**Evaluation Scheme & Syllabus**

**For**

**Master of Pharmacy (M.Pharm.)**

 **(Pharmaceutics)**

 **First Year (1st Semester)**

**AS PER PHARMACY COUNCIL OF INDIA**

(Effective from the Session: 2019-20)



**IIMT UNIVERSITY**

**IIMT Nagar, ‘O’ Pocket, Ganga Nagar Colony, Mawana Road, Meerut (U.P.)**

**Ph. : (0121) 2793500 To 507 Fax.: (0121) 2793600**

 **Website: iimtu.com**

***M.PHARM (PHARMACEUTICS)***

***Semester- I***

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| ***S.N.*** | ***Subject Code*** | ***Name of the Subject*** | ***Periods*** | ***Evaluation Scheme*** | ***Subject Total*** | ***Credits*** |
| ***L*** | ***T*** | ***P*** | ***Theory*** | ***Practical*** |
| ***CT*** | ***TA*** | ***ESE*** | ***TA*** | ***ESE*** |
| ***Discipline Specific Papers*** |
| ***Core Subject Code*** | ***Core Subject Name*** |
| *1* | *MPH101T* | *Modern Pharmaceutical Analytical Techniques* | *3* | *1* | *0* | *15* | *10* | *75* | *--* | *--* | *100* | *4* |
| *2* | *MPH102 T* | *Drug Delivery System* | *3* | *1* | *0* | *15* | *10* | *75* | *--* | *--* | *100* | *4* |
| *3* | *MPH103 T* | *Modern Pharmaceutics* | *3* | *1* | *0* | *15* | *10* | *75* | *--* | *--* | *100* | *4* |
| *4* | *MPH104 T* | *Regulatory Affair* | *3* | *1* | *0* | *15* | *10* | *75* | *--* | *--* | *100* | *4* |
| ***Practical + Tutorial*** |
| ***Course Code*** | ***Course Name*** |
| *1* | *MPH105 P* | *Pharmaceutics Practical I* | *0* |  | *12* | *--* | *--* | *--* | *50* | *100* | *150* | *6* |
| ***Elective Discipline Specific***  |
| ***Course Code*** | ***Course Name*** |
| *1* |  | *Seminar / Assignment* | *0* | *0* | *7* | *-* | *-* | *-* | *-* | *-* | *100* | *4* |
| *2* |  | *Sports* |  |  |  |  |  |  |  |  | *50* |  |
| ***Total*** | ***650*** | ***26*** |  |  |  |  |  |  |  |  | ***1000*** |

|  |
| --- |
| **MODERN PHARMACEUTICAL ANALYTICAL TECHNIQUES** |
| **Course Code (MPH101T)** | **Theory Course** | **L-T-P-C** | **3-1-0-4** |
| **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. |
| **Objective** | After completion of course student is able to know about chemicals and excipients.* The analysis of various drugs in single and combination dosage forms
* Theoretical and practical skills of the instruments
 |
| **Course Contents** | **HOURS** |
| **Unit I** | 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, Difference/ Derivative spectroscopy.
2. **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.
3. **Spectroflourimetry:** Theory of Fluorescence, Factors affecting fluorescence (Characteristics of drugs that can be analyzed by flourimetry), Quenchers, Instrumentation and Applications of fluorescence spectrophotometer.
4. **Flame emission spectroscopy and Atomic absorption spectroscopy:** Principle, Instrumentation, Interferences and Applications.
 | **12hrs** |
| **Unit 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 coupling, Coupling constant, Nuclear magnetic double resonance,Brief outline of principles of FT-NMR and 13C NMR. Applications of NMR spectroscopy.**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. | **12hrs** |
| **Unit III** | **Chromatography**: Principle, apparatus, instrumentation, chromatographic parameters, factors affecting resolution, isolation of drug from excipients, data interpretation and applications of the following:1. Thin Layer chromatography
2. High Performance Thin Layer Chromatography
3. Ion exchange chromatography
4. Column chromatography
5. Gas chromatography
6. High Performance Liquid chromatography
7. Ultra High Performance Liquid chromatography
8. Affinity chromatography

Gel Chromatography | **12hrs** |
| **Unit IV** | **Electrophoresis:** Principle, Instrumentation, Working conditions, factors affecting separation and applications of the following:1. Paper electrophoresis
2. Gel electrophoresis
3. Capillary electrophoresis
4. Zone electrophoresis
5. Moving boundaryelectrophoresis
6. Iso electric focusing .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
 | **12hrs** |
| **Unit V** | **a. Potentiometry:** Principle, working, Ion selective Electrodesand Application of potentiometry.**b**. **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. Differential Thermal Analysis (DTA): Principle, instrumentation and advantage and disadvantages, pharmaceutical applications, derivative differential thermal analysis (DDTA). TGA: Principle,instrumentation, factors affecting results, advantage and disadvantages, pharmaceutical applications. | **12hrs** |
| **References** | 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. Instrumental methods of analysis – Willards, 7th edition, CBS publishers.
4. Practical Pharmaceutical Chemistry – Beckett and Stenlake, Vol II, 4th edition, CBS Publishers, New Delhi, 1997.
5. Organic Spectroscopy - William Kemp, 3rd edition, ELBS, 1991.
6. Quantitative Analysis of Drugs in Pharmaceutical formulation - P D Sethi, 3rd Edition, CBS Publishers, New Delhi, 1997.
7. Pharmaceutical Analysis - Modern Methods – Part B - J W Munson, Vol 11, Marcel. Dekker Series
8. Spectroscopy of Organic Compounds, 2nd edn., P.S/Kalsi, Wiley estern Ltd., Delhi.

Textbook of Pharmaceutical Analysis, KA.Connors, 3rd Edition, John Wiley & Sons, 1982. |

|  |
| --- |
| **DRUG DELIVERY SYSTEMS** |
| **Course Code (MPH102T)** | **Theory Course** | **L-T-P-C** | **3-1-0-4** |
| **Scope** | This course is designed to impart knowledge on the area of advances in novel drug delivery systems. |
| **Objective** | Upon completion of the course, student shall be able to understand* The various approaches for development of novel drug delivery systems.
* The criteria for selection of drugs and polymers for the development of delivering system
* The formulation and evaluation of Novel drug delivery systems.
 |
| **Course Contents** | **HOURS** |
| **Unit I** | **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 Dosage Forms for Personalized Medicine: Introduction, Definition, Pharmacogenetics, Categories of Patients for Personalized Medicines: Customized drug delivery systems, Bioelectronic Medicines, 3D printing of pharmaceuticals, Telepharmacy. | **12 hrs** |
| **Unit II** | **Rate of Controlled Drug Delivery Systems:** Principles & Fundamentals, Types, Activation; Modulated Drug Delivery Systems;Mechanically activated, pH activated, Enzyme activated, and Osmotic activated Drug Delivery Systems Feedbackregulated Drug Delivery Systems; Principles & Fundamentals. | **12 hrs** |
| **Unit III** | **Gastro-Retentive Drug Delivery Systems:** Principle, concepts advantages and disadvantages, Modulation of GI transit timeapproaches to extend GI transit. Buccal Drug Delivery Systems: Principle of muco adhesion, advantages anddisadvantages, Mechanism of drug permeation, Methods of formulation and its evaluations. | **12 hrs** |
| **Unit IV** | **Occular Drug Delivery Systems:** Barriers of drug permeation, Methods to overcome barriers.**Vaccine delivery systems**: Vaccines, uptake of antigens, single shot vaccines, mucosal and transdermal delivery of vaccines. | **12 hrs** |
| **Unit V** | **Transdermal Drug Delivery Systems:** Structure of skin and barriers, Penetration enhancers, Transdermal Drug DeliverySystems, Formulation and evaluation.**Protein and Peptide Delivery:** Barriers for protein delivery. Formulation and Evaluation of delivery systems of proteins andother macromolecules. | **12 hrs** |
| **References** | 1. Y W. Chien, Novel Drug Delivery Systems, 2nd edition, revised and expanded, Marcel Dekker, Inc., New York, 1992.
2. Robinson, J. R., Lee V. H. L, Controlled Drug Delivery Systems, Marcel Dekker,Inc., New York, 1992.
3. Encyclopedia of controlled delivery, Editor- Edith Mathiowitz, Published by WileyInterscience Publication, John Wiley and Sons, Inc, New York! Chichester/Weinheim
4. N.K. Jain, Controlled and Novel Drug Delivery, CBS Publishers & Distributors, New Delhi, First edition 1997 (reprint in 2001).
5. S.P.Vyas and R.K.Khar, Controlled Drug Delivery - concepts and advances, VallabhPrakashan, New Delhi, First edition 2002
 |
| **Journals** | **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
 |

|  |
| --- |
| **MODERN PHARMACEUTICS** |
| **Course Code (MPH103T)** | **Theory Course** | **L-T-P-C** | **3-1-0-4** |
| **Scope** | Course designed to impart advanced knowledge and skills required to learn various aspects and concepts at pharmaceutical industries |
| **Objective** | Upon completion of the course, student shall be able to understand* The elements of preformulation studies.
* The Active Pharmaceutical Ingredients and Generic drug Product development
* Industrial Management and GMP Considerations.
* Optimization Techniques & Pilot Plant Scale Up Techniques
* Stability Testing, sterilization process & packaging of dosage forms.
 |
| **Course Contents** | **HOURS** |
| **Unit I** | **a. Preformation Concepts** – Drug Excipient interactions - different methods, kinetics of stability, Stability testing. Theories of dispersion and pharmaceutical Dispersion (Emulsion and Suspension, SMEDDS) preparation and stability Large and smallvolume parental – physiological and formulation consideration, Manufacturing and evaluation.**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 | **12 hrs** |
| **Unit II** | **Validation :** Introduction to Pharmaceutical Validation, Scope & merits of Validation, Validation and calibration of Master plan, ICH & WHO guidelines for calibration and validation of equipments, Validation of specific dosage form, Types ofvalidation. Government regulation, Manufacturing Process Model, URS, DQ, IQ, OQ & P.Q. of facilities. | **12 hrs** |
| **Unit 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, industrial and personal relationship. Concept of Total Quality Management. | **12 hrs** |
| **Unit IV** | **Compression and compaction**: Physics of tablet compression, compression, consolidation, effect of friction, distribution offorces, compaction profiles. Solubility. | **12 hrs** |
| **Unit V** | **Study of consolidation parameters;** Diffusion parameters, Dissolution parameters and Pharmacokinetic parameters, Heckelplots, Similarity factors – f2 and f1, Higuchi and Peppas plot, Linearity Concept of significance, Standard deviation , Chi square test, students T-test , ANOVA test. | **12 hrs** |
| **References** | 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; By Sidney H. Willig.
11. Quality Assurance Guide; By Organization of Pharmaceutical producers of India.
12. 12.Drug formulation manual; By D.P.S. Kohli and D.H.Shah. Eastern publishers, New Delhi.
13. How to practice GMPs; By P.P.Sharma. Vandhana Publications, Agra.
14. Pharmaceutical Process Validation; By Fra. R. Berry and Robert A. Nash.
15. Pharmaceutical Preformulations; By J.J. Wells.
16. Applied production and operations management; By Evans, Anderson, Sweeney and Williams.
17. Encyclopaedia of Pharmaceutical technology, Vol I – III.
 |
| **REGULATORY AFFAIRS** |
| **Course Code (MPH104T)** | **Theory Course** | **L-T-P-C** | **3-1-0-4** |
| **Scope** | Course designed to impart advanced knowledge and skills required to learn 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 * To know the approval process of
* To know the chemistry, manufacturing controls and their regulatory importance
* To learn the documentation requirements for
* To learn the importance and
 |
| **Objective** | Upon completion of the course, it is expected that the students will be able to understand* The Concepts of innovator and generic drugs, drug development process
* The Regulatory guidance’s and guidelines for filing and approval process
* Preparation of Dossiers and their submission to regulatory agencies in different countries
* Post approval regulatory requirements for actives and drug products
* Submission of global documents in CTD/ eCTD formats
* Clinical trials requirements for approvals for conducting clinical trials
* Pharmacovigilence and process of monitoring in clinical trials.
 |
| **Course Contents** | **HOURS** |
| **Unit I** | **Documentation in Pharmaceutical industry:**Masterformula 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. | **12 hrs** |
| **Unit II** | **Regulatory requirement for product approval:** API, biologics, novel, therapies obtaining NDA, ANDA for generic drugs ways and means of US registration for foreign drugs. | **12 hrs** |
| **Unit III** | 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 ROW countries. | **12 hrs** |
| **Unit IV** | **Non clinical drug development:** Global submission of IND, NDA, ANDA. Investigation of medicinal products dossier, dossier (IMPD) and investigator brochure (IB). | **12 hrs** |
| **Unit V** | **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. | **12 hrs** |
| **References** | * 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
	7. www.ich.org/
	8. www.fda.gov/
	9. europa.eu/index\_en.htm
	10. <https://www.tga.gov.au/tga-basics>
 |

|  |
| --- |
| **PHARMACEUTICS PRACTICAL – I** |
| **Course Code (MPH105P)** | **Practical** | **L-T-P-C** | **0-0-12-6** |
| **Course Contents** |
| **Experiment-I** | To perform In-vitro dissolution profile of CR/ SR marketed formulation |
| **Experiment-II** | Formulation and evaluation of sustained release matrix tablets |
| **Experiment-III** | Formulation and evaluation osmotically controlled DDS |
| **Experiment-IV** | Preparation and evaluation of Floating DDS- hydro dynamically balanced DDS |
| **Experiment-V** | Formulation and evaluation of Muco adhesive tablets. |
| **Experiment-VI** | Formulation and evaluation of trans dermal patches. |
| **Experiment-VII** | To carry out preformulation studies of tablets. |
| **Experiment-VIII** | To study the effect of compressional force on tablets disintegration time |
| **Experiment-IX** | To study Micromeritic properties of powders and granulation |
| **Experiment-X** | To study the effect of particle size on dissolution of a tablet |
| **Experiment-XII** | To study the effect of binders on dissolution of a tablet |
| **Experiment-XIII** | To plot Heckal plot, Higuchi and peppas plot and determine similarity factors |

***M.PHARM (PHARMACEUTICS)***

***Semester- II***

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| ***S.No.*** | ***Subject Code*** | ***Name of the Subject*** | ***Periods*** | ***Evaluation Scheme*** | ***Subject Total*** | ***Credits*** |
| ***L*** | ***T*** | ***P*** | ***Theory*** | ***Practical*** |
| ***CT*** | ***TA*** | ***ESE*** | ***TA*** | ***ESE*** |
| ***Discipline Specific Papers*** |
| ***Core Subject Code*** | ***Core Subject Name*** |
| *1* | *MPH201T* | *Molecular Pharmaceutics (Nano Technology &Targeted Dds) (Ntds)* | *3* | *1* | *0* | *10* | *15* | *75* | *--* | *--* | *100* | *4* |
| *2* | *MPH202T* | *Advanced Biopharmaceutics& Pharmacokinetics* | *3* | *1* | *0* | *10* | *15* | *75* | *--* | *--* | *100* | *4* |
| *3* | *MPH203T* | *Computer Aided Drug Development* | *3* | *1* | *0* | *10* | *15* | *75* | *--* | *--* | *100* | *4* |
| *4* | *MPH204T* | *Cosmetics And Cosmeceuticals* | *3* | *1* | *0* | *10* | *15* | *75* | *--* | *--* | *100* | *4* |
| ***Practical + Tutorial*** |
| ***Course Code*** | ***Course Subject*** |
| *1* | *MPH205P* | *Pharmaceutics Practical - II* | *-* | *-* | *12* | *--* | *--* | *--* | *50* | *100* | *150* | *6* |
| ***Elective Discipline Specific*** |
| ***Course Code*** | ***Course Name*** |
| *1* |  | *Seminar / Assignment* | *0* | *-* | *7* |  | *-* | *-* | *100* | *-* | *100* | *4* |
| *2* |  | *Sports* |  |  |  |  |  |  |  |  | *50* |  |
| ***Total*** | ***650*** | ***22*** |

|  |
| --- |
| **MOLECULAR PHARMACEUTICS (NANO TECHNOLOGY &TARGETED DDS) (NTDS)** |
| **Course Code MPH201T** | **Theory Course** | **L-T-P-C** | **3-1-0-4** |
| **Scope:** This course is designed to impart knowledge on the area of advances in novel drug delivery systems. |
| **Objectives**: Upon completion of the course student shall be able to understand* The various approaches for development of novel drug delivery systems.
* The criteria for selection of drugs and polymers for the development of NTDS
* The formulation and evaluation of novel drug delivery systems.
 |
| **Course Contents** | **HOURS** |
| **Unit I** | Targeted Drug Delivery Systems: Concepts, Events and biological process involved in drug targeting. Tumor targeting and Brain specific delivery. | **12** |
| **Unit II** | Targeting Methods: introduction preparation and evaluation.Nano Particles & Liposomes: Types, preparation and evaluation. | **12** |
| **Unit III** | Micro Capsules / Micro Spheres: Types, preparation andevaluation , Monoclonal Antibodies ; preparation and application,preparation and application of Niosomes, Aquasomes,Phytosomes, Electrosomes. | **12** |
| **Unit IV** | Pulmonary Drug Delivery Systems: Aerosols, propellents,ContainersTypes, preparation and evaluation, Intra Nasal Route Delivery systems; Types, preparation and evaluation. | **12** |
| **Unit V** | Nucleic acid based therapeutic delivery system : Gene therapy,introduction (ex-vivo & in-vivo gene therapy). Potential targetdiseases for gene therapy (inherited disorder and cancer). Geneexpression systems (viral and nonviral gene transfer). Liposomalgene delivery systems.Biodistribution and Pharmacokinetics. knowledge of therapeuticantisense molecules and aptamers as drugs of future. | **12** |
| **REFERENCES** | 1.Y W. Chien, Novel Drug Delivery Systems, 2nd edition, revised andexpanded,Marcel Dekker, Inc., New York, 1992.2. S.P.Vyas and R.K.Khar, Controlled Drug Delivery - concepts and advances, VallabhPrakashan, New Delhi, First edition 2002.3. N.K. Jain, Controlled and Novel Drug Delivery, CBS Publishers &Distributors, NewDelhi, First edition 1997 (reprint in 2001). |

|  |
| --- |
|  |
|  |
| **ADVANCED BIOPHARMACEUTICS & PHARMACOKINETICS60 Hrs** |
| **Course Code MPH202T** | **Theory Course** | **L-T-P-C** | **3-1-0-4** |
| **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. |
| **Objectives:** Upon completion of this course it is expected that students will be ableunderstand,* The basic concepts in biopharmaceutics and pharmacokinetics.
* The use raw data and derive the pharmacokinetic models and parameters the best describe the process of drug absorption,distribution, metabolism and elimination.
* The critical evaluation of biopharmaceutic studies involving drug product equivalency.
* The design and evaluation of dosage regimens of the drugs using pharmacokinetic and biopharmaceutic parameters.
* The potential clinical pharmacokinetic problems and application of basics of pharmacokinetic
 |
| **Course Contents** | **HOURS** |
| **Unit I** | **Drug Absorption from the Gastrointestinal Tract:**Gastrointestinal 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 dosage form ,Dissolution methods ,Formulation and processing factors, Correlation of in vivo data with in vitro dissolution data. Transport model: Permeability-Solubility-Charge State and the pH Partition Hypothesis, Properties of the Gastrointestinal Tract (GIT), pHMicroclimate Intracellular pH Environment, Tight-Junction Complex. | **12** |
| **Unit 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 drugformulation factors affecting drug product performance, in vitro: dissolution and drug release testing, compendial methods of dissolution, alternative methods of dissolution testing, meetingdissolution requirements,problems of variable control in dissolution testingperformance of drug products. In vitro–in vivo correlation, dissolution profile comparisons, drug productstability,considerations in the design of a drug product. | **12** |
| **Unit III** | **Pharmacokinetics**: Basic considerations, pharmacokinetic models, compartment modeling: one compartment model- IV bolus, IV infusion, extra-vascular. Multi compartment model:twocompartment - model in brief, non-linear pharmacokinetics: cause of non-linearity, Michaelis – Menten equation, estimation of kmax and vmax. Drug interactions: introduction, the effect of proteinbinding interactions, the effect of tissue-binding interactions,cytochromep450-based drug interactions, drug interactions linked to transporters. | **12** |
| **Unit IV** | **Drug Product Performance, In Vivo**: Bioavailability and Bioequivalence: drug product performance, purpose of bioavailability studies, relative and absolute availability. methodsfor 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. Permeability: In-vitro, in-situ and In-vivo methods. generic biologics (biosimilar drugproducts),clinical significance of bioequivalence studies, special concerns in bioavailability and bioequivalence studies, generic substitution. | **12** |
| **Unit V** | **Application of Pharmacokinetics**: Modified-Release Drug Products, Targeted Drug Delivery Systems and Biotechnological Products. Introduction to Pharmacokinetics andpharmacodynamic, drug interactions. Pharmacokinetics and pharmacodynamics of biotechnology drugs. Introduction, Proteins and peptides, Monoclonal antibodies, Oligonucleotides, Vaccines (immunotherapy), Gene therapies. **Analysis of variance:** One-way analysis of variance, Another Example of Variance : Unequal sample sixes and the fixed and random models, Two-way analysis of variance statistical models. Probability distribution: Binomial and normal probability distributions. | **12** |
| **REFERENCES** | 1. Biopharmaceutics and Clinical Pharmacokinetics by Milo Gibaldi, 4thedition,Philadelphia, Lea and Febiger, 19912. Biopharmaceutics and Pharmacokinetics, A. Treatise, D .M. Brahmankar and Sunil B. Jaiswal., VallabPrakashan, Pitampura, Delhi3. Applied Biopharmaceutics and Pharmacokinetics by Shargel. Land YuABC, 2ndedition, Connecticut Appleton Century Crofts, 19854. Textbook of Biopharmaceutics and Pharmacokinetics, Dr. Shobha Rani R. Hiremath,Prism Book5. Pharmacokinetics by Milo Gibaldi and D. Perrier, 2nd edition, Marcel Dekker Inc.,New York, 19826. Current Concepts in Pharmaceutical Sciences: Biopharmaceutics, Swarbrick. J, LeaandFebiger, Philadelphia, 19707. Clinical Pharmacokinetics, Concepts and Applications 3rd edition by MalcolmRowland and Thom~ N. Tozer, Lea and Febiger, Philadelphia, 19958. Dissolution, Bioavailability and Bioequivalence, Abdou. H.M, Mack Publishing Company, Pennsylvania 19899. Biopharmaceutics and Clinical Pharmacokinetics, An Introduction, 4thedition,revised and expande 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,1 stedition,Sunil S JambhekarandPhilip J Breen,pharmaceutical press, RPS Publishing,2009.13. Absorption and Drug Development- Solubility, Permeability, and Charge State, Alex Avdeef, John Wiley & Sons, Inc,2003. |

|  |
| --- |
| **COMPUTER AIDED DRUG DEVELOPMENT 60 Hrs** |
| **Course Code MPH203T** | **Theory Course** | **L-T-P-C** | **3-1-0-4** |
| **Scope**: This course is designed to impart knowledge and skills necessary for computerApplications 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. | **HOURS** |
| **Objectives:** Upon completion of this course it is expected that students will be able tounderstand,* History of Computers in Pharmaceutical Research and Development
* Computational Modeling of Drug Disposition
* Computers in Preclinical Development
* Optimization Techniques in Pharmaceutical Formulation
* Computers in Market Analysis
* Computers in Clinical Development
* Artificial Intelligence (AI) and Robotics
* Computational fluid dynamics(CFD)
 |  |
| **Course Contents** |  |
| **Unit I** | **a. Computers in Pharmaceutical Research and Development:** A General Overview: History of Computers in Pharmaceutical Research and Development. Statistical modeling in Pharmaceutical research and development: Descriptive versus Mechanistic Modeling, Statistical Parameters, Estimation, Confidence Regions, Nonlinearity at the Optimum, Sensitivity Analysis, Optimal Design, Population Modeling**b. Quality-by-Design In Pharmaceutical Development:**Introduction, ICH Q8 guideline, Regulatory and industry views on QbD, Scientifically based QbD - examples of application. | **12** |
| **Unit 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. | **12** |
| **Unit 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 | **12** |
| **Unit IV** | **a. 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 vitroin vivo correlation, Biowaiver considerations**b. Computer Simulations in Pharmacokinetics and****Pharmacodynamics:** Introduction, Computer Simulation: Whole Organism, Isolated Tissues, Organs, Cell, Proteins and Genes.**c. Computers in Clinical Development:** Clinical Data Collection and Management, Regulation of Computer Systems | **12** |
| **Unit V** | **Artificial Intelligence (AI)**, Robotics and Computational fluid dynamics: General overview, Pharmaceutical Automation, Pharmaceutical applications, Advantages and Disadvantages. Current Challenges and Future Directions. Quality control : Introduction, Control Charts, Acceptance sampling and operating characteristics curves, statistical procedures in assay development, establishing in house limits. | **12** |
| **REFERENCES** | 1. Computer Applications in Pharmaceutical Research and Development, Sean Ekins, 2006, John Wiley & Sons.2. Computer-Aided Applications in Pharmaceutical Technology, 1st Edition, JelenaDjuris, Woodhead Publishing3. Encyclopedia of Pharmaceutical Technology, Vol 13, James Swarbrick, James. G.Boylan, Marcel Dekker Inc, New York, 1996. |

|  |
| --- |
| **COSMETICS AND COSMECEUTICALS 60 Hrs** |
| **Course Code MPH204T** | **Theory Course** | **L-T-P-C** | **3-1-0-4** |
| **Scope:** This course is designed to impart knowledge and skills necessary forthefundamental need for cosmetic and cosmeceutical products. |
| * **Objectives:** Upon completion of the course, the students shall be able to understand
* Key ingredients used in cosmetics and cosmeceuticals.
* Key building blocks for various formulations.
* Current technologies in the market
* Various key ingredients and basic science to develop cosmetics and cosmeceuticals
* Scientific knowledge to develop cosmetics and cosmeceuticals withdesired Safety, stability, and efficacy.
 |
| **Course Contents** | **HOURS** |
| **Unit I** | **Cosmetics – Regulatory :** Definition of cosmetic products as perIndian regulation. Indian regulatory requirements for labeling ofcosmetics Regulatory provisions relating to import of cosmetics.,Misbranded and spurious cosmetics. Regulatory provisionsrelating to manufacture of cosmetics – Conditions for obtaininglicense, prohibition of manufacture and sale of certain cosmetics,loan license, offences and penalties. | **12** |
| **Unit II** | **Cosmetics - Biological aspects :** Structure of skin relating toproblems like dry skin, acne, pigmentation, prickly heat, wrinklesand body odor. Structure of hair and hair growth cycle. Commonproblems associated with oral cavity. Cleansing and care needsfor face, eye lids, lips, hands, feet, nail, scalp, neck, body andunder-arm. | **12** |
| **Unit III** | **Formulation Building blocks:** Building blocks for differentproduct formulations of cosmetics/cosmeceuticals. Surfactants –Classification and application. Emollients, rheological additives:classification and application. Antimicrobial used as preservatives,their merits and demerits. Factors affecting microbial preservativeefficacy. Building blocks for formulation of a moisturizing cream,vanishing cream, cold cream, shampoo and toothpaste. Soapsand syndetbars.Perfumes; Classification of perfumes. Perfume ingredients listedas allergens in EU regulation. Controversial ingredients: Parabens, formaldehyde liberators,dioxane. | **12** |
| **Unit IV** | **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** |
| **Unit V** | **Herbal Cosmetics :** Herbal ingredients used in Hair care, skincare 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** |
| **REFERENCES** | 1. Harry’s Cosmeticology. 8th edition.2. Poucher’sperfumecosmeticsandSoaps,10th edition.3. Cosmetics - Formulation, Manufacture and quality control, PP.Sharma,4thedition4. Handbook of cosmetic science and Technology A.O.Barel, M.Paye andH.I. Maibach. 3 rd edition5. Cosmetic and Toiletries recent suppliers catalogue.6. CTFA directory. |

|  |
| --- |
| **PHARMACEUTICS PRACTICALS - II** |
| **Course Code MPH205P** | **Practical** | **L-T-P-C** | **0-0-12-6** |
| **Course Contents** |
| **Experiment-I** | To study the effect of temperature change , non solvent addition,incompatible polymer addition in microcapsules preparation |
| **Experiment-II** | Preparation and evaluation of Alginate beads |
| **Experiment-III** | Formulation and evaluation of gelatin /albumin microspheres |
| **Experiment-IV** | Formulation and evaluation of liposomes/niosomes |
| **Experiment-V** | Formulation and evaluation of spherules |
| **Experiment-VI** | Improvement of dissolution characteristics of slightly soluble drug by Solid dispersion technique. |
| **Experiment – VII** | Comparison of dissolution of two different marketed products /brands |
| **Experiment- VIII** | Protein binding studies of a highly protein bound drug & poorly proteinbound drug |
| **Experiment – IX** | Bioavailability studies of Paracetamol in animals. |
| **Experiment – X** | Pharmacokinetic and IVIVC data analysis by WinnolineR software |

|  |
| --- |
| **PHARMACEUTICS PRACTICALS - III** |
| **Course Code MPH206 P.** | **Practical** | **L-T-P-C** | **0-0-12-6** |
| **Course Contents** |
| **Experiment-I** | In vitro cell studies for permeability and metabolism |
| **Experiment-II** | DoE Using Design Expert® Software |
| **Experiment-III** | Formulation data analysis Using Design Expert® Software |
| **Experiment-IV** | Quality-by-Design in Pharmaceutical Development |
| **Experiment-V** | Computer Simulations in Pharmacokinetics and Pharmacodynamics |
| **Experiment-VI** | Computational Modeling Of Drug Disposition |
| **Experiment – VII** | To develop Clinical Data Collection manual |
| **Experiment- VIII** | To carry out Sensitivity Analysis, and Population Modeling. |
| **Experiment – IX** | Development and evaluation of Creams |
| **Experiment – X** | Development and evaluation of Shampoo and Toothpaste base |
| **Experiment – XI** | To incorporate herbal and chemical actives to develop products |
| **Experiment – XII** | To address Dry skin, acne, blemish, Wrinkles, bleeding gums and dandruff |

***M.PHARM (PHARMACEUTICS)***

***Semester- III***

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| ***S.N.*** | ***Subject Code*** | ***Name of the Subject*** | ***Periods*** | ***Evaluation Scheme*** | ***Subject Total*** | ***Credits*** |
| ***L*** | ***T*** | ***P*** | ***Theory*** | ***Practical*** |
| ***CT*** | ***TA*** | ***ESE*** | ***TA*** | ***ESE*** |
| ***Discipline Specific Papers*** |
| ***Core Subject Code*** | ***Core Subject Name*** |
| *1* | *MRM30 1T* | *Research Methodology and Biostatistics* | *3* | *1* | *0* | *15* | *10* | *75* | *--* | *--* | *100* | *4* |
| ***Practical + Tutorial*** |
| ***Course Code*** | ***Course Name*** |
| *1* |  | *Research Work* | *0* |  | *28* | *--* | *--* | *--* | *50* | *100* | *350* | *14* |
| ***Elective Discipline Specific***  |
| ***Course Code*** | ***Course Name*** |
| *1* |  | *Journal Club* | *1* | *0* | *0* | *-* | *-* | *-* | *-* | *-* | *25* | *1* |
| *2* |  | *Dissertation Presentation* | *0* | *0* | *3* |  |  |  |  |  | *50* | *2* |
| *3* |  | *Sports* |  |  |  |  |  |  |  |  | *50* |  |
| ***Total*** | ***525*** | ***21*** |  |  |  |  |  |  |  |  | ***1000*** |

***M.PHARM (PHARMACEUTICS)***

***Semester- IV***

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| ***S.N.*** | ***Subject Code*** | ***Name of the Subject*** | ***Periods*** | ***Evaluation Scheme*** | ***Subject Total*** | ***Credits*** |
| ***L*** | ***T*** | ***P*** | ***Theory*** | ***Practical*** |
| ***CT*** | ***TA*** | ***ESE*** | ***TA*** | ***ESE*** |
| ***Practical + Tutorial*** |
| ***Course Code*** | ***Course Name*** |
| *1* |  | *Research Work* | *0* | *0* | *31* | *--* | *--* | *--* | *--* | *400* | *400* | *16* |
| ***Elective Discipline Specific***  |
| ***Course Code*** | ***Course Name*** |
| *1* |  | *Journal Club* | *1* | *0* | *0* | *-* | *25* | *-* | *-* | *-* | *25* | *1* |
| *2* |  | *Dissertation Presentation* | *360* | *0* | *0* | *-* | *75* | *-* | *-* | *-* | *75* | *3* |
| *3* |  | *Sports* |  |  |  |  |  |  |  |  | *50* |  |
| *Co-Curricular Activities (Attending Conference, Scientific presentation and other scholarly activities)* |  |  |  |  |  |  |  |  |  | *2 to 7\**  |
| ***Total*** | ***500*** | ***22 to27\**** |  |  |  |  |  |  | ***1000*** |

**\* Credit points for co-curricular activities minimum 02 to maximum 07.**