



# RAJJU SHROFF ROFEL UNIVERSITY, VAPI

## **FACULTY OF PHARMACY** (ROFEL SHRI G.M. BILAKHIA COLLEGE OF PHARMACY)

ACADEMIC YEAR- 2023-24

## **SYLLABUS**

# M.Pharmacy (Pharmaceutics)

## Semester I

### MPH010010 - MODERN PHARMACEUTICAL ANALYTICAL TECHNIQUES

#### 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**

**11 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. **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 HOURS**

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.

**11 HOURS**

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 HOURS**

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 HOURS**

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 Xray diffraction.

**5 HOURS**

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

# M.Pharmacy (Pharmaceutics)

## Semester I

### MPH010020 - DRUG DELIVERY SYSTEMS

#### 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 HOURS**

**10 HOURS**

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 HOURS**

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.

**11 HOURS**

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.

**06 HOURS**

4 Ocular Drug Delivery Systems: Barriers of drug permeation, Methods to overcome barriers.

**10 HOURS**

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

**08 HOURS**

6 Protein and Peptide Delivery: Barriers for protein delivery. Formulation and Evaluation of delivery systems of proteins and other macromolecules

**08 HOURS**

7 Vaccine delivery systems: Vaccines, uptake of antigens, single shot vaccines, mucosal and transdermal delivery of vaccines.

#### REFERENCES

1. Y W. Chien, Novel Drug Delivery Systems, 2nd edition, revised and expanded, Marcel Dekker, Inc., New York, 1992.
2. Robinson, J. R., Lee V. H. L, Controlled Drug Delivery Systems, Marcel Dekker, Inc., New York, 1992.
3. Encyclopedia of controlled delivery, Editor- Edith Mathiowitz, Published by Wiley Interscience 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) desirable

# M.Pharmacy (Pharmaceutics)

## Semester I

### MPH010030 - MODERN PHARMACEUTICS

#### 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 HOURS**

**10 HOURS**

1. a. Preformation Concepts – Drug Excipient interactions - different methods, kinetics of stability, Stability testing. Theories of dispersion and pharmaceutical Dispersion (Emulsion and Suspension, SMEDDS) preparation and stability large and small volume parental – physiological and formulation consideration, Manufacturing and evaluation.

**10 HOURS**

b. Optimization techniques in Pharmaceutical Formulation: Concept and parameters of optimization, Optimization techniques in pharmaceutical formulation and processing. Statistical design, Response surface method, Contour designs, Factorial designs and application in formulation

**10 HOURS**

2 Validation: Introduction to Pharmaceutical Validation, Scope & merits of Validation, Validation and calibration of Master plan, ICH & WHO guidelines for calibration and validation of equipments, Validation of specific dosage form, Types of validation. Government regulation, Manufacturing Process Model, URS, DQ, IQ, OQ & P.Q. of facilities.

**10 HOURS**

3 cGMP & Industrial Management: Objectives and policies of current good manufacturing practices, layout of buildings, services, equipments and their maintenance Production management: Production organization, , materials management, handling and transportation, inventory management and control, production and planning control, Sales forecasting, budget and cost control, industrial and personal relationship. Concept of Total Quality Management.

**10 HOURS**

4 Compression and compaction: Physics of tablet compression, compression, consolidation, effect of friction, distribution of forces, compaction profiles. Solubility.

**10 HOURS**

5 Study of consolidation parameters; Diffusion parameters, Dissolution parameters and Pharmacokinetic parameters, Heckel 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.

# M.Pharmacy (Pharmaceutics)

## Semester I

### MPH010040 - REGULATORY AFFAIRS

#### 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

**08 HOURS**

**12 HOURS**

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

**12 HOURS**

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 HOURS**

3 Non clinical drug development: Global submission of IND, NDA, ANDA. Investigation of medicinal products dossier, dossier (IMPD) and investigator brochure (IB).

**12 HOURS**

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.

#### REFERENCES

1. Generic Drug Product Development, Solid Oral Dosage forms, Leon Shargel and Isader Kaufer, Marcel Dekker series, Vol.143
2. The Pharmaceutical Regulatory Process, Second Edition Edited by 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/](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>

# M.Pharmacy (Pharmaceutics)

## Semester I

### MPH010050 - PHARMACEUTICS PRACTICALS - I

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.

# M.Pharmacy (Pharmaceutics) Semester I

MPH010060 - Seminar/Assignment - I

**Practical**

**90 Hours**

## **Microsoft office word**

- ☒ Creating, editing, saving and printing text documents
- ☒ Font and paragraph formatting
- ☒ Simple character formatting
- ☒ Inserting tables, smart art, page breaks
- ☒ Using lists and styles
- ☒ Working with images
- ☒ Using Spelling and Grammar check
- ☒ Understanding document properties

## **Microsoft office PowerPoint**

- ☒ Opening, viewing, creating, and printing slides
- ☒ Applying auto layouts
- ☒ Adding custom animation
- ☒ Using slide transitions
- ☒ Graphically representing data : Charts & Graphs
- ☒ Creating Professional Slide for Presentation.

## **Microsoft office excel**

- ☒ Spreadsheet basics
- ☒ Creating, editing, saving and printing spreadsheets
- ☒ Working with functions & formulas
- ☒ Modifying worksheets with color & autoformats
- ☒ Graphically representing data : Charts & Graphs
- ☒ Speeding data entry : Using Data Forms
- ☒ Analyzing data : Data Menu, Subtotal, Filtering Data
- ☒ Formatting worksheets
- ☒ Securing & Protecting spreadsheets

### **Reference books**

Mastering MS Office (English, Paperback, Kumar Bittu)

Master Book Of Computer: Learn MS Office, Basic Computer, MS Excel, Excel Formulas, Tally, HTML by Mangesh Bhuvad.

# M.Pharmacy (Pharmaceutics)

## Semester II

### MPH020010 - MOLECULAR PHARMACEUTICS (NANO TECHNOLOGY & TARGETED DDS) (NTDS)

#### Scope

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

#### Objectives

Upon completion of the course student shall be able to understand

- The various approaches for development of novel drug delivery systems.
- The criteria for selection of drugs and polymers for the development of NTDS
- The formulation and evaluation of novel drug delivery systems.

#### THEORY

**60 HOURS**

**12 HOURS**

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

**12 HOURS**

2 Targeting Methods: introduction preparation and evaluation. Nano Particles & Liposomes: Types, preparation and evaluation.

**12 HOURS**

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

**12 HOURS**

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

**12 HOURS**

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

#### REFERENCES

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

# M.Pharmacy (Pharmaceutics)

## Semester II

### MPH020020 - ADVANCED BIOPHARMACEUTICS & PHARMACOKINETICS

#### Scope

This course is designed to impart knowledge and skills necessary for dose calculations, dose adjustments and to apply biopharmaceutics theories in practical problem solving. Basic theoretical discussions of the principles of biopharmaceutics and pharmacokinetics are provided to help the students to clarify the concepts.

#### Objectives

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

- The basic concepts in biopharmaceutics and pharmacokinetics.
- The use raw data and derive the pharmacokinetic models and parameters the best describe the process of drug absorption, distribution, metabolism and elimination.
- The critical evaluation of biopharmaceutic studies involving drug product equivalency.
- The design and evaluation of dosage regimens of the drugs using pharmacokinetic and biopharmaceutic parameters.
- The potential clinical pharmacokinetic problems and application of basics of pharmacokinetic

#### THEORY

**60 HOURS**

**12 HOURS**

1. Drug Absorption from the Gastrointestinal Tract: Gastrointestinal tract, Mechanism of drug absorption, Factors affecting drug absorption, pH-partition theory of drug absorption. Formulation and physicochemical factors: Dissolution rate, Dissolution process, Noyes-Whitney equation and drug dissolution, Factors affecting the dissolution rate. Gastrointestinal absorption: role of the dosage form: Solution (elixir, syrup and solution) as a dosage form, Suspension as a dosage form, Capsule as a dosage form, Tablet as a dosage form, Dissolution methods, Formulation and processing factors, Correlation of in vivo data with in vitro dissolution data. Transport model: Permeability-Solubility-Charge State and the pH Partition Hypothesis, Properties of the Gastrointestinal Tract (GIT), pH Microclimate Intracellular pH Environment, Tight-Junction Complex.

**12 HOURS**

2 Biopharmaceutic considerations in drug product design and In Vitro Drug Product Performance: Introduction, biopharmaceutic factors affecting drug bioavailability, rate-limiting steps in drug absorption, physicochemical nature of the drug formulation factors affecting drug product performance, in vitro: dissolution and drug release testing, compendial methods of dissolution, alternative methods of dissolution testing, meeting dissolution requirements, problems of variable control in dissolution testing performance of drug products. In vitro-in vivo correlation, dissolution profile comparisons, drug product stability, considerations in the design of a drug product.

**12 HOURS**

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  $k_{max}$  and  $v_{max}$ . Drug interactions: introduction, the effect of protein-binding interactions, the effect of tissue-binding interactions, cytochrome p450-based drug interactions, drug interactions linked to transporters.

**12 HOURS**

4 Drug Product Performance, in vivo: Bioavailability and Bioequivalence: drug product performance, purpose of bioavailability studies, relative and absolute availability. methods for assessing bioavailability,

bioequivalence studies, design and evaluation of bioequivalence studies, study designs, crossover study designs, evaluation of the data, bioequivalence example, study submission and drug review process. biopharmaceutics classification system, methods. Permeability: In-vitro, in-situ and In-vivo methods. generic biologics (biosimilar drug products), clinical significance of bioequivalence studies, special concerns in bioavailability and bioequivalence studies, generic substitution.

### **12 HOURS**

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.

### **REFERENCES**

1. Biopharmaceutics and Clinical Pharmacokinetics by Milo Gibaldi, 4th edition, Philadelphia, Lea and Febiger, 1991
2. Biopharmaceutics and Pharmacokinetics, A. Treatise, D.M. Brahmankar and Sunil B. Jaiswal., Vallab Prakashan, Pitampura, Delhi
3. Applied Biopharmaceutics and Pharmacokinetics by Shargel. Land YuABC, 2nd edition, Connecticut Appleton Century Crofts, 1985
4. Textbook of Biopharmaceutics and Pharmacokinetics, Dr. Shobha Rani R. Hiremath, Prism Book
5. Pharmacokinetics by Milo Gibaldi and D. Perrier, 2nd edition, Marcel Dekker Inc., New York, 1982
6. Current Concepts in Pharmaceutical Sciences: Biopharmaceutics, Swarbrick. J, Lea and Febiger, Philadelphia, 1970
7. Clinical Pharmacokinetics, Concepts and Applications 3rd edition by Malcolm Rowland and Thom- N. Tozer, Lea and Febiger, Philadelphia, 1995
8. Dissolution, Bioavailability and Bioequivalence, Abdou. H.M, Mack Publishing Company, Pennsylvania 1989
9. Biopharmaceutics and Clinical Pharmacokinetics, An Introduction, 4th edition, revised and expanded by Robert. E. Notari, Marcel Dekker Inc, New York and Basel, 1987.
10. Biopharmaceutics and Relevant Pharmacokinetics by John. G Wagner and M. Pamarowski, 1st edition, Drug Intelligence Publications, Hamilton, Illinois, 1971.
11. Encyclopedia of Pharmaceutical Technology, Vol 13, James Swarbrick, James. G. Boylan, Marcel Dekker Inc, New York, 1996.
12. Basic Pharmacokinetics, 1st edition, Sunil S Jambhekar and Philip J Breen, Pharmaceutical press, RPS Publishing, 2009.
13. Absorption and Drug Development- Solubility, Permeability, and Charge State, Alex Avdeef, John Wiley & Sons, Inc, 2003.

# M.Pharmacy (Pharmaceutics)

## Semester II

### MPH020030 - COMPUTER AIDED DRUG DELIVERY SYSTEM

#### Scope

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

#### Objectives

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

- History of Computers in Pharmaceutical Research and Development
- Computational Modeling of Drug Disposition
- Computers in Preclinical Development
- Optimization Techniques in Pharmaceutical Formulation
- Computers in Market Analysis • Computers in Clinical Development
- Artificial Intelligence (AI) and Robotics • Computational fluid dynamics(CFD)

#### THEORY

**60 HOURS**

**12 HOURS**

1. Computers in Pharmaceutical Research and Development: A General Overview: History of Computers in Pharmaceutical Research and Development. Statistical modeling in Pharmaceutical research and development: Descriptive versus Mechanistic Modeling, Statistical Parameters, Estimation, Confidence Regions, Nonlinearity at the Optimum, Sensitivity Analysis, Optimal Design, Population Modeling b. Quality-by-Design In Pharmaceutical Development: Introduction, ICH Q8 guideline, Regulatory and industry views on QbD, Scientifically based QbD - examples of application.

**12 HOURS**

2 Computational Modeling of Drug Disposition: Introduction, Modeling Techniques: Drug Absorption, Solubility, Intestinal Permeation, Drug Distribution, Drug Excretion, Active Transport; P-gp, BCRP, Nucleoside Transporters, hPEPT1, ASBT, OCT, OATP, BBB-Choline Transporter.

**12 HOURS**

3 Computer-aided formulation development: Concept of optimization, Optimization parameters, Factorial design, Optimization technology & Screening design. Computers in Pharmaceutical Formulation: Development of pharmaceutical emulsions, microemulsion drug carriers Legal Protection of Innovative Uses of Computers in R&D, The Ethics of Computing in Pharmaceutical Research, Computers in Market analysis

**12 HOURS**

4 a. Computer-aided biopharmaceutical characterization: Gastrointestinal absorption simulation. Introduction, Theoretical background, Model construction, Parameter sensitivity analysis, Virtual trial, Fed vs. fasted state, In vitro dissolution and in vitro in vivo correlation, Biowaiver considerations  
b. Computer Simulations in Pharmacokinetics and Pharmacodynamics: Introduction, Computer Simulation: Whole Organism, Isolated Tissues, Organs, Cell, Proteins and Genes.  
c. Computers in Clinical Development: Clinical Data Collection and Management, Regulation of Computer Systems

**12 HOURS**

5 Artificial Intelligence (AI), Robotics and Computational fluid dynamics: General overview, Pharmaceutical Automation, Pharmaceutical applications, Advantages and Disadvantages. Current Challenges and Future Directions.

#### REFERENCES



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

# M.Pharmacy (Pharmaceutics)

## Semester II

### MPH020040 - COSMETICS AND COSMECEUTICALS

#### 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 HOURS**

**12 HOURS**

1. Cosmetics – Regulatory: Definition of cosmetic products as per Indian regulation. Indian regulatory requirements for labeling of cosmetics Regulatory provisions relating to import of cosmetics., Misbranded and spurious cosmetics. Regulatory provisions relating to manufacture of cosmetics – Conditions for obtaining license, prohibition of manufacture and sale of certain cosmetics, loan license, offences and penalties.

**12 HOURS**

2 Cosmetics - Biological aspects: Structure of skin relating to problems like dry skin, acne, pigmentation, prickly heat, wrinkles and body odor. Structure of hair and hair growth cycle. Common problems associated with oral cavity. Cleansing and care needs for face, eye lids, lips, hands, feet, nail, scalp, neck, body and under-arm.

**12 HOURS**

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 syndetbars. Perfumes; Classification of perfumes. Perfume ingredients listed as allergens in EU regulation. Controversial ingredients: Parabens, formaldehyde liberators, dioxane.

**12 HOURS**

4 Design of cosmeceutical products: Sun protection, sunscreens classification and regulatory aspects. Addressing dry skin, acne, sun-protection, pigmentation, prickly heat, wrinkles, body odor., dandruff, dental cavities, bleeding gums, mouth odor and sensitive teeth through cosmeceutical formulations.

**12 HOURS**

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.

#### REFERENCES

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

## **M.Pharmacy (Pharmaceutics) Semester II**

### **MPH020050 - PHARMACEUTICS PRACTICAL – II**

1. To study the effect of temperature change, non-solvent addition, incompatible polymer addition in microcapsules preparation
2. Preparation and evaluation of Alginate beads
3. Formulation and evaluation of gelatin /albumin microspheres
4. Formulation and evaluation of liposomes/niosomes
5. Formulation and evaluation of spherules
6. Improvement of dissolution characteristics of slightly soluble drug by Solid dispersion technique.
7. Comparison of dissolution of two different marketed products /brands
8. Protein binding studies of a highly protein bound drug & poorly protein bound drug
9. Bioavailability studies of Paracetamol in animals.
10. Pharmacokinetic and IVIVC data analysis by Winnoline R software
11. In vitro cell studies for permeability and metabolism
12. DoE Using Design Expert® Software
13. Formulation data analysis Using Design Expert® Software
14. Quality-by-Design in Pharmaceutical Development
15. Computer Simulations in Pharmacokinetics and Pharmacodynamics
16. Computational Modeling of Drug Disposition
17. To develop Clinical Data Collection manual
18. To carry out Sensitivity Analysis, and Population Modeling.
19. Development and evaluation of Creams
20. Development and evaluation of Shampoo and Toothpaste base
21. To incorporate herbal and chemical actives to develop products
22. To address Dry skin, acne, blemish, Wrinkles, bleeding gums and dandruff

# M.Pharmacy (Pharmaceutics) Semester II

MPH020060 - Seminar/Assignment - II

**Practical**

**90 Hour**

**Presentation skills:** To prepare presentations of scientific research/review work and to give presentation.

**Various software's used in project work:** Design of experiments, Minitab, SigmaPlot, GraphPad Prism, etc.

## **Reference books:**

Design of Experiments: A No-Name Approach: 138 (STATISTICS, A SERIES OF TEXTBOOKS AND MONOGRAPHS) by Thomas Lorenzen (Editor), Virgil Anderson (Editor)

Essential Biostatistics: A nonmathematical Approach by Harvey Motulsky

Sigma Plot for Scientists by Charland

# M.Pharmacy (Pharmaceutical Quality Assurance) Semester I

## MQA010010 - MODERN PHARMACEUTICAL ANALYTICAL TECHNIQUES

### 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**

**11 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. **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 HOURS**

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.

**11 HOURS**

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 HOURS**

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 HOURS**

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 Xray diffraction.

**5 HOURS**

6 Immunological assays: RIA (Radio immuno assay), ELISA, 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

# M.Pharmacy (Pharmaceutical Quality Assurance)

## Semester I

### MQA010020 - QUALITY MANAGEMENT SYSTEMS

#### Scope

This course is designed to impart fundamental knowledge and concepts about various quality management principles and systems utilized in the manufacturing industry. It also aids in understanding the quality evaluation in the pharmaceutical industries.

#### Objectives

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

- The importance of quality
- ISO management systems
- Tools for quality improvement
- Analysis of issues in quality
- Quality evaluation of pharmaceuticals
- Stability testing of drug and drug substances
- Statistical approaches for quality

#### THEORY

**60 HOURS**

**12 HOURS**

1. Introduction to Quality: Evolution of Quality, Definition of Quality, Dimensions of Quality  
Quality as a Strategic Decision: Meaning of strategy and strategic quality management, mission and vision statements, quality policy, Quality objectives, strategic planning and implementation, McKinsey 7s model, Competitive analysis, Management commitment to quality  
Customer Focus: Meaning of customer and customer focus, Classification of customers, Customer focus, Customer perception of quality, Factors affecting customer perception, Customer requirements, Meeting customer needs and expectations, Customer satisfaction and Customer delight, Handling customer complaints, Understanding customer behavior, concept of internal and external customers. Case studies.  
Cost of Quality: Cost of quality, Categories of cost of Quality, Models of cost of quality, Optimising costs, Preventing cost of quality.

**12 HOURS**

2 Pharmaceutical quality Management: Basics of Quality Management, Total Quality Management (TQM), Principles of Six sigma, ISO 9001:2008, 9001:2015, ISO 14001:2004, Pharmaceutical Quality Management – ICH Q10, Knowledge management, Quality Metrics, Operational Excellence and Quality Management Review. OSHAS guidelines, NABL certification and accreditation, CFR-21 part 11, WHO-GMP requirements.

**12 HOURS**

3 Six System Inspection model: Quality Management system, Production system, Facility and Equipment system, Laboratory control system, Materials system, Packaging and labeling system. Concept of self-inspection. Quality systems: Change Management/ Change control. Deviations, Out of Specifications (OOS), Out of Trend (OOT), Complaints - evaluation and handling, Investigation and determination of root cause, Corrective & Preventive Actions (CAPA), Returns and Recalls, Vendor Qualification, Annual Product Reviews, Batch Review and Batch Release. Concept of IPQC, area clearance/ Line clearance.

**12 HOURS**

4 Drug Stability: ICH guidelines for stability testing of drug substances and drug products. Study of ICH Q8, Quality by Design and Process development report Quality risk management: Introduction, risk assessment, risk control, risk review, risk management tools, HACCP, risk ranking and filtering according to ICH Q9 guidelines.

**08 HOURS**

5 Statistical Process control (SPC): Definition and Importance of SPC, Quality measurement in manufacturing, Statistical control charts - concepts and general aspects, Advantages of statistical control,

Process capability, Estimating Inherent or potential capability from a control chart analysis, Measuring process control and quality improvement, Pursuit of decreased process variability.

**04 HOURS**

6 Regulatory Compliance through Quality Management and development of Quality Culture  
Benchmarking: Definition of benchmarking, Reasons for benchmarking, Types of Benchmarking, Benchmarking process, Advantages of benchmarking, Limitations of benchmarking.

**REFERENCES:**

1. Implementing Juran's Road Map for Quality Leadership: Benchmarks and Results, By AI Endres, Wiley, 2000
2. Understanding, Managing and Implementing Quality: Frameworks, Techniques and Cases, By Jiju Antony; David Preece, Routledge, 2002
3. Organizing for High Performance: Employee Involvement, TQM, Reengineering, and Knowledge Management in the Fortune 1000: The CEO Report By Edward E. Lawler; Susan Albers Mohrman; George Benson, Jossey-Bass, 2001
4. Corporate Culture and the Quality Organization by James W. FairfieldSonn, Quorum Books, 2001
5. The Quality Management Sourcebook: An International Guide to Materials and Resources by Christine Avery; Diane Zabel, Routledge, 1997
6. The Quality Toolbox, Second Edition, Nancy R. Tague, ASQ Publications
7. Juran's Quality Handbook, Sixth Edition, Joseph M. Juran and Joseph A. De Feo, ASQ Publications
8. Root Cause Analysis, The Core of Problem Solving and Corrective Action, Duke Okes, 2009, ASQ Publications.



# M.Pharmacy (Pharmaceutical Quality Assurance)

## Semester I

### MQA010030 - QUALITY CONTROL AND QUALITY ASSURANCE

#### Scope

This course deals with the various aspects of quality control and quality assurance aspects of pharmaceutical industries. It covers the important aspects like cGMP, QC tests, documentation, quality certifications, GLP and regulatory affairs.

#### Objectives

Upon completion of this course the student should be able to

- Understand the cGMP aspects in a pharmaceutical industry
- To appreciate the importance of documentation
- To understand the scope of quality certifications applicable to pharmaceutical industries
- To understand the responsibilities of QA & QC departments.

#### THEORY

**60 HOURS**

**12 HOURS**

1. Introduction: Concept and evolution and scopes of Quality Control and Quality Assurance, Good Laboratory Practice, GMP, Overview of ICH Guidelines - QSEM, with special emphasis on Qseries guidelines. Good Laboratory Practices: Scope of GLP, Definitions, Quality assurance unit, protocol for conduct of non-clinical testing, control on animal house, report preparation and documentation. CPCSEA guidelines.

**12 HOURS**

2. cGMP guidelines according to schedule M, USFDA (inclusive of CDER and CBER) Pharmaceutical Inspection Convention (PIC), WHO and EMEA covering: Organization and personnel responsibilities, training, hygiene and personal records, drug industry location, design, construction and plant lay out, maintenance, sanitation, environmental control, utilities and maintenance of sterile areas, control of contamination and Good Warehousing Practice.

**12 HOURS**

3. Analysis of raw materials, finished products, packaging materials, in process quality control (IPQC), Developing specification (ICH Q6 and Q3), purchase specifications and maintenance of stores for raw materials.

In process quality control and finished products quality control for following dosage forms in Pharma industry according to Indian, US and British pharmacopoeias: tablets, capsules, ointments, suppositories, creams, parenteral, ophthalmic and surgical products (How to refer pharmacopoeias).

**12 HOURS**

4. Documentation in pharmaceutical industry: Three tier documentation, Policy, Procedures and Work instructions, and records (Formats), Basic principles- How to maintain, retention and retrieval etc. Standard operating procedures (How to write), Master Batch Record, Batch Manufacturing Record, Quality audit plan and reports. Specification and test procedures, Protocols and reports. Distribution records. Electronic data handling. Concepts of controlled and uncontrolled documents. Submission documents for regulators DMFs, as Common Technical Document and Electronic Common Technical Documentation (CTD, eCTD). Concept of regulated and non-regulated markets.

**12 HOURS**

5. Manufacturing operations and controls: Sanitation of manufacturing premises, mix-ups and cross contamination, processing of intermediates and bulk products, packaging operations, IPQC, release of finished product, process deviations, charge-in of components, time limitations on production, drug product inspection, expiry date calculation, calculation of yields, production record review, change control, sterile products, aseptic process control, packaging, reprocessing, salvaging, handling of waste and scrap disposal. Introduction, scope and importance of intellectual property rights. Concept of trade mark, copyright and patents.

## REFERENCES

1. Quality Assurance Guide by organization of Pharmaceutical Procedures of India, 3<sup>rd</sup> revised edition, Volume I & II, Mumbai, 1996.
2. Good Laboratory Practice Regulations, 2<sup>nd</sup> Edition, Sandy Weinberg Vol. 69, Marcel Dekker Series, 1995.
3. Quality Assurance of Pharmaceuticals- A compedium of Guide lines and Related materials Vol I & II, 2<sup>nd</sup> edition, WHO Publications, 1999.
4. How to Practice GMP's – P P Sharma, Vandana Publications, Agra, 1991. 126
5. The International Pharmacopoeia – vol I, II, III, IV & V - General Methods of Analysis and Quality specification for Pharmaceutical Substances, Excepients and Dosage forms, 3<sup>rd</sup> edition, WHO, Geneva, 2005.
6. Good laboratory Practice Regulations – Allen F. Hirsch, Volume 38, Marcel Dekker Series, 1989.
7. ICH guidelines
8. ISO 9000 and total quality management
9. The drugs and cosmetics act 1940 – Deshpande, Nilesh Gandhi, 4<sup>th</sup> edition, Susmit Publishers, 2006.
10. QA Manual – D.H. Shah, 1<sup>st</sup> edition, Business Horizons, 2000.
11. Good Manufacturing Practices for Pharmaceuticals a plan for total quality control – Sidney H. Willig, Vol. 52, 3<sup>rd</sup> edition, Marcel Dekker Series.
12. Steinborn L. GMP/ISO Quality Audit Manual for Healthcare Manufacturers and Their Suppliers, Sixth Edition, (Volume 1 - With Checklists and Software Package). Taylor & Francis; 2003.
13. Sarker DK. Quality Systems and Controls for Pharmaceuticals. John Wiley & Sons; 2008.
14. Packaging of Pharmaceuticals.
15. Schedule M and Schedule

# M.Pharmacy (Pharmaceutical Quality Assurance) Semester I

## MQA10040 - PRODUCT DEVELOPMENT AND TECHNOLOGY TRANSFER

### Scope

This deal with technology transfer covers the activities associated with Drug Substance, Drug Product and analytical tests and methods, required following candidate drug selection to completion of technology transfer from R&D to the first receiving site and technology transfer related to post-marketing changes in manufacturing places.

### Objectives

Upon completion of this course the student should be able to

- To understand the new product development process
- To understand the necessary information to transfer technology from R&D to actual manufacturing by sorting out various information obtained during R&D
- To elucidate necessary information to transfer technology of existing products between various manufacturing places

### THEORY

**60 HOURS**

**12HOURS**

1. Principles of Drug discovery and development: Introduction, Clinical research process. Development and informational content for Investigational New Drugs Application (IND), New Drug Application (NDA), Abbreviated New Drug Application (ANDA), Supplemental New Drug Application (SNDA), Scale Up Post Approval Changes (SUPAC) and Bulk active chemical Post approval changes (BACPAC), Post marketing surveillance, Product registration guidelines – CDSCO, USFDA.

**12HOURS**

2. Pre-formulation studies: Introduction/concept, organoleptic properties, purity, impurity profiles, particle size, shape and surface area. Solubility, Methods to improve solubility of Drugs: Surfactants & its importance, co-solvency. Techniques for the study of Crystal properties and polymorphism. Pre-formulation protocol, Stability testing during product development.

**12HOURS**

3. Pilot plant scale up: Concept, Significance, design, layout of pilot plant scale up study, operations, large scale manufacturing techniques (formula, equipment, process, stability and quality control) of solids, liquids, semisolid and parenteral dosage forms. New era of drug products: opportunities and challenges.

**12HOURS**

4. Pharmaceutical packaging: Pharmaceutical dosage form and their packaging requirements, Pharmaceutical packaging materials, Medical device packaging, Enteral Packaging, Aseptic packaging systems, Container closure systems, Issues facing modern drug packaging, Selection and evaluation of Pharmaceutical packaging materials. Quality control test: Containers, closures and secondary packing materials.

**12 HOURS**

5. Technology transfer: Development of technology by R & D, Technology transfer from R & D to production, Optimization and Production, Qualitative and quantitative technology models. Documentation in technology transfer: Development report, technology transfer plan and Exhibit.

### REFERENCES:

1. The process of new drug discovery and development. I and II Edition (2006) by Charles G. Smith, James T and O. Donnell. CRC Press, Group of Taylor and Francis.
2. Leon Lac Lachman, Herbert A. Liberman, Theory and Practice of Industrial Pharmacy. Marcel Dekker Inc. New York.

3. Sidney H Willing, Murray M, Tuckerman. Williams Hitchings IV, Good manufacturing of pharmaceuticals (A Plan for total quality control) 3<sup>rd</sup>Edition. Bhalani publishing house Mumbai.
4. Tablets Vol. I, II, III by Leon Lachman, Herbert A. Liberman, Joseph B. Schwartz, 2<sup>nd</sup>Edn. (1989) Marcel Dekker Inc. New York.
5. Text book of Bio- Pharmaceutics and clinical Pharmacokinetics by Milo Gibaldi, 3<sup>rd</sup>Edn, Lea &Febrieger, Philadelphia.
6. Pharmaceutical product development. Vandana V. Patrevala. John I. Disouza. MaharukhT.Rustomji. CRC Press, Group of Taylor and Francis.
7. Dissolution, Bioavailability and Bio-Equivalence by Abdou H.M, Mack Publishing company, Eastern Pennsylvania.
8. Remingtons Pharmaceutical Sciences, by Alfonso & Gennaro, 19<sup>th</sup>Edn.(1995)OO2C Lippincott; Williams and Wilkins A Wolters Kluwer Company, Philadelphia.
9. The Pharmaceutical Sciences; the Pharma Path way 'Pure and applied Pharmacy' by D. A Sawant, Pragathi Books Pvt. Ltd.
10. Pharmaceutical Packaging technology by D.A. Dean. E.R. Evans, I.H. Hall. 1<sup>st</sup>Edition(Reprint 2006). Taylor and Francis. London and New York.

# M.Pharmacy (Pharmaceutical Quality Assurance) Semester I

## MQA010050 - PHARMACEUTICAL QUALITY ASSURANCE PRACTICAL

1. Analysis of Pharmacopoeial compounds in bulk and in their formulations (tablet/ capsules/ semisolids) by UV Vis spectrophotometer
2. Simultaneous estimation of multi-drug 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 or AAS
7. Case studies on:
  - Total Quality Management
  - Six Sigma
  - Change Management/ Change control. Deviations,
  - Out of Specifications (OOS)
  - Out of Trend (OOT)
  - Corrective & Preventive Actions (CAPA)
  - Deviations
8. Development of Stability study protocol
9. Estimation of process capability
10. In process and finished product quality control tests for tablets, capsules, parenterals and semisolid dosage forms.
11. Assay of raw materials as per official monographs
12. Testing of related and foreign substances in drugs and raw materials
13. To carry out pre formulation study for tablets, parenterals (2 experiment).
14. To study the effect of pH on the solubility of drugs, (1 experiment)
15. Quality control tests for Primary and secondary packaging materials
16. Accelerated stability studies (1 experiment)
17. Improved solubility of drugs using surfactant systems (1 experiment)
18. Improved solubility of drugs using co-solvency method (1 experiment)
19. Determination of Pka and Log p of drug

# M.Pharmacy (Pharmaceutical Quality Assurance) Semester I

MQA010060 - Seminar/Assignment

**Practical**

**90 Hour**

## **Microsoft office word**

- ☑ Creating, editing, saving and printing text documents
- ☑ Font and paragraph formatting
- ☑ Simple character formatting
- ☑ Inserting tables, smart art, page breaks
- ☑ Using lists and styles
- ☑ Working with images
- ☑ Using Spelling and Grammar check
- ☑ Understanding document properties

## **Microsoft office Power Point**

- ☑ Opening, viewing, creating, and printing slides
- ☑ Applying auto layouts
- ☑ Adding custom animation
- ☑ Using slide transitions
- ☑ Graphically representing data: Charts & Graphs
- ☑ Creating Professional Slide for Presentation.

## **Microsoft office excel**

- ☑ Spreadsheet basics
- ☑ Creating, editing, saving and printing spreadsheets
- ☑ Working with functions & formulas
- ☑ Modifying worksheets with color & autoformats
- ☑ Graphically representing data: Charts & Graphs
- ☑ Speeding data entry: Using Data Forms
- ☑ Analyzing data: Data Menu, Subtotal, Filtering Data
- ☑ Formatting worksheets
- ☑ Securing & Protecting spreadsheets

### **Reference books**

Mastering MS Office (English, Paperback, Kumar Bittu)

Master Book Of Computer: Learn MS Office,Basic Computer,MS Excel,Excel Formulas,Tally, HTMLby Mangesh Bhuvad.

# M.Pharmacy (Pharmaceutical Quality Assurance)

## Semester II

### MQA020010 - HAZARDS AND SAFETY MANAGEMENT

#### Scope

This course is designed to convey the knowledge necessary to understand issues related to different kinds of hazard and their management. Basic theoretical and practical discussions integrate the proficiency to handle the emergency situation in the pharmaceutical product development process and provides the principle-based approach to solve the complex tribulations.

#### Objectives

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

- Understand about environmental problems among learners.
- Impart basic knowledge about the environment and its allied problems.
- Develop an attitude of concern for the industry environment.
- Ensure safety standards in pharmaceutical industry
- Provide comprehensive knowledge on the safety management
- Empower an idea to clear mechanism and management in different kinds of hazard management system
- Teach the method of Hazard assessment, procedure, methodology for provide safe industrial atmosphere.

#### THEORY

**60HOURS**

**12 HOURS**

1. Multidisciplinary nature of environmental studies: Natural Resources, Renewable and non-renewable resources, Natural resources and associated problems, a) Forest resources; b) Water resources; c) Mineral resources; d) Energy resources; e) Land resources

Ecosystems: Concept of an ecosystem and Structure and function of an ecosystem. Environmental hazards: Hazards based on Air, Water, Soil and Radioisotopes.

**12 HOURS**

2. Air based hazards: Sources, Types of Hazards, Air circulation maintenance industry for sterile area and non-sterile area, Preliminary Hazard Analysis (PHA) Fire protection system: Fire prevention, types of fire extinguishers and critical Hazard management system.

**12 HOURS**

3. Chemical based hazards: Sources of chemical hazards, Hazards of Organic synthesis, sulphonating hazard, Organic solvent hazard, Control measures for chemical hazards, Management of combustible gases, Toxic gases and Oxygen displacing gases management, Regulations for chemical hazard, Management of over-Exposure to chemicals and TLV concept.

**12 HOURS**

4. Fire and Explosion: Introduction, Industrial processes and hazards potential, mechanical electrical, thermal and process hazards. Safety and hazards regulations, Fire protection system: Fire prevention, types of fire extinguishers and critical Hazard management system mechanical and chemical explosion, multiphase reactions, transport effects and global rates. Preventive and protective management from fires and explosion electricity passivation, ventilation, and sprinkling, proofing, relief systems -relief valves, flares, scrubbers.

**12 HOURS**

5. Hazard and risk management: Self-protective measures against workplace hazards. Critical training for risk management, Process of hazard management, ICH guidelines on risk assessment and Risk management methods and Tools Factory act and rules, fundamentals of accident prevention, elements of safety programme and safety management, Physicochemical measurements of effluents, BOD, COD, Determination of some contaminants, Effluent treatment procedure, Role of emergency services.

#### REFERENCES



1. Y.K. Singh, Environmental Science, New Age International Pvt, Publishers, Bangalore
2. "Quantitative Risk Assessment in Chemical Process Industries" American Institute of Chemical Industries, Centre for Chemical Process safety.
3. Bharucha Erach, The Biodiversity of India, Mapin Publishing Pvt. Ltd., Ahmedabad – 380 013, India,
4. Hazardous Chemicals: Safety Management and Global Regulations, T.S.S. Dikshith, CRC press 13

# M.Pharmacy (Pharmaceutical Quality Assurance)

## Semester II

### MQA020020 - PHARMACEUTICAL VALIDATION

#### 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 HOURS**

**10 HOURS**

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).

**10 HOURS**

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.

**10 HOURS**

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.

**10 HOURS**

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.

**10 HOURS**

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 10

**10 HOURS**

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.

#### 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, 3<sup>rd</sup> 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, 2<sup>nd</sup> Edition, by Carleton & Agalloco, (Marcel Dekker).
5. Michael Levin, Pharmaceutical Process Scale-Up", Drugs and Pharm. Sci. Series, Vol. 157, 2<sup>nd</sup> 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

# M.Pharmacy (Pharmaceutical Quality Assurance)

## Semester II

### MQA020030 - AUDITS AND REGULATORY COMPLIANCE

#### Scope

This course deals with the understanding and process for auditing in pharmaceutical industries. This subject covers the methodology involved in the auditing process of different in pharmaceutical industries.

#### Objectives

Upon completion of this course the student should be able to

- To understand the importance of auditing
- To understand the methodology of auditing
- To carry out the audit process
- To prepare the auditing report
- To prepare the check list for auditing

#### THEORY

**60 HOURS**

**12 HOURS**

1. Introduction: Objectives, Management of audit, Responsibilities, Planning process, information gathering, administration, Classifications of deficiencies

**12 HOURS**

2 Role of quality systems and audits in pharmaceutical manufacturing environment: cGMP Regulations, Quality assurance functions, Quality systems approach, Management responsibilities, Resource, Manufacturing operations, Evaluation activities, Transitioning to quality system approach, Audit checklist for drug industries.

**12 HOURS**

3 Auditing of vendors and production department: Bulk Pharmaceutical Chemicals and packaging material Vendor audit, Warehouse and weighing, Dry Production: Granulation, tableting, coating, capsules, sterile production and packaging.

**12 HOURS**

4 Auditing of Microbiological laboratory: Auditing the manufacturing process, Product and process information, General areas of interest in the building raw materials, Water, Packaging materials.

**12 HOURS**

5 Auditing of Quality Assurance and engineering department: Quality Assurance Maintenance, Critical systems: HVAC, Water, Water for Injection systems, ETP.

#### REFERENCES

1. Compliance auditing for Pharmaceutical Manufacturers. Karen Ginsbury and Gil Bismuth, Interpharm/CRC, Boca Raton, London New York, Washington D.C.
2. Pharmaceutical Manufacturing Handbook, Regulations and Quality by Shayne Cox Gad. Wiley-Interscience, A John Wiley and sons, Inc., Publications.
3. Handbook of microbiological Quality control. Rosamund M. Baird, Norman A. Hodges, Stephen P. Denyar. CRC Press. 2000.
4. Laboratory auditing for quality and regulatory compliance. Donald C. Singer, Raluca-Ioana Stefan, Jacobus F. Van Staden. Taylor and Francis (2005).

# M.Pharmacy (Pharmaceutical Quality Assurance)

## Semester II

### MQA020040 - PHARMACEUTICAL MANUFACTURING TECHNOLOGY

#### Scope

This course is designed to impart knowledge and skills necessary to train the students with the industrial activities during Pharmaceutical Manufacturing.

#### Objectives

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

- The common practice in the pharmaceutical industry developments, plant layout and production planning
- Will be familiar with the principles and practices of aseptic process technology, non-sterile manufacturing technology and packaging technology.
- Have a better understanding of principles and implementation of Quality by design (QbD) and process analytical technology (PAT) in pharmaceutical manufacturing

#### THEORY

**60 HOURS**

**12 HOURS**

1. Pharmaceutical industry developments: Legal requirements and Licenses for API and formulation industry, Plant location Factors influencing.

Plant layout: Factors influencing, Special provisions, Storage space requirements, sterile and aseptic area layout.

Production planning: General principles, production systems, calculation of standard cost, process planning, routing, loading, scheduling, dispatching of records, production control.

**12 HOURS**

2. Aseptic process technology: Manufacturing, manufacturing flowcharts, in process-quality control tests for following sterile dosage forms: Ointment, Suspension and Emulsion, Dry powder, Solution (Small Volume & large Volume).

Advanced sterile product manufacturing technology: Area planning & environmental control, wall and floor treatment, fixtures and machineries, change rooms, personnel flow, utilities & utilities equipment location, engineering and maintenance.

Process Automation in Pharmaceutical Industry: With specific reference to manufacturing of sterile semisolids, Small Volume Parenterals & Large Volume Parenterals (SVP & LVP), Monitoring of Parenteral manufacturing facility, Cleaning in Place (CIP), Sterilization in Place (SIP), Prefilled Syringe, Powdered Jet, Needle Free Injections, and Form Fill Seal Technology (FFS). Lyophilization technology: Principles, process, equipment.

**12 HOURS**

3. Non sterile manufacturing process technology: Manufacturing, manufacturing flowcharts, in process-quality control tests for following Non-Sterile solid dosage forms: Tablets (compressed & coated), Capsules (Hard & Soft).

Advance non-sterile solid product manufacturing technology: Process Automation in Pharmaceutical Industry with specific reference to manufacturing of tablets and coated products, Improved Tablet Production: Tablet production process, granulation and palletization equipments, continuous and batch mixing, rapid mixing granulators, rota granulators, spheronizers and marumerisers, and other specialized granulation and drying equipments. Problems encountered.

Coating technology: Process, equipments, particle coating, fluidized bed coating, application techniques. Problems encountered.

**12 HOURS**

4. Containers and closures for pharmaceuticals: Types, performance, assuring quality of glass; types of plastics used, Drug plastic interactions, biological tests, modification of plastics by drugs; different types of closures and closure liners; film wrapper; blister packs; bubble packs; shrink packaging; foil / plastic

pouches, bottle seals, tape seals, breakable seals and sealed tubes; quality control of packaging material and filling equipment, flexible packaging, product package compatibility, transit worthiness of package, Stability aspects of packaging. Evaluation of stability of packaging material.

**12 HOURS**

5. Quality by design (QbD) and process analytical technology (PAT): Current approach and its limitations. Why QbD is required, Advantages, Elements of QbD, Terminology: QTPP. CMA, CQA, CPP, RLD, Design space, Design of Experiments, Risk Assessment and mitigation/minimization. Quality by Design, Formulations by Design, QbD for drug products, QbD for Drug Substances, QbD for Excipients, Analytical QbD. FDA initiative on process analytical technology. PAT as a driver for improving quality and reducing costs: quality by design (QbD), QA, QC and GAMP. PAT guidance, standards and regulatory requirements.

#### **REFERENCES**

1. Lachman L, Lieberman HA, Kanig JL. The theory and practice of industrial pharmacy, 3<sup>rd</sup>, Varghese Publishers, Mumbai 1991.
2. Sinko PJ. Martin's physical pharmacy and pharmaceutical sciences, 5<sup>th</sup>ed., B.I. Publications Pvt. Ltd, Noida, 2006.
3. Lieberman HA, Lachman L, Schwartz JB. Pharmaceutical dosage forms: nd tablets Vol. I-III, 2<sup>nd</sup> ed., CBS Publishers & distributors, New Delhi, 2005.
4. Banker GS, Rhodes CT. Modern Pharmaceutics, 4 Inc, New York, 2005. ed., Marcel Dekker
5. Sidney H Willing, Murray M, Tuckerman. Williams Hitchings IV, Good manufacturing of pharmaceuticals (A Plan for total quality control) 3<sup>rd</sup>Edition. Bhalani publishing house Mumbai.
6. Indian Pharmacopoeia. Controller of Publication. Delhi, 1996.
7. British Pharmacopoeia. British Pharmacopoeia Commission Office, London, 2008.
8. United States Pharmacopoeia. United States Pharmacopoeial Convention, Inc, USA, 2003.
9. Dean D A, Evans E R and Hall I H. Pharmaceutical Packaging Technology. London, Taylor & Francis, 1<sup>st</sup>Edition. UK.
10. Edward J Bauer. Pharmaceutical Packaging Handbook. 2009. Informa Health care USA Inc. New york.
11. Shaybe Cox Gad. Pharmaceutical Manufacturing Handbook. John Willey and Sons, New Jersey, 2008.

## **M.Pharmacy (Pharmaceutical Quality Assurance) Semester II**

### **MQA020050 - QUALITY ASSURANCE PRACTICAL – II**

1. Organic contaminants residue analysis by HPLC
2. Estimation of Metallic contaminants by Flame photometer
3. Identification of antibiotic residue by TLC
4. Estimation of Hydrogen Sulphide in Air.
5. Estimation of Chlorine in Work Environment.
6. Sampling and analysis of SO<sub>2</sub> using Colorimetric method
7. Qualification of following Pharma equipment a. Autoclave b. Hot air oven c. Powder Mixer (Dry) d. Tablet Compression Machine
8. Validation of an analytical method for a drug
9. Validation of a processing area
10. Qualification of at least two analytical instruments
11. Cleaning validation of one equipment
12. Qualification of Pharmaceutical Testing Equipment (Dissolution testing apparatus, Friability Apparatus, Disintegration Tester)
13. Check list for Bulk Pharmaceutical Chemicals vendors
14. Check list for tableting production.
15. Check list for sterile production area
16. Check list for Water for injection.
17. Design of plant layout: Sterile and non-sterile
18. Case study on application of QbD
19. Case study on application of PAT

# M.Pharmacy (Pharmaceutical Quality Assurance) Semester II

## MQA020060 - Seminar/Assignment II

**Practical**

**90 Hour**

**Presentation skills:** To prepare presentations of scientific research/review work and to give presentation.

**Various software's used in project work:** Design of experiments, Minitab, Sigma Plot, GraphPad Prism, etc.

### **Reference books:**

Design of Experiments: A No-Name Approach: 138 (STATISTICS, A SERIES OF TEXTBOOKS AND MONOGRAPHS) by Thomas Lorenzen (Editor), Virgil Anderson (Editor)

Essential Biostatistics: A nonmathematical Approach by Harvey Motulsky

Sigma Plot for Scientists by Charland



# M.Pharmacy (Pharmacology)

## Semester I

### MPL010010 MODERN PHARMACEUTICAL ANALYTICAL TECHNIQUES

#### 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**

**11 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. **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 HOURS**

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.

**11 HOURS**

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 HOURS**

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 HOURS**

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 Xray diffraction.

**5 HOURS**

6 Immunological assays: RIA (Radio immuno assay), ELISA, 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

# M.Pharmacy (Pharmacology) Semester I

## MPL010020 - ADVANCED PHARMACOLOGY – I

### Scope

The subject is designed to strengthen the basic knowledge in the field of pharmacology and to impart recent advances in the drugs used for the treatment of various diseases. In addition, this subject helps the students to understand the concepts of drug action and mechanisms involved

### Objectives

Upon completion of the course the student shall be able to:

- Discuss the pathophysiology and pharmacotherapy of certain diseases
- Explain the mechanism of drug actions at cellular and molecular level
- Understand the adverse effects, contraindications and clinical uses of drugs used in treatment of diseases

### THEORY

**60 HOURS**

**12 HOURS**

#### 1. General Pharmacology

**a. Pharmacokinetics:** The dynamics of drug absorption, distribution, biotransformation and elimination. Concepts of linear and non-linear compartment models. Significance of Protein binding.

**b. Pharmacodynamics:** Mechanism of drug action and the relationship between drug concentration and effect. Receptors, structural and functional families of receptors, quantitation of drug receptors interaction and elicited effects.

**12 HOURS**

#### 2. Neurotransmission

a. General aspects and steps involved in neurotransmission.

b. Neurohumoral transmission in autonomic nervous system (Detailed study about neurotransmitters- Adrenaline and Acetyl choline).

c. Neurohumoral transmission in central nervous system (Detailed study about neurotransmitters- histamine, serotonin, dopamine, GABA, glutamate and glycine].

d. Non adrenergic non cholinergic transmission (NANC). Cotransmission

#### Systemic Pharmacology

A detailed study on pathophysiology of diseases, mechanism of action, pharmacology and toxicology of existing as well as novel drugs used in the following systems

Autonomic Pharmacology: Parasympathomimetics and lytics, sympathomimetics and lytics, agents affecting neuromuscular junction

**12 HOURS**

#### 3. Central nervous system Pharmacology

General and local anesthetics

Sedatives and hypnotics, drugs used to treat anxiety.

Depression, psychosis, mania, epilepsy, neurodegenerative diseases.

Narcotic and non-narcotic analgesics.

**12 HOURS**

#### 4. Cardiovascular Pharmacology

Diuretics, antihypertensives, antiischemics, anti- arrhythmics, drugs for heart failure and hyperlipidemia.

Hematinics, coagulants, anticoagulants, fibrinolytics and anti- platelet drugs

**12 HOURS**

5. Autocoid Pharmacology The physiological and pathological role of Histamine, Serotonin, Kinins Prostaglandins Opioid autocoids. Pharmacology of antihistamines, 5HT antagonists.

## REFERENCES

1. The Pharmacological Basis of Therapeutics, Goodman and Gillman's
2. Principles of Pharmacology. The Pathophysiologic basis of drug Therapy by David E Golan, Armen H, Tashjian Jr, Ehrin J, Armstrong, April W, Armstrong, Wolters, Kluwer-Lippincott Williams & Wilkins Publishers.
3. Basic and Clinical Pharmacology by B.G Katzung
4. Hand book of Clinical Pharmacokinetics by Gibaldi and Prescott.
5. Applied biopharmaceutics and Pharmacokinetics by Leon Shargel and Andrew B.C.Yu.
6. Graham Smith. Oxford textbook of Clinical Pharmacology.
7. Avery Drug Treatment
8. Dipiro Pharmacology, Pathophysiological approach.
9. Green Pathophysiology for Pharmacists. 213
10. Robbins & Cortan Pathologic Basis of Disease, 9<sup>th</sup> Ed. (Robbins Pathology)
11. A Complete Textbook of Medical Pharmacology by Dr. S.K Srivastava published by APC Avichal Publishing Company
12. K D. Tripathi. Essentials of Medical Pharmacology.
13. Modern Pharmacology with Clinical Applications, Craig Charles R. & Stitzel Robert E., Lippincott Publishers.
14. Clinical Pharmacokinetics & Pharmacodynamics: Concepts and Applications – Malcolm Rowland and Thomas N. Tozer, Wolters Kluwer, Lippincott Williams & Wilkins Publishers.
15. Applied biopharmaceutics and Pharmacokinetics, Pharmacodynamics and Drug metabolism for industrial scientists.
16. Modern Pharmacology, Craig CR. & Stitzel RE, Little Brown & Company

# M.Pharmacy (Pharmacology)

## Semester I

### MPL010030 - PHARMACOLOGICAL AND TOXICOLOGICAL SCREENING METHODS – I

#### Scope

This subject is designed to impart the knowledge on preclinical evaluation of drugs and recent experimental techniques in the drug discovery and development. The subject content helps the student to understand the maintenance of laboratory animals as per the guidelines, basic knowledge of various in-vitro and in-vivo preclinical evaluation processes

#### Objectives

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

- Appraise the regulations and ethical requirement for the usage of experimental animals.
- Describe the various animals used in the drug discovery process and good laboratory practices in maintenance and handling of experimental animals
- Describe the various newer screening methods involved in the drug discovery process
- Appreciate and correlate the preclinical data to humans

#### THEORY

**60 HOURS**

**12HOURS**

#### 1.Laboratory Animals

Common laboratory animals: Description, handling and applications of different species and strains of animals.

Transgenic animals: Production, maintenance and applications

Anesthesia and euthanasia of experimental animals.

Maintenance and breeding of laboratory animals.

CPCSEA guidelines to conduct experiments on animals good laboratory practice.

Bioassay-Principle, scope and limitations and methods

**12HOURS**

2. Preclinical screening of new substances for the pharmacological activity using in vivo, in vitro, and other possible animal alternative models.

General principles of preclinical screening. CNS Pharmacology: behavioral and muscle coordination, CNS stimulants and depressants, anxiolytics, anti-psychotics, antiepileptics and nootropics. Drugs for neurodegenerative diseases like Parkinsonism, Alzheimers and multiple sclerosis. Drugs acting on Autonomic Nervous System.

**12HOURS**

3. Preclinical screening of new substances for the pharmacological activity using in vivo, in vitro, and other possible animal alternative models. Respiratory Pharmacology: anti-asthmatics, drugs for COPD and anti allergics.

Reproductive Pharmacology: Aphrodisiacs and antifertility agents Analgesics, antiinflammatory and antipyretic agents. Gastrointestinal drugs: antiulcer, anti -emetic, anti- diarrheal and laxatives.

**12HOURS**

4. Preclinical screening of new substances for the pharmacological activity using in vivo, in vitro, and other possible animal alternative models.

Cardiovascular Pharmacology: antihypertensives, antiarrhythmics, antianginal, antiatherosclerotic agents and diuretics. Drugs for metabolic disorders like anti-diabetic, antidiyslipidemic agents. Anticancer agents. Hepatoprotective screening methods.

**12HOURS**

5. Preclinical screening of new substances for the pharmacological activity using in vivo, in vitro, and other possible animal alternative models.

Immunomodulators, Immunosuppressants and immunostimulants

**General principles of immunoassay:** theoretical basis and optimization of immunoassay, heterogeneous and homogenous immunoassay systems. Immunoassay methods evaluation; protocol outline, objectives and preparation. Immunoassay for digoxin and insulin  
Limitations of animal experimentation and alternate animal experiments.  
Extrapolation of in vitro data to preclinical and preclinical to humans

#### REFERENCES

1. Biological standardization by J.H. Burn D.J. Finney and I.G. Goodwin
2. Screening methods in Pharmacology by Robert Turner. A
3. Evaluation of drugs activities by Laurence and Bachrach
4. Methods in Pharmacology by Arnold Schwartz.
5. Fundamentals of experimental Pharmacology by M.N.Ghosh
6. Pharmacological experiment on intact preparations by Churchill Livingstone
7. Drug discovery and Evaluation by Vogel H.G.
8. Experimental Pharmacology by R.K.Goyal.
9. Preclinical evaluation of new drugs by S.K. Guta
10. Handbook of Experimental Pharmacology, SK.Kulkarni
11. Practical Pharmacology and Clinical Pharmacy, SK.Kulkarni, 3<sup>rd</sup>Edition.
12. David R.Gross. Animal Models in Cardiovascular Research, 2<sup>nd</sup>Edition, Kluwer Academic Publishers, London, UK.
13. Screening Methods in Pharmacology, Robert A.Turner.
14. Rodents for Pharmacological Experiments, Dr.Tapan Kumar Chatterjee.
15. Practical Manual of Experimental and Clinical Pharmacology by Bikash Medhi (Author), Ajay Prakash (Author)

# M.Pharmacy (Pharmacology)

## Semester I

### MPL010040 - CELLULAR AND MOLECULAR PHARMACOLOGY

#### Scope:

The subject imparts a fundamental knowledge on the structure and functions of cellular components and help to understand the interaction of these components with drugs. This information will further help the student to apply the knowledge in drug discovery process.

**Objectives:** Upon completion of the course, the student shall be able to,

- Explain the receptor signal transduction processes.
- Explain the molecular pathways affected by drugs.
- Appreciate the applicability of molecular pharmacology and biomarkers in drug discovery process.
- Demonstrate molecular biology techniques as applicable for pharmacology

#### THEORY

**60 HOURS**  
**12HOURS**

##### 1. Cell biology

Structure and functions of cell and its organelles

Genome organization. Gene expression and its regulation, importance of siRNA and micro-RNA, gene mapping and gene sequencing.

Cell cycles and its regulation.

Cell death– events, regulators, intrinsic and extrinsic pathways of apoptosis.

Necrosis and autophagy.

**12HOURS**

##### 2. Cell signaling

Intercellular and intracellular signaling pathways.

Classification of receptor family and molecular structure ligand gated ion channels; G-protein coupled receptors, tyrosine kinase receptors and nuclear receptors.

Secondary messengers: cyclic AMP, cyclic GMP, calcium ion, inositol 1,4,5-trisphosphate, (IP3), NO, and diacylglycerol.

Detailed study of following intracellular signaling pathways: cyclic AMP signaling pathway, mitogen-activated protein kinase (MAPK) signaling, Janus kinase (JAK)/signal transducer and activator of transcription (STAT) signaling pathway.

**12HOURS**

3. Principles and applications of genomic and proteomic tools DNA electrophoresis, PCR (reverse transcription and real time), Gene sequencing, micro array technique, SDS page, ELISA and western blotting, Recombinant DNA technology and gene therapy

Basic principles of recombinant DNA technology-Restriction enzymes, various types of vectors. Applications of recombinant DNA technology.

Gene therapy- Various types of gene transfer techniques, clinical applications and recent advances in gene therapy.

**12HOURS**

##### 4. Pharmacogenomics

Gene mapping and cloning of disease gene.

Genetic variation and its role in health/ pharmacology

Polymorphisms affecting drug metabolism

Genetic variation in drug transporters

Genetic variation in G protein coupled receptors

Applications of proteomics science: Genomics, proteomics, metabolomics, functionomics, nutrigenomics Immunotherapeutics

**5.**

**a. Cell culture techniques**

Basic equipments used in cell culture lab. Cell culture media, various types of cell culture, general procedure for cell cultures; isolation of cells, subculture, cryopreservation, characterization of cells and their application. Principles and applications of cell viability assays, glucose uptake assay, Calcium influx assays  
Principles and applications of flow cytometry

**b. Biosimilars**

**REFERENCES:**

1. The Cell, A Molecular Approach. Geoffrey M Cooper.
2. Pharmacogenomics: The Search for Individualized Therapies. Edited by J. Licinio and M -L. Wong
3. Handbook of Cell Signaling (Second Edition) Edited by Ralph A. et.al
4. Molecular Pharmacology: From DNA to Drug Discovery. John Dickenson et.al
5. Basic Cell Culture protocols by Cheril D.Helgason and Cindy L.Miller
6. Basic Cell Culture (Practical Approach) by J. M. Davis (Editor)
7. Animal Cell Culture: A Practical Approach by John R. Masters (Editor)
8. Current porotocols in molecular biology vol I to VI edited by Frederick M.Ausuvel et la.



# M.Pharmacy (Pharmacology)

## Semester I

### MPL010050 - PHARMACOLOGICAL PRACTICAL – I

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

#### Handling of laboratory animals.

1. Various routes of drug administration.
2. Techniques of blood sampling, anesthesia and euthanasia of experimental animals.
3. Functional observation battery tests (modified Irwin test)
4. Evaluation of CNS stimulant, depressant, anxiogenics and anxiolytic, anticonvulsant activity.
5. Evaluation of analgesic, anti-inflammatory, local anesthetic, mydriatic and miotic activity.
6. Evaluation of diuretic activity.
7. Evaluation of antiulcer activity by pylorus ligation method.
8. Oral glucose tolerance test.
9. Isolation and identification of DNA from various sources (Bacteria, Cauliflower, onion, Goat liver).
10. Isolation of RNA from yeast
11. Estimation of proteins by Bradford/Lowry's in biological samples.
12. Estimation of RNA/DNA by UV Spectroscopy
13. Gene amplification by PCR.
14. Protein quantification Western Blotting.
15. Enzyme based in-vitro assays (MPO, AChEs,  $\alpha$  amylase,  $\alpha$  glucosidase).
16. Cell viability assays (MTT/Trypan blue/SRB).
17. DNA fragmentation assay by agarose gel electrophoresis.
18. DNA damage study by Comet assay.
19. Apoptosis determination by fluorescent imaging studies.
20. Pharmacokinetic studies and data analysis of drugs given by different routes of administration using softwares.
21. Enzyme inhibition and induction activity
22. Extraction of drug from various biological samples and estimation of drugs in biological fluids using different analytical techniques (UV)
23. Extraction of drug from various biological samples and estimation of drugs in biological fluids using different analytical techniques (HPLC)

#### REFERENCES

1. CPCSEA, OECD, ICH, USFDA, Schedule Y, EPA guidelines,
2. Fundamentals of experimental Pharmacology by M.N.Ghosh
3. Handbook of Experimental Pharmacology by S.K. Kulkarni.
4. Drug discovery and Evaluation by Vogel H.G.
5. Spectrometric Identification of Organic compounds - Robert M Silverstein,
6. Principles of Instrumental Analysis - Douglas A Skoog, F. James Holler, Timothy A. Nieman,
7. Vogel's Text book of quantitative chemical analysis - Jeffery, Basset, Mendham, Denney,
8. Basic Cell Culture protocols by Cheril D. Helgason and Cindy L.Mille
9. Basic Cell Culture (Practical Approach) by J. M. Davis (Editor)
10. Animal Cell Culture: A Practical Approach by John R. Masters (Editor)
11. Practical Manual of Experimental and Clinical Pharmacology by Bikash Medhi(Author), Ajay Prakash (Author) Jaypee brothers' medical publishers Pvt. Ltd

# M.Pharmacy (Pharmacology) Semester I

MPL010060 - Seminar/Assignment - I

**Practical**

**90 Hour**

## **Microsoft office word**

- ☑ Creating, editing, saving and printing text documents
- ☑ Font and paragraph formatting
- ☑ Simple character formatting
- ☑ Inserting tables, smart art, page breaks
- ☑ Using lists and styles
- ☑ Working with images
- ☑ Using Spelling and Grammar check
- ☑ Understanding document properties

## **Microsoft office PowerPoint**

- ☑ Opening, viewing, creating, and printing slides
- ☑ Applying auto layouts
- ☑ Adding custom animation
- ☑ Using slide transitions
- ☑ Graphically representing data : Charts & Graphs
- ☑ Creating Professional Slide for Presentation.

## **Microsoft office excel**

- ☑ Spreadsheet basics
- ☑ Creating, editing, saving and printing spreadsheets
- ☑ Working with functions & formulas
- ☑ Modifying worksheets with color & autoformats
- ☑ Graphically representing data : Charts & Graphs
- ☑ Speeding data entry : Using Data Forms
- ☑ Analyzing data : Data Menu, Subtotal, Filtering Data
- ☑ Formatting worksheets
- ☑ Securing & Protecting spreadsheets

## **Reference books**

Mastering MS Office (English, Paperback, Kumar Bittu)

Master Book Of Computer: Learn MS Office, Basic Computer, MS Excel, Excel Formulas, Tally, HTML by Mangesh Bhuvad.

# M.Pharmacy (Pharmacology)

## Semester II

### MPL020010 - ADVANCED PHARMACOLOGY – II

#### Scope

The subject is designed to strengthen the basic knowledge in the field of pharmacology and to impart recent advances in the drugs used for the treatment of various diseases. In addition, the subject helps the student to understand the concepts of drug action and mechanism involved

#### Objectives

Upon completion of the course the student shall be able to:

- Explain the mechanism of drug actions at cellular and molecular level
- Discuss the Pathophysiology and pharmacotherapy of certain diseases
- Understand the adverse effects, contraindications and clinical uses of drugs used in treatment of diseases

#### THEORY

**60 HOURS**  
**12 HOURS**

##### 1. Endocrine Pharmacology

Molecular and cellular mechanism of action of hormones such as growth hormone, prolactin, thyroid, insulin and sex hormones  
Anti-thyroid drugs, Oral hypoglycemic agents, Oral contraceptives, Corticosteroids.  
Drugs affecting calcium regulation

**12 HOURS**

##### 2. Chemotherapy

Cellular and molecular mechanism of actions and resistance of antimicrobial agents such as  $\beta$ -lactams, aminoglycosides, quinolones, Macrolide antibiotics. Antifungal, antiviral, and anti-TB drugs.

**12 HOURS**

##### 3. Chemotherapy

Drugs used in Protozoal Infections  
Drugs used in the treatment of Helminthiasis  
Chemotherapy of cancer  
Immunopharmacology  
Cellular and biochemical mediators of inflammation and immune response.  
Allergic or hypersensitivity reactions. Pharmacotherapy of asthma and COPD.  
Immunosuppressants and Immunostimulants

**12 HOURS**

##### 4. GIT Pharmacology

Antiulcer drugs, Prokinetics, antiemetics, anti-diarrheals and drugs for constipation and irritable bowel syndrome.

##### Chronopharmacology

Biological and circadian rhythms, applications of chronotherapy in various diseases like cardiovascular disease, diabetes, asthma and peptic ulcer.

**12 HOURS**

##### 5. Free radicals Pharmacology

Generation of free radicals, role of free radicals in etiopathology of various diseases such as diabetes, neurodegenerative diseases and cancer.

Protective activity of certain important antioxidant

Recent Advances in Treatment: Alzheimer's disease, Parkinson's disease, Cancer, Diabetes mellitus

#### REFERENCES

1. The Pharmacological basis of therapeutics- Goodman and Gillman's

2. Principles of Pharmacology. The Pathophysiologic basis of drug therapy by David E Golan et al.
3. Basic and Clinical Pharmacology by B.G -Katzung
4. Pharmacology by H.P. Rang and M.M. Dale.
5. Hand book of Clinical Pharmacokinetics by Gibaldi and Prescott.
6. Text book of Therapeutics, drug and disease management by E T. Herfindal and Gourley.
7. Applied biopharmaceutics and Pharmacokinetics by Leon Shargel and Andrew B. C. Yu.
8. Handbook of Essential Pharmacokinetics, Pharmacodynamics and Drug Metabolism for Industrial Scientists
9. Robbins & Cortan Pathologic Basis of Disease, 9<sup>th</sup> Ed. (Robbins Pathology)
10. A Complete Textbook of Medical Pharmacology by Dr. S.K Srivastava published by APC Avichal Publishing Company.
11. K D. Tripathi. Essentials of Medical Pharmacology
12. Principles of Pharmacology. The Pathophysiologic basis of drug Therapy by David E Golan, Armen H, Tashjian Jr, Ehrin J, Armstrong, April W, Armstrong, Wolters, Kluwer-Lippincott Williams & Wilkins Publishers

# M.Pharmacy (Pharmacology)

## Semester II

### MPL020020 - PHARMACOLOGICAL AND TOXICOLOGICAL SCREENING METHODS-II

#### Scope:

This subject imparts knowledge on the preclinical safety and toxicological evaluation of drug & new chemical entity. This knowledge will make the student competent in regulatory toxicological evaluation.

#### Objectives:

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

- Explain the various types of toxicity studies.
- Appreciate the importance of ethical and regulatory requirements for toxicity studies. •
- Demonstrate the practical skills required to conduct the preclinical toxicity studies.

#### THEORY

**60 HOURS**

**12 HOURS**

1. Basic definition and types of toxicology (general, mechanistic, regulatory and descriptive)

Regulatory guidelines for conducting toxicity studies OECD, ICH, EPA and Schedule Y

OECD principles of Good laboratory practice (GLP)

History, concept and its importance in drug development

**12 HOURS**

2. Acute, sub-acute and chronic- oral, dermal and inhalational studies as per OECD guidelines.

Acute eye irritation, skin sensitization, dermal irritation & dermal toxicity studies.

Test item characterization- importance and methods in regulatory toxicology studies

**12 HOURS**

3. Reproductive toxicology studies, Male reproductive toxicity studies, female reproductive studies (segment I and segment III), teratogenicity studies (segment II)

Genotoxicity studies (Ames Test, in vitro and in vivo Micronucleus and Chromosomal aberrations studies)

In vivo carcinogenicity studies

**12 HOURS**

4. IND enabling studies (IND studies)- Definition of IND, importance of IND, industry perspective, list of studies needed for IND submission.

Safety pharmacology studies- origin, concepts and importance of safety pharmacology.

Tier1- CVS, CNS and respiratory safety pharmacology, HERG assay. Tier2- GI, renal and other studies

**12 HOURS**

5. Toxicokinetics- Toxicokinetic evaluation in preclinical studies, saturation kinetics Importance and applications of toxicokinetic studies.

Alternative methods to animal toxicity testing.

#### REFERENCES

1. Hand book on GLP, Quality practices for regulated non-clinical research and development (<http://www.who.int/tdr/publications/documents/glp-handbook.pdf>).

2. Schedule Y Guideline: drugs and cosmetics (second amendment) rules, 2005, ministry of health and family welfare (department of health) New Delhi

3. Drugs from discovery to approval by Rick NG.

4. Animal Models in Toxicology, 3<sup>rd</sup> Edition, Lower and Bryan

5. OECD test guidelines.

6. Principles of toxicology by Karen E. Stine, Thomas M. Brown.

7. Guidance for Industry M3(R2) Nonclinical Safety Studies for the Conduct of Human Clinical Trials and Marketing Authorization for Pharmaceuticals

(<http://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm073246.pdf>)

# M.Pharmacy (Pharmacology)

## Semester II

### MPL020030 - PRINCIPLES OF DRUG DISCOVERY

#### Scope:

The subject imparts basic knowledge of drug discovery process. This information will make the student competent in drug discovery process

#### Objectives:

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

- Explain the various stages of drug discovery.
- Appreciate the importance of the role of genomics, proteomics and bioinformatics in drug discovery
- Explain various targets for drug discovery.
- Explain various lead seeking method and lead optimization
- Appreciate the importance of the role of computer aided drug design in drug discovery

#### THEORY

**60 HOURS**

**12 HOURS**

1. An overview of modern drug discovery process: Target identification, target validation, lead identification and lead Optimization. Economics of drug discovery.

Target Discovery and validation-Role of Genomics, Proteomics and Bioinformatics. Role of Nucleic acid microarrays, Protein microarrays, Antisense technologies, siRNAs, antisense oligonucleotides, Zinc finger proteins. Role of transgenic animals in target validation.

**12 HOURS**

2. Lead Identification- combinatorial chemistry & high throughput screening, in silico lead discovery techniques, Assay development for hit identification.

Protein structure Levels of protein structure, Domains, motifs, and folds in protein structure. Computational prediction of protein structure: Threading and homology modeling methods. Application of NMR and X-ray crystallography in protein structure prediction

**12 HOURS**

3. Rational Drug Design

Traditional vs rational drug design, Methods followed in traditional drug design, High throughput screening, Concepts of Rational Drug Design, Rational Drug Design Methods: Structure and Pharmacophore based approaches

Virtual Screening techniques: Drug likeness screening, Concept of pharmacophore mapping and pharmacophore-based Screening.

**12 HOURS**

4. Molecular docking: Rigid docking, flexible docking, manual docking; Docking based screening. De novo drug design.

Quantitative analysis of Structure Activity Relationship

History and development of QSAR, SAR versus QSAR, Physicochemical parameters, Hansch analysis, Fee Wilson analysis and relationship between them.

**12 HOURS**

5. QSAR Statistical methods – regression analysis, partial least square analysis (PLS) and other multivariate statistical methods. 3D-QSAR approaches like COMFA and COMSIA Prodrug design-Basic concept, Prodrugs to improve patient acceptability, Drug solubility, Drug absorption and distribution, site specific drug delivery and sustained drug action. Rationale of prodrug design and practical consideration of prodrug design

#### REFERENCES

1. MouldySioud. Target Discovery and Validation Reviews and Protocols: Volume 2 Emerging Molecular Targets and Treatment Options. 2007 Humana Press Inc.

2. Darryl León. Scott Markelln. Silico Technologies in Drug Target Identification and Validation. 2006 by Taylor and Francis Group, LLC.
3. Johanna K. DiStefano. Disease Gene Identification. Methods and Protocols. Springer New York Dordrecht Heidelberg London.
4. Hugo Kubiny. QSAR: Hansch Analysis and Related Approaches. Methods and Principles in Medicinal Chemistry. Publisher Wiley-VCH
5. Klaus Gubernator, Hans-Joachim Böhm. Structure-Based Ligand Design. Methods and Principles in Medicinal Chemistry. Publisher Wiley-VCH
6. Abby L .Parrill. M . Rami Reddy. Rational Drug Design. Novel Methodology and Practical Applications. ACS Symposium Series; American Chemical Society: Washington, DC, 1999.
7. J. Rick Turner. New drug development design, methodology and, analysis. John Wiley & Sons, Inc., New Jersey.

# M.Pharmacy (Pharmacology)

## Semester II

### MPL020040 - CLINICAL RESEARCH AND PHARMACOVIGILANCE

#### Scope:

This subject will provide a value addition and current requirement for the students in clinical research and pharmacovigilance. It will teach the students on conceptualizing, designing, conducting, managing and reporting of clinical trials. This subject also focuses on global scenario of Pharmacovigilance in different methods that can be used to generate safety data. It will teach the students in developing drug safety data in Pre-clinical, Clinical phases of Drug development and post market surveillance.

**Objectives:** Upon completion of the course, the student shall be able to,

- Explain the regulatory requirements for conducting clinical trial
- Demonstrate the types of clinical trial designs
- Explain the responsibilities of key players involved in clinical trials
- Execute safety monitoring, reporting and close-out activities
- Explain the principles of Pharmacovigilance
- Detect new adverse drug reactions and their assessment
- Perform the adverse drug reaction reporting systems and communication in Pharmacovigilance

#### THEORY

**60 HOURS**

**12 HOURS**

1. Regulatory Perspectives of Clinical Trials: Origin and Principles of International Conference on Harmonization - Good Clinical Practice (ICH-GCP) guidelines Ethical Committee: Institutional Review Board, Ethical Guidelines for Biomedical Research and Human Participant Schedule Y, ICMR  
Informed Consent Process: Structure and content of an Informed Consent Process Ethical principles governing informed consent process

**12 HOURS**

2 Clinical Trials: Types and Design

Experimental Study- RCT and Non RCT,

Observation Study: Cohort, Case Control, Cross sectional

Clinical Trial Study Team

Roles and responsibilities of Clinical Trial Personnel: Investigator, Study Coordinator, Sponsor, Contract Research Organization and its management

**12 HOURS**

3 Clinical Trial Documentation- Guidelines to the preparation of documents, Preparation of protocol, Investigator Brochure, Case Report Forms, Clinical Study Report Clinical Trial Monitoring Safety Monitoring in CT

Adverse Drug Reactions: Definition and types. Detection and reporting methods. Severity and seriousness assessment. Predictability and preventability assessment, Management of adverse drug reactions; Terminologies of ADR.

**12 HOURS**

4 Basic aspects, terminologies and establishment of pharmacovigilance

History and progress of pharmacovigilance, Significance of safety monitoring, Pharmacovigilance in India and international aspects, WHO international drug monitoring programme, WHO and Regulatory terminologies of ADR, evaluation of medication safety, Establishing pharmacovigilance centres in Hospitals, Industry and National programmes related to pharmacovigilance. Roles and responsibilities in Pharmacovigilance

**12 HOURS**

5 Methods, ADR reporting and tools used in Pharmacovigilance



International classification of diseases, International Non-proprietary names for drugs, Passive and Active surveillance, Comparative observational studies, Targeted clinical investigations and Vaccine safety surveillance. Spontaneous reporting system and Reporting to regulatory authorities, Guidelines for ADRs reporting. Argus, Aris G Pharmacovigilance, Vigi Flow, Statistical methods for evaluating medication safety data.

**12 HOURS**

6 Pharmacoepidemiology, pharmacoconomics, safety pharmacology

#### **REFERENCES**

1. Central Drugs Standard Control Organization- Good Clinical Practices, Guidelines for Clinical Trials on Pharmaceutical Products in India. New Delhi: Ministry of Health;2001.
2. International Conference on Harmonization of Technical requirements for registration of Pharmaceuticals for human use. ICH Harmonized Tripartite Guideline. Guideline for Good Clinical Practice.E6; May 1996.
3. Ethical Guidelines for Biomedical Research on Human Subjects 2000. Indian Council of Medical Research, New Delhi.
4. Textbook of Clinical Trials edited by David Machin, Simon Day and Sylvan Green, March 2005, John Wiley and Sons.
5. Clinical Data Management edited by R K Rondels, S A Varley, C F Webbs. Second Edition, Jan 2000, Wiley Publications.
6. Handbook of clinical Research. Julia Lloyd and Ann Raven Ed. Churchill Livingstone.
7. Principles of Clinical Research edited by Giovanna di Ignazio, Di Giovanna and Haynes.

# M.Pharmacy (Pharmacology)

## Semester II

### MPL020050 - PHARMACOLOGICAL PRACTICALS– II

1. To record the DRC of agonist using suitable isolated tissues preparation.
2. To study the effects of antagonist/potentiating agents on DRC of agonist using suitable isolated tissue preparation.
3. To determine to the strength of unknown sample by matching bioassay by using suitable tissue preparation.
4. To determine to the strength of unknown sample by interpolation bioassay by using suitable tissue preparation
5. To determine to the strength of unknown sample by bracketing bioassay by using suitable tissue preparation
6. To determine to the strength of unknown sample by multiple point bioassay by using suitable tissue preparation.
7. Estimation of PA<sub>2</sub> values of various antagonists using suitable isolated tissue preparations.
8. To study the effects of various drugs on isolated heart preparations
9. Recording of rat BP, heart rate and ECG.
10. Recording of rat ECG
11. Drug absorption studies by averted rat ileum preparation.
12. Acute oral toxicity studies as per OECD guidelines.
13. Acute dermal toxicity studies as per OECD guidelines.
14. Repeated dose toxicity studies- Serum biochemical, haematological, urine analysis, functional observation tests and histological studies.
15. Drug mutagenicity study using mice bone-marrow chromosomal aberration test.
16. Protocol design for clinical trial.(3 Nos.)
17. Design of ADR monitoring protocol.
18. In-silico docking studies. (2 Nos.)
19. In-silico pharmacophore-based screening.
20. In-silico QSAR studies.
21. ADR reporting

#### REFERENCES

1. Fundamentals of experimental Pharmacology-by M.N.Ghosh
2. Hand book of Experimental Pharmacology-S.K.Kulakarni
3. Text book of in-vitro practical Pharmacology by Ian Kitchen
4. Bioassay Techniques for Drug Development by Atta-Ur-Rahman, Iqbal Choudhary and William Thomsen
5. Applied biopharmaceutics and Pharmacokinetics by Leon Shargel and Andrew B.C.Yu.
6. Handbook of Essential Pharmacokinetics, Pharmacodynamics and Drug Metabolism for Industrial Scientists.

# M.Pharmacy (Pharmacology) Semester II

MPL020060 - Seminar/Assignment - II

**Practical**

**90 Hour**

**Presentation skills:** To prepare presentations of scientific research/review work and to give presentation.

**Various software's used in project work:** Design of experiments, Minitab, SigmaPlot, GraphPad Prism, etc.

## **Reference books:**

Design of Experiments: A No-Name Approach: 138 (STATISTICS, A SERIES OF TEXTBOOKS AND MONOGRAPHS) by Thomas Lorenzen (Editor), Virgil Anderson (Editor)

Essential Biostatistics: A nonmathematical Approach by Harvey Motulsky

Sigma Plot for Scientists by Charland

# M.Pharmacy (All Branches)

## Semester III

**MPH030010 - Research Methodology & Biostatistics**

**MQA030010 - Research Methodology & Biostatistics**

**MPL030010 - Research Methodology & Biostatistics**

### **UNIT – I**

General Research Methodology: Research, objective, requirements, practical difficulties, review of literature, study design, types of studies, strategies to eliminate errors/bias, controls, randomization, crossover design, placebo, blinding techniques.

### **UNIT – II**

Biostatistics: Definition, application, sample size, importance of sample size, factors influencing sample size, dropouts, statistical tests of significance, type of significance tests, parametric tests (students "t" test, ANOVA, Correlation coefficient, regression), non-parametric tests (Wilcoxon rank tests, analysis of variance, correlation, chi square test), null hypothesis, P values, degree of freedom, interpretation of P values.

### **UNIT – III**

Medical Research: History, values in medical ethics, autonomy, beneficence, non-maleficence, double effect, conflicts between autonomy and beneficence/non-maleficence, euthanasia, informed consent, confidentiality, criticisms of orthodox medical ethics, importance of communication, control resolution, guidelines, ethics committees, cultural concerns, truth telling, online business practices, conflicts of interest, referral, vendor relationships, treatment of family members, sexual relationships, fatality.

### **UNIT – IV**

CPCSEA guidelines for laboratory animal facility: Goals, veterinary care, quarantine, surveillance, diagnosis, treatment and control of disease, personal hygiene, location of animal facilities to laboratories, anesthesia, euthanasia, physical facilities, environment, animal husbandry, record keeping, SOPs, personnel and training, transport of lab animals.

### **UNIT – V**

Declaration of Helsinki: History, introduction, basic principles for all medical research, and additional principles for medical research combined with medical care.

# M.Pharmacy (All Branches)

## Semester III

MPH030020 - Journal Club I

MQA030020 - Journal Club I

MPL030020 - Journal Club I

### Practical

15 Hour

**Interpretation of data from scientific articles:** Practical exercises that can teach students how to extract, and analyze, data to draw conclusions or insights.

**Presentation of data in scientific work:** Practical exercises to teach students how to present the analytical data

**Patent search engines:** Practical exercise to teach students about various patent search engines such as EPFO, IPO, USPTO etc. and how to search patent using key words.

## **M.Pharmacy (All Branches)**

### **Semester IV**

**MPH040010 - Journal Club II**

**MQA040010 - Journal Club II**

**MPL040010 - Journal Club II**

#### **Practical**

**15 Hour**

Practical exercises about identifying and solving the challenges regarding the pharmaceutical formulation, drug performance, analytics etc.

Practical exercise about presenting the solved problem into a presentation form.