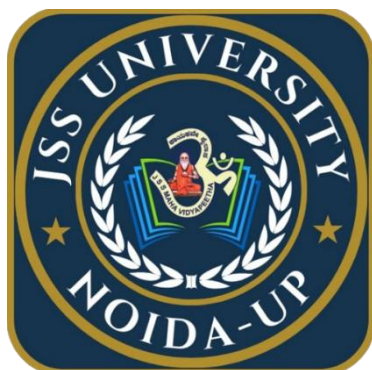


JSS MAHAVIDYAPEETHA
JSS UNIVERSITY, NOIDA



EVALUATION SCHEME AND SYLLABUS
For
M.PHARM
IN
PHARMACEUTICS, PHARMACOLOGY, PHARMACEUTICAL ANALYSIS, &
PHARMACEUTICAL REGULATORY AFFAIRS

Framed under the Pharmacy Council of India Regulations for
Master of Pharmacy (M.Pharm)

Effective from the Session
2024-2025

JSS UNIVERSITY, NOIDA
C-20/1, Sector-62, Noida, Gautam Budh Nagar,
Uttar Pradesh, India-201301

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DETAILED SYLLABUS OF PHARMACEUTICS (MPH)

Detailed Schemes for Pharmaceutics

Course Code	Course	Credit Hours	Credit Points	Hrs./wk	Marks
Semester I					
MPH101T	Modern Pharmaceutical Analytical Techniques	4	4	4	100
MPH102T	Drug Delivery System	4	4	4	100
MPH103T	Modern Pharmaceutics	4	4	4	100
MPH104T	Regulatory Affair	4	4	4	100
MPH105P	Pharmaceutics Practical I	12	6	12	150
-	Seminar/Assignment	7	4	7	100
Total		35	26	35	650
Semester II					
MPH201T	Molecular Pharmaceutics (Nano Tech and Targeted DDS)	4	4	4	100
MPH202T	Advanced Biopharmaceutics & Pharmacokinetics	4	4	4	100
MPH203T	Computer-Aided Drug Delivery System	4	4	4	100
MPH204T	Cosmetics and Cosmeceuticals	4	4	4	100
MPH205P	Pharmaceutics Practical II	12	6	12	150
-	Seminar/Assignment	7	4	7	100
Total		35	26	35	650

Course Code	Course	Internal Assessment				End Semester Exams		Total Marks
		Continuous Mode	Sessional Exams		Total	Marks	Duration (in Hrs)	
			Marks	Duration (in Hrs)				
SEMESTER I								
MPH101T	Modern Pharmaceutical Analytical Techniques	10	15	1	25	75	3	100
MPH102T	Drug Delivery System	10	15	1	25	75	3	100
MPH103T	Modern Pharmaceutics	10	15	1	25	75	3	100
MPH104T	Regulatory Affair	10	15	1	25	75	3	100
MPH105P	Pharmaceutics Practical I	20	30	6	50	100	12	150
-	Seminar/Assignment	-	-	-	-	-	-	100
Total								650
SEMESTER II								
MPH201T	Molecular Pharmaceutics (Nano Tech and Targeted DDS)	10	15	1	25	75	3	100
MPH202T	Advanced Biopharmaceutics & Pharmacokinetics	10	15	1	25	75	3	100
MPH203T	Computer-Aided Drug Delivery System	10	15	1	25	75	3	100
MPH204T	Cosmetics and Cosmeceuticals	10	15	1	25	75	3	100
MPH205P	Pharmaceutics Practical II	20	30	6	50	100	12	150
-	Seminar/Assignment	-	-	-	-	-	-	100
Total								650

MODERN PHARMACEUTICAL ANALYTICAL TECHNIQUE (MPH 101T)

Scope

This subject deals with various advanced analytical instrumental techniques for the identification, characterization and quantification of drugs. Instruments dealt with 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

UNIT I

11 Hrs

- UV-Visible spectroscopy: Introduction, Theory, Laws, Instrumentation associated with UV-Visible spectroscopy, Choice of solvents and solvent effect and Applications of UV Visible spectroscopy.
- 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
- Spectrofluorimetry: Theory of Fluorescence, Factors affecting fluorescence, Quenchers, Instrumentation and Applications of fluorescence spectrophotometer.
- Flame emission spectroscopy and Atomic absorption spectroscopy: Principle, Instrumentation, Interferences and Applications.

UNIT II

11 Hrs

NMR spectroscopy: Quantum numbers and their role in NMR, Principle, Instrumentation, Solvent requirement in NMR, Relaxation process, NMR signals in various compounds, Chemical shift, Factors influencing chemical shift, Spin-Spin coupling, Coupling constant, Nuclear magnetic double resonance, Brief outline of principles of FT-NMR and ¹³C NMR. Applications of NMR spectroscopy.

UNIT III

11 Hrs

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.

UNIT IV**11 Hrs**

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

UNIT V**11 rs**

- 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 methods, Bragg's law, Rotating crystal technique, X ray powder technique, Types of crystals and applications of X-ray diffraction.

UNIT VI**5 Hrs**

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

DRUG DELIVERY SYSTEMS (MPH 102T)

Scope

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

Objectives

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

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

THEORY

60 HOURS

UNIT I

10 Hrs

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.

UNIT II

10 Hrs

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

UNIT III

10 Hrs

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 muco adhesion, advantages and disadvantages, Mechanism of drug permeation, Methods of formulation and its evaluations.

UNIT IV

06 Hrs

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

UNIT V

10 Hrs

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

UNIT VI

08 Hrs

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

UNIT VII

06 Hrs

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 WileyInterscience Publication, John Wiley and Sons, Inc, New York! Chichester/Weinheim
4. N.K. Jain, Controlled and Novel Drug Delivery, CBS Publishers & Distributors, New Delhi, First edition 1997 (reprint in 2001).
5. S.P. Vyas and R.K.Khar, Controlled Drug Delivery - concepts and advances, Vallabh Prakashan, New Delhi, First edition 2002

JOURNALS

1. Indian Journal of Pharmaceutical Sciences (IPA)
2. Indian drugs (IDMA)
3. Journal of controlled release (Elsevier Sciences) desirable
4. Drug Development and Industrial Pharmacy (Marcel & Decker) desirable

MODERN PHARMACEUTICS (MPH103T)

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
- development
- Industrial Management and GMP Considerations.
- Optimization Techniques & Pilot Plant Scale Up Techniques
- Stability Testing, sterilization process & packaging of dosage forms.

THEORY

60 HOURS

UNIT I

20 Hrs

- 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.
- 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

UNIT II

10 Hrs

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.

UNIT III

10 Hrs

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.

UNIT IV**10 Hrs**

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

UNIT V**10 Hrs**

Study of consolidation parameters; Diffusion parameters, Dissolution parameters and Pharmacokinetic parameters, Heckel Hrs plots, Similarity factors – f_2 and f_1 , 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 – Rawbins.
10. Good manufacturing practices for Pharmaceuticals: A plan for total quality control, Second edition; By Sidney H. Willig.
11. Quality Assurance Guide; By Organization of Pharmaceutical producers of India.
12. Drug formulation manual; By D.P.S. Kohli and D.H.Shah. Eastern publishers, New Delhi.
13. How to practice GMPs; By P.P.Sharma. Vandhana Publications, Agra.
14. Pharmaceutical Process Validation; By Fra. R. Berry and Robert A. Nash.
15. Pharmaceutical Preformulations; By J.J. Wells.
16. Applied production and operations management; By Evans, Anderson, Sweeney and Williams.
17. Encyclopaedia of Pharmaceutical technology, Vol I – III.

REGULATORY AFFAIRS (MPH104T)

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

Objectives

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

- The Concepts of innovator and generic drugs, drug development process
- The Regulatory guidance's and guidelines for filing and approval process
- Preparation of Dossiers and their submission to regulatory agencies in different countries
- Post approval regulatory requirements for actives and drug products
- Submission of global documents in CTD/ eCTD formats
- Clinical trials requirements for approvals for conducting clinical trials
- Pharmacovigilance and process of monitoring in clinical trials.

THEORY

60 HOURS

UNIT I

24 Hrs

- 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

UNIT II

12 Hrs

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.

UNIT III**12 Hrs**

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

UNIT IV**12 Hrs**

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/
8. www.fda.gov/
9. europa.eu/index_en.htm
10. <https://www.tga.gov.au/tga-basics>

PHARMACEUTICS PRACTICAL I (MPH105P)

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.

**MOLECULAR PHARMACEUTICS (NANO TECHNOLOGY &
TARGETED DDS) (NTDS) (MPH 201T)**

Scope

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

Objectives

Upon completion of the course student shall be able to understand

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

THEORY

60 HOURS

UNIT I

12 Hrs

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

UNIT II

12 Hrs

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

UNIT III

12 Hrs

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

UNIT IV

12 Hrs

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

UNIT V

12 Hrs

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, VallabhPrakashan,

New Delhi, First edition 2002.

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

ADVANCED BIOPHARMACEUTICS & PHARMACOKINETICS (MPH 202T)

Scope

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

Objectives

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

THEORY

60 HOURS

UNIT I

12 Hrs

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.

UNIT II

12 Hrs

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.

UNIT III

12 Hrs

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 proteinbinding interactions, the effect of tissue-binding interactions, cytochrome p450-based drug interactions, drug interactions linked to transporters.

UNIT IV

12 Hrs

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.

UNIT V

12 Hrs

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., VallabPrakashan, Pitampura, Delhi.
3. Applied Biopharmaceutics and Pharmacokinetics by Shargel. Land YuABC, 2ndedition, Connecticut Appleton Century Crofts, 1985
4. Textbook of Biopharmaceutics and Pharmacokinetics, Dr. Shobha Rani R. Hiremath, Prism Book
5. Pharmacokinetics by Milo Gibaldi and D. Perrier, 2nd edition, Marcel Dekker Inc., New York, 1982
6. Current Concepts in Pharmaceutical Sciences: Biopharmaceutics, Swarbrick. J, Leaand Febiger, Philadelphia, 1970
7. Current Concepts in Pharmaceutical Sciences: Biopharmaceutics, Swarbrick. J, Leaand Febiger, Philadelphia, 1970

8. Clinical Pharmacokinetics, Concepts and Applications 3rd edition by Malcolm Rowland and Thomas N. Tozer, Lea and Febiger, Philadelphia, 1995
9. Dissolution, Bioavailability and Bioequivalence, Abdou. H.M, Mack Publishing Company, Pennsylvania 1989.
10. Biopharmaceutics and Clinical Pharmacokinetics, An Introduction, 4th edition, revised and expanded by Robert. E. Notari, Marcel Dekker Inc, New York and Basel, 1987.
11. Biopharmaceutics and Relevant Pharmacokinetics by John. G Wagner and M. Pamarowski, 1st edition, Drug Intelligence Publications, Hamilton, Illinois, 1971.
12. Encyclopedia of Pharmaceutical Technology, Vol 13, James Swarbrick, James. G. Boylan, Marcel Dekker Inc, New York, 1996.
13. Basic Pharmacokinetics, 1st edition, Sunil S Jambhekar and Philip J Breen, pharmaceutical press, RPS Publishing, 2009.
14. Absorption and Drug Development- Solubility, Permeability, and Charge State, Alex Avdeef, John Wiley & Sons, Inc, 2003.

COMPUTER AIDED DRUG DEVELOPMENT (MPH 203T)

Scope

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

Objectives

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

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

THEORY

60 HOURS

UNIT I

12 Hrs

- a. Computers in Pharmaceutical Research and Development: A General Overview: History of Computers in Pharmaceutical Research and Development. Statistical modelling 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.

UNIT II

12 Hrs

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.

UNIT III

12 Hrs

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

UNIT IV

12 Hrs

- 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

UNIT V

12 Hrs

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, 1st Edition Jelena Djuris, Woodhead Publishing
3. Encyclopedia of Pharmaceutical Technology, Vol 13, James Swarbrick, James. G.Boylan, Marcel Dekker Inc, New York, 1996.

COSMETICS AND COSMECEUTICALS (MPH 204T)

Scope

This course is designed to impart knowledge and skills necessary for the fundamental need for cosmetic and cosmeceutical products.

Objectives

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

- Key ingredients used in cosmetics and cosmeceuticals.
- Key building blocks for various formulations.
- Current technologies in the market
- Various key ingredients and basic science to develop cosmetics and cosmeceuticals
- Scientific knowledge to develop cosmetics and cosmeceuticals with desired Safety, stability, and efficacy.

THEORY

60 HOURS

UNIT I

12 Hrs

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.

UNIT II

12 Hrs

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.

UNIT III

12 Hrs

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.

UNIT IV

12 Hrs

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.

UNIT V

12 Hrs

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

PHARMACEUTICS PRACTICALS – II (MPH 205P)

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

DETAILED SYLLABUS OF PHARMACOLOGY (MPL)

Detailed Schemes for Pharmacology

Course Code	Course	Credit Hours	Credit Points	Hrs./wk	Marks
Semester I					
MPL101T	Modern Pharmaceutical Analytical Techniques	4	4	4	100
MPL102T	Advanced Pharmacology-I	4	4	4	100
MPL103T	Pharmacological and Toxicological Screening Methods I	4	4	4	100
MPL104T	Cellular and Molecular Pharmacology	4	4	4	100
MPL105P	Pharmacology Practical I	12	6	12	150
-	Seminar/Assignment	7	4	7	100
Total		35	26	35	650
Semester II					
MPL201T	Advanced Pharmacology II	4	4	4	100
MPL202T	Pharmacological and Toxicological Screening Methods II	4	4	4	100
MPL203T	Principles of Drug Discovery	4	4	4	100
MPL204T	Clinical research and pharmacovigilance	4	4	4	100
MPL205P	Experimental Pharmacology Practical II	12	6	12	150
-	Seminar/Assignment	7	4	7	100
Total		35	26	35	650

Course Code	Course	Internal Assessment				End Semester Exams		Total Marks
		Continuous Mode	Sessional Exams		Total	Marks	Duration (in Hrs)	
			Marks	Duration (in Hrs)				
SEMESTER I								
MPL101T	Modern Pharmaceutical Analytical Techniques	10	15	1	25	75	3	100
MPL102T	Advanced Pharmacology-I	10	15	1	25	75	3	100
MPL103T	Pharmacological and Toxicological Screening Methods I	10	15	1	25	75	3	100
MPL104T	Cellular and Molecular Pharmacology	10	15	1	25	75	3	100
MPL105P	Pharmacology Practical I	20	30	6	50	100	12	150
-	Seminar/Assignment	-	-	-	-	-	-	100
Total								650
SEMESTER II								
MPL201T	Advanced Pharmacology II	10	15	1	25	75	3	100
MPL202T	Pharmacological and Toxicological Screening Methods II	10	15	1	25	75	3	100
MPL203T	Principles of Drug Discovery	10	15	1	25	75	3	100
MPL204T	Clinical research and pharmacovigilance	10	15	1	25	75	3	100
MPL205P	Experimental Pharmacology Practical II	20	30	6	50	100	12	150
-	Seminar/Assignment	-	-	-	-	-	-	100
Total								650

MODERN PHARMACEUTICAL ANALYTICAL TECHNIQUE (MPL 101T)

Scope

This subject deals with various advanced analytical instrumental techniques for the identification, characterization and quantification of drugs. Instruments dealt with are NMR, Mass spectrometer, IR, HPLC, GC etc.

Objectives

After completion of course, student is able to know about,

- Chemicals and Excipients
- The analysis of various drugs in single and combination dosage forms
- Theoretical and practical skills of the instruments

THEORY

60 HOURS

UNIT I

10 Hrs

UV-Visible spectroscopy: Introduction, Theory, Laws, Instrumentation associated with UV-Visible spectroscopy, Choice of solvents and solvent effect and Applications of UV-Visible spectroscopy, Difference/ Derivative spectroscopy.

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, Data Interpretation.

Spectrofluorimetry: Theory of Fluorescence, Factors affecting fluorescence (Characteristics of drugs that can be analysed by fluorimetry), Quenchers, Instrumentation and Applications of fluorescence spectrophotometer. Flame emission spectroscopy and Atomic absorption spectroscopy: Principle, Instrumentation, Interferences and Applications.

UNIT II

10 Hrs

NMR spectroscopy: Quantum numbers and their role in NMR, Principle, Instrumentation, Solvent requirement in NMR, Relaxation process, NMR signals in various compounds, Chemical shift, Factors influencing chemical shift, Spin-Spin coupling, Coupling constant, Nuclear magnetic double resonance. Brief outline of principles of FT-NMR and ¹³C NMR. Applications of NMR spectroscopy.

UNIT III

10 Hrs

Mass Spectroscopy: Principle, Theory, Instrumentation of Mass Spectroscopy, Different types of ionization techniques like electron impact, chemical, field desorption, FAB and MALDI, APCI, ESI, APPI Analyzers and detectors. Meta stable ions, Isotopic peaks and Applications of Mass spectroscopy

UNIT IV

10 Hrs

Chromatography: Principle, apparatus, instrumentation, chromatographic parameters, factors affecting resolution, isolation of drug from excipients, data interpretation and applications of the following:

- a) Thin Layer chromatography
- b) High Performance Thin Layer Chromatography
- c) Ion exchange chromatography
- d) Column chromatography
- e) Gas chromatography
- f) High Performance Liquid chromatography
- g) Ultra High Performance Liquid chromatography
- h) Affinity chromatography
- i) Gel Chromatography

UNIT V

10 Hrs

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
- 8 Hrs

X ray Crystallography: Production of X rays, Different X ray methods, Bragg's law, Rotating crystal technique, X ray powder technique, Types of crystals and applications of X-ray diffraction.

UNIT VI

10 Hrs

Potentiometry: Principle, working, Ion selective Electrodes and Application of potentiometry. Thermal Techniques: Principle, thermal transitions and Instrumentation (Heat flux and power-compensation and designs), Modulated DSC, Hyper DSC, experimental parameters (sample preparation, experimental conditions, calibration, heating and cooling rates, resolution, source of errors) and their influence, advantage and disadvantages, pharmaceutical applications. Differential Thermal Analysis (DTA): Principle, instrumentation and advantage and disadvantages, pharmaceutical applications, derivative differential thermal analysis (DDTA). TGA: Principle, instrumentation, factors affecting results, advantage and disadvantages, pharmaceutical applications.

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 Organic Spectroscopy by Donald L. Paviya, 5th Edition.
 8. Spectroscopy of Organic Compounds, 2nd edn., P.S/Kalsi, Wiley estern Ltd., Delhi.
 9. Textbook of Pharmaceutical Analysis, KA.Connors, 3rd Edition, John Wiley & Sons, 1982.

ADVANCED PHARMACOLOGY – I (MPL 102T)

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

UNIT I

12 Hrs

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.

UNIT II

12 Hrs

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.

UNIT III**12 Hrs**

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.

UNIT IV**12 Hrs**

Cardiovascular Pharmacology Diuretics, antihypertensives, antiischemics, anti-arrhythmics, drugs for heart failure and hyperlipidemia. Hematinics, coagulants, anticoagulants, fibrinolytics and antiplatelet drugs

UNIT V**12 Hrs**

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.
10. Robbins & Cortan Pathologic Basis of Disease, 9th Ed. (Robbins Pathology)
11. A Complete Textbook of Medical Pharmacology by Dr. S.K Srivastava published by APC Avichal Publishing Company
12. KD.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.

**PHARMACOLOGICAL AND TOXICOLOGICAL SCREENING METHODS – I (MPL
103T)**

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

UNIT I

12 Hrs

Laboratory Animals

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

Transgenic animals: Production, maintenance and applications Anaesthesia 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

UNIT II

12 Hrs

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, anti epileptics and nootropics. Drugs for neurodegenerative diseases like Parkinsonism, Alzheimers and multiple sclerosis. Drugs acting on the Autonomic Nervous System.

UNIT III

12 Hrs

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: anti ulcer, anti -emetic, antidiarrheal and laxatives.

UNIT IV

12 Hrs

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, antidyslipidemic agents. Anti cancer agents. Hepatoprotective screening methods.

UNIT V

12 Hrs

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, 3rd Edition.
12. David R.Gross. Animal Models in Cardiovascular Research, 2nd 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)

CELLULAR AND MOLECULAR PHARMACOLOGY (MPL 104T)

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

UNIT I

12 Hrs

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.

UNIT II

12 Hrs

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.

UNIT III

12 Hrs

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.

UNIT IV

12 Hrs

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 Types of immunotherapeutics, humanisation antibody therapy, Immunotherapeutics in clinical practice

UNIT V

12 Hrs

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.

PHARMACOLOGICAL PRACTICAL – I (MPL 105P)

1. Analysis of pharmacopoeial compounds and their formulations by UV Vis spectrophotometer
2. Simultaneous estimation of multi component containing formulations by UV spectrophotometry
3. Experiments based on HPLC
4. Experiments based on Gas Chromatography
5. Estimation of riboflavin/quinine sulphate by fluorimetry
6. Estimation of sodium/potassium by flame photometry

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, α amylase, α 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

ADVANCED PHARMACOLOGY – II (MPL 201T)

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

UNIT I

12 Hrs

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

UNIT II

12 Hrs

Chemotherapy

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

UNIT III

12 Hrs

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

UNIT IV

12 Hrs

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

UNIT V

12 Hrs

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 Gill man'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, 9th Ed. (Robbins Pathology)
10. A Complete Textbook of Medical Pharmacology by Dr. S.K Srivastava published by APC Avichal Publishing Company.
11. KD.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

PHARMACOLOGICAL AND TOXICOLOGICAL SCREENING METHODS-II (MPL 202T)

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

UNIT I

12 Hrs

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

UNIT II

12 Hrs

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

UNIT III

12 Hrs

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

UNIT IV

12 Hrs

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

UNIT V

12 Hrs

Toxicokinetics- Toxicokinetic evaluation in preclinical studies, saturation kinetics Importance and applications of toxicokinetic studies. Alternative methods to animal toxicity testing.

REFERENCES

1. Handbook on GLP, Quality practices for regulated non-clinical research and development (<http://www.who.int/tdr/publications/documents/glphandbook.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, 3rd 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>)

PRINCIPLES OF DRUG DISCOVERY (MPL 203T)

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

UNIT I

12 Hrs

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.

UNIT II

12 Hrs

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

UNIT III

12 Hrs

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.

UNIT IV

12 Hrs

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.

UNIT V

12 Hrs

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 Targetsand Treatment Options. 2007 Humana Press Inc.
2. Darryl León. Scott MarkelIn. 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 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.

MODERN PHARMACEUTICAL ANALYTICAL TECHNIQUE (MPL 101T)

Scope

This subject deals with various advanced analytical instrumental techniques for the identification, characterization and quantification of drugs. Instruments dealt with are NMR, Mass spectrometer, IR, HPLC, GC etc.

Objectives

After completion of course, student is able to know about,

- Chemicals and Excipients
- The analysis of various drugs in single and combination dosage forms
- Theoretical and practical skills of the instruments

THEORY

60 HOURS

UNIT I

10 Hrs

UV-Visible spectroscopy: Introduction, Theory, Laws, Instrumentation associated with UV-Visible spectroscopy, Choice of solvents and solvent effect and Applications of UV-Visible spectroscopy, Difference/ Derivative spectroscopy.

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, Data Interpretation.

Spectrofluorimetry: Theory of Fluorescence, Factors affecting fluorescence (Characteristics of drugs that can be analysed by fluorimetry), Quenchers, Instrumentation and Applications of fluorescence spectrophotometer. Flame emission spectroscopy and Atomic absorption spectroscopy: Principle, Instrumentation, Interferences and Applications.

UNIT II

10 Hrs

NMR spectroscopy: Quantum numbers and their role in NMR, Principle, Instrumentation, Solvent requirement in NMR, Relaxation process, NMR signals in various compounds, Chemical shift, Factors influencing chemical shift, Spin-Spin coupling, Coupling constant, Nuclear magnetic double resonance. Brief outline of principles of FT-NMR and ¹³C NMR. Applications of NMR spectroscopy.

UNIT III

10 Hrs

Mass Spectroscopy: Principle, Theory, Instrumentation of Mass Spectroscopy, Different types of ionization techniques like electron impact, chemical, field desorption, FAB and MALDI, APCI, ESI, APPI Analyzers and detectors. Meta stable ions, Isotopic peaks and Applications of Mass spectroscopy

UNIT IV

10 Hrs

Chromatography: Principle, apparatus, instrumentation, chromatographic parameters, factors affecting resolution, isolation of drug from excipients, data interpretation and applications of the following:

- j) Thin Layer chromatography
- k) High Performance Thin Layer Chromatography
- l) Ion exchange chromatography
- m) Column chromatography
- n) Gas chromatography
- o) High Performance Liquid chromatography
- p) Ultra High Performance Liquid chromatography
- q) Affinity chromatography
- r) Gel Chromatography

UNIT V

10 Hrs

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 8 Hrs

X ray Crystallography: Production of X rays, Different X ray methods, Bragg's law, Rotating crystal technique, X ray powder technique, Types of crystals and applications of X-ray diffraction.

UNIT VI

10 Hrs

Potentiometry: Principle, working, Ion selective Electrodes and Application of potentiometry. Thermal Techniques: Principle, thermal transitions and Instrumentation (Heat flux and power-compensation and designs), Modulated DSC, Hyper DSC, experimental parameters (sample preparation, experimental conditions, calibration, heating and cooling rates, resolution, source of errors) and their influence, advantage and disadvantages, pharmaceutical applications. Differential Thermal Analysis (DTA): Principle, instrumentation and advantage and disadvantages, pharmaceutical applications, derivative differential thermal analysis (DDTA). TGA: Principle, instrumentation, factors affecting results, advantage and disadvantages, pharmaceutical applications.

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 Organic Spectroscopy by Donald L. Paviya, 5th Edition.
 8. Spectroscopy of Organic Compounds, 2nd edn., P.S/Kalsi, Wiley estern Ltd., Delhi.
 9. Textbook of Pharmaceutical Analysis, KA.Connors, 3rd Edition, John Wiley & Sons, 1982.

ADVANCED PHARMACOLOGY – I (MPL 102T)

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

UNIT I

12 Hrs

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.

UNIT II

12 Hrs

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.

UNIT III**12 Hrs**

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.

UNIT IV**12 Hrs**

Cardiovascular Pharmacology Diuretics, antihypertensives, antiischemics, anti-arrhythmics, drugs for heart failure and hyperlipidemia. Hematinics, coagulants, anticoagulants, fibrinolytics and antiplatelet drugs

UNIT V**12 Hrs**

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.
10. Robbins & Cortan Pathologic Basis of Disease, 9th Ed. (Robbins Pathology)
11. A Complete Textbook of Medical Pharmacology by Dr. S.K Srivastava published by APC Avichal Publishing Company
12. KD.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.

**PHARMACOLOGICAL AND TOXICOLOGICAL SCREENING METHODS – I (MPL
103T)**

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

UNIT I

12 Hrs

Laboratory Animals

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

Transgenic animals: Production, maintenance and applications Anaesthesia 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

UNIT II

12 Hrs

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, anti epileptics and nootropics. Drugs for neurodegenerative diseases like Parkinsonism, Alzheimers and multiple sclerosis. Drugs acting on the Autonomic Nervous System.

UNIT III

12 Hrs

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: anti ulcer, anti -emetic, antidiarrheal and laxatives.

UNIT IV

12 Hrs

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, antidyslipidemic agents. Anti cancer agents. Hepatoprotective screening methods.

UNIT V

12 Hrs

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, 3rd Edition.
12. David R.Gross. Animal Models in Cardiovascular Research, 2nd 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)

CELLULAR AND MOLECULAR PHARMACOLOGY (MPL 104T)

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

UNIT I

12 Hrs

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.

UNIT II

12 Hrs

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.

UNIT III

12 Hrs

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.

UNIT IV**12 Hrs**

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 Types of immunotherapeutics, humanisation antibody therapy, Immunotherapeutics in clinical practice

UNIT V**12 Hrs**

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 protocols in molecular biology vol I to VI edited by Frederick M.Ausuvel et la.

PHARMACOLOGICAL PRACTICAL – I (MPL 105P)

1. Analysis of pharmacopoeial compounds and their formulations by UV Vis spectrophotometer
2. Simultaneous estimation of multi component containing formulations by UV spectrophotometry
3. Experiments based on HPLC
4. Experiments based on Gas Chromatography
5. Estimation of riboflavin/quinine sulphate by fluorimetry
6. Estimation of sodium/potassium by flame photometry

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, α amylase, α 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

ADVANCED PHARMACOLOGY – II (MPL 201T)

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

UNIT I

12 Hrs

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

UNIT II

12 Hrs

Chemotherapy

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

UNIT III

12 Hrs

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

UNIT IV

12 Hrs

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

UNIT V

12 Hrs

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 Gill man'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, 9th Ed. (Robbins Pathology)
10. A Complete Textbook of Medical Pharmacology by Dr. S.K Srivastava published by APC Avichal Publishing Company.
11. KD.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

PHARMACOLOGICAL AND TOXICOLOGICAL SCREENING METHODS-II (MPL 202T)

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

UNIT I

12 Hrs

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

UNIT II

12 Hrs

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

UNIT III

12 Hrs

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

UNIT IV

12 Hrs

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

UNIT V

12 Hrs

Toxicokinetics- Toxicokinetic evaluation in preclinical studies, saturation kinetics Importance and applications of toxicokinetic studies. Alternative methods to animal toxicity testing.

REFERENCES

1. Handbook on GLP, Quality practices for regulated non-clinical research and development (<http://www.who.int/tdr/publications/documents/glphandbook.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, 3rd 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>)

PRINCIPLES OF DRUG DISCOVERY (MPL 203T)

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

UNIT I

12 Hrs

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.

UNIT II

12 Hrs

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

UNIT III

12 Hrs

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.

UNIT IV

12 Hrs

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.

UNIT V

12 Hrs

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 Markel In. 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.
6. Methods and Principles in Medicinal Chemistry. Publisher Wiley-VCH 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.

CLINICAL RESEARCH AND PHARMACOVIGILANCE (MPL 204T)

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

UNIT I

12 Hrs

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

UNIT II

12 Hrs

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

UNIT III

12 Hrs

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.

UNIT IV

12 Hrs

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

UNIT V

12 Hrs

Methods, ADR reporting and tools used in Pharmacovigilance International classification of diseases, International Nonproprietary 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, VigiFlow, Statistical methods for evaluating medication safety data.

UNIT V

12 Hrs

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.

PHARMACOLOGICAL PRACTICAL – II (MPL 205P)

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 PA₂ 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.

**DETAILED SYLLABUS OF
PHARMACEUTICAL ANALYSIS
(MPA)**

Detailed Scheme of Pharmaceutical Analysis

Course Code	Course	Credit Hours	Credit Points	Hrs./wk	Marks
Semester I					
MPA101T	Modern Pharmaceutical Analytical technique	4	4	4	100
MPA102T	Advanced Pharmaceutical Analysis	4	4	4	100
MPA103T	Pharmaceutical Validation	4	4	4	100
MPA104T	Food Analysis	4	4	4	100
MPA105P	Pharmaceutical Analysis Practical-I	12	6	12	150
-	Seminar /Assignment	7	4	7	100
Total		35	26	35	650
Semester II					
MPA201T	Advanced Instrumental Analysis	4	4	4	100
MPA202T	Modern Bio-Analytical Techniques	4	4	4	100
MQA203T	Quality Control and Quality Assurance	4	4	4	100
MPA204T	Herbal and Cosmetic Analysis	4	4	4	100
MPA205P	Pharmaceutical Analysis Practical II	12	6	12	150
-	Seminar/Assignment	7	4	7	100
Total		35	26	35	650

Course Code	Course	Internal Assessment				End Semester Exams		Total Marks
		Continuous Mode	Sessional Exams		Total	Marks	Duration (in Hrs)	
			Marks	Duration (in Hrs)				
SEMESTER I								
MPA101T	Modern Pharmaceutical Analytical technique	10	15	1	25	75	3	100
MPA102T	Advanced Pharmaceutical Analysis	10	15	1	25	75	3	100
MPA103T	Pharmaceutical Validation	10	15	1	25	75	3	100
MPA104T	Food Analysis	10	15	1	25	75	3	100
MPA105P	Pharmaceutical Analysis Practical-I	20	30	6	50	100	12	150
-	Seminar /Assignment	-	-	-	-	-	-	100
Total								650
SEMESTER II								
MPA201T	Advanced Instrumental Analysis	10	15	1	25	75	3	100
MPA202T	Modern Bio-Analytical Techniques	10	15	1	25	75	3	100
MQA203T	Quality Control and Quality Assurance	10	15	1	25	75	3	100
MPA204T	Herbal and Cosmetic Analysis	10	15	1	25	75	3	100
MPA205P	Pharmaceutical Analysis Practical II	20	30	6	50	100	12	150
-	Seminar/Assignment	-	-	-	-	-	-	100
Total								650

MODERN PHARMACEUTICAL ANALYTICAL TECHNIQUE (MPA 101T)

Scope

This subject deals with various advanced analytical instrumental techniques for the identification, characterization and quantification of drugs. Instruments dealt with are NMR, Mass spectrometer, IR, HPLC, GC etc.

Objectives

After completion of the course, student can know,

- The spectroscopic analysis of various drugs in single and combination dosage forms
- Theoretical and practical skills of the spectroscopic and chromatographic instruments

THEORY

60 HOURS

UNIT I

10 Hrs

UV-Visible spectroscopy: Introduction, Theory, Laws, Instrumentation associated with UV-Visible spectroscopy, Choice of solvents and solvent effect and Applications of UV-Visible spectroscopy, Difference/ Derivative spectroscopy.

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, Data Interpretation.

Spectrofluorimetry: Theory of Fluorescence, Factors affecting fluorescence (Characteristics of drugs that can be analysed by fluorimetry), Quenchers, Instrumentation and Applications of fluorescence spectrophotometer. Flame emission spectroscopy and Atomic absorption spectroscopy: Principle, Instrumentation, Interferences and Applications.

UNIT II

10 Hrs

NMR spectroscopy: Quantum numbers and their role in NMR, Principle, Instrumentation, Solvent requirement in NMR, Relaxation process, NMR signals in various compounds, Chemical shift, Factors influencing chemical shift, Spin-Spin coupling, Coupling constant, Nuclear magnetic double resonance. Brief outline of principles of FT-NMR and ¹³C NMR. Applications of NMR spectroscopy.

UNIT III

10 Hrs

Mass Spectroscopy: Principle, Theory, Instrumentation of Mass Spectroscopy, Different types of ionization techniques like electron impact, chemical, field desorption, FAB and MALDI, APCI, ESI, APPI Analyzers and detectors. Meta stable ions, Isotopic peaks and Applications of Mass spectroscopy

UNIT IV

10 Hrs

Chromatography: Principle, apparatus, instrumentation, chromatographic parameters, factors affecting resolution, isolation of drug from excipients, data interpretation and applications of the following:

- s) Thin Layer chromatography
- t) High Performance Thin Layer Chromatography
- u) Ion exchange chromatography
- v) Column chromatography
- w) Gas chromatography
- x) High Performance Liquid chromatography
- y) Ultra High Performance Liquid chromatography
- z) Affinity chromatography
- aa) Gel Chromatography

UNIT V

10 Hrs

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 8 Hrs

X ray Crystallography: Production of X rays, Different X ray methods, Bragg's law, Rotating crystal technique, X ray powder technique, Types of crystals and applications of X-ray diffraction.

UNIT VI

10 Hrs

Potentiometry: Principle, working, Ion selective Electrodes and Application of potentiometry. Thermal Techniques: Principle, thermal transitions and Instrumentation (Heat flux and power-compensation and designs), Modulated DSC, Hyper DSC, experimental parameters (sample preparation, experimental conditions, calibration, heating and cooling rates, resolution, source of errors) and their influence, advantage and disadvantages, pharmaceutical applications. Differential Thermal Analysis (DTA): Principle, instrumentation and advantage and disadvantages, pharmaceutical applications, derivative differential thermal analysis (DDTA). TGA: Principle, instrumentation, factors affecting results, advantage and disadvantages, pharmaceutical applications.

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
 8. Organic Spectroscopy by Donald L. Paviya, 5th Edition.

ADVANCED PHARMACEUTICAL ANALYSIS (MPA 102T)

Scope

This subject deals with the various aspects of Impurity, Impurities in new drug products, in residual solvents, Elemental impurities, Impurity profiling and characterization of degradants, Stability testing of phytopharmaceuticals and their protocol preparation. It also covers the biological testing of various vaccines and their principle and procedure.

Objectives

After the completion of the course, it is expected that the student shall be able to know

- Appropriate analytical skills required for the analytical method development.
- Principles of various reagents used in functional group analysis that renders necessary support in research methodology and demonstrates its application in the practical related problems.
- Analysis of impurities in drugs, residual solvents and stability studies of drugs and biological products

THEORY

60 HOURS

UNIT I

10 Hrs

Impurity and stability studies: Definition, classification of impurities in drug Substance or Active Pharmaceutical Ingredients and quantification of impurities as per ICH guidelines

Impurities in new drug products: Rationale for the reporting and control of degradation products, reporting degradation products content of batches, listing of degradation products in specifications, qualification of degradation products

Impurities in residual solvents: General principles, classification of residual solvents, Analytical procedures, limits of residual solvents, reporting levels of residual solvents

UNIT II

10 Hrs

Elemental impurities: Element classification, control of elemental impurities, Potential Sources of elemental Impurities, Identification of Potential Elemental Impurities, analytical procedures, instrumentation & C, H, N and S analysis.

Stability testing protocols: Selection of batches, container orientation, test parameters, sampling frequency, specification, storage conditions, recording of results, concept of stability, commitment etc. Important mechanistic and stability related information provided by results of study of factors like temperature, pH, buffering species ionic strength and dielectric constant etc. on the reaction rates. With practical considerations.

UNIT III**10 Hrs**

Impurity profiling and degradant characterization: Method development, Stability studies and concepts of validation accelerated stability testing & shelf life calculation, WHO and ICH stability testing guidelines, Stability zones, steps in development, practical considerations. Basics of impurity profiling and degradant characterization with special emphasis. Photostability testing guidelines, ICH stability guidelines for biological products

UNIT IV**10 Hrs**

Stability testing of phytopharmaceuticals: Regulatory requirements, protocols, HPTLC/HPLC finger printing, interactions and complexity.

UNIT V**10 Hrs**

Biological tests and assays of the following:

a. Adsorbed Tetanus vaccine b. Adsorbed Diphtheria vaccine c. Human anti haemophilic vaccine d. Rabies vaccine e. Tetanus Anti toxin f. Tetanus Anti serum g. Oxytocin h. Heparin sodium IP i. Antivenom. PCR, PCR studies for gene regulation, instrumentation (Principle and Procedures).

UNIT VI**10 Hrs**

Immunoassays (IA) Basic principles, Production of antibodies, Separation of bound and unbound drug, Radioimmunoassay, Optical IA, Enzyme IA, Fluoro IA, Luminiscence IA, Quantification and applications of IA.

REFERENCES

1. Vogel, s textbook of quantitative chemical analysis - Jeffery J Bassett, J. Mendham, R. C. Denney, 5th edition, ELBS, 1991.
2. Practical Pharmaceutical Chemistry - Beckett and Stenlake, Vol II, 4th Edition, CBS publishers, New Delhi, 1997.
3. Textbook of Pharmaceutical Analysis - K A Connors, 3rd Edition, John Wiley & Sons, 1982.
4. Pharmaceutical Analysis - Higuchi, Brochmman and Hassen, 2nd Edition, Wiley – Inter science Publication, 1961.
5. Quantitative Analysis of Drugs in Pharmaceutical formulation – P D Sethi, 3rd Edition, CBS Publishers New Delhi, 1997.
6. Pharmaceutical Analysis- Modern methods - J W Munson – Part B, Volume 11, Marcel Dekker Series.
7. The Quantitative analysis of Drugs - D C Carratt, 3rd edition, CBS Publishers, NewDelhi, 1964.
8. Indian Pharmacopoeia Vol I , II & III 2007, 2010, 2014.

9. Methods of sampling and microbiological examination of water, first revision, BIS
10. Practical HPLC method development – Snyder, Kirkland, Glajch, 2nd edition, John Wiley & Sons.
11. Analytical Profiles of drug substances – Klaus Florey, Volume 1 – 20, Elsevier, 2005
12. Analytical Profiles of drug substances and Excipients – Harry G Brittan, Volume 21 – 30, Elsevier, 2005.
13. The analysis of drugs in biological fluids - Joseph Chamberlain, 2nd edition, CRC press, London.
14. ICH Guidelines for impurity profiles and stability studies.

PHARMACEUTICAL VALIDATION (MPA 103T)

Scope

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

Objectives

Upon completion of the subject student shall be able to

- Explain the aspect of validation
- Carryout validation of manufacturing processes
- Apply the knowledge of validation to instruments and equipments
- Validate the manufacturing facilities

THEORY

60 HOURS

UNIT I

12 Hrs

Introduction: Definition of Qualification and Validation, Advantage 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), Qualification of Manufacturing Equipments, Qualification of Analytical Instruments and Laboratory equipments.

UNIT II

12 Hrs

Qualification of analytical instruments: Electronic balance, pH 12 meter, UV-Visible spectrophotometer, FTIR, GC, HPLC, HPTLC Hrs Qualification of Glassware: Volumetric flask, pipette, Measuring cylinder, beakers and burette.

UNIT III

12 Hrs

Validation of Utility systems: Pharmaceutical Water System & 12 pure steam, HVAC system, Compressed air and nitrogen. Hrs Cleaning Validation: Cleaning Validation - Cleaning Method development, Validation and validation of analytical method used in cleaning. Cleaning of Equipment, Cleaning of Facilities. Cleaning in place (CIP).

UNIT IV

12 Hrs

Analytical method validation: General principles, Validation of 12 analytical method as per ICH guidelines and USP. Computerized system validation: Electronic records and digital significance-21 CFR part 11 and GAMP 5.

UNIT V

12 Hrs

General Principles of Intellectual Property: Concepts of 12 Intellectual Property (IP), Intellectual Property Protection (IPP), Hrs 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 applications; 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, 3rd edition, Leon Lachman, Herbert A. Lieberman, Joseph. L. Karig, Varghese Publishing House, Bombay.
3. Validation Master plan by Terveeks or Deeks, Davis Harwood International publishing.
4. Validation of Aseptic Pharmaceutical Processes, 2nd Edition, by Carleton & Agalloco, (Marcel Dekker).
5. Michael Levin, Pharmaceutical Process Scale-Upl, Drugs and Pharm. Sci. Series, Vol. 157,2nd Ed., Marcel Dekker Inc., N.Y.
6. Validation Standard Operating Procedures: A Step by Step Guide for Achieving Compliance in the Pharmaceutical, Medical Device, and Biotech Industries, Syed Imtiaz Haider
7. Pharmaceutical Equipment Validation: The Ultimate Qualification Handbook, Phillip A. Cloud, Interpharm Press
8. Validation of Pharmaceutical Processes: Sterile Products, Frederick J. Carlton (Ed.) and James Agalloco (Ed.), Marcel Dekker, 2nd Ed.
9. Analytical Method validation and Instrument Performance Verification by Churg Chan, Heiman Lam, Y.C. Lee, Yue. Zhang, Wiley Inter Science.

FOOD ANALYSIS (MPA 104T)

Scope

This course is designed to impart knowledge on analysis of food constituents and finished food products. The course includes application of instrumental analysis in the determination of pesticides in variety of food products.

Objectives

At completion of this course student shall be able to understand various analytical techniques in the determination of

- Food constituents
- Food additives
- Finished food products
- Pesticides in food
- And also student shall have the knowledge on food regulations and legislations.

THEORY

60 HOURS

UNIT I

12 Hrs

Carbohydrates – classification and properties of food carbohydrates, General methods of analysis of food carbohydrates, Changes in food carbohydrates during processing, Digestion, absorption and metabolism of carbohydrates, Dietary fibre, crude fibre and application of food carbohydrates

Proteins - Chemistry and classification of amino acids and proteins, Physico-Chemical properties of protein and their structure, general methods of analysis of proteins and amino acids, Digestion, absorption and metabolism of proteins

UNIT II

12 Hrs

Lipids – Classification, general methods of analysis, refining of fats and oils; hydrogenation of vegetable oils, Determination of adulteration in fats and oils, Various methods used for measurement of spoilage of fats and fatty foods.

Vitamins – classification of vitamins, methods of analysis of vitamins, Principles of microbial assay of vitamins of B-series.

UNIT III

12 Hrs

Food additives – Introduction, analysis of Preservatives, antioxidants, artificial sweeteners, flavors, flavor enhancers, stabilizers, thickening and jelling agent

Pigments and synthetic dyes - Natural pigments, their occurrence and characteristic properties, permitted synthetic dyes, Non-permitted synthetic dyes used by industries, Method of detection of natural, permitted and non-permitted dyes

UNIT IV**12 Hrs**

General Analytical methods for milk, milk constituents and milk products like ice cream, milk powder, butter, margarine, cheese including adulterants and contaminants of milk.

Analysis of fermentation products like wine, spirits, beer and vinegar.

UNIT V**12 Hrs**

Pesticide analysis: Effects of pest and insects on various food, use of pesticides in agriculture, pesticide cycle, organophosphorous and organo chlorine pesticides analysis, determination of pesticide residues in grain, fruits, vegetables, milk and milk products.

Legislation regulations of food products with special emphasis on BIS, Agmark and US-FDA

REFERENCES

1. The chemical analysis of foods – David Pearson, Seventh edition, Churchill Livingstone, Edinburgh London, 1976
2. Introduction to the Chemical analysis of foods – S. Nielsen, Jones & Bartlett publishers, Boston London, 1994.
3. Official methods of analysis of AOAC International, sixth edition, Volume I & II, 1997.
4. Analysis of Food constituents – Multon, Wiley VCH.
5. Dr. William Horwitz, Official methods of analysis of AOAC International, 18th edition, 2005.

PHARMACEUTICAL ANALYSIS PRACTICAL II (MPA 105P)

1. Analysis of Pharmacopoeial compounds and their formulations by UV Vis spectrophotometer
2. Simultaneous estimation of multi component containing formulations by UV spectrophotometry
3. Experiments based on HPLC
4. Experiments based on Gas Chromatography
5. Estimation of riboflavin/quinine sulphate by fluorimetry
6. Estimation of sodium/potassium by flame photometry
7. Assay of official compounds by different titrations
8. Assay of official compounds by instrumental techniques.
8. Quantitative determination of hydroxyl group.
9. Quantitative determination of amino group
10. Colorimetric determination of drugs by using different reagents
11. Impurity profiling of drugs
12. Calibration of glasswares
13. Calibration of pH meter
14. Calibration of UV-Visible spectrophotometer
15. Calibration of FTIR spectrophotometer
16. Calibration of GC instrument
17. Calibration of HPLC instrument
18. Cleaning validation of any one equipment
19. Determination of total reducing sugar
20. Determination of proteins
21. Determination of saponification value, Iodine value, Peroxide value, Acid value in food products
22. Determination of fat content and rancidity in food products
23. Analysis of natural and synthetic colors in food
24. Determination of preservatives in food
25. Determination of pesticide residue in food products
26. Analysis of vitamin content in food products
27. Determination of density and specific gravity of foods
28. Determination of food additives

ADVANCED INSTRUMENTAL ANALYSIS (MPA 201T)

Scope

This subject deals with various hyphenated analytical instrumental techniques for identification, characterization and quantification of drugs. Instruments dealt are LC-MS, GC-MS, ATR-IR, DSC etc.

Objectives

After completion of course, student is able to know,

- Interpretation of the NMR, Mass and IR spectra of various organic compounds
- Theoretical and practical skills of the hyphenated instruments
- Identification of organic compounds

THEORY

60 HOURS

UNIT I

12 Hrs

HPLC: Principle, instrumentation, pharmaceutical applications, peak shapes, capacity factor, selectivity, plate number, plate height, resolution, band broadening, pumps, injector, detectors, columns, column problems, gradient HPLC, HPLC solvents, trouble shooting, sample preparation, method development, New developments in HPLC-role and principles of ultra, nano liquid chromatography in pharmaceutical analysis. Immobilized polysaccharide CSP's: Advancement in enantiomeric separations, revised phase Chiral method development and HILIC approaches. HPLC in Chiral analysis of pharmaceuticals. Preparative HPLC, practical aspects of preparative HPLC.

UNIT II

12 Hrs

Biochromatography: Size exclusion chromatography, ion exchange chromatography, ion pair chromatography, affinity chromatography general principles, stationary phases and mobile phases. Gas chromatography: Principles, instrumentation, derivatization, head space sampling, columns for GC, detectors, quantification.

UNIT III

12 Hrs

High performance Thin Layer chromatography: Principles, instrumentation, pharmaceutical applications. Super critical fluid chromatography: Principles, instrumentation, pharmaceutical applications. Capillary electrophoresis: Overview of CE in pharmaceutical analysis, basic configuration, CE characteristics, principles of CE, methods and modes of CE. General considerations and method development in CE, Crown ethers as buffer additives in capillary electrophoresis. CE-MS hyphenation.

UNIT IV

12 Hrs

Mass spectrometry: Principle, theory, instrumentation of mass spectrometry, different types of ionization like electron impact, chemical, field, FAB and MALD, APCI, ESI, APPI mass fragmentation and its

rules, meta stable ions, isotopic peaks and applications of mass spectrometry. LC-MS hyphenation and DART MS analysis. Mass analysers (Quadrupole, Time of flight, FT-ICR, ion trap and Orbitrap) instruments. MS/MS systems (Tandem: QqQ, TOF-TOF; Q-IT, Q-TOF, LTQ-FT, LTQ-Orbitrap).

UNIT V

12 Hrs

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 with reference to ¹³CNMR: Spin spin and spin lattice relaxation phenomenon. ¹³C NMR, 1-D and 2-D NMR, NOESY and COSY techniques, Interpretation and Applications of NMR spectroscopy. LC-NMR hyphenations.

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. Organic Spectroscopy - William Kemp, 3rd edition, ELBS, 1991.
5. Quantitative analysis of Pharmaceutical formulations by HPTLC - P D Sethi, CBS Publishers, New Delhi.
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.
8. Organic Spectroscopy by Donald L. Paviya, 5th Edition.

MODERN BIO-ANALYTICAL TECHNIQUES (MPA 202T)

Scope

This subject is designed to provide detailed knowledge about the importance of analysis of drugs in biological matrices.

Objectives

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

- Extraction of drugs from biological samples
- Separation of drugs from biological samples using different techniques
- Guidelines for BA/BE studies.

THEORY

60 HOURS

UNIT I

12 Hrs

Extraction of drugs and metabolites from biological matrices: General need, principle and procedure involved in the Bioanalytical methods such as Protein precipitation, Liquid - Liquid extraction and Solid phase extraction and other novel sample preparation approach.

Bioanalytical method validation: USFDA and EMEA guidelines.

UNIT II

12 Hrs

Biopharmaceutical Consideration: Introduction, Biopharmaceutical Factors Affecting Drug Bioavailability, In Vitro: Dissolution and Drug Release Testing, Alternative Methods of Dissolution Testing Transport models, Biopharmaceutics Classification System. Solubility: Experimental methods. Permeability: In-vitro, in-situ and In-vivo methods.

UNIT III

12 Hrs

Pharmacokinetics and Toxicokinetics: Basic consideration, Drug interaction (PK-PD interactions), The effect of protein-binding interactions, the effect of tissue-binding interactions, Cytochrome P450-based drug interactions, Drug interactions linked to transporters. Microsomal assays Toxicokinetics-Toxicokinetic evaluation in preclinical studies, Importance and applications of toxicokinetic studies. LC-MS in bioactivity screening and proteomics.

UNIT IV

12 Hrs

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 applications. Principles and applications of cell viability assays (MTT assays), Principles and applications of flow cytometry.

Metabolite identification: In-vitro / in-vivo approaches, protocols and sample preparation. Microsomal approaches (Rat liver microsomes (RLM) and Human liver microsomes (HLM) in Met –ID. Regulatory perspectives. In-vitro assay of drug metabolites & drug metabolizing enzymes.

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, Generic Biologics (Biosimilar Drug Products), Clinical Significance of Bioequivalence Studies.

REFERENCES

1. Analysis of drugs in Biological fluids - Joseph Chamberlain, 2nd Edition. CRC Press, Newyork. 1995.
2. Principles of Instrumental Analysis - Doglas A Skoog, F. James Holler, Timothy A. Nieman, 5th edition, Eastern press, Bangalore, 1998.
3. Pharmaceutical Analysis - Higuchi, Brochmman and Hassen, 2nd Edition, Wiley – Interscience Publications, 1961.
4. Pharmaceutical Analysis- Modern methods – Part B - J W Munson, Volume 11, Marcel Dekker Series
5. Practical HPLC method Development – Snyder, Kirkland, Glaich, 2nd Edition, John Wiley & Sons, New Jercey. USA.
6. Chromatographic Analysis of Pharmaceuticals – John A Adamovics, 2nd Edition, Marcel Dekker, Newyork, USA. 1997.
7. Chromatographic methods in clinical chemistry & Toxicology – Roger L Bertholf, Ruth E Winecker, John Wiley & Sons, New Jercey, USA. 2007.
8. Good Laboratory Practice Regulations, 2nd Edition, Sandy Weinberg Vol. 69, Marcel Dekker Series, 1995.
9. Good laboratory Practice Regulations – Allen F. Hirsch, Volume 38, Marcel Dekker Series, 1989.
10. ICH, USFDA & CDSCO Guidelines.
11. Palmer

QUALITY CONTROL AND QUALITY ASSURANCE (MPA 203T)

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

At the completion of this subject it is expected that the student shall be able to know

- 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

UNIT I

12 Hrs

Concept and Evolution of Quality Control and Quality Assurance Good Laboratory Practice, GMP, Overview of ICH Guidelines QSEM, with special emphasis on Q-series 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.

UNIT II

12 Hrs

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. CPCSEA guidelines.

UNIT III

12 Hrs

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 formulation in Pharma industry according to Indian, US and British pharmacopoeias: tablets, capsules, ointments, suppositories, creams, parenterals, ophthalmic and surgical products (How to refer pharmacopoeias), Quality control test for containers, closures and secondary packing materials.

UNIT IV

12 Hrs

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 Formula Record, Batch Formula Record, Quality audit plan and reports. Specification and test procedures, Protocols and reports. Distribution records. Electronic data.

UNIT V

12 Hrs

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.

REFERENCES

1. Quality Assurance Guide by organization of Pharmaceutical Procedures of India, 3rd revised edition, Volume I & II, Mumbai, 1996.
2. Good Laboratory Practice Regulations, 2nd 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, 2nd edition, WHO Publications, 1999.
4. How to Practice GMP's – P P Sharma, Vandana Publications, Agra, 1991.
5. The International Pharmacopoeia – vol I, II, III, IV & V - General Methods of Analysis and Quality specification for Pharmaceutical Substances, Excipients and Dosage forms, 3rd 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, 4th edition, Susmit Publishers, 2006.
10. QA Manual – D.H. Shah, 1st edition, Business Horizons, 2000.
11. Good Manufacturing Practices for Pharmaceuticals a plan for total quality control – Sidney H. Willig, Vol. 52, 3rd 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.

HERBAL AND COSMETIC ANALYSIS (MPA 204T)

Scope

This course is designed to impart knowledge on analysis of herbal products. Regulatory requirements, herbal drug interaction with monographs. Performance evaluation of cosmetic products is included for the better understanding of the equipments used in cosmetic industries for the purpose.

Objectives

At completion of this course student shall be able to understand

- Determination of physical constants of cosmetic raw materials.
- Cosmetic raw materials, additives and their analysis
- Analysis of finished cosmetic products
- Principles of performance evaluation of cosmetic products.

THEORY

60 HOURS

UNIT I

12 Hrs

Herbal remedies- Toxicity and Regulations: Herbals vs Conventional drugs, Efficacy of herbal medicine products, Validation of Herbal Therapies, Pharmacodynamic and Pharmacokinetic issues. Herbal drug standardization: WHO and AYUSH guidelines.

UNIT II

12 Hrs

Adulteration and Deterioration: Introduction, types of adulteration/substitution of herbal drugs, Causes and Measure of adulteration, Sampling Procedures, Determination of Foreign Matter, DNA fingerprinting techniques in identification of drugs of natural origin, heavy metals, pesticide residues, phototoxin and microbial contamination in herbal formulations. Regulatory requirements for setting herbal drug industry: Global marketing management, Indian and international patent law as applicable herbal drugs and natural products and its protocol.

UNIT III

12 Hrs

Testing of natural products and drugs: Effect of herbal medicine on clinical laboratory testing, Adulterant Screening using modern analytical instruments, Regulation and dispensing of herbal drugs, Stability testing of natural products, protocol.

Monographs of Herbal drugs: Study of monographs of herbal drugs and comparative study in IP, USP, Ayurvedic Pharmacopoeia, American herbal Pharmacopoeia, British herbal Pharmacopoeia, Siddha and Unani Pharmacopoeia, WHO guidelines in quality assessment of herbal drugs.

UNIT IV

12 Hrs

Herbal drug-drug interaction: WHO and AYUSH guidelines for 12 safety monitoring of natural medicine, Spontaneous reporting Hrs schemes for bio drug adverse reactions, bio drug-drug and bio drug-food interactions with suitable examples. Challenges in monitoring the safety of herbal medicines.

UNIT V

12 Hrs

Evaluation of cosmetic products: Determination of acid value, 12 ester value, saponification value, iodine value, peroxide value, Hrs rancidity, moisture, ash, volatile matter, heavy metals, fineness of powder, density, viscosity of cosmetic raw materials and finished products. Study of quality of raw materials and general methods of analysis of raw material used in cosmetic manufacture as per BIS.

Indian Standard specification laid down for sampling and testing of various cosmetics in finished forms such as baby care products, skin care products, dental products, personal hygiene preparations, lips sticks. Hair products and skin creams by the Bureau Indian Standards.

REFERENCES

1. Pharmacognosy by Trease and Evans
2. Pharmacognosy by Kokate, Purohit and Gokhale
3. Quality Control Methods for Medicinal Plant, WHO, Geneva
4. Pharmacognosy & Pharmacobiotechnology by Ashutosh Kar
5. Essential of Pharmacognosy by Dr.S.H.Ansari
6. Cosmetics – Formulation, Manufacturing and Quality Control, P.P. Sharma, 4th edition, Vandana Publications Pvt. Ltd., Delhi
7. Indian Standard specification, for raw materials, BIS, New Delhi.
8. Indian Standard specification for 28 finished cosmetics BIS, New Delhi
9. Harry's Cosmeticology 8th edition
10. Suppliers catalogue on specialized cosmetic excipients
11. Wilkinson, Moore, seventh edition, George Godwin. Poucher's Perfumes, Cosmetics and Soaps
12. Hilda Butler, 10th Edition, Kluwer Academic Publishers. Handbook of Cosmetic Science and Technology, 3rd Edition,

PHARMACEUTICAL ANALYSIS PRACTICALS I (MPA 205P)

1. Comparison of absorption spectra by UV and Wood ward – Fiesure rule
2. Interpretation of organic compounds by FT-IR
3. Interpretation of organic compounds by NMR
4. Interpretation of organic compounds by MS
5. Determination of purity by DSC in pharmaceuticals
6. Identification of organic compounds using FT-IR, NMR, CNMR and Mass spectra
7. Bio molecules separation utilizing various sample preparation techniques and Quantitative analysis of components by gel electrophoresis.
8. Bio molecules separation utilizing various sample preparation techniques and Quantitative analysis of components by HPLC techniques.
9. Isolation of analgesics from biological fluids (Blood serum and urine).
10. Protocol preparation and performance of analytical/Bioanalytical method validation.
11. Protocol preparation for the conduct of BA/BE studies according to guidelines.
12. In process and finished product quality control tests for tablets, capsules, parenterals and creams
13. Quality control tests for Primary and secondary packing materials
14. Assay of raw materials as per official monographs.
15. Testing of related and foreign substances in drugs and raw materials
16. Preparation of Master Formula Record.
17. Preparation of Batch Manufacturing Record.
18. Quantitative analysis of rancidity in lipsticks and hair oil 19. Determination of aryl amine content and Developer in hair dye
19. Determination of foam height and SLS content of Shampoo.
20. Determination of total fatty matter in creams (Soap, skin and hair creams)
21. Determination of acid value and saponification value.
22. Determination of calcium thioglycolate in depilatories

**DETAILED SYLLABUS OF
PHARMACEUTICAL
REGULATORY AFFAIRS (MRA)**

Detailed Schemes for Pharmaceutical Regulatory Affairs

Course Code	Course	Credit Hours	Credit Points	Hrs./wk	Marks
Semester I					
MRA101T	Good Regulatory Practices	4	4	4	100
MRA102T	Documentation and Regulatory Writing	4	4	4	100
MRA103T	Clinical Research Regulations	4	4	4	100
MRA104T	Regulations and Legislation for Drugs & Cosmetics, Medical Devices, Biologicals & Herbals, and Food & Nutraceuticals in India and Intellectual Property Rights	4	4	4	100
MRA105P	Regulatory Affairs Practical I	12	6	12	150
-	Seminar/Assignment	7	4	7	100
Total		35	26	35	650
Semester II					
MRA201T	Regulatory Aspects of Drugs & Cosmetics	4	4	4	100
MRA202T	Regulatory Aspects of Herbal & Biologicals	4	4	4	100
MRA203T	Regulatory Aspects of Medical Devices	4	4	4	100
MRA204T	Regulatory Aspects of Food & Nutraceuticals	4	4	4	100
MRA205P	Regulatory Affairs Practical II	12	6	12	150
-	Seminar/Assignment	7	4	7	100
Total		35	26	35	650

Course Code	Course	Internal Assessment				End Semester Exams		Total Marks
		Continuous Mode	Sessional Exams		Total	Marks	Duration (in Hrs)	
			Marks	Duration (in Hrs)				
SEMESTER I								
MRA101T	Good Regulatory Practices	10	15	1	25	75	3	100
MRA102T	Documentation and Regulatory Writing	10	15	1	25	75	3	100
MRA103T	Clinical Research Regulations	10	15	1	25	75	3	100
MRA104T	Regulations and Legislation for Drugs & Cosmetics, Medical Devices, Biologicals & Herbals, and Food & Nutraceuticals in India and Intellectual Property Rights	10	15	1	25	75	3	100
MRA105T	Regulatory Affairs Practical I	20	30	6	50	100	12	150
-	Seminar/Assignment	-	-	-	-	-	-	100
Total								650
SEMESTER II								
MRA201T	Regulatory Aspects of Drugs & Cosmetics	10	15	1	25	75	3	100
MRA202T	Regulatory Aspects of Herbal & Biologicals	10	15	1	25	75	3	100
MRA203T	Regulatory Aspects of Medical Devices	10	15	1	25	75	3	100
MRA204T	Regulatory Aspects of Food & Nutraceuticals	10	15	1	25	75	3	100
MRA205P	Regulatory Affairs Practical II	20	30	6	50	100	12	150
-	Seminar/Assignment	-	-	-	-	-	-	100
Total								650

GOOD REGULATORY PRACTICES (MRA 101T)

Scope

This course is designed to impart fundamental knowledge on various Good Regulatory Practices viz., cGMP, GLP, GALP and GDP for Pharmaceuticals, Cosmetics, Food & Nutraceuticals, Medical devices, In-vitro Diagnostic Medical Devices (IVDs) and biological products and understand the rationale behind these requirements and will propose ways and means of complying with them.

Objectives

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

- The key regulatory and compliance elements with respect to Good Manufacturing Practices, Good Laboratory Practices, Good Automated Laboratory Practices and Good Documentation Practices.
- Prepare and implement the check lists and SOPs for various Good Regulatory Practices
- Implement Good Regulatory Practices in the Healthcare and related Industries
- Prepare for the readiness and conduct of audits and inspections.

THEORY

60 HOURS

UNIT I

12 Hrs

Current Good Manufacturing Practices: Introduction, US cGmp Part 210 and Part 211.EC Principles of GMP (Directive 91/356/EEC) Article 6 to Article 14 and WHO cGMP guidelines GAMP-5; Medical device and IVDs Global Harmonization Task Force(GHTF) Guidance docs.

UNIT II

12 Hrs

Good Laboratory Practices: Introduction, USFDA GLP Regulations (Subpart A to Subpart K), Controlling the GLP inspection process, Documentation, Audit, goals of Laboratory Quality Audit, Audit tools, Future of GLP regulations, relevant ISO and Quality Council of India (QCI) Standards

UNIT III

12 Hrs

Good Automated Laboratory Practices: Introduction to GALP, Principles of GALP, GALP Requirements, SOPs of GALP, Training Documentation, 21 CFR Part 11, General checklist of 21CFR Part 11, Software Evaluation checklist, relevant ISO and QCI Standards.

UNIT IV

12 Hrs

Good Distribution Practices: Introduction to GDP, Legal GDP requirements put worldwide, Principles, Personnel, Documentation, Premises and Equipment, Deliveries to Customers, Returns, Self-Inspection, Provision of information, Stability testing principles, WHO GDP, USP GDP (Supply chain integrity), relevant CDSCO guidance and ISO standards.

Quality management systems: Concept of Quality, Total Quality Management, Quality by design, Six Sigma concept, Out of Specifications (OOS), Change control. Validation: Types of Validation, Types of Qualification, Validation master plan (VMP), Analytical Method Validation. Validation of utilities, [Compressed air, steam, water systems, Heat Ventilation and Air conditioning (HVAC)]and Cleaning Validation. The International Conference on Harmonization (ICH) process, ICH guidelines to establish quality, safety and efficacy of drug substances and products, ISO 13485, Sch MIII and other relevant CDSCO regulatory guidance documents.

REFERENCES

1. Good Laboratory Practice Regulations, by Sandy Weinberg, Fourth Edition Drugs and the Pharmaceutical Sciences, Vol.168
2. Good Pharmaceutical Manufacturing practice, Rational and compliance by John Sharp, CRC Press
3. Establishing a cGMP Laboratory Audit System, A practical Guide by David M.Bleisner, Wiley Publication.
4. How to practice GLP by PP Sharma, Vandana Publications.
5. Laboratory Auditing for Quality and Regulatory compliance bu Donald C.Singer, Drugs and the Pharmaceutical Sciences, Vol.150.
6. Drugs & Cosmetics Act, Rules & Amendments.

DOCUMENTATION AND REGULATORY WRITING (MRA 102T)

Scope

This course is designed to impart fundamental knowledge on documentation and general principles involved in regulatory writing and submission to agencies.

Objectives

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

- Know the various documents pertaining to drugs in pharmaceutical industry
- Understand the basics of regulatory compilation
- Create and assemble the regulation submission as per the requirements of agencies
- Follow up the submissions and post approval document requirements

THEORY

60 HOURS

UNIT I

12 Hrs

Documentation in pharmaceutical industry: Exploratory Product Development Brief (EPDB) for Drug substance and Drug product, Product Development Plan (PDP), Product Development Report (PDR), Master Formula Record, Batch Manufacturing Record and its calculations, Batch Reconciliation, Batch Packaging Records, Print pack specifications, Distribution records, Certificate of Analysis (CoA), Site Master File and Drug Master Files (DMF).

UNIT II

12 Hrs

Dossier preparation and submission: Introduction and overview of dossiers, contents and organization of dossier, binders and sections, compilation and review of dossier. Paper submissions, overview and modules of CTD, electronic CTD submissions; Electronic submission: Planning electronic submission, requirements for submission, regulatory bindings and requirements, Tool and Technologies, electronic dossier submission process and validating the submission, Electronic Submission Gateway (ESG). Non eCTD electronic submissions (NeeS), Asian CTD formats (ACTD) submission. Organizing, process and validation of submission. Submission in Sugam system of CDSCO.

UNIT III

12 Hrs

Audits: Introduction, Definition, Summary, Types of audits, GMP compliance audit, Audit policy, Internal and External Audits, Second Party Audits, External third party audits, Auditing strategies, Preparation and conducting audit, Auditing strategies, audit analysis, audit report, audit follow up. Auditing/inspection of manufacturing facilities by regulatory agencies. Timelines for audits/inspection. GHTF study group 4 guidance document. ISO 13485.

UNIT IV

12 Hrs

Inspections: Pre-approval inspections, Inspection of pharmaceutical manufacturers, Inspection of drug distribution channels, Quality systems requirements for national good manufacturing practice inspectorates, inspection report, model certificate of good manufacturing practices, Root cause analysis, Corrective and Preventive action (CAPA).

UNIT V

12 Hrs

Product life cycle management: Prior Approval Supplement (PAS), Post Approval Changes [SUPAC], Changes Being Effected in 30 Days (CBE-30), Annual Report, Post marketing Reporting Requirements, Post approval Labeling Changes, Lifecycle Management, FDA Inspection and Enforcement, Establishment Inspection Report (EIR), Warning Letters, Recalls, Seizure and Injunctions. ISO Risk Management Standard

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-loana Stefan, Jacobus F. Van Staden. Taylor and Francis (2005).
5. Implementing Juran's Road Map for Quality Leadership: Benchmarks and Results, By Al Endres, Wiley, 2000
6. Understanding, Managing and Implementing Quality: Frameworks, Techniques and Cases, By Jiju Antony; David Preece, Routledge, 2002
7. 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
8. Corporate Culture and the Quality Organization By James W. Fairfield- Sonn, Quorum Books, 2001
9. The Quality Management Sourcebook: An International Guide to Materials and Resources By Christine Avery; Diane Zabel, Routledge, 1997
10. The Quality Toolbox, Second Edition, Nancy R. Tague, ASQ Publications
11. Juran's Quality Handbook, Sixth Edition, Joseph M. Juran and Joseph A. De Feo, ASQ Publications
12. Root Cause Analysis, The Core of Problem Solving and Corrective Action, Duke Okes, 2009, ASQ Publications
13. International Medical Device Regulators Forum (IMDRF) Medical Device Single Audit Program (MDSAP)

CLINICAL RESEARCH REGULATIONS (MRA 103T)

Scope

This course is designed to impart the fundamental knowledge on the clinical development process of drugs, pharmaceuticals and Medical Devices, phases and conduct of clinical trials and research, regulations and guidance governing the conduct of clinical research in India, USA and EU. It prepares the students to learn in detail on various laws, legislations and guidance related to safety, efficacy, ethical conduct and regulatory approval of clinical research.

Objectives

Upon completion of the course, the student shall be able to (know, do and appreciate)

- History, origin and ethics of clinical and biomedical research and evaluation
- Clinical drug, medical device development process and different types and phases of clinical trials
- Regulatory requirements and guidance for conduct of clinical trials and research

THEORY

60 HOURS

UNIT I

12 Hrs

Clinical Drug Development Process

- Different types of Clinical Studies
- Phases of clinical trials, Clinical Trial protocol
- Phase 0 studies
- Phase I and subtype studies (single ascending, multiple ascending, dose escalation, methods, food effect studies, drug – drug interaction, PK end points)
- Phase II studies (proof of concept or principle studies to establish efficacy)
- Phase III studies (Multi ethnicity, global clinical trial, registration studies)
- Phase IV studies (Post Marketing Studies; PSUR)
- Clinical Investigation and Evaluation of Medical Devices & IVDs Different Types of Studies
- Key Concepts of Medical Device Clinical Evaluation
- Key concepts of Clinical Investigation

UNIT II

12 Hrs

Ethics in Clinical Research:

- Historical Perspectives: Nuremberg Code, Thalidomide study, Nazis Trials, Tuskegee Syphilis Study, The Belmont Report, The declaration of Helsinki
- Origin of International Conference on Harmonization – Good Clinical Practice (ICH-GCP) guidelines.
- The ethics of randomized clinical trials

- The role of placebo in clinical trials
- Ethics of clinical research in special population
- Institutional Review Board/Independent Ethics Committee/Ethics Committee – composition, roles, responsibilities, review and approval process and ongoing monitoring of safety data
- Data safety monitoring boards.
- Responsibilities of sponsor, CRO, and investigator in ethical conduct of clinical research
- Ethical principles governing informed consent process
- Patient Information Sheet and Informed Consent Form
- The informed consent process and documentation

UNIT III

12 Hrs

Regulations governing Clinical Trials

- India: Clinical Research regulations in India – Schedule Y &
- Medical Device Guidance USA: Regulations to conduct drug studies in USA (FDA)
- NDA 505(b) (1) of the FD&C Act (Application for approval of a new drug)
- NDA 505(b) (2) of the FD&C Act (Application for approval of a new drug that relies, at least in part, on data not developed by the applicant)
- ANDA 505(j) of the FD&C Act (Application for approval of a generic drug product)
- FDA Guidance for Industry - Acceptance of Foreign Clinical Studies
- FDA Clinical Trials Guidance Document: Good Clinical Practice
- EU: Clinical Research regulations in European Union (EMA)

UNIT IV

12 Hrs

Clinical Research Related Guidelines

- Good Clinical Practice Guidelines (ICH GCP E6)
- Indian GCP Guidelines
- ICMR Ethical Guidelines for Biomedical Research
- CDSCO guidelines

GHTF study group 5 guidance documents

Regulatory Guidance on Efficacy and Safety ICH Guidance's

- E4 – Dose Response Information to support Drug Registration
- E7 – Studies in support of General Population: Geriatrics
- E8 – General Considerations of Clinical Trials
- E10 – Choice of Control Groups and Related Issues in Clinical Trials,
- E 11 – Clinical Investigation of Medicinal Products in the Pediatric Population

- General biostatistics principle applied in clinical research

UNIT V

12 Hrs

- USA & EU Guidance
- USA: FDA Guidance
- CFR 21Part 50: Protection of Human Subjects
- CFR 21Part 54: Financial Disclosure by Clinical Investigators
- CFR 21Part 312: IND Application
- CFR 21Part 314: Application for FDA Approval to Market a New Drug
- CFR 21Part 320: Bioavailability and bioequivalence requirements
- CFR 21Part 812: Investigational Device Exemptions
- CFR 21Part 822: Post-market surveillance
- FDA Safety Reporting Requirements for INDs and BA/BE Studies
- FDA Med Watch
- Guidance for Industry: Good Pharmacovigilance Practices and Pharmacoepidemiologic Assessment
European Union: EMA Guidance
- EU Directives 2001
- EudraLex (EMA) Volume 3 – Scientific guidelines for medicinal products for human use
- EU Annual Safety Report (ASR)
- Volume 9A – Pharmacovigilance for Medicinal Products for Human Use
- EU MDD with respect to clinical research
- ISO 14155

REFERENCES

1. Clinical Trials and Human Research: A Practical Guide to Regulatory Compliance By Fay A. Rozovsky and Rodney K. Adams
2. HIPAA and Human Subjects Research: A Question and Answer Reference Guide By Mark Barnes, JD, LLM and Jennifer Kulynych, JD, PhD
3. Principles and Practices of Clinical Research, Second Edition Edited by John I. Gallin and Frederick P. Ognibene
4. Reviewing Clinical Trials: A Guide for the Ethics Committee; Johan PE Karlberg and Marjorie A Speers; Karlberg, Johan Petter Einar, Hong Kong.
5. International Pharmaceutical Product Registration: Aspects of Quality, Safety and Efficacy; Anthony C. Cartwright; Taylor & Francis Inc., USA.
6. New Drug Approval Process: The Global Challenge; Guarino, Richard A; Marcel Dekker Inc., NY.

7. FDA regulatory affairs: a guide for prescription drugs, medical devices, and biologics; Douglas J. Pisano, David Mantus; CRC Press, USA
8. Country Specific Guidelines from official websites.
9. Drugs & Cosmetics Act & Rules and Amendments.

RECOMMENDED WEBSITES:

1. EU Clinical Research Directive 2001: <http://www.eortc.be/services/doc/clinical-eudirective-04-april-01.pdf>
2. Code of Federal Regulations, FDA: <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfrcfr/cfrsearch.cfm>
3. Guidelines of International Conference on Harmonization: <http://www.ich.org/products/guidelines.html>
4. Eudralex Guidelines: <http://www.gmpcompliance.info/euguide.htm>
5. FDA New Drug Application:
6. <http://www.fda.gov/regulatoryinformation/legislation/FederalFoodDrugandCosmeticctFDCAct/FDCAcChapterVDrugsandDevices/ucm108125.htm>.
7. Medicines and Healthcare products Regulatory Agency: <http://www.mhra.gov.uk>
8. Central Drugs Standard Control Organization Guidance for Industry: <http://cdsco.nic.in/CDSCO-GuidanceForIndustry.pdf>
9. ICMR Ethical Guidelines for Biomedical Research: http://icmr.nic.in/ethical_guidelines.pdf

REGULATIONS AND LEGISLATION FOR DRUGS & COSMETICS, MEDICAL DEVICES, BIOLOGICALS & HERBALS, AND FOOD & NUTRACEUTICALS IN INDIA AND INTELLECTUAL PROPERTY RIGHTS (MRA 104T)

Scope

This course is designed to impart fundamental knowledge on regulations and legislation in India w.r.t. Drugs & Cosmetics, Medical Devices, Biologicals & Herbals, and Food & Nutraceuticals. It prepares the students for basic regulatory requirements in India of Drugs & Cosmetics, Medical Devices, Biologicals & Herbals, and Food & Nutraceuticals. for manufacture, import & registration, export, sale, marketing authorization, clinical trials and intellectual property rights.

Objectives

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

- Know different Acts and guidelines that regulate Drugs & Cosmetics, Medical Devices, Biologicals & Herbals, and Food & Nutraceuticals industry in India.
- Understand the approval process and regulatory requirements for Drugs & Cosmetics, Medical Devices, Biologicals & Herbals, and Food & Nutraceuticals.

THEORY

60 HOURS

UNIT I

12 Hrs

Biologicals & Herbals, and Food & Nutraceuticals Acts and Rules (with latest amendments):

1. Drugs and Cosmetics Act 1940 and Rules 1945: DPCO and NPPA
2. Other relevant provisions (rules schedules and guidelines for approval of Drugs & Cosmetics, Medical Devices, Biologicals & Herbals, and Food & Nutraceuticals in India

Other relevant Acts: Narcotics Drugs and Psychotropic Substances Act; Medicinal and Toilet Preparations (Excise Duties) Act, 1955; Pharmacy Act, 1948; Drugs and Magic Remedies (Objectionable Advertisements) Act, 1955; Prevention of Cruelty to Animals Act.

UNIT II

12 Hrs

Regulatory requirements and approval procedures for Drugs & Cosmetics Medical Devices, Biologicals & Herbals, and Food & Nutraceuticals

CDSCO (Central Drug Standard Control Organization) and State Licensing Authority: Organization, Responsibilities

- Rules, regulations, guidelines and standards for regulatory filing of Drugs & Cosmetics, Medical Devices, Biologicals & Herbals, and Food & Nutraceuticals
- Format and contents of Regulatory dossier filing Clinical trial/ investigations

UNIT III**12 Hrs**

Indian Pharmacopoeial Standards, BIS standards and ISO and other relevant standards

UNIT IV**12 Hrs**

Bioavailability and Bioequivalence data (BA &BE), BCS Classification of Drugs, Regulatory Requirements for Bioequivalence study Stability requirements: ICH and WHO

Guidelines for Drug testing in animals/Preclinical Studies Animal testing: Rationale for conducting studies, CPCSEA Guidelines

Ethical guidelines for human participants ICMR-DBT Guidelines for Stem Cell Research

UNIT V**12 Hrs**

Intellectual Property Rights: Patent, Trademark, Copyright, Industrial Designs and Geographical Indications, Indian Patent Scenario. IPR vs Regulatory Affairs.

REFERENCES

1. Manual of Patent Practice & Procedure, 3rd Edition, by The Patent Office of India
2. Patent Failure How Judges, Bureaucrats, and Lawyers put innovators at risk by James Bessen and Michael J. Meurer
3. Principles and Practice of Clinical Trial Medicine by Richard Chin and Bruce Y. Lee
4. Ethical Guidelines for Biomedical Research on Human Participants by Indian Council of Medical Research New delhi 2006.
5. CPCSEA Guidelines for Laboratory Animal Facility by Committee for the purpose of control and supervision on experiments on animals (CPCSEA)
6. ICH E6 Guideline — Good Clinical Practice by ICH Harmonised Tripartite
7. Guidance for Industry on Submission of Clinical Trial Application for Evaluating Safety and Efficacy by CDSCO (Central Drug Standard Control Organisation)
8. Guidance for Industry on Requirement of Chemical & Pharmaceutical Information including Stability Study Data before approval of clinical trials / BE studies by CDSCO
9. Guidelines for Import and Manufacture of Medical Devices by CDSCO
10. Guidelines from official website of CDSCO

REGULATORY AFFAIRS PRACTICAL – I (MRA 105P)

1. Case studies (4 Nos.) of each of Good Pharmaceutical Practices.
2. Documentation for in process and finished products Quality control tests for Solid, liquid, Semisolid and Sterile preparations.
3. Preparation of SOPs, Analytical reports (Stability and validation)
4. Protocol preparation for documentation of various types of records (BMR, MFR, DR)
5. Labeling comparison between brand & generics.
6. Preparation of clinical trial protocol for registering trial in India
7. Registration for conducting BA/ BE studies in India
8. Import of drugs for research and developmental activities
9. Preparation of regulatory dossier as per Indian CTD format and submission in SUGAM
10. Registering for different Intellectual Property Rights in India
11. GMP Audit Requirements as per CDSCO
12. Preparation and documentation for Indian Patent application.
13. Preparation of checklist for registration of IND as per ICH CTD format.
14. Preparation of checklist for registration of NDA as per ICH CTD format.
15. Preparation of checklist for registration of ANDA as per ICH CTD format.
16. Case studies on response with scientific rationale to USFDA Warning Letter
17. Preparation of submission checklist of IMPD for EU submission.
18. Comparison study of marketing authorization procedures in EU.
19. Comparative study of DMF system in US, EU and Japan
20. Preparation of regulatory submission using eCTD software
21. Preparation of Clinical Trial Application (CTA) for US submission
22. Preparation of Clinical Trial Application (CTA) for EU submission
23. Comparison of Clinical Trial Application requirements of US, EU and Japan of a dosage form.
24. Regulatory requirements checklist for conducting clinical trials in India.
25. Regulatory requirements checklist for conducting clinical trials in Europe.
26. Regulatory requirements checklist for conducting clinical trials in USA

REGULATORY ASPECTS OF DRUGS & COSMETICS (MRA 201T)

Scope

This course is designed to impart the fundamental knowledge on the drug development process, regulatory requirements for approval of new drugs, drug products and cosmetics in regulated and semi-regulated countries. It prepares the students to learn in detail on the regulatory requirements, documentation requirements, and registration procedures for marketing the drug products and cosmetics in regulated and semi-regulated countries.

Objectives

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

- Process of drug discovery and development and generic product development
- Regulatory approval process and registration procedures for API and drug products in US, EU
- Cosmetics regulations in regulated and semi-regulated countries
- A comparative study of India with other global regulated markets.

THEORY

60 HOURS

UNIT I

12 Hrs

USA & CANADA: Organization structure and functions of FDA. Federal register and Code of Federal Regulations (CFR), History and evolution of United States Federal, Food, Drug and Cosmetic Act (FFDCA), Hatch Waxman act and Orange book, Purple book, Drug Master Files (DMF) system in US, Regulatory Approval Process for Investigational New Drug (IND), New Drug Application (NDA), Abbreviated New Drug Application (ANDA), Supplemental New Drug Application (SNDA); Regulatory requirements for Orphan drugs and Combination Products, Changes to an approved NDA / ANDA. Regulatory considerations for manufacturing, packaging and labeling of pharmaceuticals in USA. Legislation and regulations for import, manufacture, distribution and sale of cosmetics in USA and Canada.

UNIT II

12 Hrs

European Union & Australia: Organization and structure of EMA & EDQM, General guidelines, Active Substance Master Files (ASMF) system in EU, Content and approval process of IMPD, Marketing Authorization procedures in EU (Centralized procedure, Decentralized procedure, Mutual recognition procedure and National Procedure). Regulatory considerations for manufacturing, packaging and labeling of pharmaceuticals in EU, Eudralex directives for human medicines, Variations & extensions, Compliance of European Pharmacopoeia (CEP)/ Certificate of Suitability (CoS), Marketing Authorization (MA) transfers, Qualified Person (QP) in EU. Legislation and regulations for import, manufacture, distribution and sale of cosmetics in European Union & Australia.

UNIT III

12 Hrs

Japan: Organization of the PMDA, Pharmaceutical Laws and regulations, types of registration applications, DMF system in Japan, drug regulatory approval process, Regulatory considerations for manufacturing, packaging and labeling of pharmaceuticals in Japan, Post marketing surveillance in Japan. Legislation and regulations for import, manufacture, distribution and sale of cosmetics in Japan

UNIT IV

12 Hrs

Emerging Market: Introduction, Countries covered, Study of the world map, study of various committees across the globe (ASEAN, APEC, EAC, GCC, PANDRH, SADC)

WHO: WHO, GMP, Regulatory Requirements for registration of drugs and post approval requirements in WHO through prequalification programme, Certificate of Pharmaceutical Product (CoPP) - General and Country Specific (South Africa, Egypt, Algeria and Morocco, Nigeria, Kenya and Botswana)

UNIT V

12 Hrs

Brazil, ASEAN, CIS and GCC Countries: ASIAN Countries: Introduction to ACTD, Regulatory Requirements for registration of drugs and post approval requirements in China and South Korea & Association of Southeast Asian Nations (ASEAN) Region i.e. Vietnam, Malaysia, Philippines, Singapore and Thailand.

CIS (Commonwealth Independent States): Regulatory prerequisites related to Marketing authorization requirements for drugs and post approval requirements in CIS countries i.e.

Russia, Kazakhstan and Ukraine GCC (Gulf Cooperation Council) for Arab states: Regulatory prerequisites related to Marketing authorization requirements for drugs and post approval requirements in Saudi Arabia and UAE

Legislation and regulations for import, manufacture, distribution and sale of cosmetics in Brazil, ASEAN, CIS and GCC Countries.

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, Edited by Ira R. Berry Marcel Dekker Series, Vol.144
3. 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.
4. New Drug Approval Process: Accelerating Global Registrations By Richard A Guarino, MD, 5th edition, Drugs and the Pharmaceutical Sciences, Vol.190.

5. Guidebook for drug regulatory submissions / Sandy Weinberg. By John Wiley & Sons. Inc.
6. Drugs: From Discovery to Approval, Second Edition By Rick Ng
7. New Drug Development: A Regulatory Overview, Eighth Edition By Mark Mathieu
8. Pharmaceutical Risk Management By Jeffrey E. Fetterman, Wayne L. Pines and Gary H. Slatko
9. Preparation and Maintenance of the IND Application in eCTD Format By William K. Sietsema
10. Country Specific Guidelines from official websites.
11. http://www.who.int/medicines/areas/quality_safety/regulation_legislation/ListMRAWebsites.pdf
12. Roadmap to an ASEAN economic community Edited by Denis Hew. ISEAS Publications, Singapore 2005, ISBN981-230-347-2
13. ASEAN, Rodolfo C. Severino, ISEAS Publications, Singapore 2005, ISBN 978-981-230-750-7
14. Building a Future with Brics: The Next Decade for Offshoring, Mark Kobayashi-Hillary, Springer
15. Outsourcing to India: The Offshore Advantage, Mark Kobayashi-Hillary, Springer Trade performance and Regional Integration of the CIS Countries, Lev Freinkman,
16. The world Bank, Washington, DC, ISBN: 0-8212-5896-0
17. Global Pharmaceutical Policy: Ensuring Medicines for Tomorrow's World ByFrederick M. Abbott, Graham Dukes, Maurice Nelson Graham Dukes
18. The Gulf Cooperation Council: A Rising Power and Lessons for ASEAN by Linda Low and Lorraine Carlos Salazar (Nov 22, 2010)
19. Doing Business in the Asean Countries, Balbir Bhasin, Business Expert Press ISBN:13:978-1-60649-108-9
20. Realizing the ASEAN Economic Community: A Comprehensive Assessment, Michael G Plummer (Editor), Chia Siow Yue (Editor), Institute of South east asian studies, Singapore

REGULATORY ASPECTS OF HERBAL AND BIOLOGICALS (MRA 202T)

Scope

This course is designed to impart fundamental knowledge on Regulatory Requirements, Licensing and Registration, Regulation on Labelling of Biologics in India, USA and Europe It prepares the students to learn in detail on Regulatory Requirements for biologics, Vaccines and Blood Products

Objectives

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

- Know the regulatory Requirements for Biologics and Vaccines
- Understand the regulation for newly developed biologics and biosimilars
- Know the pre-clinical and clinical development considerations of biologics
- Understand the Regulatory Requirements of Blood and/or Its Components Including Blood Products and label requirements

THEORY

60 HOURS

UNIT I

12 Hrs

India: Introduction, Applicable Regulations and Guidelines, Principles for Development of Similar Biologics, Data Requirements for Preclinical Studies, Data Requirements for Clinical Trial Application, Data Requirements for Market Authorization Application, Post-Market Data for Similar Biologics, Pharmacovigilance. GMP and GDP.

UNIT II

12 Hrs

USA: Introduction to Biologics; biologics, biological and biosimilars, different biological products, difference between generic drug and biosimilars, laws, regulations and guidance on biologics/ biosimilars, development and approval of biologics and biosimilars (IND, PMA, BLA, NDA, 510(k), pre-clinical and clinical development considerations, advertising, labelling and packing of biologics

UNIT III

12 Hrs

European Union: Introduction to Biologics; directives, scientific guidelines and guidance related to biologics in EU, comparability/ biosimilarity assessment, Plasma master file, TSE/ BSE evaluation, development and regulatory approval of biologics (Investigational medicinal products and biosimilars), pre-clinical and clinical development considerations; stability, safety, advertising, labelling and packing of biologics in EU

UNIT IV

12 Hrs

Vaccine regulations in India, US and European Union: Clinical evaluation, Marketing authorisation, Registration or licensing, Quality assessment, Pharmacovigilance, Additional requirements Blood and

Blood Products Regulations in India, US and European Union: Regulatory Requirements of Blood and/or Its Components Including Blood Products, Label Requirements, ISBT (International Society of Blood Transfusion) and IHN (International Haemovigilance Network)

UNIT V

12 Hrs

Herbal Products: Quality, safety and legislation for herbal products in India, USA and European Union.

REFERENCES

1. FDA Regulatory Affairs: A Guide for Prescription Drugs, Medical Devices, and Biologics, Douglas J. Pisano , David S. Mantus ; Informa ,2008
2. Biological Drug Products: Development and Strategies; Wei Wang , Manmohan Singh ; wiley ,2013
3. Development of Vaccines: From Discovery to Clinical Testing; Manmohan Singh , Indresh K. Srivastava ;Wiley, 2011
4. www.who.int/biologicals/en
5. www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/
6. www.ihn-org.com
7. www.isbtweb.org
8. Guidelines on Similar Biologics: Regulatory Requirements for Marketing Authorization in India
9. www.cdsc0.nic.in
10. www.ema.europa.eu › scientific guidelines › Biologics
11. www.fda.gov/biologicsbloodVaccines/GuidanceComplianceRegulatoryInformation (Biologics)

REGULATORY ASPECTS OF MEDICAL DEVICES (MRA 203T)

Scope

This course is designed to impart the fundamental knowledge on the medical devices and in vitro diagnostics, basis of classification and product life cycle of medical devices, regulatory requirements for approval of medical devices in regulated countries like US, EU and Asian countries along with WHO regulations. It prepares the students to learn in detail on the harmonization initiatives, quality and ethical considerations, regulatory and documentation requirements for marketing medical devices and IVDs in regulated countries.

Objectives

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

- basics of medical devices and IVDs, process of development, ethical and quality considerations
- harmonization initiatives for approval and marketing of medical devices and IVDs
- regulatory approval process for medical devices and IVDs in India, US, Canada, EU, Japan and ASEAN
- clinical evaluation and investigation of medical devices and IVDs

THEORY

60 HOURS

UNIT I

12 Hrs

Medical Devices: Introduction, Definition, Risk based classification and Essential Principles of Medical Devices and IVDs. Differentiating medical devices IVDs and Combination Products from that of pharmaceuticals, History of Medical Device Regulation, Product Lifecycle of Medical Devices and Classification of Medical Devices. IMDRF/GHTF: Introduction, Organizational Structure, Purpose and Functions, Regulatory Guidelines, Working Groups, Summary Technical Document (STED), Global Medical Device Nomenclature (GMDN).

UNIT II

12 Hrs

Ethics: Clinical Investigation of Medical Devices, Clinical Investigation Plan for Medical Devices, Good Clinical Practice for Clinical Investigation of medical devices (ISO 14155:2011) Quality: Quality System Regulations of Medical Devices: ISO 13485, Quality Risk Management of Medical Devices: ISO 14971, Validation and Verification of Medical device, Adverse Event Reporting of Medical device

UNIT III

12 Hrs

USA: Introduction, Classification, Regulatory approval process for Medical Devices (510k) Pre-market Notification, Pre-Market Approval (PMA), Investigational Device Exemption (IDE) and In vitro Diagnostics, Quality System Requirements 21 CFR Part 820, Labeling requirements 21 CFR Part 801,

Post marketing surveillance of MD and Unique Device Identification (UDI). Basics of In vitro diagnostics, classification and approval process.

UNIT IV

12 Hrs

European Union: Introduction, Classification, Regulatory approval process for Medical Devices (Medical Device Directive, Active Implantable Medical Device Directive) and In vitro Diagnostics (In Vitro Diagnostics Directive), CE certification process.

Basics of In vitro diagnostics, classification and approval process.

UNIT V

12 Hrs

ASEAN, China & Japan: Medical Devices and IVDs, Regulatory registration procedures, Quality System requirements and clinical evaluation and investigation. IMDRF study groups and guidance documents.

REFERENCES

1. FDA regulatory affairs: a guide for prescription drugs, medical devices, and biologics by Douglas J. Pisano, David Mantus.
2. Medical Device Development: A Regulatory Overview by Jonathan S. Kahan
3. Medical Product Regulatory Affairs: Pharmaceuticals, Diagnostics, Medical Devices by John J. Tobin and Gary Walsh
4. Compliance Handbook for Pharmaceuticals, Medical Devices and Biologics by Carmen Medina
5. Country Specific Guidelines from official websites.

REGULATORY ASPECTS OF FOOD & NUTRACEUTICALS (MRA 204T)

Scope

This course is designed to impart the fundamental knowledge on Regulatory Requirements, Registration and Labeling Regulations of Nutraceuticals in India, USA and Europe.

It prepares the students to learn in detail on Regulatory Aspects for nutraceuticals and food supplements.

Objectives

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

- Know the regulatory Requirements for nutraceuticals
- Understand the regulation for registration and labeling of nutraceuticals and food supplements in India, USA and Europe.

THEORY

60 HOURS

UNIT I

12 Hrs

Nutraceuticals: Introduction, History of Food and Nutraceutical Regulations, Meaning of Nutraceuticals, Dietary Supplements, Functional Foods, Medical Foods, Scope and Opportunities in Nutraceutical Market.

UNIT II

12 Hrs

Global Aspects: WHO guidelines on nutrition.

NSF International: Its Role in the Dietary Supplements and Nutraceuticals Industries, NSF Certification, NSF Standards for Food and Dietary Supplements. Good Manufacturing Practices for Nutraceuticals.

UNIT III

12 Hrs

India: Food Safety and Standards Act, Food Safety and Standards Authority of India: Organization and Functions, Regulations for import, manufacture and sale of nutraceutical products in India, Recommended Dietary Allowances (RDA) in India.

UNIT IV

12 Hrs

USA: US FDA Food Safety Modernization Act, Dietary Supplement Health and Education Act. U.S. regulations for manufacture and sale of nutraceuticals and dietary supplements, Labelling Requirements and Label Claims for Dietary Supplements, Recommended Dietary Allowances (RDA) in the U.S

UNIT V

12 Hrs

European Union: European Food Safety Authority (EFSA): Organization and Functions. EU Directives and regulations for manufacture and sale of nutraceuticals and dietary supplements. Nutrition labelling. European Regulation on Novel Foods and Novel Food Ingredients. Recommended Dietary Allowances (RDA) in Europe.

REFERENCES

1. Regulation of Functional Foods and Nutraceuticals: A Global Perspective by Clare M. Hasler (Wiley Online Library)
2. Nutraceutical and Functional Food Regulations in the United States and Around the World by Debasis Bagchi (Academic Press, Elsevier)
3. <http://www.who.int/publications/guidelines/nutrition/en/>
4. [http://www.europarl.europa.eu/RegData/etudes/STUD/2015/536324/IPOL_STU\(2015\)536324_EN.pdf](http://www.europarl.europa.eu/RegData/etudes/STUD/2015/536324/IPOL_STU(2015)536324_EN.pdf)
5. Handbook of Nutraceuticals by Yashwant Pathak (CRC Press)
6. Food Regulation: Law, Science, Policy and Practice by Neal D. Fortin (Wiley)
7. Country Specific Guidelines from official websites.

REGULATORY AFFAIRS PRACTICAL – II (MRA 205P)

1. Case studies on
2. Change Management/ Change control. Deviations
3. Corrective & Preventive Actions (CAPA)
4. Documentation of raw materials analysis as per official monographs
5. Preparation of audit checklist for various agencies
6. Preparation of submission to FDA using eCTD software
7. Preparation of submission to EMA using eCTD software
8. Preparation of submission to MHRA using eCTD software
9. Preparation of Biologics License Applications (BLA)
10. Preparation of documents required for Vaccine Product Approval
11. Comparison of clinical trial application requirements of US, EU and India of Biologics
12. Preparation of Checklist for Registration of Blood and Blood Products
13. Registration requirement comparison study in 5 emerging markets (WHO) and preparing check list for market authorization
14. Registration requirement comparison study in emerging markets (BRICS) and preparing check list for market authorization
15. Registration requirement comparison study in emerging markets (China and South Korea) and preparing check list for market authorization
16. Registration requirement comparison study in emerging markets (ASEAN) and preparing check list for market authorization
17. Registration requirement comparison study in emerging markets (GCC) and preparing check list for market authorization
18. Checklists for 510k and PMA for US market
19. Checklist for CE marking for various classes of devices for EU
20. STED Application for Class III Devices
21. Audit Checklist for Medical Device Facility
22. Clinical Investigation Plan for Medical Devices

**DETAILED SYLLABUS OF
SECOND YEAR**

Schemes for internal assessments and end semester examinations (Semesters III& IV)

Course Code	Course	Credit Hours	Credit Points
Semester III			
MRM 301T	Research Methodology and Biostatistics*	4	4
-	Journal Club	1	1
-	Discussion / Presentation (Proposal Presentation)	2	2
-	Research Work	28	14
Total		35	21
Semester IV			
-	Journal Club	1	1
-	Research Work	31	16
-	Discussion/Final Presentation	3	3
Total		35	20

Course Code	Course	Internal Assessment				End Semester Exams		Total Marks
		Continuous Mode	Sessional Exams		Total	Marks	Duration	
			Marks	Duration				
SEMESTER III								
MRM 301T	Research Methodology and Biostatistics*	10	15	1 Hr	25	75	3 Hrs	100
-	Journal club	-	-	-	25	-	-	25
-	Discussion / Presentation (Proposal Presentation)	-	-	-	50	-	-	50
-	Research work*	-	-	-	-	350	1 Hr	350
Total								525
SEMESTER IV								
-	Journal club	-	-	-	25	-	-	25
-	Discussion / Presentation (Department Research Audit)	-	-	-	75	-	-	75
-	Research work and Colloquium	-	-	-	-	400	1 Hr	400
Total								500

SEMESTER III
RESEARCH METHODOLOGY & BIostatISTICS (MRM 301T)

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.
