

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

Course Code	Course	Credit Hours	Credit Points	Hrs./week	Marks
Semester I					
MPH101T	Modern Pharmaceutical Analytical Techniques	4	4	4	100
MPH102T	Drug Delivery System	4	4	4	100
MPH103T	Modern Pharmaceutics	4	4	4	100
MPH104T	Regulatory Affair	4	4	4	100
MPH105P	Pharmaceutics Practical I	12	6	12	150
-	Seminar/Assignment	7	4	7	100
Total		35	26	35	650



(Approved by AICTE, PCI and Affiliated to Osmania University)

## 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 HOURS

1. a. UV-Visible spectroscopy: Introduction, Theory, Laws, 11 Instrumentation associated with UV-Visible spectroscopy, Hrs 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 (Approved by AICTE, PCI and Affiliated to Osmania University)
  - c. Spectrofluorimetry: 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. 11
- 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 <sup>13</sup>C NMR. Applications of NMR spectroscopy. Hrs

- 3 Mass Spectroscopy: Principle, Theory, Instrumentation of Mass 11 Spectroscopy, Different types of ionization like electron impact, Hrs 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
- 4 Chromatography: Principle, apparatus, instrumentation, 11 chromatographic parameters, factors affecting resolution and Hrs 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
- 5 a. Electrophoresis: Principle, Instrumentation, Working 11 conditions, factors affecting separation and applications of the Hrs 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.
- 6 Immunological assays: RIA (Radio immuno assay), ELISA, 5 Hrs Bioluminescence assays.

#### REFERENCES

1. Spectrometric Identification of Organic compounds – Robert M Silverstein, Sixth edition, John Wiley & Sons, 2004.
2. Principles of Instrumental Analysis – Douglas 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, Volume 11, Marcel Dekker Series

## DRUG DELIVERY SYSTEMS (MPH 102T)

### SCOPE

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

### OBJECTIVES

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

The various approaches for development of novel drug delivery systems.

The criteria for selection of drugs and polymers for the development of delivering system

The formulation and evaluation of Novel drug delivery systems..

### THEORY

60 Hrs

1. Sustained Release(SR) and Controlled Release (CR) formulations: 10 Hrs  
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.
2. Rate Controlled Drug Delivery Systems: Principles & 10 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.
3. Gastro-Retentive Drug Delivery Systems: Principle, concepts 10 Hrs advantages and disadvantages, Modulation of GI transit time approaches to extend GI transit. Buccal Drug Delivery Systems: Principle of muco adhesion, advantages and disadvantages, Mechanism of drug permeation, Methods of formulation and its evaluations.
4. Ocular Drug Delivery Systems: Barriers of drug permeation, 06 Hrs  
Methods to overcome barriers.

- 5 Transdermal Drug Delivery Systems: Structure of skin and 10 barriers, Penetration enhancers, Transdermal Drug Delivery Hrs Systems, Formulation and evaluation.
- 6 Protein and Peptide Delivery: Barriers for protein delivery. 08 Formulation and Evaluation of delivery systems of proteins and Hrs other macromolecules.
- 7 Vaccine delivery systems: Vaccines, uptake of antigens, single 06 shot vaccines, mucosal and transdermal delivery of vaccines. Hrs

#### REFERENCES

1. Y W. Chien, Novel Drug Delivery Systems, 2nd edition, revised and expanded, Marcel Dekker, Inc., New York, 1992.
2. Robinson, J. R., Lee V. H. L, Controlled Drug Delivery Systems, Marcel Dekker, Inc., New York, 1992.
3. Encyclopedia of controlled delivery, Editor- Edith Mathiowitz, Published by 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) to Osmania University)
2. Indian drugs (IDMA)
3. Journal of controlled release (Elsevier Sciences) desirable
4. Drug Development and Industrial Pharmacy (Marcel & Decker) desirable

## MODERN PHARMACEUTICS (MPH 103T)

### Scope

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

### Objectives

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

The elements of preformulation studies.

The Active Pharmaceutical Ingredients and Generic drug Product development

Industrial Management and GMP Considerations.

Optimization Techniques & Pilot Plant Scale Up Techniques

Stability Testing, sterilization process & packaging of dosage forms.

### THEORY

60 HRS

1. a. Preformation Concepts – Drug Excipient interactions – 10 different methods, kinetics of stability, Stability testing. Theories of Hrs 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: 10 Concept and parameters of optimization, Optimization techniques Hrs in pharmaceutical formulation and processing. Statistical design, Response surface method, Contour designs, Factorial designs and application in formulation
- 2 Validation : Introduction to Pharmaceutical Validation, Scope & 10 merits of Validation, Validation and calibration of Master plan, Hrs 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.
- 3 cGMP & Industrial Management: Objectives and policies of 10 current good manufacturing practices, layout of buildings, Hrs 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.

- 4 Compression and compaction: Physics of tablet compression, 10 compression, consolidation, effect of friction, distribution of Hrs forces, compaction profiles. Solubility.
- 5 Study of consolidation parameters; Diffusion parameters, 10 Dissolution parameters and Pharmacokinetic parameters, Heckel Hrs plots, Similarity factors – f<sub>2</sub> and f<sub>1</sub>, Higuchi and Peppas plot, Linearity Concept of significance, Standard deviation, Chi square test, students T-test, ANOVA test.

#### REFERENCES

1. Theory and Practice of Industrial Pharmacy By Lachmann and Libermann
2. Pharmaceutical dosage forms: Tablets Vol. 1–3 by Leon Lachmann.
3. Pharmaceutical Dosage forms: Disperse systems, Vol, 1–2; By 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, Second edition; By Sidney H. Willig.
11. Quality Assurance Guide; By Organization of Pharmaceutical producers of India.
12. Drug formulation manual; By D.P.S. Kohli and D.H. Shah. Eastern publishers, New Delhi.
13. How to practice GMPs; By P.P. Sharma. Vandhana Publications, Agra.
14. Pharmaceutical Process Validation; By Fra. R. Berry and Robert A. Nash.
15. Pharmaceutical Preformulations; By J.J. Wells.
16. Applied production and operations management; By Evans, Anderson, Sweeney and Williams.
17. Encyclopaedia of Pharmaceutical technology, Vol I – III.

## REGULATORY AFFAIRS (MPH 104T)

### Scope

Course designed to impart advanced knowledge and skills required to learn the 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 12 formula record, DMF (Drug Master File), distribution records. 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 12 products and medical devices. CTD and ECTD format, industry Hrs and FDA liaison. ICH – Guidelines of ICH–Q, S E, M. Regulatory requirements of EU, MHRA, TGA and ROW countries.

3 Non clinical drug development: Global submission of IND, 12 Hrs NDA, ANDA. Investigation of medicinal products dossier, dossier

(IMPD) and investigator brochure (IB).

- 4 Clinical trials: Developing clinical trial protocols. Institutional 12 review board/ independent ethics committee Formulation and Hrs working procedures informed Consent process and procedures. HIPAA– new, requirement to clinical study process, pharmacovigilance safety monitoring in clinical trials.

#### REFERENCES

1. Generic Drug Product Development, Solid Oral Dosage forms, Leon 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 (University)
7. [www.ich.org/](http://www.ich.org/)
8. [www.fda.gov/](http://www.fda.gov/)
9. [europa.eu/index\\_en.htm](http://europa.eu/index_en.htm)
10. <https://www.tga.gov.au/tga-basics>

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 Muco adhesive tablets.
12. Formulation and evaluation of trans dermal patches.
13. To carry out preformulation 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.

St. Paul's  
College of Pharmacy

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