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

<table>
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<tr>
<th>Sr. No.</th>
<th>Subject Code</th>
<th>Type of Subject</th>
<th>Subject</th>
<th>Teaching Scheme</th>
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<td>Quality management system</td>
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<td>1. Pharmaceutical Preformulation</td>
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<td>2. Pharmaceutical and Industrial Biotechnology</td>
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<td>3. Methods in Biological Evaluation of Drugs</td>
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Total Credits 26
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1. NDDS: Multidisciplinary and Regulatory Aspects
2. Analysis of Recombinant Proteins and Diagnostics
3. Quality Improvement Techniques in Drug Manufacturing

**Total Credits** 26
# M. Pharm. Semester – III

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## M. Pharm. Semester – IV

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**Total Credits: 20**

Total Credits: 96
UNIT- I
UV-VISIBLE SPECTROSCOPY:

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

UNIT- II
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.
3. Instrumental Method of Analysis - Willard Dean & Merrit.
8. Pharmaceutical Analysis — Higuchi, Bechmman, Hassan.
14. IP/BP/USP.
1. Use of colorimeter for analysis of Pharmacopoeial compounds and their formulations.
2. Use of Spectrophotometer for analysis of 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. Antihypertensives 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.
   IR, NMR and Mass Spectroscopy – Interpretation of spectra & Structural elucidation
   (atleast for 4 compounds each).
7. Any other relevant exercises based on theory.
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.  

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.  

UNIT - II


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.  

UNIT - IV

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

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.

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
4. Packaging and Pharmaceuticals and health care products by H. Lockhart, Frank A. Paine
6. Establishing a CGMP laboratory audit system- A Practical guide by David M. Bliesner.
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.
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

**RECOMMENDED BOOKS**

8. Establishing A cGMP Lab; Audit System- A practical guide, David M.Bleisner, Wiley Interscience.
10. How To Practice GLP, Good Laboratory Practice, Sharma PP, Vandana Publications
13. Laboratory Auditing for Quality and Regulatory Compliance, by Donald C.Singer, Stefan and Stedan, Drugs and Pharmaceutical Sciences, Vol.150
19. Laboratory Auditing for quality and regulatory compliance, Donald C. Singer, Taylor and Francis.
UNIT – I

General Considerations, Spectroscopy and Assay development, dissociation, partitioning and Solubility of Pharmaceutical Solids, pKa, salts, solvents, $K_{ow}$, 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.
10. Solubility and Solubilization in Aqueous Media by S. Yalkowsky.
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 teratogenicity and mutagenecity.
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.
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
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.
3. Instrumental Method of Analysis - Willard Dean & Merrit.
8. Pharmaceutical Analysis — Higuchi, Bechman, Hassan.
14. IP/BP/USP.
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  


UNIT – II  


UNIT – III  


UNIT-IV


RECOMMENDED BOOKS

2. The Pharmaceutical Regulatory Process, Edited by Ira R. Berry Marcel Dekker Series,Vol.144
8. HIPAA and Human Subjects Research: A Question and Answer Reference Guide By Mark Barnes, JD, LLM and Jennifer Kulynych, JD, PhD
10. Drugs: From Discovery to Approval, Second Edition By Rick Ng
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 Devices By 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 varieties, 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.


UNIT - II


UNIT - III


**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 career 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, Nanocapulesls, Polymeric beads, etc.)
- Vesicular Drug delivery (Liposomes, Ethosomes, Neosomes, etc.)
- In situ 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)
Biotechnological 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:
3. Pharmaceutical Dispensing by Husa
4. Dispensing Pharmacy by Cooper and Goons
6. www.fda.gov/RegulatoryInformation/Guidances
7. Drug stability (Principles and Practices) by Jens Carstensen
8. Stability of drugs and dosage forms by Yoskioka
9. Modern Pharmaceutics by G. S. Banker
10. Biodegradable polymers as drug delivery systems by Cahsin
11. Biopolymers for medical and pharmaceutical applications, Volumes: I-II by Alexander Steinbüchel
12. Controlled drug delivery: Fundamentals and applications by Robinson
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
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
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. Biodhesive 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 immunoassays, 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


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
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

   A. Title –Title of project with authors name
   B. Abstract- Statement of the problem, Background list in brief and purpose and scope.
   C. Key Words.
   D. Methodology-subject, apparatus, instrumentation & procedure.
   E. Results- tables, graphs, figures & statistical presentation
   F. Discussion support or non support of hypothesis, practical & theoretical Implications
   G. Conclusion
   H. Acknowledgements.
   I. References
   J. Errata
   K. Importance of Spell check for entire project
   L. Uses of footnotes

7. Presentation (especially for oral presentation) 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


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
5. Scientist in legal Systems- Ann labor science
7. Writing a technical paper- Donald Menzel
9. Protection of industrial Property rights- P. Das & Gokul Das
10. Spelling for the millions- Edna Furmess
11. Preparation for publication – King Edward Hospital Fund for London
12. Information Technology – The Hindu speaks
15. Manual for the preparation of industrial feasibility studies
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.

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
RECOMMENDED BOOKS

2. Good Manufacturing Practices for Pharmaceuticals: A Plan for Total Quality Control from Manufacturer to Consumer, Sidney J. Willig, Marcel Dekker, 5th Ed.
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)