II

3. Harmonization of regulatory requirements-The International Conference on Harmonization (ICH) process, guidelines to establish quality, safety and efficacy of drug substances and products. Study of ICH common technical documents, harmonization of pharmacopoeial standards The International Organization for Standardization (ISO) 9000 series of quality systems standards, ISO 14000

4. Quality evaluation and batch release: Change Control, Deviation-(planned and unplanned), Corrective Action and Preventive Action (CAPA), Handling of non-conformance, Vendor evaluation process, Out of specification (OOS), batch reconciliation and finished goods release, Market recalls & Market complaints.

UNIT - III

5. Good Laboratory Practices (GLP): Scope of GLP, Quality assurance unit, Standard operating procedures (SOP), protocols for conduct of non clinical testing, control on animal house, report preparation and documentation.

6. National Accreditation Board for testing and Calibration Laboratory (NABL) certification and accreditation procedure

UNIT - IV

7. Stability testing: ICH and WHO guidelines, Photostability studies

8. Good Clinical Practices (GCP): International regulatory requirements for pharmaceutical development regarding clinical research practices. Current issues in GCP; standards for design, conduct, performance, monitoring, auditing, recording, analysis, and reporting of clinical trials. Schedule Y of Indian Drugs and Cosmetics Act 1940, Role of Regulatory affairs in Product development, Clinical phase, Preclinical Phase, Manufacturing phase and Marketing Phase. Indian Council of Medical Research (ICMR) Guidelines for Ethics in Biomedical Research.

RECOMMENDED BOOKS

1. Quality planning and Analysis by JM Juran and FM Gryna, Tata McGrawHill-India.
2. Total Quality Management, Dale H. Besterfield, Pearson Education, 3rd Ed., 2003.
3. Total Quality Management, Principles, Implementation & Cases, Sharma D.D., Sultan Chand & Sons, New Delhi, 2000.
4. Fundamentals of Total Quality Management, Process Analysis and Improvement by Jens.J Daulgard, Kai Kriestensen and Gopal K.Kanji. Taylor and Francis
5. Total Quality Management, Organization, and Strategy, James R. Evans, Thomson, 4th Ed., 2007.
6. Quality Control, Besterfield, D.H., Pearson, 7th Ed., 2004.
7. Implementing ISO 14000: a practical, comprehensive guide to the ISO 14000 environmental management standards, Authors: Tom Tibor, Ira Feldman , Editors: Tom Tibor, Ira Feldman, Irwin Professional Pub., 1997.
8. Establishing A cGMP Lab; Audit System- A practical guide, David M.Bleisner, Wiley Interscience.
9. The manager's guide to ISO 9000, Kenneth L. Arnold, Free Press, 1994.
10. How To Practice GLP, Good Laboratory Practice, Sharma PP, Vandana Publications
11. GLP Essentials: A Concise Guide to Good Laboratory Practice, Second Edition, Milton A. Anderson, Informa Healthcare.
12. GLP Quality Audit Manual, Milton A. Anderson, Third Edition, Informa Healthcare.
13. Laboratory Auditing for Quality and Regulatory Compliance, by Donald C.Singer, Stefan and Stedan, Drugs and Pharmaceutical Sciences, Vol.150
14. Handbook of Stability Testing in Pharmaceutical Development: Regulations, Methodologies, and Best Practices, Huynh-Ba, Kim, Springer.
15. International Stability Testing, Mazzo J. Mazzo, David J. Mazzo, Informa Healthcare
    Pharmaceutical Stability Testing To Support Global Markets (biotechnology: Pharmaceutical Aspects), Kim Huynh-ba, Springer.
16. Good Laboratory Practice Regulations, Third Edition, Revised and Expanded Edited by Sandy Weinberg
17. Handbook of Stability Testing in Pharmaceutical Development: Regulations, Methodologies, and Best Practices, Kim Huynh-ba, Springer.

18. Good Clinical Practice: Standard Operating Procedures for Clinical Researchers, Wiley.
19. Laboratory Auditing for quality and regulatory compliance, Donald C. Singer, Taylor and Francis.
20. Current Good Manufacturing Practices, MA Potdhar, BS Publications.

Multidisciplinary/ Elective Subject-I

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

UNIT – I

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

UNIT – II

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

UNIT - III

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

UNIT – IV

Characterization of Biopharmaceutical drugs and Phytomedicines.

REFERENCES

1. Modern Pharmaceutics by G. Banker.
2. Physical Characterization of Pharmaceutical Solids by H. Brittain.
3. Polymorphism in Pharmaceutical Solids by H. Brittain.
4. Solid State Chemistry of Drugs by S.R. Byrn.
5. Chemical Stability of Pharmaceuticals by K.A. Connors.
6. Pharmaceutical Preformulation and Formulation by M. Gibson.
7. Solubility Behavior of Organic Compounds by D.J.W. Grant and T. Higuchi.
8. Remingtons “Pharmaceutical Sciences” 19th edition.

9. Pharmaceutical Preformulation by J. Wells.
10. Solubility and Solubilization in Aqueous Media by S. Yalkowsky.
11. Pharmaceutics “The Science of Dosage form design” by Aulton.
12. Hand book of Preformulation by Sarfaraz K. Niazi.

SAURASHTRA UNIVERSITY M. PHARM. SYLLABUS

Semester – I

Multidisciplinary / Elective paper - I

Methods in Biological Evaluation of Drugs Theory

(Four hours per week, 4 credits)

UNIT - I

- **A.** Biological standardization, general principles, Scope and limitation of bio-assay, bioassay of some official drugs.
- **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.
- **C.** Selected topics in screening of drugs:
  - **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 - II

- **A.** Pyrogens: Sources, Chemistry and properties of bacterial pyrogens and endotoxins, Official pyrogen tests
- **B.** Microbiological assay of antibiotics and vitamins.
- **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 - III

- **A.** Parasympathomimetics, Parasympathetic blocking agents, Sympathomimetics, Sympathetic blocking agents, Ganglion stimulants and blockers, Neuromuscular stimulants and blockers.
- **B.** General and local Anesthetics, Sedatives and Hypnotics, Antiepileptics, Psychopharmacological agents, Analgesics, Anti-inflammatory agents, Anti-Parkinson's drugs, CNS Stimulants.
- **C.** Cardiotonics, Anti-hypertensive drugs, Anti-arrhythmic drugs, Drugs used in Ischemic Heart Diseases, Drugs used in Atherosclerosis.

UNIT - IV

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

Books recommended (Latest Edition):

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

SAURASHTRA UNIVERSITY M. PHARM. SYLLABUS
Semester – I
Multidisciplinary / Elective paper - I
Pharmaceutical and Industrial Biotechnology Theory
(Four 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

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 :

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 :

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 :

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

OPTICAL ROTARY DISPERSION :

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 :

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 :

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-III

(Six hours per week, 3 credits)

1. Experiments on Electrophoresis.
2. Experiments of Chromatography.
    (a) Thin Layer Chromatography.
    (b) Paper Chromatography.
3. Experiments based on HPLC & GC.
4. Thermaograph – Interpretation of spectra (atleast for 4 compounds each).
5. Any other relevant exercises based on theory.

SAURASHTRA UNIVERSITY M. PHARM. SYLLABUS
Semester – II
(Pharmaceutical Drug Regulatory Affairs)
Subject of Specialization paper – IV (Core Subject-IV)
International Regulatory Requirements Theory
(Four hours per week, 6 credits)

THEORY

UNIT- I

1. Generic Drug Product development: Introduction, Quality Control and Quality Assurance (QC &QA), Hatch-Waxman update, Drug product performance- *in vitro,* ANDA Regulatory Approval Process, Bioequivalence and Drug Product Assessment- *in vivo,* Scale up Post approval changes, Post marketing surveillance, Outsourcing Bioavailability and Bioequivalence studies to Contract Research organizations. Formats for marketing authorization submission to US, EU, Asia-PAC (includes countries of East Asia, southeast Asia, Australasia, Oceania) etc., Data privacy Protection, Pharmaceutical Labeling, Advertising and Promotion, Risk Management in regulatory affairs

UNIT – II

2. Regulatory requirements for product approvals: Active Pharmaceutical Ingredients, Biologics, Novel therapies, special categories [Over the counter (OTCS), herbal medicines and Homeopathics] obtaining New Drug Application (NDA), Abbreviated New Drug Application (ANDA)for generic drugs, ways and means of US Registration for foreign drugs, Chemistry, Manufacturing and controls (CMC), Post approval Regulatory affairs, Regulation for combination products (Controlled release systems), medical device, Environmental concerns and regulations 21 Code of Federal Regulations (CFR) Part 11 and LIMS (Laboratory information Management System).

UNIT - III

3. FDA Approvable indications and other considerations: Data procession for Global submission, Text and Tabular exposition- Common Technical Document (CTD)/ electronic Common Technical Document (eCTD) Format, working with contract Research Organization (CRO), Industry and FDA Liaison, Role of European Commission Competent Authorities and Notified Bodies and USFDA Authorities

UNIT-IV

4. Nonclinical drug development: Global submission of Investigational New Drug application (IND), New Drug application (NDA), Abbreviated New Drug Application (ANDA), Investigation medicinal product Dossier (IMPD) & Investigator Brochure (IB), New product Applications for Global Pharmaceutical Product approvals, US NDA vs Global CTD Formats, ANDA & Supplemental Abbreviated New Drug Application (SNDA), CTD and eCTD for registration of pharmaceuticals for Human use, combination products (Controlled release systems).

5. Clinical trials: Developing clinical trial protocols, Institutional Review Board/ Independent Ethics committee-formation and working procedures, Informed consent-process and procedures, HIPAA- A new requirement to clinical study process, Code of Federal Regulations (CFR)/ International Conference on Harmonization (ICH)/EU GCP obligations of Investigators, sponsors & Monitors, Importance of Quality Assurance in clinical trials, Managing and Monitoring clinical trials, European clinical trials (CT) directives-implementation and update., Pharmacovigilance-safety monitoring in clinical trials.

RECOMMENDED BOOKS

1. Generic Drug Product Development, Solid Oral Dosage forms, Leon Shargel and Isader Kaufer, Marcel Dekker series, Vol.143
2. The Pharmaceutical Regulatory Process, Edited by Ira R. Berry Marcel Dekker Series,Vol.144
3. The Pharmaceutical Regulatory Process, Second Edition Edited by Ira R. Berry and Robert P. Martin, Drugs and the Pharmaceutical Sciences,Vol.185 Informa Health care Publishers.
4. New Drug Approval Process: Accelerating Global Registrations By Richard A Guarino, MD, 5th edition, Drugs and the Pharmaceutical Sciences,Vol.190.
5. Guidebook for drug regulatory submissions / Sandy Weinberg. By John Wiley & Sons. Inc.
6. FDA regulatory affairs : a guide for prescription drugs, medical devices, and biologics /edited by Douglas J. Pisano, David Mantus.
7. Clinical Trials and Human Research: A Practical Guide to Regulatory Compliance By Fay A. Rozovsky and Rodney K. Adams
8. HIPAA and Human Subjects Research: A Question and Answer Reference Guide By Mark Barnes, JD, LLM and Jennifer Kulynych, JD, PhD
9. Principles and Practices of Clinical Research, Second Edition Edited by John I. Gallin and Frederick P. Ognibene
10. Drugs: From Discovery to Approval, Second Edition By Rick Ng

11. New Drug Development: A Regulatory Overview, Eighth Edition By Mark Mathieu
12. Pharmaceutical Risk Management By Jeffrey E. Fetterman, Wayne L. Pines and Gary H. Slatko
13. Preparation and Maintenance of the IND Application in eCTD Format By William K. Sietsema
14. Medical Device Development: A Regulatory Overview By Jonathan S. Kahan
15. Medical Product Regulatory Affairs: Pharmaceuticals, Diagnostics, Medical DevicesBy John J. Tobin and Gary Walsh

SAURASHTRA UNIVERSITY M. PHARM. SYLLABUS
Semester – II
(Pharmaceutical Drug Regulatory Affairs)
Subject of Specialization paper – V (Core Subject-V)
International Regulatory Requirements Practical - IV
(Twelve hours per week, 6 credits)

PRACTICALS :

Twenty Assignments to be carried out and submitted on the aforementioned theoretical aspects like

- Preparation of regulatory compliance checklist tabulating cGMP requirements as per 21 CFR 210 and 211.
- Preparation of global list of documents for registration of IND, NDA, ANDA as per ICH CTD format.
- Preparation of Annual report for regulatory on approved ANDA
- Case studies on response with scientific rationale to USFDA Warning Letter
- Preparation of an IMPD for EU submission.
- Preparation of a Clinical Trial Protocol for submission to Regulatory.
- Preparation of regulatory compliance requirements for BA/BE study.
- Preparation and documentation for Indian Patent.
- Patent challenge / non infringement (Para IV) case studies.
- Preparation of Annual Product Quality Review (APQR).
- Preparation of Periodic Safety Update Report (PSUR).
- Comparison of key GMP requirements of India, US, EU and Japan of a dosage form.
- Comparison of Clinical Trial Application Requirements of India, US, EU and Japan of a dosage form.
- Fast track approval in different countries considering different class of drugs (e.g. Anti HIV and anticancer), therapeutic area (rare diseases)

etc.

- Annotated side by side comparison of labels, Prescribing Information and Patient Information Leaflet.
- Preparation of generic product registration application as per Association of South East Asian Nations [ASEAN] CTD (ACTD)

- Preparation of a marketing authorization application for OTC, homeopathic and Herbal Medicinal Product.

SAURASHTRA UNIVERSITY M. PHARM. SYLLABUS

Semester – II

(Pharmaceutical Drug Regulatory Affairs)

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

Intellectual Property Rights (IPR)

Theory

(Four hours per week, 4 credits)

UNIT - I

1. **Introduction to IPRs:-** IP vs Conventional property. Introduction to 8 different IP mechanisms –patents, industrial designs , integrated circuits and layout designs, plant verities, geographical indicators, copyright, trademark, trade secrets. Their characteristics, properties. Usefulness of patents for researchers. Factors affecting choice of IP protection; Penalties for violation/ infringement. IPRs vs Regulatory affairs- similarities and differences. IPRs and new career opportunities for pharma students.

2. **Patenting in India:-** Development of IP law in India. Patent legislation and introduction to current IP laws in India. Amendments in Indian Patent Laws and their significance; Requirement for patenting- Novelty, Inventive step (Non obviousness) and industrial application (utility). Patent specification & claims, Patent infringement. Procedure for filing patent in India-provisional, complete, divisional, additional and convention patent applications; Forms and fee. Prior art search and sources of patent information – free and paid databases. Patent analysis and landscaping. Patent Search Maps. Infringement analysis.

UNIT - II

3. **International Patenting:-** Introduction to international patenting. Patent Co-operation Treaty (PCT), Regional routes and direct filing abroad. American & European patent systemvs Indian Patent System. Budget estimates – Govt. Free and other expeses.

4. **International treaties and conventions on IPR:-** GATT/WTO; TRIPS, Paris convention, PCT , WIPO- organizational structure, function and importance for researchers in Pharmaceutical Sciences. Mechanisms for prevention of misuse of patents- Compulsory licensing, Laws against ever greening of patents. Case studies. DOHA declaration. POST WTO Product Patent Regime from 2005; Challenges for Indian Pharma Industry in the context of globalization of IP;

UNIT - III

5. **Generic Drugs and their approval:-** The Hatch-Waxman Act (Drug Price Competition and Patent Term Restoration Act): Concepts, Provisions, Recent Changes, Implications for Indian Pharma firms. Compulsory licensing. Case studies and examples. IPRs and options for Indian Pharma Industry in post-TRIPS scenario.

6. **Ethics and Values in IP:-** Ethics in IP and patenting . Positive and negative aspects of Intellectual Property Protection. Role of ethics and values in preventing societal conflicts. Specifics significance in case of Pharma. Factors affecting ethics and values in modern context. Sources of ethics and values. Practical strategies and approaches to safeguard ethics and values. Eco-ethics: Voluntary adoption of eco-friendly technologies/ strategies. Corporate examples and case studies.

UNIT - IV

7. **Licensing of Patents and Commercialization :-** Significance of Patent Licensing/ Commercialization. Mandatory requirements regarding submission of information to patent office regarding working and non-working of patents. Strategies and models for promoting licensing of patents. Professional agencies for assisting in licensing of patents in India and abroad- APCTT, NRDC, TIFAC, BCIL, TBSE/SIDBI, AUTM AND OTHERS. Licensing related documentation –Confidentiality Agreements, MOUs, Legal issues. Funding sources and incentive for patent commercialization-NRDC, TePP, HGT,TDB, PRDSF AND DBT SCHEMES.

8. **Career Opportunities in IPR for Pharma Professionals**: Emerging carreer opportunities for pharma students in IPRs – patenting and patent licensing. Essential requirements, job profiles. Patent Agent Examination- qualifications, examination pattern. Introduction to MIPC(Germany) and FPLC (USA). Role of AUTM, LESI. Practical strategies for enhancing IP related qualifications and skills.

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)

UNIT- I **(6 hours)**

Introduction and overview of Novel Drug Delivery Systems (NDDSs)

- Particulate Drug delivery (Microshpres, Microcapsules, Nanosheres, Nanocapusels, Polymeric beads, etc.)
- Vesicular Drug delivery (Liposmes, Ethosomes, Neosomes, etc.)
- Insitu gelling systems
- Transdermal Drug delivery
- Microemulsion, Nanoemulsion, Self emulsifying systems, Nanosuspension,etc.
- Targeted Drug delivery
- Liquid and Semisolid preparations
- Sterile products, Cosmetic products and Aerosolized systems.

UNIT- II **(6 hours)**

Consideration of various regulations in product development

- Organic volatile impurities
- Trace impurities
- API and product stability
- Product registration

UNIT- III **(6 hours)**

Biotechnoligical Products:

- Formulation development aspects for biotechnological products
- Delivery aspects for biotechnologically derived products (Recombinat DNA, Recombinat proteins, Gene delivery, Enzymes, Hormones, etc.)
- Product stabilization aspects with consideration of ICH QE5 Section.
- Regulatory considerations with consideration of global regulatory guidelines.

UNIT- IV **(6 hours)**

- Herbal and naturally derived Products:
- Formulation development aspects
- Delivery aspects for herbal and naturally derived medicinal products (Herbal extracts, crud extracts, incorporation of product performance enhancers, etc.)
- Product stabilization aspects with consideration of ICH guideline.
- Regulatory considerations with consideration of global regulatory guidelines.

UNIT- V **(6 hours)**

Synthetic and Semisynthetic medicines

- Formulation development aspects
- Delivery aspects for Synthetic and Semisynthetic medicines.
- Product stabilization aspects with consideration of ICH guideline.
- Regulatory considerations with consideration of global regulatory guidelines.

Books Recommended:

1. Remingtons “Pharmaceutical Sciences” 19th Edition.
2. Pharmaceutics “The Science of Dosage Form Design” by Michael Aulton
3. Pharmaceutical Dispensing by Husa
4. Dispensing Pharmacy by Cooper and Goons
5. Encyclopedia of Pharmaceutical Technology, Volumes: I-VI, 3rd Edition
6. www.fda.gov/RegulatoryInformation/Guidances
7. Drug stability (Principles and Practices) by Jens Carstensen
8. Stability of drugs and dosage forms by Yoskioka
9. Modern Pharmaceutics by G. S. Banker
10. Biodegradable polymers as drug delivery systems by Cahsin
11. Biopolymers for medical and pharmaceutical applications, Vlumes: I-II by Alexander Steinbüchel
12. Controlled drug delivery: Fundamentals and applications by Robinson
13. Microencapsulation 2nd Edition by Benita
14. Nanoparticulate Drug delivery systems by Thassu
15. Novel drug delivery systems by Chein
16. Pharmaceutical Dissolution Testing by Dressman
17. Protein biotechnology: isolation, characterization, and stabilization By Felix Franks
18. Active Pharmaceutical Ingredients: Development, Manufacturing, and Regulation, Second Edition by Stanley Nusim
19. Compliance Handbook for Pharmaceuticals, Medical Devices, and Biologics by Carmen medina
20. Herbal Supplements - Drug Interactions: Scientific and Regulatory Perspectives by Y.W. Francis Lam
21. Textbook of Complementary and Alternative Medicine by Chun-su Yuan
22. FDA Regulatory Affairs: A Guide for Prescription Drugs, Medical Devices, and Biologics by Douglas J. Pisano
23. Cell Technology for Cell Products (ESACT Proceedings) by Rodney Smith

24. Poucher's Perfumes, Cosmetics and Soaps by H. Butler
25. Nanotechnology in Drug Delivery (Biotechnology: Pharmaceutical Aspects) by Melgardt M. de Villiers
26. Antigen Delivery Systems: Immunological and Technological Issues (Drug Targeting and Delivery) by Bruno Gander
27. Targeted & Controlled Drug Delivery: Novel Carrier Systems by Vyas / Khar
28. Bioadhesive Drug Delivery Systems: Fundamentals, Novel Approaches, and Development (Drugs and the Pharmaceutical Sciences) by Edith Mathiowitz
29. Pharmaceutical Gene Delivery Systems (Drugs and the Pharmaceutical Sciences) by Alain Rolland
30. Microparticulate Systems for the Delivery of Proteins and Vaccines (Drugs and the Pharmaceutical Sciences) by Smadar Cohen
31. Protein Formulation and Delivery (Drugs and the Pharmaceutical Sciences) by Eugene J. McNally
32. Herbal Drugs and Phytopharmaceuticals, Third Edition - Hardcover by Max Wichtl

SAURASHTRA UNIVERSITY M. PHARM. SYLLABUS

Semester – II

Multidisciplinary / Elective paper – II

Analysis of Recombinant Proteins and Diagnostics Theory

(Four hours per week, 4 credits)

A. Analysis:

UNIT - I

- **Total protein assay:** Quantitative amino acids analysis, Folin-Lowry protein assay, BCA assay, UV spectrophotometry etc.
- **Purity:** Protein impurities, contaminants, electrophoretic analysis, HPLC based analysis, DNA content analysis, immunological assays for impurities, combined immunological and electrophoretic methods, host-cell impurities etc.

UNIT - II

- **Test procedures:** ICH guidelines.
- **Potency assays:** In-vitro biochemical methods. cell-line derived assays, whole animal assays etc.

B. Diagnostics:

UNIT - III

- Principles, methods and applications: Principles and methods of some clinically used diagnostic immunoassays, e.g., homogeneous immuno assays, fluorescence, chemiluminescence and bioluminescence enzyme immunoassays etc., immunosensors.

UNIT - IV

- Principles, methods applications: DNA probe based diagnostics, sample preparation, hybridization, separation, detection, PCR-RFLP in paternity and forensic cases, SNP detection MALDI and DHPLC.
- Cancer diagnostics, human retroviral diseases specially AIDS. Role of enzymes in diagnostics.

REFERENCE BOOKS

1. Practical Biochemistry: Principles and Techniques, Fifth Edition – 2005, K. Wilson and J. Walker
2. Experimental Biochemistry, Third Edition – 1999, R. L. Switzer and L. F. Garrity W. H. Freeman and Company
3. US Pharmacopeia Vol. 1-3 National Formulary 25, 2007 (Biotechnological drugs) The USP Convention
4. Indian Pharmacopoeia -2007 Vol. 1-3 (Biotechnology products) The IP Commission, Ghaziabad
5. Related review Articles

SAURASHTRA UNIVERSITY M. PHARM. SYLLABUS

Semester – II

Multidisciplinary / Elective paper – II

Quality Improvement Techniques in Drug Manufacturing

Theory

(Four hours per week, 4 credits)

UNIT- I **(6 hours)**

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

UNIT- II **(6 hours)**

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

UNIT- III **(6 hours)**

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

UNIT- IV **(6 hours)**

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

UNIT- V **(6 hours)**

Lean manufacturing

Malcolm Baldrige National Quality Award – MBNQA

European Foundation for Quality Management (EFQM) excellence model

M. Pharm. Semester-III

SAURASHTRA UNIVERSITY M. PHARM. SYLLABUS
Semester – III
Interdisciplinary paper - V
Research Methodology Theory
(Four hours per week, 4 credits)

UNIT - I

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

UNIT - II

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.

UNIT – III

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

UNIT – IV

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
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 Furmess
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

(Four hours per week, 4 credits)

UNIT- I

1. Intellectual property, importance and types of intellectual property.
2. Paris conventional, World Trade Organization, WIPO and GATT.
3. US Patent System and European Patent System

UNIT- II

The Indian Patents Act 1970 and Indian patents (Amendments) Act 2005 and issue related to Patents, Importance, parts of patent, type of patent, provisional application, Oppositions, Patent infringement, Patent search engines

UNIT- III

Biostatistics and Various statistical methods i. e.Null hypothesis, t- Test, Regression analysis, ANOVA, Chi-square, etc.

UNIT- IV

Optimization Techniques and its applications in relation to subject specialization
Design of experiments, Factorial designs
Grid search technique, Response surface methodology, contour plots, etc. its application in pharmaceutical sciences.

SAURASHTRA UNIVERSITY M. PHARM. SYLLABUS
Semester – III
(Pharmaceutical Drug Regulatory Affairs)
Subject of Specialization paper – VII (Core Subject-VII)
Pharmaceutical Validation Theory
(Six hours per week, 6 credits)

THEORY

UNIT - I

1. An Introduction to the Basic Concepts of Process Validation & How it Differs from Qualification (Installation Qualification (IQ), Operational Qualification (OQ) & Performance Qualification (PQ) Procedures, Validation master plan (VMP)

2. A Review of Prospective, Concurrent, Retrospective Validation & Revalidation including the use of Statistical Process Control (SPC)

UNIT - II

3. Planning & Managing a Validation Program including Change Control,

Scale-Up and Post-Approval Changes (SUPAC), Pre Approval Inspections (PAI) & Technology Transfer Issues

4. Validation of Water (Demineralised, Distilled and Water for Injection) & Thermal Systems, including Heat Ventilation and Air conditioning (HVAC), Facilities & Cleaning Validation

UNIT - III

5. Process Validation of Active Pharmaceutical Ingredients (APIs) and finished products

6. Validation of Sterile and Non-Sterile Facility

UNIT - IV

7. Medical Device, *In Vitro* Diagnostics & Packaging Validation Issues

8. Validation of Analytical Methods, Automated Systems, International Conference on Harmonization (ICH) and World Health Organization (WHO) Guidelines for calibration of equipments, Validation of process: mixing, granulation, drying, compression, filtration, filling, Validation of sterilization methods and equipments: dry heat sterilization, autoclaving, membrane filtration. Validation of analytical procedures, Validation of air handling equipments and facilities in sterile and non sterile areas.

RECOMMENDED BOOKS

1. Pharmaceutical Process Validation**,** 3rd Edition, Edited by Robert Nash and Alfred Wachter, Marcel Dekker
2. Good Manufacturing Practices for Pharmaceuticals: A Plan for Total Quality Control from Manufacturer to Consumer, Sidney J. Willig, Marcel Dekker, 5th Ed.
3. Validation of Pharmaceutical Processes: Sterile Products, Frederick J. Carlton (Ed.) and James Agalloco (Ed.), Marcel Dekker, 2nd Ed.
4. Validation Standard Operating Procedures: A Step by Step Guide for Achieving Compliance in the Pharmaceutical, Medical Device, and Biotech Industries, Syed Imtiaz Haider
5. Pharmaceutical Equipment Validation: The Ultimate Qualification Handbook, Phillip A. Cloud, Interpharm Press
6. Pharmaceutical Quality Assurance by Manohar A. Potdhar, 2nd edition, Nirali Prakashan.

SAURASHTRA UNIVERSITY M. PHARM. SYLLABUS
Semester – III
(Pharmaceutical Drug Regulatory Affairs)
Subject of Specialization paper – VIII (Core Subject-VIII)
Pharmaceutical Validation Practical - V
(Twelve hours per week, 6 credits)

PRACTICALS: (75 Hrs)

Twenty Assignments to be carried out and submitted on the aforementioned theoretical aspects like

- Preparation of protocols on various validation requirements
- Validation of machines & analytical instruments used for Pharmaceutical formulations.
- Process Validation of various pharmaceutical dosage forms.
- Validation of medical devices.(viz., Nebulizers, Inhalers, Infusion pump, Insulin pens)
- Cleaning Validation
- Analytical methods Validation

SAURASHTRA UNIVERSITY M. PHARM. SYLLABUS

Semester – III

(Pharmaceutical Drug Regulatory Affairs)

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

Seminar to Dissertation

(Eight hours per week, 4 credits)

SAURASHTRA UNIVERSITY M. PHARM. SYLLABUS

Semester – III

(Pharmaceutical Drug Regulatory Affairs)

Subject of Specialization paper – X to XII (Core Subject - IX)

Dissertation & Viva-Voice

(Minimum 20 hours per week, 20 credits)