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

Syllabus

For

M.Pharm. (Pharmaceutics)

(Effective from the Session: 2016-17)

Course Structure and Evaluation Scheme for M. Pharm. Courses (All Subjects/ Specialization) (Effective from Session 2016-17)

PHARMACEUTICS

Semester-I

S.N.	Subject Code	Name of the Subject	Periods			Credit	Evaluation Scheme					Subject Total
							Theory			Practical		
			L	T	P		CT	TA	ESE	TA	ESE	
1	*MPA101*	Modern Pharmaceutical Analytical Techniques	3	0	0	3	20	10	70	--	--	100
2	*MPH101/ MPH201*	Modified Release Drug Delivery System/ Molecular Pharmaceutics (Nano Tech & Targeted DDS)	3	0	0	3	20	10	70	--	--	100
3	*MPH102/ MPH204*	Modern Pharmaceutics/ Cosmetic & Cosmeceuticals	3	0	0	3	20	10	70	--	--	100
4	*MPH103*	Pharmaceutical Regulatory Affair	3	0	0	3	20	10	70	--	--	100
5	*RPM101*	Research Process & Methodology	3	0	0	3	20	10	70	--	--	100
6	*MPA105*	Modern Pharmaceutical Analytical Techniques Practical	-	-	2	1	--	--	--	20	30	50
7	*MPH104*	Pharmaceutics Practical-I	-	-	3	2	--	--	--	20	30	50
Total						**18**						**600**

Semester-II

S.N.	Subject Code	Name of the Subject	Periods			Credit	Evaluation Scheme					Subject Total
							Theory			Practical		
			L	T	P		CT	TA	ESE	TA	ESE	
1	*MPH201/ MPH101*	Molecular Pharmaceutics (Nano Tech & Targeted DDS)/ Modified Release Drug Delivery System	3	0	0	3	20	10	70	--	--	100
2	*MPH202*	Advanced Biopharmaceutics & Pharmacokinetics	3	0	0	3	20	10	70	--	--	100
3	*MPH203*	Computer Aided Drug Delivery System	3	0	0	3	20	10	70	--	--	100
4	*MPH204/ MPH102*	Cosmetic & Cosmeceuticals/ Modern Pharmaceutics	3	0	0	3	20	10	70	--	--	100
5	*MPH205*	Pharmaceutical Design & Development	3	0	0	3	20	10	70	--	--	100
6	*MPH206*	Pharmaceutics Practical-II	-	-	2	1	--	--	--	20	30	50
7	*MPH207*	Seminar-I (Synopsis)	-	-	3	2	--	--	--	50	--	50
Total						**18**						**600**

Semester-III

S.N.	Subject Code	Name of the Subject	Periods			Credit	Evaluation Scheme					Subject Total
							Theory			Practical		
			L	T	P		CT	TA	ESE	TA	ESE	
1	*MPH301*	Seminar-II	0	0	6	3	--	--	--	100	--	100
2	*MPH302*	Dissertation (Research Project Audit)	0	0	30	15	--	--	--	200	300	500
Total						**18**						**600**

Semester-IV

S.N.	Subject Code	Name of the Subject	Periods			Credit	Evaluation Scheme					Subject Total
							Theory			Practical		
			L	T	P		CT	TA	ESE	TA	ESE	
1	*MPH401*	Dissertation (Final)	0	0	36	18	--	--	--	200	400	600
Total						**18**						**600**

M. Pharm. (Pharmaceutics)
First Semester

MODERN PHARMACEUTICAL ANALYTICAL TECHNIQUES (*MPA101*)

Unit-I

UV-Visible spectroscopy: Introduction, theory and laws associated with UV-visible spectroscopy, chromophores, auxochromes and their interaction with UV-Vis radiations, choice of solvents and solvent effect. Woodward- Fieser rule and applications of UV-visible spectroscopy.

IR Spectroscopy: Theory, modes of molecular vibrations, factors affecting vibrational frequencies and applications of IR spectroscopy. FT-IR. Interpretation of IR spectra of organic compounds.

Unit-II

Mass spectrometry: Different ionization methods (EI, CI, FAB, ESI, MALDI), analyzers of quadrupole and time of flight. Fragmentation patterns and its rules, relative abundance of ions, molecular ion peak, meta stable ions, isotopic peaks, Mc-Lafferty rearrangement, ring rule. Applications of mass spectrometry.

Flame emission spectroscopy and atomic absorption spectroscopy*:* Principle, interferences and applications of flame emission spectroscopy and atomic absorption spectroscopy.

Unit-III

NMR Spectroscopy: Principle, chemical shift, factors influencing chemical shift, spin-spin coupling, coupling constant, solvent requirement in NMR, NMR active compounds, free induction decay, relaxation process and NMR signals in various compounds. Applications of NMR spectroscopy.

Unit-IV

Chromatography: Principle, chromatographic parameters, factors affecting and applications of: Thin Layer chromatography, column chromatography, gas chromatography, affinity chromatography, ion exchange chromatography, size exclusion chromatography, high performance liquid chromatography, high performance thin layer chromatography.

Unit-V

Miscellaneous techniques:

Thermal methods of analysis: Introduction, principle, instrumentation and application of TGA, DTA and DSC.

Electron microscopy: Principle, instrumentation and applications of scanning electron microscopy (SEM), transmission electron, microscopy (TEM).

Radioimmuno assay: ELISA.

SUGGESTED BOOKS:

1. Pharmacopoeia of India, Ministry of Health, Govt. of India.
2. Skoog D.A., Holler F.J., Crouch S. R., Instrumental Analysis, Indian Edition, Brooks/Cole, Boston.
3. Willard H.H., Merrit L.L., Dean J.A., Settle P.A., Instrumental Methods of analysis, 7th Edition, CBS Publishers & Distributors New Delhi.
4. Kemp W., Organic Spectroscopy, 3rd Edition, Palgrave, New York.
5. Becket A.H. and Stenlake J.B., Practical Pharmaceutical Chemistry Vol. I and II, The Athlone Press of the University of London.
6. Pavia D.L., Lampman G.M., and Kriz G.S., Introduction to Spectroscopy, 3rd Edition, Harcourt College Publishers, Philadelphia.
7. Kalsi P.S., Spectroscopy of Organic Compounds, New Age International Publishers, New Delhi.
8. Florey K., Analytical Profile of Drug Substance (All volume), Academic Press, Elsevier, Massachusetts.

9. Chatten L.G., A Text Book of Pharmaceutical Chemistry, Vol. I & II, Marcel Dekker, New York.
10. Silverstein R.M., Spectrometric Identification of Organic compounds, 6th Edition, John Wiley & Sons, New Jersey.
11. Obonson J.W.R., Undergraduate Instrumental Analysis, Marcel Dekker Inc, New York.
12. Parikh V.H., Absorption Spectroscopy of Organic Molecules, Addison-Wesley Publishing Co., London.
13. Stahl E., Thin Layer Chromatography: A Laboratory Handbook, Springer, Berlin.

MODIFIED RELEASE DRUG DELIVERY SYSTEM (*MPH101/MPH201*)

Unit-I

Rate controlled drug delivery systems: Introduction and basic concepts, physicochemical (dose size, ionization, pKa, aqueous solubility, partition coefficient, stability) and biological (biological half life, absorption and metabolism) approaches for SR/CR oral formulation, mechanism of drug delivery from SR/CR oral formulation.
Polymers for modified release: Classification, properties and application.

Unit-II

Gastro-retentive drug delivery systems: Principle, concepts advantages and disadvantages, modulation of gastro intestinal (GI) transit time approaches to extend GI transit, formulation and evaluation of floating tablets.

Unit-III

Mucosal drug delivery systems: Principle of mucoadhesion, various mucosal routes, advantages and disadvantages, mechanism of drug permeation through rectal and buccal cavity, formulation and evaluation of buccal gel.
Ocular and nasal drug delivery: Basic concept, advantages and disadvantages, mechanism of drug absorption.

Unit-IV

Transdermal drug delivery systems (TDDS): Structure of skin and barriers, classification of transdermal drug delivery systems, introduction to Lipinski rule, formulation and evaluation of transdermal patches. Introduction to iontophoresis, sonophoresis and electroporation.

Unit-V

Fast release tablets: Concept, excipients, various techniques and significance. Formulation of fast release tablet and its evaluation parameters.

BOOKS RECOMMENDED:

1. Chien Y.W., Novel Drug Delivery Systems, Marcel Dekker, Inc., New York.
2. Robinson J.R. and Lee V.H.L., Controlled Drug Delivery Systems, Marcel Dekker, Inc., New York.
3. Chichester and Weinheim, Encyclopedia of Controlled Delivery, Editor- E. Mathiowitz, Wiley Interscience Publication, New York.
4. Jain N.K., Advances in Controlled and Novel Drug Delivery, CBS Publishers and Distributors, New Delhi.
5. Vyas S.P., and Khar R.K., Controlled Drug Delivery: Concepts and Advances, Vallabh Prakashan, New Delhi.
6. Banker G.S. and Rhodes C.T., Modern Pharmaceutics, Marcel Dekker, New York.
7. Cohen S. and Bernstein H., Microparticulate Systems for the Delivery of Proteins and Vaccines, Marcel Dekker, New York.

MODERN PHARMACEUTICS (*MPH102/MPH204*)

Unit-I

Advances in granulation technology: Roller compaction technology, high-shear granulation, low-shear granulation, extrusion/ spheronization as a granulation technique, effervescent granulation, melt granulation and pelletization, rapid release granulation, continuous granulation technologies.

Unit-II

Lyophilization: Principle of lyophilization, factors affecting lyophilization efficiency, working of freeze dryers, types of freeze dryers, pharmaceutical and other industrial applications of lyophilization.
Clean rooms and AHUs: Environmental control (air flow) design, filters (HEPA and VEPA), and laminar air flow bench types (design, mechanism of filtration, speed, size, efficiency), testing of aseptic rooms. AHUs: Construction, components, configuration.

Unit-III

Small volume parental: Physiological parameters, formulation principles, container effects on formulation, stability evaluation, special types of parenterals (suspension, emulsion, dried forms).
Large volume parenterals: Concept of formulation (physiological parameters, formulation parameters, electrolytes, carbohydrates and nutritionals, parenteral nutrition, stress testing, stability evaluation, admixture considerations), Formulation development and solution quality.

Unit-IV

Implantable drug delivery system: Introduction, classification, formulation and evaluations of subdermal, ocuserts and dental implants and their marketed products.

Pediatric and geriatric dosage form: Introduction, pharmacokinetic and pharmacodynamic factors, formulation aspects.

Unit-V

Validation: Introduction to pharmaceutical validation, scope and merits of validation, types of validation, validation and calibration of master plan, ICH and WHO guidelines for calibration and validation of equipments, user requirement specification (URS), design qualification(DQ), installation qualification(IQ), operational qualification(OQ)and performance qualification (PQ), maintenance qualification, component qualification (CQ), instrument requalification of facilities.

SUGGESTED BOOKS:

1. Lachmann L. and Libermann H.A., Theory and Practice of Industrial Pharmacy, Lea and Febiger, Philadelphia.
2. Lachmann L., Pharmaceutical Dosage Forms: Tablets, Vol. 1-3, Marcel Dekker Inc., New York.
3. Lachmann L., Pharmaceutical Dosage Forms: Disperse Systems, Vol 1-2, Marcel Dekker Inc., New York.
4. Lachmann L., Pharmaceutical Dosage Forms: Parenterals, Vol. 1-3, Marcel Dekker Inc., New York.
5. Gilbert R. and Banker S., Modern Pharmaceutics. Marcel Dekker Inc., New York.
6. Gennaro A.R., Remington's Pharmaceutical Sciences, Vol. I & Vol. II, Mack Publishing Co., Easton.
7. Bean H.S. and Beckett A.H., Advances in Pharmaceutical Sciences Vol. 1-5, Academic Press, Cambridge.
8. Martin A., Bustamante P. and Chun A.H.C., Physical Pharmacy, Lea and Febiger, Philadelphia.
9. Rawlins E.A., Bentley's Text Book of Pharmaceutics, ELBS, Bailliere Tyndall.
10. Kohli D.P.S. and Shah D.H., Drug formulation Manual, Eastern Publishers, New Delhi.
11. Sharma P.P., How to Practice GMPs, Vandana Publications, Agra.
12. Berry F.R. and Nash R.A., Pharmaceutical Process Validation, Marcel Dekker, New York.
13. Parikh D.M. Handbook of Pharmaceutical Granulation Technology, Marcel Dekker, New York.
14. Berry R. and Nash R.A., Pharmaceutical Process Validation, Marcel Dekker, New York.

PHARMACEUTICAL REGULATORY AFFAIRS (*MPH103*)

Unit-I

Documentation in pharmaceutical industry: SOP and development of SOPs, master formula record, drug master file (DMF), distribution records, chemistry manufacturing and control (CMC),common technical document (CTD) and electronic common technical document (ECTD) format, investigation medicinal products dossier (IMPD) and investigator brochure (IB), introduction to generic drugs product development, outsourcing of bioavailability (BA) and bioequivalence(BE) to contract research organization(CRO).

Unit-II

Regulatory requirement for product approval: Hatch- Waxman act and amendments, code of federal regulation (CFR), post approval regulatory affairs, regulation for combination products and medical devices, industry and FDA liaison, regulatory requirements of EU, MHRA, USFDA.

Unit-III

Process of product approval: Introduction to API, biologics and novel material of approval, process for obtaining IND, NDA, ANDA for new drugs and generic drugs, US registration for foreign drugs.

Unit-IV

Intellectual property rights: Introduction and different mechanism of protection of IPR (patents, copyrights, trademarks, industrial design, geographical indications, registration of plant varieties and trade secrets).

Recent amendments to Indian Patent Act 1970.

Unit-V

Schedule M and Y of Drugs and cosmetics Act 1940 and rules 1945.

Introduction to ICH guidelines: Q, S, E, M (quality, safety, efficacy and multidisciplinary guidelines).

SUGGESTED BOOKS:

1. Shargel L. and Kaufer I., Generic Drug Product Development, Solid Oral Dosage Forms, Vol.143, Marcel Dekker series, New York.
2. Berry I.R. and Martin R.P., The Pharmaceutical Regulatory Process, Drugs and the Pharmaceutical Sciences, Vol.185, Informa Healthcare Publishers, London.
3. Richard A., Guarino M.D., New Drug Approval Process: Accelerating Global Registrations Drugs and the Pharmaceutical Sciences, Vol.190, Oxford Pharmaceutical Resource Inc., Totowa.
4. Weinberg S., Guidebook for Drug Regulatory Submissions, John Wiley and Sons, New Jersey.
5. Pisano D. J., Mantus D., FDA Regulatory Affairs: A guide for Prescription Drugs, Medical Devices, and Biologics, CRC Press, Florida.
6. Malik V., Drugs and Cosmetics Act 1940 and Rules 1945.
7. Willing S.W. and Stoker, Good Manufacturing Practices for Pharmaceuticals, Vol.7, Marcel Dekker, New York.
8. Guarino R.A., New Drug Approval Process, Marcel Dekker, New York.
9. Bansol, IPR Guidelines for Pharm students and Researchers.
10. www.ich.org/
11. www.fda.gov/
12. europa.eu/index_en.htm
13. https://www.tga.gov.au/tga-basics
14. https://www.ipindia.nic.in.

RESEARCH PROCESS & METHODOLOGY (*RPM101*)

Unit-I

Fundamentals of research: Meaning, objective and importance of research methodology, types of research (basic, applied and patent oriented), defining research problem, research design including various methods, research process and steps involved. Literature survey and documentation.

Unit-II

Data collection, analysis and hypothesis testing: Classification of data, methods of data collection, sample size, sampling procedure and methods. Data processing and graphical representation of data. Statistical inference and hypothesis: Types of hypothesis (experimental and non-experimental), hypothesis testing (Parametric and non-parametric tests), generalization and interpretation of results. Use of statistical softwares/ packages in data analysis (SPSS, Graph Pad Prism).

Unit-III

Multivariate analysis: Introduction to multivariate analysis (Linear and non linear methods) and their validation methods (Statistical parameters).

Research ethics, plagiarism and impact of research: Research ethics, responsibility and accountability of the researchers, ethical consideration during animal experimentation including CPCSEA guidelines. Plagiarism and use of plagiarism detection softwares such as-VIPER. Impact of research on environment and society, commercialization of research, intellectual ownership.

Unit-IV

Technical writing and reporting of research: Types of research report: Dissertation and thesis, research paper, review article, short communication, conference presentation, meeting report etc. Structure and organization of research reports: Title, abstract, key words, introduction, methodology, results, discussion, conclusion, acknowledgement, references, footnotes, tables and illustrations. Impact factor, rating, indexing and citation of journals. Detailed study of 'Instruction to Authors' of any research journal, a thorough understanding of steps involved in submitting articles electronically to any research journal (Registration, new article submission, tracking process, submitting revised articles).

Unit-V

Funding agencies and research grants: Introduction to various research funding agencies such as-DST, DBT, AICTE, UGC, CSIR, ICMR, AAYUSH, and DRDO along with their function in India. Writing a research project and procurement of research grant. Project cost analysis.

SUGGESTED BOOKS:

1. Kothari C.R., Research Methodology Methods and Techniques, Wishwa Prakashan, New Delhi.
2. Lokesh K., Methodology of Educational research, Vikash Publishing House Pvt. Ltd., New Delhi.
3. Kumar R., Research Methodology, Dorling Kindersley (India) Pvt. Ltd., New Delhi.
4. Rao G.N., Research Methodology and Qualitative Methods, B.S. Publications, Hyderabad.
5. Saunders M., Lewis P. and Thornhill A., Research Methods for Business Students, Dorling Kindersley (India) Pvt. Ltd., New Delhi.
6. Bolton S. and Bon C., Pharmaceutical Statistics: Practical and Clinical Applications, Marcel Dekker, New York.
7. Garg, B.L., Karadia, R., Agarwal, F. and Agarwal, An introduction to Research Methodology, RBSA Publishers, Jaipur.
8. Fisher R.A. Statistical Methods for Research Works, Oliver and Boyd, Edinburgh.
9. Chow S.S. and Liu J.P., Statistical Design and Analysis in Pharmaceutical Sciences, Marcel Dekker, New York.
10. Buncher C.R., Statistics in the Pharmaceutical Industry, Marcel Dekker, New York.

MODERN PHARMACEUTICAL ANALYTICAL TECHNIQUES PRACTICAL (*MPA105*)

1. Determination of the wavelength of maximum absorbance (λ max) of given compounds by UV-Visible spectrophotometry.
2. Quantitative estimation of Pharmacopoeial compounds by UV-Visible spectrophotometry.
3. UV-Vis spectrophotometric assay of pharmaceutical formulations containing Pharmacopoeial compounds as active ingredients.
4. Simultaneous estimation of multi component containing formulations by UV-Visible spectrophotometry.
5. Quantitative estimation of caffeine in beverages using UV-Vis spectrophotometer.
6. Study and interpretation of the FT-IR/IR spectra of given compounds.
7. Separation of the organic compounds from given mixture by thin layer chromatography (TLC).
8. Isolation of the organic compounds from given mixture by two-dimensional thin layer chromatography (2D-TLC).
9. Separation and quantitative estimation of organic compounds in the given mixture by thin layer chromatography (Preparative TLC).
10. Column packing and separation of organic compounds with the help of column chromatography.
11. Simultaneous estimation of any marketed formulation using RP-HPLC method.
12. Stability studies of marketed formulation by RP-HPLC method as per ICH guidelines.
13. Estimation of Sodium/ Potassium by flame photometry.

PHARMACEUTICS PRACTICAL-I (*MPH104*)

The practicals may be chosen from the following suggested list of experiments based on the subjects opted in that particular semester-

1. Formulation and evaluation of sustained release matrix tablets.
2. Preparation and evaluation of Floating DDS- hydro dynamically balanced DDS.
3. Formulation and evaluation of mucoadhesive tablets.
4. Formulation and evaluation of transdermal patches.
5. To study the effect of compressional force on tablets disintegration time.
6. To draw Heckal, Higuchi and Peppas plots and determine similarity factors.
7. To study the effect of temperature change, non solvent addition, incompatible polymer addition in microcapsules preparation.
8. Preparation and evaluation of alginate beads.
9. Formulation and evaluation of gelatin microspheres.
10. Formulation and evaluation of liposomes.
11. Formulation and evaluation of niosomes.
12. Improvement of dissolution characteristics of slightly soluble drug by solid dispersion technique.
13. Comparison of dissolution of two different marketed products/brands.
14. To perform accelerated stability testing of the given formulation.
15. Protein binding studies of a highly protein bound drug and poorly protein bound drug.
16. Design of experiments (DoE) using Design Expert ® Software.
17. Formulation data analysis using Design Expert ® Software.
18. Pharmacokinetic and IVIVC data analysis by WinNonLin software.
19. Formulation and evaluation of creams.
20. Formulation and evaluation of gels.
21. Formulation and evaluation of floating beads.
22. Formulation and evaluation of buccal gel.
23. Formulation and evaluation of albumin microspheres.
24. Formulation and evaluation of shampoo.

25. Formulation and evaluation of sterile water for injection and antibiotic injection.
26. To determine the various pharmacokinetic parameters following one compartment open model I.V. bolus administration.
27. To determine the various pharmacokinetic parameters following one compartment open model oral administration.
28. To determine the various pharmacokinetic parameters using urinary excretion data.
29. Formulation and evaluation of a baby powder.
30. Formulation and evaluation of toothpaste.
31. Formulation and evaluation of effervescent tablets.
32. Formulation and evaluation of pediatric suspension.

Second Semester

MOLECULAR PHARMACEUTICS (NANO TECHNOLOGY AND TARGETED DDS) (*MPH201/MPH101*)

Unit-I

Targeted drug delivery systems: Concept, types and key elements, ideal carrier system and approach with special reference to organ targeting (e.g., nose to brain, lung, liver, colon and lymphatics), basic of temperature, pH and magnetically induced targeting tactics.

Unit-II

Microparticles and dispersed system: Types, preparation, evaluation and application of microcapsules and microspheres.
Preparation, evaluation and application of self emulsifying drug delivery systems (SEDDS), self microemulsifying drug delivery systems (SMEDDS).

Unit-III

Nanoparticles: Introduction, significance, classification, formulation evaluation and application: nanoemulsion, solid lipid nanoparticle (SLN), nanostructured lipid carrier (NLC).
Carbon nanoparticles: Introduction, method of preparation and application.

Unit-IV

Vesicular drug delivery systems: Preparation, evaluation parameters and application of niosomes, ethosomes, liposomes and transferosomes.

Unit-V

Protein and vaccine delivery: Barriers for protein delivery, preformulation study, formulation and evaluation of delivery systems of proteins. Vaccines: uptake of antigens, single shot vaccines, mucosal and transdermal delivery of vaccines. Monoclonal antibodies: Preparation and application.

SUGGESTD BOOKS:

1. Chien Y.W., Novel Drug Delivery Systems, Marcel Dekker, Inc., New York.
2. Vyas S.P. and Khar R.K., Controlled Drug Delivery: Concepts and Advances, Vallabh Prakashan, New Delhi.
3. Jain N.K., Controlled and Novel Drug Delivery, CBS Publishers and Distributors, New Delhi.
4. Schreier H., Drug Targeting Technology Physical, Chemical and Biological Methods, Marcel Dekker, New York.
5. Roland A., Particulate Carriers: Therapeutic Applications, Marcel Dekker, New York.

ADVANCED BIOPHARMACEUTICS AND PHARMACOKINETICS (*MPH202*)

Unit-I

Drug absorption and drug interaction: pH–partition theory of drug absorption, factors affecting drug absorption, rate-limiting steps in drug absorption. Gastrointestinal absorption: Solution as a dosage form, suspension as a dosage form, capsule as a dosage form, tablet as a dosage form, biopharmaceutics classification system. Drug interactions: Introduction, the effect of protein-binding interactions, the effect of tissue-binding interactions, cytochrome P450-based drug interactions.

Unit-II

***In-vitro* drug dissolution:** Dissolution and drug release testing, compendial methods of dissolution, alternative methods of dissolution testing, problems of variable control in dissolution testing, performance of drug products, comparative drug release kinetics of oral dosage forms (conventional tablet, modified tablets, solution, suspension, emulsion) *in vitro* – i*n vivo* correlation (IVIVC).

Unit-III

Pharmacokinetics: Basic considerations, pharmacokinetic models, compartment modeling: One compartment model- IV bolus, IV infusion, extra vascular, two compartment model, non- linear pharmacokinetics, causes of non-linearity, Michaelis – Menten equation, SAS pharmacokinetic software.

Unit-IV

Drug product performance: Purpose of bioavailability studies, biopharmaceutical factors affecting drug bioavailability, relative and absolute availability, methods for assessing bioavailability, bioequivalence studies, design and evaluation of bioequivalence studies, study designs, evaluation of the data, clinical significance of bioequivalence studies, generic substitution.

Unit-V

Drug metabolism and excretion: Renal and hepatic excretion of drug, renal impairment, dose adjustment in renal diseases. Pharmacogenomics: Introduction, genetic polymorphism in drug metabolism, drug transport and drug targets.

SUGGESTED BOOKS:

1. Gibaldi M., Biopharmaceutics and Clinical Pharmacokinetics, Lea and Febiger, Philadelphia.
2. Shargel L. and Yu A.B.C., Applied Biopharmaceutics and Pharmacokinetics, Appleton Century Crofts, Connecticut.
3. Rani S., Hiremath R., Textbook of Biopharmaceutics and Pharmacokinetics, Prism Book, Chennai.
4. Gibaldi M., and Perrier D., Pharmacokinetics, Marcel Dekker Inc., New York.
5. Swarbrick J., Current Concepts in pharmaceutical sciences: Biopharmaceutics, Lea and Febiger, Philadelphia.
6. Rowland M. and Tozer T.N., Clinical Pharmacokinetics, Concepts and Applications, Lea and Febiger, Philadelphia.
7. Abdou. H.M, Dissolution, Bioavailability and Bioequivalence, Mack Publishing Company, Pennsylvania.
8. Notari R.E., Biopharmaceutics and Clinical Pharmacokinetics, An Introduction, Marcel Dekker Inc, New York.
9. Brahmankar D.M. and Jaiswal S.B., Biopharmaceutics and Pharmacokinetics: A Treatise, Vallabh Prakashan, Delhi.
10. Wagner J.G. and Pemarowski M., Biopharmaceutics and Relevant Pharmacokinetics, Drug Intelligence Publications, Hamilton.
11. Swarbrick J., Boylan J.G., Encyclopedia of Pharmaceutical Technology, Vol.-13, Marcel Dekker Inc., New York.
12. Jambhekar S.S. and Breen P.J., Basic Pharmacokinetics, Pharmaceutical Press, London.
13. Avdeef A., Absorption and Drug Development- Solubility, Permeability, and Charge State, John Wiley and Sons, New Jersey

COMPUTER AIDED DRUG DEVELOPMENT (*MPH203*)

Unit-I

Computers in pharmaceutical research and development: Statistical modeling in pharmaceutical research and development: Descriptive versus mechanistic modeling, statistical parameter, estimation. Confidence Regions: Nonlinearity at the optimum, sensitivity analysis, optimal design, population modeling.

Unit-II

Computational modeling of drug disposition ADMET modeling: Introduction, modeling techniques: Drug absorption, solubility, intestinal permeation, drug distribution, drug excretion, active transport; P-gp, breast cancer resistant protein (BCRP), nucleoside transporters, apical sodium dependent bile transporter(ASBT), organic cation transporter (OCT), organic anion transporter protein(OATP).

Unit-III

Computer-aided formulation development: Computers in pharmaceutical formulation: Development of pharmaceutical emulsions, microemulsion drug carriers legal protection of innovative uses of Computers in R and D, the ethics of computing in pharmaceutical research.

Unit-IV

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.
Computer simulations in pharmacokinetics and pharmacodynamics: Introduction, computer simulation: whole organism, isolated tissues and organs, cell, proteins and genes.
Computers in clinical development: Clinical data collection and management, regulation of computer systems.

Unit -V

Artificial intelligence (AI) robotics and computational fluid dynamics: General overview, pharmaceutical automation, pharmaceutical applications, advantages and disadvantages. Current challenges and future directions.

SUGGESTED BOOKS:

1. Ekins S., Computer Applications in Pharmaceutical Research and Development, John Wiley and Sons, New Jersey.
2. Djuris J., Computer-aided Applications in Pharmaceutical Technology, Woodhead Publishing, Cambridge.
3. Swarbrick J., Boylan J.G., Encyclopedia of Pharmaceutical Technology, Vol.-13, Marcel Dekker Inc, New York.

COSMETICS & COSMECEUTICALS (*MPH204/MPH102*)

Unit-I

Introduction to cosmetics and cosmeceuticals: Definition of cosmetic (as per D and C Act 1940) and cosmeceuticals (as per EU guidelines). Brief introduction to skin related problems and their associated cosmetic products: dry skin (causes, treatment and preparations-cream, emulsion, lotion, moisturizers), acne (treatment and preparations-lotion, creams) and wrinkles (cause, prevention and preparations-moisturizers).

Unit-II

Cosmetic ingredients: Classification and application: emollients, preservatives, thickening agents, antioxidants and surfactants. Regulatory requirements for selection and international nomenclature of color and perfume as per International nomenclature of cosmetic ingredients (INCI).

Unit-III

Design of cosmeceutical products:
Sunscreen agents: Classification, sun protection factor (SPF), mechanism of action, formulation of sunscreen lotion.
Anti-ageing products: Classification, factors for ageing, treatment for ageing, formulation of anti ageing creams.
Baby care products: Classification, difference between baby skin and adult skin, selection of cosmetic ingredients for baby care products, formulation of baby oil and diaper rashes cream.

Unit-IV

Plant layout: Location and surroundings, design and plant layout, building, lighting, ventilation, water supply and disposal of waste, health, clothing and sanitary requirement of staff, medical services, packaging facilities, sanitation in the manufacturing premises.

Unit-V

Herbal cosmetics: Herbal ingredients used in hair care, skin care and oral care. Review of guidelines for herbal cosmetics by private bodies like COSMOS with respect to preservatives, emollients, foaming agents, emulsifiers and rheology modifiers, Challenges in formulating herbal cosmetics, introduction and applications of phytosomes.

SUGGESTED BOOKS:

1. Harry R.G., Reiger M.M., Harry's Cosmeticology, Chemical Publishing Company. New York.
2. Sharma P.P., Cosmetics Formulation, Manufacturing and Quality Control, Vandana Publication Pvt. Ltd., Delhi.
3. Paye M., Basel A.O., Maibach H.I., Handbook of Cosmetic Science and Technology, Informa Healthcare. New York.
4. Balsam M.S., Sagarin E., Cosmetics: Science and Technology, Wiley Interscience, New York.
5. Rao Y.M., Shayeda, Cosmeceuticals, PharmaMed Press, Hyderabad.
6. Poucher W.A., Butler H., Poucher's Perfumes, Cosmetic and Soaps, Springer India Pvt. Ltd., New Delhi.
7. Nanda S., Nanda A., Cosmetic Technology, 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. Cosmetic and Toiletries Recent Suppliers Catalogue.
11. CTFA Directory.

PHARMACEUTICAL DESIGN & DEVELOPMENT (*MPH205*)

Unit-I

Aspects of product design: Scope of pre-formulation studies, pre-formulation testing criteria, design of pre-formulation studies, pre-formulation worksheet, criteria for selection of drug candidate and dosage form, safety and efficacy aspects of dosage form, solubility and solubility enhancement techniques, kinetics of stability, stability testing.
Packaging and labeling design, ecofriendly packaging material.

Unit-II

Active pharmaceutical ingredient and excipients: Drug-excipients interactions: Procedure, methods for identifying drug-excipient interactions. Classification of excipients, selection of excipients: safety, efficacy and evaluation of solid (lactose, crospovidone), liquid (parabens, SPAN) and semisolid excipients (PEG, petrolatum).Introduction to generally recognized as safe (GRAS) excipients.

Unit-III

Optimization techniques in pharmaceutical formulation: Concept and parameters of optimization, optimization techniques in pharmaceutical formulation and processing, statistical design, concept of significance, response surface method, contour designs, factorial designs and application in formulation development.

Unit-IV

Pilot plant scale up: Introduction, importance and technique involved in scale up**,** scale up of product batches, layout of pharmaceutical pilot plant, organization structure, personnel, activities, pilot plant scale up of tablets, semisolids, and parenterals.
Protocols for technology transfer, process automation technology (PAT) in pharmaceutical manufacturing, post approval changes (SUPAC).

Unit-V

Pharmaceutical product disposal and recall: Introduction to safe disposal of unwanted pharmaceuticals, disposal methods, sorting categories of pharmaceuticals, recommended disposal methods of sorting categories, recall classification, strategy for effective recall, FDA requested recall, firm initiated recall, recall status reports, termination of recall. Introduction to finished product reprocessing and salvaging.

SUGGESTED BOOKS:

1. Yalkowsky S.H., Techniques of Solubilization of drugs, Marcel Decker Inc., New York.
2. Martin A., Physical Pharmacy, B.I. Waverly Pvt. Ltd., New Delhi.
3. Wells J.I., Pharmaceutical Pre-formulation: The Physicochemical Properties of Drug Substances, Ellis Horwood, Chiechester.
4. Jain N.K., Pharmaceutical Product Development, CBS Publishers and Distributer, New Delhi.
5. Jain N.K., Controlled and Novel Drug Delivery Systems, CBS Publishers and Distributers, New Delhi.
6. Banker G.S. and Rhodes C.T., Modern Pharmaceutics, Marcel Decker Inc., New York.
7. Vyas S.P. and Khar R.K., Controlled Drug Delivery, Concept and Advances, Vallabh Prakashan, Delhi.
8. USP 25/NF 20, USP Convention, Rockville MD.
9. British Pharmacopoeia, Stationery Office, London.
10. Gibson M. Pharmaceutical Pre-formulation and Formulation, CRC Press, Florida.
11. Weiner M.L., and Kotkoskie L.A., 'Excipient Toxicity and Safety' Marcel Dekker, New York.
12. Wells J.J., Pharmaceutical Pre-formulations, Ellis Horwood Limited, Chiechester.

PHARMACEUTICS PRACTICAL-II (*MPH206*)

The practicals may be chosen from the following suggested list of experiments based on the subjects opted in that particular semester-

1. Formulation and evaluation of sustained release matrix tablets.
2. Preparation and evaluation of Floating DDS- hydro dynamically balanced DDS.
3. Formulation and evaluation of mucoadhesive tablets.
4. Formulation and evaluation of transdermal patches.
5. To study the effect of compressional force on tablets disintegration time.
6. To draw Heckal, Higuchi and Peppas plots and determine similarity factors.
7. To study the effect of temperature change, non solvent addition, incompatible polymer addition in microcapsules preparation.
8. Preparation and evaluation of alginate beads.
9. Formulation and evaluation of gelatin microspheres.
10. Formulation and evaluation of liposomes.
11. Formulation and evaluation of niosomes.
12. Improvement of dissolution characteristics of slightly soluble drug by solid dispersion technique.
13. Comparison of dissolution of two different marketed products/brands.
14. To perform accelerated stability testing of the given formulation.
15. Protein binding studies of a highly protein bound drug and poorly protein bound drug.
16. Design of experiments (DoE) using Design Expert ® Software.
17. Formulation data analysis using Design Expert ® Software.
18. Pharmacokinetic and IVIVC data analysis by WinNonLin software.
19. Formulation and evaluation of creams.
20. Formulation and evaluation of gels.
21. Formulation and evaluation of floating beads.
22. Formulation and evaluation of buccal gel.
23. Formulation and evaluation of albumin microspheres.
24. Formulation and evaluation of shampoo.
25. Formulation and evaluation of sterile water for injection and antibiotic injection.
26. To determine the various pharmacokinetic parameters following one compartment open model I.V. bolus administration.
27. To determine the various pharmacokinetic parameters following one compartment open model oral administration.
28. To determine the various pharmacokinetic parameters using urinary excretion data.
29. Formulation and evaluation of a baby powder.
30. Formulation and evaluation of toothpaste.
31. Formulation and evaluation of effervescent tablets.
32. Formulation and evaluation of pediatric suspension.

SYNOPSIS (SEMINAR-I) (*MPH207*)