**ANAND PHARMACY COLLEGE, ANAND**
**(An Autonomous College under UGC Regulations 2023)**
**Managed by Shri Ramkrishna Seva Mandal**
(Approved by PCI, NAAC Accredited – A+ Grade, 3.38 CGPA)
Awarding University: Gujarat Technological University, Ahmedabad

Name of Program: **M. Pharm**
Branch: – **A03 - Pharmaceutical Quality Assurance**
Semester: **I**
Course Code: **M000101TT**
Course Name: **Modern Pharmaceutical Analytical Techniques**
Course Type: **Core**
Year of Implementation: **2024 – 25**

**Teaching and Examination Scheme:**

| Number of hours/ Week | | | Number of credits | | | Total credits | Evaluation Scheme (Marks) | | | | | | | | Total Marks |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | | | Sessional Exams | | | | | | Term End Assessment | | |
| | | | | | | | Theory | | | Practical | | | | | |
| L | Tu | P | L | Tu | P | | CIE | E | T | CIE | E | T | T | P | |
| 4 | 0 | 0 | 4 | 0 | 0 | 4 | 10 | 15 | 25 | 0 | 0 | 0 | 75 | 0 | 100 |

**Scope:**
This subject deals with various advanced analytical instrumental techniques for identification, characterization, and quantification of drugs. Instruments dealt are NMR, Mass spectrometer, IR, HPLC, GC etc.

**Course Outcomes (CO):**
Upon completion of the course student shall be able to

| | |
|---|---|
| CO1 | Understand different chromatographic principles, instrumentation and techniques |
| CO2 | Understand principles and instrumentation for electrophoresis, X-ray crystallography, potentiometry, and thermal analysis |
| CO3 | Understand and apply principles, instrumentation, and techniques of various spectroscopic methods |
| CO4 | Apply principles of spectroscopic techniques to identify and quantify various drugs |

**Detailed Syllabus:**
Total Teaching hours: **60 hours**

| | | |
|---|---|---|
| **Unit 1** | **UV-Visible spectroscopy:** Introduction, Theory, Laws, Instrumentation associated with UV-Visible spectroscopy, Choice of solvents and solvent effect and Applications of UV-Visible Spectroscopy, Simultaneous equation method, Derivative spectroscopic method, Difference spectroscopic method | **04 hours** |
| | **IR spectroscopy:** Theory, Modes of Molecular vibrations, Sample handling, Instrumentation of Dispersive and Fourier - Transform IR Spectrometer, Factors affecting vibrational frequencies and Applications of IR spectroscopy, Data interpretation | **04 hours** |

| | | |
|---|---|---|
| | **Spectrofluorimetry:** Theory of Fluorescence, Factors affecting fluorescence, Quenchers, Instrumentation and Applications of fluorescence Spectrophotometer<br><br>**Flame emission spectroscopy and atomic absorption spectroscopy**: Principle, Instrumentation, Interferences and Applications | **02 hours**<br><br>**02 hours** |
| **Unit 2** | **NMR spectroscopy:** Quantum numbers and their role in NMR, Principle, Instrumentation, Solvent requirement in NMR, Relaxation process, NMR signals in various compounds, Chemical shift, Factors influencing chemical shift, Spin-Spin coupling, Coupling constant, Nuclear magnetic double resonance. Brief outline of principles of FT-NMR and 13C NMR. Applications of NMR spectroscopy | **11 hours** |
| **Unit 3** | **Mass Spectroscopy:** Principle, Theory, Instrumentation of Mass Spectroscopy, Different types of ionization like electron impact, chemical, field, FAB and MALDI, APCI, ESI, APPI Analyzers of Quadrupole and Time of Flight, Mass fragmentation and its rules, Meta stable ions, Isotopic peaks, and Applications of Mass Spectroscopy | **10 hours** |
| **Unit 4** | **Chromatography:** Principle, apparatus, instrumentation, chromatographic parameters, factors affecting resolution and applications of the following:<br>**a)** Paper chromatography<br>**b)** Thin Layer chromatography<br>**c)** Ion exchange chromatography<br>**d)** Column chromatography<br>**e)** Gas chromatography<br>**f)** High Performance Liquid chromatography<br>**g)** Affinity chromatography | **03 hours**<br>**03 hours**<br>**02 hours**<br>**03 hours** |
| **Unit 5** | **Electrophoresis:** Principle, Instrumentation, working conditions, factors affecting separation and applications of the following:<br>**a)** Paper electrophoresis<br>**b)** Gel electrophoresis<br>**c)** Capillary electrophoresis<br>**d)** Zone electrophoresis<br>**e)** Moving boundary electrophoresis<br>**f)** Iso electric focusing<br><br>**X ray Crystallography:** Production of X rays, Different X ray diffraction methods, Bragg's law, Rotating crystal technique, X ray powder technique, Types of crystals and applications of Xray diffraction. | **06 hours**<br><br>**03 hours** |
| **Unit 6** | **Potentiometry:** Principle, Ion selective Electrodes and Application of potentiometry.<br><br>**Thermal Analysis:** Principle, thermal transitions, and instrumentation (heat flux and power compensation and designs) working, Polymer behavior, factors affecting and instrumentation and working, application of TGA | **04 hours**<br><br>**03 hours** |

**Recommended Books^: (Latest Editions)**


1. Silverstein RM, Bassler GC. Spectrometric identification of organic compounds. John Wiley & Sons. New York
2. Doglas A Skoog, F. James Holler, Timothy A. Nieman. Principles of Instrumental Analysis Eastern press. Bangalore.
3. Willard H, Merritt LL, Dean JA, Settle FA. Instrumental methods of analysis. CBS publisher and distributors. New Delhi. India
4. Beckett AH and Stenlake JB. Practical Pharmaceutical Chemistry. CBS Publishers. New Delhi. India
5. Kemp W. Organic Spectroscopy. ELBS. Macmillan
6. Sethi PD. Quantitative analysis of drugs in pharmaceutical formulations. Unique Publishers. New Delhi. India.
7. Munson JW. Pharmaceutical analysis: modern methods. B. Drugs and the pharmaceutical sciences. Marcel Dekker. New York.


L= Lecture, Tu= Tutorial, P= Practical, T = Theory

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Awarding University: Gujarat Technological University, Ahmedabad

Name of Program: **M. Pharm**
Branch: **A03 - Pharmaceutical Quality Assurance**
Semester: **I**
Course Code: **M030102TT**
Course Name: **Quality Management Systems**
Course Type: **Core**
Year of Implementation: **2024 – 25**

**Teaching and Examination Scheme:**

| Number of hours/ Week | | | Number of credits | | | Total credits | Evaluation Scheme (Marks) | | | | | | | | Total Marks |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | | | Sessional Exams | | | | | | Term End Assessment | | |
| | | | | | | | Theory | | | Practical | | | | | |
| L | Tu | P | L | Tu | P | | CIE | E | T | CIE | E | T | T | P | |
| 4 | 0 | 0 | 4 | 0 | 0 | 4 | 10 | 15 | 25 | 0 | 0 | 0 | 75 | 0 | 100 |

**Scope:** This course deals with the various aspects of quality control and quality assurance aspects of pharmaceutical industries. It covers the important aspects like cGMP, QC tests, documentation, quality certifications, GLP and regulatory affairs.

**Course Outcomes (CO):**
Upon completion of the course student shall be able to

| | |
|---|---|
| CO1 | Understand the evolution and dimensions of quality, and apply strategic quality management principles for customer satisfaction |
| CO2 | Understand and implement total quality management and statistical process control tools to enhance pharmaceutical quality management and achieve operational excellence |
| CO3 | Understand regulatory compliance and manage quality systems in pharmaceutical production |
| CO4 | Illustrate and apply ICH guidelines for drug stability testing, quality by design, risk management tools and risk control in pharmaceuticals |

**Detailed Syllabus:**
Total Teaching hours: **60 hours**

| | | |
|---|---|---|
| **Unit 1** | **Introduction to Quality:** Evolution of Quality, Definition of Quality, Dimensions of Quality | **02 hours** |
| | **Quality as a Strategic Decision**: Meaning of strategy and strategic quality management, mission and vision statements, quality policy, Quality objectives, strategic planning and implementation, McKinsey 7s model, Competitive analysis, Management commitment to quality | **03 hours** |

| | | |
|---|---|---|
| | **Customer Focus:** Meaning of customer and customer focus, Classification of customers, Customer perception of quality, Factors affecting customer perception, Customer requirements, Meeting customer needs and expectations, Customer satisfaction and Customer delight, Handling customer complaints, Understanding customer behavior, concept of internal and external customers. Case studies.<br><br>**Cost of Quality:** Cost of quality, Categories of cost of Quality, Models of cost of quality, optimizing costs, Preventing cost of quality. | **04 hours**<br><br>**03 hours** |
| **Unit 2** | **Pharmaceutical quality Management:** Basics of Quality Management, Total Quality Management (TQM), Principles of Six sigma, ISO 9001:2008, 9001:2015, ISO 14001:2004<br><br>Pharmaceutical Quality Management – ICH Q10, Knowledge management, Quality Metrics, Operational Excellence and Quality Management Review. OSHAS guidelines, NABL certification and accreditation, CFR-21 part 11, WHO-GMP requirements. | **06 hours**<br><br>**06 hours** |
| **Unit 3** | **Six System Inspection model:** Quality Management system, Production system, Facility and Equipment system, Laboratory control system, Materials system, Packaging, and labelling system. Concept of self-inspection.<br><br>**Quality systems:** Change Management/ Change control. Deviations, Out of Specifications (OOS), Out of Trend (OOT), Complaints - evaluation and handling, Investigation and determination of root cause, Corrective & Preventive Actions (CAPA), Returns and Recalls, Vendor Qualification, Annual Product Reviews, Batch Review and Batch Release. Concept of IPQC, area clearance/ Line clearance. | **06 hours**<br><br>**06 hours** |
| **Unit 4** | **Drug Stability:** ICH guidelines for stability testing of drug substances and drug products.<br><br>Study of ICH Q8, Quality by Design and Process development report<br><br>**Quality risk management:** Introduction, risk assessment, risk control, risk review, risk management tools, HACCP, risk ranking and filtering according to ICH Q9 guidelines | **04 hours**<br><br>**03 hours**<br><br>**05 hours** |
| **Unit 5** | **Statistical Process control (SPC):** Definition and Importance of SPC, Quality measurement in manufacturing, Statistical control charts - concepts and general aspects, Advantages of statistical control, Process capability, Estimating Inherent or potential capability from a control chart analysis, Measuring process control and quality improvement, Pursuit of decreased process variability | **08 hours** |
| **Unit 6** | **Regulatory Compliance through Quality Management and development of Quality Culture Benchmarking:** Definition of benchmarking, Reasons for benchmarking, Types of Benchmarking, Benchmarking process, Advantages of benchmarking, Limitations of benchmarking. | **04 hours** |

**Recommended Books^: (Latest Editions)**


1. Implementing Juran's Road Map for Quality Leadership: Benchmarks and Results, By Al Endres, Wiley, 2000.
2. Understanding, Managing and Implementing Quality: Frameworks, Techniques and Cases, By Jiju Antony; David Preece, Routledge, 2002.
3. Organizing for High Performance: Employee Involvement, TQM, Reengineering, and Knowledge Management in the Fortune 1000: The CEO Report by Edward E. Lawler; Susan Albers Mohrman; George Benson, Jossey-Bass, 2001
4. Corporate Culture and the Quality Organization by James W. Fairfield- Sonn, Quorum Books, 2001
5. The Quality Management Sourcebook: An International Guide to Materials and Resources by Christine Avery; Diane Zabel, Routledge, 1997.
6. The Quality Toolbox, Second Edition, Nancy R. Tague, ASQ Publications.
7. Juran's Quality Handbook, Sixth Edition, Joseph M. Juran and Joseph A. De Feo, ASQ Publications.
8. Root Cause Analysis, The Core of Problem Solving and Corrective Action, Duke Okes, 2009, ASQ Publications.


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Awarding University: Gujarat Technological University, Ahmedabad

Name of Program: **M. Pharm**
Branch: **A03 - Pharmaceutical Quality Assurance**
Semester: **I**
Course Code: **M030103TT**
Course Name: **Quality Control and Quality Assurance**
Course Type: **Core**
Year of Implementation: **2024 – 25**

**Teaching and Examination Scheme:**

| Number of hours/ Week | | | Number of credits | | | Total credits | Evaluation Scheme (Marks) | | | | | | | | Total Marks |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | | | Sessional Exams | | | | | | Term End Assessment | | |
| | | | | | | | Theory | | | Practical | | | | | |
| L | Tu | P | L | Tu | P | | CIE | E | T | CIE | E | T | T | P | |
| 4 | 0 | 0 | 4 | 0 | 0 | 4 | 10 | 15 | 25 | 0 | 0 | 0 | 75 | 0 | 100 |

**Scope:** This course is designed to impart fundamental knowledge and concepts about various quality management principles and systems utilized in the manufacturing industry. It also aids in understanding the quality evaluation in the pharmaceutical industries.

**Course Outcomes (CO):**
Upon completion of the course student shall be able to

| | |
|---|---|
| CO1 | Understand the evolution and scope of Quality Control and Quality Assurance in the pharmaceutical industry |
| CO2 | Understand and apply principles of Good Laboratory Practices, CCSEA guidelines, and cGMP guidelines for pharmaceutical industries |
| CO3 | Illustrate documentation practices and gain knowledge for compiling regulatory submissions |
| CO4 | Comprehend and apply pharmacopoeial guidelines to analyze raw materials, finished products, and packaging for IPQC, ensuring compliance with Indian, US, and British standards |

**Detailed Syllabus:**
Total Teaching hours: **60 hours**

| | | |
|---|---|---|
| **Unit 1** | Introduction: Concept and evolution and scopes of Quality Control and Quality Assurance, Good Laboratory Practice, GMP, Overview of ICH Guidelines - QSEM, with special emphasis on Q-series guidelines. | **6 hours** |
| | Good Laboratory Practices: Scope of GLP, Definitions, Quality assurance unit, protocol for conduct of non-clinical testing, control on animal house, report preparation and documentation. CPCSEA guidelines. | **6 hours** |

| | | |
|---|---|---|
| **Unit 2** | cGMP guidelines according to schedule M, USFDA (inclusive of CDER and CBER) Pharmaceutical Inspection Convention (PIC), WHO and EMEA covering: Organization and personnel responsibilities, training, hygiene and personal records, drug industry location, design, construction, and plant layout, maintenance, sanitation, environmental control, utilities and maintenance of sterile areas, control of contamination and Good Warehousing Practice | **12 hours** |
| **Unit 3** | Analysis of raw materials, finished products, packaging materials, in process quality control (IPQC), Developing specification (ICH Q6 and Q3), purchase specifications and maintenance of stores for raw materials.<br>In process quality control and finished products quality control for following dosage forms in Pharma industry according to Indian, US and British pharmacopoeias: tablets, capsules, ointments, suppositories, creams, Parenterals, ophthalmic and surgical products (How to refer pharmacopoeias). | **4 hours**<br>**8 hours** |
| **Unit 4** | Documentation in pharmaceutical industry: Three tier documentation, Policy, Procedures and Work instructions, and records (Formats), Basic principles- How to maintain, retention and retrieval etc. Standard operating procedures (How to write), Master Batch Record, Batch Manufacturing Record, Quality audit plan and reports. Specification and test procedures, Protocols, and reports. Distribution records. Electronic data handling. Concepts of controlled and uncontrolled documents.<br>Submission documents for regulators DMFs, as Common Technical Document and Electronic Common Technical Documentation (CTD, eCTD). Concept of regulated and non-regulated markets. | **8 hours**<br>**4 hours** |
| **Unit 5** | Manufacturing operations and controls: Sanitation of manufacturing premises, mix-ups and cross contamination, processing of intermediates and bulk products, packaging operations, IPQC, release of finished product, process deviations, charge-in of components, time limitations on production, drug product inspection, expiry date calculation, calculation of yields, production record review, change control, sterile products, aseptic process control, packaging, reprocessing, salvaging, handling of waste and scrap disposal.<br>Introduction, scope, and importance of intellectual property rights. Concept of trade mark, copyright, and patents. | **9 hours**<br>**3 hours** |

**Recommended Books^: (Latest Editions)**


1. Quality Assurance Guide by organization of Pharmaceutical Procedures of India, 3rd revised edition, Volume I & II, Mumbai, 1996.
2. Good Laboratory Practice Regulations, 2nd Edition, Sandy Weinberg Vol. 69, Marcel Dekker Series, 1995.
3. Quality Assurance of Pharmaceuticals- A compendium of Guide lines and Related materials Vol I & II, 2nd edition, WHO Publications, 1999.
4. Sharma PP. How to Practice GMP's. Vandana Publications. Agra. Delhi.

5. The International Pharmacopoeia – Vol I, II, III, IV & V - General Methods of Analysis and Quality specification for Pharmaceutical Substances, Excipients and Dosage forms. WHO, Geneva.
6. Hirsch AF. Good laboratory Practice Regulations. Marcel Dekker Series.
7. ICH guidelines
8. ISO 9000 and Total Quality Management
9. Deshpande SW. Gandhi N. The Drugs and Cosmetics Act 1940. Susmit Publishers. Pune.
10. Shah DH. QA Manual. Business Horizons. New Delhi. India.
11. Sidney HW. Good Manufacturing Practices for Pharmaceuticals a Plan for Total Quality Control. Marcel Dekker Series.
12. Steinborn L. GMP/ISO Quality Audit Manual for Healthcare Manufacturers and Their Suppliers, Sixth Edition, (Volume 1 - With Checklists and Software Package). Taylor & Francis.

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Awarding University: Gujarat Technological University, Ahmedabad

Name of Program: **M. Pharm**
Branch: **A03 - Pharmaceutical Quality Assurance**
Semester: **I**
Course Code: **M030104TT**
Course Name: **Product Development and Technology Transfer**
Course Type: **Core**
Year of Implementation: **2024 – 25**

**Teaching and Examination Scheme:**

| Number of hours/ Week | | | Number of credits | | | Total credits | Evaluation Scheme (Marks) | | | | | | | | Total Marks |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | | | Sessional Exams | | | | | | Term End Assessment | | |
| | | | | | | | Theory | | | Practical | | | | | |
| L | Tu | P | L | Tu | P | | CIE | E | T | CIE | E | T | T | P | |
| 4 | 0 | 0 | 4 | 0 | 0 | 4 | 10 | 15 | 25 | 0 | 0 | 0 | 75 | 0 | 100 |

**Scope:** This deal with technology transfer covers the activities associated with Drug Substance, Drug Product and analytical tests and methods, required following candidate drug selection to completion of technology transfer from R&D to the first receiving site and technology transfer related to post-marketing changes in manufacturing places.

**Course Outcomes (CO):**
Upon completion of the course student shall be able to

| | |
|---|---|
| CO1 | Understand key concepts in drug discovery, clinical research, and regulatory applications like IND, NDA, ANDA, and post-marketing surveillance for new product |
| CO2 | Understand and evaluate critical pre-formulation factors, pharmaceutical packaging requirements for effective development and marketing of new drugs and products |
| CO3 | Comprehend the scaling-up process from pilot plant to large-scale manufacturing for different dosage forms |
| CO4 | Illustrate and apply technology transfer processes from R&D to production, optimizing procedures and preparing essential documentation, including development reports and transfer plans |

**Detailed Syllabus:**
Total Teaching hours: **60 hours**

| | | |
|---|---|---|
| **Unit 1** | Principles of Drug discovery and development: Introduction, 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 | **12 hours** |

| | | |
|---|---|---|
| | chemical Post approval changes (BACPAC), Post marketing surveillance, Product registration guidelines – CDSCO, USFDA | |
| **Unit 2** | Pre-formulation studies: Introduction/concept, organoleptic properties, purity, impurity profiles, particle size, shape, and surface area. Solubility, Methods to improve solubility of Drugs: Surfactants & its importance, cosolvency.<br>Techniques for the study of Crystal properties and polymorphism. Pre-formulation protocol, Stability testing during product development | **8 hours**<br>**4 hours** |
| **Unit 3** | Pilot plant scale up: Concept, Significance, design, layout of pilot plant scales up study, operations, large scale manufacturing techniques (formula, equipment, process, stability, and quality control) of solids, liquids, semisolid and parenteral dosage forms.<br>New era of drug products: opportunities and challenges | **10 hours**<br>**2 hours** |
| **Unit 4** | Pharmaceutical packaging: Pharmaceutical dosage form and their packaging requirements, pharmaceutical packaging materials, medical device packaging, Enteral Packaging, Aseptic packaging systems, Container closure systems, Issues facing modern drug packaging, Selection, and evaluation of pharmaceutical packaging materials.<br>Quality control test: Containers, closures and secondary packing materials. | **8 hours**<br>**4 hours** |
| **Unit 5** | Technology transfer: Development of technology by R & D, Technology transfer from R & D to production, Optimization and Production, Qualitative and quantitative technology models.<br>Documentation in technology transfer: Development report, technology transfer plan and Exhibit. | **8 hours**<br>**4 hours** |

**Recommended Books^: (Latest Editions)**


1. Smith CG. James T and Donnell O. The Process of New Drug Discovery and Development. CRC Press. USA.
2. Lachman LL. Herbert AL. Theory and Practice of Industrial Pharmacy. Marcel Dekker Inc. New York.
3. Sidney H Willing, Murray M, Tuckerman. Williams Hitchings IV, Good manufacturing of pharmaceuticals (A Plan for total quality control). Bhalani Publishing House Mumbai.
4. Gibaldi M. Text book of Bio- Pharmaceutics and Clinical Pharmacokinetics. Lea & Febriger. Philadelphia.
5. Patravale VV, John ID, Rustomjee MT. Pharmaceutical Product Development. CRC Press, Group of Taylor and Francis. USA.
6. Abdou HM. Dissolution, Bioavailability and Bio-Equivalence. Mack Publishing Company. Eastern Pennsylvania.
7. Alfonso & Gennaro. Remingtons Pharmaceutical Sciences. Lippincott; Williams and Wilkins A Wolters Kluwer Company, Philadelphia.
8. Sawant DA. The Pharmaceutical Sciences; The Pharma Path way 'Pure and applied Pharmacy' Pragati Books Pvt. Ltd. Pune.
9. Dean DA, Evans ER. Hall IH. Pharmaceutical Packaging technology. Taylor and Francis. London and New York.


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Name of Program: **M. Pharm**
Branch: **A03 - Pharmaceutical Quality Assurance**
Semester: **I**
Course Code: **M030105PP**
Course Name: **Pharmaceutical Quality Assurance Practical**
Course Type: **Core**
Year of Implementation: **2024 – 25**

**Teaching and Examination Scheme:**

| Number of hours/ Week | | | Number of credits | | | Total credits | Evaluation Scheme (Marks) | | | | | | | | Total Marks |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | | | Sessional Exams | | | | | | Term End Assessment | | |
| | | | | | | | Theory | | | Practical | | | | | |
| L | Tu | P | L | Tu | P | | CIE | E | T | CIE | E | T | T | P | |
| 0 | 0 | 12 | 0 | 0 | 6 | 6 | 0 | 0 | 0 | 20 | 30 | 50 | 0 | 100 | 150 |

**Course Outcomes (CO):**
Upon completion of the course student shall be able to

| | |
|---|---|
| CO1 | Develop skills to Apply advanced spectrophotometric and chromatographic techniques for quantitative analysis of pharmacopoeial compounds and multi-component formulations. |
| CO2 | Perform and evaluate quality control tests for compliance with pharmacopoeial standards and case studies for process improvement. |

**List of Practicals:**
Total Teaching hours: 180 hours

**PART A:**

1. Analysis of pharmacopoeial compounds and their formulations by UV Vis spectrophotometer
2. Simultaneous estimation of multi component containing formulations by UV spectrophotometry
3. Experiments based on HPLC
4. Experiments based on Gas Chromatography
5. Estimation of riboflavin/quinine sulphate by fluorimetry
6. Estimation of sodium/potassium by flame photometry

**PART B:**

1. Case studies on

   a) Total Quality Management
   b) Six Sigma
   c) Change Management/ Change control. Deviations,
   d) Out of Specifications (OOS)
   e) Out of Trend (OOT)
   f) Corrective & Preventive Actions (CAPA)
   g) Deviations

2. Development of Stability study protocol
3. Estimation of process capability
4. In process and finished product quality control tests for tablets, capsules, Parenterals and semisolid dosage forms.
5. Testing of related and foreign substances in drugs and raw materials
6. To carry out pre formulation study for tablets, Parenterals (2 experiment).
7. To study the effect of pH on the solubility of drugs, (1 experiment)
8. Quality control tests for Primary and secondary packaging materials
9. Accelerated stability studies (1 experiment)
10. Improved solubility of drugs using surfactant systems (1 experiment)
11. Improved solubility of drugs using co-solvency method (1 experiment)
12. Determination of pKa and Log P of drugs.

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Awarding University: Gujarat Technological University, Ahmedabad

Name of Program: **M. Pharm**
Branch: **A03 - Pharmaceutical Quality Assurance**
Semester: **II**
Course Code: **M030201TT**
Course Name: **Hazards and Safety Management**
Course Type: **Core**
Year of Implementation: **2024 – 25**

**Teaching and Examination Scheme:**

| Number of hours/ Week | | | Number of credits | | | Total credits | Evaluation Scheme (Marks) | | | | | | | | Total Marks |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | | | Sessional Exams | | | | | | Term End Assessment | | |
| | | | | | | | Theory | | | Practical | | | | | |
| L | Tu | P | L | Tu | P | | CIE | E | T | CIE | E | T | T | P | |
| 4 | 0 | 0 | 4 | 0 | 0 | 4 | 10 | 15 | 25 | 0 | 0 | 0 | 75 | 0 | 100 |

**Scope:**
This course is designed to convey the knowledge necessary to understand issues related to different kinds of hazard and their management. Basic theoretical and practical discussions integrate the proficiency to handle the emergency in the pharmaceutical product development process and provides the principle-based approach to solve the complex tribulations.

**Course Outcomes (CO):**
Upon completion of the course student shall be able to

| | |
|---|---|
| CO1 | Understand the impact of natural and non-renewable resources on ecosystems, focusing on forest, water, mineral, energy, and land resources |
| CO2 | Evaluate air-based hazards and fire protection systems for maintaining sterile and non-sterile industrial areas |
| CO3 | Gain comprehensive knowledge on safety management techniques for controlling chemical hazards |
| CO4 | Develop an attitude of concern in pharmaceutical industry by integrating safety programs and emergency services effectively |

**Detailed Syllabus:**
Total Teaching hours: **60 hours**

| | | |
|---|---|---|
| **Unit 1** | Multidisciplinary nature of environmental studies: Natural Resources, Renewable and non-renewable resources, Natural resources and associated problems, a) Forest resources; b) Water resources; c) Mineral resources; d) Energy resources e) Land resources | **7 hours** |
| | Ecosystems: Concept of an ecosystem and Structure and function of an | **5 hours** |

| | | |
|---|---|---|
| | ecosystem. Environmental hazards: Hazards based on Air, Water, Soil and Radioisotopes. | |

| | | |
|---|---|---|
| **Unit 2** | Air based hazards: Sources, Types of Hazards, Air circulation maintenance industry for sterile area and non-sterile area, Preliminary Hazard Analysis (PHA)<br>Fire protection system: Fire prevention, types of fire extinguishers and critical Hazard management system. | **7 hours**<br>**5 hours** |
| **Unit 3** | Chemical based hazards: Sources of chemical hazards, Hazards of Organic synthesis, sulphonating hazard, Organic solvent hazard, Control measures for chemical hazards<br>Management of combustible gases, Toxic gases and Oxygen displacing gases management, Regulations for chemical hazard, Management of over-Exposure to chemicals and TLV concept | **6 hours**<br>**6 hours** |
| **Unit 4** | Fire and Explosion: Introduction, Industrial processes and hazards potential, mechanical electrical, thermal and process hazards. Safety and hazards regulations,<br>Fire protection system: Fire prevention, types of fire extinguishers and critical, Hazard management system mechanical and chemical explosion, multiphase reactions, transport effects and global rates. Preventive and protective management from fires and explosion electricity passivation, ventilation, and sprinkling, proofing, relief systems-relief valves, flares, scrubbers | **4 hours**<br>**8 hours** |
| **Unit 5** | Hazard and risk management: Self-protective measures against workplace hazards. Critical training for risk management, Process of hazard management, ICH guidelines on risk assessment and Risk management methods and Tools<br>Factory act and rules, fundamentals of accident prevention, elements of safety programme and safety management, Physicochemical measurements of effluents, BOD, COD, Determination of some contaminants, Effluent treatment procedure, Role of emergency services. | **6 hours**<br>**6 hours** |

**Recommended Books^: (Latest Editions)**


1. Sing YK. Environmental Science. New Age International Pvt Publishers. Bangalore.
2. Quantitative Risk Assessment in Chemical Process Industries. American Institute of Chemical Industries. Centre for Chemical Process safety.
3. Bharucha Erach. The Biodiversity of India. Mapin Publishing Pvt. Ltd. Ahmedabad. India.
4. Dikshit TSS. Hazardous Chemicals: Safety Management and Global Regulations. CRC press. USA.


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**ANAND PHARMACY COLLEGE, ANAND**
**(An Autonomous College under UGC Regulations 2023)**
**Managed by Shri Ramkrishna Seva Mandal**
(Approved by PCI, NAAC Accredited – A+ Grade, 3.38 CGPA)
Awarding University: Gujarat Technological University, Ahmedabad

Name of Program: **M. Pharm**
Branch: **A03 - Pharmaceutical Quality Assurance**
Semester: **II**
Course Code: **M030202TT**
Course Name: **Pharmaceutical Validation**
Course Type: **Core**
Year of Implementation: **2024 – 25**

**Teaching and Examination Scheme:**

| Number of hours/ Week | | | Number of credits | | | Total credits | Evaluation Scheme (Marks) | | | | | | | | Total Marks |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | | | Sessional Exams | | | | | | Term End Assessment | | |
| | | | | | | | Theory | | | Practical | | | | | |
| L | Tu | P | L | Tu | P | | CIE | E | T | CIE | E | T | T | P | |
| 4 | 0 | 0 | 4 | 0 | 0 | 4 | 10 | 15 | 25 | 0 | 0 | 0 | 75 | 0 | 100 |

**Scope:**
The main purpose of the subject is to understand about validation and how it can be applied to industry and thus improve the quality of the products. The subject covers the complete information about validation, types, methodology and application.

**Course Outcomes (CO):**
Upon completion of the course student shall be able to

| | |
|---|---|
| CO1 | Understand and apply basic concepts of calibration, qualification, and validation in pharmaceutical industry |
| CO2 | Understand the role of intellectual property and patent filing procedure in pharmaceutical industry |
| CO3 | Develop and apply skills for qualification and validation of different equipment as per guidelines |
| CO4 | Describe the key concepts and documentation for process and cleaning validation as per guidelines |

**Detailed Syllabus:**
Total Teaching hours: **60 hours**

| | | |
|---|---|---|
| **Unit 1** | Introduction to validation: Definition of Calibration, Qualification and Validation, Scope, frequency, and importance. Difference between calibration and validation. Calibration of weights and measures. Advantages of Validation, scope of Validation, Organization for Validation, Validation Master plan, Types of Validation, Streamlining of qualification & Validation process and Validation Master Plan. | **6 hours** |

| | | |
|---|---|---|
| | Qualification: User requirement specification, Design qualification, Factory Acceptance Test (FAT)/Site Acceptance Test (SAT), Installation qualification, Operational qualification, Performance qualification, Re-Qualification (Maintaining status Calibration Preventive Maintenance, Change management). | **5 hours** |
| **Unit 2** | Qualification of manufacturing equipment: Dry Powder Mixers, Fluid Bed and Tray dryers, Tablet Compression (Machine), Dry heat sterilization/Tunnels, Autoclaves, Membrane filtration, Capsule filling machine.<br>Qualification of analytical instruments: UV-Visible spectrophotometer, FTIR, DSC, GC, HPLC, HPTLC, LC-MS. | **5 hours**<br>**6 hours** |
| **Unit 3** | Qualification of laboratory equipment's: Hardness tester, Friability test apparatus, tap density tester, Disintegration tester, Dissolution test apparatus<br>Validation of Utility systems: Pharmaceutical water system & pure steam, HVAC system, Compressed air and nitrogen. | **5 hours**<br>**5 hours** |
| **Unit 4** | Process Validation: Concept, Process, and documentation of Process Validation. Prospective, Concurrent & Retrospective Validation, Re validation criteria, Process Validation of various formulations (Coated tablets, Capsules, Ointment/Creams, Liquid Orals, and aerosols.),<br>Aseptic filling: Media fill validation, USFDA guidelines on Process Validation-A life cycle approach.<br>Analytical method validation: General principles, Validation of analytical method as per ICH guidelines and USP. | **5 hours**<br>**3 hours**<br>**2 hours** |
| **Unit 5** | Cleaning Validation: Cleaning Method development, Validation of analytical method used in cleaning, Cleaning of Equipment, Cleaning of Facilities. Cleaning in place (CIP).<br>Validation of facilities in sterile and non-sterile plant.<br>Computerized system validation: Electronic records and digital signature 21CFR Part11and GAMP | **3 hours**<br>**3 hours**<br>**3 hours** |
| **Unit 6** | General Principles of Intellectual Property: Concepts of Intellectual Property (IP), Intellectual Property Protection (IPP), Intellectual Property Rights (IPR); Economic importance, mechanism for protection of Intellectual Property –patents, Copyright, Trademark; Factors affecting choice of IP protection; Penalties for violation; Role of IP in pharmaceutical industry; Global ramification and financial implications. Filing a patent application; patent application forms and guidelines.<br>Types patent applications provisional and non-provisional, PCT and convention patent applications; International patenting requirement procedures and costs; Rights and responsibilities of a patentee; Practical aspects regarding maintaining of a Patent file; Patent infringement meaning and scope. Significance of transfer technology (TOT), IP and ethics-positive and negative aspects of IPP; Societal responsibility, avoiding unethical practices | **5 hours**<br>**4 hours** |

**Recommended Books^: (Latest Editions)**


1. Loftus BT, Nash RA. Pharmaceutical Process Validation Drugs and Pharm Science. Series. Marcel Dekker. New York.
2. Leon Lachman, Herbert A. Lieberman, Joseph. L. Karig. The Theory &Practice of Industrial Pharmacy. Varghese Publishing House, Bombay.
3. Terveeks or Deeks. Validation Master plan. Davis Harwood International Publishing
4. Carleton FJ, Agalloco JP. Validation of Aseptic Pharmaceutical Processes. M. Decker. New York.
5. Levin M. Pharmaceutical process scale-up.: Marcel Dekker; New York.
6. Haider SI. Validation standard operating procedures: A step-by-step guide for achieving compliance in the pharmaceutical, medical device, and biotech industries. CRC Press. USA
7. Cloud P. Pharmaceutical equipment validation: The ultimate qualification guidebook. CRC Press. USA.
8. Carleton FJ, Agalloco JP. Validation of Pharmaceutical Processes: Sterile Products. Informa Health Care. CRS press. USA.
9. Chan CC, Lam H, Lee YC, Zhang XM, editors. Analytical method validation and instrument performance verification. Hoboken: John Wiley & Sons. New York.
10. Huber L. Validation and qualification in analytical laboratories. CRC Press. USA.
11. Wingate G. Validating Corporate Computer Systems: Good IT Practice for Pharmaceutical Manufacturers. CRC Press.
12. Le Blanc DA. Validated Cleaning Technologies for Pharmaceutical Manufacturing. Interpharm Press. USA.


L= Lecture, Tu= Tutorial, P= Practical, T = Theory

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Awarding University: Gujarat Technological University, Ahmedabad

Name of Program: **M. Pharm**
Branch: **A03 - Pharmaceutical Quality Assurance**
Semester: **II**
Course Code: **M030203TT**
Course Name: **Audits and Regulatory Compliance**
Course Type: **Core**
Year of Implementation: **2024 – 25**

**Teaching and Examination Scheme:**

| Number of hours/ Week | | | Number of credits | | | Total credits | Evaluation Scheme (Marks) | | | | | | | | Total Marks |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | | | Sessional Exams | | | | | | Term End Assessment | | |
| | | | | | | | Theory | | | Practical | | | | | |
| L | Tu | P | L | Tu | P | | CIE | E | T | CIE | E | T | T | P | |
| 4 | 0 | 0 | 4 | 0 | 0 | 4 | 10 | 15 | 25 | 0 | 0 | 0 | 75 | 0 | 100 |

**Scope:**
This course deals with the understanding and process for auditing in pharmaceutical industries. This subject covers the methodology involved in the auditing process of different in pharmaceutical industries.

**Course Outcomes (CO):**
Upon completion of the course student shall be able to

| | |
|---|---|
| CO1 | Understand the concept of quality systems and audits in pharmaceutical manufacturing |
| CO2 | Illustrate the methodology of auditing and apply auditing techniques to assess compliance in various areas |
| CO3 | Evaluate the effectiveness of quality assurance and engineering systems focusing on critical systems enabling improvements based on audit findings |
| CO4 | Create detailed audit checklists for pharmaceutical industry by application of principles of quality systems, regulatory requirements, and risk management strategies |

**Detailed Syllabus:**
Total Teaching hours: **60 hours**

| | | |
|---|---|---|
| **Unit 1** | Introduction: Objectives, Management of audit, Responsibilities, Planning process, Information gathering, administration, Classifications of deficiencies. | **12 hours** |
| **Unit 2** | Role of quality systems and audits in pharmaceutical manufacturing environment: cGMP Regulations, Quality assurance functions, Quality systems approach, Management responsibilities, Resource, Manufacturing operations, Evaluation activities, Transitioning to quality system approach. Audit checklist for drug industries | **10 hours**<br><br>**2 hours** |

| | | |
|---|---|---|
| **Unit 3** | Auditing of vendors and production department: Bulk Pharmaceutical Chemicals and packaging material Vendor audit, Warehouse and weighing<br>Dry Production: Granulation, tableting, coating, capsules, sterile production, and packaging | **6 hours**<br><br>**6 hours** |
| **Unit 4** | Auditing of Microbiological laboratory: Auditing the manufacturing process, Product, and process information<br>General areas of interest in the building raw materials, Water, Packaging materials. | **6 hours**<br><br>**6 hours** |
| **Unit 5** | Auditing of Quality Assurance and engineering department: Quality Assurance Maintenance<br>Critical systems: HVAC, Water, Water for Injection systems, ETP. | **6 hours**<br><br>**6 hours** |

**Recommended Books^: (Latest Editions)**


1. Karen G, Gil B. Compliance Auditing for Pharmaceutical Manufacturers. New York: CRC Press. USA.
2. Shayne Cox Gad. Manufacturing Handbook, Regulations and Quality. Wiley Inter science, A John Wiley and Sons, Inc., Publications.
3. Baird RM, Hodges NA, Denyer SP. Handbook of Microbiological Quality Control in Pharmaceuticals and Medical Devices. CRC Press. USA
4. Singer DC, Stefan RI, Van Staden JF. Laboratory Auditing for Quality and Regulatory Compliance. (No Title). 2005 Jul 25.


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Awarding University: Gujarat Technological University, Ahmedabad

Name of Program: **M. Pharm**
Branch: **A03 - Pharmaceutical Quality Assurance**
Semester: **II**
Course Code: **M030204TT**
Course Name: **Pharmaceutical Manufacturing Technology**
Course Type: **Core**
Year of Implementation: **2024 – 25**

**Teaching and Examination Scheme:**

| Number of hours/ Week | | | Number of credits | | | Total credits | Evaluation Scheme (Marks) | | | | | | | | Total Marks |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | | | Sessional Exams | | | | | | Term End Assessment | | |
| | | | | | | | Theory | | | Practical | | | | | |
| L | Tu | P | L | Tu | P | | CIE | E | T | CIE | E | T | T | P | |
| 4 | 0 | 0 | 4 | 0 | 0 | 4 | 10 | 15 | 25 | 0 | 0 | 0 | 75 | 0 | 100 |

**Scope:**
This course is designed to impart knowledge and skills necessary to train the students with the industrial activities during Pharmaceutical Manufacturing.

**Course Outcomes (CO):**
Upon completion of the course student shall be able to

| | |
|---|---|
| CO1 | Understand the legal and plant related requirements for production in the pharmaceutical industry |
| CO2 | Gain knowledge on the practices of the quality control tests for containers and closures as per industry standards and regulatory requirements |
| CO3 | Understand the QbD and PAT principles along with risk assessment for quality improvement |
| CO4 | Illustrate and apply the knowledge of aseptic process technology, non-sterile manufacturing and packaging to optimize production for ensuring product safety and efficacy |

**Detailed Syllabus:**
Total Teaching hours: **60 hours**

| | | |
|---|---|---|
| **Unit 1** | Pharmaceutical industry developments: Legal requirements and Licenses for API and formulation industry, Plant location Factors influencing. | **3 hours** |
| | Plant layout: Factors influencing, Special provisions, Storage space requirements, sterile and aseptic area layout. | **3 hours** |
| | Production planning: General principles, production systems, calculation of standard cost, process planning, routing, loading, scheduling, dispatching of records, production control | **4 hours** |

| | | |
|---|---|---|
| **Unit 2** | Aseptic process technology: Manufacturing, manufacturing flowcharts, in process-quality control tests for following sterile dosage forms: Ointment, Suspension and Emulsion, Dry powder, Solution (Small Volume & large Volume).<br>Advanced sterile product manufacturing technology: Area planning & environmental control, wall and floor treatment, fixtures, and machineries, change rooms, personnel flow, utilities & utilities equipment location, engineering, and maintenance.<br>Process Automation in Pharmaceutical Industry: With specific reference to manufacturing of sterile semisolids, Small Volume Parenterals & Large Volume Parenterals (SVP &LVP), Monitoring of Parenteral manufacturing facility, Cleaning in Place (CIP), Sterilization in Place (SIP), Prefilled Syringe, Powdered Jet, Needle Free Injections, and Form Fill Seal Technology (FFS). Lyophilization technology: Principles, process, equipment. | **4 hours**<br>**3 hours**<br>**5 hours** |
| **Unit 3** | Non sterile manufacturing process technology: Manufacturing, manufacturing flowcharts, in process-quality control tests for following Nonsterile solid dosage forms: Tablets (compressed & coated), Capsules (Hard &Soft).<br>Advance non-sterile solid product manufacturing technology: Process Automation in Pharmaceutical Industry with specific reference to manufacturing of tablets and coated products.<br>Improved Tablet Production: Tablet production process, granulation and palletisation equipment's, continuous and batch mixing, rapid mixing granulators, rota granulators, spheronizers and marumerisers, and other specialized granulation and drying equipment's. Problems encountered.<br>Coating technology: Process, equipment's, particle coating, fluidized bed coating, application techniques. Problems encountered. | **3 hours**<br>**3 hours**<br>**4 hours**<br>**2 hours** |
| **Unit 4** | Containers and closures for pharmaceuticals: Types, performance, assuring quality of glass; types of plastics used, Drug plastic interactions, biological tests, modification of plastics by drugs.<br>Different types of closures and closure liners; film wrapper; blister packs; bubble packs; shrink packaging; foil / plastic pouches, bottle seals, tape seals, breakable seals, and sealed tubes.<br>Quality control of packaging material and filling equipment, flexible packaging, product package compatibility, transit worthiness of package, Stability aspects of packaging. Evaluation of stability of packaging material | **4 hours**<br>**4 hours**<br>**4 hours** |
| **Unit 5** | Quality by design (QbD) and process analytical technology (PAT): Current approach and its limitations. Why QbD is required, Advantages, Elements of QbD, Terminology: QTPP. CMA, CQA, CPP, RLD, Design space, Design of Experiments, Risk Assessment, and mitigation/minimization.<br>Quality by Design, Formulations by Design, QbD for drug products, QbD for Drug Substances, QbD for Excipients, Analytical QbD. FDA initiative on process analytical technology.<br>PAT as a driver for improving quality and reducing costs: quality by design (QbD), QA, QC and GAMP. PAT guidance, standards, and regulatory requirements | **6 hours**<br>**3 hours**<br>**3 hours** |

**Recommended Books^: (Latest Editions)**


1. Lachman L. Lieberman H. A. Kanig JL. The Theory and Practice of Industrial Pharmacy. Varghese Publishers. Mumbai.
2. Sinko PJ. Martin's Physical Pharmacy and Pharmaceutical Sciences. Lippincott Williams and Wilkins. Noida.
3. Lieberman HA, Lachman L, Schwartz JB. Pharmaceutical Dosage Forms: Tablets. CBS Publishers & Distributors. New Delhi.
4. Banker GS, Rhodes CT. Modern Pharmaceutics, 4 Inc, New York.
5. Sidney H Willing, Murray M, Tuckerman. Williams Hitchings IV, Good Manufacturing of Pharmaceuticals (A Plan for total quality control). Bhalani Publishing House Mumbai.
6. Indian Pharmacopoeia.
7. British Pharmacopoeia.
8. United States Pharmacopoeia.
9. Dean DA, Evans ER and Hall IH. Pharmaceutical Packaging Technology. Taylor &Francis. UK.
10. Edward J Bauer. Pharmaceutical Packaging Handbook. 2009.Informa Healthcare USA Inc. New York. USA.
11. Shaybe Cox Gad. Pharmaceutical Manufacturing Handbook. John Willey and Sons, New Jersey. USA.


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Awarding University: Gujarat Technological University, Ahmedabad

Name of Program: **M. Pharm**
Branch: **A03 - Pharmaceutical Quality Assurance**
Semester: **II**
Course Code: **M030205PP**
Course Name: **Pharmaceutical Quality Assurance Practical**
Course Type: **Core**
Year of Implementation: **2024 – 25**

**Teaching and Examination Scheme:**

| Number of hours/ Week | | | Number of credits | | | Total credits | Evaluation Scheme (Marks) | | | | | | | | Total Marks |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | | | Sessional Exams | | | | | | Term End Assessment | | |
| | | | | | | | Theory | | | Practical | | | | | |
| L | Tu | P | L | Tu | P | | CIE | E | T | CIE | E | T | T | P | |
| 0 | 0 | 12 | 0 | 0 | 6 | 6 | 0 | 0 | 0 | 20 | 30 | 50 | 0 | 100 | 150 |

**Course Outcomes (CO):**
Upon completion of the course student shall be able to

| | |
|---|---|
| CO1 | Understand and gain knowledge related to techniques for contaminant analysis, equipment qualification, method validation, check list preparation and design in pharmaceutical manufacturing |
| CO2 | Perform and evaluate contaminants and pollutants, perform equipment qualification and method validation, design plant layout and apply QbD and PAT principles through case studies |

**List of practicals:**
**Total Teaching hours: 120 hours**

1. Organic contaminants residue analysis by HPLC
2. Estimation of Metallic contaminants by Flame photometer
3. identification of antibiotic residue by TLC
4. Estimation of Hydrogen Sulphide in Air
5. Estimation of Chlorine in Work Environment
6. Sampling and analysis of $SO_2$ using Colorimetric method
7. Qualification of following Pharma equipment
   a) Autoclave
   b) Hot air oven
   c) Powder Mixer (Dry)
   d) Tablet Compression Machine

8. Validation of an analytical method for a drug
9. Validation of a processing area
10. Qualification of atleast two analytical instruments
11. Cleaning validation of one equipment
12. Qualification of Pharmaceutical Testing Equipment (Dissolution testing apparatus, Friability Apparatus, Disintegration Tester)
13. Check list for Bulk Pharmaceutical Chemicals vendors
14. Check list for tableting production
15. Check list for sterile production area
16. Check list for Water for injection
17. Design of plant layout: Sterile and non-sterile
18. Case study on application of QbD
19. Case study on application of PAT

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Awarding University: Gujarat Technological University, Ahmedabad

Name of Program: **M. Pharm**
Branch: – **A04 - Pharmaceutical Technology**
Semester: **I**
Course Code: **M000101TT**
Course Name: **Modern Pharmaceutical Analytical Techniques**
Course Type: **Core**
Year of Implementation: **2024 – 25**

**Teaching and Examination Scheme:**

| Number of hours/ Week | | | Number of credits | | | Total credits | Evaluation Scheme (Marks) | | | | | | | | Total Marks |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | | | Sessional Exams | | | | | | Term End Assessment | | |
| | | | | | | | Theory | | | Practical | | | | | |
| L | Tu | P | L | Tu | P | | CIE | E | T | CIE | E | T | T | P | |
| 4 | 0 | 0 | 4 | 0 | 0 | 4 | 10 | 15 | 25 | 0 | 0 | 0 | 75 | 0 | 100 |

**Scope:**
This subject deals with various advanced analytical instrumental techniques for identification, characterization, and quantification of drugs. Instruments dealt are NMR, Mass spectrometer, IR, HPLC, GC etc.

**Course Outcomes (CO):**
Upon completion of the course student shall be able to

| | |
|---|---|
| CO1 | Understand different chromatographic principles, instrumentation and techniques |
| CO2 | Understand principles and instrumentation for electrophoresis, X-ray crystallography, potentiometry, and thermal analysis |
| CO3 | Understand and apply principles, instrumentation, and techniques of various spectroscopic methods |
| CO4 | Apply principles of spectroscopic techniques to identify and quantify various drugs |

**Detailed Syllabus:**
Total Teaching hours: **60 hours**

| | | |
|---|---|---|
| **Unit 1** | **UV-Visible spectroscopy:** Introduction, Theory, Laws, Instrumentation associated with UV-Visible spectroscopy, Choice of solvents and solvent effect and Applications of UV-Visible Spectroscopy, Simultaneous equation method, Derivative spectroscopic method, Difference spectroscopic method | **4 hours** |
| | **IR spectroscopy:** Theory, Modes of Molecular vibrations, Sample handling, Instrumentation of Dispersive and Fourier - Transform IR Spectrometer, Factors affecting vibrational frequencies and Applications of IR spectroscopy, Data interpretation | **2 hours** |
| | **Spectrofluorimetry:** Theory of Fluorescence, Factors affecting fluorescence, Quenchers, Instrumentation and Applications of fluorescence | **2 hours** |

| | | |
|---|---|---|
| | Spectrophotometer<br>**Flame emission spectroscopy and atomic absorption spectroscopy:** Principle, Instrumentation, Interferences and Applications | **2 hours** |
| **Unit 2** | **NMR spectroscopy:** Quantum numbers and their role in NMR, Principle, Instrumentation, Solvent requirement in NMR, Relaxation process, NMR signals in various compounds, Chemical shift, Factors influencing chemical shift, Spin-Spin coupling, Coupling constant, Nuclear magnetic double resonance. Brief outline of principles of FT-NMR and 13C NMR. Applications of NMR spectroscopy | **11 hours** |
| **Unit 3** | **Mass Spectroscopy:** Principle, Theory, Instrumentation of Mass Spectroscopy, Different types of ionization like electron impact, chemical, field, FAB and MALDI, APCI, ESI, APPI Analyzers of Quadrupole and Time of Flight, Mass fragmentation and its rules, Meta stable ions, Isotopic peaks, and Applications of Mass Spectroscopy | **10 hours** |
| **Unit 4** | **Chromatography:** Principle, apparatus, instrumentation, chromatographic parameters, factors affecting resolution and applications of the following:<br>a) Paper chromatography b) Thin Layer chromatography<br>c) Ion exchange chromatography d) Column chromatography<br>e) Gas chromatography<br>f) High Performance Liquid chromatography g) Affinity chromatography | <br><br>**3 hours**<br>**3 hours**<br>**2 hours**<br>**3 hours** |
| **Unit 5** | **Electrophoresis:** Principle, Instrumentation, working conditions, factors affecting separation and applications of the following:<br>a) Paper electrophoresis b) Gel electrophoresis c) Capillary electrophoresis d) Zone electrophoresis e) Moving boundary electrophoresis f) Iso electric focusing<br>**X ray Crystallography:** Production of X rays, Different X ray diffraction methods, Bragg's law, Rotating crystal technique, X ray powder technique, Types of crystals and applications of Xray diffraction. | **6 hours**<br><br><br><br><br>**3 hours** |
| **Unit 6** | **Potentiometry:** Principle, Ion selective Electrodes and Application of potentiometry.<br>**Thermal Analysis:** Principle, thermal transitions, and instrumentation (heat flux and power compensation and designs) working, Polymer behavior, factors affecting and instrumentation, and working, application of TGA | **4 hours**<br><br>**3 hours** |

**Recommended Books^: (Latest Editions)**


1. Silverstein RM, Bassler GC. Spectrometric identification of organic compounds. John Wiley & Sons. New York
2. Doglas A Skoog, F. James Holler, Timothy A. Nieman. Principles of Instrumental Analysis Eastern press. Bangalore.
3. Willard H, Merritt LL, Dean JA, Settle FA. Instrumental methods of analysis. CBS publisher and distributors. New Delhi. India
4. Beckett AH and Stenlake JB. Practical Pharmaceutical Chemistry. CBS Publishers. New Delhi. India Kemp W. Organic Spectroscopy. ELBS. Macmillan
5. Sethi PD. Quantitative analysis of drugs in pharmaceutical formulations. Unique Publishers. New Delhi. India.

6. Munson JW. Pharmaceutical analysis: modern methods. B. Drugs and the pharmaceutical sciences. Marcel Dekker. New York.

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Awarding University: Gujarat Technological University, Ahmedabad

Name of Program: **M. Pharm**
Branch: **A04 - Pharmaceutical Technology**
Semester: **I**
Course Code: **M040102TT**
Course Name: **Advances in Drug Delivery Systems**
Course Type: **Core**
Year of Implementation: **2024 – 25**

**Teaching and Examination Scheme:**

| Number of hours/ Week | | | Number of credits | | | Total credits | Evaluation Scheme (Marks) | | | | | | | | Total Marks |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | | | Sessional Exams | | | | | | Term End Assessment | | |
| | | | | | | | Theory | | | Practical | | | | | |
| L | Tu | P | L | Tu | P | | CIE | E | T | CIE | E | T | T | P | |
| 4 | 0 | 0 | 4 | 0 | 0 | 4 | 10 | 15 | 25 | 0 | 0 | 0 | 75 | 0 | 100 |

**Scope:**
This course is designed to impart knowledge on the area of advances in novel drug delivery systems.

**Course Outcomes (CO):**
Upon completion of the course student shall be able to

| | |
|---|---|
| CO1 | Understand physicochemical properties to develop modified release controlled, targeted and novel drug delivery systems |
| CO2 | Identify the need and differentiate the concept of varied drug delivery systems |
| CO3 | Apply the understanding of different drug delivery system based on route of administration |
| CO4 | Integrate the concepts of personalized medicine, bioelectronic medicines, and 3D printing technologies to create customized drug delivery systems |

**Detailed Syllabus:**
Total Teaching hours: **60 hours**

| | | |
|---|---|---|
| **Unit 1** | **Sustained Release (SR) and Controlled Release (CR) formulations:** Introduction & basic concepts, advantages/ disadvantages, factors influencing, physicochemical & biological approaches for SR/CR formulation, mechanism of drug delivery from SR/CR formulation. **Polymers**: Introduction, definition, classification, properties and application. | **10 hours** |
| **Unit 2** | **Rate Controlled Drug Delivery Systems**: Principles & fundamentals, types, mechanism, activation; modulated drug delivery systems; principles & fundamentals of mechanically activated, pH activated, enzyme activated, and osmotic activated drug delivery systems, feedback regulated drug delivery systems | **05 hours** |

| | | |
|---|---|---|
| **Unit 3** | **Micro encapsulation:**<br>Definition, objectives of microencapsulation. Release & stability kinetics, materials used for microencapsulation, various approaches for the preparation of microcapsules, evaluation & application of microencapsulation. | **10 hours** |
| **Unit 4** | **Gastro-Retentive Drug Delivery Systems**:<br>Principle, fundamentals, advantages and disadvantages, modulation of GI transit time approaches to extend GI transit, evaluation and application of GRDDS | **05 hours** |
| **Unit 5** | **Implants and Inserts:**<br>Reaction of host to implant, reaction of implant to host, subcutaneous implants, intra muscular implants, intra ocular implants, intra vaginal inserts, intra uterine implants. | **10 hours** |
| **Unit 6** | **Transdermal Drug Delivery Systems**:<br>Structure of skin and barriers, penetration enhancers, formulation and evaluation of TDDS, application, recent advances in TDDS | **10 hours** |
| **Unit 7** | **Dosage Forms for Personalized Medicine**:<br>Introduction, need, definition, pharmacogenetics, categories of patients for personalized medicines, customized drug delivery systems, **Bioelectronic medicines** – Introduction, approaches and application **3D printing of pharmaceuticals** – Introduction, technology and application<br>**Telepharmacy** - Introduction, technique and application | **10 hours** |

**Recommended Books^: (Latest Editions)**


1. Encyclopaedia of Pharmaceutical Technology, Jasmes Swarbrick and James C. Boylan, Marcel Dekker Inc., New York.
2. Theory and Practice of Industrial Pharmacy, L. Lachman, Vargish Publication, Bombay.
3. Modern Pharmaceutics, G. S. Banker and C. T. Rhodes, Marcel Dekker, Inc., New York.
4. Controlled Drug Delivery: J. R. Robinson and V. H. Lee, Marcel Dekker, Inc., New York.
5. Novel Drug Delivery Systems, Y. W. Chien, Marcel Dekker, Inc., New York.
6. Progress in Controlled and Novel Delivery Systems, edited by N. K. Jain, CBS Publishers & Distributors, New Delhi.


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Awarding University: Gujarat Technological University, Ahmedabad

Name of Program: **M. Pharm**
Branch: **A04 - Pharmaceutical Technology**
Semester: **I**
Course Code: **M040103TT**
Course Name: **Pharmaceutical Formulation and Development**
Course Type: **Core**
Year of Implementation: **2024 – 25**

**Teaching and Examination Scheme:**

| Number of hours/ Week | | | Number of credits | | | Total credits | Evaluation Scheme (Marks) | | | | | | | | Total Marks |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | | | Sessional Exams | | | | | | Term End Assessment | | |
| | | | | | | | Theory | | | Practical | | | | | |
| L | Tu | P | L | Tu | P | | CIE | E | T | CIE | E | T | T | P | |
| 4 | 0 | 0 | 4 | 0 | 0 | 4 | 10 | 15 | 25 | 0 | 0 | 0 | 75 | 0 | 100 |

**Scope:**
Course designed to impart advanced knowledge and skills required to learn various aspects and concepts at pharmaceutical formulation development.

**Course Outcomes (CO):**
Upon completion of the course student shall be able to

| | |
|---|---|
| CO1 | Understand the fundamentals of preformulation study in the designing of a dosage form. |
| CO2 | Identify the suitable excipients or biomaterial for a pharmaceutical formulation. |
| CO3 | Apply the principles of preformulation concept to formulate a stable, safe and effective dosage form. |
| CO4 | Execute the knowledge of regulatory guidelines of stability study to develop a stable product. |

**Detailed Syllabus:**
Total Teaching hours: **60 hours**

| | | |
|---|---|---|
| **Unit 1** | **Preformulation Study:**<br>• Physical, chemical and pharmaceutical factors influencing formulation<br>• Solid-state characterization: crystallinity, hygroscopicity, particle size and particle size distribution, compaction properties<br>• Crystalline and polymorphism and its evaluation. Rationale for selecting the preferred polymorph/crystalline form<br>• General principles and applications of various characterization techniques viz: differential thermal analysis differential scanning calorimetry, X-Ray diffraction FTIR in preformulation study.<br>• Drug-excipient compatibility study<br>• Traces of organic volatile impurities (OVIs) and their regulatory | **15 hours** |

| | | |
|---|---|---|
| | limits (residual solvents).<br>• Preformulation studies of Biotechnological derived products and reference guidelines. | |
| **Unit 2** | **Solubilization and Solubilized System**:<br>• Theoretical aspects and applications in drug solubilization.<br>• Techniques for improvement in drug solubilization for development of various Dosage forms | **10 hours** |
| **Unit 3** | **Dissolution study**:<br>• Importance, objectives, equipment's,<br>• Biological classification system (BCS); its significance on dissolution study and Application in dosage form development.<br>• Selection of dissolution media and conditions.<br>• Comparison of dissolution profile by model independent (similarity and dissimilarity factor) and dependent methods. | **10 hours** |
| **Unit 4** | **Stability Study:**<br>• Basic concept and objectives of stability study,<br>• Order of reaction and their applications in predicting shelf life and half-life of pharmaceutical formulations,<br>• Importance of accelerated stability study,<br>• 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.<br>• Regulatory requirements related to stability testing with emphasis on matrixing /bracketing techniques, climates zone, impurities in stability study, photostability testing etc.,<br>• Applications of microcalorimetry in stability study. | **15 hours** |
| **Unit 5** | **Excipients for Pharmaceutical formulations**:<br>• Factors affecting the selection (including safety considerations), drug-excipient and excipient- package interactions,<br>• Study of newer excipients like cyclodextrin, ion exchange resins, film coating materials, super-disintegrants, directly compressible vehicles, surfactants, thickeners.<br>• Co-processed excipients. | **06 hours** |
| **Unit 6** | **Biomaterials**:<br>Types, applications of biomaterials in pharmaceutical formulations & medicine, safety considerations of biomaterials, mechanism of biodegradation. | **04 hours** |

**Recommended Books^: (Latest Editions)**


1. Drug Stability, J. T. Carstensen, Marcel Dekker, New York.
2. Theory & Practice of Industrial Pharmacy, L. Lachman, Varghese Publication, Bombay.
3. Modern Pharmaceutics, G.S. Banker and C.T. Rhodes, Marcel Dekker, NY.
4. Physical Characterization of Pharmaceutical Solids, H. G. Brittain, Marcel Dekker, NY.
5. Physical Pharmacy, A. Martin, Lea and Febiger, Philadelphia.
6. Pharmaceutical dissolution testing, U.V. Banaker, Marcel Dekker, Inc., New York.
7. Pharmaceutical Dosage Forms: Parenteral Medications, Avis K. E., Leon Lachman and H. Lieberman, Marcel Dekker, New York
8. Pharmaceutical Dosage Forms: tablets, Lierberman H. A. and Leon Lachman, Marcel Dekker, New York

9. Biodegradable polymers as drug delivery systems, edited by M.Chasin, R.langer, Marcel Dekker, New York.
10. Handbook of Preformulations, S. K. Niazi, Informa Healthcare, New York.

L= Lecture, Tu= Tutorial, P= Practical, T = Theory

^ This is not an exhaustive list

**ANAND PHARMACY COLLEGE, ANAND**
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(Approved by PCI, NAAC Accredited – A+ Grade, 3.38 CGPA)
Awarding University: Gujarat Technological University, Ahmedabad

Name of Program: **M. Pharm**
Branch: **A04 - Pharmaceutical Technology**
Semester: **I**
Course Code: **M040104TT**
Course Name: **Pharmaceutical Regulatory Affairs**
Course Type: **Core**
Year of Implementation: **2024 – 25**

**Teaching and Examination Scheme:**

| Number of hours/ Week | | | Number of credits | | | Total credits | Evaluation Scheme (Marks) | | | | | | | | Total Marks |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | | | Sessional Exams | | | | | | Term End Assessment | | |
| | | | | | | | Theory | | | Practical | | | | | |
| L | Tu | P | L | Tu | P | | CIE | E | T | CIE | E | T | T | P | |
| 4 | 0 | 0 | 4 | 0 | 0 | 4 | 10 | 15 | 25 | 0 | 0 | 0 | 75 | 0 | 100 |

**Scope:**
The Course designed to impart advanced knowledge and skills required to learn various aspects and concepts at pharmaceutical industries.

**Course Outcomes (CO):**
Upon completion of the course student shall be able to

| | |
|---|---|
| CO1 | Understand regulatory guidelines and documentation requirements in the pharmaceutical industry, including the filing and approval processes |
| CO2 | Identify the need of the regulatory process to conduct a clinical study |
| CO3 | Apply the knowledge of regulatory procedure and documentation in dossiers submission of drug product and medical devices by CTD/eCTD |
| CO4 | Distinguish innovator and generic drug approval process and its regulatory guidelines according to various countries |

**Detailed Syllabus:**
Total Teaching hours: **60 hours**

| | | |
|---|---|---|
| **Unit 1** | **Documentation in Pharmaceutical industry:**<br>Master formula record, DMF (Drug Master File), distribution records. Generic drugs product development-Introduction, Hatch- Waxman act and amendments, CFR (code of federal regulation), drug product performance, in-vitro, ANDA regulatory approval process, NDA approval process, BE and drug product assessment, in –vivo, scale up process approval changes, post marketing surveillance, outsourcing BA and BE to CRO.<br>**Regulatory requirement for product approval:**<br>API, biologics, novel products, therapies obtaining NDA, ANDA for generic drugs ways and means of US registration for foreign drugs | **15 hours** |

| | | |
|---|---|---|
| **Unit 2** | **CMC** (chemistry Manufacturing control), post approval regulatory affairs. Regulation for combination Products and medical devices. CTD and eCTD format, industry and FDA liaison. ICH - Guidelines of ICH-Q, S E, M. Regulatory requirements of EU, MHRA, TGA and ROW countries. | **15 hours** |
| **Unit 3** | **Non clinical drug development**: Global submission procedure and documentation of IND, NDA, ANDA. Investigation of medicinal products dossier, dossier (IMPD) and investigator brochure (IB). | **15 hours** |
| **Unit 4** | **Clinical trials:** Developing criteria of clinical trial protocols and its fomat. Institutional review board/ independent ethics committee Formulation and working procedures informed Consent process and procedures. HIPAA- new requirement to clinical study process, pharmacovigilance safety monitoring in clinical trials. | **15 hours** |

**Recommended Books:**


1. Generic Drug Product Development, Solid Oral Dosage forms, Leon Shargel and IsaderKaufer,Marcel Dekker series, Vol.143
2. 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.
3. New Drug Approval Process: Accelerating Global Registrations By Richard A Guarino, MD,5th edition, Drugs and the Pharmaceutical Sciences, Vol.190.
4. Guidebook for drug regulatory submissions / Sandy Weinberg. By John Wiley & Sons. Inc.
5. FDA regulatory affairs: a guide for prescription drugs, medical devices, and biologics/edited By Douglas J. Pisano, David Mantus.
6. Clinical Trials and Human Research: A Practical Guide to Regulatory Compliance By Fay A. Rozovsky and Rodney K. Adams


**Links:**

1. www.ich.org/
2. www.fda.gov/
3. europa.eu/index_en.html
4. https://www.tga.gov.au/tga-basic

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Awarding University: Gujarat Technological University, Ahmedabad

Name of Program: **M. Pharm**
Branch: **A04 - Pharmaceutical Technology**
Semester: **I**
Course Code: **M040105PP**
Course Name: **Pharmaceutical Technology Practicals- I**
Course Type: **Core**
Year of Implementation: **2024 – 25**

**Teaching and Examination Scheme:**

| Number of hours/ Week | | | Number of credits | | | Total credits | Evaluation Scheme (Marks) | | | | | | | | Total Marks |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | | | Sessional Exams | | | | | | Term End Assessment | | |
| | | | | | | | Theory | | | Practical | | | | | |
| L | Tu | P | L | Tu | P | | CIE | E | T | CIE | E | T | T | P | |
| 0 | 0 | 12 | 0 | 0 | 6 | 6 | 0 | 0 | 0 | 20 | 30 | 50 | 0 | 100 | 150 |

**Scope:**
Course designed to impart advanced knowledge and skills required to learn the concept of quality assurance, statistical inference in development of analytical method, validation and product optimization process.

**Course Outcomes (CO):**
Upon completion of the course student shall be able to

| | |
|---|---|
| CO1 | Recall the impact of pre-formulation parameters, ingredients, and process variables on the formulation and evaluation of modified release solid dosage forms. |
| CO2 | Design, optimize, and evaluate modified release solid dosage forms, and analyze the impact of process and material attributes. |

**Detailed Syllabus:**
Total Teaching hours: **180 hours**

1. Determination of the wavelength of maximum absorbance (λ max) of given compounds by UV Visible spectrophotometry.
2. Quantitative estimation of Pharmacopeial compounds by UV-Visible spectrophotometry.
3. UV-Vis spectrophotometric assay of pharmaceutical formulations containing Pharmacopeial compounds as active ingredients.
4. Simultaneous estimation of multi component containing formulations by UV-Visible spectrophotometry.
5. Simultaneous estimation of any marketed formulation using RP-HPLC method.
6. Stability studies of marketed formulation by RP-HPLC method as per ICH guidelines.
7. Estimation of riboflavin/quinine sulphate by fluorimetry.
8. Effect of particle size of Paracetamol on the dissolution rate (Micronization).
9. Effect of polymorphism on the dissolution rate testing of Ibuprofen (Co- crystallization).

10. Formulation and evaluation of sustained release matrix tablets.
11. To perform In-vitro dissolution profile of CR/ SR marketed formulation.
12. To plot Heckal plot, Higuchi and peppas plot and determine similarity factor.
13. Preparation and evaluation of floating DDS.
14. Formulation and evaluation of transdermal patch.
15. Preparation and evaluation of in situ gel/Ophthalmic formulation.
16. Formulation and evaluation of gelatin microcapsules/beads.
17. Formulation and evaluation of enteric coating tablets.
18. Accelerated stability studies of Aspirin. (Effect temperature on rate of Hydrolysis of Aspirin & Determination of Shelf life).
19. Development of dissolution medium for a poorly soluble drug. (Solubility Enhancement- Complexation)
20. In process and finished product quality control tests for tablets and capsules (minitablet/Pulsincap).

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Awarding University: Gujarat Technological University, Ahmedabad

Name of Program: **M. Pharm**
Branch: **A04 - Pharmaceutical Technology**
Semester: **II**
Course Code: **M040201TT**
Course Name: **Pharmaceutical Production Management & Technology**
Course Type: **Core**
Year of Implementation: **2024 – 25**

**Teaching and Examination Scheme:**

| Number of hours/ Week | | | Number of credits | | | Total credits | Evaluation Scheme (Marks) | | | | | | | | Total Marks |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | | | Sessional Exams | | | | | | Term End Assessment | | |
| | | | | | | | Theory | | | Practical | | | | | |
| L | Tu | P | L | Tu | P | | CIE | E | T | CIE | E | T | T | P | |
| 4 | 0 | 0 | 4 | 0 | 0 | 4 | 10 | 15 | 25 | 0 | 0 | 0 | 75 | 0 | 100 |

**Scope:**
The Course designed to impart advanced knowledge and skills required to learn various aspects and concepts at pharmaceutical industries.

**Course Outcomes (CO):**
Upon completion of the course student shall be able to

| | |
|---|---|
| CO1 | Understand the processes and technology involved in manufacturing of sterile and non-sterile dosage forms. |
| CO2 | Demonstrate the significance of pilot plant and manufacturing scale up technique for different dosage form. |
| CO3 | Apply the principles of industrial management to optimize the usage of available resources. |
| CO4 | Integrate the skills and knowledge to increase industrial safety and to manage waste. |

**Detailed Syllabus:**
Total Teaching hours: **60 hours**

| | | |
|---|---|---|
| **Unit 1** | **Pharmaceutical Manufacturing, manufacturing flowcharts, in process-quality control tests for following sterile dosage forms**: Types of sterile dosage form SVP and LVP, ointment, suspension and micro and nano emulsion, dry powder, solution (small volume & large volume) advance sterile product manufacturing technology: area planning & environmental control, wall and floor treatment, fixtures and machineries, change rooms, personnel flow, utilities & utilities equipment location, engineering and maintenance. process automation in pharmaceutical industry with specific reference to manufacturing of sterile semisolids, small volume parenteral & large volume parenteral (SVP & LVP), monitoring of parenteral manufacturing facility, cleaning in place (CIP), sterilization in place (SIP), prefilled syringe, powdered | **11 hours** |

| | | |
|---|---|---|
| | jet, needle free injections, and form fill seal technology (FFS), lyophilization technology: principles, process and equipment's. | |
| **Unit 2** | **Manufacturing, manufacturing flowcharts, in process-quality control tests for following non-sterile solid dosage forms**: Tablets (compressed & coated), capsules (hard & soft) advance non-sterile solid product manufacturing technology: process automation in pharmaceutical industry with specific reference to manufacturing of tablets and coated products, improved tablet production: tablet production process, granulation and palletisation equipment's, continuous and batch mixing, rapid mixing granulators, rota granulators, spheronizers and marumeriser, and other specialized granulation and drying equipment's. Problems encountered. Coating technology: process, equipment, particle coating, fluidized bed coating, and application techniques. Remedies for commonly encountered problem. | **15 hours** |
| **Unit 3** | **Pilot plant and manufacturing scale up technique:** Pilot plant scale up and its significance, and general requirements, scale up study of some important dosage forms such as tablets, capsules, semi solids, liquids orals and injectable; discussion on important parameters such as formula, equipment's, product uniformity, stability, and challenges. | **15 hours** |
| **Unit 4** | **Production, Planning, Control and Documentation:** Production scheduling and forecasting; vendor development capacity assessment (plant, machines, raw materials, human resources); production management, production organization, objectives and policies guide to pharmaceutical manufacturing practices and facilities; implications of reducing costs; documentation. control charts and quality metrics, calculation of Cp and Cpk. | **10 hours** |
| **Unit 5** | **Packaging Technology:** Unit dose packaging, strip packaging materials, packaging of dosage forms: solid dosage forms, parenterals, ophthalmic dosage forms, stability aspects of packaging, evaluation of packaging material: material properties, testing methods, regulatory requirements, evaluation of stability of packaging material: shelf-life studies, environmental testing, impact on product quality, packaging innovations and trends. | **05 hours** |
| **Unit 6** | **Plant Design**: Basic requirements of design, plant layout, design of large-scale manufacturing unit for sterile and nonsterile products (with special reference to tablets, capsules as per schedule m), the emphasis be also given to design of facilities & utilities, design of pilot plant for tablets, capsules, equipment selection vs plant design, heating, ventilation, and air conditioning system (HVAC) design and specification, environmental control, air filtration and purification, temperature and humidity control, energy efficiency, maintenance and monitoring | **08 hours** |
| **Unit 7** | **Industrial safety and waste management:** Hazards – fire, mechanical, electrical, chemical and pharmaceutical, monitoring & prevention systems. Waste management: sewage water treatments (waste water treatment), treatments of other waste from pharma industry, industrial effluent testing & treatment. Control of environmental pollution. | **07 hours** |

**Recommended Books:**


1. Good manufacturing Practices for Pharmaceuticals: A plan fir total quality control by Sidney H, Willig 2000, 5th edition.
2. Applied production and operations management: by Evans, Anderson, Sweeney and Williams. 3rd edition west publish company ltd. st. paul USA 1985
3. A Text of Pharmacy management, HW Tomski, Logan Page ltd. London
4. ISO 9000 and 14000 series brian Rothery Gower pub company 3rd edition, 1985
5. Pharmaceutical Production and management by C. V. S. Subrahmanyam, Vallabh Prakashan 2005.
6. Pilot plant model and scale up methods, Johnstone and Thring 1995, McGraw Hill
7. Pharmaceutical Production Facilities, design and applications, by G. C. Cole. Taylor and Francis, 1998-2nd edition illustrated
8. Pharmaceutical Project Management. T. Kennedy, vol. 86, Marcel Dekker, NY 2008,edition 2nd edition illustrated
9. Theory & Practice of Industrial Pharmacy, L. Lachman, Varghese Publication, Bomay- 2015.
10. Safety assessment for pharmaceuticals, Gad, Shayne-John wiley & sons, 2000


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Awarding University: Gujarat Technological University, Ahmedabad

Name of Program: **M. Pharm**
Branch: **A04 - Pharmaceutical Technology**
Semester: **II**
Course Code: **M040202TT**
Course Name: **Principles of Biopharmaceutics & Pharmacokinetics**
Course Type: **Core**
Year of Implementation: **2024 – 25**

**Teaching and Examination Scheme:**

| Number of hours/ Week | | | Number of credits | | | Total credits | Evaluation Scheme (Marks) | | | | | | | | Total Marks |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | | | Sessional Exams | | | | | | End Semester Assessment | | |
| | | | | | | | Theory | | | Practical | | | | | |
| L | Tu | P | L | Tu | P | | CIE | E | T | CIE | E | T | T | P | |
| 4 | 0 | 0 | 4 | 0 | 0 | 4 | 10 | 15 | 25 | 0 | 0 | 0 | 75 | 0 | 100 |

**Scope:**
This course is designed to impart knowledge and skills necessary for dose calculations, dose adjustments and to apply biopharmaceutics theories in practical problem solving. Basic theoretical discussions of the principles of biopharmaceutics and pharmacokinetics are provided to help the students to clarify the concepts.

**Course Outcomes (CO):**
Upon completion of the course student shall be able to

| | |
|---|---|
| CO1 | Understand the factors affecting drug absorption to formulate a pharmaceutical product |
| CO2 | Relate the biopharmaceutic considerations in drug product design, in-vitro and in-vivo performance |
| CO3 | Demonstrate the understanding and application of pharmacokinetic in designing a dosage form |
| CO4 | Apply the concept of Bioavailability and Bioequivalence to develop innovator and generic product |

**Detailed Syllabus:**
Total Teaching hours: **60 hours**

| | | |
|---|---|---|
| **Unit 1** | **Drug Absorption from the Gastrointestinal Tract:**<br>Gastrointestinal tract, Properties of the Gastrointestinal Tract (GIT), Mechanism of drug absorption - Transport model<br>Factors affecting drug absorption –<br>Formulation factors - nature and type of the dosage form: solution (elixir, syrup and solution) as a dosage form, suspension as a dosage form, capsule as a dosage form, tablet as a dosage form, formulation and processing factors, | **15 hours** |

| | | |
|---|---|---|
| | Physicochemical factors - pH–partition theory of drug absorption and theories of drug dissolution: Noyes–Whitney equation. Microclimate pH, pH partition hypothesis.<br>Patient related factors – anatomic, physiologic and pathologic factors tight-junction complex, intracellular pH environment, permeability-solubility-charge state | |
| **Unit 2** | **Biopharmaceutic considerations in drug product design and In Vitro Drug Product Performance:** Introduction, biopharmaceutic factors affecting drug bioavailability, rate-limiting steps in drug absorption, physicochemical nature of the drug formulation factors affecting drug product performance, in vitro: dissolution and drug release testing, compendial methods of dissolution, alternative methods of dissolution testing, meeting dissolution requirements, problems of variable control in dissolution testing performance of drug products. in vitro–in vivo correlation, dissolution profile comparisons, drug product stability, considerations in the design of a drug product. | **15 hours** |
| **Unit 3** | **Pharmacokinetics:** Basic considerations, pharmacokinetic models, compartment modeling: one compartment model- IV bolus, IV infusion, extra-vascular. Multi compartment model: two compartment - model in brief, non-linear pharmacokinetics: cause of non-linearity, Michaelis – Menten equation, estimation of kmax and vmax.<br>Drug interactions: Introduction, the effect of protein binding interactions, the effect of tissue binding interactions, cytochrome p450-based drug interactions, and drug interactions linked to transporters. Brief outline of clinical pharmacokinetic | **15 hours** |
| **Unit 4** | **Drug Product Performance, In-Vivo:** bioavailability and bioequivalence: drug product performance, purpose of bioavailability studies, relative and absolute availability. Methods for assessing bioavailability, bioequivalence studies, design and evaluation of bioequivalence studies, study designs, crossover study designs, evaluation of the data, bioequivalence example, study submission and drug review process. biopharmaceutics classification system, methods. Concept of BCDDS and biowaivers permeability: in-vitro, in-situ and in-vivo methods. Generic biologics (biosimilar drug products), clinical significance of bioequivalence studies, special concerns in bioavailability and bioequivalence studies, generic substitution. Prediction of in vivo profile from in vitro drug dissolution. | **15 hours** |

**Recommended Books^: (Latest Editions)**


1. Biopharmaceutics and Clinical Pharmacokinetics by Milo Gibaldi, 4th edition, Philadelphia, Lea and Febiger, 1991.
2. Biopharmaceutics and Pharmacokinetics, A. Treatise, D .M. Brahmankar and Sunil B. Jaiswal., Vallabh Prakashan, Pitampura, Delhi.
3. Applied Biopharmaceutics and Pharmacokinetics by Shargel. Land YuABC, 2nd edition, Connecticut Appleton Century Crofts, 1985.
4. Textbook of Biopharmaceutics and Pharmacokinetics, Dr. Shobha Rani R. Hiremath, Prism Book.

5. Pharmacokinetics by Milo Gibaldi and D. Perrier, 2nd edition, Marcel Dekker Inc., New York, 1982.
6. Current Concepts in Pharmaceutical Sciences: Biopharmaceutics, Swarbrick. J, Leaand Febiger, Philadelphia, 1970.
7. Clinical Pharmacokinetics, Concepts and Applications 3rd edition by Malcolm Rowland and Thom~N. Tozer, Lea and Febiger, Philadelphia, 1995.
8. Dissolution, Bioavailability and Bioequivalence, Abdou. H. M, Mack Publishing Company, Pennsylvania 1989.
9. Biopharmaceutics and Clinical Pharmacokinetics, An Introduction, 4th edition, revised and expanded by Robert. E. Notari, Marcel Dekker Inc, New York and Basel, 1987.
10. Biopharmaceutics and Relevant Pharmacokinetics by John. G Wagner and M. Pemarowski, 1st edition, Drug Intelligence Publications, Hamilton, Illinois, 1971.
11. Encyclopedia of Pharmaceutical Technology, Vol 13, James Swarbrick, James. G. Boylan, Marcel Dekker Inc., New York, 1996.
12. Basic Pharmacokinetics, 1st edition, Sunil S Jambhekar and Philip J Breen, pharmaceutical press, RPS Publishing, 2009.
13. Absorption and Drug Development- Solubility, Permeability, and Charge State, Alex Avdeef, John Wiley & Sons, Inc., 2003.

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Awarding University: Gujarat Technological University, Ahmedabad

Name of Program: **M. Pharm**
Branch: **A04 - Pharmaceutical Technology**
Semester: **II**
Course Code: **M040203TT**
Course Name: **Good Manufacturing Practice and Process Validation**
Course Type: **Core**
Year of Implementation: **2024 – 25**

| Number of hours/ Week | | | Number of credits | | | Total credits | Evaluation Scheme (Marks) | | | | | | | | Total Marks |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | | | Sessional Exams | | | | | | Term End Assessment | | |
| | | | | | | | Theory | | | Practical | | | | | |
| L | Tu | P | L | Tu | P | | CIE | E | T | CIE | E | T | T | P | |
| 4 | 0 | 0 | 4 | 0 | 0 | 4 | 10 | 15 | 25 | 0 | 0 | 0 | 75 | 0 | 100 |

**Scope:**
Course designed to impart advanced knowledge and skills required to learn the concept of quality assurance, statistical inference in development of analytical method, validation and product optimization process.

**Course Outcomes (CO):**
Upon completion of the course student shall be able to

| | |
|---|---|
| CO1 | Understand the concepts of cGMP (Current Good Manufacturing Practices), GLP (Good Laboratory Practices), Process Analytical Technology, ICH guidelines including their significance in ensuring product quality and compliance. |
| CO2 | Identify the need of applicability of various regulatory guideline during product development. |
| CO3 | Demonstrate the need of validated analytical methods for effective quality control testing of pharmaceutical products. |
| CO4 | Apply the understanding of different regulatory and ICH guidelines for designing a dosage form. |

**Course Contents:**
Total Teaching hours: **60 hours**

| | | |
|---|---|---|
| **Unit 1** | Basic concepts of quality assurance & quality control, requirements of cGMP/GLP, ISO 9000 series, process analytical technology, quality audits etc. | **10 hours** |
| **Unit 2** | Precision, accuracy and biases, sampling and operating characteristic curves, sampling plans, statistical inference in estimation of hypothesis testing, statistical procedures in assay development. Development of new analytical method and its validation. | **10 hours** |
| **Unit 3** | Role of raw material testing, finished product testing, in process quality control in assuring quality of drug products to consumers. In-process quality control tests for sterile and non-sterile dosage forms including packaging and labelling operations. | **10 hours** |

| | | |
|---|---|---|
| **Unit 4** | Factors affecting the stability of a formulation including solid state stability, methods involved in stabilization and stability testing. | **10 hours** |
| **Unit 5** | Validation: Introduction to pharmaceutical validation, scope & merits of validation, validation and calibration of master plan, ICH & WHO guidelines for calibration and validation of equipment, validation of specific dosage form- tablets, capsules, infusions, types of validation. government regulation, manufacturing process model, URS, DQ, IQ, OQ & P.Q. of facilities, calculation of parameters (quality matrices) of industrial importance. | **10 hours** |
| **Unit 6** | ICH Guidelines: Quality topics Q7: Good manufacturing practices for Active Pharmaceutical Ingredients, Q8: Pharmaceutical Development, Q9: Quality Risk Management, Q10: Pharmaceutical Quality System. | **10 hours** |

**Recommended Books^: (Latest Editions)**


1. How to practice GMP: P. P. Sharma, 5th Edition, Vandhana Publications, New Delhi.
2. Pharmaceutical Process validation, Bernard T.L. and Robert A.Nash Volumes 23, Marcel Decker. 2003 3rd edition illustrated vol: 129.
3. Good Manufacturing Practice for pharmaceuticals, Sidney H.Willing, Mercel Decker Inc. 5th edition, 2000.
4. Validation of Pharmaceutical Process, James Agalloco, 3rd Edition, Informa Healthcare USA 3 rd edition, 2007.
5. Validation of Pharmaceutical Processes, Sterile Products, F.J.Carleton, Marcel Dekker Inc. 2nd edition illustrated 1999.
6. Guidelines on cGMP & Quality of Pharmaceutical Products, S.Lyer, Career Publication, 2003.
7. Validation in Pharmaceutical Industry (Concept, Approaches & Guidelines) P.P. Sharma, Vandhana Publications, New Delhi


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Awarding University: Gujarat Technological University, Ahmedabad

Name of Program: **M. Pharm**
Branch: **A04 - Pharmaceutical Technology**
Semester: **II**
Course Code: **M040204TT**
Course Name: **Regulatory Requirements for Pharmaceutical Manufacturing**
Course Type: **Core**
Year of Implementation: **2024 – 25**

**Teaching and Examination Scheme:**

| Number of hours/ Week | | | Number of credits | | | Total credits | Evaluation Scheme (Marks) | | | | | Duration of Exam (Hrs) | | | | Total Marks |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | | | Sessional Exams | | | Term End Assessment | | Sessional Exams | | Term End Assessment | | |
| L | Tu | P | L | Tu | P | | CE | T | P | T | P | T | P | T | P | |
| 4 | 0 | 0 | 4 | 0 | 0 | 4 | 10 | 15 | 0 | 40 | 0 | 1 | 0 | 75 | 0 | 100 |

**Scope:**
This subject will provide valuable insight behind implementation of QbD (Quality by Design) principles in modern pharmaceutical product development. QbD has become a crucial element of a stream-lined drug development process. This subject syllabus basic principle of the QbD approach in pharmaceutical development and manufacturing

**Course Outcomes (CO):**
Upon completion of the course student shall be able to

| | |
|---|---|
| CO1 | Understand the fundamentals of QbD, QRM, and PAT in the Pharmaceutical product development. |
| CO2 | Identify the risk of any development process in context to quality of the product. |
| CO3 | Apply the regulatory knowledge of QbD and QRM to optimize a product or process. |
| CO4 | Integrate knowledge of PAT and control strategies for improving manufacturing processes and product quality. |

**Detailed Syllabus:**
Total Teaching hours: **60 hours**

| | | |
|---|---|---|
| **Unit 1** | **Introduction to QbD:** History, current approach and its limitations. Why QbD is required, advantages, elements of QbD, and Terminology: QTPP. CMA, CQA, CPP, RLD, Design space, Design of Experiments, Risk Assessment and mitigation/minimization. Detailed case study of QbD for Immediate release dosage forms, modified release dosage forms. Emphasis should be given to prototype QbD for various dosage forms considering manufacturing process variables, raw materials and desired attributes.<br><br>Design of experiments – Methods and applications optimization techniques: Concept of optimization, optimization parameters, | **16 hours** |

| | | |
|---|---|---|
| | classical optimization. Statistical designs, Question Based Review (QbR). | |
| **Unit 2** | **Pharmaceutical Development:** Objective, Scope, Component of drug product, Manufacturing process development, container closure system, microbiological attributes, compatibility, Design space, control strategy, Product life cycle management and continual improvement. Submission of Pharmaceutical Development and Related Information In Common Technical Documents (CTD) Format. | **10 hours** |
| **Unit 3** | **Quality Risk Management:** Introduction- What is quality? Relevance of quality with respect to pharmaceuticals, Scope, Principles of Quality Risk Management ICH Q9, HACCP, FMEA, General Quality Risk Management Process. Review some QRM tools (FMEA, risk ranking) and apply FMEA to control strategy selection know the relationship between PQS and GMP and how they link to Control Strategy. | **10 hours** |
| **Unit 4** | **Pharmaceutical Quality System:** Pharmaceutical quality system, management responsibility, continual improvement of process performance and product quality, continual improvement of the pharmaceutical quality system. understand the implications of relevant ICH, EMA, and FDA guidelines learn about the QbD process | **12 hours** |
| **Unit 5** | **Process Analytical Technology:** Introduction, scope, background, PAT framework, PAT tools, risk-based approach, integrated systems approach, real time release, strategy for implementation, regulatory approach, examples of PAT implementation. | **12 hours** |

**Teaching hours: 60 Hours**

**Recommended Books^: (Latest Editions)**


1. ICH Guidelines
2. FDA Guidelines


L= Lecture, Tu= Tutorial, P= Practical, T = Theory

^ This is not an exhaustive list

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(Approved by PCI, NAAC Accredited – A+ Grade, 3.38 CGPA)
Awarding University: Gujarat Technological University, Ahmedabad

Name of Program: **M. Pharm**
Branch: **A04 - Pharmaceutical Technology**
Semester**: II**
Course Code: **M040205PP**
Course Name: **Pharmaceutical Technology Practicals- II**
Course Type: **Core**
Year of Implementation: **2024-25**

**Teaching and Examination Scheme:**

| Number of hours/ Week | | | Number of credits | | | Total credits | Evaluation Scheme (Marks) | | | | | | | | Total Marks |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | | | Sessional Exams | | | | | | Term End Assessment | | |
| | | | | | | | Theory | | | Practical | | | | | |
| L | Tu | P | L | Tu | P | | CIE | E | T | CIE | E | T | T | P | |
| 0 | 0 | 12 | 0 | 0 | 6 | 6 | 0 | 0 | 0 | 20 | 30 | 50 | 0 | 100 | 150 |

**Scope:**
Course designed to impart advanced knowledge and skills required to learn the concept of quality assurance, statistical inference in development of analytical method, validation and product optimization process.

**Course Outcomes (CO):**
Upon completion of the course student shall be able to

| | |
|---|---|
| CO1 | Recall the formulation optimization techniques and evaluation parameters of modified drug delivery system and techniques for assessment of packaging materials. |
| CO2 | Development and Optimization of modified drug delivery system using statistical softwares and assessment of packaging materials. |

**List of Practicals**
Total Teaching hours: **180 hours**

1. Diffusion studies on Paracetamol Suspension/Organogel using Egg Semi permeable membrane.
2. In vitro cell studies for permeability and metabolism.
3. Bioavailability studies of Paracetamol in animals.
4. Protein binding studies of a highly protein bound drug & poorly protein bound drug.
5. Pharmacokinetic and IVIVC data analysis by Winnoline R software.
6. Case study on application of QbD.
7. Design of Ishikawa diagram for given dosage forms.
8. Calculation of RPN (Risk Priority Number) in Failure Mode and Effects Analysis Model.
9. Screening of variables by Plackett-burman design.
10. Demonstration of Design Expert® Software.
11. Formulation data analysis by factorial design using Design Expert® Software.
12. To prepare regulatory dossier as per Indian CTD format and submission in SUGAM.
13. To study the registration procedure for conducting BA/BE studies in India.

**14.** To prepare regulatory submissions using eCTD software.
**15.** To prepare regulatory Labelling requirements for USA, Canada & Europe countries.
**16.** Quality control tests for Primary and secondary packing materials.
**17.** Qualification and calibration of pharmaceutical testing equipment (dissolution testing apparatus, friability apparatus, disintegration tester).
**18.** Documentation of certain standard records related to manufacture and quality control as per pharmaceutical industry.

- Prepare BMR for SR tablet.
- Prepare testing reports for Experiment no. 16.
- Prepare validation report and calibration report for experiment no. 17.

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Awarding University: Gujarat Technological University, Ahmedabad

Name of Program: **M. Pharm**
Branch: – **A05 - Pharmaceutics**
Semester: **I**
Course Code: **M000101TT**
Course Name: **Modern pharmaceutical analytical techniques**
Course Type: **Core**
Year of Implementation: **2024 – 25**

**Teaching and Examination Scheme:**

| Number of hours/ Week | | | Number of credits | | | Total credits | Evaluation Scheme (Marks) | | | | | | | | Total Marks |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | | | Sessional Exams | | | | | | Term End Assessment | | |
| | | | | | | | Theory | | | Practical | | | | | |
| L | Tu | P | L | Tu | P | | CIE | E | T | CIE | E | T | T | P | |
| 4 | 0 | 0 | 4 | 0 | 0 | 4 | 10 | 15 | 25 | 0 | 0 | 0 | 75 | 0 | 100 |

**Scope:**
This subject deals with various advanced analytical instrumental techniques for identification, characterization, and quantification of drugs. Instruments dealt are NMR, Mass spectrometer, IR, HPLC, GC etc.

**Course Outcomes (CO):**
Upon completion of the course student shall be able to

| | |
|---|---|
| CO1 | Understand different chromatographic principles, instrumentation and techniques |
| CO2 | Understand principles and instrumentation for electrophoresis, X-ray crystallography, potentiometry, and thermal analysis |
| CO3 | Understand and apply principles, instrumentation, and techniques of various spectroscopic methods |
| CO4 | Apply principles of spectroscopic techniques to identify and quantify various drugs |

**Detailed Syllabus:**
Total Teaching hours: **60 hours**

| | | |
|---|---|---|
| **Unit 1** | **UV-Visible spectroscopy:** Introduction, Theory, Laws, Instrumentation associated with UV-Visible spectroscopy, Choice of solvents and solvent effect and Applications of UV-Visible Spectroscopy, Simultaneous equation method, Derivative spectroscopic method, Difference spectroscopic method<br>**IR spectroscopy:** Theory, Modes of Molecular vibrations, Sample handling, Instrumentation of Dispersive and Fourier - Transform IR Spectrometer, Factors affecting vibrational frequencies and Applications of | **4 hours**<br><br>**4 hours** |

| | | |
|---|---|---|
| | IR spectroscopy, Data interpretation<br>**Spectrofluorimetry:** Theory of Fluorescence, Factors affecting fluorescence, Quenchers, Instrumentation and Applications of fluorescence Spectrophotometer<br>**Flame emission spectroscopy and atomic absorption spectroscopy**: Principle, Instrumentation, Interferences and Applications | **2 hours**<br>**2 hours** |
| **Unit 2** | **NMR spectroscopy:** Quantum numbers and their role in NMR, Principle, Instrumentation, Solvent requirement in NMR, Relaxation process, NMR signals in various compounds, Chemical shift, Factors influencing chemical shift, Spin-Spin coupling, Coupling constant, Nuclear magnetic double resonance. Brief outline of principles of FT-NMR and 13C NMR. Applications of NMR spectroscopy | **11 hours** |
| **Unit 3** | **Mass Spectroscopy:** Principle, Theory, Instrumentation of Mass Spectroscopy, Different types of ionization like electron impact, chemical, field, FAB and MALDI, APCI, ESI, APPI Analyzers of Quadrupole and Time of Flight, Mass fragmentation and its rules, Meta stable ions, Isotopic peaks, and Applications of Mass Spectroscopy | **10 hours** |
| **Unit 4** | **Chromatography:** Principle, apparatus, instrumentation, chromatographic parameters, factors affecting resolution and applications of the following:<br>a) Paper chromatography b) Thin Layer chromatography<br>c) Ion exchange chromatography d) Column chromatography<br>e) Gas chromatography<br>f) High Performance Liquid chromatography g) Affinity chromatography | **3 hours**<br>**3 hours**<br>**2 hours**<br>**3 hours** |
| **Unit 5** | **Electrophoresis:** Principle, Instrumentation, working conditions, factors affecting separation and applications of the following:<br>a) Paper electrophoresis b) Gel electrophoresis c) Capillary electrophoresis d) Zone electrophoresis e) Moving boundary electrophoresis f) Iso electric focusing<br>**X ray Crystallography:** Production of X rays, Different X ray diffraction methods, Bragg's law, Rotating crystal technique, X ray powder technique, Types of crystals and applications of Xray diffraction. | **6 hours**<br>**3 hours** |
| **Unit 6** | **Potentiometry:** Principle, Ion selective Electrodes and Application of potentiometry.<br>**Thermal Analysis:** Principle, thermal transitions, and instrumentation (heat flux and power compensation and designs) working, Polymer behaviour, factors affecting and instrumentation, and working, application of TGA | **4 hours**<br>**3 hours** |

**Recommended Books^: (Latest Editions)**


1. Silverstein RM, Bassler GC. Spectrometric identification of organic compounds. John Wiley & Sons. New York
2. Doglas A Skoog, F. James Holler, Timothy A. Nieman. Principles of Instrumental Analysis Eastern press. Bangalore.
3. Willard H, Merritt LL, Dean JA, Settle FA. Instrumental methods of analysis. CBS publisher and distributors. New Delhi. India
4. Beckett AH and Stenlake JB. Practical Pharmaceutical Chemistry. CBS Publishers. New Delhi. India

5. Kemp W. Organic Spectroscopy. ELBS. Macmillan
6. Sethi PD. Quantitative analysis of drugs in pharmaceutical formulations. Unique Publishers. New Delhi. India.
7. Munson JW. Pharmaceutical analysis: modern methods. B. Drugs and the pharmaceutical sciences. Marcel Dekker. New York.

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Awarding University: Gujarat Technological University, Ahmedabad

Name of Program: **M. Pharm**
Branch: **A05 - Pharmaceutics**
Semester: **I**
Course Code: **M050102TT**
Course Name: **Drug Delivery Systems**
Course Type: **Core**
Year of Implementation: **2024 – 25**

**Teaching and Examination Scheme:**

| Number of hours/ Week | | | Number of credits | | | Total credits | Evaluation Scheme (Marks) | | | | | | | | Total Marks |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | | | Sessional Exams | | | | | | Term End Assessment | | |
| | | | | | | | Theory | | | Practical | | | | | |
| L | Tu | P | L | Tu | P | | CIE | E | T | CIE | E | T | T | P | |
| 4 | 0 | 0 | 4 | 0 | 0 | 4 | 10 | 15 | 25 | 0 | 0 | 0 | 75 | 0 | 100 |

**Scope:**
This course is designed to impart knowledge on the area of advances in novel drug delivery systems.

**Course Outcomes (CO):**
Upon completion of the course student shall be able to

| | |
|---|---|
| CO1 | Understand physicochemical properties to develop modified release controlled, targeted and novel drug delivery systems. |
| CO2 | Identify the need and differentiate the concept of varied drug delivery systems. |
| CO3 | Apply the understanding of different drug delivery system based on route of administration. |
| CO4 | Integrate the concepts of personalized medicine, bioelectronic medicines, and 3D printing technologies to create customized drug delivery systems. |

**Detailed Syllabus:**
Total Teaching hours: **60 hours**

| | | |
|---|---|---|
| **Unit 1** | **Sustained Release (SR) and Controlled Release (CR) formulations:** Introduction & basic concepts, advantages/ disadvantages, factors influencing, Physicochemical & biological approaches for SR/CR formulation, Mechanism of drug delivery from SR/CR formulation.<br>**Polymers**: Introduction, definition, classification, properties and application.<br>**Dosage Forms for Personalized Medicine**: Introduction, need, definition, pharmacogenetics, categories of patients for personalized medicines, customized drug delivery systems.<br>Bioelectronic medicines – Introduction, approaches and application<br>3D printing of pharmaceuticals – Introduction, technology and application. | **10 hours** |

| | | |
|---|---|---|
| | Telepharmacy - Introduction, technique and application. | |
| **Unit 2** | **Rate Controlled Drug Delivery Systems**:<br>Principles & Fundamentals, types, activation mechanism<br>Modulated drug delivery systems - Principles & fundamentals of mechanically activated, pH activated, Enzyme activated, and osmotic activated drug delivery systems, feedback regulated drug delivery systems. | **10 hours** |
| **Unit 3** | **Gastro-Retentive Drug Delivery Systems**:<br>Principle, concepts, fundamentals, advantages and disadvantages, Modulation of GI transit time approaches to extend GI transit, evaluation and application of GRDDS.<br>**Buccal Drug Delivery Systems**: Introduction, Principle of muco adhesion, advantages and disadvantages, mechanism of drug permeation, methods of formulation, evaluations and application. | **10 hours** |
| **Unit 4** | **Occular Drug Delivery Systems**:<br>Introduction, need, structure of eye, barriers of drug permeation, approaches to overcome barriers, evaluation and application. Recent advances in Occular drug delivery system. | **6 hours** |
| **Unit 5** | **Transdermal Drug Delivery Systems**:<br>Structure of skin and barriers, penetration enhancers, formulation and evaluation of TDDS, application, recent advances in TDDS. | **10 hours** |
| **Unit 6** | **Protein and Peptide Delivery:**<br>Introduction, need, limitation of conventional therapies, barriers for protein delivery. Various approaches of formulation and Evaluation and other macromolecules. | **8 hours** |
| **Unit 7** | **Vaccine Delivery Systems:**<br>Introduction and types of vaccines, uptake of antigens, single shot vaccines, mucosal and transdermal delivery of vaccines. Formulation consideration of vaccine and its evaluation. | **6 hours** |

**Recommended Books^: (Latest Editions)**


1. Encyclopaedia of Pharmaceutical Technology, Jasmes Swarbrick and James C. Boylan, Marcel Dekker Inc., New York.
2. Theory and Practice of Industrial Pharmacy, L. Lachman, Vargish Publication, Bombay.
3. Modern Pharmaceutics, G. S. Banker and C. T. Rhodes, Marcel Dekker, Inc., New York.
4. Controlled Drug Delivery: J. R. Robinson and V. H. Lee, Marcel Dekker, Inc., New York.
5. Novel Drug Delivery Systems, Y. W. Chien, Marcel Dekker, Inc., New York.
6. Progress in Controlled and Novel Delivery Systems, edited by N. K. Jain, CBS Publishers & Distributors, New Delhi.


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Awarding University: Gujarat Technological University, Ahmedabad

Name of Program: **M. Pharm**
Branch: **A05 - Pharmaceutics**
Semester: **I**
Course Code: **M050103TT**
Course Name: **Modern Pharmaceutics**
Course Type: **Core**
Year of Implementation: **2024 – 25**

**Teaching and Examination Scheme:**

| Number of hours/ Week | | | Number of credits | | | Total credits | Evaluation Scheme (Marks) | | | | | | | | Total Marks |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | | | Sessional Exams | | | | | | Term End Assessment | | |
| | | | | | | | Theory | | | Practical | | | | | |
| L | Tu | P | L | Tu | P | | CIE | E | T | CIE | E | T | T | P | |
| 4 | 0 | 0 | 4 | 0 | 0 | 4 | 10 | 15 | 25 | 0 | 0 | 0 | 75 | 0 | 100 |

**Scope:**
Course designed to impart advanced knowledge and skills required to learn various aspects and concepts at pharmaceutical industries

**Course Outcomes (CO):**
Upon completion of the course student shall be able to

| | |
|---|---|
| CO1 | Understand the fundamentals of preformulation study in the designing of a dosage form. |
| CO2 | Recognize the concepts of QbD and regulatory guidelines to ensure product quality and compliance. |
| CO3 | Apply the principles of preformulation concept to formulate a stable, safe and effective dosage form. |
| CO4 | Relate the tablet compression, compaction profiles and consolidation parameter to develop an optimize product. |

**Detailed Syllabus:**
Total Teaching hours: **60 hours**

| | | |
|---|---|---|
| **Unit 1a** | **Preformation Concepts** – includes foundational principles critical for drug formulation, including drug-excipient interactions that affect stability and performance. Key advance analytical techniques involve assessing chemical and physical interactions with suitable case studies.<br>**Stability testing.**<br>Importance of stability testing, kinetics of stability through zero-order higher order degradation models and Long- short Term Stability studies purpose, Regulatory requirement and Data analysis. | **10 hours** |

| | | |
|---|---|---|
| | **Pharmaceutical dispersion** Theories of dispersion Emulsion and Suspension, SMEDDS preparation included definition, mechanism, method of preparation and stability studies.<br>**Large and small volume parental stability** – physiological factors (injection route, pH) and formulation choices (excipients, containers) manufacturing processes (aseptic filling, terminal sterilization) and evaluation methods of stability through tests. | |
| **Unit 1b** | **Optimization techniques in Pharmaceutical Formulation:** Definition, terms, advantage, Concept and parameters of optimization, Statistical design includes factorial and RSM design, Technique of optimization (Evolutionary operations, Simplex method, Lagrangian method, Search method, Canonical analysis) and its application in formulation (Oral solid dosage form and NDDS case studies) | **10 hours** |
| **Unit 2** | **Validation:** Introduction to pharmaceutical validation, scope & merits of validation, validation and calibration of master plan, ICH & WHO guidelines for calibration and validation of equipment's, validation of specific dosage form, types of validation. government regulation, manufacturing process model, URS, DQ, IQ, OQ & P.Q. of facilities | **10 hours** |
| **Unit 3** | **cGMP & Industrial Management:** Objectives and policies of current good manufacturing practices, layout of buildings, services, equipment and their maintenance<br>Production management: Production organization, materials management, handling and transportation, inventory management and control, production and planning control, Sales forecasting, budget and cost control, industrial and personal relationship. Concept of Total Quality Management | **10 hours** |
| **Unit-4** | **Consolidation Parameters**: Heckel Plots, definition, application and its significance in powder compaction. Diffusion parameter, Dissolution parameters its significance, model independent (Similarity factors– f2 and f1,) and dependent approach (zero order, first order Higuchi Plot and Korsmeyer-Peppas) and pharmacokinetic parameters (bioavailability, absorption rate constant, volume of distribution, clearance, half-life. linearity, standard deviation, chi square test, student T test, ANOVA test. | **10 hours** |
| **Unit 5** | **Compression and compaction:** Basic of tablet making, compression cycle and effect of applied forces, factors influencing the compaction of pharmaceutical powders, compaction and consolidation, physics of compression, compaction profiles, force-time profiles, force-displacement profile and die wall force profile, compaction equations: Kawakita equation, hackle plot and<br>improvement of compaction behaviour of powder bed. | **10 hours** |

**Recommended Books^: (Latest Editions)**


1. Theory and Practice of Industrial Pharmacy By Lachmann and Libermann
2. Pharmaceutical dosage forms: Tablets Vol. 1-3 by Leon Lachmann.
3. Pharmaceutical Dosage forms: Disperse systems, Vol, 1-2; By Leon Lachmann.
4. Pharmaceutical Dosage forms: Parenteral medications Vol. 1-2; By Leon Lachmann.
5. Modern Pharmaceutics; By Gillbert and S. Banker.
6. Remington's Pharmaceutical Sciences.
7. Advances in Pharmaceutical Sciences Vol. 1-5; By H.S. Bean & A.H.Beckett.
8. Physical Pharmacy; By Alfred martin
9. Bentley's Textbook of Pharmaceutics – by Rawlins.
10. Good manufacturing practices for Pharmaceuticals: A plan for total quality control, Second edition;
11. By Sidney H. Willig.
12. Quality Assurance Guide; By Organization of Pharmaceutical producers of India.
13. Drug formulation manual; By D.P.S. Kohli and D.H.Shah. Eastern publishers, New Delhi.
14. How to practice GMPs; By P.P.Sharma. Vandhana Publications, Agra.
15. Pharmaceutical Process Validation; By Fra. R. Berry and Robert A. Nash.
16. Pharmaceutical Preformulations; By J.J. Wells.
17. Applied production and operations management; By Evans, Anderson, Sweeney and Williams.
18. Encyclopaedia of Pharmaceutical technology, Vol I – III.


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Awarding University: Gujarat Technological University, Ahmedabad

Name of Program: **M. Pharm**
Branch: **A05 - Pharmaceutics**
Semester: **I**
Course Code: **M050104TT**
Course Name: **Regulatory Affairs**
Course Type: **Core**
Year of Implementation: **2024 – 25**

**Teaching and Examination Scheme:**

| Number of hours/ Week | | | Number of credits | | | Total credits | Evaluation Scheme (Marks) | | | | | | | | Total Marks |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | | | Sessional Exams | | | | | | Term End Assessment | | |
| | | | | | | | Theory | | | Practical | | | | | |
| L | Tu | P | L | Tu | P | | CIE | E | T | CIE | E | T | T | P | |
| 4 | 0 | 0 | 4 | 0 | 0 | 4 | 10 | 15 | 25 | 0 | 0 | 0 | 75 | 0 | 100 |

**Scope:**
The Course designed to impart advanced knowledge and skills required to learn various aspects and concepts at pharmaceutical industries.

**Course Outcomes (CO):**
Upon completion of the course student shall be able to

| | |
|---|---|
| CO1 | Understand regulatory guidelines and documentation requirements in the pharmaceutical industry, including the filing and approval processes. |
| CO2 | Identify the need of the regulatory process to conduct a clinical study. |
| CO3 | Apply the knowledge of regulatory procedure and documentation in dossiers submission of drug product and medical devices by CTD/eCTD. |
| CO4 | Distinguish innovator and generic drug approval process and its regulatory guidelines according to various countries. |

**Detailed Syllabus:**
Total Teaching hours: **60 hours**

| | | |
|---|---|---|
| **Unit 1** | **Documentation in Pharmaceutical industry:**<br>Master formula record, DMF (Drug Master File), distribution records. Generic drugs product development-Introduction, Hatch- Waxman act and amendments, CFR (code of federal regulation), drug product performance, in-vitro, ANDA regulatory approval process, NDA approval process, BE and drug product assessment, in –vivo, scale up process approval changes, post marketing surveillance, outsourcing BA and BE to CRO.<br>**Regulatory requirement for product approval:**<br>API, biologics, novel products, therapies obtaining NDA, ANDA for generic drugs ways and means of US registration for foreign drugs Basics of New Drugs and Clinical Trials (NDCT) Rules, 2019 | **20 hours** |

| | | |
|---|---|---|
| **Unit 2** | **CMC (chemistry Manufacturing control),** post approval regulatory affairs. Regulation for combination Products and medical devices. CTD and ECTD format, industry and FDA liaison. ICH - Guidelines of ICH-Q, S E, M. Regulatory requirements of EU, MHRA, TGA and ROW countries. | **15 hours** |
| **Unit 3** | **Non clinical drug development**: Global submission procedure and documentation of IND, NDA, ANDA. Investigation of medicinal products dossier, dossier (IMPD) and investigator brochure (IB). | **15 hours** |
| **Unit 4** | **Clinical trials:** Developing criteria of clinical trial protocols and its format. Institutional review board/ independent ethics committee Formulation and working procedures informed Consent process and procedures. HIPAA- new requirement to clinical study process, pharmacovigilance safety monitoring in clinical trials. | **10 hours** |

**Recommended Books^: (Latest Editions)**


1. Generic Drug Product Development, Solid Oral Dosage forms, Leon Shargel and
2. IsaderKaufer, Marcel Dekker series, Vol.143
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,
5. MD, 5th edition, Drugs and the Pharmaceutical Sciences, Vol.190.
6. Guidebook for drug regulatory submissions / Sandy Weinberg. By John Wiley & Sons.Inc.
7. FDA regulatory affairs: a guide for prescription drugs, medical devices, and biologics/edited By Douglas J. Pisano, David Mantus.
8. Clinical Trials and Human Research: A Practical Guide to Regulatory Compliance By Fay A.Rozovsky and Rodney K. Adams


**Links:**

1. www.ich.org/
2. www.fda.gov/
3. europa.eu/index_en.html
4. https://www.tga.gov.au/tga-basic

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Awarding University: Gujarat Technological University, Ahmedabad

Name of Program: **M. Pharm**
Branch: **A05 - Pharmaceutics**
Semester: **I**
Course Code: **M050105PP**
Course Name: **Pharmaceutics Practical – I**
Course Type: **Core**
Year of Implementation: **2024 – 25**

**Teaching and Examination Scheme:**

| Number of hours/ Week | | | Number of credits | | | Total credits | Evaluation Scheme (Marks) | | | | | | | | Total Marks |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | | | Sessional Exams | | | | | | Term End Assessment | | |
| | | | | | | | Theory | | | Practical | | | | | |
| L | Tu | P | L | Tu | P | | CIE | E | T | CIE | E | T | T | P | |
| 0 | 0 | 12 | 0 | 0 | 6 | 6 | 0 | 0 | 0 | 20 | 30 | 50 | 0 | 100 | 150 |

**Scope:**
This course deals with the fundamentals of Pharmaceutics and principles of formulation and evaluation of the same.

**Course Outcomes (CO):**
Upon completion of the course student shall be able to

| | |
|---|---|
| CO1 | Recall the impact of pre-formulation parameters, ingredients, and process variables on the formulation and evaluation of modified release solid dosage forms. |
| CO2 | Design, optimize, and evaluate modified release solid dosage forms, and analyze the influence of process and material attributes. |

**List of Praticals**
Total Teaching hours: **180 hours**

1. Analysis of pharmacopoeial compounds and their formulations by UV Vis spectrophotometer
2. Simultaneous estimation of multi component containing formulations by UV
3. spectrophotometry
4. Experiments based on HPLC
5. Experiments based on Gas Chromatography
6. Estimation of riboflavin/quinine sulphate by fluorimetry
7. Estimation of sodium/potassium by flame photometry
8. To study Micromeritic properties of powders and granulation.
9. To carry out preformulation studies of tablets.
10. To study the effect of compressional force on tablets disintegration time.
11. To study the effect of particle size on dissolution of a tablet.
12. To study the effect of binders on dissolution of a tablet.
13. Formulation and evaluation of sustained release matrix tablets.
14. To perform In-vitro dissolution profile of CR/ SR marketed formulation.

15. To perform calibration study of dissolution test apparatus.
16. To plot Heckal plot, Higuchi and peppas plot and determine similarity factors.
17. To calculate standard deviation; perform Chi square test, students T-test and ANOVA test for given data.
18. Formulation and evaluation osmotically controlled DDS.
19. Preparation and evaluation of Floating DDS- hydro dynamically balanced DDS.
20. Formulation and evaluation of Muco adhesive tablets.
21. Formulation and evaluation of Transdermal patches.
22. To prepare and evaluate self-micro emulsifying drug delivery system (SMEDDS).
23. To perform stability testing of formulated SMEDDS.

L= Lecture, Tu= Tutorial, P= Practical, T = Theory

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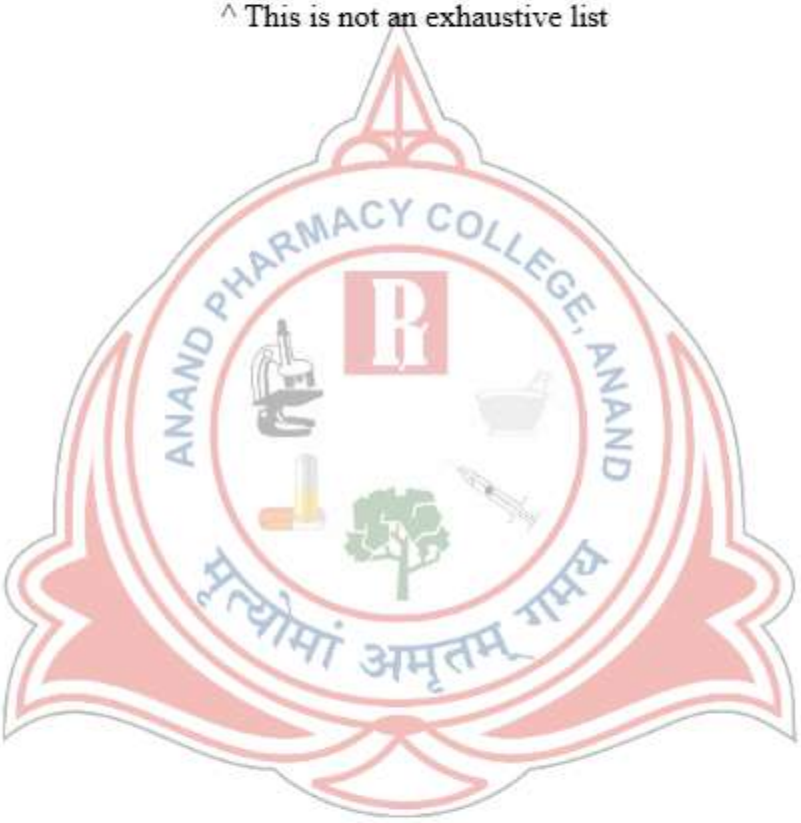

**ANAND PHARMACY COLLEGE, ANAND**
**(An Autonomous College under UGC Regulations 2023)**
**Managed by Shri Ramkrishna Seva Mandal**
(Approved by PCI, NAAC Accredited – A+ Grade, 3.38 CGPA)
Awarding University: Gujarat Technological University, Ahmedabad

Name of Program: **M. Pharm**
Branch: **A05 - Pharmaceutics**
Semester: **II**
Course Code: **M050201TT**
Course Name: **Molecular Pharmaceutics (Nano Tech and Targeted DDS)**
Course Type: **Core**
Year of Implementation: **2024 – 25**

**Teaching and Examination Scheme:**

| Number of hours/ Week | | | Number of credits | | | Total credits | Evaluation Scheme (Marks) | | | | | | | | Total Marks |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | | | Sessional Exams | | | | | | Term End Assessment | | |
| | | | | | | | Theory | | | Practical | | | | | |
| L | Tu | P | L | Tu | P | | CIE | E | T | CIE | E | T | T | P | |
| 4 | 0 | 0 | 4 | 0 | 0 | 4 | 10 | 15 | 25 | 0 | 0 | 0 | 75 | 0 | 100 |

**Scope:**
This course is designed to impart knowledge on the area of advances in novel drug delivery systems.

**Course Outcomes (CO):**
Upon completion of the course student shall be able to

| | |
|---|---|
| CO1 | Understand the concept of various approaches to design targeted and novel drug delivery system. |
| CO2 | Identify the criteria for selection of drug and excipients to develop novel formulations. |
| CO3 | Apply the principles to formulate and evaluate various novel and targeted drug delivery system. |
| CO4 | Integrate the fundamentals and approaches to design a safe, stable and effective disease specific dosage form. |

**Detailed Syllabus**
Total Teaching hours: **60 hours**

| | | |
|---|---|---|
| **Unit 1** | **Targeted Drug Delivery Systems:**<br>Concepts, Events and biological process involved in drug targeting.<br>**Tumor targeting** - Introduction, need, Basics about tumor and its growth and various approaches.<br>**Brain specific delivery** – Introduction, need, structure of Blood Brain Barrier and various approaches. | **12 hours** |
| **Unit 2** | **Targeting Methods**:<br>**Nanoparticles** - Introduction, types, preparation, evaluation and application.<br>**Liposomes** - Introduction, preparation, evaluation and application. | **12 hours** |
| **Unit 3** | **Micro Capsules / Micro Spheres**: Introduction, preparation, evaluation and application. | **12 hours** |

| | | |
|---|---|---|
| | **Monoclonal Antibodies** – Introduction, preparation, evaluation and application.<br>**Niosomes, Aquasomes, Phyotosomes, Electrosomes** - Introduction, preparation, evaluation and application. | |
| **Unit 4** | **Pulmonary Drug Delivery Systems**:<br>Introduction, need, aerosols, propellants, containers types & its evaluation, preparation, evaluation and recent advances.<br>**Intra Nasal Route Delivery systems**- Introduction, types, preparation and evaluation. | **12 hours** |
| **Unit 5** | **Nucleic acid based therapeutic delivery system**:<br>Gene therapy, introduction (ex-vivo & in-vivo gene therapy). Potential target diseases for gene therapy (inherited disorder and cancer). Gene expression systems (viral and nonviral gene transfer). Liposomal gene delivery systems. Bio distribution and Pharmacokinetics. Knowledge of therapeutic antisense molecules and aptamers as drugs of future | **12 hours** |

**Recommended Books^: (Latest Editions)**


1. Y. W. Chien, Novel Drug Delivery Systems, 2nd edition, revised and expanded, Marcel Dekker,Inc., NewYork, 1992
2. S.P.Vyas and R.K.Khar, Controlled Drug Delivery - concepts and advances, Vallabh Prakashan, New Delhi, First edition 2002
3. N.K. Jain, Controlled and Novel Drug Delivery, CBS Publishers & Distributors, New Delhi, First edition 1997 (reprint in2001).


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Awarding University: Gujarat Technological University, Ahmedabad

Name of Program: **M. Pharm**
Branch: **A05 - Pharmaceutics**
Semester: **II**
Course Code: **M050202TT**
Course Name: **Advanced Biopharmaceutics & Pharmacokinetics**
Course Type: **Core**
Year of Implementation: **2024 – 25**

**Teaching and Examination Scheme:**

| Number of hours/ Week | | | Number of credits | | | Total credits | Evaluation Scheme (Marks) | | | | | | | | Total Marks |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | | | Sessional Exams | | | | | | Term End Assessment | | |
| | | | | | | | Theory | | | Practical | | | | | |
| L | Tu | P | L | Tu | P | | CIE | E | T | CIE | E | T | T | P | |
| 4 | 0 | 0 | 4 | 0 | 0 | 4 | 10 | 15 | 25 | 0 | 0 | 0 | 75 | 0 | 100 |

**Scope:**
This course is designed to impart knowledge and skills necessary for dose calculations, dose adjustments and to apply biopharmaceutics theories in practical problem solving. Basic theoretical discussions of the principles of biopharmaceutics and pharmacokinetics are provided to help the students to clarify the concepts.

**Course Outcomes (CO):**
Upon completion of the course student shall be able to

| | |
|---|---|
| CO1 | Understand and implement the factors affecting drug absorption to formulate a pharmaceutical product. |
| CO2 | Relate the biopharmaceutic considerations in drug product design, in-vitro and in-vivo performance. |
| CO3 | Demonstrate the understanding and application of pharmacokinetic in designing a dosage form. |
| CO4 | Apply the concept of Bioavailability and Bioequivalence to develop innovator and generic product |

**Detailed Syllabus:**
Total Teaching hours: **45 hours**

| | | |
|---|---|---|
| **Unit 1** | **Drug Absorption from the Gastrointestinal Tract:**<br>Gastrointestinal tract, Properties of the Gastrointestinal Tract (GIT), Mechanism of drug absorption - Transport model<br>Factors affecting drug absorption –<br>Formulation factors - Nature and type of the dosage form: Solution (elixir, syrup and solution) as a dosage form, Suspension as a dosage form, Capsule as a dosage form, Tablet as a dosage form, formulation and processing factors, | **12 hours** |

| | | |
|---|---|---|
| | Physicochemical factors - pH–partition theory of drug absorption and theories of drug dissolution: Noyes–Whitney equation. Microclimate pH, pH Partition Hypothesis.<br>Patient related factors – anatomic, physiologic and pathologic factors Tight-Junction Complex, Intracellular pH Environment, Permeability-Solubility-Charge State | |
| **Unit 2** | **Biopharmaceutic considerations in drug product design and In Vitro Drug Product Performance**:<br>Introduction, biopharmaceutic factors affecting drug bioavailability and Rationale of drug product design, rate-limiting steps in drug absorption, physicochemical nature of the drug formulation factors affecting drug product performance, in vitro: dissolution and drug release testing, compendial methods of dissolution, alternative methods of dissolution testing, meeting dissolution requirements, problems of variable control in dissolution testing performance of drug products. In vitro–in vivo correlation, dissolution profile comparisons, drug product stability, considerations in the design of a drug product. | **12 hours** |
| **Unit 3** | **Pharmacokinetics:** Basic considerations, pharmacokinetic models, compartment modelling: one compartment model- IV bolus, IV infusion, extra-vascular. Multi compartment model: two compartment - model in brief, non-linear pharmacokinetics: cause of non-linearity, Michaelis – Menten equation, estimation of kmax and vmax.<br>Drug interactions: introduction, the effect of protein binding interactions, the effect of tissue-binding interactions, cytochrome p450-based drug interactions, drug interactions linked to transporters | **12 hours** |
| **Unit 4** | **Drug Product Performance, in vivo: Bioavailability and Bioequivalence**: drug product performance, purpose of bioavailability studies, relative and absolute availability. Methods for assessing bioavailability, bioequivalence studies, design and evaluation of bioequivalence studies, study designs, crossover study designs, evaluation of the data, bioequivalence example, study submission and drug review process.<br>Biopharmaceutics classification system, methods. Permeability: In-vitro, in-situ and In-vivo methods. generic biologics (biosimilar drug products), clinical significance of bioequivalence studies, special concerns in bioavailability and bioequivalence studies, generic substitution, Basics of Biowaiver | **12 hours** |
| **Unit 5** | **Application of Pharmacokinetics:** Modified-release drug products, targeted drug delivery systems and biotechnological products. Introduction to pharmacokinetics and pharmacodynamic, drug interactions. Pharmacokinetics and pharmacodynamics of biotechnology drugs. introduction, proteins and peptides, monoclonal antibodies, oligonucleotides, vaccines (immunotherapy), gene therapies | **12 hours** |

**Recommended Books^: (Latest Editions)**


1. Biopharmaceutics and Clinical Pharmacokinetics by Milo Gibaldi, 4th edition, Philadelphia, Lea and Febiger, 1991.
2. Biopharmaceutics and Pharmacokinetics, A. Treatise, D .M. Brahmankar and Sunil B. Jaiswal., Vallabh Prakashan, Pitampura, Delhi.
3. Applied Biopharmaceutics and Pharmacokinetics by Shargel. Land YuABC, 2nd edition, Connecticut Appleton Century Crofts, 1985.
4. Textbook of Biopharmaceutics and Pharmacokinetics, Dr. Shobha Rani R. Hiremath, Prism Book.
5. Pharmacokinetics by Milo Gibaldi and D. Perrier, 2nd edition, Marcel Dekker Inc., New York, 1982.
6. Current Concepts in Pharmaceutical Sciences: Biopharmaceutics, Swarbrick. J, Leaand Febiger, Philadelphia, 1970.
7. Clinical Pharmacokinetics, Concepts and Applications 3rd edition by Malcolm Rowland and ThomN. Tozer, Lea and Febiger, Philadelphia, 1995.
8. Dissolution, Bioavailability and Bioequivalence, Abdou. H. M, Mack Publishing Company, Pennsylvania 1989.
9. Biopharmaceutics and Clinical Pharmacokinetics, An Introduction, 4th edition, revised and expanded by Robert. E. Notari, Marcel Dekker Inc, New York and Basel, 1987.
10. Biopharmaceutics and Relevant Pharmacokinetics by John. G Wagner and M. Pemarowski, 1st edition, Drug Intelligence Publications, Hamilton, Illinois, 1971.
11. Encyclopedia of Pharmaceutical Technology, Vol 13, James Swarbrick, James. G. Boylan, Marcel Dekker Inc., New York, 1996.
12. Basic Pharmacokinetics, 1st edition, Sunil S Jambhekar and Philip J Breen, pharmaceutical press, RPS Publishing, 2009.
13. Absorption and Drug Development- Solubility, Permeability, and Charge State, Alex Avdeef, John Wiley & Sons, Inc., 2003.


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Awarding University: Gujarat Technological University, Ahmedabad

Name of Program: **M. Pharm**
Branch: **A05 - Pharmaceutics**
Semester: **II**
Course Code: **M050203TT**
Course Name: **Computer Aided Drug Development**
Course Type: **Core**
Year of Implementation: **2024 – 25**

**Teaching and Examination Scheme:**

| Number of hours/ Week | | | Number of credits | | | Total credits | Evaluation Scheme (Marks) | | | | | | | | Total Marks |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | | | Sessional Exams | | | | | | Term End Assessment | | |
| | | | | | | | Theory | | | Practical | | | | | |
| L | Tu | P | L | Tu | P | | CIE | E | T | CIE | E | T | T | P | |
| 4 | 0 | 0 | 4 | 0 | 0 | 4 | 10 | 15 | 25 | 0 | 0 | 0 | 75 | 0 | 100 |

**Scope:**
This course is designed to impart knowledge and skills necessary for computer Applications in pharmaceutical research and development who want to understand the application of computers across the entire drug research and development process. Basic theoretical discussions of the principles of more integrated and coherent use of computerized information (informatics) in the drug development process are provided to help the students to clarify the concepts.

**Course Outcomes (CO):**
Upon completion of the course student shall be able to

| | |
|---|---|
| CO1 | Understand the history of Computers in Pharmaceutical Research and Development and its Regulatory and industry views. |
| CO2 | Recognize the concept of computational modelling of drug disposition and various transporters in real world. |
| CO3 | Apply the knowledge of computers in preclinical development, clinical development, and in market analysis. |
| CO4 | Rationalize the implementation of Artificial Intelligence, Robotics and Computational fluid dynamics in the Pharmaceutical field. |

**Detailed Syllabus:**
Total Teaching hours: **60 hours**

| | | |
|---|---|---|
| **Unit 1** | **Computers in Pharmaceutical Research and Development**: General Overview: History of Computers in Pharmaceutical Research and Development.<br>Statistical modelling in pharmaceutical research and development: Descriptive versus mechanistic modelling, statistical parameters, estimation, and confidence regions.<br>**Nonlinearity at the Optimum**- Definition and importance examples and application, | **12 hours** |

| | | |
|---|---|---|
| | **Sensitivity Analysis**- Definition, purpose, methods and techniques and examples<br>**Optimal Design**; Definition and objectives, importance in product development, applications in pharmaceutical product development<br>**Population Modelling:** Concepts and methods its application in drug development<br>**Quality-by Design in Pharmaceutical Development**: Introduction, definition and principles evolution of QbD in pharmaceutical development benefits and challenges of implementing QbD. ICH Q8 guideline, regulatory and industry views on QbD, scientifically based QbD-examples of application | |
| **Unit 2** | **Computational Modelling of Drug Disposition:** Introduction, modelling techniques: drug absorption, solubility, intestinal permeation, drug distribution, drug excretion.<br>**Modelling Active Transport**: Modelling active transport mechanisms is crucial in understanding drug disposition. P-gp, BCRP, Nucleoside Transporters, hPEPT1, ASBT, OCT, OATP, BBB-Choline Transporter (challenges in drug delivery to the central nervous system). | **12 hours** |
| **Unit 3** | **Computer-aided formulation development:** Concept of optimization, Optimization parameters, Factorial design, Optimization technology & Screening design.<br>Computers in Pharmaceutical Formulation: Development of pharmaceutical emulsions, microemulsion drug carriers Legal protection of innovative uses of computers in R&D, the ethics of computing in pharmaceutical research, computers in market analysis | **12 hours** |
| **Unit 4** | **Computer-aided biopharmaceutical characterization**: Gastrointestinal absorption simulation. introduction, theoretical background, model construction, parameter sensitivity analysis, virtual trial, fed vs. fasted state, in vitro dissolution and in vitro in vivo correlation, bio waiver considerations<br>**Computer Simulations in Pharmacokinetics and Pharmacodynamics:** Introduction, computer simulation: whole organism, isolated tissues, organs, cell, proteins and genes.<br>**Computers in Clinical Development**: Introduction to clinical data management (CDM), importance of CDM in clinical research, key components of CDM, roles and responsibilities in CDM, types of clinical data management systems (CDMS)<br>data validation and error handling, data integrity and quality assurance, advantages of CDM in India, future trends in clinical data management and Regulation of Computer Systems | **12 hours** |
| **Unit 5** | **Introduction of Artificial Intelligence (AI), Robotics, and Computational Fluid Dynamics (CFD)**<br>Introduction and basic concepts of AI, advantages and disadvantages, potential drawbacks and ethical considerations, AI in drug discovery and development, AI in personalized medicine and treatment plans, use of AI in predictive analytics for drug efficacy and safety technical challenges in implementing AI, regulatory and compliance issues, future trends and innovations in AI for pharmacy | **12 hours** |

| | | |
|---|---|---|
| | **Robotics:** Role of robotics in automating pharmaceutical processes, advantages of robotics in pharmacy, robotics in pharmacy operations.<br>**Computational fluid dynamics:**<br>General overview, pharmaceutical automation, pharmaceutical applications, advantages and disadvantages. current challenges and future directions | |

**Recommended Books^: (Latest Editions)**


1. Computer Applications in Pharmaceutical Research and Development, Sean Ekins, 2006, John Wiley &Sons.
2. Computer-Aided Applications in Pharmaceutical Technology, 1st Edition, Jelena Djuris, Woodhead Publishing
3. Encyclopaedia of Pharmaceutical Technology, Vol 1
4. James Swarbrick, James. G. Boylan, Marcel Dekker Inc, New York,1996.


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(Approved by PCI, NAAC Accredited – A+ Grade, 3.38 CGPA)
Awarding University: Gujarat Technological University, Ahmedabad

Name of Program: **M. Pharm**
Branch: **A05 - Pharmaceutics**
Semester: **II**
Course Code: **M050204TT**
Course Name: **Cosmetics and Cosmeceuticals**
Course Type: **Core**
Year of Implementation: **2024 – 25**

**Teaching and Examination Scheme:**

| Number of hours/ Week | | | Number of credits | | | Total credits | Evaluation Scheme (Marks) | | | | | | | | Total Marks |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | | | Sessional Exams | | | | | | Term End Assessment | | |
| | | | | | | | Theory | | | Practical | | | | | |
| L | Tu | P | L | Tu | P | | CIE | E | T | CIE | E | T | T | P | |
| 4 | 0 | 0 | 4 | 0 | 0 | 4 | 10 | 15 | 25 | 0 | 0 | 0 | 75 | 0 | 100 |

**Scope:**
This course is designed to impart knowledge and skills necessary for the fundamental need for cosmetic and cosmeceutical products.

**Course Outcome (CO):**
Upon completion of the course, the students shall be able to understand

| | |
|---|---|
| CO1 | Understand the challenges and its remedies to form cosmetics. |
| CO2 | Identify the role of various excipient to formulate cosmetics and cosmeceuticals. |
| CO3 | Apply scientific knowledge to develop cosmetics and cosmeceuticals with desired safety, stability, and efficacy. |
| CO4 | Assemble the knowledge of Indian cosmetic laws, standards, and compliance requirements to ensure product quality. |

**Detailed Syllabus:**
Total Teaching hours: **60 hours**

| | | |
|---|---|---|
| **Unit 1** | **Cosmetics – Regulatory:** Definition of cosmetic products as per Indian regulation. Indian regulatory requirements for labelling of cosmetics Regulatory provisions relating to import of cosmetics, Misbranded and spurious cosmetics. Regulatory provisions relating to manufacture of cosmetics – Conditions for obtaining license, prohibition of manufacture and sale of certain cosmetics, loan license, offences and penalties | **12 hours** |
| **Unit 2** | **Cosmetics - Biological aspects:** Structure of skin relating to problems like dry skin, acne, pigmentation, prickly heat, wrinkles and body odour. Structure of hair and hair growth cycle. Common problems associated with oral cavity. Cleansing and care needs for face, eye lids, lips, hands, feet, nail, scalp, neck, body and under-arm. | **12 hours** |
| **Unit 3** | **Formulation Building blocks:** Building blocks for different product formulations of cosmetics/cosmeceuticals. Surfactants – Classification and application. Emollients, rheological additives: classification and | **12 hours** |

| | | |
|---|---|---|
| | application. Antimicrobial used as preservatives, their merits and demerits. Factors affecting microbial preservative efficacy. Building blocks for formulation of a moisturizing cream, vanishing cream, cold cream, shampoo and toothpaste. Soaps and syndet bars.<br>**Perfumes;** Classification of perfumes. Perfume ingredients listed as allergens in EU regulation.<br>**Controversial ingredients:** Parabens, formaldehyde liberators, dioxane. | |
| **Unit 4** | **Design of cosmeceutical products:** Sun protection, sunscreens classification and regulatory aspects. Addressing dry skin, acne, sun-protection, pigmentation, prickly heat, wrinkles, body odor. dandruff, dental cavities, bleeding gums, mouth odor and sensitive teeth through cosmeceutical formulations. | **12 hours** |
| **Unit 5** | **Herbal Cosmetics:** Herbal ingredients used in Hair care, skin care and oral care. Review of guidelines for herbal cosmetics by private bodies like cosmos with respect to preservatives, emollients, foaming agents, emulsifiers and rheology modifiers. Challenges in formulating herbal cosmetics. | **12 hours** |

**Recommended Books^: (Latest Editions)**


1. Harry's Cosmeticology. 8th edition.
2. Poucher's perfume cosmetics and Soaps, 10th edition.
3. Cosmetics - Formulation, Manufacture and quality control, PP.Sharma, 4th edition
4. Handbook of cosmetic science and Technology A.O. Barel, M. Paye and H.I. Maibach. 3rd edition
5. Cosmetic and Toiletries recent suppliers' catalogue. 6. CTFA directory.


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Awarding University: Gujarat Technological University, Ahmedabad

Name of Program: **M. Pharm**
Branch: **A05 - Pharmaceutics**
Semester: **II**
Course Code: **M050205PP**
Course Name: **Pharmaceutics Practicals - II**
Course Type: **Core**
Year of Implementation: **2024 – 25**

**Teaching and Examination Scheme:**

| Number of hours/ Week | | | Number of credits | | | Total credits | Evaluation Scheme (Marks) | | | | | | | | Total Marks |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | | | Sessional Exams | | | | | | Term End Assessment | | |
| | | | | | | | Theory | | | Practical | | | | | |
| L | Tu | P | L | Tu | P | | CIE | E | T | CIE | E | T | T | P | |
| 0 | 0 | 12 | 0 | 0 | 6 | 6 | 0 | 0 | 0 | 20 | 30 | 50 | 0 | 100 | 150 |

**Scope:**
This course deals with the fundamentals of Pharmaceutics and principles of formulation and evaluation of the same.

**Course Outcomes (CO):**
Upon completion of the course student shall be able to

| | |
|---|---|
| CO1 | Recall the optimization, formulation techniques and evaluation parameters of novel drug delivery system. |
| CO2 | Systematic development and evaluation of novel drug delivery system; apply the principles of computer simulation and computational modelling in pharmaceutical field. |

**List of Practicals**
Total Teaching hours: **60 hours**

1. To study the effect of temperature change, non-solvent addition, incompatible polymer addition in microcapsules preparation
2. Preparation and evaluation of Alginate beads
3. Formulation and evaluation of gelatin /albumin microspheres
4. Formulation and evaluation of liposomes/niosomes
5. Formulation and evaluation of spherules/Pellets.
6. Improvement of dissolution characteristics of slightly soluble drug by Solid dispersion technique.
7. Comparison of dissolution of two different marketed products /brands
8. Protein binding studies of a highly protein bound drug & poorly protein bound drug
9. Bioavailability studies of Paracetamol in animals.
10. Pharmacokinetic and IVIVC data analysis by PK solver, DD solver and MS-Excel.
11. In vitro cells studies for permeability and metabolism
12. DoE Using Design Expert® Software
13. Formulation data analysis Using Design Expert® Software

14. Quality-by-Design in Pharmaceutical Development
15. Computer Simulation sin Pharmacokinetics and Pharmacodynamics
16. Computational Modeling of Drug Disposition
17. To develop Clinical Data Collection manual
18. To carry out Sensitivity Analysis, and Population Modeling.
19. Development and evaluation of Creams for Dry skin, acne, blemish & Wrinkles by incorporating herbal and chemical actives.
20. Development and evaluation of anti-dandruff Shampoo.
21. To prepare novel and Toothpaste base formulation for bleeding gums.

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Name of Program: **M. Pharm**
Branch: – **A06 - Pharmacology**
Semester: **I**
Course Code: **M000101TT**
Course Name: **Modern pharmaceutical analytical techniques**
Course Type: **Core**
Year of Implementation: **2024 – 25**

**Teaching and Examination Scheme:**

| Number of hours/ Week | | | Number of credits | | | Total credits | Evaluation Scheme (Marks) | | | | | | | | Total Marks |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | | | Sessional Exams | | | | | | Term End Assessment | | |
| | | | | | | | Theory | | | Practical | | | | | |
| L | Tu | P | L | Tu | P | | CIE | E | T | CIE | E | T | T | P | |
| 4 | 0 | 0 | 4 | 0 | 0 | 4 | 10 | 15 | 25 | 0 | 0 | 0 | 75 | 0 | 100 |

**Scope:**
This subject deals with various advanced analytical instrumental techniques for identification, characterization, and quantification of drugs. Instruments dealt are NMR, Mass spectrometer, IR, HPLC, GC etc.

**Course Outcomes (CO):**
Upon completion of the course student shall be able to

| | |
|---|---|
| CO1 | Understand different chromatographic principles, instrumentation and techniques |
| CO2 | Understand principles and instrumentation for electrophoresis, X-ray crystallography, potentiometry, and thermal analysis |
| CO3 | Understand and apply principles, instrumentation, and techniques of various spectroscopic methods |
| CO4 | Apply principles of spectroscopic techniques to identify and quantify various drugs |

**Detailed Syllabus:**
Total Teaching hours: **60 hours**

| | | |
|---|---|---|
| **Unit 1** | **UV-Visible spectroscopy:** Introduction, Theory, Laws, Instrumentation associated with UV-Visible spectroscopy, Choice of solvents and solvent effect and Applications of UV-Visible Spectroscopy, Simultaneous equation method, Derivative spectroscopic method, Difference spectroscopic method<br>**IR spectroscopy:** Theory, Modes of Molecular vibrations, Sample handling, Instrumentation of Dispersive and Fourier - Transform IR Spectrometer, Factors affecting vibrational frequencies and Applications of | **4 hours**<br><br>**4 hours** |

| | | |
|---|---|---|
| | IR spectroscopy, Data interpretation<br>**Spectrofluorimetry:** Theory of Fluorescence, Factors affecting fluorescence, Quenchers, Instrumentation and Applications of fluorescence Spectrophotometer<br>**Flame emission spectroscopy and atomic absorption spectroscopy**: Principle, Instrumentation, Interferences and Applications | **2 hours**<br><br>**2 hours** |
| **Unit 2** | **NMR spectroscopy:** Quantum numbers and their role in NMR, Principle, Instrumentation, Solvent requirement in NMR, Relaxation process, NMR signals in various compounds, Chemical shift, Factors influencing chemical shift, Spin-Spin coupling, Coupling constant, Nuclear magnetic double resonance. Brief outline of principles of FT-NMR and 13C NMR. Applications of NMR spectroscopy | **11 hours** |
| **Unit 3** | **Mass Spectroscopy:** Principle, Theory, Instrumentation of Mass Spectroscopy, Different types of ionization like electron impact, chemical, field, FAB and MALDI, APCI, ESI, APPI Analyzers of Quadrupole and Time of Flight, Mass fragmentation and its rules, Meta stable ions, Isotopic peaks, and Applications of Mass Spectroscopy | **10 hours** |
| **Unit 4** | **Chromatography:** Principle, apparatus, instrumentation, chromatographic parameters, factors affecting resolution and applications of the following:<br>a) Paper chromatography<br>b) Thin Layer chromatography<br>c) Ion exchange chromatography<br>d) Column chromatography<br>e) Gas chromatography<br>f) High Performance Liquid chromatography<br>g) Affinity chromatography | <br><br>**3 hours**<br>**3 hours**<br>**2 hours**<br>**3 hours** |
| **Unit 5** | **Electrophoresis:** Principle, Instrumentation, working conditions, factors affecting separation and applications of the following:<br>a) Paper electrophoresis<br>b) Gel electrophoresis<br>c) Capillary electrophoresis<br>d) Zone electrophoresis<br>e) Moving boundary electrophoresis<br>f) Iso electric focusing<br>**X ray Crystallography:** Production of X rays, Different X ray diffraction methods, Bragg's law, Rotating crystal technique, X ray powder technique, Types of crystals and applications of Xray diffraction. | **6 hours**<br><br><br><br><br><br><br>**3 hours** |
| **Unit 6** | **Potentiometry:** Principle, Ion selective Electrodes and Application of potentiometry.<br>**Thermal Analysis: :** Principle, thermal transitions, and instrumentation (heat flux and power compensation and designs) working, Polymer behaviour, factors affecting and instrumentation, and working, application of TGA | **4 hours**<br><br>**3 hours** |

**Recommended Books^: (Latest Editions)**


1. Silverstein RM, Bassler GC. Spectrometric identification of organic compounds. John Wiley & Sons. New York
2. Doglas A Skoog, F. James Holler, Timothy A. Nieman. Principles of Instrumental Analysis Eastern press. Bangalore.
3. Willard H, Merritt LL, Dean JA, Settle FA. Instrumental methods of analysis. CBS publisher and distributors. New Delhi. India
4. Beckett AH and Stenlake JB. Practical Pharmaceutical Chemistry. CBS Publishers. New Delhi. India
5. Kemp W. Organic Spectroscopy. ELBS. Macmillan
6. Sethi PD. Quantitative analysis of drugs in pharmaceutical formulations. Unique Publishers. New Delhi. India.
7. Munson JW. Pharmaceutical analysis: modern methods. B. Drugs and the pharmaceutical sciences. Marcel Dekker. New York.


L= Lecture, Tu= Tutorial, P= Practical, T = Theory

**ANAND PHARMACY COLLEGE, ANAND**
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**Managed by Shri Ramkrishna Seva Mandal**
(Approved by PCI, NAAC Accredited – A+ Grade, 3.38 CGPA)
Awarding University: Gujarat Technological University, Ahmedabad

Name of Program: **M Pharm**
Branch: – **A06 - Pharmacology**
Semester: **I**
Course Code: **M060102TT**
Course Name: **Advanced Pharmacology-I**
Course Type: **Core**
Year of Implementation: **2024 – 25**

**Teaching and Examination Scheme:**

| Number of hours/ Week | | | Number of credits | | | Total credits | Evaluation Scheme (Marks) | | | | | Total Marks |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | | | Sessional Exams | | | Term End Assessment | | |
| | | | | | | | Theory | | | | | |
| L | Tu | P | L | Tu | P | | CIE | E | T | T | P | |
| 4 | - | - | 4 | - | - | 4 | 10 | 15 | 25 | 75 | 75 | 100 |

**Scope:**
The subject is designed to strengthen the basic knowledge in the field of pharmacology and to impart advances in the drugs used to treat various diseases. In addition, this subject helps the students to understand the concepts of drug action and the mechanisms involved.

**Course Outcomes (CO):**
Upon completion of the course, the student shall be able to

| | |
|---|---|
| CO1 | To integrate and apply principles of pharmacokinetics and pharmacodynamics in the selection of drug. |
| CO2 | To interpret and articulate an understanding of neurotransmission and pharmacology in the autonomic and central nervous systems. |
| CO3 | To illustrate and describe the pharmacology of various drugs acting on the central nervous system with special emphasis on recent advances. |
| CO4 | To classify and explain cardiovascular and autacoid pharmacology along with recent advances. |

**Detailed Syllabus:**
Total Teaching hours: **60 hours**

| | | |
|---|---|---|
| **Unit 1** | **General Pharmacology:**<br>**a. Pharmacokinetics:** The dynamics of drug absorption, distribution, biotransformation and elimination. Concepts of linear and non-linear compartment models. Significance of Protein Binding. | **06 hours** |

| | | |
|---|---|---|
| | **b. Pharmacodynamics:** Mechanism of drug action and the relationship between drug concentration and effect. Receptors, structural and functional families of receptors, quantitation of drug receptors interaction, and elicited effects. | **06 hours** |
| **Unit 2** | **Neurotransmission:**<br>a. General aspects and steps involved in neurotransmission.<br>b. Neurohumoral transmission in the autonomic nervous system (Detailed study about neurotransmitters- Adrenaline and Acetylcholine).<br>c. Neurohumoral transmission in the central nervous system (Detailed study about neurotransmitters- histamine, serotonin, dopamine, GABA, glutamate, and glycine].<br>d. Non-adrenergic non-cholinergic transmission (NANC). Cotransmission.<br>**Systemic Pharmacology:**<br>A detailed study on the pathophysiology of diseases, mechanism of action, pharmacology, and toxicology of existing as well as novel drugs used in the following systems<br>**Autonomic Pharmacology:**<br>Parasympathomimetics and parasympatholytics, sympathomimetics and Sympatholytics, agents affecting neuromuscular junction | **04 hours**<br><br>**08 hours** |
| **Unit 3** | **Central nervous system Pharmacology:**<br>General, and local anaesthetics<br>Sedatives and hypnotics, drugs used to treat anxiety.<br>Depression, psychosis, mania, epilepsy, neurodegenerative diseases.<br>Narcotic and non-narcotic analgesics | **12 hours** |
| **Unit 4** | **Cardiovascular Pharmacology:**<br>Diuretics, anti-hypertensives, anti-ischemics, anti-arrhythmics, drugs for heart failure and hyperlipidaemia. Hematinics, coagulants, anticoagulants, fibrinolytic and antiplatelet Drugs | **12 hours** |
| **Unit 5** | **Autocoid Pharmacology :**<br>The physiological and pathological role of Histamine, Serotonin, Kinins, Prostaglandins Opioid autocoids. Pharmacology of antihistamines, 5HT antagonists | **12 hours** |

**Recommended Books^: (Latest Editions)**


1. The Pharmacological Basis of Therapeutics, Goodman and Gillman's
2. Principles of Pharmacology. The Pathophysiologic basis of drug Therapy by David E Golan, Armen H, Tashjian Jr, Ehrin J, Armstrong, April W, Armstrong, Wolters, Kluwer-Lippincott Williams & Wilkins Publishers.
3. Basic and Clinical Pharmacology by B.G Katzung
4. Handbook of Clinical Pharmacokinetics by Gibaldi and Prescott.
5. Applied Biopharmaceutics and Pharmacokinetics by Leon Shargel and Andrew B.C. Yu.
6. Graham Smith. Oxford textbook of Clinical Pharmacology.
7. Robbins & Cortan Pathologic Basis of Disease, 9th Ed. (Robbins Pathology)
8. A Complete Textbook of Medical Pharmacology by Dr. S.K Srivastava published by APC Avichal Publishing Company
9. K.D. Tripathi. Essentials of Medical Pharmacology.
10. Modern Pharmacology with Clinical Applications, Craig Charles R. & Stitzel Robert E., Lippincott Publishers.
11. Clinical Pharmacokinetics & Pharmacodynamics: Concepts and Applications – Malcolm Rowland and Thomas N. Tozer, Wolters Kluwer, Lippincott Williams & Wilkins Publishers.
12. Applied biopharmaceutics and Pharmacokinetics, Pharmacodynamics, and Drug metabolism for industrial scientists.


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^ This is not an exhaustive list

Name of Program: **M Pharm**
Branch: – **A06 - Pharmacology**
Semester: **I**
Course Code: **M060103TT**
Course Name: **Pharmacological and Toxicological Screening Methods-I**
Course Type: **Core**
Year of Implementation: **2024-25**

**Teaching and Examination Scheme:**

| Number of hours/ Week | | | Number of credits | | | Total credits | Evaluation Scheme (Marks) | | | | | | | | Total Marks |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | | | Sessional Exams | | | | | | Term End Assessment | | |
| | | | | | | | Theory | | | Practical | | | | | |
| L | Tu | P | L | Tu | P | | CIE | E | T | CIE | E | T | T | P | |
| 4 | - | - | 4 | - | - | 4 | 10 | 15 | 25 | - | - | - | 75 | - | 100 |

**Scope:** This subject is designed to impart knowledge on the preclinical evaluation of drugs and recent experimental techniques in drug discovery and development. The subject content helps the student to understand the maintenance of laboratory animals as per the CCSEA guidelines, and basic knowledge of various in-vitro and in-vivo preclinical evaluation processes.

**Course Outcomes (CO):**
Upon completion of the course, the student shall be able to

| | |
|---|---|
| CO1 | To describe, demonstrate, and apply the knowledge of GLP and CCSEA guidelines in laboratory animals. |
| CO2 | To utilize general principles of preclinical screening methods for the screening of drugs affecting CNS and ANS. |
| CO3 | To apply preclinical screening methods to evaluate respiratory, reproductive, analgesic, gastrointestinal, cardiovascular, metabolic, anti-cancer, and hepatoprotective agents. |
| CO4: | To describe and articulate the principles of immunopharmacology and immunoassays, in the assessment of drugs |

**Detailed Syllabus:**
Total Teaching hours: **60 hours**

| | | |
|---|---|---|
| **Unit 1** | **Laboratory Animals**<br>**Common laboratory animals:**<br>Description, handling, and applications of different species and strains of animals.<br>Anaesthesia and euthanasia of experimental animals,<br>Maintenance and breeding of laboratory animals. | **08 hours** |

| | | |
|---|---|---|
| | CCSEA guidelines for conducting experiments on animals,<br>Good laboratory practice<br>**Transgenic animals:** Production, maintenance, and applications.<br>**Bioassay**-Principle, scope and limitations, and methods | **04 hours** |
| **Preclinical screening of new substances for pharmacological activity using in vivo, in vitro, and other possible animal alternative models.** | | |
| **Unit 2** | General principles of preclinical screening. | **01 hour** |
| | **CNS Pharmacology:**<br>Behavioral and muscle coordination,<br>CNS stimulants and depressants,<br>Anxiolytics,<br>Anti-psychotics,<br>Anti-epileptics, and<br>Nootropics.<br>Drugs for neurodegenerative diseases like Parkinsonism, Alzheimer's, and multiple sclerosis. | **08 hours** |
| | Drugs acting on Autonomic Nervous System | **03 hours** |
| **Unit 3** | **Respiratory Pharmacology:**<br>Anti-asthmatics,<br>Drugs for COPD, and<br>Anti-allergics. | **03 hours** |
| | **Reproductive Pharmacology:**<br>Aphrodisiacs and<br>Antifertility agents. | **02 hours** |
| | Analgesics,<br>Anti-inflammatory and antipyretic agents. | **03 hours** |
| | **Gastrointestinal drugs:**<br>Anti-ulcer,<br>Anti-emetic,<br>Antidiarrheal and laxatives | **04 hours** |
| **Unit 4** | **Cardiovascular Pharmacology:**<br>Anti-hypertensives,<br>Anti-arrhythmics,<br>Anti-anginal,<br>Anti-atherosclerotic agents, and<br>Diuretics. | **04 hours** |
| | Drugs for metabolic disorders like anti-diabetic, and anti-dyslipidemic agents. | **04 hours** |
| | Anti-cancer agents. | **02 hours** |
| | Hepatoprotective screening methods | **02 hours** |
| **Unit 5** | Immunomodulators, Immunosuppressants, and immunostimulants. | **04 hours** |
| | **General principles of immunoassay:**<br>Theoretical basis and optimization of immunoassay, heterogeneous and homogenous immunoassay systems. | **04 hours** |
| | **Immunoassay methods evaluation**; protocol outline, objectives, and preparation. Immunoassay for digoxin and insulin | **02 hours** |

| | | |
|---|---|---|
| | Limitations of animal experimentation and alternate animal experiments. Extrapolation of in vitro data to preclinical and preclinical to humans. | **02 hours** |

**Recommended Books^: (Latest Editions)**


1. Biological Standardization by J.H. Burn D.J. Finney and I.G. Goodwin
2. Screening Methods in Pharmacology by Robert Turner. A
3. Evaluation of drug activities by Laurence and Bachrach
4. Methods in Pharmacology by Arnold Schwartz.
5. Fundamentals of Experimental Pharmacology by M.N. Ghosh
6. Drug Discovery and Evaluation by Vogel H.G.
7. Practical in Pharmacology by R. K. Goyal.
8. Preclinical evaluation of new drugs by S.K. Gupta
9. Handbook of Experimental Pharmacology, S.K. Kulkarni
10. Practical Pharmacology and Clinical Pharmacy, S.K. Kulkarni, 3rd Edition.
11. Screening Methods in Pharmacology, Robert A. Turner.
12. Rodents for Pharmacological Experiments, Dr. Tapan Kumar Chatterjee.
13. Practical Manual of Experimental and Clinical Pharmacology by Bikash Medhi (Author), Ajay Prakash (Author).


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Awarding University: Gujarat Technological University, Ahmedabad

Name of Program: **M Pharm**
Branch: – **A06 - Pharmacology**
Semester: **I**
Course Code: **M060104TT**
Course Name: **Cellular and Molecular Pharmacology**
Course Type: **Core**
Year of Implementation: **2024-25**

**Teaching and Examination Scheme:**

| Number of hours/ Week | | | Number of credits | | | Total credits | Evaluation Scheme (Marks) | | | | | | | | Total Marks |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | | | Sessional Exams | | | | | | Term End Assessment | | |
| | | | | | | | Theory | | | Practical | | | | | |
| L | Tu | P | L | Tu | P | | CIE | E | T | CIE | E | T | T | P | |
| 4 | - | - | 4 | - | - | 4 | 10 | 15 | 25 | - | - | - | 75 | - | 100 |

**Scope:** This subject is designed to impart the knowledge on preclinical evaluation of drugs and recent experimental techniques in the drug discovery and development. The subject content helps the student to understand the maintenance of laboratory animals as per the guidelines, basic knowledge of various in-vitro and in-vivo preclinical evaluation processes.

**Course Outcomes (CO):**
Upon completion of the course, the student shall be able to

| | |
|---|---|
| CO1 | Understand the foundations of cell biology and correlate receptor signal transduction pathway. |
| CO2 | Comprehend the principles and application of genomic and proteomic tools |
| CO3 | Relate the knowledge of pharmacogenomics and immunotherapeutics in clinical practice. |
| CO4: | Demonstrate the cell culture techniques involved in drug discovery process. |

**Detailed Syllabus:**
Total Teaching hours: **60 hours**

| | | |
|---|---|---|
| **Unit 1** | **Cell biology:**<br>Structure and functions of the cell and its organelles, Genome organization, Gene expression and its regulation, importance of siRNA and micro RNA, gene mapping and gene sequencing, Cell cycles and its regulation.<br><br>**Cell death:** Events, regulators, intrinsic and extrinsic pathways of apoptosis. Necrosis and autophagy. | **09 hours**<br><br>**03 hours** |

| | | |
|---|---|---|
| **Unit 2** | **Cell signaling:**<br>Intercellular and intracellular signaling pathways. Classification of receptor family and molecular structure ligand-gated ion channels; G-protein coupled receptors, tyrosine kinase receptors, and nuclear receptors. Secondary messengers: cyclic AMP, cyclic GMP, calcium ion, inositol 1, 4, 5-trisphosphate, (IP3), NO, and diacylglycerol.<br><br>**Detailed study of following intracellular signaling pathways:** Cyclic AMP signaling pathway, mitogen-activated protein kinase (MAPK) signaling, Janus kinase (JAK)/signal transducer, and activator of transcription (STAT) signaling pathway. | **08 hours**<br><br>**04 hours** |
| **Unit 3** | **Principles and applications of genomic and proteomic tools:**<br>DNA electrophoresis, PCR (reverse transcription and real-time), Gene sequencing, microarray technique, SDS page, ELISA and western blotting, Recombinant DNA technology and gene therapy, Basic principles of recombinant DNA technology-Restriction enzymes, various types of vectors, Applications of recombinant DNA technology.<br><br>**Gene therapy**- Various types of gene transfer techniques, clinical applications, and recent advances in gene therapy. | **09 hours**<br><br>**03 hours** |
| **Unit 4** | **Pharmacogenomics:**<br>Gene mapping and cloning of disease genes, Genetic variation and its role in health/ pharmacology, Polymorphisms affecting drug metabolism, Genetic variation in drug transporters, Genetic variation in G protein-coupled receptors,<br><br>**Applications of proteomics science:** Genomics, proteomics, metabolomics, function-omics, nutrigenomics<br><br>**Immunotherapeutics:** Types of immunotherapeutics, humanization antibody therapy, Immunotherapeutics in clinical practice. | **04 hours**<br><br>**05 hours**<br><br>**03 hours** |
| **Unit 5** | **a. Cell culture techniques**:<br>Basic equipment used in cell culture lab, Cell culture media, various types of cell culture, General procedure for cell cultures: isolation of cells, subculture, cryopreservation, characterization of cells, and their application, Principles and applications of cell viability assays, glucose uptake assay, Calcium influx assay, Principles and applications of flow cytometry<br>**b. Biosimilars.**<br>In-vivo cell line-based assay, peptides, and biosimilars | **10 hours**<br><br>**02 hours** |

**Recommended Books^: (Latest Editions)**


1. The Cell, A Molecular Approach. Geoffrey M Cooper.
2. Rang & Dale's Pharmacology 10th edition.
3. Molecular Biology of the Cell by Bruce Albert and Alexander Johnson 4th edition
4. Pharmacogenomics: The Search for Individualized Therapies. Edited by J. Licinio and ML. Wong
5. Handbook of Cell Signaling (Second Edition) Edited by Ralph A. et.al
6. Molecular Pharmacology: From DNA to Drug Discovery. John Dickenson et.al
7. Basic Cell Culture Protocols by Cheril D. Helgason and Cindy L. Miller
8. Basic Cell Culture (Practical Approach) by J. M. Davis (Editor)
9. Animal Cell Culture: A Practical Approach by John R. Masters (Editor)
10. Current Protocols in Molecular Biology vol I to VI edited by Frederick M. Ausuvelet al.
11. Culture of Animal Cells A Manual of Basic Technique and Specialized Application by
    R. Ian Freshney 7th edition.


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(Approved by PCI, NAAC Accredited – A+ Grade, 3.38 CGPA)
Awarding University: Gujarat Technological University, Ahmedabad

Name of Program: **M. Pharm**
Branch: – **A06 - Pharmacology**
Semester: **I**
Course Code: **M060105PP**
Course Name: **Pharmacology Practical I**
Course Type: **Core**
Year of Implementation: **2024 – 25**

**Teaching and Examination Scheme:**

| Number of hours/ Week | | | Number of credits | | | Total credits | Evaluation Scheme (Marks) | | | | | | | | Total Marks |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | | | Sessional Exams | | | | | | End Semester Assessment | | |
| | | | | | | | Theory | | | Practical | | | | | |
| L | Tu | P | L | Tu | P | | CIE | E | T | CIE | E | T | T | P | |
| - | - | 12 | - | - | 6 | 6 | - | - | - | 20 | 30 | 50 | - | 100 | 150 |

**Scope:** This course deals with the fundamentals of analytical chemistry and principles of electrochemical analysis of drugs

**Course Outcomes (CO):**
Upon completion of the course, the student shall be able to

| | |
|---|---|
| CO1 | Understand regulations and ethical requirements for the usage of experimental animals and perform various animal models used in the drug discovery process |
| CO2 | Isolation and estimation of genetic material using various methods. |

**List of Practicals:**
Total Teaching hours: **60 hours**
**PART A:**

1. Analysis of pharmacopoeial compounds and their formulations by UV Vis spectrophotometer
2. Simultaneous estimation of multi-component containing formulations by UV spectrophotometry
3. Experiments based on HPLC
4. Experiments based on Gas Chromatography
5. Estimation of riboflavin/quinine sulphate by fluorimetry
6. Estimation of sodium/potassium by flame photometry

**PART B:**
Handling of laboratory animals.

1. Dose conversion from NOAEL, Human dose to animal dose.
2. Various routes of drug administration.
3. Techniques of blood sampling, anaesthesia, and euthanasia of experimental animals.

4. Functional observation battery tests (modified Irwin test)
5. Evaluation of CNS stimulant, depressant, anxiogenics, and anxiolytic, anticonvulsant activity.
6. Evaluation of analgesic, anti-inflammatory, local anaesthetic, mydriatic, and miotic activity.
7. Evaluation of diuretic activity.
8. Evaluation of antiulcer activity by pylorus ligation method.
9. Oral glucose tolerance test.
10. Isolation and identification of DNA from various sources (Bacteria, Cauliflower, onion, Goat liver). Isolation of RNA from yeast
11. Estimation of proteins by Braford/Lowry's in biological samples. 12. Estimation of RNA/DNA by UV Spectroscopy
12. Gene amplification by PCR.
13. Protein quantification Western Blotting.
14. Enzyme-based in-vitro assays (MPO, AChEs, α amylase, α glucosidase).
15. Cell viability assays (MTT/Trypan blue/SRB).
16. DNA fragmentation assay by agarose gel electrophoresis.
17. DNA damage study by Comet assay.
18. Apoptosis determination by fluorescent imaging studies.
19. Pharmacokinetic studies and data analysis of drugs given by different routes of administration using softwares (PK Solver, WinNolin)
20. Enzyme inhibition and induction activity
21. Extraction of drug from various biological samples and estimation of drugs in biological fluids using different analytical techniques (UV)
22. Extraction of drug from various biological samples and estimation of drugs in biological fluids using different analytical techniques (ELISA)

**Recommended Books^: (Latest Editions)**


1. CCSEA, OECD, ICH, USFDA, Schedule Y, EPA guidelines,
2. Fundamentals of Experimental Pharmacology by M.N. Ghosh
3. Handbook of Experimental Pharmacology by S.K. Kulkarni.
4. Drug Discovery and Evaluation pharmacological assays by Vogel H.G.
5. Spectrometric Identification of Organic Compounds - Robert M Silverstein,
6. Principles of Instrumental Analysis - Doglas A Skoog, F. James Holler, Timothy A. Nieman,
7. Vogel's Textbook of quantitative chemical analysis - Jeffery, Basset, Mendham, Denney,
8. Basic Cell Culture Protocols by Cheril D. Helgason and Cindy L. Mille
9. Basic Cell Culture (Practical Approach) by J. M. Davis (Editor)
10. Animal Cell Culture: A Practical Approach by John R. Masters (Editor)
11. Practical Manual of Experimental and Clinical Pharmacology by Bikash Medhi (Author), Ajay Prakash (Author) Jaypee brothers' medical publishers Pvt. Ltd


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Awarding University: Gujarat Technological University, Ahmedabad

Name of Program: **M Pharm**
Branch: – **A06 - Pharmacology**
Semester: **II**
Course Code: **M060201TT**
Course Name: **Advanced Pharmacology-II**
Course Type: **Core**
Year of Implementation: **2024-25**

**Teaching and Examination Scheme:**

| Number of hours/ Week | | | Number of credits | | | Total credits | Evaluation Scheme (Marks) | | | | | Total Marks |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | | | Sessional Exams | | | Term End Assessment | | |
| | | | | | | | Theory | | | | | |
| L | Tu | P | L | Tu | P | | CIE | E | T | T | P | |
| 4 | - | - | 4 | - | - | 4 | 10 | 15 | 25 | 75 | 75 | 100 |

**Scope:**
The subject is designed to strengthen the basic knowledge in the field of pharmacology and to impart recent advances in the drugs used for the treatment of various diseases. In addition, the subject helps the student to understand the concepts of drug action and the mechanism involved.

**Course Outcomes (CO):**
Upon completion of the course, the student shall be able to

| | |
|---|---|
| CO1 | To understand the molecular and cellular mechanism of action of various hormones & pharmacology of drugs acting on the endocrine system |
| CO2 | To explain the pharmacology of chemotherapeutic agents, drugs acting on GIT disorders, and applications of Chronopharmacology |
| CO3 | To Apply the concepts of pathophysiology and immunopharmacology in the treatment of asthma and COPD |
| CO4 | To understand the concepts of Free radicals and recent advances of free radical scavengers in various disorders |

**Detailed Syllabus:**
Total Teaching hours: **60 hours**

| | | |
|---|---|---|
| **Unit 1** | **Endocrine Pharmacology**:<br>Molecular and cellular mechanism of action of hormones such as growth hormone, prolactin, thyroid, insulin, and sex hormones<br>Anti-thyroid drugs, Oral hypoglycaemic agents, Oral contraceptives, and Corticosteroids. Drugs affecting calcium regulation | **04 hours**<br><br>**08 hours** |
| **Unit 2** | **Chemotherapy:** Cellular and molecular mechanism of actions and resistance of antimicrobial agents such as ß-lactams, aminoglycosides, quinolones,and macrolide antibiotics. Antifungal, antiviral, and anti-TB | **12 hours** |

| | | |
|---|---|---|
| | drugs | |
| **Unit 3** | **Chemotherapy:**<br>Drugs used in Protozoal Infections<br>Drugs used in the treatment of Helminthiasis Chemotherapy of cancer<br>**Immunopharmacology:**<br>Cellular and biochemical mediators of inflammation and immune response. Allergic or hypersensitivity reactions.<br>Pharmacotherapy of asthma and COPD. Immunosuppressants and Immunostimulants | **05 hours**<br><br><br><br>**07 hours** |
| **Unit 4** | **GIT Pharmacology:**<br>Antiulcer drugs, Prokinetics, anti-emetics, anti-diarrheal, and drugs for constipation and irritable bowel syndrome.<br>**Chronopharmacology:**<br>Biological and circadian rhythms, applications of chronotherapy in various diseases like cardiovascular disease, diabetes, asthma, and peptic ulcer | **07 hours**<br><br>**05 hours** |
| **Unit 5** | **Free radicals Pharmacology:**<br>Generation of free radicals, the role of free radicals in etiopathology of various diseases such as diabetes, neurodegenerative diseases, and cancer. Protective activity of certain important antioxidants.<br>**Recent Advances in Treatment:** Alzheimer's disease, Parkinson's disease, Cancer, Diabetes mellitus | **06 hours**<br><br><br>**06 hours** |

**Recommended Books^: (Latest Editions)**


1. The Pharmacological basis of therapeutics-Goodman and Gillman's
2. Principles of Pharmacology. The pathophysiologic basis of drug therapy by David E Golan et al.
3. Basic and Clinical Pharmacology by B.G –Katzung
4. Pharmacology by H.P. Rang and M.M. Dale 10th edition.
5. Textbook of Therapeutics, drug and disease management by E T. Herfindal and Gourley.
6. Applied biopharmaceutics and Pharmacokinetics by Leon Shargel and Andrew B.C. Yu.
7. Handbook of Essential Pharmacokinetics, Pharmacodynamics and Drug Metabolism for Industrial Scientists
8. Robbins & Cortan Pathologic Basis of Disease, 9th Ed. (Robbins Pathology)
9. A Complete Textbook of Medical Pharmacology by Dr. S.K Srivastava published by APC Avichal Publishing Company.
10. KD. Tripathi. Essentials of Medical Pharmacology 8 th edition
11. Principles of Pharmacology. The Pathophysiologic basis of drug Therapy by David E Golan, Armen H, Tashjian Jr, Ehrin J, Armstrong, April W, Armstrong, Wolters, Kluwer Lippincott Williams & Wilkins Publishers 6 th edition


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Awarding University: Gujarat Technological University, Ahmedabad

Name of Program: **M Pharm**
Branch: – **A06 - Pharmacology**
Semester: **II**
Course Code: **M060202TT**
Course Name: **Pharmacological and Toxicological Screening Methods II**
Course Type: **Core**
Year of Implementation: **2024-25**

**Teaching and Examination Scheme:**

| Number of hours/ Week | | | Number of credits | | | Total credits | Evaluation Scheme (Marks) | | | | | | | | Total Marks |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | | | Sessional Exams | | | | | | Term End Assessment | | |
| | | | | | | | Theory | | | Practical | | | | | |
| L | Tu | P | L | Tu | P | | CIE | E | T | CIE | E | T | T | P | |
| 4 | - | - | 4 | - | - | 4 | 10 | 15 | 25 | - | - | - | 75 | - | 100 |

**Scope:** This subject imparts knowledge of the preclinical safety and toxicological evaluation of drugs &new chemical entities. This knowledge will make the student competent in regulatory toxicological evaluation.

**Course Outcomes (CO):**
Upon completion of the course, the student shall be able to

| | |
|---|---|
| CO1 | Understand and apply the principles of toxicology and regulatory guidelines for conducting toxicity studies required for drug development |
| CO2 | Describe the principles of reproductive toxicology, genotoxicity studies, and in vivo carcinogenicity studies |
| CO3 | Utilize the concepts of IND studies and safety pharmacology |
| CO4: | Understand the basic concepts of toxicokinetic |

**Detailed Syllabus:**
Total Teaching hours: **60 hours**

| | | |
|---|---|---|
| **Unit 1** | Basic definition and types of toxicology (general, mechanistic, regulatory, and descriptive), Regulatory guidelines for conducting toxicity studies: OECD, ICH, EPA and Schedule Y, OECD principles of good laboratory practice (GLP): History, concept and its importance in drug development | **12 hours** |
| **Unit 2** | **Toxicity Studies:**<br>Acute, sub-acute, and chronic- oral, dermal, and inhalational studies as per OECD guidelines. Acute eye irritation, skin sensitization, dermal | **12 hours** |

| | | |
|---|---|---|
| | irritation & dermal toxicity studies. Test item characterization-importance and methods in regulatory toxicology studies | |
| **Unit 3** | **Reproductive toxicology studies:**<br>Male reproductive toxicity studies, female reproductive studies (segment I and segment III), teratogenicity studies (segment II), Genotoxicity studies (Ames Test, in vitro and in vivo Micronucleus and Chromosomal aberrations studies), In vivo carcinogenicity studies | **12 hours** |
| **Unit 4** | **IND enabling studies (IND studies):**<br>Definition of IND, importance of IND, industry perspective, list of studies needed for IND submission<br>Safety pharmacology studies- origin, concepts, and importance of safety pharmacology, Tier 1- CVS, CNS and respiratory safety pharmacology, HERG assay, Tier2-GI, renal, and other studies | **12 hours** |
| **Unit 5** | **Toxicokinetics:**<br>Toxicokinetic evaluation in preclinical studies, saturation kinetics Importance and applications of toxicokinetic studies.<br>Alternative methods to animal toxicity testing | **12 hours** |

**Recommended Books^: (Latest Editions)**


1. Handbook on GLP, Quality practices for regulated non-clinical research and development
2. Schedule Y Guideline: Drugs and Cosmetics (second amendment) rules, 2005, Ministry of Health and Family Welfare (Department of Health) New Delhi
3. Drugs from discovery to approval by Rick N G.
4. Animal Models in Toxicology, 3rd Edition, Lower and Bryan.
5. OECD test guidelines.
6. Principles of Toxicology by Karen E. Stine, Thomas M. Brown.
7. Guidance for Industry M3(R2) Nonclinical Safety Studies for the Conduct of Human Clinical Trials and Marketing Authorization for Pharmaceuticals.


**Links:**

1. http://www.who.int/tdr/publications/documents/glphandbook.pdf
2. http://www.fda.gov/downloads/drugs/guidancecomplianceregulatory information /guidances / ucm073246.pdf

L= Lecture, Tu= Tutorial, P= Practical, T = Theory

^ This is not an exhaustive list

**ANAND PHARMACY COLLEGE, ANAND**
**(An Autonomous College under UGC Regulations 2023)**
**Managed by Shri Ramkrishna Seva Mandal**
(Approved by PCI, NAAC Accredited – A+ Grade, 3.38 CGPA)
Awarding University: Gujarat Technological University, Ahmedabad

Name of Program: **M Pharm**
Branch: – **A06 - Pharmacology**
Semester: **II**
Course Code: **M060203TT**
Course Name: **Principles of Drug Discovery**
Course Type: **Core**
Year of Implementation: **2024-25**

**Teaching and Examination Scheme:**

| Number of hours/ Week | | | Number of credits | | | Total credits | Evaluation Scheme (Marks) | | | | | | | | Total Marks |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | | | Sessional Exams | | | | | | End Semester Assessment | | |
| | | | | | | | Theory | | | Practical | | | | | |
| L | Tu | P | L | Tu | P | | CIE | E | T | CIE | E | T | T | P | |
| 4 | - | - | 4 | - | - | 4 | 10 | 15 | 25 | - | - | - | 75 | - | 100 |

**Scope:** The subject imparts basic knowledge of the drug discovery process. This information will make the student competent in the drug discovery process.

**Course Outcomes (CO):**
Upon completion of the course, the student shall be able to

| | |
|---|---|
| CO1 | To apply the concepts of the modern drug discovery process |
| CO2 | To utilize the methods of Lead Identification in the modern drug discovery process |
| CO3 | To describe the traditional and Rational Drug Design methods |
| CO4 | To articulate molecular docking and QSAR techniques for screening compounds |

**Detailed Syllabus:**
Total Teaching hours: **60 hours**

| | | |
|---|---|---|
| **Unit 1** | **An overview of the modern drug discovery process:** Target identification, target validation, lead identification, and lead Optimization. Economics of drug discovery. Target Discovery and validation-Role of Genomics, Proteomics and Bioinformatics. Role of Nucleic acid microarrays, Protein microarrays, Antisense technologies, siRNAs, antisense oligonucleotides, Zinc finger proteins. Role of transgenic animals in target validation. | **12 hours** |
| **Unit 2** | **Lead Identification:** Combinatorial chemistry & high throughput screening, in silico lead discovery techniques, and assay development for hit identification. Protein structure Levels of protein structure, Domains, motifs, and folds in protein structure. Computational prediction of protein | **12 hours** |

| | | |
|---|---|---|
| | structure: Threading and homology modelling methods. Application of NMR and X-ray crystallography in protein structure prediction | |
| **Unit 3** | Rational Drug Design Traditional vs rational drug design, Methods followed in traditional drug design, High throughput screening, Concepts of Rational Drug Design, Rational Drug Design Methods: Structure and Pharmacophore based approaches Virtual Screening techniques: Drug likeness screening, Concept of pharmacophore mapping and pharmacophore-based Screening | **12 hours** |
| **Unit 4** | **Molecular docking:**<br>Rigid docking, flexible docking, manual docking;<br>Docking-based screening. Denovo drug design. Quantitative analysis of Structure-Activity Relationship History and development of QSAR, SAR versus QSAR, Physicochemical parameters, Hansch analysis, Fee Wilson analysis, and the relationship between them | **12 hours** |
| **Unit 5** | **QSAR Statistical methods:**<br>Regression analysis, partial least square analysis (PLS), and other multivariate statistical methods. 3D QSAR approaches like COMFA and COMSIA Prodrug design-Basic concept, Prodrugs to improve patient acceptability, Drug solubility, Drug absorption and distribution, site-specific drug delivery, and sustained drug action. Rationale of prodrug design and practical consideration of prodrug design | **12 hours** |

**Recommended Books^: (Latest Editions)**


1. Mouldy Sioud. Target Discovery and Validation Reviews and Protocols: Volume 2 Emerging Molecular Targets and Treatment Options. 2007 Humana Press Inc
2. Johanna K. DiStefano. Disease Gene Identification. Methods and Protocols. Springer New York Dordrecht Heidelberg London
3. Hugo Kubiny. QSAR: Hansch Analysis and Related Approaches. Methods and Principles in Medicinal Chemistry. Publisher Wiley-VCH
4. Klaus Gubernator, Hans-Joachim Böhm. Structure-Based Ligand Design. Methods and Principles in Medicinal Chemistry. Publisher Wiley-VCH
5. Abby L. Parrill. M. Rami Reddy. Rational Drug Design. Novel Methodology and Practical Applications. ACS Symposium Series; American Chemical Society: Washington, DC, 1999
6. J. Rick Turner. New drug development design, methodology, and analysis. John Wiley & Sons, Inc., New Jersey
7. The Process of New Drug Discovery and Development edited by Charles G. Smith and James T. O' Donnell 2nd edition.


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Awarding University: Gujarat Technological University, Ahmedabad

Name of Program: **M Pharm**
Branch: – **A06 - Pharmacology**
Semester: **II**
Course Code: **M060204TT**
Course Name: **Clinical Research and Pharmacovigilance**
Course Type: **Core**
Year of Implementation: **2024-25**

**Teaching and Examination Scheme:**

| Number of hours/ Week | | | Number of credits | | | Total credits | Evaluation Scheme (Marks) | | | | | | | | Total Marks |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | | | Sessional Exams | | | | | | Term End Assessment | | |
| | | | | | | | Theory | | | Practical | | | | | |
| L | Tu | P | L | Tu | P | | CIE | E | T | CIE | E | T | T | P | |
| 4 | - | - | 4 | - | - | 4 | 10 | 15 | 25 | - | - | - | 75 | - | 100 |

**Scope:** This subject will provide a value addition and current requirement for the students in clinical research and pharmacovigilance. It will teach the students about conceptualizing, designing, conducting, managing, and reporting clinical trials. This subject also focuses on the global scenario of Pharmacovigilance in different methods that can be used to generate safety data. It will teach the students to develop drug safety data in the Pre-clinical and clinical phases of Drug development and post-market surveillance.

**Course Outcomes (CO):**
Upon completion of the course, the student shall be able to

| | |
|---|---|
| CO1 | To explain the regulatory requirements for conducting clinical trials and concepts of Clinical Trial Documentation |
| CO2 | To describe the clinical trial designs and explain the responsibilities of key players involved in clinical trials. |
| CO3 | To utilize principles of pharmacovigilance in the detection, assessment, and reporting of ADR |
| CO4 | To understand the concepts of Pharmacoepidemiology, Pharmacoeconomics, and safety pharmacology |

**Detailed Syllabus:**
Total Teaching hours: **60 hours**

| | | |
|---|---|---|
| **Unit 1** | **Regulatory Perspectives of Clinical Trials:**<br>Origin and Principles of International Conference on Harmonization-Good Clinical Practice (ICH-GCP) guidelines Ethical Committee: Institutional Review Board, Ethical Guidelines for Biomedical Research and Human Participant, Schedule Y, ICMR Informed Consent Process: Structure and content of an Informed Consent Process Ethical principles governing informed consent process | **10 hours** |

| | | |
|---|---|---|
| **Unit 2** | **Clinical Trials:**<br>Types and Design Experimental Study-RCT and Non-RCT,<br>**Observation Study:**<br>Cohort, Case-Control, Cross-sectional Clinical Trial Study Team.<br>**Roles and responsibilities of Clinical Trial Personnel:**<br>Investigator, Study Coordinator, Sponsor, Contract Research Organization and its management | **02 hours**<br><br>**03 hours**<br><br>**05 hours** |
| **Unit 3** | **Clinical Trial Documentation:**<br>Guidelines for the preparation of documents, Preparation of protocol, Investigator Brochure, Case Report Forms, Clinical Study Report Clinical Trial Monitoring Safety Monitoring in CT<br><br>Adverse Drug Reactions: Definition and types. Detection and reporting methods. Severity and seriousness assessment. Predictability and preventability assessment, Management of adverse drug reactions; Terminologies of ADR | **05 hours**<br><br>**05 hours** |
| **Unit 4** | Basic aspects, terminologies and establishment of pharmacovigilance History and progress of pharmacovigilance, Significance of safety monitoring, Pharmacovigilance in India and international aspects, WHO international drug monitoring programme, WHO and Regulatory terminologies of ADR, evaluation of medication safety, establishing pharmacovigilance centres in Hospitals, Industry and National programmes related to pharmacovigilance. Roles and responsibilities in Pharmacovigilance | **10 hours** |
| **Unit 5** | **Methods, ADR reporting, and tools used in Pharmacovigilance**<br>International classification of diseases, International Non-proprietary names for drugs, Passive and Active surveillance, Comparative observational studies, Targeted clinical investigations, and Vaccine safety surveillance. Spontaneous reporting system and reporting to regulatory authorities, as well as guidelines for ADR reporting. Argus, Aris G Pharmacovigilance, VigiFlow, Statistical methods for evaluating medication safety data. | **10 hours** |
| **Unit 6** | **Pharmacoepidemiology:**<br>Introduction, sources, methodology, and special applications.<br>**Pharmacoeconomics**:<br>Introduction, decision modeling techniques, cost of illness, Markov modeling, retrospective database analysis, Cost minimization analysis, Cost-effective analysis, Budget impact analysis,<br>**Safety pharmacology** | **10 hours** |

**Recommended Books: (Latest Edition)**


1. Central Drugs Standard Control Organization- Good Clinical Practices, Guidelines for Clinical Trials on Pharmaceutical Products in India. New Delhi: Ministry ofHealth;2001
2. International Conference on Harmonization of Technical requirements for registration of Pharmaceuticals for human use. ICH Harmonized Tripartite Guideline. Guideline for Good Clinical Practice.E6; May1996
3. Ethical Guidelines for Biomedical Research on Human Subjects 2000. Indian Council of Medical Research, New Delhi
4. Textbook of Clinical Trials edited by David Machin, Simon Dayand Sylvan Green, March 2005, John Wiley and Sons.
5. Fundamentals of Clinical Research by Antonella Bacchieri and Giovanni Della Cioppa


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Awarding University: Gujarat Technological University, Ahmedabad

Name of Program: **M. Pharm**
Branch: – **A06 - Pharmacology**
Semester: **II**
Course Code: **M060205PP**
Course Name: **Pharmacology Practical II**
Course Type: **Core**
Year of Implementation: **2024 – 25**

**Teaching and Examination Scheme:**

| Number of hours/ Week | | | Number of credits | | | Total credits | Evaluation Scheme (Marks) | | | | | | | | Total Marks |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | | | Sessional Exams | | | | | | End Semester Assessment | | |
| | | | | | | | Theory | | | Practical | | | | | |
| L | Tu | P | L | Tu | P | | CIE | E | T | CIE | E | T | T | P | |
| - | - | 12 | - | - | 6 | 6 | - | - | - | 20 | 30 | 50 | - | 100 | 150 |

**Scope:** This course deals with the fundamentals of analytical chemistry and principles of electrochemical analysis of drugs

**Course Outcomes (CO):**
Upon completion of the course, the student shall be able to

| | |
|---|---|
| CO1 | Determine the strength and potency of the drug using in vitro tissue experiments and record cardiovascular vitals in experimental animals. |
| CO2 | Understand and apply global guidelines to evaluate drug toxicities and design in-silico studies. |

**List of Practical's:**
Total Teaching hours: **60 hours**

1. To record the DRC of agonist using suitable isolated tissues preparation.
2. To study the effects of antagonist/potentiating agents on DRC of agonist using suitable isolated tissue preparation.
3. To determine to the strength of unknown sample by matching bioassay by using suitable isolated tissue preparation.
4. To determine to the strength of unknown sample by interpolation bioassay by using suitable isolated tissue preparation.
5. To determine to the strength of unknown sample by bracketing bioassay by using suitable isolated tissue preparation.
6. To determine to the strength of unknown sample by multiple point bioassay by using suitable isolated tissue preparation.
7. Estimation of PA2 values of various antagonists using suitable isolated tissue preparations.

8. To study the effects of various drugs on isolated heart preparations
9. Recording of rat BP, heart rate, and ECG.
10. Recording of rat ECG
11. Interpretation of data by simulated tissue experiments.
12. Demonstration of VigiFlow
13. Perform histology of various organs (heart, liver, kidney, brain, and lungs) and interpret the slides
14. Demonstration of different staining methods
15. Drug absorption studies by averted rat ileum preparation
16. Acute oral toxicity studies as per OECD guidelines.
17. Acute dermal to toxicity studies as per OECD guidelines.
18. Repeated dose t toxicity studies - Serum biochemical, haematological, urine analysis, functional observation tests and histological studies.
19. Drug mutagenicity study using mice bone-marrow chromosomal aberration test. 16. Protocol design for clinical trial. (3Nos.)
20. Design of ADR monitoring protocol.
21. In-silico docking studies. (2Nos.)
22. In-silico pharmacophore-based screening.
23. In-silico QSAR studies.
24. ADR reporting.

**Recommended Books^: (Latest Editions)**


1. Fundamentals of Experimental Pharmacology-by M.N. Ghosh
2. Handbook of Experimental Pharmacology-S.K. Kulkarni
3. Bioassay Techniques for Drug Development by Atta-ur-Rahman, Iqbal Choudhary, and William Thomsen
4. Applied Biopharmaceutics and Pharmacokinetics by Leon Shargel and Andrew B.C. Yu.


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Name of Program: **M. Pharm**
Branch: **A07 - Regulatory Affair**
Semester: **I**
Course Code: **M070101TT**
Course Name: **Good Regulatory Practices**
Course Type: **Core**
Year of Implementation: **2024 – 25**

**Teaching and Examination Scheme:**

| Number of hours/ Week | | | Number of credits | | | Total credits | Evaluation Scheme (Marks) | | | | | | | | Total Marks |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | | | Sessional Exams | | | | | | Term End Assessment | | |
| | | | | | | | Theory | | | Practical | | | | | |
| L | Tu | P | L | Tu | P | | CIE | E | T | CIE | E | T | T | P | |
| 4 | 0 | 0 | 4 | 0 | 0 | 4 | 10 | 15 | 25 | 0 | 0 | 0 | 75 | 0 | 100 |

**Scope:**
This course is designed to impart fundamental knowledge on various Good Regulatory Practices viz., cGMP, GLP, GALP and GDP for Pharmaceuticals, Cosmetics, Food & Nutraceuticals, Medical devices, In-vitro Diagnostic Medical Devices (IVDs) and biological products and understand the rationale behind these requirements and will propose ways and means of complying with them.

**Course Outcomes (CO):**
Upon completion of the course student shall be able to

| | |
|---|---|
| CO1 | Understand and apply the knowledge of regulatory elements with respect to cGMP, GAMP, GDP and IMDRF/GHTF guidance |
| CO2 | Understand and implement the concepts of GLP principles and audits with adherence to relevant USFDA, ISO and QCI standards |
| CO3 | Comprehend and apply the key aspects of regulatory components for Good Automated Laboratory Practices |
| CO4 | Gain knowledge on various quality tools, validation, qualification and ICH, ISO, CDSCO guidance documents |

**Detailed Syllabus:**
Total Teaching hours: **60 hours**

| | | |
|---|---|---|
| **Unit 1** | **Current Good Manufacturing Practices:** Introduction, US cGMP Part 210 and Part 211.EC Principles of GMP (Directive 91/356/EEC) Article 3 to Article 14, WHO cGMP guidelines | **08 hours** |
| | GAMP-5 | **01 hour** |
| | Medical device and IVDs Global Harmonization Task Force IMDRF/GHTF Guidance docs | **03 hours** |

| | | |
|---|---|---|
| **Unit 2** | **Good Laboratory Practices:** Introduction, USFDA GLP Regulations (Subpart A to Subpart K), Controlling the GLP inspection process, Documentation, Future of GLP regulations, Audit, goals of Laboratory Quality Audit, Audit tools | **10 hours** |
| **Unit 3** | **Good Automated Laboratory Practices**: Introduction to GALP, Principles of GALP, GALP Requirements, SOPs of GALP, Training Documentation | **07 hours** |
| | 21 CFR Part 11, General check list of 21CFR Part 11, Software Evaluation checklist | **03 hours** |
| | Relevant ISO and QCI Standards for GALP | **02 hours** |
| **Unit 4** | **Good Distribution Practices:** Introduction to GDP, Legal GDP requirements put worldwide, Principles, Personnel, Documentation, Premises and Equipment, Deliveries to Customers, Returns, Self-Inspection, Provision of information, Stability testing principles | **08 hours** |
| | WHO GDP, USP GDP (Supply chain integrity) | **02 hours** |
| | Relevant CDSCO guidance and ISO standards | **02 hours** |
| **Unit 5** | **Quality management systems:** Concept of Quality, Total Quality Management, Quality by design, Six Sigma concept, Out of Specifications (OOS), Change control. | **04 hours** |
| | **Validation:** Types of Validation, Types of Qualification, Validation master plan (VMP), Analytical Method Validation. Validation of utilities, [Compressed air, steam, water systems, Heat Ventilation and Air conditioning (HVAC)]and Cleaning Validation. | **04 hours** |
| | The International Conference on Harmonization (ICH) process, ICH guidelines to establish quality, safety and efficacy of drug substances and products | **02 hours** |
| | ISO 13485 (Quality Management System for Medical Devices) | **01 hour** |
| | Sch MIII and other relevant CDSCO regulatory guidance documents. | **01 hour** |

**Recommended Books: (Latest Editions)**


1. Sandy Weinberg. Good Laboratory Practice Regulations. Informa Healthcare USA. New York London
2. John Sharp. Good Pharmaceutical Manufacturing Practice: Rationale and Compliance. CRC Press. London, UK.
3. David M. Bleisner. Establishing a cGMP Laboratory Audit System, A practical Guide. Published by John Wiley & Sons, Inc., Hoboken, New Jersey.
4. P.P. Sharma. How to practice GLP. Vandana Publications PVT. LTD. Delhi.
5. Donald C. Singer. Laboratory Auditing for Quality and Regulatory compliance: Drugs and the Pharmaceutical Sciences. T&F India.
6. Drugs & Cosmetics Act, Rules &Amendment.


**Links:**

1. https://cdsco.gov.in/opencms/opencms/en/Acts-Rules/

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Awarding University: Gujarat Technological University, Ahmedabad

Name of Program: **M. Pharm**
Branch: **A07 - Regulatory Affair**
Semester: **I**
Course Code: **M070102TT**
Course Name: **Documentation and Regulatory Writing**
Course Type: **Core**
Year of Implementation: **2024 – 25**

**Teaching and Examination Scheme:**

| Number of hours/ Week | | | Number of credits | | | Total credits | Evaluation Scheme (Marks) | | | | | | | | Total Marks |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | | | Sessional Exams | | | | | | Term End Assessment | | |
| | | | | | | | Theory | | | Practical | | | | | |
| L | Tu | P | L | Tu | P | | CIE | E | T | CIE | E | T | T | P | |
| 4 | 0 | 0 | 4 | 0 | 0 | 4 | 10 | 15 | 25 | 0 | 0 | 0 | 75 | 0 | 100 |

**Scope:**
This course is designed to impart fundamental knowledge on documentation and general principles involved in regulatory writing and submission to agencies.

**Course Outcomes (CO):**
Upon completion of the course student shall be able to

| | |
|---|---|
| CO1 | Review and understand various pharmaceutical documents essential for drug industry operations and regulatory compliance |
| CO2 | Assemble and create regulatory submissions, applying foundational knowledge of regulatory requirements |
| CO3 | Gain knowledge on management of audits and inspections for assessing manufacturing facilities and systems in accordance to regulatory standards |
| CO4 | Apply fundamental concepts for follow up of submissions and post approval requirements |

**Detailed Syllabus:**
Total Teaching hours: **60 hours**

| | | |
|---|---|---|
| **Unit 1** | **Documentation in pharmaceutical industry:** Exploratory Product Development Brief (EPDB) for Drug substance and Drug product, Product Development Plan (PDP), Product Development Report (PDR) | **04 hours** |
| | Master Formula Record, Batch Manufacturing Record and its calculations, Batch Reconciliation, Batch Packaging Records, Print pack specifications, Distribution records, | **06 hours** |
| | Certificate of Analysis (CoA), Site Master File and Drug Master Files (DMF) | **02 hours** |

| | | |
|---|---|---|
| **Unit 2** | **Dossier preparation and submission:** Introduction and overview of dossiers, contents and organization of dossier, binders and sections, compilation and review of dossier. Paper submissions, overview and modules of CTD, electronic CTD submissions,<br>**Electronic submission:** Planning electronic submission, requirements for submission, regulatory bindings and requirements, Tool and Technologies, electronic dossier submission process and validating the submission, Electronic Submission Gateway (ESG). Non e C T D electronic submissions (NeeS),<br>Asian CTD formats (ACTD) submission. Organizing, process and validation of submission. Submission in Sugam system of CDSCO. | **04 hours**<br>**6 hours**<br>**02 hours** |
| **Unit 3** | **Audits:** Introduction, Definition, Summary, Types of audits, GMP compliance audit, Audit policy, Internal and External Audits, Second Party Audits, External third-party audits, Auditing strategies, Preparation and conducting audit, Auditing strategies, audit analysis, audit report, audit follow up, Auditing/inspection of manufacturing facilities by regulatory agencies. Timelines for audits/inspection,<br>IMDRF/GHTF study group 4 guidance document. ISO 13485(Quality management for Medical Devices | **10 hours**<br>**02 hours** |
| **Unit 4** | **Inspections:** Pre-approval inspections, Inspection of pharmaceutical manufacturers, Inspection of drug distribution channels, Quality systems requirements for national good manufacturing practice inspectorates, inspection report, model certificate of good manufacturing practices,<br>Root cause analysis, Corrective and Preventive action (CAPA). | **08 hours**<br>**04 hours** |
| **Unit 5** | **Product life cycle management:** Prior Approval Supplement (PAS), Post Approval Changes [SUPAC], Changes Being Affected in 30 Days (CBE-30), Annual Report,<br>Post marketing Reporting Requirements, Post approval Labelling Changes, Lifecycle Management, FDA Inspection and Enforcement,<br>Establishment Inspection Report (EIR), Warning Letters, Recalls, Seizure and Injunctions,<br>ISO Risk Management Standard | **05 hours**<br>**05 hours**<br>**02 hours** |

**Recommended Books: (Latest Editions)**


1. Karen Ginsbury and Gil Bismuth. Compliance auditing for Pharmaceutical Manufacturers. Interpharm/CRC, Boca Raton, London New York, Washington D.C.
2. Shayne Cox Gad. Pharmaceutical Manufacturing Handbook, Regulations and Quality. Wiley-Interscience, A John Wiley and sons, Inc., Publications. , Hoboken, New Jersey
3. Rosamund M. Baird, Norman A. Hodges, Stephen P. Denyar. Handbook of Microbiological Quality Control in Pharmaceuticals and Medical Devices. CRC Press. USA.
4. Donald C. Singer, Raluca-Ioana Stefan, Jacobus F. van Staden. Laboratory Auditing for Quality and Regulatory Compliance. CRC Press. Boca Raton

5. Implementing Juran's road map for quality leadership: benchmarks and results. Wiley & Sons. New York
6. Jiju Antony; David Preece. Understanding, Managing and Implementing Quality: Frameworks, Techniques and Cases. Routledge. London & New York
7. Edward E. Lawler; Susan Albers Mohrman; George Benson. Organizing for High Performance: Employee Involvement, TQM, Reengineering, and Knowledge Management in the Fortune 1000: The CEO Report. Jossey-Bass Wiley. San Francisco
8. James W. Fairfield- Sonn. Corporate Culture and the Quality Organization. Bloomsbury Publishing. USA
9. Christine Avery; Diane Zabel. The Quality Management Sourcebook: An International Guide to Materials and Resources. Routledge. London & USA
10. Nancy R. Tague. The Quality Toolbox. ASQ/Infotech. USA
11. Joseph M. Juran and Joseph A. De Feo. Juran's Quality Handbook. McGraw-Hill. New York Chicago San Francisco Lisbon London Madrid Mexico City Milan New Delhi San Juan Seoul Singapore Sydney Toronto.
12. Duke Okes. Root Cause Analysis, The Core of Problem Solving and Corrective Action. ASQ Publications. United States of America.
13. International Medical Device Regulators Forum (IMDRF) Medical Device Single Audit Program (MDSAP).

**Link:**

1. https://www.imdrf.org/working-groups/medical-device-single-audit- program-mdsap

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Awarding University: Gujarat Technological University, Ahmedabad

Name of Program: **M. Pharm**
Branch: **A07 - Regulatory Affair**
Semester: **I**
Course Code: **M070103TT**
Course Name: **Clinical Research Regulations**
Course Type: **Core**
Year of Implementation: **2024 – 25**

**Teaching and Examination Scheme:**

| Number of hours/ Week | | | Number of credits | | | Total credits | Evaluation Scheme (Marks) | | | | | | | | Total Marks |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | | | Sessional Exams | | | | | | Term End Assessment | | |
| | | | | | | | Theory | | | Practical | | | | | |
| L | Tu | P | L | Tu | P | | CIE | E | T | CIE | E | T | T | P | |
| 4 | 0 | 0 | 4 | 0 | 0 | 4 | 10 | 15 | 25 | 0 | 0 | 0 | 75 | 0 | 100 |

**Scope:**
This course is designed to impart the fundamental knowledge on the clinical development process of drugs, pharmaceuticals and Medical Devices, phases and conduct of clinical trials and research, regulations and guidance governing the conduct of clinical research in India, USA, and EU. It prepares the students to learn in detail on various laws, legislations and guidance related to safety, efficacy, ethical conduct and regulatory approval of clinical research

**Course Outcomes (CO):**
Upon completion of the course student shall be able to

| | |
|---|---|
| CO1 | Understand the history, ethics, and origin of clinical and biomedical research |
| CO2 | Gain the knowledge of clinical drug development process, including the clinical evaluation of medical devices and IVDs |
| CO3 | Comprehend and apply regulatory requirements for clinical trial conduct and research in India, EU, USA as per guidelines |
| CO4 | Understand and apply key elements of regulatory requirements as per ICH and ISO guidelines |

**Detailed Syllabus:**
Total Teaching hours: **60 hours**

| | | |
|---|---|---|
| **Unit 1** | **Clinical Drug Development Process:**<br>Different types of Clinical Studies, Phases of clinical trials, Clinical Trial protocol, Different Types of Studies<br>• Phase 0 studies<br>• Phase I and subtype studies (single ascending, multiple ascending, dose escalation, methods, food effect studies drug – drug interaction, PK end points<br>• Phase II studies (proof of concept or principle studies to establish efficacy)<br>• Phase III studies (Multi ethnicity, global clinical trial, registration studies)<br>• Phase IV studies (Post Marketing Studies; PSUR)<br>Clinical Investigation and Evaluation of Medical Devices & IVDs, Key<br>Concepts of Medical Device, Clinical Evaluation, Key concepts of Clinical Investigation | **08 hours**<br><br>**04 hours** |
| **Unit 2** | **Ethics in Clinical Research:**<br>Historical Perspectives: Nuremberg Code, Thalidomide study, Nazis Trials, Tuskegee Syphilis Study, The Belmont Report, The declaration of Helsinki<br>• The ethics of randomized clinical trials<br>• The role of placebo in clinical trials<br>• Ethics of clinical research in special population<br>• Origin of International Conference on Harmonization – Good Clinical Practice (ICH-GCP) guidelines, Institutional Review Board/Independent Ethics Committee/Ethics Committee – composition, roles, responsibilities, review and approval process and ongoing monitoring of safety data, Data safety monitoring boards, Responsibilities of sponsor, CRO, and investigator in ethical conduct of clinical research<br>Ethical principles governing informed consent process, Patient Information<br>Sheet and Informed Consent Form, The informed consent process and documentation | **05 hours**<br><br>**05 hours**<br><br>**02 hours** |
| **Unit 3** | **Regulations governing Clinical Trials:**<br>**India:** Clinical Research regulations in India – Schedule Y (The New Drugs and Clinical Trials Rules, 2019) & Medical Device Guidance<br>**USA:** Regulations to conduct drug studies in USA (FDA)<br>• NDA 505(b)(1) of the FD&C Act (Application for approval of a new drug) | **03 hours**<br><br>**07 hours** |

| | | |
|---|---|---|
| | • NDA 505(b)(2) of the FD&C Act (Application for approval of a new drug that relies, at least in part, on data not developed by the applicant)<br>• ANDA 505(j) of the FD&C Act (Application for approval of a generic drug product)<br>• FDA Guidance for Industry - Acceptance of Foreign Clinical Studies<br>• FDA Clinical Trials Guidance Document: Good Clinical Practice<br>**EU:** Clinical Research regulations in European Union (EMA) | **02 hours** |
| **Unit 4** | **Clinical Research Related Guidelines:**<br>• Indian GCP Guidelines<br>• ICMR Ethical Guidelines for Biomedical Research<br>• CDSCO guidelines<br>• GHTF study group 5 guidance documents<br>• General biostatics principle applied in clinical research<br>• E6- Good Clinical Practice Guidelines (ICH GCP E6)<br>• E4 – Dose Response Information to support Drug Registration<br>• E7 – Studies in support of General Population: Geriatrics<br>• E8 – General Considerations of Clinical Trials<br>• E10 – Choice of Control Groups and Related Issues in Clinical Trials<br>• E 11 – Clinical Investigation of Medicinal Products in the Paediatric Population<br>Regulatory Guidance on Efficacy and Safety ICH Guidance's | **05 hours**<br>**07 hours** |
| **Unit 5** | **USA & EU Guidance:**<br>**USA: FDA Guidance**<br>• CFR 21Part 50: Protection of Human Subjects<br>• CFR 21Part 54: Financial Disclosure by Clinical Investigators<br>• CFR 21Part 312: IND Application<br>• CFR 21Part 314: Application for FDA Approval to Market a New Drug<br>• CFR 21Part 320: Bioavailability and bioequivalence requirements<br>• CFR 21Part 812: Investigational Device Exemptions<br>• CFR 21Part 822: Post-market surveillance<br>• FDA Safety Reporting Requirements for INDs and BA/BE studies<br>• FDA Med Watch | **05 hours** |

| | | |
|---|---|---|
| | **EU: Guidance**<br>• Guidance for Industry: Good Pharmacovigilance Practices and Pharmacoepidemiologic Assessment European Union: EMA Guidance<br>• EU Directives 2001<br>• EudraLex (EMEA) Volume 3 – Scientific guidelines for medicinal products for human use<br>• EU Annual Safety Report (ASR)<br>• Volume 9A – Pharmacovigilance for Medicinal Products for Human Use<br>• EU MDD with respect to clinical research | **05 hours** |
| | ISO 14155 | **02 hours** |

**Recommended Books^: (Latest Editions)**


1. Fay A. Rozovsky and Rodney K. Adams. Clinical Trials and Human Research: A Practical Guide to Regulatory Compliance. Jossey-Bass. San Francisco.
2. Mark Barnes, Jennifer Kulynych. HIPAA and Human Subjects Research: A Question-and-Answer Reference Guide. Barnett International. USA.
3. John I. Gallin, Frederick P Ognibene. Principles and Practices of Clinical Research. Academic Press. USA.
4. Johan PE Karlberg and Marjorie A Speers. Reviewing Clinical Trials: A Guide for the Ethics Committee. Karlberg, Johan Petter Einar. Hong Kong, PR China.
5. Anthony C. Cartwright, Brian R. Matthews. International Pharmaceutical Product Registration: Aspects of Quality, Safety and Efficacy. CRC Press. Boca Raton, London.
6. Richard A. Guarino. New Drug Approval Process: The Global Challenge. Marcel Dekker Inc. NY.
7. Douglas J. Pisano, David S. Mantus. FDA regulatory affairs: a guide for prescription drugs, medical devices, and biologics. CRC Press, USA.
8. Country Specific Guidelines from official websites.


**Recommended websites:**

1. **EU Clinical Research Directive 2001: http://www.eortc.be/services/doc /clinical-eudirective04-april-01.pdf.**
2. **Code of Federal Regulations, FDA: http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/cfrsearch.cfm**
3. **Guidelines of International Conference on Harmonization: http://www.ich.org/products/guidelines.html**
4. **Eudralex Guidelines: http://www.gmpcompliance.info/euguide.htm**
5. **FDA New Drug Application: http://www.fda.gov/regulatoryinformation/legislation/FederalFoodDrugandCosmeticActFDCAct/FDCActChapterVDrugsandDevices/ucm108125.htm**
6. **Medicines and Healthcare products Regulatory Agency: http://www.mhra.gov.uk**
7. Drugs & Cosmetics Act & Rules and Amendments https://cdsco.gov.in/opencms/opencms/en/Acts-Rules/

8. Central Drugs Standard Control Organization Guidance for Industry: http://cdsco.nic.in/CDSCO-GuidanceForIndustry.pdf
9. ICMR Ethical Guidelines for Biomedical Research: https://main.icmr.nic.in/guidelines?field_select_disease_tid=97

L= Lecture, Tu= Tutorial, P= Practical, T = Theory

^ this is not an exhaustive list

**ANAND PHARMACY COLLEGE, ANAND**
**(An Autonomous College under UGC Regulations 2023)**
**Managed by Shri Ramkrishna Seva Mandal**
(Approved by PCI, NAAC Accredited – A+ Grade, 3.38 CGPA)
Awarding University: Gujarat Technological University, Ahmedabad

Name of Program: **M. Pharm**
Branch: **A07 - Regulatory Affair**
Semester: **I**
Course Code: **M070104TT**
Course Name: **Regulations and Legislation for Drugs & Cosmetics, Medical Devices, Biologicals & Herbals, And Food & Nutraceuticals in India and Intellectual Property Rights**
Course Type: **Core**
Year of Implementation: **2024 – 25**

**Teaching and Examination Scheme:**

| Number of hours/ Week | | | Number of credits | | | Total credits | Evaluation Scheme (Marks) | | | | | | | | Total Marks |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | | | Sessional Exams | | | | | | Term End Assessment | | |
| | | | | | | | Theory | | | Practical | | | | | |
| L | Tu | P | L | Tu | P | | CIE | E | T | CIE | E | T | T | P | |
| 4 | 0 | 0 | 4 | 0 | 0 | 4 | 10 | 15 | 25 | 0 | 0 | 0 | 75 | 0 | 100 |

**Scope:**
This course is designed to impart fundamental knowledge on regulations and legislation in India w.r.t. Drugs & Cosmetics, Medical Devices, Biologicals & Herbals, and Food & Nutraceuticals. It prepares the students for basic regulatory requirements in India of Drugs & Cosmetics, Medical Devices, Biologicals & Herbals, and Food & Nutraceuticals. for manufacture, import & registration, export, sale, marketing authorization, clinical trials and intellectual property rights.

**Course Outcomes (CO):**
Upon completion of the course student shall be able to

| | |
|---|---|
| CO1 | Gain understanding on acts, rules, regulatory guidelines for marketing of Drugs, Cosmetics, Medical Devices, Biologicals, Herbals, and Food & Nutraceuticals |
| CO2 | Comprehend the knowledge for application of Indian Pharmacopoeial, BIS, ISO standards and Intellectual Property Rights |
| CO3 | Understand the format and contents of regulatory process for dossier filing of Drugs, Cosmetics, Medical Devices, Biologicals, Herbals, and Food & Nutraceuticals |
| CO4 | Understand the key concepts of bioavailability, bioequivalence and apply regulatory standards for animal testing as per guideline |

**Detailed Syllabus:**

Total Teaching hours: **60 hours**

| | | |
|---|---|---|
| **Unit 1** | **Biologicals & Herbals, and Food & Nutraceuticals Acts and Rules (with latest amendments):**<br>Drugs and Cosmetics Act 1940 and Rules 1945<br>DPCO and NPPA | **03 hours** |
| | Other relevant provisions (rules schedules and guidelines for approval of Drugs & Cosmetics, Medical Devices, Biologicals & Herbals, and Food & Nutraceuticals in India | **04 hours** |
| | Other relevant Acts: Narcotics Drugs and Psychotropic Substances Act; Medicinal and Toilet Preparations (Excise Duties) Act, 1955; Pharmacy Act, 1948; Drugs and Magic Remedies (Objectionable Advertisements) Act, 1955; Prevention of Cruelty to Animals Act. | **05 hours** |
| **Unit 2** | **Regulatory requirements and approval procedures** for Drugs & Cosmetics, Medical Devices, Biologicals & Herbals, and Food & Nutraceuticals, CDSCO (Central Drug Standard Control Organization) and State Licensing Authority: Organization, Responsibilities | **06 hours** |
| | Rules, regulations, guidelines and standards for regulatory filing of Drugs & Cosmetics, Medical Devices, Biologicals & Herbals, and Food & Nutraceuticals, Format and contents of Regulatory dossier filing | **04 hours** |
| | Clinical trial/ investigations | **02 hours** |
| **Unit 3** | Indian Pharmacopoeial Standards: History, Introduction to monograph, IP review process. | **04 hours** |
| | BIS standards: Introduction, Objective, Certification. | **04 hours** |
| | ISO and other relevant standards | **04 hours** |
| **Unit 4** | **Bioavailability and Bioequivalence data (BA & BE)**, BCS Classification of Drugs, Regulatory Requirements for Bioequivalence study | **05 hours** |
| | Stability requirements: ICH and WHO,<br>Guidelines for Drug testing in animals/Preclinical Studies | **03 hours** |
| | Animal testing: Rationale for conducting studies, CPCSEA Guidelines | **02 hours** |
| | Ethical guidelines for human participants | |
| | ICMR-DBT Guidelines for Stem Cell Research | **02 hours** |
| **Unit 5** | **Intellectual Property Rights:** Patent, Trademark, Copyright, Industrial Designs and Geographical Indications, Indian Patent Scenario. | **12 hours** |

Recommended Link^: (Latest Editions)


1. Manual of Patent Practice & Procedure. The Patent Office of India. https://ipindia.gov.in/writereaddata/Portal/Images/pdf/Manual_for_Patent_Office_Practice_and_Procedure_.pdf
2. James Bessen, Michael J. Meurer. Patent Failure: How Judges, Bureaucrats, and Lawyers Put Innovators at Risk. Princeton University Press. USA.
3. Richard Chin, Bruce Y Lee. Principles and Practice of Clinical Trial Medicine. Academic Press. USA
4. Ethical Guidelines for Biomedical Research on Human Participants by Indian Council of Medical Research New Delhi https://www.kem.edu/wpcontent/uploads/2019/12/ICMR_ethical-guidelines-2000.pdf .
5. CPCSEA Guidelines for Laboratory Animal Facility by Committee. https://www.biochem.du.ac.in/userfiles/downloads/Guidelines%20for%20Animal%20Facility.pdf
6. ICH E6 Guideline — Good Clinical Practicel by ICH Harmonised Tripartite. https://database.ich.org/sites/default/files/E6_R2_Addendum.pdf
7. Guidance for Industry on Submission of Clinical Trial Application for Evaluating Safety and Efficacy by CDSCO. https://cdsco.gov.in/opencms/resources/UploadCDSCOWeb/2018/UploadPublic_NoticesFiles/CDSCO%20-%20Revised%20Guidance%20for%20Industry%20-%20Stakeholders%20Comments%20Website.pdf
8. Guidance for Industry on Requirement of Chemical & Pharmaceutical Information including Stability Study Data before approval of clinical trials / BE studies by CDSCO. https://www.cdsco.gov.in/opencms/resources/UploadCDSCOWeb/2018/UploadImmunization/Guidance_for_CMC_&_Stability_Data_for.pdf
9. Guidelines for Import and Manufacture of Medical Devices by CDSCO. https://cdsco.gov.in/opencms/resources/UploadCDSCOWeb/2018/UploadImmunization/11GUIDELINES1.pdf
10. Guidelines from official website of CDSCO. https://cdsco.gov.in/opencms/opencms/en/Home/


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Awarding University: Gujarat Technological University, Ahmedabad

Name of Program: **M. Pharm**
Branch: **A07 - Regulatory Affair**
Semester: **I**
Course Code: **M070105PP**
Course Name: **Regulatory Affairs Practical-I**
Course Type: **Core**
Year of Implementation: **2024 – 25**

**Teaching and Examination Scheme:**

| Number of hours/ Week | | | Number of credits | | | Total credits | Evaluation Scheme (Marks) | | | | | | | | Total Marks |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | | | Sessional Exams | | | | | | Term End Assessment | | |
| | | | | | | | Theory | | | Practical | | | | | |
| L | Tu | P | L | Tu | P | | CIE | E | T | CIE | E | T | T | P | |
| 0 | 0 | 12 | 0 | 0 | 6 | 6 | 0 | 0 | 0 | 20 | 30 | 50 | 0 | 100 | 150 |

**Course Outcomes (CO):**
Upon completion of the course student shall be able to

| | |
|---|---|
| CO1 | Understand, examine and apply comprehension of regulatory requirements in different regions |
| CO2 | Develop skill for evaluating and applying various good pharmaceutical practices, create regulatory dossiers, and manage post-approval processes and documentation for clinical trials and patents |

**List of Practicals:**
Total Teaching hours: **12 hours**

1. Case studies (4 Nos.) of each of Good Pharmaceutical Practices.
2. Documentation for in process and finished products Quality control tests for solid, liquid, Semisolid and Sterile preparations.
3. Preparation of SOPs, Analytical reports (Stability and validation)
4. Protocol preparation for documentation of various types of records (BMR, MFR, DR)
5. Labelling comparison between brand & generics.
6. Preparation of clinical trial protocol for registering trial in India
7. Registration for conducting BA/ BE studies in India
8. Import of drugs for research and developmental activities
9. Preparation of regulatory dossier as per Indian CTD format and submission in SUGAM
10. Registering for different Intellectual Property Rights in India
11. GMP Audit Requirements as per CDSCO
12. Preparation and documentation for Indian Patent application.
13. Preparation of checklist for registration of IND as per ICH CTD format.

14. Preparation of checklist for registration of NDA as per ICH CTD format
15. Preparation of checklist for registration of ANDA as per ICH CTD format.
16. Case studies on response with scientific rationale to USFDA Warning Letter
17. Preparation of submission checklist of IMPD for EU submission.
18. Comparison study of marketing authorization procedures in EU.
19. Comparative study of DMF system in US, EU and Japan
20. Preparation of regulatory submission using eCTD software
21. Preparation of Clinical Trial Application (CTA) for US submission
22. Preparation of Clinical Trial Application (CTA) for EU submission
23. Comparison of Clinical Trial Application requirements of US, EU and Japan of a dosage form.
24. Regulatory requirements checklist for conducting clinical trials in India.
25. Regulatory requirements checklist for conducting clinical trials in Europe.
26. Regulatory requirements checklist for conducting clinical trials in USA

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Awarding University: Gujarat Technological University, Ahmedabad

Name of Program: **M. Pharm**
Branch: **A07 - Regulatory Affair**
Semester: **II**
Course Code: **M070201TT**
Course Name: **Regulatory Aspects of Drugs & Cosmetics**
Course Type: **Core**
Year of Implementation: **2024 – 25**

**Teaching and Examination Scheme:**

| Number of hours/ Week | | | Number of credits | | | Total credits | Evaluation Scheme (Marks) | | | | | | | | Total Marks |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | | | Sessional Exams | | | | | | Term End Assessment | | |
| | | | | | | | Theory | | | Practical | | | | | |
| L | Tu | P | L | Tu | P | | CIE | E | T | CIE | E | T | T | P | |
| 4 | 0 | 0 | 4 | 0 | 0 | 4 | 10 | 15 | 25 | 0 | 0 | 0 | 75 | 0 | 100 |

**Scope:**
This course is designed to impart the fundamental knowledge on the drug development process, regulatory requirements for approval of new drugs, drug products and cosmetics in regulated and semi-regulated countries It prepares the students to learn in detail on the regulatory requirements, documentation requirements, and registration procedures for marketing the drug products and cosmetics in regulated and semi-regulated countries.

**Course Outcomes (CO):**
Upon completion of the course student shall be able to

| | |
|---|---|
| CO1 | Understand and interpret the regulations for approval of API and drug products in regulated and emerging markets |
| CO2 | Gain knowledge on regulatory considerations for manufacturing, packaging and labelling of pharmaceuticals in regulated and emerging markets |
| CO3 | Categorize key differences and similarities of regulatory requirements in different jurisdictions |
| CO4 | Comprehend and apply the regulatory requirements for approval of cosmetics in regulated and emerging markets |

**Detailed Syllabus:**
Total Teaching hours: **60 hours**

| | | |
|---|---|---|
| **Unit 1** | **USA:** Organization structure and functions of FDA, Federal register and Code of Federal Regulations (CFR), History and evolution of United States Federal, Food, Drug and Cosmetic Act (FFDCA), Hatch Waxman act and Orange book, Purple book, Drug Master Files (DMF) system in US, Regulatory Approval Process for Investigational New Drug (IND), New Drug Application (NDA), | **10 hours** |

| | | |
|---|---|---|
| | Abbreviated New Drug Application (ANDA), Supplemental New Drug Application (SNDA); packaging and labelling of pharmaceuticals in USA. Regulatory requirements for Orphan drugs and Combination Products, Changes to an approved NDA/ANDA. Regulatory considerations for manufacturing<br>USA and Canada: Legislation and regulations for import, manufacture, distribution and sale of cosmetics in Canada. | **02 hours** |
| **Unit 2** | **European Union & Australia:** Organization and structure of EMA & EDQM, General guidelines, Active Substance Master Files (ASMF) system in EU, Content and approval process of IMPD, Marketing Authorization procedures in EU (Centralized procedure Decentralized procedure, Mutual recognition procedure and National Procedure) | **06 hours** |
| | Regulatory considerations for manufacturing, packaging and labelling of pharmaceuticals in EU, Eudralex directives for human medicines, Variations & extensions, Compliance of European Pharmacopoeia (CEP)/ Certificate of Suitability (CoS), Marketing Authorization (MA) transfers, Qualified Person (QP) in EU. Legislation and regulations for import, manufacture, distribution and sale of cosmetics in European Union. | **05 hours** |
| | Legislation and regulations for import, manufacture, distribution and sale of cosmetics in Australia. | **01 hours** |
| **Unit 3** | **Japan:** Organization of the PMDA, Pharmaceutical Laws and regulations, types of registration applications, DMF system in Japan, drug regulatory approval process, Regulatory considerations for manufacturing, packaging and labelling of pharmaceuticals in Japan, Post marketing surveillance in Japan. | **10 hours** |
| | Legislation and regulations for import, manufacture, distribution and sale of cosmetics in Japan. | **02 hours** |
| **Unit 4** | **Emerging Market:** Introduction, Countries covered, Study of the world map, study of various committees across the globe (ASEAN, APEC, EAC, GCC, PANDRH, SADC) | **04 hours** |
| | **WHO:** WHO, GMP, Regulatory Requirements for registration of drugs and post approval requirements in WHO through prequalification programme | **04 hours** |
| | Certificate of Pharmaceutical Product (COPP) - General and Country Specific (South Africa, Egypt, Algeria and Morocco, Nigeria, Kenya and Botswana) | **04 hours** |

| | | |
|---|---|---|
| **Unit 5** | **Brazil, ASEAN, CIS and GCC Countries:**<br><br>**ASIAN Countries:** Introduction to ACTD, Regulatory Requirements for registration of drugs and post approval requirements in China and South Korea & Association of Southeast Asian Nations (ASEAN) Region i.e. Vietnam, Malaysia, Philippines, Singapore and Thailand.<br><br>**CIS (Commonwealth Independent States):** Regulatory prerequisites<br>related to Marketing authorization requirements for drugs and post approval requirements in CIS countries i.e. Russia, Kazakhstan and Ukraine.<br><br>**GCC (Gulf Cooperation Council) for Arab states:** Regulatory prerequisites related to Marketing authorization requirements for drugs and post approval requirements in Saudi Arabia and UAE,<br>Legislation and regulations for import, manufacture, distribution and sale of cosmetics in Brazil, ASEAN, CIS and GCC Countries. | **04 hours**<br><br>**04 hours**<br><br>**02 hours**<br><br>**02 hours** |

**Recommended Books^: (Latest Editions)**


1. Shargel, L., & Kaufer, I. (Eds.). Generic Drug Product Development, Solid Oral Dosage Forms. Marcel Dekker. New York.
2. Berry, I. R. (Ed.). The Pharmaceutical Regulatory Process. Marcel Dekker. New York.
3. Ira R. Berry and Robert P. Martin. The Pharmaceutical Regulatory Process. Drugs and the Pharmaceutical Sciences. Informa Healthcare Publishers
4. Berry, I. R., & Martin, R. P. (Eds.). The Pharmaceutical Regulatory Process. Informa Healthcare Publishers, New York.
5. Guarino, R. A. New Drug Approval Process: Accelerating Global Registrations. Drugs and the Pharmaceutical Sciences. Informa Healthcare Publishers. New York.
6. Ng, R. Drugs: From Discovery to Approval. Informa Healthcare Publishers. New York.
7. Mark Mathieu. New Drug Development: A Regulatory Overview.
8. Jeffrey E. Fetterman, Wayne L. Pines and Gary H. Slatko. Pharmaceutical Risk Management
9. William K. Sietsema. Preparation and Maintenance of the IND Application in eCTD Format
10. Country Specific Guidelines from official websites
11. ListMRAWebsites.pdf
12. Denis Hew. Roadmap to an ASEAN economic community. ISEAS Publications. Singapore.
13. Rodolfo C. Severino. ASEAN. ISEAS Publications. Singapore
14. Mark Kobayashi-Hillary. Building a Future with Brics: The Next Decade for Offshoring. Springer.
15. Mark Kobayashi-Hillary. Outsourcing to India: The Offshore Advantage. Springer
16. The world Bank. Washington. DC.
17. Frederick M. Abbott, Graham Dukes, Maurice Nelson Graham Dukes. Global Pharmaceutical Policy: Ensuring Medicines for Tomorrow's World.

18. Linda Low and Lorraine Carlos alazar. The Gulf Cooperation Council: A Rising Power and Lessons for ASEAN.
19. Michael G Plummer, Chia Siow Yue. Realizing the ASEAN Economic Community: A Comprehensive Assessment. Institute of South east Asian studies. Singapore

**Links:**

1. http://www.who.int/medicines/areas/quality_safety/regulation_legislation/

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Awarding University: Gujarat Technological University, Ahmedabad

Name of Program: **M. Pharm**
Branch: **A07- Regulatory Affair**
Semester: **II**
Course Code: **M070202TT**
Course Name: **Regulatory Aspects of Herbal & Biologicals**
Course Type: **Core**
Year of Implementation: **2024 – 25**

| Number of hours/ Week | | | Number of credits | | | Total credits | Evaluation Scheme (Marks) | | | | | | | | Total Marks |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | | | Sessional Exams | | | | | | Term End Assessment | | |
| | | | | | | | Theory | | | Practical | | | | | |
| L | Tu | P | L | Tu | P | | CIE | E | T | CIE | E | T | T | P | |
| 4 | 0 | 0 | 4 | 0 | 0 | 4 | 10 | 15 | 25 | 0 | 0 | 0 | 75 | 0 | 100 |

**Scope:**
This course is designed to impart fundamental knowledge on Regulatory Requirements, Licensing and Registration, Regulation on Labelling of Biologics in India, USA and Europe It prepares the students to learn in detail on Regulatory Requirements for biologics, Vaccines and Blood Products.

**Course Outcomes (CO):**
Upon completion of the course student shall be able to

| | |
|---|---|
| CO1 | Understand and interpret the regulations for approval of biologics, biosimilar and vaccines in India, US and European Union |
| CO2 | Gain knowledge of pre-clinical and clinical development considerations for biologics |
| CO3 | Understand the concepts for applying regulatory requirements for blood products |
| CO4 | Compare and contrast various regulatory requirements in different jurisdictions |

**Detailed Syllabus:**
Total Teaching hours: **60 hours**

| | | |
|---|---|---|
| **Unit 1** | **India:** Introduction, Applicable Regulations and Guidelines, Principles for Development of Similar Biologics, Data Requirements for Preclinical Studies, Data Requirements for Clinical Trial Application, Data Requirements for Market Authorization Application, Post-Market Data for Similar Biologics<br><br>Pharmacovigilance, GMP and GDP | **08 hours**<br><br>**04 hours** |
| **Unit 2** | **USA:** Introduction to Biologics; biologics, biological and biosimilars, different biological products, difference between generic drug and biosimilars, laws, regulations and guidance on biologics/ biosimilars, Development and Approval of biologics and biosimilars (IND, PMA, BLA, NDA,510(k)), Pre-clinical and clinical development Considerations | **10 hours** |

| | | |
|---|---|---|
| | Advertising, labelling and packing of Biologics | **02 hours** |
| **Unit 3** | **European Union:** Introduction to Biologics; directives, scientific guidelines and guidance related to biologics in EU, comparability/ bio-similarity assessment, Plasma master file, TSE/ BSE evaluation, Development and regulatory approval of biologics (Investigational medicinal products and biosimilars), Pre-clinical and clinical development considerations; stability, safety | **10 hours** |
| | advertising, labelling and packing of biologics in EU | **02 hours** |
| **Unit 4** | **Vaccine regulations in India, US and European Union:** Clinical evaluation, Marketing authorization, Registration or licensing, Quality assessment, Pharmacovigilance | **05 hours** |
| | Regulations in India, US and European Union: Regulatory Requirements of Blood and/or Its Components Including Blood Products, Label Requirements, Additional requirements Blood and Blood Products | **04 hours** |
| | ISBT (International Society of Blood Transfusion) and IHN (International Haemovigilence Network) | **03 hours** |
| **Unit 5** | **Herbal Products in India:** Quality, safety and legislation for herbal products. | **04 hours** |
| | **Herbal Products in USA:** Quality, safety and legislation for herbal products. | **04 hours** |
| | **Herbal Products in European Union:** Quality, safety and legislation for herbal products. | **04 hours** |

**Recommended Books^: (Latest Editions)**


1. Douglas J. Pisano, David S. Mantus. FDA Regulatory Affairs: A Guide for Prescription Drugs, Medical Devices, and Biologics. Informa.
2. Wei Wang, Manmohan Singh. Biological Drug Products: Development and Strategies. Wiley.
3. Manmohan Singh, IndreshK. Srivastava. Development of Vaccines: From Discovery to Clinical Testing. Wiley.
4. Guidelines on Similar Biologics: Regulatory Requirements for Marketing Authorization in India.
5. EMA-www.ema.europa.eu ›scientific guidelines ›Biologicals

**Recommended websites:**

1. CDSCO- www.cdsco.nic.in.
2. FDA Biologics- www.fda.gov/biologics blood Vaccines/Guidance Compliance Regulatory Information
3. WHO -www.who.int/biologicals/en
4. FDA-www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/
5. International Hemovigilance Network-www.ihn-org.com
6. The International Society of Blood Transfusion-www.isbtweb.org

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Name of Program: **M. Pharm**
Branch: **A07 - Regulatory Affair**
Semester: **II**
Course Code: **M070203TT**
Course Name: **Regulatory Aspects of Medical Devices**
Course Type: **Core**
Year of Implementation: **2024 – 25**

**Teaching and Examination Scheme:**

| Number of hours/ Week | | | Number of credits | | | Total credits | Evaluation Scheme (Marks) | | | | | | | | Total Marks |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | | | Sessional Exams | | | | | | Term End Assessment | | |
| | | | | | | | Theory | | | Practical | | | | | |
| L | Tu | P | L | Tu | P | | CIE | E | T | CIE | E | T | T | P | |
| 4 | 0 | 0 | 4 | 0 | 0 | 4 | 10 | 15 | 25 | 0 | 0 | 0 | 75 | 0 | 100 |

**Scope:**
This course is designed to impart the fundamental knowledge on the medical devices and in vitro diagnostics, basis of classification and product life cycle of medical devices, regulatory requirements for approval of medical devices in regulated countries like US, EU and Asian countries along with WHO regulations. It prepares the students to learn in detail on the harmonization initiatives, quality and ethical considerations, regulatory and documentation requirements for marketing medical devices and IVDs in regulated countries.

**Course Outcomes (CO):**
Upon completion of the course student shall be able to

| | |
|---|---|
| CO1 | Understand basics and apply harmonization initiatives for marketing of medical devices and IVDs as per IMDRF/GHTF guidance |
| CO2 | Comprehend and apply the knowledge of regulatory requirements for approval of medical devices and IVDs in regulated and semi regulated markets |
| CO3 | Gain knowledge on clinical investigation and evaluation of medical devices and IVDs |
| CO4 | Compare and contrast various regulatory requirements in different jurisdictions |

**Detailed Syllabus:**
Total Teaching hours: **60 hours**

| | | |
|---|---|---|
| **Unit 1** | **Medical Devices:** Introduction, Definition, Risk based classification and Essential Principles of Medical Devices and IVDs. Differentiating medical devices IVDs and Combination Products from that of pharmaceuticals, History of Medical Device Regulation, Product | **06 hours** |
| | Lifecycle of Medical Devices and Classification of Medical Devices. IMDRF/GHTF: Introduction, Organizational Structure, Purpose and Functions, Regulatory Guidelines, Working Groups, IMDRF study groups and guidance documents, Summary Technical Document (STED), Global Medical Device Nomenclature (GMDN). | **06 hours** |
| **Unit 2** | **Ethics:** Clinical Investigation of Medical Devices, Clinical Investigation Plan for Medical Devices, Good Clinical Practice for Clinical Investigation of medical devices (ISO 14155:2011) | **06 hours** |
| | Quality: Quality System Regulations of Medical Devices: ISO 13485, Quality Risk Management of Medical Devices: ISO 14971, Validation and Verification of Medical device, Adverse Event Reporting of Medical device | **06 hours** |
| **Unit 3** | **USA:** Introduction, Classification, Regulatory approval process for Medical Devices (510k) Premarket Notification, Pre-Market Approval (PMA), Humanitarian Device Exemption (HDE), De Novo Classification, Investigational Device Exemption (IDE) | **05 hours** |
| | Quality System Requirements21CFR Part820, Labelling requirements 21 CFR Part 801 | **03 hours** |
| | Post marketing surveillance of MD and Unique Device Identification (UDI) | **02 hours** |
| | Basics of In vitro diagnostics, classification and approval process of MDs | **02 hours** |
| **Unit 4** | **European Union:** Introduction, Classification, Regulatory approval process for Medical Devices (Medical Device Directive, Active Implantable Medical Device Directive) and In vitro Diagnostics (In Vitro Diagnostics Directive), CE certification process | **10 hours** |
| | Basics of In vitro diagnostics, classification and approval process | **02 hours** |

| | | |
|---|---|---|
| **Unit 5** | **ASEAN:** Medical Devices and IVDs, Regulatory registration procedures, Quality System requirements and clinical evaluation and investigation. | **04 hours** |
| | **China:** Medical Devices and IVDs, Regulatory registration procedures, Quality System requirements and clinical evaluation and investigation. | **04 hours** |
| | **Japan:** Medical Devices and IVDs, Regulatory registration procedures, Quality System requirements and clinical evaluation and investigation. | **04 hours** |

**Recommended Books^: (Latest Editions)**

1. Douglas J. Pisano, David Mantus. FDA regulatory affairs: a guide for prescription drugs, medical devices, and biologics.
2. Jonathan S. Kahan. Medical Device Development: A Regulatory Overview.
3. John J. Tobin and Gary Walsh. Medical Product Regulatory Affairs: Pharmaceuticals, Diagnostics, Medical Devices.
4. Carmen Medina. Compliance Handbook for Pharmaceuticals, Medical Devices and Biologics.

**Recommended websites:**

1. PMDA-https://www.pmda.go.jp/english/review-services/reviews/approved-information/devices/0002.html
2. NMPA- https://english.nmpa.gov.cn/medicaldevices.html
3. EMA- https://www.ema.europa.eu/en/human-regulatory-overview/medical-devices
4. Country Specific Guidelines from official websites.

L= Lecture, Tu= Tutorial, P= Practical, T = Theory

^ This is not an exhaustive list

**ANAND PHARMACY COLLEGE, ANAND**
**(An Autonomous College under UGC Regulations 2023)**
**Managed by Shri Ramkrishna Seva Mandal**
(Approved by PCI, NAAC Accredited – A+ Grade, 3.38 CGPA)
Awarding University: Gujarat Technological University, Ahmedabad

Name of Program: **M. Pharm**
Branch: **A07 - Regulatory Affair**
Semester: **II**
Course Code: **M070204TT**
Course Name: **Regulatory Aspects of Food & Nutraceuticals**
Course Type: **Core**
Year of Implementation: **2024 – 25**

**Teaching and Examination Scheme:**

| Number of hours/ Week | | | Number of credits | | | Total credits | Evaluation Scheme (Marks) | | | | | | | | Total Marks |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | | | Sessional Exams | | | | | | Term End Assessment | | |
| | | | | | | | Theory | | | Practical | | | | | |
| L | Tu | P | L | Tu | P | | CIE | E | T | CIE | E | T | T | P | |
| 4 | 0 | 0 | 4 | 0 | 0 | 4 | 10 | 15 | 25 | 0 | 0 | 0 | 75 | 0 | 100 |

**Scope:**
This course is designed to impart the fundamental knowledge on Regulatory Requirements, Registration and Labelling Regulations of Nutraceuticals in India, USA and Europe. It prepares the students to learn in detail on Regulatory Aspects for nutraceuticals and food supplements.

**Course Outcomes (CO):**
Upon completion of the course student shall be able to

| | |
|---|---|
| CO1 | Comprehend basic understanding of nutraceuticals, dietary and food supplement |
| CO2 | Understand and apply global regulatory requirements for nutraceuticals and food supplements |
| CO3 | Understand and apply the knowledge of regulatory, labelling and RDA requirements of nutraceuticals and food supplements in India, USA and Europe |
| CO4 | Compare and contrast regulations of nutraceuticals in different jurisdiction |

**Detailed Syllabus:**
Total Teaching hours: **60 hours**

| | | |
|---|---|---|
| **Unit 1** | **Nutraceuticals:** Introduction, History of Food and Nutraceutical Regulations, Meaning of Nutraceuticals | **06 hours** |
| | Dietary Supplements, Functional Foods, Medical Foods, Scope and Opportunities in Nutraceutical Market. | **06 hours** |
| **Unit 2** | **Global Aspects:** WHO guidelines on nutrition, Good Manufacturing Practices for Nutraceuticals. | **06 hours** |
| | **NSF International:** It's Role in the Dietary Supplements and Nutraceuticals Industries, NSF Certification, NSF Standards for Food and Dietary Supplements, Industries, NSF Certification, Industries, NSF Certification, and NSF Standards for Food and Dietary Supplements. Good Manufacturing Practices for Nutraceuticals and NSF Standards for Food and Dietary Supplements. | **06 hours** |

| | | |
|---|---|---|
| **Unit 3** | **India:** Food Safety and Standards Act, Food Safety and Standards Authority of India: Organization and Functions | **04 hours** |
| | Regulations for import, manufacture and sale of nutraceutical products in India, Recommended Dietary Allowances (RDA) in India | **08 hours** |
| **Unit 4** | **USA:** US FDA Food Safety Modernization Act, Dietary Supplement Health and Education Act. U.S. regulations for manufacture and sale of nutraceuticals and dietary supplements | **06 hours** |
| | Labelling Requirements and Label Claims for Dietary Supplements, Recommended Dietary Allowances (RDA) in the U.S | **06 hours** |
| **Unit 5** | **European Union:** European Food Safety Authority (EFSA): Organization and Functions. EU Directives and regulations for manufacture and sale of nutraceuticals and dietary supplements | **06 hours** |
| | Nutrition labelling. European Regulation on Novel Foods and Novel Food Ingredients. Recommended Dietary Allowances (RDA) in Europe | **06 hours** |

**Recommended Books^: (Latest Editions)**


1. Clare M. Hasler. Regulation of Functional Foods and Nutraceuticals: A Global Perspective. Wiley Online Library.
2. Debasis Bagchi. Nutraceutical and Functional Food Regulations. United States and Around the World. Academic Press Elsevier.
3. Yashwant Pathak. Handbook of Nutraceuticals. CRC Press
4. Neal D. Fortin. Food Regulation: Law, Science, Policy and Practice. Wiley
5. Country Specific Guidelines from official websites


**Recommended Websites:**

1. WHO- http://www.who.int/publications/guidelines/nutrition/en/
2. EU- http://www.europarl.europa.eu/RegData/etudes/STUD/2015/536324/IPOL_STU(2015)536324_EN.pdf
3. USA-https://www.fda.gov/food/guidance-regulation-food-and-dietary-supplements/food-safety-modernization-act-fsma
4. FSSAI- https://www.fssai.gov.in/cms/food-safety-and-standards-regulations.php
5. NSF- https://www.nsf.org/knowledge-library/who-is-nsf-international

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Awarding University: Gujarat Technological University, Ahmedabad

Name of Program: **M. Pharm**
Branch: **A07 - Regulatory Affair**
Semester: **II**
Course Code: **M070205PP**
Course Name: **Regulatory Affairs Practical – II**
Course Type: **Core**
Year of Implementation: **2024 – 25**

**Teaching and Examination Scheme:**

| Number of hours/ Week | | | Number of credits | | | Total credits | Evaluation Scheme (Marks) | | | | | | | | Total Marks |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | | | Sessional Exams | | | | | | Term End Assessment | | |
| | | | | | | | Theory | | | Practical | | | | | |
| L | Tu | P | L | Tu | P | | CIE | E | T | CIE | E | T | T | P | |
| 0 | 0 | 12 | 0 | 0 | 6 | 6 | 0 | 0 | 0 | 20 | 30 | 50 | 0 | 100 | 150 |

**Course Outcomes (CO):**
Upon completion of the course student shall be able to

| | |
|---|---|
| CO1 | Understand, examine, and apply comprehensive knowledge of regulatory requirements in different regions |
| CO2 | Create CTD/eCTD dossiers for regulated and semi-regulated markets by understanding regulatory requirements, clinical trial requirements and checklist preparation for drugs, biologics and medical devices |

**List of Practical:**
Total Teaching hours: **60 hours**

1. Case studies on
2. Change Management/Change control. Deviations
3. Corrective & Preventive Actions (CAPA)
4. Documentation of raw materials analysis as per official monographs
5. Preparation of audit checklist for various agencies
6. Preparation of submission to FDA using eCTD software
7. Preparation of submission to EMA using eCTD software
8. Preparation of submission to MHRA using eCTD software
9. Preparation of Biologics License Applications (BLA)
10. Preparation of documents required for Vaccine Product Approval
11. Comparison of clinical trial application requirements of US, EU and India of Biologics
12. Preparation of Checklist for Registration of Blood and Blood Products
13. Registration requirement comparison study in 5 emerging markets (WHO) and preparing checklist for market authorization

14. Registration requirement comparison study in emerging markets (BRICS) and preparing checklist for market authorization
15. Registration requirement comparison study in emerging markets (China and South Korea) and preparing check list for market authorization
16. Registration requirement comparison study in emerging markets (ASEAN) and preparing checklist for market authorization
17. Registration requirement comparison study in emerging markets (GCC) and preparing check list for market authorization
18. Checklists for 510k and PMA for US market
19. Check list for CE marking for various classes of devices for EU
20. STED Application for Class III Devices
21. Audit Checklist for Medical Device Facility
22. Clinical Investigation Plan for Medical Devices

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