ROYAL GLOBAL UNIVERSITY
GUWAHATI

# ROYAL SCHOOL OF PHARMACY
## (RSP)
## Master of Pharmacy (M.Pharm)

## SYLLABUS
## &
## COURSE STRUCTURE

**M.Pharm. (Pharmaceutics)**

**PCI Syllabus 2016**

## M.PHARM. (PHARMACEUTICS)

### Programme Structure

| Semester-I | | | | | | | |
|---|---|---|---|---|---|---|---|
| **Sl.No.** | **Subject Code** | **Names of subjects** | **L** | **T** | **P** | **C** | **TCP** |
| **Core Subjects** | | | | | | | |
| 1 | MPH101T | Modern Pharmaceutical Analytical Techniques | 3 | 1 | 0 | 4 | 4 |
| 2 | MPH102T | Drug Delivery System | 3 | 1 | 0 | 4 | 4 |
| 3 | MPH103T | Modern Pharmaceutics | 3 | 1 | 0 | 4 | 4 |
| 4 | MPH104T | Regulatory Affair | 3 | 1 | 0 | 4 | 4 |
| 5 | MPH105P | Pharmaceutics Practical I | 0 | 0 | 12 | 6 | 12 |
| 6 | MPH106S | Seminar /Assignment | 0 | 0 | 7 | 4 | 7 |
| | | **TOTAL** | **12** | **4** | **19** | **26** | **35** |

| Semester-II | | | | | | | |
|---|---|---|---|---|---|---|---|
| **Sl. No.** | **Subject Code** | **Names of subjects** | **L** | **T** | **P** | **C** | **TCP** |
| **Core Subjects** | | | | | | | |
| 1 | MPH201T | Molecular Pharmaceutics (NanoTech and Targeted DDS) | 3 | 1 | 0 | 4 | 4 |
| 2 | MPH202T | Advanced Biopharmaceutics & Pharmacokinetics | 3 | 1 | 0 | 4 | 4 |
| 3 | MPH203T | Computer Aided Drug Delivery System | 3 | 1 | 0 | 4 | 4 |
| 4 | MPH204T | Cosmetic and Cosmeceuticals | 3 | 1 | 0 | 4 | 4 |
| 5 | MPH205P | Pharmaceutics Practical II | 0 | 0 | 12 | 6 | 12 |
| 6 | MPH206S | Seminar/Assignment | 0 | 0 | 7 | 4 | 7 |
| | | **TOTAL** | **12** | **4** | **19** | **26** | **35** |

| 3rdSemester | | | | | | | |
|---|---|---|---|---|---|---|---|
| **Sl.No.** | **Subject Code** | **Names of subjects** | **L** | **T** | **P** | **C** | **TCP** |
| **Core Subjects** | | | | | | | |
| 1 | MRM301T | Research Methodology and Biostatistics | 3 | 1 | 0 | 4 | 4 |
| 2 | MPH302S | Journal Club | 0 | 0 | 1 | 1 | 1 |
| 3 | MPH303P | Discussion/ Presentation (Proposal Presentation) | 0 | 0 | 2 | 2 | 2 |
| 4 | MPH304P | Research work | 3 | 0 | 28 | 14 | 28 |
| | | **TOTAL** | **3** | **1** | **31** | **21** | **35** |

| 4thSemester | | | | | | | |
|---|---|---|---|---|---|---|---|
| **Sl.No.** | **Subject Code** | **Names of subjects** | **L** | **T** | **P** | **C** | **TCP** |
| **Core Subjects** | | | | | | | |
| 1 | MPH401S | Journal Club | 0 | 0 | 1 | 1 | 1 |
| 2 | MPH402P | Research work | 0 | 0 | 31 | 16 | 31 |
| 3 | MPH 403P | Discussion / Final Presentation | 0 | 0 | 3 | 3 | 3 |
| 4 | MPH 404S | Co-Curricular activities | | | | | |
| **TOTAL** | | | **0** | **0** | **35** | **20** | **35** |

**Table–1: Semester wise credits distribution**

| Semester | Credit Points |
|---|---|
| I | 26 |
| II | 26 |
| III | 21 |
| IV | 20 |
| *Co-curricular Activities<br>(a) Participation in National Level Seminar/Conference/Workshop/Symposium/ Training Programs(related to the specialisation of the student-01)<br>(b) Research/Review Publication in National Journals (Indexed in Scopus/Web of Science-01) | Min-02*/Max-07 |
| Total Credit Points | Min-95 & Max. 100 |

**Scheme of Evaluation**

| **Theory Papers (T):** | **Practical Papers (P):** |
|---|---|
| • **Internal assessment: 25%**<br>• **End Term Examination:75%** | • **Internal assessment: 30%**<br>• **End Term examination: 70%** |

## Internal assessment: Continuous mode

The marks allocated for Continuous mode of Internal Assessment shall be awarded as per the scheme given below.

Table–2: Scheme for awarding internal assessment: Continuous mode

| Theory | |
|---|---|
| Criteria | Maximum Marks |
| Attendance (Refer Table–3) | 8 |
| Student–Teacher interaction | 2 |
| Total | 10 |
| Practical | |
| Attendance (ReferTable–3 | 10 |
| Based on Practical Records,Regular viva-voce,etc. | 10 |
| Total | 20 |

Table–3: Guidelines for the allotment of marks for attendance

| Percentage of Attendance | Theory | Practical |
|---|---|---|
| 95–100 | 8 | 10 |
| 90–94 | 6 | 7.5 |
| 85–89 | 4 | 5 |
| 80–84 | 2 | 2.5 |
| Less than 80 | 0 | 0 |

# SEMESTER-I SYLLABUS

**Paper I / Subject Name: MODERN PHARMACEUTICAL ANALYTICAL TECHNIQUES (MPH 101T)**

**L-T-P-C – 4-0-0-4** **Credit Units:4** **Scheme of Evaluation:(T)**

**Objective:** 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 Outcome:** Upon completion of the course, the student shall be able to

CO1: Understand the operation and applications of modern analytical instruments used in drug analysis, including UV-Visible, IR, Spectrofluorimetry, flame emission, and atomic absorption spectroscopy.

CO2: Understand the principles of NMR and mass spectroscopy and learn to interpret data for identifying organic compounds.

CO3: Understand chromatographic separation processes and apply them to the analysis of pharmaceutical compounds, gaining practical skills in chromatography and electrophoresis techniques.

CO4: Explore X-ray crystallography and immunological assays (RIA, ELISA) for characterizing and quantifying biological compounds. Develop skills in drug analysis using advanced techniques, and learn to interpret NMR, Mass, and IR spectra for identifying and characterizing organic compounds.

**Detailed Syllabus:**

| Module | Topics (if applicable)/Course Content | Hours |
|---|---|---|
| **I.** | **UV-Visible spectroscopy:** Introduction, Theory, Laws, Instrumentation associated with UV-Visible spectroscopy, Choice of solvents and solvent effect and Applications of UV-Visible spectroscopy, Difference/ Derivative spectroscopy.<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 IR spectroscopy, Data Interpretation.<br>**Spectroflourimetry:** Theory of Fluorescence, Factors affecting fluorescence (Characteristics of drugs that can be analysed by fluorimetry), Quenchers, Instrumentation and Applications of fluorescence spectrophotometer.<br>Flame emission spectroscopy and atomic absorption spectroscopy: Principle, Instrumentation, Interferences and Applications. | **15 hrs** |
| **II.** | **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 | **15 hrs** |

| | | |
|---|---|---|
| | coupling, Coupling constant, Nuclear magnetic double resonance, Brief outline of principles of FT-NMR and 13C NMR. Applications of NMR spectroscopy.<br>**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. | |
| **III.** | **Chromatography:** Principle, apparatus, instrumentation, chromatographic parameters, factors affecting resolution, isolation of drug from excipients, data interpretation and applications of the following:<br>**a. Thin Layer chromatography**<br>**b. High Performance Thin Layer Chromatography**<br>**c. Ion exchange chromatography**<br>**d. Column chromatography**<br>**e. Gas chromatography**<br>**f. High Performance Liquid chromatography**<br>**g. Ultra High Performance Liquid chromatography**<br>**h. Affinity chromatography**<br>**i. Gel Chromatography** | **15 hrs** |
| **IV.** | **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 methods, Bragg's law, Rotating crystal technique, X ray powder technique, Types of crystals and applications of X-ray diffraction.<br>**Potentiometry:** Principle, working, Ion selective Electrodes and Application of potentiometry.<br>**Thermal Techniques:** Principle, thermal transitions and Instrumentation (Heat flux and power-compensation and designs), Modulated DSC, Hyper DSC, experimental parameters (sample preparation, experimental conditions, calibration, heating and cooling rates, resolution, source of errors) and their influence, advantage and disadvantages, pharmaceutical applications.<br>Differential Thermal Analysis (DTA): Principle, instrumentation and advantages and disadvantages, pharmaceutical applications, derivative differential thermal analysis (DDTA).<br>**TGA:** Principle, instrumentation, factors affecting results, advantage and disadvantages, pharmaceutical applications. | **15 hrs** |
| **TOTAL** | | **60 hrs** |

**Text Books:**


1. Instrumental methods of analysis – Willards, 7th edition, CBS publishers.
2. Quantitative Analysis of Drugs in Pharmaceutical formulation - P D Sethi, 3rd Edition, CBS Publishers, New Delhi, 1997.
3. Pharmaceutical Analysis - Modern Methods – Part B - J W Munson, Vol 11, Marcel. Dekker Series.
4. Spectroscopy of Organic Compounds, 2nd edn., P.S/Kalsi, Wiley estern Ltd., Delhi.
5. Textbook of Pharmaceutical Analysis, KA.Connors, 3rd Edition, John Wiley & Sons, 1982.


**Reference Books:**


1. Spectrometric Identification of Organic compounds - Robert M Silverstein, Sixth edition, John Wiley & Sons, 2004.
2. Principles of Instrumental Analysis - Doglas A Skoog, F. James Holler, Timothy A. Nieman, 5th edition, Eastern press, Bangalore, 1998.
3. Practical Pharmaceutical Chemistry – Beckett and Stenlake, Vol II, 4th edition, CBS Publishers, New Delhi, 1997.
4. Organic Spectroscopy - William Kemp, 3rd edition, ELBS, 1991.


**Teaching Learning Process and Assessment Methods:**

| Unit No. | Course Learning Outcomes | Teaching and Learning Activity | Assessment Tasks |
|---|---|---|---|
| **I.** | CO1: Students will understand and apply principles of UV-Visible, IR, and Spectrofluorimetry, as well as flame emission and atomic absorption spectroscopy in drug analysis. | Traditional teaching, PPT | Class tests, assignments, MCQs |
| **II.** | CO2: Students will understand the principles of ionization and mass fragmentation and learn to interpret Mass and NMR spectroscopy data. | Traditional teaching, PPT | Class tests, assignments, MCQs |
| **III.** | CO3: Students will gain practical skills in chromatography and electrophoresis techniques for the separation and analysis of compounds. | Traditional teaching, PPT | Class tests, assignments, MCQs |
| **IV.** | CO4: Students will explore X-ray crystallography methods and immunological assays (RIA, ELISA) for the characterization and quantification of biological compounds. | Traditional teaching, PPT | Class tests, assignments, MCQs |

**PaperI/SubjectName: DRUG DELIVERY SYSTEMS (THEORY)**

**Code: MPH102T**

**L-T-P-C–3-1-0-4** **Credit Units: 4** **Scheme of Evaluation: (T)**

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

**Course Outcome**: Upon completion of the course the student will be able to
CO1: Compare the various approaches for development of novel drug delivery systems.
CO2: Identify the criteria for selection of drugs and polymers for the development of drug delivery system
CO3: Formulate and evaluate various types of Novel drug delivery systems.

**Detailed Syllabus**

| Modules | Topics (ifapplicable) & Course Contents | Period |
|---|---|---|
| **I.** | **Sustained Release (SR) and Controlled Release(CR) formulations:** Introduction & basic concepts, advantages/ disadvantages, factors influencing, Physicochemical & biological approachesforSR/CR formulation,Mechanism of Drug Delivery from SR/CR formulation. **Polymers:** introduction, definition, classification, properties and application. **Dosage Forms for Personalized Medicine:** Introduction, Definition, Pharmacogenetics, Categories of Patients for Personalized Medicines: Customized drug delivery systems, Bioelectronic Medicines, 3Dprinting of pharmaceuticals, Telepharmacy. | **15 hr** |
| **II.** | **Rate Controlled Drug Delivery Systems:** Principles & Fundamentals, Types, Activation; Modulated Drug Delivery Systems; Mechanically activated, pH activated, Enzyme activated, and Osmotic activated Drug Delivery Systems Feed back regulated Drug Delivery Systems; Principles & Fundamentals. | **15 hr** |
| **III.** | **Gastro-Retentive Drug Delivery Systems:** Principle, concepts advantages anddisadvantages, Modulation of GI transit time approachesto extend GI transit. **Buccal Drug Delivery Systems:** Principle of mucoadhesion, advantages and disadvantages, Mechanism of drug permeation, Methods of formulation and itsevaluations. **Occular Drug Delivery Systems:** Barriers of drug permeation, Methods to overcome barriers. | **15 Hr** |
| **IV** | **Transdermal Drug Delivery Systems:** Structure of skin and barriers, Penetration enhancers, Transdermal Drug Delivery Systems, Formulation and evaluation. **Protein and Peptide Delivery:** Barriers for protein delivery. Formulation and Evaluation of delivery systems of proteins and other macromolecules. **Vaccine delivery systems:**Vaccines, uptake of antigens, single shot vaccines, mucosal and transdermal delivery of vaccines | **15 hr** |
| **TOTAL** | | **60 hours** |

**TEXTBOOKS:**


1. Controlled and Novel Drug Delivery, N.K. Jain, Second Edition, 2023, CBS Publishers and Distributors Pvt. Ltd.
2. Controlled Drug Delivery - concepts andadvances, S.P.Vyas and R.K.Khar, First edition, 2012, Vallabh Prakashan.


**REFERENCE BOOKS:**


1. Novel Drug Delivery Systems, Yie Chien, 2nd edition, Volume 50, 1991, MarcelDekker Inc., CRC Press Inc.
2. Controlled Drug Delivery Systems, Joseph Robinson, Vincent H.L. Lee, Second Edition, 1987, CRC Press.
3. Encyclopedia of controlled delivery, Editor- Edith Mathiowitz, Volume 3, 1999, Published by WileyInterscience Publication.

**JOURNALS**

1. Indian Journal of Pharmaceutical Sciences (IPA)
2. Indian drugs (IDMA)
3. Journal of controlled release (Elsevier Sciences) desirable
4. Drug Development and Industrial Pharmacy (Marcel &Decker) desirable

**Teaching Learning Process and Assessment Methods**

| Unit No. | Course Learning Outcomes | Teaching and Learning Activity | Assessment Tasks |
|---|---|---|---|
| I, II, | **CO1:** Compare the various approaches for development of novel drug delivery systems. . | Class room lectures though online resources, Educational Softwares, digital simulations, concept videos, practical demonstrations, case based presentations, scientific report discussions (Research articles, research reports etc.) | Seminar, quiz, assignments, journal club, problem based assignments, report writing, Internal assessments (Sessional exams), continuous evaluation) and End Sem Examinations, |
| I, II, III, IV | **CO2:** Identify the criteria for selection of drugs and polymers for the development of drug delivery system | Class room lectures though online resources, Educational Softwares, digital simulations, concept videos, practical demonstrations, case based presentations, scientific report discussions (Research articles, research reports etc.) | Seminar, quiz, assignments, journal club, problem based assignments, report writing, Internal assessments (Sessional exams), continuous evaluation) and End Sem Examinations, |
| III &IV | **CO3:** Formulate and evaluate various types of Novel drug delivery systems. | Class room lectures though online resources, Educational Softwares, digital simulations, concept videos, practical demonstrations, case based presentations, scientific report discussions (Research articles, research reports etc.) | Seminar, quiz, assignments, journal club, problem based assignments, report writing, Internal assessments (Sessional exams), continuous evaluation) and End Sem Examinations, |

**PaperII/Subject Name: MODERN PHARMACEUTICS (Theory)**

**Code: MPH103T**

**L-T-P-C–3-1-0-0** **Credit Units: 4** **Scheme of Evaluation: (T)**

**Objective**: This course is designed to impart advanced knowledge and skills required to learn various aspects and concepts at pharmaceutical industries

**Course Outcome**: Upon completion of the course the student will be able to:

CO1: Identify the elements of preformulation studies and experiment on formulation development.
CO2: Select drug candidate for development of various types of drug product.
CO3: Inspect and apply the principle of GMP in Industrial Management.
CO4: Apply optimization techniques during pilot Plant ScaleUp Techniques
CO5: Design and conduct StabilityTesting, sterilization process & packaging of dosage forms.

**DetailedSyllabus**

| Modules | Topics(ifapplicable)&Course Contents | Periods |
|---|---|---|
| **I.** | **(a) Preformation Concepts**–Drug Excipient interactions- different methods, kinetics ofstability, Stabilitytesting. Theoriesof dispersion and pharmaceutical Dispersion (Emulsion and Suspension, SMEDDS) preparation andstability Large and small volume parental – physiological and formulation consideration, Manufacturing and evaluation.<br>**(b) Optimization techniques in Pharmaceutical Formulation:** Concept and parameters of optimization, Optimization techniques in pharmaceutical formulation and processing. Statistical design, Response surface method,Contour designs, Factorial designs and application in formulation | **17 hours** |
| **II.** | **Validation:** Introduction to Pharmaceutical Validation, Scope & merits ofValidation, Validation and calibrationof Master plan, ICH & WHO guidelinesfor calibrationand validation of equipments, Validation of specificdosage form, Types of validation. Government regulation, Manufacturing Process Model, URS, DQ, IQ, OQ & P.Q. of facilities. | **13 hours** |
| **III.** | **cGMP & Industrial Management:** Objectives and policies of current good manufacturing practices, layout of buildings, services, equipments and their maintenance Production management: Production organization, , materials management, handling and transportation, inventory management and control, production and planning control, Sales forecasting, budget and cost control,industrialand personal relationship. Concept of Total Quality Management. | **12 hours** |
| **IV.** | **Compression and compaction:** Physics of tablet compression, compression, consolidation,effect of friction, distribution of forces, compaction profiles. Solubility.<br>**Study of consolidation parameters;** Diffusionparameters, Dissolution parameters andPharmacokinetic parameters, Heckel plots, Similarity factors – f2 and f1, Higuchiand Peppas plot, Linearity Concept of significance,Standard deviation , Chi square test, students T-test , ANOVA test. | **18 hours** |
| **TOTAL** | | **60 hours** |

**TextBook:**


1. Theory and Practice of Industrial Pharmacy By Lachmann and Liberman, Fourth Edition, 2020, CBS Publisher.
2. ModernPharmaceutics; By Gillbert S. Banker and Christopher Rhodes, Fourth Edition, 2002, Informa Healthcare.


**Reference Books**


1. Pharmaceutical dosage forms:Tablets Vol.1-3, Herbert A. Lieberman, Leon Lachman and Joseph B. Schwartz, Second Edition, CRC Press.
2. Pharmaceutical Dosage forms: Disperse systems, Vol,1-2; Gilbert S. Banker, A. Liberman and Martin M. Rieger, Second Edition, 2008, Informa Healthcare.
3. Pharmaceutical Dosage forms: Parenteral medications Vol.1-2; Kenneth E. Avis, Herbert Lieberman and Leon Lachman, Second Edition, 1993, CRC Press.
4. Remington The Science and Practice of Pharmacy, Adrejare A., 23rd Edition, 2021, Elsevier.
5. Advances inPharmaceuticalSciencesVol.1-5; H.S.Bean & A.H. Beckett, First Edition, 2009, Elsevier.
6. Martin's Physical Pharmacy and Pharmaceutical Sciences; Patrick J. Sinko, Sixth Edition, 2010, Lippincott Williams & Wilkins.
7. Bentley'sTextbook of Pharmaceutics, E.A Rawlins, Eight Edition, 2010, Elsevier.
8. Good manufacturing practices for Pharmaceuticals: A planfor total quality control, Graham P. Bunn, Seventh Edition, 2019, CRC Press.
9. Quality Assurance Guide; By Organization of Pharmaceutical producers of India
10. Drugformulationmanual; D.P.S.Kohli and D.H.Shah, First Edition, 2003, Eastern publishers.
11. How to practice GMPs; P.P.Sharma, Seventh Edition, 2015, Vandhana Publications.
12. PharmaceuticalProcessValidation; Ira.R.Berry andRobertA.Nash, Second Edition, 57 Volume, 1993, CRC Press.
13. PharmaceuticalPreformulations and Formulation, Mark Gibson, Second Edition, Volume 199, 2009, CRC Press Inc..


**Teaching learning process and assessment**

| Unit No. | CourseLearning Outcomes | TeachingandLearning Activity | AssessmentTasks |
|---|---|---|---|
| I. | **CO1:** Identify the elements of preformulation studies and experiment on formulation development. | Class room lectures though online resources, Educational Softwares, concept videos, practical demonstrations, case based presentations, scientific report discussions (Research articles, research reports etc.) | Seminar, quiz, assignments, journal club, problem based assignments, report writing, Internal assessments (Sessional exams), continuous evaluation) and End Sem Examinations, |
| I | **CO2:** Select drug candidate for development of various types of drug product. | Class room lectures though online resources, Educational Softwares, concept videos, practical demonstrations, case based presentations, scientific report discussions (Research articles, research reports etc.) | Seminar, quiz, assignments, report writing, Internal assessments (Sessional exams), continuous evaluation) and End Sem Examinations, |
| II, III | **CO3:** Inspect and apply the principle of GMP in Industrial Management. | Class room lectures though online resources, concept videos, scientific report discussions (Research articles, research reports etc.) | Seminar, quiz, assignments, report writing, Internal assessments |

| | | | |
|---|---|---|---|
| | | | (Sessional exams), continuous evaluation) and End Sem Examinations, |
| I, IV, | **CO4:** Apply optimization techniques during pilot Plant ScaleUp Techniques | Class room lectures though online resources, Educational Softwares, concept videos, practical demonstrations, case based presentations, scientific report discussions (Research articles, research reports etc.) | Seminar, quiz, assignments, report writing, Internal assessments (Sessional exams), continuous evaluation) and End Sem Examinations, |
| I, II, IV | **CO5:** Design and conduct Stability Testing, sterilization process & packaging of dosage forms. | Class room lectures though online resources, Educational Softwares, concept videos, practical demonstrations, case based presentations, scientific report discussions (Research articles, research reports etc.) | Seminar, quiz, assignments, report writing, Internal assessments (Sessional exams), continuous evaluation) and End Sem Examinations. |

| PaperIII/Subject Name: REGULATORY AFFAIRS | | Code: MPH104T |
|---|---|---|
| L-T-P-C–3-1-0-0 | Credit Units: 4 | Scheme of Evaluation: (T) |

**Objective:** This course is designed to impart advanced knowledge and skills required tolearn the concept of generic drug and their development, various regulatory filings in different countries, different phases of clinical trials and submitting regulatory documents: filing process of IND, NDA and ANDA drug application procedures.

**Course Outcome**: Upon completion of this course the student will be able to:

CO1: Evaluate the concept of of innovator and generic drugs during drug development process.
CO2: Interpret the Regulatory guidance and guidelines for filing and approval process
CO3: Prepare Dossiers and their submission to regulatory agencies in different countries.
CO4: Understand the Post approval regulatory requirements for API and drug products
CO5: Evaluate the submission of global documents in CTD/eCTD formats including approval documents for conducting clinical trials.

**Detailed Syllabus**

| Modules | Topics (ifapplicable) & Course Contents | Periods |
|---|---|---|
| **I.** | (a) Documentation in Pharmaceutical industry: Master formula record, DMF (Drug Master File), distribution records. Generic drugsproduct development Introduction , Hatch-Waxman act and amendments, CFR (CODE OF FEDERAL REGULATION) ,drug product performance, in-vitro, ANDA regulatory approval process, NDAapproval process, BE anddrug product assessment, in –vivo, scale up process approvalchanges,post marketing surveillance, outsourcing BA andBE to CRO.<br>(b) Regulatory requirement for product approval: API biologics, novel,therapies obtaining NDA, ANDA for generic drugs ways and means of US registration for foreign drugs | **15hours** |
| **II.** | CMC, 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 ROWcountries. | **15 hours** |
| **III.** | Nonclinical drug development: Global submission of IND, NDA, ANDA.Investigation of medicinal products dossier, dossier (IMPD) and investigator brochure (IB). | **15 hours** |
| **IV.** | Clinical trials: Developing clinical trial protocols. 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** |
| **Total** | | **60 hours** |

**Text Book:**

1. Good manufacturing practices for pharmaceuticals-a plan for total quality control. Sidney H. Willig, Murray M, Marcel Dekker, Seventh Edition, 2019, CRC Press.
2. Pharmaceutical Regulatory Affairs, Jigar Vyas, Nensi Raytthatha and Isha Shah, First Edition, 2023, CBS Publishers.

**Reference Books**

1. Generic Drug Product Development, Solid Oral Dosage forms, Leon Shargel and Isader Kaufer, Marcel Dekker series, Second Edition, Vol.212, 2013, Taylor and Francis Inc. The Pharmaceutical Regulatory Process, Ira R. Berry and Robert P.Martin, Drugs and thePharmaceuticalSciences, Second Edition, Vol.185, CRC Press Inc..
2. New Drug Approval Process: Accelerating Global Registrations By RichardA Guarino, MD, 5th edition, Volume 190, Drugs and the Pharmaceutical Sciences, CRC Press Inc.
3. Guide book for drug regulatory submissions; SandyWeinberg. First Edition, 2009, JohnWiley & Sons.Inc.
4. FDA regulatory affairs: a guide for prescription drugs, medical devices, and biologics; Douglas J. Pisano, David S. Mantus, Second Edition, 2008, CRC Press.
5. Clinical Trials and Human Research: A Practical Guide to Regulatory Compliance By Fay A.Rozovsky and Rodney K. Adams
    - www.ich.org/
    - www.fda.gov/
    - europa.eu/index_en.htm
    - https://www.tga.gov.au/tga-basics

**Teaching learning process and assessment**

| Unit No. | Course Learning Outcomes | Teaching and Learning Activity | Assessment Tasks |
|---|---|---|---|
| I. | **CO1**: Evaluate the concept of of innovator and generic drugs during drug development process. | Class room lectures though online resources, concept videos, practical demonstrations, case based presentations, scientific report discussions (Research articles, research reports etc.) | Seminar, quiz, assignments, journal club, problem based assignments, report writing, Internal assessments (Sessional exams), continuous evaluation) and End Sem Examinations, |
| I, II | **CO2:** Interpret the Regulatory guidance and guidelines for filing and approval process | Class room lectures though online resources, practical demonstrations, case based presentations, scientific report discussions. | Seminar, quiz, assignments, report writing, Internal assessments (Sessional exams), continuous evaluation) and End Sem Examinations, |

| | | | |
|---|---|---|---|
| II, III | **CO3:** Prepare Dossiers and their submission to regulatory agencies in different countries. | Class room lectures though online resources, concept videos, scientific report discussions. | Seminar, quiz, assignments, report writing, Internal assessments (Sessional exams), continuous evaluation) and End Sem Examinations, |
| I, II | **CO4:** Understand the Post approval regulatory requirements for API and drug products | Class room lectures though online resources, concept videos, practical demonstrations, case based presentations, scientific review paper discussions. | Seminar, quiz, assignments, report writing, Internal assessments (Sessional exams), continuous evaluation) and End Sem Examinations, |
| II, IV | **CO5:** Evaluate the submission of global documents in CTD/eCTD formats including approval documents for conducting clinical trials. | Class room lectures though online resources, concept videos, practical demonstrations, case based presentations. | Seminar, quiz, assignments, report writing, Internal assessments (Sessional exams), continuous evaluation) and End Sem Examinations. |

**PHARMACEUTICS PRACTICAL - I (MPH 105 P)**

**Detailed Syllabus**

| Modules | Topics (ifapplicable) & Course Contents | Periods |
|---|---|---|
| **I.** | 1. Analysis of pharmacopoeial compounds and their formulations by UV-Vis spectrophotometer<br>2. Simultaneous estimation of multi-component containing formulations by UV spectrophotometry.<br>3. Experiments based on HPLC<br>4. Experiments based on Gas Chromatography | **12 hr/wk** |
| **II.** | 5. Estimation of riboflavin/quinine sulphate by fluorimetry<br>6. Estimation of sodium/potassium by flame photometry<br>7. To perform In-vitro dissolution profile of CR/SR marketed formulation<br>8. Formulation and evaluation of sustained release matrix tablets<br>9. Formulation and evaluation osmotically controlled DDS | **12 hr/wk** |
| **III.** | 10. Preparation and evaluation of Floating DDS-hydrodynamically balanced DDS<br>11. Formulation and evaluation of Mucoadhesive tablets.<br>12. Formulation and evaluation of transdermal patches.<br>13. To carry out preformulation studies of tablets.<br>14. To study the effect of compressional force on tablets disintegration time. | **12 hr/wk** |
| **IV** | 15. To study Micromeritic properties of powders and granulation.<br>16. To study the effect of particle size on dissolution of a tablet.<br>17. To study the effect of binders on dissolution of a tablet.<br>18. To plot Heckal plot, Higuchi and peppas plot and determine similarity factors. | **12 hr/wk** |
| **TOTAL** | | **180 hr** |

# SEMESTER-II SYLLABUS

**Paper I/Subject Name: MOLECULAR PHARMACEUTICS (NANO TECHNOLOGY AND TARGETED DDS (NTDS) CODE: MPH201**

**L-T-P-C: 3-1-0-4 Credit Units: 4 Scheme of evaluation: (T)**

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

**Course Outcome**: Upon completion of the course the student will be able to

**CO1:** Categorize and evaluate the various approaches for development of novel drug delivery systems.

**CO2:** Select drugs and polymers for the design and development of NTDS

**CO3:** Evaluate and design various types of novel drug delivery systems.

**Detailed Syllabus**

| Modules | Topics (ifapplicable) & Course Contents | Period |
|---|---|---|
| I. | **1. Targeted Drug Delivery Systems:** Concepts, Events and biological process involved in drug targeting.Tumor targeting and Brain specific delivery.<br>**2. Targeting Methods:** introduction preparation and evaluation.<br>Nano Particles & Liposomes: Types, preparation and evaluation. | **15 hr** |
| II. | **Micro Capsules / MicroSpheres**: Types, preparation and evaluation, Monoclonal Antibodies; preparation and application, preparation and application of Niosomes, Aquasomes, Phytosomes, Electrosomes. | **15 hr** |
| III. | **Pulmonary Drug Delivery Systems:** Aerosols, propellents, Containers Types, preparation and evaluation, Intra Nasal Route Delivery systems; Types, preparation and evaluation. | **15 Hr** |
| IV | **Nucleic acid based therapeutic delivery system:** Gene therapy, introduction (ex-vivo & in-vivo gene therapy). Potential target diseases for genetherapy (inherited disorder andcancer). Gene expression systems (viral andnonviral gene transfer). Liposomal gene delivery systems. Biodistribution and Pharmacokinetics. Knowledge of therapeutic antisense molecules and aptamers as drugs of future. | **15 hr** |
| **TOTAL** | | **60 hours** |

**TEXTBOOKS:**


1. Molecular Pharmaceutics (Nanothechnology and Targeted Drug Delivery System), N.G Raghavendra Rao, M.A Sheela, Aarati Maurya and Irfan Ali, First Edition, 2024, JEC Publication.
2. Molecular Pharmaceutics: Nanothechnology and Targeted Drug Delivery System, Suryakanta Swain, Sarwar Beg and Rabinarayan Parhi, First Edition, 2019, Woodhead Publishing India in Medicine.


**REFERENCE BOOKS:**


1. Novel Drug Delivery Systems, YW.Chien, 2nd edition, 1992, Marcel Dekker Inc.
2. Controlled Drug Delivery-concepts and advances, S.P.Vyas and R.K. Khar, First edition 2002, VallabhPrakashan.

3. Controlled and Novel Drug Delivery, N.K.Jain, First edition 1997 (reprint in 2001), CBS Publishers & Distributors.

**Teaching Learning Process and Assessment Methods**

| Unit No. | Course Learning Outcomes | Teaching and Learning Activity | Assessment Tasks |
|---|---|---|---|
| I, II, | **CO1:** Categorize and evaluate the various approaches for development of novel drug delivery systems. | Class room lectures though online resources, Educational Softwares, digital simulations, concept videos, practical demonstrations, case based presentations, scientific report discussions (Research articles, research reports etc.) | Seminar, quiz, assignments, journal club, problem based assignments, report writing, Internal assessments (Sessional exams), continuous evaluation) and End Sem Examinations, |
| I, II, III, IV | **CO2:** Select drugs and polymers for the design and development of NTDS | Class room lectures though online resources, Educational Softwares, digital simulations, concept videos, practical demonstrations, case based presentations, scientific report discussions (Research articles, research reports etc.) | Seminar, quiz, assignments, journal club, problem based assignments, report writing, Internal assessments (Sessional exams), continuous evaluation) and End Sem Examinations, |
| III &IV | **CO3:** Evaluate and design various types of novel drug delivery systems. | Class room lectures though online resources, Educational Softwares, digital simulations, concept videos, practical demonstrations, case based presentations, scientific report discussions (Research articles, research reports etc.) | Seminar, quiz, assignments, journal club, problem based assignments, report writing, Internal assessments (Sessional exams), continuous evaluation) and End Sem Examinations, |

**Paper II/Subject Name: ADVANCED BIOPHARMACEUTICS & PHARMACOKINETICS**
**COURSE CODE: MPH202T**

**L-T-P-C: 3-1-0-4** **Credit Units: 4** **Scheme of evaluation: (T)**

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

**Course Outcome**: Upon completion of the course the student will be able to
**CO1:** Apply pharmacokinetic models and parameters to best describe the process of drug absorption, distribution, metabolism and elimination.
**CO2:** Evaluate and estimate the results of biopharmaceutic studies involving drug product equivalency.
**CO3:** Evaluate and design dosage regimens of the drugs using pharmacokinetic and biopharmaceutic parameters.
**CO4:** Apply, analyze and interpret the potential clinical pharmacokinetic problems associated with drug products.

**Detailed Syllabus**

| Modules | Topics (ifapplicable) & Course Contents | Period |
|---|---|---|
| **I.** | **Drug Absorption from the Gastrointestinal Tract:** Gastro intestinal tract, Mechanism of drug absorption, Factors affecting drug absorption, pH–partition theory of drug absorption. Formuulation and physicochemical factors: Dissolution rate, Dissolution process, Noyes–Whitney equation and drug dissolution, Factors affecting the dissolution rate. Gastrointestinal absorption: role 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 dosageform ,Dissolution methods ,Formulation and processing factors, Correlation of invivo data with in vitro dissolution data.Transport model: Permeability-Solubility-Charge State and the pH Partition Hypothesis, Properties of the Gastrointestinal Tract (GIT), pH Microclimate Intracellular pH Environment, Tight-Junction Complex. | **15 hr** |
| **II.** | **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 hr** |
| **III.** | **Pharmacokinetics:** Basicconsiderations, 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 – | **15 Hr** |

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| | Menten equation, estimation of kmaxand vmax. Drug interactions: introduction, the effect of protein- binding interactions, the effect of tissue-binding interactions, cytochrome p450-based drug interactions, drug interactionslinked to transporters. | |
| **IV** | **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 bioequivalencestudies, study designs, cross over study designs, evaluation of the data, bioequivalence example, study submission and drug review process. 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.<br>**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 andpeptides, Monoclonal antibodies, Oligonucleotides, Vaccines (immunotherapy), Gene therapies. | **15 hr** |
| **TOTAL** | | **60 hours** |

**TEXTBOOKS:**


1. Biopharmaceutics and Pharmacokinetics, A. Treatise, D .M. Brahmankar and Sunil B. Jaiswal., First Edition, 2015, Vallab Prakashan.
2. Textbook of Biopharmaceutics and Pharmacokinetics, Dr. Shobha Rani R. Hiremath, Second Edition, 2021, Prism Publications.
3. Advanced Biopharmaceutics and Pharmacikinetics, Md. Rageeb Md. Usman, Atish A. Salunkhe, Pralhad K. Kanke and Kiran D. Baviskar, First Edition, 2020, S Vikas and Company.


**REFERENCE BOOKS:**


1. Biopharmaceutics and Clinical Pharmacokinetics; Milo Gibaldi, Fourth edition, 2005, Pharma Book Syndicate.
2. Applied Biopharmaceutics and Pharmacokinetics; Leon Shargel and Andrew B.C.Yu, Seventh Edition, 2016, McGraw-Hill Education (Asia).
3. Pharmacokinetics; Milo Gibaldi and D. Perrier, Second Edition, 1982, Marcel Dekker Inc.
4. Current Concepts in Pharmaceutical Sciences: Biopharmaceutics, James Swarbrick, 1971, Lea and Febiger.
5. Clinical Pharmacokinetics, Concepts and Applications; MalcolmRowland and Thom~N. Tozer, Third Edition, 1995, Lea and Febiger.
6. Dissolution, Bioavailability and Bioequivalence, Abdou. H.M, 1989, Mack PublishingCompany.
7. Biopharmaceutics and Clinical Pharmacokinetics, An Introduction, Robert. E.Notari, 4th edition, 1987, Marcel Dekker Inc.
8. Biopharmaceutics and Relevant Pharmacokinetics; John.G Wagner and M.Pemarowski, First edition, 1971, Drug Intelligence Publications.
9. Encyclopedia of Pharmaceutical Technology, James Swarbrick, James. G.Boylan, Volume 13, 1996, Marcel Dekker Inc.
10. Basic Pharmacokinetics, Sunil S Jambhekar and Philip J Breen, First Edition, 2009, Pharmaceutical press, RPSPublishing.
11. Absorption and Drug Development- Solubility, Permeability and Charge State, Alex Avdeef, 2003, John Wiley & Sons, Inc.

**Teaching Learning Process and Assessment Methods**

| Unit No. | Course Learning Outcomes | Teaching and Learning Activity | Assessment Tasks |
|---|---|---|---|
| I, II, | **CO1:** Apply pharmacokinetic models and parameters to best describe the process of drug absorption, distribution, metabolism and elimination. | Class room lectures though online resources, Educational Softwares, digital simulations, concept videos, practical demonstrations, case based presentations, scientific report discussions (Research articles, research reports etc.) | Seminar, quiz, assignments, journal club, problem based assignments, report writing, Internal assessments (Sessional exams), continuous evaluation) and End Sem Examinations, |
| I, II, III, IV | **CO2:** Evaluate and estimate the results of biopharmaceutic studies involving drug product equivalency. | Class room lectures though online resources, Educational Softwares, digital simulations, concept videos, practical demonstrations, case based presentations, scientific report discussions (Research articles, research reports etc.) | Seminar, quiz, assignments, journal club, problem based assignments, report writing, Internal assessments (Sessional exams), continuous evaluation) and End Sem Examinations, |
| II, III &IV | **CO3:** Evaluate and design dosage regimens of the drugs using pharmacokinetic and biopharmaceutic parameters. | Class room lectures though online resources, Educational Softwares, digital simulations, concept videos, practical demonstrations, case based presentations, scientific report discussions (Research articles, research reports etc.) | Seminar, quiz, assignments, journal club, problem based assignments, report writing, Internal assessments (Sessional exams), continuous evaluation) and End Sem Examinations, |
| III&IV | **CO4:** Apply, analyze and interpret the potential clinical pharmacokinetic problems associated with drug products. | Class room lectures though online resources, Educational Softwares, digital simulations, concept videos, practical demonstrations, case based presentations, scientific report discussions (Research articles, research reports etc.) | Seminar, quiz, assignments, journal club, problem based assignments, report writing, Internal assessments (Sessional exams), continuous evaluation) and End Sem Examinations, |

**Paper III/Subject Name: COMPUTER AIDED DRUG DEVELOPMENT**
**COURSE CODE: MPH203T**

**L-T-P-C: 3-1-0-4** **Credit Units: 4** **Scheme of evaluation: (T)**

**Objective:** 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 ofcomputerized information (informatics) in the drug development process are provided to help the students to clarify the concepts.

**Course Outcome**: Upon completion of the course the student will be able to
**CO1:** Understand the history of Computers in Pharmaceutical Research and Development.
CO2: Identify and apply the tools of Computational Modeling in preclinical and drug disposition studies.
CO3: Apply OptimizationTechniques in Pharmaceutical Formulation
CO4: Experiment and analyze market analysis data using Computer.
CO5: Utilize, analyze and create study design using clinical data in Computers.
CO6: Learn and solve problems using Artificial Intelligence (AI), Robotics and computational fluid dynamics.

**Detailed Syllabus**

| Modules | Topics (ifapplicable) & Course Contents | Period |
|---|---|---|
| **I.** | **a. Computers in Pharmaceutical Research and Development:** A General Overview: History of Computers in Pharmaceutical Research and Development. Statistical modeling in Pharmaceutical research anddevelopment: Descriptive versus Mechanistic Modeling, Statistical Parameters, Estimation, Confidence Regions, Nonlinearity at the Optimum, Sensitivity Analysis, Optimal Design,PopulationModeling **b.Quality-by-Design In Pharmaceutical Development:** Introduction, ICH Q8guideline, Regulatory andindustry views on QbD, Scientifically based QbD - examplesof application. | **15 hr** |
| **II.** | **Computational Modeling Of Drug Disposition:** Introduction ,Modeling Techniques: Drug Absorption, Solubility, Intestinal Permeation, Drug Distribution ,Drug Excretion, Active Transport; P-gp, BCRP, Nucleoside Transporters, hPEPT1, ASBT, OCT, OATP, BBB-Choline Transporter | **15 hr** |
| **III.** | **Computer-aided formulation development:** Concept of optimization, Optimization parameters, Factorial design, Optimization technology & Screening design. Computers in Pharmaceutical Formulation: Development of pharmaceutical emulsions, microemulsion drug carriers Legal Protection of Innovative Uses of Computers in R&D, The Ethics of Computingin Pharmaceutical Research, Computers in Market analysis | **15 Hr** |

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| **IV** | **a. Computer-aided biopharmaceutical characterization:** Gastrointestinal absorption simulation. Introduction, Theoretical background, Model construction, Parameter sensitivity analysis, Virtual trial, Fed vs.fasted state, Invitro dissolution andin vitro- in vivo correlation, Biowaiver considerations<br>**b.Computer Simulations in Pharmacokinetics and Pharmacodynamics:** Introduction, Computer Simulation: Whole Organism, Isolated Tissues, Organs, Cell, Proteins and Genes.<br>c. **Computers in Clinical Development:** Clinical Data Collection and Management, Regulation of Computer Systems<br>**Artificial Intelligence (AI), Robotics and Computational fluid dynamics:** General overview, Pharmaceutical Automation, Pharmaceutical applications, Advantages and Disadvantages. CurrentChallengesandFutureDirections. | **15 hr** |
| **TOTAL** | | **60 hours** |

**TEXTBOOKS:**

1. Computer Aided Drug Development, Rabinarayan Parhi, Suryakanta Swain and Sandip Prasad Tiwari, First Edition, 2022, Woodhead Publishing India Pvt. Ltd.
2. Computer Aided Drug Development, Karri VVS Narayana Reddy, K. Gowthamarajan and Arun Radhakrishnan, First Edition, 2020, Pee Vee Publication.

**REFERENCE BOOKS:**

1. ComputerApplications in Pharmaceutical Research and Development, Sean Ekins, 2006, John Wiley & Sons.
2. Computer-Aided Applications in Pharmaceutical Technology, Jelena Djuris, First Edition, Woodhead Publishing.
3. Encyclopedia of Pharmaceutical Technology, JamesSwarbrick, James. G.Boylan, Volume 13, 1996, Marcel Dekker Inc.

**Teaching Learning Process and Assessment Methods**

| Unit No. | Course Learning Outcomes | Teaching and Learning Activity | Assessment Tasks |
|---|---|---|---|
| I, II, | **CO1:** Understand the history of Computers in Pharmaceutical Research and Development. | Class room lectures though online resources, Educational Softwares, digital simulations, concept videos, practical demonstrations, case based presentations, scientific report discussions (Research articles, research reports etc.) | Seminar, quiz, assignments, journal club, problem based assignments, report writing, Internal assessments (Sessional exams), continuous evaluation) and End Sem Examinations, |
| I, II, III, IV | **CO2:** Identify and apply the tools of Computational Modeling in preclinical and drug disposition studies. | Class room lectures though online resources, Educational Softwares, digital simulations, concept videos, practical demonstrations, case based | Seminar, quiz, assignments, journal club, problem based assignments, report writing, Internal assessments (Sessional exams), continuous evaluation) and End Sem Examinations, |

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|---|---|---|---|
| | | presentations, scientific report discussions (Research articles, research reports etc.) | |
| II, III &IV | **CO3:** Apply OptimizationTechniques in Pharmaceutical Formulation | Class room lectures though online resources, Educational Softwares, digital simulations, concept videos, practical demonstrations, case based presentations, scientific report discussions (Research articles, research reports etc.) | Seminar, quiz, assignments, journal club, problem based assignments, report writing, Internal assessments (Sessional exams), continuous evaluation) and End Sem Examinations, |
| III&IV | **CO4:** Experiment and analyze market analysis data using Computer. | Class room lectures though online resources, Educational Softwares, digital simulations, concept videos, practical demonstrations, case based presentations, scientific report discussions (Research articles, research reports etc.) | Seminar, quiz, assignments, journal club, problem based assignments, report writing, Internal assessments (Sessional exams), continuous evaluation) and End Sem Examinations, |
| I, II, IV | **CO5:** CO5: Utilize, analyze and create study design using clinical data in Computers. | Class room lectures though online resources, Educational Softwares, digital simulations, concept videos, practical demonstrations, case based presentations, scientific report discussions (Research articles, research reports etc.) | Seminar, quiz, assignments, journal club, problem based assignments, report writing, Internal assessments (Sessional exams), continuous evaluation) and End Sem Examinations, |
| IV | **CO6:** Learn and solve problems using Artificial Intelligence (AI), Robotics and computational fluid dynamics. | Class room lectures though online resources, Educational Softwares, digital simulations, concept videos, practical demonstrations, case based presentations, scientific report discussions (Research articles, research reports etc.) | Seminar, quiz, assignments, journal club, problem based assignments, report writing, Internal assessments (Sessional exams), continuous evaluation) and End Sem Examinations, |

**Paper IV/Subject Name: COSMETICS AND COSMECEUTICALS**
**COURSE CODE: MPH204T**

**L-T-P-C: 3-1-0-4** **Credit Units: 4** **Scheme of evaluation: (T)**

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

**Course Outcome**: Upon completion of the course the student will be able to
**CO1:** Identify and evaluate the key ingredients used in cosmetics and cosmeceuticals.
**CO2:** Choose and combine Key building blocks for various cosmetic formulations.
**CO3:** Understand, apply and evaluate the current technologies in the market
**CO4:** Select and design cosmetics and cosmeceuticals using key ingredients.
**CO5:** Design studies to evaluate safety, stability and efficacy of cosmetics and cosmeceuticals.

**Detailed Syllabus**

| Modules | Topics (ifapplicable) & Course Contents | Period |
|---|---|---|
| I. | **Cosmetics –Regulatory:** Definitionof cosmetic products as per Indian regulation. Indian regulatory requirements for labelingof cosmeticsRegulatoryprovisions 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. | **15 hr** |
| II. | **Cosmetics-Biological aspects:** Structure of skin relating to problems like dry skin, acne, pigmentation, prickly heat, wrinkles and bodyodor. Structure of hairandhair growth cycle. Common problems associated with oral cavity.Cleansing and careneeds forface, eyelids, lips,hands,feet,nail,scalp,neck, bodyand under-arm. | **15 hr** |
| III. | **Formulation Building blocks**: Building blocks for different product formulations of cosmetics/cosmeceuticals. Surfactants– Classification and application. Emollients, rheological additives: classification and application.Antimicrobial usedas 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 syndetbars. **Perfumes;** Classification of perfumes. Perfume ingredients listed As allergens in EU regulation. Controversial ingredients: Parabens, formaldehyde liberators, dioxane | **15 Hr** |
| IV | **Design of cosmeceutical products:** Sun protection, sunscreens classification andregulatory aspects. Addressing dry skin, acne, sun-protection, pigmentation, prickly heat, wrinkles, body odor., dandruff,dental cavities, bleedinggums, mouthodorand sensitive teeth through cosmeceutical formulations. **HerbalCosmetics:** Herbal ingredients used in Haircare, 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. | **15 hr** |
| **TOTAL** | | **60 hours** |

**TEXTBOOKS:**

1. Cosmetics and Cosmeceuticals, Shailesh Sharma, Neelam Sharma and Punam Gaba, First Edition, 2022, Nirali Prakashan.
2. Text book of Cosmetics and Cosmeceuticals, Shikha Baghel Chauhan, First Edition, 2022, Walnut Publication.

**REFERENCE BOOKS:**

1. Harry's Cosmeticology, Martin M. Rieger, Eight Edition, 2009, Chemical Publishing Co. Inc.
2. Poucher'sperfumecosmeticsandSoaps, H. Butler, Tenth Edition, 2000, Chapman and Hall.
3. Cosmetics - Formulation, Manufacture and quality control, PP.Sharma, Fourth Edition, Vandana Publications Pvt. Ltd.
4. Handbook of cosmetic science and Technology, Andre.O.Barel, Marc.Paye and Howard.I.Maibach, Third Edition, 2009, Taylor & Francis.
5. Cosmetic and Toiletriesrecent suppliers catalogue.
6. CTFAdirectory.

**Teaching Learning Process and Assessment Methods**

| Unit No. | Course Learning Outcomes | Teaching and Learning Activity | Assessment Tasks |
|---|---|---|---|
| II,III, IV | **CO1:** Identify and evaluate the key ingredients used in cosmetics and cosmeceuticals. | Class room lectures though online resources, Educational Softwares, digital simulations, concept videos, practical demonstrations, case based presentations, scientific report discussions (Research articles, research reports etc.) | Seminar, quiz, assignments, journal club, problem based assignments, report writing, Internal assessments (Sessional exams), continuous evaluation) and End Sem Examinations, |
| III, IV | **CO2:** Choose and combine Key building blocks for various cosmetic formulations. | Class room lectures though online resources, Educational Softwares, digital simulations, concept videos, practical demonstrations, case based presentations, scientific report discussions (Research articles, research reports etc.) | Seminar, quiz, assignments, journal club, problem based assignments, report writing, Internal assessments (Sessional exams), continuous evaluation) and End Sem Examinations, |
| I, II, III &IV | **CO3:** Understand, apply and evaluate the current technologies in the market | Class room lectures though online resources, Educational Softwares, digital simulations, concept videos, practical demonstrations, case based presentations, scientific report discussions (Research articles, research reports etc.) | Seminar, quiz, assignments, journal club, problem based assignments, report writing, Internal assessments (Sessional exams), continuous evaluation) and End Sem Examinations, |

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| II, III &IV | **CO4:** Select and design cosmetics and cosmeceuticals using key ingredients. | Class room lectures though online resources, Educational Softwares, digital simulations, concept videos, practical demonstrations, case based presentations, scientific report discussions (Research articles, research reports etc.) | Seminar, quiz, assignments, journal club, problem based assignments, report writing, Internal assessments (Sessional exams), continuous evaluation) and End Sem Examinations, |
| IV | **CO5:** Design studies to evaluate safety, stability and efficacy of cosmetics and cosmeceuticals. | Class room lectures though online resources, Educational Softwares, digital simulations, concept videos, practical demonstrations, case based presentations, scientific report discussions (Research articles, research reports etc.) | Seminar, quiz, assignments, journal club, problem based assignments, report writing, Internal assessments (Sessional exams), continuous evaluation) and End Sem Examinations, |

**PHARMACEUTICS PRACTICAL - II (MPH 205 P)**

**Detailed Syllabus**

| Modules | Topics (ifapplicable) & Course Contents | Periods |
|---|---|---|
| **I.** | 1. To study the effect of temperature change, non solvent addition, incompatible polymer addition in microcapsules preparation<br>2. Preparation and evaluation of Alginate beads<br>3. Formulation and evaluation of gelatin/album in microspheres<br>4. Formulation and evaluation of liposomes/niosomes<br>5. Formulation and evaluation of spherules<br>6. Improvement of dissolution characteristics of slightly soluble drug by Solid dispersion technique. | **12 hr/wk** |
| **II.** | 7. Comparison of dissolution of two different marketed products/brands<br>8. Protein binding studies of a highly protein bound drug & poorly protein bound drug<br>9. Bioavailability studies of Paracetamol in animals.<br>10. Pharmacokinetic and IVIVC data analysis by Winnoline R software<br>11. Invitro cell studies for permeability and metabolism | **12 hr/wk** |
| **III.** | 12. DoE Using Design Expert® Software<br>13. Formulation data analysis Using DesignExpert®Software<br>14. Quality-by-Design in Pharmaceutical Development<br>15. Computer Simulations in Pharmacokinetics and Pharmacodynamics<br>16. Computational Modeling Of Drug Disposition | **12 hr/wk** |
| **IV** | 17. To develop Clinical Data Collection manual<br>18. To carryout Sensitivity Analysis, and Population Modeling.<br>19. Development and evaluation of Creams<br>20. Development and evaluation of Shampoo and Toothpaste base<br>21. To incorporate herbal and chemical actives to develop products<br>22. To address Dryskin, acne, blemish,Wrinkles, bleeding gums and dandruff | **12 hr/wk** |
| **TOTAL** | | **180 hr** |