**JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY ANANTAPUR**

**Course Structure and Syllabi for M.Pharm-Pharmaceutics**

**(JNTUA-Affiliated Pharmacy Colleges 2017-18)**

**I YEAR - I Semester**

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| S.No | CourseCode | Subjects | L | T | P | C |
| 1 | 17S01101 | Modern Pharmaceutical Analytical Techniques | 4 | - | - | 4 |
| 2 | 17S03101 | Drug Delivery System  | 4 | - | - | 4 |
| 3 | 17S03102 | Modern Pharmaceutics | 4 | - | - | 4 |
| 4 | 17S03103 | Regulatory Affair  | 4 | - | - | 4 |
| **5** | **17S03104** | **Pharmaceutical Analysis Practical for Pharmaceutics** | **-** | **-** | **6** | **3** |
| **6** | **17S03105** | **Drug Delivery Systems Practical** | **-** | **-** | **6** | **3** |
| **7** | **17S03106** | **Seminar/Assignment**  | **-** | **-** | **7** | **4** |
|  Total | 16 | - | 19 | 26 |

**I YEAR II Semester**

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| S.No | Course Code | Subject | L | T | P | C |
| 1 | 17S03201 | Molecular Pharmaceutics(Nano Tech and Targeted DDS) | 4 | - | - | 4 |
| 2 | 17S03202 | Advanced Biopharmaceutics &Pharmacokinetics | 4 | - | - | 4 |
| 3 | 17S03203 | Computer Aided Drug Delivery System | 4 | - | - | 4 |
| 4 | 17S03204 | Cosmetic and Cosmeceuticals | 4 | - | - | 4 |
| **5** | **17S03205** | **Nano Technology & Targeted Dds (Ntds) Practical** | **-** | **-** | **6** | **3** |
| **6** | **17S03206** | **Advanced Biopharmaceutics & Pharmacokinetics****Practical** | **-** | **-** | **6** | **3** |
| 7 | 17S03207 | Seminar/Assignment | - | - | 7 | 4 |
|  Total | 16 | - | 19 | 26 |

**III SEMESTER**

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| S.No | Subject Code | Subject | L | T | P | C |
| 1. | 17S01301 | Research Methodology and Biostatistics | 4 | - | - | 4 |
| 2.  | 17S03301 | Journal Club | 1 | - | - | 1 |
| 3. | 17S03302 | Teaching Assignment | 10 | - | - | 2 |
| 4. | 17S03303 | Comprehensive viva voce | - | - | - | 2 |
| 5. | 17S03304 | Discussion / Presentation (Proposal presentation) | - | - | 2 | 2 |
| 6.  | 17S03305 | Research Work | - | - | 28 | 14 |
|  Total | 15 | - | 30 | 25 |

**IV SEMESTER**

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| S.No | Subject Code | Subject | L | T | P | C |
| 1. | 17S03401 | Journal Club | 1 | - | - | 1 |
| 2. | 17S03402 | Research work | 31 | - | - | 16 |
| 3. | 17S03403 | Discussion/ Final Presentation | 3 | - | - | 3 |
|  Total | 35 | - | - | 20 |

**JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY ANANTAPUR**

**M. Pharm – I year I Sem. (Pharmaceutics) L T P C**

 **4 0 0 4**

**(17S01101) MODERN PHARMACEUTICAL ANALYTICAL TECHNIQUES**

**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.

**Objectives**

After completion of course student is able to know,

* Chemicals and Excipients
* The analysis of various drugs in single and combination dosage forms
* Theoretical and practical skills of the instruments

**THEORY 60 HOURS**

1. 11 hrs

a. UV-Visible spectroscopy: Introduction, Theory, Laws, Instrumentation associated with UV Visible spectroscopy, Choice of solvents and solvent effect and Applications of UV Visible spectroscopy.

b. IR spectroscopy: Theory, Modes of Molecular vibrations, Sample handling,

Instrumentation of Dispersive and Fourier -Transform IR Spectrometer, Factors

affecting vibrationalfrequencies and Applications of IR spectroscopy

c. Spectroflourimetry: Theory of Fluorescence, Factorsaffecting fluorescence, Quenchers,

Instrumentation andApplications of fluorescence spectrophotometer.

d. Flame emission spectroscopy and Atomic absorptionspectroscopy: Principle,

Instrumentation, Interferences andApplications.

1. 11hrs

 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-Spincoupling, Coupling constant, Nuclear magnetic double resonance,Brief outline of principles of FT-NMR and 13C NMR. Applicationsof NMR spectroscopy.

1. 11hrs

Mass Spectroscopy: Principle, Theory, Instrumentation of MassSpectroscopy, Different types of ionization like electron impact,chemical, field, FAB and MALDI, APCI, ESI, APPI Analyzers ofQuadrupole and Time of Flight, Mass fragmentation and its rules,Meta stable ions, Isotopic peaks and Applications of Mass spectroscopy

1. 11hrs

Chromatography: Principle, apparatus, instrumentation, chromatographic parameters, factors affecting resolution and applications of the following: a)Paper chromatography b) Thin Layer chromatographyc) Ion exchange chromatography d) Column chromatographye) Gas chromatography f) High Performance Liquidchromatographyg) Affinity chromatography

5 11hrs

a. Electrophoresis: Principle, Instrumentation, Working conditions, factors affecting separation and applications of the following:

a) Paper electrophoresis b) Gel electrophoresis c) Capillary electrophoresis

d) Zone electrophoresis e) Moving boundary electrophoresis f) Iso electric focusing

b. X ray Crystallography: Production of X rays, Different X raydiffraction methods, Bragg‘s

law, Rotating crystal technique, Xray powder technique, Types of crystals and applications of Xray diffraction.

c. Immunological assays: RIA (Radio immuno assay), ELISA, Bioluminescence assays.5hrs

**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, 4thedition, 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, 3rdEdition, CBS Publishers, New Delhi, 1997.
7. Pharmaceutical Analysis- Modern methods – Part B - J W Munson, Volume11, Marcel Dekker Series

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**M. Pharm – I year I Sem. (Pharmaceutics) L T P C**

 **4 0 0 4**

**(17S03101) DRUG DELIVERY SYSTEMS**

**SCOPE**

This course is designed to impart knowledge on the area of advances in noveldrug delivery systems.

**OBJECTIVES**

Upon completion of the course, student shall be able to understand

* The various approaches for development of novel drug deliverysystems.
* The criteria for selection of drugs and polymers for the development ofdelivering system
* The formulation and evaluation of Novel drug delivery systems..

**THEORY 60 Hrs**

**1.** 10 hrs

Sustained Release(SR) and Controlled Release (CR)formulations: Introduction & basic concepts, advantages/disadvantages, factors influencing, Physicochemical & biologicalapproaches for SR/CR formulation, Mechanism of Drug Deliveryfrom SR/CR formulation. Polymers: introduction, definition,classification, properties and application Dosage Forms forPersonalized Medicine: Introduction, Definition,Pharmacogenetics, Categories of Patients for PersonalizedMedicines: Customized drug delivery systems, BioelectronicMedicines, 3D printing of pharmaceuticals, Telepharmacy.

**2**  10hrs

Rate Controlled Drug Delivery Systems: Principles &Fundamentals, Types, Activation; Modulated Drug DeliverySystems;Mechanically activated, pH activated, Enzyme activated,and Osmotic activated Drug Delivery Systems Feedbackregulated Drug Delivery Systems; Principles & Fundamentals.

**3**  10hrs

Gastro-Retentive Drug Delivery Systems: Principle, conceptsadvantages 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 offormulation and its evaluations.

**4**  6hrs

a) Occular Drug Delivery Systems: Barriers of drug permeation,Methods to overcome barriers.

 10hrs

b) Transdermal Drug Delivery Systems: Structure of skin andbarriers, Penetration enhancers, Transdermal Drug DeliverySystems, Formulation and evaluation.

**5**  8 hrs

a) Protein and Peptide Delivery: Barriers for protein delivery.Formulation and Evaluation of delivery systems of proteins andother macromolecules.

 6 hrs

b) Vaccine delivery systems: Vaccines, uptake of antigens, singleshot vaccines, mucosal and transdermal delivery of vaccines.

REFERENCES

1. Y W. Chien, Novel Drug Delivery Systems, 2nd edition, revised andexpanded,Marcel Dekker, Inc., New York, 1992.

2. Robinson, J. R., Lee V. H. L, Controlled Drug Delivery Systems, MarcelDekker,Inc., New York, 1992.

3. Encyclopedia of controlled delivery, Editor- Edith Mathiowitz, Published byWileyInterscience 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

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

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**M. Pharm – I year I Sem. (Pharmaceutics) L T P C**

 **4 0 0 4**

**(17S03102) MODERN PHARMACEUTICS**

**SCOPE**

Course designed to impart advanced knowledge and skills required to learnvarious aspects and concepts at pharmaceutical industries

**Objectives**

Upon completion of the course, student shall be able to understand

* The elements of preformulation studies.
* The Active Pharmaceutical Ingredients and Generic drug Productdevelopment
* Industrial Management and GMP Considerations.
* Optimization Techniques & Pilot Plant Scale Up Techniques
* Stability Testing, sterilization process & packaging of dosage forms.

**THEORY 60 HRS**

1.10 HRS

 a. Preformation Concepts – Drug Excipient interactions -different methods, kinetics of stability, Stability testing. Theories ofdispersion and pharmaceutical Dispersion (Emulsion andSuspension, SMEDDS) preparation and stability Large and small volume parental –physiological and formulation consideration,Manufacturing and evaluation.

b. Optimization techniques in Pharmaceutical Formulation:Concept and parameters of optimization, Optimization techniquesin pharmaceutical formulation and processing. Statistical design,Response surface method, Contour designs, Factorial designs and application in formulation

2 10 HRS

Validation : Introduction to Pharmaceutical Validation, Scope &merits of Validation, Validation and calibration of Master plan,ICH& WHO guidelines for calibration and validation ofequipments, Validation of specific dosage form, Types ofvalidation. Government regulation, Manufacturing Process Model,URS, DQ, IQ, OQ & P.Q. of facilities.

3 10 HRS

cGMP & Industrial Management: Objectives and policies ofcurrent good manufacturing practices, layout of buildings,services, equipments and their maintenance Productionmanagement: Production organization, , materials management,handling and transportation, inventory management and control,production and planning control, Sales forecasting, budget andcost control, industrial and personal relationship. Concept of TotalQuality Management.

4 10 HRS

Compression and compaction: Physics of tablet compression,compression, consolidation, effect of friction, distribution offorces, compaction profiles. Solubility.

5 10 HRS

Study of consolidation parameters; Diffusion parameters,Dissolution parameters and Pharmacokinetic parameters, Heckelplots, Similarity factors – f2 and f1, Higuchi and Peppasplot,Linearity Concept of significance, Standard deviation , Chi square test, students T-test , ANOVA test.

REFERENCES

1. Theory and Practice of Industrial Pharmacy ByLachmann and Libermann

2. Pharmaceutical dosage forms: Tablets Vol. 1-3 by Leon Lachmann.

3. Pharmaceutical Dosage forms: Disperse systems, Vol, 1-2; By LeonLachmann.

4. Pharmaceutical Dosage forms: Parenteral medications Vol. 1-2; By LeonLachmann.

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 producersofIndia.

12.Drug formulation manual; By D.P.S. Kohli and D.H.Shah. Easternpublishers, 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.

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**M. Pharm – I year I Sem. (Pharmaceutics) L T P C**

 **4 0 0 4**

**(17S03103) REGULATORY AFFAIRS**

**SCOPE**

Course designed to impart advanced knowledge and skills required to learn theconcept of generic drug and their development, various regulatory filings indifferent countries, different phases of clinical trials and submitting regulatorydocuments : filing process of IND, NDA and ANDA

* To know the approval process of
* To know the chemistry, manufacturing controls and their regulatoryimportance
* To learn the documentation requirements for
* To learn the importance

**Objectives:**

Upon completion of the course, it is expected that the students will be able tounderstand

* The Concepts of innovator and generic drugs, drug developmentprocess
* The Regulatory guidance’s and guidelines for filing and approvalprocess
* Preparation of Dossiers and their submission to regulatory agencies indifferent 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.

**THEORY 60 Hrs**

1. 12 hrs

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 FEDERALREGULATION) ,drug product performance, in-vitro, ANDAregulatory approval process, NDA approval process, BE and drugproduct assessment, in –vivo, scale up process approvalchanges, post marketing surveillance, outsourcing BA and BE toCRO.

2.

Regulatory requirement for product approval: API,biologics, novel, therapies obtaining NDA, ANDA for genericdrugs ways and means of US registration for foreign drugs

3 12 hrs

CMC, post approval regulatory affairs. Regulation for combinationproducts and medical devices.CTD and ECTD format, industryand FDA liaison. ICH - Guidelines of ICH-Q, S E, M. Regulatoryrequirements of EU, MHRA, TGA and ROW countries.

4 12 hrs

Non clinical drug development: Global submission of IND,NDA, ANDA. Investigation of medicinal products dossier, dossier(IMPD) and investigator brochure (IB).

5 12 hrs

Clinical trials: Developing clinical trial protocols. Institutionalreview board/ independent ethics committee Formulation andworking procedures informed Consent process and procedures.HIPAA- new, requirement to clinical study process,pharmacovigilance safety monitoring in clinical trials.

**REFERENCES**

1. Generic Drug Product Development, Solid Oral Dosage forms, Leon ShargelandIsaderKaufer,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 AGuarino, 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, andbiologics/edited By Douglas J. Pisano, David Mantus.

6. Clinical Trials and Human Research: A Practical Guide to RegulatoryComplianceBy 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

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**M. Pharm – I year I Sem. (Pharmaceutics) L T P C**

 **0 0 6 3**

**(17S03104) PHARMACEUTICAL ANALYSIS PRACTICAL FOR PHARMACEUTICS**

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

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**M. Pharm – I year I Sem. (Pharmaceutics) L T P C**

 **0 0 6 3**

**(17S03105) DRUG DELIVERY SYSTEMS PRACTICAL**

1. To perform In-vitro dissolution profile of CR/ SR marketed formulation
2. Formulation and evaluation of sustained release matrix tablets
3. Formulation and evaluation osmotically controlled DDS
4. Preparation and evaluation of Floating DDS- hydro dynamically balancedDDS
5. Formulation and evaluation of Muco adhesive tablets.
6. Formulation and evaluation of trans dermal patches.
7. To carry out preformulation studies of tablets.
8. To study the effect of compressional force on tablets disintegration time.
9. To study Micromeritic properties of powders and granulation.
10. To study the effect of particle size on dissolution of a tablet.
11. To study the effect of binders on dissolution of a tablet.
12. To plot Heckal plot, Higuchi and peppas plot and determine similarity factors.

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**M. Pharm – I year II Sem. (Pharmaceutics) L T P C**

 **4 0 0 4**

**(17S03201) MOLECULAR PHARMACEUTICS (NANO TECHNOLOGY & TARGETED DDS) (NTDS)**

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.

**THEORY 60 Hrs**

1. 12 hrs

Targeted Drug Delivery Systems: Concepts, Events andbiological process involved in drug targeting. Tumor targeting andBrain specific delivery.

2 12 hrs

Targeting Methods: introduction preparation and evaluation.Nano Particles & Liposomes: Types, preparation and evaluation.

3 12 hrs

Micro Capsules / Micro Spheres: Types, preparation andevaluation, Monoclonal Antibodies; preparation and application,preparation and application of Niosomes, Aquasomes,Phytosomes, Electrosomes.

4 12 hrs

Pulmonary Drug Delivery Systems: Aerosols, propellents,ContainersTypes, preparation and evaluation, Intra Nasal RouteDelivery systems; Types, preparation and evaluation.

5 12 hrs

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.

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 andadvances, 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).

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 **4 0 0 4**

**(17S03202) ADVANCED BIOPHARMACEUTICS & PHARMACOKINETICS**

Scope

This course is designed to impart knowledge and skills necessary for dosecalculations, dose adjustments and to apply biopharmaceutics theories inpractical problem solving. Basic theoretical discussions of the principles ofbiopharmaceutics and pharmacokinetics are provided to help the students’ toclarify 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 andparameters the best describe the process of drug absorption,distribution, metabolism and elimination.
* The critical evaluation of biopharmaceutic studies involving drugproduct equivalency.
* The design and evaluation of dosage regimens of the drugs usingpharmacokinetic and biopharmaceutic parameters.
* The potential clinical pharmacokinetic problems and application ofbasics of pharmacokinetic

**THEORY 60 Hrs**

1. 12 hrs

Drug Absorption from the Gastrointestinal Tract:Gastrointestinal tract, Mechanism of drug absorption, Factorsaffecting drug absorption, pH–partition theory of drug absorption.Formuulation and physicochemical factors: Dissolution rate,Dissolution process, Noyes–Whitney equation and drugdissolution, Factors affecting the dissolution rate. Gastrointestinalabsorption: role of the dosage form: Solution (elixir, syrup andsolution) as a dosage form ,Suspension as a dosage form,Capsule as a dosage form, Tablet as a dosage form ,Dissolutionmethods ,Formulation and processing factors, Correlation of invivo data with in vitro dissolution data.Transportmodel:Permeability-Solubility-Charge State and the pH PartitionHypothesis, Properties of the Gastrointestinal Tract (GIT), pHMicroclimate Intracellular pH Environment, Tight-JunctionComplex.

2 12 hrs

Biopharmaceutic considerations in drug product designand In Vitro Drug Product Performance: Introduction,biopharmaceutic factors affecting drug bioavailability, rate-limitingsteps in drug absorption, physicochemical nature of the drugformulation factors affecting drug product performance, in vitro:dissolution and drug release testing, compendial methods ofdissolution, alternative methods of dissolution testing,meetingdissolutionrequirements,problems of variable control in dissolutionTestingperformance of drug products. In vitro–in vivo correlation,dissolution profile comparisons, drug productstability,considerations in the design of a drug product.

3 12 hrs

Pharmacokinetics: Basic considerations, pharmacokineticmodels, compartment modeling: one compartment model- IVbolus, IV infusion, extra-vascular. Multi compartment model:twocompartment - model in brief, non-linear pharmacokinetics: causeof non-linearity, Michaelis – Menten equation, estimation of kmaxandvmax. Drug interactions: introduction, the effect of proteinbindinginteractions,the effect of tissue-bindinginteractions,cytochrome p450-based drug interactions,druginteractions linked to transporters.

4 12 hrs

Drug Product Performance, In Vivo: Bioavailability andBioequivalence: drug product performance, purpose ofbioavailability studies, relative and absolute availability. Methodsfor assessing bioavailability, bioequivalence studies, design andevaluation of bioequivalence studies, study designs, crossoverstudy designs, evaluation of the data, bioequivalence example,study submission and drug review process. Biopharmaceutics classification system, methods. Permeability: In-vitro, in-situ andIn-vivo methods.generic biologics (biosimilardrugproducts),clinical significance of bioequivalence studies, special concerns in bioavailability and bioequivalence studies, genericsubstitution.

5 12 hrs

Application of Pharmacokinetics: Modified-Release DrugProducts, Targeted Drug Delivery Systems and BiotechnologicalProducts. Introduction to Pharmacokinetics andpharmacodynamic,druginteractions. Pharmacokinetics andpharmacodynamics of biotechnology drugs. Introduction, Proteinsand peptides, Monoclonal antibodies,

REFERENCES

1. Biopharmaceutics and Clinical Pharmacokinetics by Milo Gibaldi, 4thedition,Philadelphia, Lea and Febiger, 1991

2. Biopharmaceutics and Pharmacokinetics, A. Treatise, D .M. Brahmankarand Sunil B. Jaiswal., VallabPrakashan, Pitampura, Delhi

3. Applied Biopharmaceutics and Pharmacokinetics by Shargel. LandYuABC, 2ndedition, Connecticut Appleton Century Crofts, 1985

4. Textbook of Biopharmaceutics and Pharmacokinetics, Dr. Shobha Rani R.Hiremath,Prism Book

5. Pharmacokinetics by Milo Gibaldi and D. Perrier, 2nd edition, MarcelDekkerInc.,New York, 1982

6. Current Concepts in Pharmaceutical Sciences: Biopharmaceutics,Swarbrick. J, LeaandFebiger, Philadelphia, 1970

7. Clinical Pharmacokinetics, Concepts and Applications 3rd edition byMalcolmRowland and Thom~ N. Tozer, Lea and Febiger, Philadelphia,1995

8. Dissolution, Bioavailability and Bioequivalence, Abdou. H.M, MackPublishingCompany, Pennsylvania 1989

9. Biopharmaceutics and Clinical Pharmacokinetics, An Introduction, 4thedition,revised and expande by Robert. E. Notari, Marcel Dekker Inc, NewYork and Basel,1987.

10. Biopharmaceutics and Relevant Pharmacokinetics by John. G Wagner andM.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,1stedition,Sunil S JambhekarandPhilipJBreen,pharmaceutical press, RPS Publishing,2009.

13. Absorption and Drug Development- Solubility, Permeability, and ChargeState, Alex Avdeef, John Wiley & Sons, Inc,2003.

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**M. Pharm – I year II Sem. (Pharmaceutics) L T P C**

 **4 0 0 4**

**(17S03203) COMPUTER AIDED DRUG DELIVERY SYSTEM**

**Scope**

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

**Objectives**

Upon completion of this course it is expected that students will be able to understand,

* 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)

**THEORY 60 Hrs**

1.12 hrs

 a. Computers in Pharmaceutical Research andDevelopment: A General Overview: History of Computers inPharmaceutical Research and Development. Statistical modelingin Pharmaceutical research and development: Descriptive versusMechanistic Modeling, Statistical Parameters, Estimation,Confidence Regions, Nonlinearity at the Optimum, SensitivityAnalysis, Optimal Design, Population Modeling

b. Quality-by-Design In Pharmaceutical Development:Introduction, ICH Q8 guideline, Regulatory and industry views onQbD, Scientifically based QbD - examples of application.

2 12 hrs

Computational Modeling Of Drug Disposition: Introduction,Modeling Techniques: Drug Absorption, Solubility, IntestinalPermeation, Drug Distribution,Drug Excretion, Active Transport;P-gp, BCRP, Nucleoside Transporters, hPEPT1, ASBT, OCT,OATP, BBB-Choline Transporter.

3 12 hrs

Computer-aided formulation development:: Concept ofoptimization, Optimization parameters, Factorial design,Optimization technology & Screening design. Computers inPharmaceutical Formulation: Development of pharmaceuticalemulsions, microemulsion drug carriers Legal Protection ofInnovative Uses of Computers in R&D, The Ethics of Computing in Pharmaceutical Research, Computers in Market analysis

4 12 hrs

a. Computer-aided biopharmaceutical characterization:Gastrointestinal absorption simulation. Introduction, Theoreticalbackground, Model construction, Parameter sensitivity analysis,Virtual trial, Fed vs. fasted state, In vitro dissolution and in vitroinvivo correlation, Biowaiver considerations

b. Computer Simulations in Pharmacokinetics andPharmacodynamics: Introduction, Computer Simulation: WholeOrganism, Isolated Tissues, Organs, Cell, Proteins and Genes.

c. Computers in Clinical Development: Clinical Data Collectionand Management, Regulation of Computer Systems

5 12 hrs

Artificial Intelligence (AI), Robotics and Computational fluiddynamics: General overview, Pharmaceutical Automation,Pharmaceutical applications, Advantages and Disadvantages.Current Challenges and Future Directions.

**REFERENCES**

1. Computer Applications in Pharmaceutical Research and Development,SeanEkins, 2006, John Wiley & Sons.

2. Computer-Aided Applications in Pharmaceutical Technology, 1st Edition,JelenaDjuris, Woodhead Publishing

3. Encyclopedia of Pharmaceutical Technology, Vol 13, James Swarbrick,James. G.Boylan, Marcel Dekker Inc, New York, 1996.

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 **4 0 0 4**

**(17S03204) COSMETICS AND COSMECEUTICALS**

Scope

This course is designed to impart knowledge and skills necessary For the fundamental 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 andcosmeceuticals
* Scientific knowledge to develop cosmetics and cosmeceuticalswithdesired Safety, stability, and efficacy.

**THEORY 60 Hrs**

1. 12 hrs

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.

2 12 hrs

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.

3 12 hrs

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. Soapsandsyndetbars.Perfumes; Classification of perfumes. Perfume ingredients listedas allergens in EU regulation.Controversial ingredients: Parabens, formaldehyde liberators,dioxane.

4 12 hrs

Design of cosmeceutical products: Sun protection, sunscreensclassification and regulatory aspects. Addressing dry skin, acne,sun-protection, pigmentation, prickly heat, wrinkles, body odor.,dandruff, dental cavities, bleeding gums, mouth odor andsensitive teeth through cosmeceutical formulations.

5 12 hrs

Herbal Cosmetics : Herbal ingredients used in Hair care, skincare and oral care. Review of guidelines for herbal cosmetics byprivate bodies like cosmos with respect to preservatives,emollients, foaming agents, emulsifiers and rheology modifiers.Challenges in formulating herbal cosmetics.

**REFERENCES**

1. Harry’s Cosmeticology. 8th edition.

2. Poucher’sperfumecosmeticsandSoaps, 10th edition.

3. Cosmetics - Formulation, Manufacture and quality control, PP.Sharma, 4thedition

4. Handbook of cosmetic science and Technology A.O.Barel, M.PayeandH.I. Maibach. 3 rd edition

5. Cosmetic and Toiletries recent suppliers’ catalogue.

6. CTFA directory.

**JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY ANANTAPUR**

**M. Pharm – I year II Sem. (Pharmaceutics) L T P C**

 **0 0 6 3**

**(17S03205) NANO TECHNOLOGY & TARGETED Dds (Ntds) PRACTICAL**

1. To study the effect of temperature change , non solvent addition, incompatible polymer

addition in microcapsules preparation

2. Preparation and evaluation of Alginate beads

3. Formulation and evaluation of gelatin /albumin microspheres

4. Formulation and evaluation of liposomes/niosomes

5. Formulation and evaluation of spherules

6. Improvement of dissolution characteristics of slightly soluble drug by Solid dispersion

technique.

7. Comparison of dissolution of two different marketed products /brands

8. Protein binding studies of a highly protein bound drug & poorly proteinbound drug

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**M. Pharm – I year II Sem. (Pharmaceutics) L T P C**

 **0 0 6 3**

**(17S03206) ADVANCED BIOPHARMACEUTICS & PHARMACOKINETICS**

**PRACTICAL**

1. Bioavailability studies of Paracetamol in animals.
2. Pharmacokinetic and IVIVC data analysis by WinnolineR software
3. In vitro cell studies for permeability and metabolism
4. DoE Using Design Expert® Software
5. Formulation data analysis Using Design Expert® Software
6. Quality-by-Design in Pharmaceutical Development
7. Computer Simulations in Pharmacokinetics and Pharmaco dynamics
8. Computational Modeling Of Drug Disposition
9. To develop Clinical Data Collection manual
10. To carry out Sensitivity Analysis, and Population Modeling.
11. Development and evaluation of Creams
12. Development and evaluation of Shampoo and Toothpaste base
13. To incorporate herbal and chemical actives to develop products
14. To address Dry skin, acne, blemish, Wrinkles, bleeding gums and dandruff

**JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY ANANTAPUR**

**M. Pharm – III Sem. (Pharmaceutics) L T P C**

 **4 0 0 4**

**(17S01301) RESEARCH METHODOLOGY & BIOSTATISTICS**

UNIT – I

General Research Methodology: Research, objective, requirements, practical difficulties, review of literature, study design, types of studies, strategies to eliminate errors/bias, controls, randomization, crossover design, placebo, blinding techniques.

UNIT – II

Biostatistics: Definition, application, sample size, importance of sample size, factors influencing sample size, dropouts, statistical tests of significance, type of significance tests, parametric tests(students “t” test, ANOVA, Correlation coefficient, regression), non-parametric tests (wilcoxan rank tests, analysis of variance, correlation, chi square test), null hypothesis, P values, degree of freedom, interpretation of P values.

UNIT – III

Medical Research: History, values in medical ethics, autonomy, beneficence, non-maleficence, double effect, conflicts between autonomy and beneficence/non-maleficence, euthanasia, informed consent, confidentiality, criticisms of orthodox medical ethics, importance of communication, control resolution, guidelines, ethics committees, cultural concerns, truth telling, online business practices, conflicts of interest, referral, vendor relationships, treatment of family members, sexual relationships, fatality.

UNIT – IV

CPCSEA guidelines for laboratory animal facility: Goals, veterinary care, quarantine, surveillance, diagnosis, treatment and control of disease, personal hygiene, location of animal facilities to laboratories, anesthesia, euthanasia, physical facilities, environment, animal husbandry, record keeping, SOPs, personnel and training, transport of lab animals.

UNIT – V

Declaration of Helsinki: History, introduction, basic principles for all medical research, and additional principles for medical research combined with medical care.

References

1. *C.R.Kothari* “*Research Methodology Methods & Techniques”, Second Edition, New Delhi: New Age International publisher*
2. *Pharmaceutical Statistics 5th edition by Sanford Bolton and Charles Bon.*
3. *Biostatistics by R.S. Shukla and P.S.Chandel-S.Chand.*
4. *Guidelines On The Regulation Of Scientific Experiments On Animals; Government of India June 2007*, <https://www.aaalac.org/resources/SOP_CPCSEA.pdf>.
5. *WMA Declaration of Helsinki - Ethical Principles for Medical Research Involving Human Subjects:* [*http://anesthesia.gr/wp-content/uploads/2012/01/Decleration-of-Helsinki.pdf*](http://anesthesia.gr/wp-content/uploads/2012/01/Decleration-of-Helsinki.pdf)*.*
6. *Garrett et. al., Health Care Ethics. Prentice Hall, 2nd Edition, 1993,*