DR. A.P.J. ABDUL KALAM TECHNICAL UNIVERSITY, UTTAR PRADESH, LUCKNOW

Syllabus

For

M.Pharm. (Pharmaceutics)

(Effective from the Session: 2017-18)

Master of Pharmacy (M. Pharm.)

SCHEMES FOR INTERNAL ASSESSMENTS AND END SEMESTER EXAMINATIONS (SEM. I & II)
(W.E.F. Session 2017-18)

PHARMACEUTICS- MPH

Course Code	Course	Internal Assessment				End Semester Exams		Total Marks	Credit Points
		Continuous Mode	Sessional Exams		Total	Marks	Duration		
			Marks	Duration					
Semester I									
MPH101T (New)	Modern Pharmaceutical Analytical Techniques	10	15	1 Hrs	25	75	3 Hrs	100	4
MPH102T (New)	Drug Delivery System	10	15	1 Hrs	25	75	3 Hrs	100	4
MPH103T (New)	Modern Pharmaceutics	10	15	1 Hrs	25	75	3 Hrs	100	4
MPH104T (New)	Regulatory Affairs	10	15	1 Hrs	25	75	3 Hrs	100	4
MPH105P (New)	Pharmaceutics Practical I	20	30	6 Hrs	50	100	6 Hrs	150	6
-	Seminar/Assignment	-	-	-	-	-	-	100	4
							Total	650	26
Semester II									
MPH201T (New)	Molecular Pharmaceutics (Nano Tech and Targeted DDS)	10	15	1 Hr	25	75	3 Hrs	100	4
MPH202T (New)	Advanced Biopharmaceutics & Pharmacokinetics	10	15	1 Hr	25	75	3 Hrs	100	4
MPH203T (New)	Computer Aided Drug Delivery System	10	15	1 Hr	25	75	3 Hrs	100	4
MPH204T (New)	Cosmetic and Cosmeceuticals	10	15	1 Hr	25	75	3 Hrs	100	4
MPH205P (New)	Pharmaceutics Practical II	20	30	6 Hrs	50	100	6 Hrs	150	6
-	Seminar /Assignment	-	-	-	-	-	-	100	4
Total								650	26

Schemes for Internal Assessments and End Semester Examinations (Semester III & IV)

Course Code	Course	Internal Assessment				End Semester Exams		Total Marks	Credit Points
		Continuous Mode	Sessional Exams		Total	Marks	Duration		
			Marks	Duration					
Semester III									
MRM301T (New)	Research Methodology and Biostatistics	40	60	2 Hr	100	-	-	100	4
MRM302T (New)	Journal Club	-	-	-	25	-	-	25	1
MRM303P (New)	Discussion /Presentation (Proposal Presentation)	-	-	-	50	-	-	50	2
MRM304P (New)	Research Work	350	-	-	-	-	-	350	14
							Total	525	21
Semester IV									
MRM401T (New)	Journal Club	-	-	-	25	-	-	25	1
MRM402P (New)	Discussion / Presentation (Proposal Presentation)	-	-	-	75	-	-	75	3
MRM403P (New)	Research Work and Colloquium	-	-	-	-	400	1 Hr	400	16
							Total	500	20

FIRST SEMESTER

PHARMACEUTICS (MPH)

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 Hrs**

1. **a. UV-Visible spectroscopy:** Introduction, theory, laws, instrumentation associated with UV-Visible spectroscopy. Choice of solvents and solvent effect. 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. 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 and applications.
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, APPI analyzers of quadrupole and time of flight. Mass Fragmentation and its rules, meta stable ions, isotopic peaks. Applications of mass spectroscopy. **11 Hrs**
4. **Chromatography:** Principle, apparatus, instrumentation, chromatographic parameters, factors affecting resolution and application of the following: **11 Hrs**
   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.

5. **a. Electrophoresis:** Principle, instrumentation, working conditions, factors affecting separation and applications of the following: **11 Hrs**
   a) Paper electrophoresis
   b) Gel electrophoresis
   c) Capillary electrophoresis
   d) Zone electrophoresis
   e) Moving boundary electrophoresis
   f) Isoelectric focusing.

   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.
6. **a. Potentiometry:** Principle, working, Ion selective electrodes and application of potentiometry. **5 Hrs**

   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.

   c. Immunological Assays: RIA (Radio immune assay), ELISA, bioluminescence assays.

REFERNCES

1. Spectrometric Identification of Organic Compounds by Robert M Silverstein, Sixth Edition, John Wiley & Sons, 2004.
2. Principles of Instrumental Analysis by Doglas A Skoog, F. James Holler, Timothy A. Nieman, 5th edition, Eastern press, Bangalore, 1998.
3. Instrumental Methods of Analysis by Willards, 7th edition, CBS publishers.
4. Practical Pharmaceutical Chemistry by Beckett and Stenlake, Vol II, 4th edition, CBS Publishers, New Delhi, 1997.
5. Organic Spectroscopy by William Kemp, 3rd Edition, ELBS, 1991.
6. Quantitative Analysis of Drugs in Pharmaceutical Formulation by P.D. Sethi, 3rd Edition, CBS Publishers New Delhi, 1997.
7. Pharmaceutical Analysis Modern Methods- Part B by J. W. Munson, Volume 11, Marcel Dekker Series.
8. Pharmacopoeia of India, Ministry of Health, Govt. of India.
9. Introduction to Spectroscopy by Pavia D.L., Lampman G.M., and Kriz G.S., 3rd Edition, Harcourt College Publishers, Philadelphia.
10. Analytical Profile of Drug Substance (All volume) by Florey K., Academic Press, Elsevier, Massachusetts.
11. Spectroscopy of Organic Compounds by Kalsi P.S., New Age International Publishers, New Delhi.

12. Undergraduate Instrumental Analysis by Obonson J.W.R., Marcel Dekker Inc, New York.
13. Absorption Spectroscopy of Organic Molecules by Parikh V.H., Addison-Wesley Publishing Co., London.
14. Thin Layer Chromatography: A Laboratory Handbook by Stahl E., Springer, Berlin.
15. A Text Book of Pharmaceutical Chemistry by Chatten L.G., Vol. I & II, Marcel Dekker, New York.

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, 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. **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-Retentative Drug Delivery Systems:** Principle, concepts advantages and disadvantages, modulation of GI transit time approaches to extend 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 10 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**

REFERNCES

1. Novel Drug Delivery Systems by Chien, Y W., 2nd edition, revised and expanded, Marcel Dekker, Inc., New York, 1992.
2. Controlled Drug Delivery Systems by Robinson, J. R., Lee V. H. L, Marcel Dekker,Inc., New York, 1992.

3. Chichester and Weinheim Encyclopedia of controlled delivery, Editor- Edith Mathiowitz, Published by WileyInterscience Publication, John Wiley and Sons, Inc, New York! Chichester/Weinheim.
4. Controlled and Novel Drug Delivery by Jain, N.K. CBS Publishers & Distributors, New Delhi, First edition 1997 (reprint in 2001).
5. Controlled Drug Delivery - concepts and advances by Vyas S.P. and Khar, R.K. Vallabh Prakashan, New Delhi, First edition 2002.
6. Modern Pharmaceutics by Banker G.S. and Rhodes C.T., Marcel Dekker, New York.
7. Microparticulate Systems for the Delivery of Proteins and Vaccines by Cohen S. and Bernstein H., Marcel Dekker, New York.

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
(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 pre-formulation 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 **60 Hrs**

1.	**(A)**. **Pre-formation 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. **(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, compaction profiles, solubility.	**06 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**

REFERNCES

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, by Sidney H. Willig. Second edition.
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 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.
- To know the chemistry, manufacturing controls and their regulatory importance.
- To learn the documentation requirements.
- To learn the importance.

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.
- 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 **60Hrs**

1. **a. Documentation in Pharmaceutical Industry:** Master formula record, DMF (Drug Master File), distribution records. **12 Hrs**
   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.
   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.
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 (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**

REFERNCES

1. Generic Drug Product Development, Solid Oral Dosage Forms by Leon Shargel and Isader Kaufer, 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 Healthcare 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.
11. Drugs and Cosmetics Act 1940 and Rules 1945 by Malik V.
12. New Drug Approval Process, by Guarino R.A., Marcel Dekker, New York.
13. Guidebook for Drug Regulatory Submissions by Weinberg S., John Wiley and Sons, New Jersey.

PHARMACEUTICS PRACTICALS – I
(MPH 105P)

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 perform in-vitro dissolution profile of CR/ SR marketed formulation.
8. Formulation and evaluation of sustained release matrix tablets.
9. Formulation and evaluation osmotically controlled DDS.
10. Preparation and evaluation of Floating DDS- hydro dynamically balanced DDS.
11. Formulation and evaluation of mucoadhesive tablets.
12. Formulation and evaluation of transdermal patches.
13. To carry out pre-formulation studies of tablets.
14. To study the effect of compressional force on tablets disintegration time.
15. To study micromeritic properties of powders and granulation.
16. To study the effect of particle size on dissolution of a tablet.
17. To study the effect of binders on dissolution of a tablet.
18. To plot Heckal plot, Higuchi and peppas plot and determine similarity factors.

SECOND SEMESTER

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 **60Hrs**

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. Nano Particles & Liposomes: Types, preparation and evaluation. **12 Hrs**
3. **Micro Capsules/ Micro Spheres:** Types, preparation and evaluation. **12 Hrs**
   Monoclonal antibodies; Preparation and application, preparation and application of niosomes, aquasomes, phytosomes, electrosomes.
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 gene transfer). Liposomal gene delivery systems. **12 Hrs**
   Biodistribution and pharmacokinetics. Knowledge of therapeutic antisense molecules and aptamers as drugs of future.

REFERNCES

1. Novel Drug Delivery Systems by Y W. Chien, 2nd edition, revised and expanded, Marcel Dekker, Inc., New York, 1992.
2. Controlled Drug Delivery - concepts and advances, S.P.Vyas and R.K.Khar, Vallabh Prakashan, New Delhi, First Edition 2002.
3. N.K. Jain, Controlled and Novel Drug Delivery, CBS Publishers & Distributors, New Delhi, First edition 1997 (reprint in 2001).
4. Drug Targeting Technology Physical, Chemical and Biological Methods, Schreier H., Marcel Dekker, New York.
5. Roland A., Particulate Carriers: Therapeutic Applications, Marcel Dekker, New York.

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 biopharmaceutical studies involving drug product equivalency.
- The design and evaluation of dosage regimens of the drugs using pharmacokinetic and biopharmaceutical 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. Formulation 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), pH microclimate intracellular pH environment, tight-junction complex. **12 Hrs**
2. **Biopharmaceutical Considerations in Drug Product Design and In Vitro Drug Product Performance:** Introduction, biopharmaceutical factors affecting drug bioavailability, rate-limiting steps in drug absorption, physicochemical nature of the drug formulation factors affecting drug product performance, in vitro: dissolution and drug release testing, compendial methods of dissolution, alternative methods of dissolution testing ,meeting dissolution requirements ,problems of variable control in dissolution testing performance of drug products. In vitro–in vivo correlation, dissolution profile comparisons, drug product stability, considerations in the design of a drug product. **12 Hrs**
3. **Pharmacokinetics:** Basic considerations, pharmacokinetic models, compartment modeling: one compartment model- IV bolus, IV infusion, extra-vascular. Multi compartment model: two compartment - model in brief, non-linear pharmacokinetics: cause of non-linearity, Michaelis–Menten equation, estimation of kmax and vmax. Drug interactions: Introduction, the effect of protein binding interactions, the effect of tissue-binding interactions, cytochrome p450-based drug interactions, and drug interactions linked to transporters. **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. Biopharmaceutics classification system, methods. Permeability: In-vitro, in-situ and In-vivo methods. Generic biologics (biosimilar drug products), clinical significance of bioequivalence studies, special concerns in bioavailability and bioequivalence studies, generic substitution. **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), gene therapies. **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, 2ndedition, Connecticut Appleton Century Crofts, 1985
4. Textbook of Biopharmaceutics and Pharmacokinetics by Shobha Rani R. Hiremath, Prism Book.
5. Pharmacokinetics by Milo Gibaldi and D. Perrier, 2nd edition, Marcel Dekker Inc.,New York, 1982
6. Current Concepts in Pharmaceutical Sciences: Biopharmaceutics, Swarbrick. J, Leaand Febiger, Philadelphia, 1970.
7. Clinical Pharmacokinetics, Concepts and Applications 3rd edition by Malcolm Rowland and Thom~ N. Tozer, Lea and Febiger, Philadelphia,1995
8. Dissolution, Bioavailability and Bioequivalence, Abdou H.M, Mack Publishing Company, Pennsylvania 1989.
9. Biopharmaceutics and Clinical Pharmacokinetics, An Introduction, 4th edition, revised and expanded by Robert. E. Notari, Marcel Dekker Inc, New York and Basel, 1987.
10. Biopharmaceutics and Relevant Pharmacokinetics by John. G Wagner and M. Pemarowski, 1st edition, Drug Intelligence Publications, Hamilton, Illinois, 1971.
11. Encyclopedia of Pharmaceutical Technology, Vol 13, James Swarbrick, James. G. Boylan, Marcel Dekker Inc, New York, 1996.
12. Basic Pharmacokinetics, 1st edition, Sunil S Jambhekarand 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 guidelines, 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, fed vs. fasted state, In vitro dissolution and in-vitro in-vivo correlation, biowaiver considerations. **12 Hrs**

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.

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

COSMETICS AND COSMECEUTICALS
(MPH 204T)

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 and cosmeceuticals.
- Scientific knowledge to develop cosmetics and cosmeceuticals with desired safety, stability, and efficacy.

THEORY **60 Hrs**

1. **Cosmetics Regulatory:** Definition of cosmetic products as per Indian regulation. Indian regulatory requirements for labeling of cosmetics Regulatory provisions relating to import of cosmetics. Misbranded and spurious cosmetics. Regulatory provisions relating to manufacture of cosmetics: Conditions for obtaining license, prohibition of manufacture and sale of certain cosmetics, loan license, offences and penalties. **12 Hrs**
2. **Cosmetics - Biological Aspects:** Structure of skin relating to problems like dry skin, acne, pigmentation, prickly heat, wrinkles and body odor. Structure of hair and hair growth cycle. Common problems associated with oral cavity. Cleansing and care needs for face, eye lids, lips, hands, feet, nail, scalp, neck, body and under-arm. **12 Hrs**
3. **Formulation Building Blocks:** Building blocks for different product 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 preservative efficacy. Building blocks for formulation of a moisturizing cream, vanishing cream, cold cream, shampoo and toothpaste. Soaps and syndet bars. Perfumes: Classification of perfumes, perfume ingredients listed as allergens in EU regulation. Controversial ingredients: Parabens, formaldehyde liberators, dioxane. **12 Hrs**
4. **Design of Cosmeceutical Products:** Sun protection, sunscreens classification and regulatory aspects. Addressing dry skin, acne, sun-protection, pigmentation, prickly heat, wrinkles, body odor, dandruff, dental cavities, bleeding gums, mouth odor and sensitive teeth through cosmeceutical formulations. **12 Hrs**
5. **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 Hrs**

REFERENCES

1. Harry's Cosmeticology. 8th edition.
2. Poucher's Perfume Cosmetics and Soaps, 10th edition.
3. Cosmetics - Formulation, Manufacture and Quality Control, P.P. Sharma, 4th edition.
4. Handbook of Cosmetic Science and Technology A.O. Barel, M. Paye and H.I. Maibach. 3rd edition.
5. Cosmetic and Toiletries Recent Suppliers' Catalogue.
6. CTFA Directory.
7. Cosmetic Technology by Nanda S., Nanda A., Birla Publication, Delhi.
8. SCCS's Notes of Guidance for the Testing of Cosmetic Ingredients and their Safety Evaluation, European Commission, Brussels.
9. Indian Pharmacopoeia, Ministry of Health and Family Welfare, Govt. of India.
10. Paye M., Basel A.O., Maibach H.I., Handbook of Cosmetic Science and Technology, Informa Healthcare. New York.
11. Balsam M.S., Sagarin E., Cosmetics: Science and Technology, Wiley Interscience, New York.
12. Rao Y.M., Shayeda, Cosmeceuticals, PharmaMed Press, Hyderabad.

PHARMACEUTICS PRACTICALS - II
(MPH 205P)

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 protein bound drug.
9. Bioavailability studies of Paracetamol in animals.
10. Pharmacokinetic and IVIVC data analysis by WinnolineR software.
11. In vitro cell studies for permeability and metabolism.
12. DoE using Design Expert® Software.
13. Formulation data analysis using Design Expert® Software.
14. Quality-by-design in pharmaceutical development.
15. Computer simulations in pharmacokinetics and pharmacodynamics.
16. Computational modeling of drug disposition.
17. To develop clinical data collection manual.
18. To carry out sensitivity analysis, and population modeling.
19. Development and evaluation of creams.
20. Development and evaluation of shampoo and toothpaste base.
21. To incorporate herbal and chemical actives to develop products.
22. To address dry skin, acne, blemish, wrinkles, bleeding gums and dandruff.