2016

THE MASTER OF PHARMACY (M. PHARM.)

COURSE REGULATION 2014

(BASED ON NOTIFICATION IN THE GAZETTE OF INDIA No. 362, DATED DECEMBER 11, 2014)

SCHEME AND SYLLABUS

PHARMACY COUNCIL OF INDIA
Combined Council's Building, Kotla Road,
Alwan-E-Ghalib Marg, New Delhi-110 002.
Website : www.pci.nic.

COURSE STRUCTURE AND SYLLABUS
For
M. PHARM

MPH R 20 Regulations

(Applicable for batches admitted from 2020-2021)

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY: KAKINADA
KAKINADA - 533 003, Andhra Pradesh, India

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ADITYA COLLEGE OF PHARMACY SURAMPALEM

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Aditya College of Pharmacy
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PHARMACY COUNCIL OF INDIA

NOTIFICATION

New Delhi, the 10th December, 2014

The Master of Pharmacy (M.Pharm) Course Regulations, 2014

No. 14-136/ 2014-PCI.—In exercise of the powers conferred by Sections 10 and 18 of the Pharmacy Act, 1948 (8 of 1948), the Pharmacy Council of India, with the approval of the Central Government hereby makes the following regulations namely–

CHAPTER –I: REGULATIONS

1. Short Title and Commencement

These regulations shall be called as "The Revised Regulations for the Master of Pharmacy (M. Pharm.) Degree Program-Credit Based Semester System (CBSS) of the Pharmacy Council of India, New Delhi". They shall come into effect from the Academic Year 2016-17. The regulations framed are subject to modifications from time to time by the authorities of the university.

2. Minimum qualification for admission

A Pass in the following examinations

a) B. Pharm Degree examination of an Indian university established by law in India from an institution approved by Pharmacy Council of India and has scored not less than 55% of the maximum marks (aggregate of 4years of B.Pharm.)

b) Every student, selected for admission to post graduate pharmacy program in any PCI approved institution should have obtained registration with the State Pharmacy Council or should obtain the same within one month from the date of his/her admission, failing which the admission of the candidate shall becancelled.

Note: It is mandatory to submit a migration certificate obtained from the respective university where the candidate had passed his/her qualifying degree (B.Pharm.)

3. Duration of the program

The program of study for M.Pharm shall extend over a period of four semesters (two academic years). The curricula and syllabi for the program shall be prescribed from time to time by Phamacy Council of India, New Delhi.

4. Medium of instruction and examinations

Medium of instruction and examination shall be in English.

5. Working days in each semester

Each semester shall consist of not lessthan 100 working days. The odd semesters shall be conduted from the month of June/July to November.December and the even semesters shall be conducted from the month of December/January to May/June in every calendar year.

6. Attendance and progress

- A student shall be eligible to write University examinations if he acquires a minimum of 75% of attendance in aggregate of all the subjects/courses, and with minimum 50% in each and every course including practicals.
- Condonation of shortage of attendance in aggregate up to 10% (65% and above and below 75%) in each semester shall be granted by the College Academic Committee.
- Shortage of Attendance below 65% in aggregate shall not be condoned and not eligible to write their end semester examination of that class.
- Students whose shortage of attendance is not condoned in any semester are not eligible to write their end semester examination of that class.
- A prescribed fee shall be payable towards Condonation of shortage of attendance.
- A student shall not be promoted to the next semester unless, he satisfies the attendance requirement of the present semester, as applicable. They may seek re-admission into that semester when offered next. If any candidate fulfills the

attendance requirement in the present semester, he shall not be eligible for re-admission into the same class.

7. Program/Course credit structure

As per the philosophy of Credit Based Semester System, certain quantum of academic work viz. theory classes, practical classes, seminars, assignments, etc. are measured in terms of credits. On satisfactory completion of the courses, a candidate earns credits. The amount of credit associated with a course is dependent upon the number of hours of instruction per week in that course. Similarly the credit associated with any of the other academic, co/extra-curricular activities is dependent upon the quantum of work expected to be put in for each of these activities per week/ per activity.

7.1. Credit assignment

7.1.1. Theory and Laboratory courses

Courses are broadly classified as Theory and Practical, Theory courses consist of lecture (L) and Practical (P) courses consist of hours spent in the laboratory. Credits (C) for a course is dependent on the number of hours of instruction per week in that course, and is obtained by using a multiplier of one (1) for lecture and a multiplier of half (1/2) for practical (laboratory) hours.Thus, for example, a theory course having four lectures per week throughout the semester carries a credit of 4. Similarly, a practical having four laboratory hours per week throughout semester carries a credit of 2.

The contact hours of seminars, assignments and research work shall be treated as that of practical courses for the purpose of calculating credits i.e., the contact hours shall be multiplied by 1/2. Similarly, the contact hours of journal club, research work presentations and discussions with the supervisor shall be considered as theory course and multiplied by 1.

7.2. Minimum credit requirements

The minimum credit points required for the award of M.Pharm. degree is 95. However based on the credit points earned by the students under the head of co-curricular activities, a student shall earn a maximum of 100 credit points. These credits are divided into Theory courses, Practical, Seminars, Assignments, Research work, Discussions with the supervisor, Journal club and Co-Curricular activities over the duration of four semesters. The credits are distributed semester-wise as shown in Table 14. Courses generally progress in sequence, building competencies and their positioning indicates certain academic maturity on the part of the learners. Learners are expected to follow the semester-wise schedule of courses given in the syllabus.

8. Academic work

A regular record of attendance both in Theory, Practical, Seminar, Assignment, Journal club, Discussion with the supervisor, Research work presentation and Dissertation shall be maintained by the department/ teaching staff of respective courses.

M.Pharm I & II Semester Practicals:

- The individual student of the respective specialization need to carry out at least 75% of the practical prescribed in the syllabus.
- Based and depending upon the software available with the institute the practical can be designed.
- Some experiments have to be carried out only by Demonstration. Students are advised to know the Principle and Protocol of the experiment.

9. Course of study

The specializations in M.Pharm program is given in Table 1.

Table – 1: List of M.Pharm. Specializations and their Code

S. No.	Specialization	Code
1.	Pharmaceutics	MPH
2.	Industrial Pharmacy	MIP
3.	Pharmaceutical Chemistry	MPC
4.	Pharmaceutical Analysis	MPA
5.	Pharmaceutical Quality Assurance	MQA
6.	Pharmaceutical Regulatory Affairs	MRA
7.	Pharmaceutical Biotechnology	MPB
8.	Pharmacy Practice	MPP
9.	Pharmacology	MPL
10.	Pharmacognosy	MPG

The course of study for M.Pharm specializations shall include Semester wise Theory & Practical as given in Table – 2 to 11. The number of hours to be devoted to each theory and practical course in any semester shall not be less than that shown in Table – 2 to 11.

Table – 2: Course of study for M. Pharm. (Pharmaceutics)

Course Code	Course	Credit Hours	Credit Points	Hrs./ wk	Marks
Semester I					
MPH101T	Modern Pharmaceutical Analytical Techniques	4	4	4	100
MPH102T	Drug Delivery System	4	4	4	100
MPH103T	Modern Pharmaceutics	4	4	4	100
MPH104T	Regulatory Affair	4	4	4	100
MPH105PA	Pharmaceutics Practical I	6	3	6	75
MPH105PB	Pharmaceutical Practical II	6	3	6	75
-	Seminar/Assignment	7	4	7	100
Total		35	26	35	650
Semester II					
MPH201T	Molecular Pharmaceutics (Nano Technology and Targeted DDS) (NTDS)	4	4	4	100
MPH202T	Advanced Biopharmaceutics & Pharmacokinetics	4	4	4	100
MPH203T	Computer Aided Drug Development	4	4	4	100
MPH204T	Formulation Development of Pharmaceutical and Cosmetic Products	4	4	4	100
MPH205PA	Pharmaceutics Practical III	6	3	6	75
MPH205PB	Pharmaceutics Practical IV	6	3	6	75
-	Seminar/Assignment	7	4	7	100
	Total	35	26	35	650

PHARMACEUTICS (MPH)

SEMESTER - 1

MODERN PHARMACEUTICAL ANALYTICAL TECHNIQUES (MPH 101T)

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. 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. 11 Hrs
   b. 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
   c. Spectroflourimetry: Theory of Fluorescence, Factors affecting fluorescence, Quenchers, Instrumentation and Applications of fluorescence spectrophotometer.
   d. Flame emission spectroscopy and Atomic absorption spectroscopy: Principle, Instrumentation, Interferences andApplications.

2. NMR spectroscopy: Quantum numbers and their role in NMR, Principle, Instrumentation, Solvent requirement in NMR, Relaxation process, NMR signals in various compounds, Chemical shift, Factors influencing chemical shift, Spin-Spin coupling, Coupling constant, Nuclear magnetic double resonance, Brief outline of principles of FT-NMR and 13C NMR. Applications of NMR spectroscopy. 11 Hrs

3	Mass Spectroscopy: Principle, Theory, Instrumentation of Mass Spectroscopy, Different types of ionization like electron impact, chemical, field, FAB and MALDI, APCI, ESI, APPI Analyzers of Quadrupole and Time of Flight, Mass fragmentation and its rules, Metastable ions, Isotopic peaks and Applications of Mass spectroscopy	11 Hrs
4	Chromatography: Principle, apparatus, instrumentation, chromatographic parameters,factors affecting resolution and applications of the following: a) Paper chromatography b) Thin Layer chromatography c) Ion exchange chromatography d) Column chromatography e) Gas chromatography f) High Performance Liquid chromatography g) Affinity chromatography	11 Hrs
5	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 electricfocusing b. X ray Crystallography: Production of X rays, Different X ray diffraction methods, Bragg's law, Rotating crystal technique, X ray powder technique, Types of crystals and applications of X-ray diffraction.	11 Hrs
6	Immunological assays : RIA (Radio immuno assay), ELISA, Bioluminescenceassays.	5 Hrs

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, Easternpress, 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 – PD Sethi, 3rd Edition, CBS Publishers, New Delhi, 1997.
7. Pharmaceutical Analysis –Modern methods –Part B- JW Munson, Volume 11, Marcel Dekker Series

DRUG DELIVERY SYSTEMS
(MPH 102T)

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 delivering system.
- The formulation and evaluation of Novel drug delivery systems.

THEORY 60 Hrs

1.	Sustained Release (SR) and Controlled Release (CR) formulations: Introduction & basic concepts, advantages/ disadvantages, factorsinfluencing, 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.	10 Hrs
2	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 Feedback regulated Drug Delivery Systems; Principles & Fundamentals.	10 Hrs
3	Gastro-Retentive Drug Delivery Systems: Principle, concepts advantages and disadvantages, Modulation of GI transit time approaches toextend GI transit. Buccal Drug Delivery Systems: Principle of mucoadhesion, advantages and disadvantages, Mechanism of drug permeation, Methods of formulation and its evaluations.	10 Hrs
4	Occular Drug Delivery Systems: Barriers of drug permeation, Methods to overcome barriers.	06 Hrs

5	Transdermal Drug Delivery Systems: Structure of skin and barriers, Penetration enhancers, Transdermal Drug Delivery Systems, Formulation and evaluation.	10 Hrs
6	Protein and Peptide Delivery: Barriers for protein delivery. Formulation and Evaluation of delivery systems of proteins and other macromolecules.	08 Hrs
7	Vaccine delivery systems: Vaccines, uptake of antigens, single shot vaccines, mucosal and transdermal delivery of vaccines.	06 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 Wiley Inter science 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,Vallabh Prakashan, New Delhi, First edition 2002

JOURNALS

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

MODERN PHARMACEUTICS
(MPH 103T)

Scope

Course designed to impart advanced knowledge and skills required to learn various 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 Product development
- Industrial Management and GMP Considerations.
- Optimization Techniques & Pilot Plant Scale Up Techniques
- Stability Testing, sterilization process & packaging of dosage forms.

THEORY 60HRS

1. 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 small volume parental – physiological and formulation consideration, Manufacturing and evaluation. 10 Hrs

   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 10 Hrs

2 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 of validation. Government regulation, Manufacturing Process Model, URS, DQ, IQ, OQ& P.Q. of facilities. 10 Hrs

3 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. 10 Hrs

4	Compression and compaction: Physics of tablet compression, compression, consolidation, effect of friction, distribution of forces, compactionprofiles.Solubility.	10 Hrs
5	Study of consolidation parameters; Diffusion parameters, Dissolution parameters and Pharmacokinetic parameters, Heckel plots, Similarity factors – f2 and f1, Higuchi and Peppas plot, Linearity Concept of significance, Standard deviation , Chi square test, students T-test , ANOVA test.	10 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 LeonLachmann.
4. Pharmaceutical Dosage forms: Parenteral medications Vol. 1-2; By LeonLachmann.
5. Modern Pharmaceutics; By Gillbert and S.Banker.
6. Remington's PharmaceuticalSciences.
7. Advances in Pharmaceutical Sciences Vol. 1-5; By H.S. Bean &A.H.Beckett.
8. Physical Pharmacy; By Alfredmartin
9. Bentley'sTextbookofPharmaceutics–byRawlins.
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. 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

(MPH 104T)

Scope

Course designed to impart advanced knowledge and skills required to learn the conceptof 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 the irregulatory
- importance.
- To learn the documentation requirements

Objectives:

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
- Postapproval 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 60Hrs

1. a. Documentation in Pharmaceutical industry: Master formula record, DMF (Drug Master File), distribution records. Generic drugs product development Introduction, Hatch- Waxman act and amendments, CFR (CODE OF FEDERAL REGULATION) ,drug product performance, in-vitro, ANDA regulatory approval process, NDA approval process,BEand drug product assessment, in –vivo, scale up process approval changes, postmarketingsurveillance,outsourcingBAandBEtoCRO. 12 Hrs

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 12 Hrs

2	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
3	Non clinical drug development: Global submission of IND, NDA, ANDA. Investigation of medicinal products dossier, dossier (IMPD) and investigator brochure (IB).	12 Hrs
4	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 Isader Kaufer, Marcel Dekker series, Vol.143
2. The Pharmaceutical Regulatory Process, Second Edition Edited by IraR. Berryand 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. Guide book 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 Trialsand 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
(MPH 105PA)

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

PHARMACEUTICS PRACTICAL - II
(MPH 105PB)

1. To study the effect of particle size on dissolution of a tablet.
2. To study the effect of binders on dissolution of a tablet.
3. To plot Heckal plot, Higuchi and peppas plot and determine similarityfactors.
4. To perform In-vitro dissolution profile of CR/ SR marketed formulation
5. Formulation and evaluation of sustained release matrix tablets
6. Formulation and evaluation osmotically controlled DDS
7. Preparation and evaluation of Floating DDS- hydro dynamically balanced DDS
8. Formulation and evaluation of Muco adhesive tablets.
9. Formulation and evaluation of trans dermal patches.

SEMESTER - II

MOLECULAR PHARMACEUTICS (NANO TECHNOLOGY & TARGETED DDS) (NTDS)

(MPH 201T)

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. Targeted Drug Delivery Systems: Concepts, Events and biological process involved in drug targeting. Tumor targeting and Brain specific delivery. 12 Hrs

2 Targeting Methods: introduction preparation and evaluation. NanoParticles & Liposomes: Types, preparation and evaluation. 12 Hrs

3 Micro Capsules / Micro Spheres: Types, preparation and evaluation, Monoclonal Antibodies; preparation and application, preparation and application of Niosomes, Aquasomes, Phytosomes, Electrosomes. 12 Hrs

4 Pulmonary Drug Delivery Systems: Aerosols, propellents, Containers Types, preparation and evaluation, Intra Nasal Route Delivery systems; Types, preparation and evaluation. 12 Hrs

5 Nucleic acid based therapeutic delivery system: Gene therapy, introduction (ex-vivo & in-vivo gene therapy). Potential target diseases for gene therapy (inherited disorder and cancer). Gene expression systems (viral and nonviral genetransfer). Liposomal gene delivery systems.
Bio distribution and Pharmacokinetics. Knowledge of therapeutic antisense molecules and aptamers as drugs of future. 12 Hrs

REFERENCES

1. Y W. Chien, Novel Drug Delivery Systems, 2nd edition, revised and expanded, Marcel Dekker, Inc., NewYork, 1992.
2. S.P.Vyas and R.K.Khar, Controlled Drug Delivery - concepts and advances, Vallabh Prakashan, New Delhi, First edition 2002.
3. N.K.Jain, Controlled and Novel Drug Delivery, CBS Publishers & Distributors, NewDelhi, First edition 1997 (reprint in 2001).

ADVANCED BIOPHARMACEUTICS & PHARMACOKINETICS
(MPH 202T)

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 able understand,

- 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

THEORY 60Hrs

1. 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 invivo data with invitro dissolution data. Transportmodel: Permeability - Solubility - Charge State and the pH Partition Hypothesis, Properties of the Gastrointestinal Tract (GIT), pH Microclimate Intracellular pH Environment, Tight-Junction Complex. 12 Hrs
2. Biopharmaceutic considerations in drug product design and In Vitro Drug Product Performance: Introduction, biopharmaceutic factors affecting drug bioavailability, rate-limiting steps in drug absorption, physicochemical nature of the drug formulation factors affecting drug product performance, in vitro: dissolution and drug release testing, compendial methods of dissolution, alternative methods of dissolution testing, meeting dissolution requirements, problems of variable control in dissolution testing performance of drug products. Invitro–invivo correlation, dissolution profile comparisons, drug product stability, considerations in the design of a drug product. 12 Hrs

3. Pharmacokinetics: Basic considerations, pharmacokinetic models, compartment modeling: one compartment model –IV bolus, IV infusion, extra- vascular. Multicompartment model: two compartment- model in brief, non-linear pharmacokinetics: cause of non-linearity, Michaelis–Menten equation, estimation of kmax and vmax. Drug interactions: introduction, the effect of protein-binding interactions, the effect of tissue-binding interactions, cytochrome p450-based drug interactions, drug interactions linked to transporters. 12 Hrs
4. Drug Product Performance, In Vivo: Bioavailability and Bioequivalence: drug product performance, purpose of bioavailability studies, relative and absolute availability, methods for assessing bioavailability, bioequivalence studies, design and evaluation of bioequivalence studies, study designs, crossover study designs, evaluation of the data, bioequivalence example, study submission and drug review process. Biopharmaceutical 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. 12 Hrs
5. Application of Pharmacokinetics: Modified-Release Drug Products, Targeted Drug Delivery Systems and Biotechnological Products. Introduction to Pharmacokinetics and pharmacodynamic, drug interactions. Pharmacokinetics and pharmacodynamics of biotechnology drugs.Introduction, Proteins and peptides, Monoclonal antibodies, Oligonucleotides, Vaccines (immunotherapy), Genetherapies. 12 Hrs

REFERENCES

1. Biopharmaceutics and Clinical Pharmacokinetics by Milo Gibaldi, 4th edition,Philadelphia, Lea and Febiger,1991
2. Biopharmaceutics and Pharmacokinetics, A. Treatise, D .M. Brahmankar and Sunil B.Jaiswal,Vallab Prakashan,Pitampura, Delhi
3. Applied Biopharmaceutics and Pharmacokinetics by Shargel. Land Yu ABC, 2nd edition, Connecticut Appleton Century Crofts, 1985
4. Textbook of Biopharmaceutics and Pharmacokinetics, Dr.Shobha Rani R. Hiremath, Prism Book
5. Pharmacokinetics by Milo Gibaldi and D. Perrier, 2nd edition, Marcel Dekker Inc.,New York,1982
6. Current Concepts in Pharmaceutical Sciences: Biopharmaceutics, Swarbrick.J, Lea and Febiger, Philadelphia, 1970
7. Clinical Pharmacokinetics, Concepts and Applications 3rd edition by MalcolmRowland and Thom~ N. Tozer, Lea and Febiger, Philadelphia, 1995
8. Dissolution, Bioavailability and Bioequivalence, Abdou. H.M, Mack Publishing Company, Pennsylvania 1989
9. Biopharmaceutics and Clinical Pharmacokinetics, An Introduction, 4th edition, revised and 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, 1st edition, Sunil S Jambhekar and Philip J Breen, pharmaceutical press, RPS Publishing, 2009.
13. Absorption and Drug Development- Solubility, Permeability and Charge State, Alex Avdeef, John Wiley & Sons, Inc, 2003.

COMPUTER AIDED DRUG DEVELOPMENT
(MPH 203T)

Scope

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

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. 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 — 12 Hrs

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

2 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 Hrs

3	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 Computing in Pharmaceutical Research, Computers in Market analysis	12 Hrs
4	a. Computer-aided biopharmaceutical characterization: Gastrointestinal absorption simulation. Introduction, Theoretical background, Model construction, Parameter sensitivity analysis, Virtual trial, Fedvs.fasted state, In vitro dissolution and in vitro- in 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 Hrs
5	Artificial Intelligence (AI), Robotics and Computational fluid dynamics: General overview, Pharmaceutical Automation, Pharmaceutical applications, Advantages and Disadvantages. Current Challenges and Future Directions.	12 Hrs

REFERENCES

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

FORMULATION DEVELOPMENT OF PHARMACEUTICAL AND COSMETIC PRODUCTS
(MPH204T)

Scope

This course is designed to impart knowledge and skills necessary to train the students on par with the routine of Industrial activities in R&D and F&D.

Objectives

On completion of this course it is expected that students will be able to understand-
The scheduled activities in a Pharmaceutical firm.
The pre formulation studies of pilot batches of pharmaceutical industry. The significance of dissolution and product stability

THEORY 60 Hrs

1. Preformulation Studies: 12 Hrs
   Molecular optimization of APIs (drug substances), crystal morphology and variations, powder flow, structure modification, drug-excipient compatibility studies, methods of determination.

2. Formulation Additives: 12 Hrs
   Study of different formulation additives, factors influencing their incorporation, role of formulation development and processing, new developments in excipient science. Design of experiments – factorial design for product and process development.

3. Solubility & Dissolution: 12 Hrs
   Importance, experimental determination, phase- solubility analysis, pH-solubility profile, solubility techniques to improve solubility and utilization of analytical methods – cosolvency, salt formation, complexation, solid dispersion, micellar solubilization and hydrotropy.Theories and mechanisms of dissolution, in-vitro dissolution testing models – sink and non-sink. Factor influencing dissolution and intrinsic dissolution studies. Dissolution test apparatus – designs, dissolution testing for conventional and controlled release products. Data handling and correction factor.Biorelevent media, in-vitro and in- vivo correlations, levels of correlations.

4. Product Stability: 12 Hrs
   Degradation kinetics, mechanisms, stability testing of drugs and pharmaceuticals, factors influencing-media effects and pH effects, accelerated stability studies, interpretation of kinetic data (API & tablets). Solid state stability and shelf life assignment.Stability protocols, reports and ICH guidelines.

5. Cosmetics: 12 Hrs
   Formulation, Evaluation and packaging of the following cosmetic products: Dentrifices like tooth powders, pastes and gels. Manicure preparations like nail polish, lipsticks, eye lashes, Baby care products, Moisturizing cream, vanishing cream, cold cream, shampoo, Soaps and syndetbars

REFERENCES

1. Lachman L, Lieberman HA, Kanig JL. The Theory and Practice of Industrial Pharmacy, 3rd ed., Varghese Publishers, Mumbai1991.
2. Sinko PJ. Martin's physical pharmacy and pharmaceutical sciences, 5 ed., B.I. Publications Pvt. Ltd, Noida, 2006.
3. Lieberman HA, Lachman L, Schwartz JB. Pharmaceutical dosage forms: tablets Vol. I-III, 2nd ed., CBS Publishers & distributors, New Delhi, 2005.
4. Conners KA. A Text book of pharmaceutical analysis Wells JI. Pharmaceutical preformulation: The physicochemical properties of drug substances. Ellis Horwood Ltd., England, 1998.
5. Yalkowsky SH. Techniques of solubilization of drugs. Vol-12. Marcel Dekker Inc., New York, 1981
6. Dressman J, Kramer J. Pharmaceutical dissolution testing. Saurah printer pvt. Ltd., New Delhi, 2005.
7. Sethi PD. Quantitative analysis of drugs in pharmaceutical formulations, 3rded., CBS publications, New Delhi,2008.
8. Carstensen JT, Rhodes CT. Drug stability principles and practices, 3rded., CBS Publishers & distributors, New Delhi,2005.
9. Yoshioka S, Stella VJ. Stability of drugs and dosage forms, Springer (India) Pvt. Ltd., New Delhi, 2006.
10. Banker GS, Rhodes CT. Modern Pharmaceutics, 4th ed., Marcel Dekker Inc, New York, 2005.
11. W. Grimm - Stability testing of drugproducts.
12. Mazzo DJ. International stability testing. Eastern Press Pvt. Ltd., Bangalore, 1999.
13. Beckett AH, Stenlake JB. Practical pharmaceutical chemistry, Part I &II.,4thed., CBS Publishers & distributors, New Delhi,2004.
14. Indian Pharmacopoeia. Controller of Publication. Delhi, 1996.
15. British Pharmacopoeia. British Pharmacopoeia Commission Office, London, 2008.
16. United States Pharmacopoeia. United States Pharmacopeial Convention, Inc, USA, 2003.
17. Encyclopaedia of Pharm. Technology, Vol I –III.
18. Wells J. I. Pharmaceutical Preformulation: The physicochemical properties of drug substances, Ellis Horwood Ltd. England, 1988.
19. Harry's Cosmeticology. 8th edition.
20. Poucher's perfume cosmetics and Soaps, 10th edition.
21. Cosmetics - Formulation, Manufacture and quality control, PP.Sharma,4th edition
22. Handbook of cosmetic science and Technology A.O.Barel, M.Paye and H.I. Maibach. 3rd edition.

PHARMACEUTICS PRACTICAL - III
(MPH 205PA)

1. To study the effect of temperature change, non solvent addition, incompatible polymer addition in microcapsulespreparation
2. Preparation and evaluation of Alginatebeads
3. Formulation and evaluation of gelatin /albuminmicrospheres
4. Formulation and evaluation of liposomes/niosomes
5. Formulation and evaluation ofspherules
6. Improvement of dissolution characteristics of slightly soluble drug by Solid dispersion technique.
7. Comparison of dissolution of two different marketed products /brands
8. Protein binding studies of a highly protein bound drug & poorly protein bound drug
9. Bioavailability studies of Paracetamol inanimals.
10. Pharmacokinetic and IVIVC data analysis by Winnoline^{R} software
11. In vitro cell studies for permeability and metabolism

PHARMACEUTICS PRACTICAL - IV
(MPH 205PB)

1. DoE Using Design Expert®Software
2. Formulation data analysis Using Design Expert®Software
3. Quality-by-Design in Pharmaceutical Development
4. Computer Simulations in Pharmacokinetics and Pharmacodynamics
5. Computational Modeling Of DrugDisposition
6. To develop Clinical Data Collection manual
7. To carry out Sensitivity Analysis, and Population Modeling.
8. Development and evaluation of Creams
9. Development and evaluation of Shampoo and Toothpaste base
10. Formulation Development of Multi Vitamnin Syrup
11. Use of Optimization techniques in Formulation Development of Tablets