Kavyatri Bahinabai Chaudhari

North Maharashtra University, Jalgaon (M.S.)

Syllabus of
First Year of Master of Pharmacy
(M. Pharm.)

Specialization
PHARMACEUTICAL TECHNOLOGY

Faculty of Science and Technology

Pharmaceutical Technology (MPT)

Course of study for M. Pharm. (Pharmaceutical Technology) (MPT)

Course Code	Course	Credit Hours	Credit Points	Hrs./wk	Marks
SEMINAR- I					
MPT 101T	Modern Pharmaceutical Analytical Techniques	4	4	4	100
MPT 102T	Advance Pharmaceutical Technology I	4	4	4	100
MPT 103T	Advances in drug delivery	4	4	4	100
MPT 104T	Drug Regulatory Affairs	4	4	4	100
MPT 105P	Advance Pharmaceutical Technology Practical I	12	6	12	150
-	**Seminar/Assignment**	7	4	7	100
Total		**35**	**26**	**35**	**650**
SEMINAR- II					
MPT 201T	Advance Pharmaceutical Technology II	4	4	4	100
MPT 202T	Cosmetics and cosmeceuticals	4	4	4	100
MPT 203T	Advanced Biopharmaceutics & Pharmacokinetics	4	4	4	100
MPT 204T	Pharmaceutical Validation	4	4	4	100
MPT 205P	Advance Pharmaceutical Technology Practical II	12	6	12	150
-	**Seminar/Assignment**	7	4	7	100
Total		**35**	**26**	**35**	**650**

SEM III & SEM IV

Table –: Course of study for M. Pharm. III Semester

(Common for All Specializations)

Course Code	Course	Credit Hours	Credit Points
MRM 301T	**Research Methodology and Biostatistics***	**4**	**4**
--	**Journal club**	**1**	**1**
--	**Discussion / Presentation (Proposal Presentation)**	**2**	**2**
--	**Research Work**	**28**	**14**

*** Non University Exam (Question paper will be provided by university and answer books assessed at institute)**

Table –: Course of study for M. Pharm. IV Semester (Common for All Specializations)

Course Code	Course	Credit Hours	Credit Points
--	**Journal Club**	**1**	**1**
--	**Research Work**	**31**	**16**
--	**Discussion/Final Presentation**	**3**	**3**
--	**Total**	**35**	**20**

Table –: Semester wise credits distribution

Semester	Credit Points
I	26
II	26
III	21
IV	20
Co-curricular Activities (Attending Conference, Scientific Presentations and Other Scholarly Activities)	Minimum=02 Maximum=07*
Total Credit Points	Minimum=95 Maximum=100*

***Credit Points for Co-Curricular Activities**

Guidelines for Awarding Credit Points for Co-Curricular Activities

Name of the Activity	Maximum Credit Points Eligible / Activity
Participation in National Level Seminar/Conference/Workshop/Symposium/Training Programs (related to the specialization of the student)	**01**
Participation in international Level Seminar/Conference/Workshop/Symposium/ Training Programs (related to the specialization of the student)	**02**
Academic Award/Research Award from State Level/National Agencies	**01**
Academic Award/Research Award from International Agencies	**02**
Research / Review Publication in National Journals (Indexed in Scopus / Web of Science)	**01**
Research / Review Publication in International Journals (Indexed in Scopus / Web of Science)	**02**

Note: International Conference: Held Outside India

International Journal: The Editorial Board Outside India

***The credit points assigned for extracurricular and or co-curricular activities shall be given by the Principals of the colleges and the same shall be submitted to the University. The criteria to acquire this credit point shall be defined by the colleges from time to time.**

Pharmaceutical Technology (MPT)

Schemes for internal assessments and end semester examinations (Pharmaceutical Technology - MPT)

Course Code	Course	Internal Assessment				End Semester Exams		Total Marks
		Continuous Mode	Sessional Exams			Total Marks	Duration	
			Marks	Duration				
SEMISTER I								
MPT 101T	Modern Pharmaceutical Analytical Techniques	10	15	1 Hr	25	75	3 Hr	100
MPT 102T	Advance Pharmaceutical Technology I	10	15	1 Hr	25	75	3 Hr	100
MPT 103T	Advances in drug delivery	10	15	1 Hr	25	75	3 Hr	100
MPT 104T	Drug Regulatory Affairs	10	15	1 Hr	25	75	3 Hr	100
MPT 105P	Advance Pharmaceutical Technology Practical I	20	30	6 Hr	50	100	6 Hr	150
--	Seminar /Assignment							100
TOTAL								**650**
SEMISTER II								
MPT 201T	Advance Pharmaceutical Technology II	10	15	1 Hr	25	75	3 Hr	100
MPT 202T	Cosmetics and cosmeceuticals	10	15	1 Hr	25	75	3 Hr	100
MPT 203T	Advanced Biopharmaceutics & Pharmacokinetics	10	15	1 Hr	25	75	3 Hr	100
MPT 204T	Pharmaceutical Validation	10	15	1 Hr	25	75	3 Hr	100
MPT 205T	Advance Pharmaceutical Technology Practical II	20	30	6 Hr	50	100	6 Hr	150
--	Seminar/ Assignment							100
	TOTAL							**650**

Schemes for internal assessments and end semester examinations

(Semester III& IV)

Course Code	Course	Internal Assessment				End Semester Exams		Total Marks
		Continuous Mode	Sessional Exams		Total	Marks	Duration	
			Marks	Duration				
SEMISTER III								
MRM301T	Research Methodology and Biostatistics*	10	15	1 Hr	25	75	3 Hr	100
--	Journal club	--	--	--	25	--	--	25
--	Discussion / Presentation (Proposal Presentation)	--	--	--	50	--	--	50
--	Research work*					350	1Hr	350
TOTAL								**525**
SEMISTER IV								
--	Journal club	--	--	--	25	--	--	25
--	Discussion / Presentation (Proposal Presentation)	--	--	--	75	--	--	75
--	Research work	--	--	--	--	400	1Hr	400
	TOTAL							**650**

*Non University Examination **(Question paper will be provided by university and answer books assessed by institute)**

Syllabus for Pharmaceutical Technology (MPT)

Modern Pharmaceutical Analytical Techniques

(MPT 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.

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 and Applications. **11Hrs**

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. **11Hrs**

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, Meta stable 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 electric 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. **11 Hrs**

6. **Immunological assays**: RIA (Radio immuno-assay), ELISA, Bioluminescence assays.

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, Eastern press, Bangalore, 1998.

3. Instrumental methods of analysis – Willards, 7th edition, CBS publishers.

4. Practical Pharmaceutical Chemistry – Beckett and Stenlake, Vol II, 4th edition, CBS Publishers, New Delhi, 1997.

5. Organic Spectroscopy - William Kemp, 3rd edition, ELBS, 1991.

6. Quantitative Analysis of Drugs in Pharmaceutical formulation - P D Sethi, 3rd

Edition, CBS Publishers, New Delhi, 1997.

7. Pharmaceutical Analysis- Modern methods – Part B - J W Munson, Vol.11, Marcel Dekker

ADVANCE PHARMACEUTICAL TECHNOLOGY I

(MPT 102T)

Scope: This course is designed to impart knowledge and skills necessary to train the students on various activities in R&D and F&D of pharmaceutical industry.

Objectives: On completion of this course it is expected that students will be able to understand-

- The regular activities in a Pharmaceutical industry
- The pre formulation studies of pilot batches of pharmaceutical industry.
- The significance of dissolution and product stability

THEORY **60 HRS**

1. Pre-Formulation Technology

Organoleptic properties of drug powder, purity of drug substances, particle size, shape and surface area, porosity, solubility, pKa and partition coefficient. Crystallinity, polymorphism, and drug- excipient interaction studies by X ray diffraction, DSC, TGA, HPLC (impurity). Hygroscopicity, flow ability and compressibility of powders. **10 Hrs**

2. **Optimization Techniques in Product Development Technology**

Optimization techniques, Quality by design (QbD), Design of Experiments(DOE) like factorial, artificial neural network (ANN). Identifying formulation and process variables, formulation optimization, response surface methodology, in-vitro test systems to evaluate and monitor the performance of different types of dosage forms. **10 Hrs**

3. Tablet Technology:

Systematic and modern approach to tablet components and production designs. Process of compression and physics of tablet compression, effect of additives on tablet strength, crushing strength, tensile strength, friability. Press design and layout, press control (off line and online) and automization, trouble shooting, recent tablet technologies.

Tablet coating theory, techniques of coating, mechanism of coat formation (aqueous and nonaqueous coat), coating compositions, physico–mechanical properties of polymer films, coating of single unit and multi-particulate systems. Industrial coaters, process atomization and optimization, coating problems and troubleshooting. **10 Hrs**

4. **Capsule formulation development**

Consideration for design of large scale manufacturing unit including intricate design criteria for units to manufacture of Capsules. **05 Hrs**

5. **Packaging**

Design and development of packaging units including recent advances in packaging techniques for various types of sterile and non sterile dosage forms. Stability aspects of packaging.

05 Hrs

6. **Dissolution Technology and IVIVC**

Historical Development, Compendial and noncompendial dissolution methodologies; US FDA Guidance; Techniques of dissolution enhancement; in vitro drug release kinetics, Introduction to BCS & IVIVC; Levels of correlation , prediction of IVIVC based on BCS; Development of level A correlation and dissolution testing methods ;bio-relevant media; evaluation of predictability of correlation ;Bioavailability studies for development of IVIVC; dissolution data analysis with view to IVIVC ; BCS and IVIVC based biowaivers. **10 Hrs**

7. **Stability Testing**

Predicting shelf life and half-life of pharmaceutical formulations. Destabilization modes and techniques of stabilization of pharmaceuticals. Importance of accelerated stability study, stress test method, Freeze thaw methods, centrifugal methods. Accelerated stability testing of new drug substances and new dosage forms. Photo stability testing of new drug substances and products. Bracketing and matrixing designs for stability testing of new drug substances and products. Evaluation of stability data. **10 Hrs**

REFERENCES

1. Fundamentals of Applied Statistics, S. C. Gupta, V. K. Kapoor, S. Chand and Sons, 2008.

2. Introduction to probability and Statistics, Henry L. Alder and Edward B. Roessler.

3. Mathematics and Statistics for use in Pharmacy, Biology, Chemistry, Saunders and Flemming.

4. B. K. Mahajan. Methods in Biostatistics (for Medical students and Research worker), 6th Ed, 1997, Jaypee Brothers Medical publishers (P) Ltd., New Delhi.

5. Theory and Practice of Industrial Pharmacy, Lachmann and Lieberman, Varghese, Publishing House, Bombay, 3rd Ed. – 1991

6. Physical Pharmacy, A. Martin, Lippincott Williams and Wilkins, London, 4th Ed. – 2001.

7. Drug stability: Principles and practices. Jens T. Carstensen

8. Stability Testing of Drug Products. W. Grimm.
9. Stability of Drugs and Dosage Forms by Yoshioka and Stella.
10. Pharmaceutical Dosage Form Tablets, Vol-I, II, III, Lieberman, Lachman and IB Schwartz, Marcel Dekker, New York, 2nd Ed. – 2008.
11. Pharmaceutical preformulation by J.T. Cartensen.
12. P. J. Tarcha; Polymers for controlled Drug Delivery; CRC Press
13. Tablet Machine instrumentation in pharmaceuticals, PR Watt, Ellis Horwoods, UK.
14. Swarbrick J and Boylon J.C., Encyclopedia of Pharmaceutical Technology, Vol. 1-3,Mercel Decker Inc.
12. Pharmaceutical Dissolution Testing; Ed by Jennifer Dressman and Johannes Kramer; Taylor & Francis.

ADVANCES IN DRUG DELIVERY

(MPT 103T)

Scope: This course is designed to impart knowledge and skills necessary to train the students in the area of Advanced drug delivery systems.

Objective: On completion of this course it is expected that students will be able to understand,

- The need, concept, design and evaluation of various customized, sustained and controlled release dosage forms.
- To formulate and evaluate various 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-Retentive 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.

10Hrs

4 Occular Drug Delivery Systems: Barriers of drug permeation, Methods to overcome barriers. **06Hrs**

5 Transdermal Drug Delivery Systems: Structure of skin and barriers, Penetration enhancers, Transdermal Drug Delivery Systems, Formulation and evaluation. **10Hrs**

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. **06Hrs**

REFERENCES

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

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

3. Encyclopedia of controlled delivery, Editor- Edith Mathiowitz, Published by WileyInterscience Publication, John Wiley and Sons, Inc, New York! Chichester/Weinheim

4. N.K. Jain, Controlled and Novel Drug Delivery, CBS Publishers & Distributors, New Delhi, First edition 1997 (reprint in 2001).

5. S.P.Vyas and R.K.Khar, Controlled Drug Delivery - concepts and advances, Vallabh Prakashan, New Delhi, First edition 2002.

JOURNALS

1. Indian Journal of Pharmaceutical Sciences (IPA)

2. Indian drugs (IDMA)

3. Journal of controlled release (Elsevier Sciences) desirable

4. Drug Development and Industrial Pharmacy (Marcel & Decker)

DRUG REGULATORY AFFAIRS

(MPT 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 of
- To know the chemistry, manufacturing controls and their regulatory
- importance
- To learn the documentation requirements for
- To learn the importance and

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
- Pharmacovigilance and process of monitoring in clinical trials.

THEORY **60 Hrs**

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, 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.

12Hrs

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). **12Hrs**

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 IsaderKaufer,Marcel Dekker series, Vol.143
2. The Pharmaceutical Regulatory Process, Second Edition Edited by Ira R. Berry and Robert P.Martin, Drugs and the Pharmaceutical Sciences,Vol.185, Informa Health care Publishers.
3. New Drug Approval Process: Accelerating Global Registrations By Richard A Guarino, MD,5th edition, Drugs and the Pharmaceutical Sciences,Vol.190.
4. Guidebook for drug regulatory submissions / Sandy Weinberg. By John Wiley & Sons.Inc.
5. FDA regulatory affairs: a guide for prescription drugs, medical devices, and biologics/edited By Douglas J. Pisano, David Mantus.
6. Clinical Trials and Human Research: A Practical Guide to Regulatory Compliance By Fay A.Rozovsky and Rodney K. Adams
7. www.ich.org/
8. www.fda.gov/
9. europa.eu/index_en.htm
10. https://www.tga.gov.au/tga-basics

ADVANCE PHARMACEUTICAL TECHNOLOGY PRACTICAL I (MPT 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 study of effect of particle size, moisture content and lubricants on flowability and compressibility of powders
8. To study of effect of various binding agents on the properties of tablets.
9. To evaluate drug-excipient compatibility in a formulation.
10. To demonstrate product development protocols from preformulation data.
11. To formulate matrix tablets using polymers and study their release behaviors.
12. To formulate and evaluate sugar/non-enteric/enteric coated tablets.
13. To study rate of sedimentation and the effect of suspending agents on the rate of sedimentation of the given sample.
14. Study the effect of temperature, surface area and viscosity of the liquid on the rate of evaporation
15. To study the effect of surface area, material bed thickness, temperature and moisture content on the rate of drying.
16. To study phase behaviour of three component system and construct ternary phase diagram.
17 Preparation and evaluation of pellets using certain techniques like extrusion spheronization, etc.
18. To perform an experiment demonstrating IVIVC studies.
19. Development of formulation and determination of its shelf life and half -life.
20. Process controls and analysis of the output for certain products.

REFERENCES

1. Practical Manual of Pharmaceutical Engineering. Munira Momin, Tejal A. Mehta, B. S. Shah Prakashan, Ahmedabad. Second Edition: 2009
2. Pharmaceutical Engineering: Practical Manual 2/ed Sudhakara Reddy Pondugula,

M. Gopal Rao, Govinda Rajan Gudala, R. Vamsi Krishna
3. Practical Physical Pharmacy, H. N. More and A. A. Hajare; Third Edition, Career Publications, Nashik.
4. Practical Physical Pharmacy. Gaud and Gupta; Vallabh Prakashan, Delhi.
5. Dermatological Formulation – Percutaneous Absorption. Srian W. Berry, Marcel Dekker Inc. New York.
6. Controlled Drug Delivery, Second Edition, Lee and Robinson, Marcel Decker Inc
7. Novel Drug Delivery Systems, Y. W. Chein, Marcel Dekker, Inc
8. Microencapsulation, Simon Benita, Pub. Marcel Dekker Inc.
9. Specialized Drug Delivery Systems, Praveen Tyle, Pub. Marcel Dekker Inc.
10. Controlled and Novel Drug delivery, N. K. Jain, 1st Ed. CBS Publisher and Distributor.
11. Controlled release of drugs; Morton Rosoff; VCH Publishers.
12. Topical drug delivery formulations; Osborne, and Amann; Marcel Dekker.
13. Dermatological formulation; Barry: Marcel Dekker
14. Pharmaceutical Inhalation Aerosol Technology; A. J. Hickey; Marcel, Dekker.
15. Targeted and Controlled drug delivery- Novel Career System. Vyas S. P. and Khar R. K., CBS Publications, New Delhi.
16. Encyclopedia of Pharmaceutical Technology. Swarbrick J and Boylon J. C., Vol. 1-3, Marcel Decker Inc.
17. Nanoparticles. Ram, Marcel Dekker.
18. Microcapsules and Microencapsulation Techniques. M. I. Gutcho, Noyes Data, Corporation, 1976.
19. Introduction to Chemical Engineering, W.L.Badger & J. T. Banthero.
20. Unit Process in Pharmacy, David Ganderton. Medical Books Ltd. London
21. Unit Operations, G.G. Brown; CBS Publishers and Distributors, New Delhi.
22. Perry's Chemical Engineering Hand Book, Robbert H. Perry, Don W, Green; 7th edition, International Edition, McGraw Hill
23. Industrial Instrumentation, Donald P. Eckman Seventh Wiley Eastern, Reprint, 1983, Wiley Eastern Ltd, 4835/24, Ansari Road, Daryaganj, New Delhi 110 002.

ADVANCE PHARMACEUTICAL TECHNOLOGY II

(MPT 201T)

Scope

This course is designed to impart knowledge and skills necessary to train the students with the fundamental aspects of sustained, controlled and targeted drug delivery system

Objectives

At completion of this course it is expected that students will be able to

understand,

- How to design and developments of Oral controlled drug delivery system
- Manufacturing aspects of sterile formulations
- Formulation and evaluation of transdermal drug delivery systems
- Understand different targeting technologies
- Able to know role of polymer technology in drug delivery systems

THEORY **60 Hrs**

1. Fundamentals of sustained, controlled and targeted drug delivery: Basics, design of sustained release dosage forms. Biopharmaceutics of sustained and controlled drug delivery systems. Need and fundamentals, techniques of targeting, design of targeting compounds and devices.

05 Hrs

2.**Oral controlled drug delivery system (OCDDS)**

Therapeutic needs of OCDDS. Design parameters/characteristics and their ranges for OCDDS. Properties of drugs suitable/unsuitable for OCDDS. Types of OCDDS, design and evaluation of gastro retentive and colon specific drug delivery systems. In vitro, ex vivo and in vivo evaluation of OCDDS. **10 Hrs**

3.**Sterile formulation**

Preformulation studies, Requirement, components, materials, Pharmacopoeial requirements for SVP & LVP, special types of parenterals such as suspensions, emulsions, dried forms, sterile diagnostics and radiopharmaceuticals. Environmental control: Temperature and humidity control, air handing systems and their validation, GMP and regulatory guidelines Sustained Release Parenterals: Liposomes, and niosomes, nanoparticles, proteins and peptides, implants, loaded erythrocytes.

Ophthalmic products Drug absorption in eye, formulation consideration and evaluation of ophthalmic products, contact lenses, occuserts, container and closures, safety.

10 Hrs

4.**Transdermal drug delivery systems**

Theory, design, formulation and evaluation including iontophoresis, sonophoresis and other latest developments in skin delivery systems. Development and evaluation of transdermal devices and osmotic pumps. Design and development of packaging units including recent advances in packaging techniques for various types of sterile and non sterile dosage forms. Stability aspects of packaging.

10 Hrs

5.**Pelletisation Technology**

Techniques of pelletisation and advantages of pellets. Extrusion sphernoisation process, process controls and formulation variables in Extrusion-spheronisation. Hot melt extrusion: On line, in line and off line process controls. Applications of both processes in dosage form design.

05 Hrs

6.**Aerosols**

Advances in metered dose inhaler designs and dry powder inhalers. Respules for inhalation. Particle engineering techniques to improve inhalable fraction and evaluation thereof.

05 Hrs

7.**Drug Targeting Technologies**

Need, fundamentals and techniques of targeting. A) Physical Targeting Approaches like-Enteric/colonic Targeting Through Coating, Lipid-Based Formulations for Oral Administration for Bioavailability Enhancement and Lipoprotein Targeting of Lipophilic Drugs, B) Chemical Targeting Approaches: Drug Targeting by Retrometabolic Design: Soft Drugs and Chemical Delivery Systems, Neoglyco- and Neopeptide Albumins for Cell- Specific Delivery of Drugs and and prodrugs, C) Biological Targeting Approaches- Gene Delivery with Artificial Viral Envelopes, Evolution of Viral Liposomes: Improvements and Applications, Targeting of Viral Vectors for Cancer Gene Therapy.

10 Hrs

8.**Polymer Technology**

Introduction, classification, properties and characterization of polymers. Biodegradable polymers, thermodynamics of polymer solution, phase separation, polymers in solid state, polymer properties crucial in drug delivery and formulation design.

05 Hrs

REFERENCES

1. Dermatological Formulation – Percutaneous Absorption. Srian W. Berry, Marcel Dekker Inc. New York.
2. Lee and Robinson, Controlled Drug Delivery, Second Edition, Marcel Decker Inc
3. Novel Drug Delivery Systems, Y. W. Chein, Marcel Dekker, Inc
4. Microencapsulation, Simon Benita, Pub. Marcel Dekker Inc.
5. Specialized Drug Delivery Systems, Praveen Tyle, Pub. Marcel Dekker Inc.
6. Controlled and Novel Drug delivery, N. K. Jain, 1st Ed. CBS Publisher and Distributor.
7. Drug Delivery Devices, fundamental and applications; P. Tyle; Marcel Dekker.
8. Controlled release of drugs; Morton Rosoff; VCH Publishers.
9. Topical drug delivery formulations; Osborne, and Amann; Marcel Dekker.
10. Barry: Dermatological formulation; Marcel Dekker
11. Mechanisms of Transdermal drug delivery; R. O. Potts, and R.H. Guy; Marcel Dekker.
12. Nanotechnology in Drug Delivery (Biotechnology: Pharmaceutical Aspects) by Melgardt M. de Villiers
13. Pharmaceutical Inhalation Aerosol Technology; A. J. Hickey; Marcel, Dekker.
14. Targeted and Controlled drug delivery- Novel Career System. Vyas S. P. and Khar R. K., CBS Publications, New Delhi..

COSMETICS AND COSMECEUTICALS
(MPT 202T)

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. **12Hrs**

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. **12Hrs**

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.

12Hrs

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. **12Hrs**

5. 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. **12Hrs**

REFERENCES

1. Harry's Cosmeticology. 8th edition.
2. Poucher'sperfumecosmeticsandSoaps,10th edition.
3. Cosmetics - Formulation, Manufacture and quality control, PP.Sharma,4th edition
4. Handbook of cosmetic science and Technology A.O.Barel, M.Paye and H.I. Maibach. 3 rd edition
5. Cosmetic and Toiletries recent suppliers catalogue.
6. CTFA directory.

ADVANCED BIOPHARMACEUTICS AND PHARMACOKINETICS (MPT 203T)

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 biopharmaceutics 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 **60 Hrs**

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 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. **12Hrs**

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 testingperformance 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, drug interactions linked to transporters**.**

12Hrs

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.

12Hrs

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. **12Hrs**

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., VallabPrakashan, Pitampura, Delhi

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

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

5. Pharmacokinetics by Milo Gibaldi and D. Perrier, 2nd edition, 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 MalcolmRowland and Thom~ N. Tozer, Lea and Febiger, Philadelphia,1995

8. Dissolution, Bioavailability and Bioequivalence, Abdou. H.M, Mack PublishingCompany, 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,1 st edition,Sunil S JambhekarandPhilip J Breen,pharmaceutical press, RPS Publishing,2009.

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

PHARMACEUTICAL VALIDATION

(MPT 204T)

Scope

The main purpose of the subject is to understand about validation and how it can be applied to industry and thus improve the quality of the products. The subject covers the complete information about validation, types, methodology and application.

Objectives

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

- The concepts of calibration, qualification and validation
- The qualification of various equipments and instruments
- Process validation of different dosage forms
- Validation of analytical method for estimation of drugs
- Cleaning validation of equipments employed in the manufacture of
- pharmaceuticals

THEORY **60 Hrs**

1.**Introduction to validation:** Definition of Calibration, Qualification and Validation, Scope, frequency and importance. Difference between calibration and validation. Calibration of weights and measures. Advantages of Validation, scope of Validation, Organization for Validation, Validation Master plan, Types of Validation, Streamlining of qualification & Validation process and Validation Master Plan. Qualification: User requirement specification, Design qualification, Factory Acceptance Test (FAT)/Site Acceptance Test (SAT), Installation qualification, Operational qualification, Performance qualification, Re-Qualification (Maintaining status- Calibration Preventive Maintenance, Change management).

10Hrs

2. **Qualification of manufacturing equipment**: Dry Powder Mixers, Fluid Bed and Tray dryers, Tablet Compression (Machine), Dry heat sterilization/Tunnels, Autoclaves, Membrane

filtration, Capsule filling machine. Qualification of analytical instruments: UV-Visible spectrophotometer, FTIR, DSC, GC, HPLC, HPTLC, LC-MS. **10Hrs**

3. **Qualification of laboratory equipments**: Hardness tester, Friability test apparatus, tap density tester, Disintegration tester, Dissolution test apparatus Validation of Utility systems: Pharmaceutical water system & pure steam, HVAC system, Compressed air and nitrogen.

10Hrs

4. **Process Validation:** Concept, Process and documentation of Process Validation. Prospective, Concurrent & Retrospective Validation, Re-validation criteria, Process Validation of various formulations (Coated tablets, Capsules, Ointment/Creams, Liquid Orals and aerosols.), Aseptic filling: Media fill validation, USFDA guidelines on Process Validation- A life cycle approach. Analytical method validation: General principles, Validation of analytical method as per ICH guidelines and USP. **10Hrs**

5 **Cleaning Validation:** Cleaning Method development, Validation of analytical method used in cleaning, Cleaning of Equipment, Cleaning of Facilities. Cleaning in place (CIP). Validation of facilities in sterile and non-sterile plant. Computerized system validation: Electronic records and digital signature - 21 CFR Part 11 and GAMP. **10Hrs**

6 **General Principles of Intellectual Property:** Concepts of Intellectual Property (IP), Intellectual Property Protection (IPP), Intellectual Property Rights (IPR); Economic importance, mechanism for protection of Intellectual Property –patents, Copyright, Trademark; Factors affecting choice of IP protection; Penalties for violation; Role of IP in pharmaceutical industry; Global ramification and financial implications. Filing a patent application; patent application forms and guidelines. Types patent applications-provisional and non provisional, PCT and convention patent applications; International patenting requirement procedures and costs; Rights and responsibilities of a patentee; Practical aspects regarding maintaining of a Patent file; Patent infringement meaning and scope. Significance of transfer technology (TOT), IP and ethics-positive and negative aspects of IPP; Societal responsibility, avoiding unethical practices. **10 Hrs**

REFERENCES

1. B. T. Loftus & R. A. Nash, "Pharmaceutical Process Validation", Drugs and

Pharm Sci. Series, Vol. 129, 3rd Ed., Marcel Dekker Inc., N.Y.

2. The Theory & Practice of Industrial Pharmacy, 3rd edition, Leon Lachman,

Herbert A. Lieberman, Joseph. L. Karig, Varghese Publishing House,Bombay.

3. Validation Master plan by Terveeks or Deeks, Davis Harwood International

publishing.

4. Validation of Aseptic Pharmaceutical Processes, 2nd Edition, by Carleton

& Agalloco,

5. (Marcel Dekker).

6. Michael Levin, Pharmaceutical Process Scale-Up", Drugs and Pharm. Sci.

Series, Vol. 157,2nd Ed., Marcel Dekker Inc., N.Y.

7. Validation Standard Operating Procedures: A Step by Step Guide for Achieving Compliance in the Pharmaceutical, Medical Device, and Biotech Industries, Syed Imtiaz Haider

8. Pharmaceutical Equipment Validation: The Ultimate Qualification Handbook, Phillip A. Cloud, Interpharm Press

9. Validation of Pharmaceutical Processes: Sterile Products, Frederick J. Carlton (Ed.) and James Agalloco (Ed.), Marcel Dekker

10. Analytical Method validation and Instrument Performance Verification by Churg Chan, Heiman Lam, Y.C. Lee, Yue. Zhang, Wiley Interscience.

11. Huber L. Validation and Qualification in Analytical Laboratories. Informa Healthcare

12. Wingate G. Validating Corporate Computer Systems: Good IT Practice for Pharmaceutical Manufacturers. Interpharm Press

13. LeBlanc DA. Validated Cleaning Technologies for Pharmaceutical Manufacturing. Interpharm Press.

ADVANCE PHARMACEUTICAL TECHNOLOGY PRACTICAL II (MPT 205T)

1. Study of drug diffusion study through various polymer membranes.
2.Preparation and evaluation of wax embedded microspheres.
3.Preparation and study on in vitro evaluation of mucoadhesive system.
4. Preparation and evaluation of hydrogel.
5.Study of Mier's super solubility curve for the given samples.
6. Determine the effect of various factors on the rate of filtration.
7.To determine overall heat transfer coefficient of drying process.
8.To determine moisture content in a given sample by Karl Fischer Titrator or IR moisture balance.
9.To study effect of filter aid concentration on rate of filtration.
10.Preparation of polymer films containing different drugs and study of film characteristics and release patterns.
11.Preparation and study on in-vitro evaluation of mucoadhesive system.
12.Preparation and evaluation for ocusert.
13. Development and evaluation of Creams
14. Development and evaluation of Shampoo and Toothpaste base
15. To incorporate herbal and chemical actives to develop products
16. To address Dry skin, acne, blemish, Wrinkles, bleeding gums and dandruff.
17. Comparison of dissolution of two different marketed products /brands
18. Protein binding studies of a highly protein bound drug & poorly protein bound drug
19. Bioavailability studies of Paracetamol in animals.
20. Pharmacokinetic and IVIVC data analysis by software
21. In vitro cell studies for permeability and metabolism

REFERENCES

1. Practical Manual of Pharmaceutical Engineering. Munira Momin, Tejal A. Mehta, B. S. Shah Prakashan, Ahmedabad. Second Edition: 2009
2. Pharmaceutical Engineering: Practical Manual 2/ed Sudhakara Reddy Pondugula,M. Gopal Rao, Govinda Rajan Gudala, R. Vamsi Krishna
3. Practical Physical Pharmacy, H. N. More and A. A. Hajare; Third Edition, Career Publications, Nashik.

4. Practical Physical Pharmacy. Gaud and Gupta; Vallabh Prakashan, Delhi.

5. Dermatological Formulation – Percutaneous Absorption. Srian W. Berry, Marcel Dekker Inc. New York.

6. Controlled Drug Delivery, Second Edition, Lee and Robinson, Marcel Decker Inc

7. Novel Drug Delivery Systems, Y. W. Chein, Marcel Dekker, Inc

8. Microencapsulation, Simon Benita, Pub. Marcel Dekker Inc.

9. Specialized Drug Delivery Systems, Praveen Tyle, Pub. Marcel Dekker Inc.

10. Controlled and Novel Drug delivery, N. K. Jain, 1st Ed. CBS Publisher and Distributor.

11. Controlled release of drugs; Morton Rosoff; VCH Publishers.

12. Topical drug delivery formulations; Osborne, and Amann; Marcel Dekker.

13. Dermatological formulation; Barry: Marcel Dekker

14. Pharmaceutical Inhalation Aerosol Technology; A. J. Hickey; Marcel, Dekker.

15. Encyclopaedia of Pharmaceutical Technology. Swarbrick J and Boylon J. C., Vol.1-3, Marcel Decker Inc.

16. Microcapsules and Microencapsulation Techniques. M. I. Gutcho, Noyes Data, Corporation, 1976.

17. Unit Process in Pharmacy, David Ganderton. Medical Books Ltd. London

18. Unit Operations, G.G. Brown; CBS Publishers and Distributors, New Delhi.