SYLLABUS

For

Master of Pharmacy

(M.PHARM.)

(For admission in 2022-23 and onwards)
MODERN PHARMACEUTICAL ANALYTICAL TECHNIQUES (MPH 101T)

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

Objectives
After completion of course student is able to know,
- Chemicals and Excipients
- The analysis of various drugs in single and combination dosage forms
- Theoretical and practical skills of the instruments

THEORY 60 HOURS

b. IR spectroscopy: Theory, Modes of Molecular vibrations, Sample handling, Instrumentation of Dispersive and Fourier - Transform IR Spectrometer, Factors affecting vibrational frequencies and Applications of IR spectroscopy.


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

4. Chromatography: Principle, apparatus, instrumentation, chromatographic parameters, factors affecting resolution and applications of the following:
   a) Paper chromatography
   b) Thin Layer chromatography
   c) Ion exchange chromatography
   d) Column chromatography
   e) Gas chromatography
   f) High Performance Liquid chromatography
   g) Affinity chromatography

5. a. Electrophoresis: Principle, Instrumentation, Working conditions, factors affecting separation and applications of the following:
   a) Paper electrophoresis
   b) Gel electrophoresis
   c) Capillary electrophoresis
   d) Zone electrophoresis
   e) Moving boundary electrophoresis
   f) Iso electric focusing
   b. X ray Crystallography: Production of X rays, Different X ray diffraction methods, Bragg's law, Rotating crystal technique, X ray powder technique, Types of crystals and applications of X-ray diffraction.

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

REFERENCES
DRUG DELIVERY SYSTEMS
(MPH 102T)

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

OBJECTIVES
Upon completion of the course, student shall be able to understand
- The various approaches for development of novel drug delivery systems.
- The criteria for selection of drugs and polymers for the development of delivering system
- The formulation and evaluation of Novel drug delivery systems.

THEORY 60 Hrs


6 Protein and Peptide Delivery: Barriers for protein delivery. Formulation and Evaluation of delivery systems of proteins and other macromolecules.
7 Vaccine delivery systems: Vaccines, uptake of antigens, single shot vaccines, mucosal and transdermal delivery of vaccines.

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

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  
(MPH 103T)

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

Objectives
Upon completion of the course, student shall be able to understand
- The elements of preformulation studies.
- The Active Pharmaceutical Ingredients and Generic drug Product development
- Industrial Management and GMP Considerations.
- Optimization Techniques & Pilot Plant Scale Up Techniques
- Stability Testing, sterilization process & packaging of dosage forms.

THEORY  60 HRS

b. Optimization techniques in Pharmaceutical Formulation: 10 Hrs 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


3. cGMP & Industrial Management: Objectives and policies of current good manufacturing practices, layout of buildings, services, equipments and their maintenance Production management: Production organization, , materials management, handling and transportation, inventory management and control, production and planning control, Sales forecasting, budget and cost control, industrial and personal relationship. Concept of Total Quality Management.
4 Compression and compaction: Physics of tablet compression, 10 compression, consolidation, effect of friction, distribution of Hrs forces, compaction profiles. Solubility.

5 Study of consolidation parameters; Diffusion parameters, 10 Dissolution parameters and Pharmacokinetic parameters, Heckel Hrs plots, Similarity factors – f2 and f1, 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
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.
8. Physical Pharmacy; By Alfred martin
11. Quality Assurance Guide; By Organization of Pharmaceutical producers of India.
13. How to practice GMPs; By P.P.Sharma. Vandhana Publications, Agra.
15. Pharmaceutical Preformulations; By J.J. Wells.
16. Applied production and operations management; By Evans, Anderson, Sweeney and Williams.
17. Encyclopaedia of Pharmaceutical technology, Vol I – III.
REGULATORY AFFAIRS
(MPH 104T)

Scope
Course designed to impart advanced knowledge and skills required to learn the concept of generic drug and their development, various regulatory filings in different countries, different phases of clinical trials and submitting regulatory documents: filing process of IND, NDA and ANDA
- To know the approval process of
- To know the chemistry, manufacturing controls and their regulatory importance
- To learn the documentation requirements for
- To learn the importance and

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

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

THEORY

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1. a. Documentation in Pharmaceutical industry: Master formula record, DMF (Drug Master File), distribution records. Generic drugs product development Introduction, Hatch-Waxman act and amendments, CFR (CODE OF FEDERAL REGULATION), drug product performance, in-vitro, ANDA regulatory approval process, NDA approval process, BE and drug product assessment, in-vivo, scale up process approval changes, post marketing surveillance, outsourcing BA and BE to CRO.

b. Regulatory requirement for product approval: API, biologics, novel, therapies obtaining NDA, ANDA for generic drugs ways and means of US registration for foreign drugs
2 CMC, post approval regulatory affairs. Regulation for combination products and medical devices. CTD and ECTD format, industry and FDA liaison. ICH – Guidelines of ICH-Q, S E, M. Regulatory requirements of EU, MHRA, TGA and ROW countries.

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

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

REFERENCES
7. www.ich.org/
8. www.fda.gov/
9. europa.eu/index_en.htm
PHARMACEUTICS PRACTICALS - I  
(MPH 105P)

1. Analysis of pharmacopoeial compounds and their formulations by UV Vis spectrophotometer
2. Simultaneous estimation of multi component containing formulations by UV spectrophotometry
3. Experiments based on HPLC
4. Experiments based on Gas Chromatography
5. Estimation of riboflavin/quinine sulphate by fluorimetry
6. Estimation of sodium/potassium by flame photometry
7. To perform In-vitro dissolution profile of CR/ SR marketed formulation
8. Formulation and evaluation of sustained release matrix tablets
9. Formulation and evaluation osmotically controlled DDS
10. Preparation and evaluation of Floating DDS- hydro dynamically balanced DDS
11. Formulation and evaluation of Muco adhesive tablets.
12. Formulation and evaluation of trans dermal patches.
13. To carry out preformulation studies of tablets.
14. To study the effect of compressional force on tablets disintegration time.
15. To study Micromeric 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 Hrs

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

   Nano Particles & Liposomes: Types, preparation and evaluation.
   12 Hrs

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

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

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

REFERENCES
1. Y W. Chien, Novel Drug Delivery Systems, 2nd edition, revised and
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 &
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 understand,

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

THEORY 60 Hrs

1. Drug Absorption from the Gastrointestinal Tract: 12 Hrs

3 Pharmacokinetics: Basic considerations, pharmacokinetic models, compartment modeling: one compartment model – IV bolus, IV infusion, extra-vascular. Multi compartment model: two compartment – model in brief, non-linear pharmacokinetics: cause of non-linearity, Michaelis–Menten equation, estimation of $k_{\text{max}}$ and $V_{\text{max}}$. Drug interactions: introduction, the effect of protein–binding interactions, the effect of tissue–binding interactions, cytochrome p450-based drug interactions, drug interactions linked to transporters.

4 Drug Product Performance, In Vivo: Bioavailability and Bioequivalence: drug product performance, purpose of bioavailability studies, relative and absolute availability. methods for assessing bioavailability, bioequivalence studies, design and evaluation of bioequivalence studies, study designs, crossover study designs, evaluation of the data, bioequivalence example, study submission and drug review process. biopharmaceutics classification system, methods. Permeability: In-vitro, in-situ and In-vivo methods. generic biologics (biosimilar drug products), clinical significance of bioequivalence studies, special concerns in bioavailability and bioequivalence studies, generic substitution.

REFERENCES
2. Biopharmaceutics and Pharmacokinetics, A. Treatise, D. M. Brahman and Sunil B. Jaiswal, VallabhPrakashan, Pitampura, Delhi
4. Textbook of Biopharmaceutics and Pharmacokinetics, Dr. Shobha Rani R. Hiremath, Prism Book
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 Hrs
2. Computational Modeling Of Drug Disposition: Introduction 12 Hrs
   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.
c. Computers in Clinical Development: Clinical Data Collection and Management, Regulation of Computer Systems
5 Artificial Intelligence (AI), Robotics and Computational fluid dynamics: General overview, Pharmaceutical Automation, Pharmaceutical applications, Advantages and Disadvantages. Current Challenges and Future Directions.

REFERENCES
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 Hrs


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

Controversial ingredients: Parabens, formaldehyde liberators, dioxane.

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

5 Herbal Cosmetics : Herbal ingredients used in Hair care, skin care and oral care. Review of guidelines for herbal cosmetics by private bodies like cosmos with respect to preservatives, emollients, foaming agents, emulsifiers and rheology modifiers. Challenges in formulating herbal cosmetics.

REFERENCES
2. Poucher’s perfume and cosmetics and Soaps, 10th edition.
5. Cosmetic and Toiletries recent suppliers catalogue.
6. CTFA directory.
1. To study the effect of temperature change, non solvent addition, incompatible polymer addition in microcapsules preparation
2. Preparation and evaluation of Alginate beads
3. Formulation and evaluation of gelatin /albumin microspheres
4. Formulation and evaluation of liposomes/niosomes
5. Formulation and evaluation of spherules
6. Improvement of dissolution characteristics of slightly soluble drug by Solid dispersion technique.
7. Comparison of dissolution of two different marketed products /brands
8. Protein binding studies of a highly protein bound drug & poorly protein bound drug
9. Bioavailability studies of Paracetamol in animals.
10. Pharmacokinetic and IVIVC data analysis by Winnoline® software
11. In vitro cell studies for permeability and metabolism
12. DoE Using Design Expert® Software
13. Formulation data analysis Using Design Expert® Software
14. Quality-by-Design in Pharmaceutical Development
15. Computer Simulations in Pharmacokinetics and Pharmacodynamics
16. Computational Modeling Of Drug Disposition
17. To develop Clinical Data Collection manual
19. Development and evaluation of Creams
20. Development and evaluation of Shampoo and Toothpaste base
21. To incorporate herbal and chemical actives to develop products
22. To address Dry skin, acne, blemish, Wrinkles, bleeding gums and dandruff
INDUSTRIALPHARMACY(MIP)
MODERN PHARMACEUTICAL ANALYTICAL TECHNIQUES
(MIP 101T)

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

Objectives
After completion of course student is able to know,
- The analysis of various drugs in single and combination dosage forms
- Theoretical and practical skills of the instruments

THEORY 60 HOURS


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.

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

4  Chromatography: Principle, apparatus, instrumentation, chromatographic parameters, factors affecting resolution and applications of the following:
   a) Paper chromatography b) Thin Layer chromatography
c) Ion exchange chromatography d) Column chromatography
e) Gas chromatography f) High Performance Liquid chromatography
g) Affinity chromatography

5  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

   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.

6. Immunological Assays: Radioimmunology assay (RIA), ELISA (Theory & practical) and knowledge on Bioluminescence assays.

REFERENCES
PHARMACEUTICAL FORMULATION DEVELOPMENT
(MIP 102T)

Scope
This course is designed to impart knowledge and skills necessary to train the
students on par with the routine of Industrial activities in R&D and F&D.

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

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

THEORY 60 Hrs

1. Preformulation Studies: Molecular optimization of APIs (drug substances), crystal morphology and variations, powder flow, structure modification, drug-excipient compatibility studies, methods of determination.

2. Formulation Additives: Study of different formulation additives, factors influencing their incorporation, role of formulation development and processing, new developments in excipient science. Design of experiments – factorial design for product and process development.


REFERENCES
17. Encyclopaedia of Pharm. Technology, Vol I – III.
NOVEL DRUG DELIVERY SYSTEMS
(MIP 103T)

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

Objective
On completion of this course it is expected that students will be able to understand,
- The need, concept, design and evaluation of various customized, sustained and controlled release dosage forms.
- To formulate and evaluate various novel drug delivery systems

THEORY 60 Hrs
1. Concept & Models for NDDS: Classification of rate controlled drug delivery systems (DDS), rate programmed release, activation modulated & feedback regulated DDS, effect of system parameters in controlled drug delivery, computation of desired release rate and dose for controlled release DDS, pharmacokinetic design for DDS - intermittent, zero order & first order release.


2 Study of Various DDS: Concepts, design, formulation & evaluation of controlled release oral DDS, Mucoadhesive DDS Hrs (buccal, nasal, pulmonary) Pulsatile, colon specific, liquid sustained release systems, Ocular delivery systems

3 Transdermal Drug Delivery Systems: Theory, design, formulation & evaluation including iontophoresis and other latest developments in skin delivery systems

4 Sub Micron Cosmeceuticals: Biology, formulation science and evaluation of various cosmetics for skin, hair, nail, eye etc and it’s regulatory aspects.


Biotechnology in Drug Delivery Systems: Brief review of 06 major areas–recombinant DNA technology, monoclonal antibodies, Hrs gene therapy.

New trends for Personalized Medicine: Introduction, Definition, 06 Pharmacogenetics, Categories of Patients for Personalized Hrs Medicines: Customized drug delivery systems, Bioelectronic Medicines, 3D printing of pharmaceuticals, Telepharmacy.

REFERENCES
3. Transdermal Controlled Systemic Medications, YW Chein, Vol 31, Marcel Dekker, NY.
INTELLECTUAL PROPERTY RIGHTS  
(MIP 104T)

Scope
This course is designed to impart knowledge and skills necessary to train the 
students to be on par with the routine of Industrial activities in drug regulatory 
affairs

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

- Assist in Regulatory Audit process.
- Establish regulatory guidelines for drug and drug products
- The Regulatory requirements for contract research organization

THEORY 60 Hrs

2 Role of GATT, TRIPS, and WIPO 12 Hrs
3 Brief introduction to Trademark protection and WHO Patents. IPR’s and its types, Major bodies regulating Indian Pharmaceutical sector.
4 Brief introduction to CDSCO. WHO, USFDA, EMEA, TGA, MHRA, MCC, ANVISA 12 Hrs
5 Regulatory requirements for contract research organization. Regulations for Biosimilars. 12 Hrs

REFERENCES:
2. Applied Production and Operation Management By Evans, Anderson and Williams
3. GMP for pharmaceuticals Material Management by K.K. Ahuja Published by CBS publishers
4. ISO 9000–Norms and explanations
5. GMP for pharmaceuticals– Willing S.H. Marcel and Dekker
INDUSTRIAL PHARMACY PRACTICAL - I
(MIP 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 / GC
4. Estimation of riboflavin/quinine sulphate by fluorimetry
5. Estimation of sodium/potassium by flame photometry
6. Effect of surfactants on the solubility of drugs.
7. Effect of pH on the solubility of drugs.
8. Stability testing of solution and solid dosage forms for photo degradation.

9. Stability studies of drugs in dosage forms at 25 °C, 60% RH and 40 °C, 75% RH.
10. Compatibility evaluation of drugs and excipients (DSC & FTIR).
11. Preparation and evaluation of different polymeric membranes.
12. Formulation and evaluation of sustained release oral matrix tablet/ oral reservoir system.
13. Formulation and evaluation of microspheres / microcapsules.
14. Formulation and evaluation of transdermal drug delivery systems.
15. Design and evaluation of face wash, body- wash, creams, lotions, shampoo, toothpaste, lipstick.
17. Preparation and evaluation of Liposome delivery system.
ADVANCED BIOPHARMACEUTICS & PHARMACOKINETICS
(MIP 201T)

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.

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

- The basic concepts in Biopharmaceutics and pharmacokinetics.
- The use of raw data and derive the pharmacokinetic models and parameters the best describe the process of drug absorption, distribution, metabolism and elimination.
- To critically evaluate Biopharmaceutics studies involving drug product equivalency.
- To design and evaluate dosage regimens of the drugs using pharmacokinetic and biopharmaceutic parameters.

THEORY

1. Drug Absorption From The Gastrointestinal Tract: 12 Hrs

2. Biopharmaceutic Considerations in Drug Product Design 12 Hrs
   and In Vitro Drug Product Performance: Introduction,
   - Biopharmaceutic Factors Affecting Drug Bioavailability, Rate-Limiting Steps in Drug Absorption, Physicochemical Nature of the


REFERENCES

2. Biopharmaceutics and Pharmacokinetics, A. Treatise, D. M. Brahmkaran and Sunil B. aiswal., Vallab Prakashan, Pitampura, Delhi
4. Textbook of Biopharmaceutics and Pharmacokinetics, Dr. Shobha Rani R. Hiremath,Prism Book
SCALE UP AND TECHNOLOGY TRANSFER
(MIP 202T)

Scope
This course is designed to impart knowledge and skills necessary to train the students to be on scale up, technology transfer process and industrial safety issues.

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

- Manage the scale up process in pharmaceutical industry.
- Assist in technology transfer.
- To establish safety guidelines, which prevent industrial hazards.

THEORY

1. Pilot plant design: Basic requirements for design, facility, equipment selection, for tablets, capsules, liquid orals, parenteral and semisolid preparations.

Scale up: Importance, Technology transfer from R & D to pilot plant to plant scale, process scale up for tablets, capsules, liquid orals, semisolids, parenteral, NDDS products – stress on formula, equipments, product uniformity, stability, raw materials, physical layout, input, in-process and finished product specifications, problems encountered during transfer of technology

2 Validation: General concepts, types, procedures & protocols, documentation, VMF. Analytical method validation, cleaning validation and vendor qualification.


4 Process validation: Importance, validation of mixing, granulation, drying, compression, tablet coating, liquid filling and sealing, sterilization, water process systems, environmental control.
Industrial safety: Hazards – fire, mechanical, electrical, 12 chemical and pharmaceutical, Monitoring & prevention systems, Hrs industrial effluent testing & treatment. Control of environmental pollution.

REFERENCES
1. Pharmaceutical process validation, JR Berry, Nash, Vol 57, Marcel Dekker, NY.
3. Pharmaceutical project management, T.Kennedy, Vol 86, Marcel Dekker, NY.
5. Tablet machine instruments in pharmaceuticals, PR Watt, John Wiloy.
6. Pharmaceutical dosage forms, Tablets, Vol 1, 2, 3 by Lachman, Lieberman, Marcel Dekker, NY.
7. Pharmaceutical dosage forms, Parentral medications, Vol 1, 2 by K.E. Avis, Marcel Dekker, NY.
8. Dispersed system Vol 1, 2, 3 by Lachman, Lieberman, Marcel Dekker, NY.
PHARMACEUTICAL PRODUCTION TECHNOLOGY
(MIP 203T)

Scope
This course is designed to impart knowledge and skills necessary to train the students to be on par with the routine of Industrial activities in Production.

Objectives
On completion of this course it is expected that students will be able to understand,
- Handle the scheduled activities in a Pharmaceutical firm.
- Manage the production of large batches of pharmaceutical formulations.

THEORY 60 Hrs

Improved Tablet Production: Tablet production process, unit 12 Hrs

1. Operation improvements, granulation and pelletization equipments, continuous and batch mixing, rapid mixing granulators, rota granulators, spheronizers and marumerisers, and other specialized granulation and drying equipments. Problems encountered.


2 Parenteral Production: Area planning & environmental control, 12 Hrs
wall and floor treatment, fixtures and machineries, change rooms, personnel flow, utilities & utilities equipment location, engineering and maintenance.

3 Lyophilization & Spray drying Technology: Principles, 12 Hrs
process, freeze-drying and spray drying equipments.

4 Capsule Production: Production process, improved capsule manufacturing and filling machines for hard and soft gelatin capsules. Layout and problems encountered.

Disperse Systems Production: Production processes, applications of mixers, mills, disperse equipments including fine solids dispersion, problems encountered.
Packaging Technology: Types of packaging materials, machinery, labeling, package printing for different dosage forms.


REFERENCES
1. The Theory & Practice of Industrial Pharmacy, L. Lachman, Varghese Publ, Bombay.
2. Modern Pharmaceutics by Banker, Vol 72, Marcel Dekker, NY.
3. Pharmaceutical Dosage Forms, Vol 1, 2, 3 by Lachman, Lieberman, Marcel Dekker, NY.
4. Pharmaceutical Dosage Forms, Parenteral medications, Vol 1, 2 by K.E. Avis, Marcel Dekker, NY.
6. Dispersed System Vol 1, 2, 3 by Lachman, Lieberman, Marcel Dekker, NY.
7. Product design and testing of polymeric materials by N.P. Chezerisionoff.
10. Quality Control of Packaging Materials in Pharmaceutical Industry, Kharburn, Marcel Dekker, NY.
12. Tablet Machine Instrumentation In Pharmaceuticals, PR Watt, Ellis Horwoods, UK.
ENTREPRENEURSHIP MANAGEMENT
(MIP 204T)

Scope
This course is designed to impart knowledge and skills necessary to train the students on entrepreneurship management.

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

- The Role of enterprise in national and global economy
- Dynamics of motivation and concepts of entrepreneurship
- Demands and challenges of Growth Strategies And Networking

THEORY 60 Hrs


2 Entrepreneur: Entrepreneurial motivation – dynamics of motivation. Entrepreneurial competency -Concepts. Developing Entrepreneurial competencies – requirements and understanding the process of entrepreneurship development, self-awareness, interpersonal skills, creativity, assertiveness, achievement, factors affecting entrepreneur role.


Preparing Project Proposal To Start On New Enterprise

Project work – Feasibility report; Planning, resource mobilisation and implementation.

REFERENCES

INDUSTRIAL PHARMACY PRACTICAL - II
(MIP 205P)

1. Improvement of dissolution characteristics of slightly soluble drug by Solid dispersion technique.
2. Comparison of dissolution of two different marketed products / brands
3. Protein binding studies of a highly protein bound drug & poorly protein bound drug
5. Pharmacokinetic and IVIVC data analysis by WinnolineR software
6. In vitro cell studies for permeability and metabolism
7. Formulation and evaluation of tablets
8. Formulation and evaluation of capsules
9. Formulation and evaluation of injections
10. Formulation and evaluation of emulsion
11. Formulation and evaluation of suspension.
12. Formulation and evaluation of enteric coating tablets.
13. Preparation and evaluation of a freeze dried formulation.
PHARMACEUTICALCHEMISTRY(MPC)

MODERN PHARMACEUTICAL ANALYTICAL TECHNIQUES
(MPC 101T)

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

Objectives
After completion of course student is able to know about chemicals and excipients
- The analysis of various drugs in single and combination dosage forms
- Theoretical and practical skills of the instruments

THEORY 60 Hrs

   b. IR spectroscopy: Theory, Modes of Molecular vibrations, Sample handling, Instrumentation of Dispersive and Fourier – Transform IR Spectrometer, Factors affecting vibrational frequencies and Applications of IR spectroscopy, Data Interpretation.
   c. Spectrofluorimetry: Theory of Fluorescence, Factors affecting fluorescence (Characteristics of drugs that can be analysed by fluorimetry), Quenchers, Instrumentation and Applications of fluorescence spectrophotometer.

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

4 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

5 a.Electrophoresis: Principle, Instrumentation, Working conditions, factors affecting separation and applications of the following:
   a) Paper electrophoresis b) Gel electrophoresis c) Capillary electrophoresis d) Zone electrophoresis e) Moving boundary electrophoresis f) Iso electric focusing
   b) X-ray Crystallography: Production of X rays, Different X ray methods, Bragg’s law, Rotating crystal technique, X ray powder technique, Types of crystals and applications of X-ray diffraction.


   b. 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
ADVANCED ORGANIC CHEMISTRY - I  
(MPC 102T)

Scope
The subject is designed to provide in-depth knowledge about advances in organic chemistry, different techniques of organic synthesis and their applications to process chemistry as well as drug discovery.

Objectives

Upon completion of course, the student shall be to understand

- The principles and applications of retrosynthesis
- The mechanism & applications of various named reactions
- The concept of disconnection to develop synthetic routes for small target molecule.
- The various catalysts used in organic reactions
- The chemistry of heterocyclic compounds

THEORY 60 Hrs

1. Basic Aspects of Organic Chemistry: 12 Hrs
   2. Types of reaction mechanisms and methods of determining them,
   3. Detailed knowledge regarding the reactions, mechanisms and their relative reactivity and orientations.

Addition reactions

a) Nucleophilic uni- and bimolecular reactions (SN1 and SN2)

b) Elimination reactions (E1 & E2; Hoffman & Saytzeff’s rule)

c) Rearrangement reaction

2 Study of mechanism and synthetic applications of following named Reactions: 12 Hrs

Ugi reaction, Brook rearrangement, Ullmann coupling reactions, Dieckmann Reaction, Doebner–Miller Reaction, Sandmeyer Reaction, Mitsunobu reaction, Mannich reaction, Vilsmeier–Haack Reaction, Sharpless asymmetric epoxidation, Baeyer–Villiger oxidation, Shapiro & Suzuki reaction, Ozonolysis and Michael addition reaction
3 Synthetic Reagents & Applications:
Aluminiumisopropoxide, N-bromosuccinamide, diazomethane, dicyclocexylcarbodiimide, Wilkinson reagent, Witting reagent.
Osmium tetroxide, titanium chloride, diazopropane, diethyl azodicarboxylate, Triphenylphosphine, Benzotriazol–1–yloxy) tris (dimethylamino) phosphonium hexafluoro–phosphate (BOP).

Protecting groups
a. Role of protection in organic synthesis
b. Protection for the hydroxyl group, including 1,2- and 1,3-diols: ethers, esters, carbonates, cyclic acetals & ketals
c. Protection for the Carbonyl Group: Acetals and Ketals
d. Protection for the Carboxyl Group: amides and hydrazides, esters
e. Protection for the Amino Group and Amino acids: carbamates and amides

4 Heterocyclic Chemistry:
Organic Name reactions with their respective mechanism and application involved in synthesis of drugs containing five, six membered and fused heterocyclcs such as Debus–Radziszewski imidazole synthesis, Knorr Pyrazole Synthesis Pinner Pyrimidine Synthesis, Combes Quinoline Synthesis, Bernthesen Acridine Synthesis, Smiles rearrangement and Traube purine synthesis.

Synthesis of few representative drugs containing these heterocyclic nucleus such as Ketoconazole, Metronidazole, Miconazole, celecoxib, antipyrin, Metamizole sodium, Terconazole, Alprazolam, Triamterene, Sulfamerazine, Trimethoprim, Hydroxychloroquine, Quinine, Chloroquine, Quinacrine, Amsacrine, Prochlorperazine, Promazine, Chlorpromazine, Theophylline , Mercaptapurine and Thioguanine.

5 Synthon approach and retrosynthesis applications
i. Basic principles, terminologies and advantages of Hrs retrosynthesis; guidelines for dissection of molecules. Functional group interconversion and addition (FGI and FGA)
ii. C-X disconnections; C-C disconnections – alcohols and carbonyl compounds; 1,2-, 1,3-,1,4-, 1,5-, 1,6-difunctionalized compounds
iii. Strategies for synthesis of three, four, five and six-membered ring.
REFERENCES
ADVANCED MEDICINAL CHEMISTRY
(MPC 103T)

Scope
The subject is designed to impart knowledge about recent advances in the field of medicinal chemistry at the molecular level including different techniques for the rational drug design.

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

- Different stages of drug discovery
- Role of medicinal chemistry in drug research
- Different techniques for drug discovery
- Various strategies to design and develop new drug like molecules for biological targets
- Peptidomimetics

THEORY 60 Hrs

1. Drug discovery: Stages of drug discovery, lead discovery; identification, validation and diversity of drug targets. 12 Hrs

Biological drug targets: Receptors, types, binding and activation, theories of drug receptor interaction, drug receptor interactions, agonists vs antagonists, artificial enzymes.

2. Prodrug Design and Analog design: 12 Hrs
   a) Prodrug design: Basic concept, Carrier linked prodrugs/ Bioprecursors, Prodrugs of functional group, 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.

   b) Combating drug resistance: Causes for drug resistance, strategies to combat drug resistance in antibiotics and anticancer therapy, Genetic principles of drug resistance.

   c) Analog Design: Introduction, Classical & Non classical, Bioisosteric replacement strategies, rigid analogs,
alteration of chain branching, changes in ring size, ring position isomers, design of stereo isomers and geometric isomers, fragments of a lead molecule, variation in inter atomic distance.

3 a) Medicinal chemistry aspects of the following class of drugs 12 Hrs

Systematic study, SAR, Mechanism of action and synthesis of new generation molecules of following class of drugs:

a) Anti-hypertensive drugs, Psychoactive drugs, Anticonvulsant drugs, H1 & H2 receptor antagonist, COX1 & COX2 inhibitors, Adrenergic & Cholinergic agents, Antineoplastic and Antiviral agents.

b) Stereochemistry and Drug action: Realization that stereo selectivity is a pre-requisite for evolution. Role of chirality in selective and specific therapeutic agents. Case studies, Enantio selectivity in drug adsorption, metabolism, distribution and elimination.

4 Rational Design of Enzyme Inhibitors 12 Hrs

Enzyme kinetics & Principles of Enzyme inhibitors, Enzyme inhibitors in medicine, Enzyme inhibitors in basic research, rational design of non-covalently and covalently binding enzyme inhibitors.

5 Peptidomimetics 12 Hrs

Therapeutic values of Peptidomimetics, design of peptidomimetics by manipulation of the amino acids, modification of the peptide backbone, incorporating conformational constraints locally or globally. Chemistry of prostaglandins, leukotrienes and thromboxones.

REFERENCES

1. Medicinal Chemistry by Burger, Vol I - VI.
3. Comprehensive Medicinal Chemistry - Corwin and Hansch.
4. Computational and structural approaches to drug design edited by Robert M Stroud and Janet. F Moore
5. Introduction to Quantitative Drug Design by Y.C. Martin.
CHEMISTRY OF NATURAL PRODUCTS
(MPC 104T)

Scope
The subject is designed to provide detail knowledge about chemistry of medicinal compounds from natural origin and general methods of structural elucidation of such compounds. It also emphasizes on isolation, purification and characterization of medicinal compounds from natural origin.

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

- Different types of natural compounds and their chemistry and medicinal importance
- The importance of natural compounds as lead molecules for new drug discovery
- The concept of rDNA technology tool for new drug discovery
- General methods of structural elucidation of compounds of natural origin
- Isolation, purification and characterization of simple chemical constituents from natural source

THEORY

1. Study of Natural products as leads for new pharmaceuticals for the following class of drugs
   a) Drugs Affecting the Central Nervous System: Morphine Alkaloids
   b) Anticancer Drugs: Paclitaxel and Docetaxel, Etoposide, and Teniposide
   c) Cardiovascular Drugs: Lovastatin, Teprotide and Dicoumarol
   d) Neuromuscular Blocking Drugs: Curare alkaloids
   e) Anti-malarial drugs and Analogues
   f) Chemistry of macrolid antibiotics (Erythromycin, Azithromycin, Roxithromycin, and Clarithromycin) and β-Lactam antibiotics (Cephalosporins and Carbapenem)

2. Alkaloids
   General introduction, classification, isolation, purification, molecular modification and biological activity of alkaloids, general methods of structural determination of alkaloids, structural elucidation and stereochemistry of ephedrine, morphine, ergot, emetine and reserpine.
b) Flavonoids
Introduction, isolation and purification of flavonoids, General methods of structural determination of flavonoids; Structural elucidation of quercetin.

c) Steroids
General introduction, chemistry of sterols, sapogenin and cardiac glycosides. Stereochemistry and nomenclature of steroids, chemistry of contraceptive agents male & female sex hormones (Testosterone, Estradiol, Progesterone), adrenocorticoids (Cortisone), contraceptive agents and steroids (Vit - D).

3 a) Terpenoids 12 Hrs
Classification, isolation, isoprene rule and general methods of structural elucidation of Terpenoids; Structural elucidation of drugs belonging to mono (citol, menthol, camphor), di(retinol, Phytol, taxol) and tri terpenoids (Squalene,Ginsenoside) carotinoids (β carotene).

b) Vitamins
Chemistry and Physiological significance of Vitamin A, B1, B2, B12, C, E, Folic acid and Niacin.

4 a). Recombinant DNA technology and drug discovery 12 Hrs
rDNA technology, hybridoma technology, New pharmaceuticals derived from biotechnology; Oligonucleotide therapy. Gene therapy: Introduction, Clinical application and recent advances in gene therapy, principles of RNA & DNA estimation

b). Active constituent of certain crude drugs used in Indigenous system Diabetic therapy – Gymnema sylvestre, Salacia reticulate, Pterocarpus marsupiam, Swertia chirata, Trigonella foenum graccum; Liver dysfunction – Phyllanthus niruri; Antitumor – Curcuma longa Linn.

5 Structural Characterization of natural compounds 12 Hrs
Structural characterization of natural compounds using IR, 1HNMR, 13CNMR and MS Spectroscopy of specific drugs e.g., Penicillin, Morphine, Camphor, Vit-D, Quercetin and Digitalis glycosides.
REFERENCES
4. Chemistry of natural products Vol I onwards IWPAC.
8. Introduction to molecular Phytochemistry – CHJ Wells, Chapmannstall.
16. Burger’s Medicinal Chemistry.
PHARMACEUTICAL CHEMISTRY PRACTICAL - I  
(MPC 105P)

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

To perform the following reactions of synthetic importance
1. Purification of organic solvents, column chromatography
2. Claisen-schimdt reaction.
3. Benzylic acid rearrangement.
5. Hoffmann rearrangement
6. Mannich reaction
7. Synthesis of medicinally important compounds involving more than one step along with purification and Characterization using TLC, melting point and IR spectroscopy (4 experiments)
8. Estimation of elements and functional groups in organic natural compounds
9. Isolation, characterization like melting point, mixed melting point, molecular weight determination, functional group analysis, co-chromatographic technique for identification of isolated compounds and interpretation of UV and IR data.
10. Some typical degradation reactions to be carried on selected plant constituents
ADVANCED SPECTRAL ANALYSIS  
(MPC 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
At completion of this course it is expected that students will be able to understand-

- 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

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<tbody>
<tr>
<td>1. UV and IR spectroscopy:</td>
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<tr>
<td>Wood ward – Fieser rule for 1,3- butadienes, cyclic dienes and α, β-carbonyl compounds and interpretation compounds of enones. ATR–IR, IR Interpretation of organic compounds. 12 Hrs</td>
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<td>2 NMR spectroscopy:</td>
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<tr>
<td>1-D and 2-D NMR, NOESY and COSY, HECTOR, INADEQUATE techniques, Interpretation of organic compounds.</td>
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<td>3 Mass Spectroscopy</td>
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<td>Mass fragmentation and its rules, Fragmentation of important functional groups like alcohols, amines, carbonyl groups and alkanes, Meta stable ions, Mc Lafferty rearrangement, Ring rule, Isotopic peaks, Interpretation of organic compounds.</td>
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<td>4 Chromatography:</td>
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<td>Principle, Instrumentation and Applications of the following :</td>
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<tr>
<td>a) GC-MS  b) GC-AAS  c) LC-MS  d) LC-FTIR  e) LC-NMR  f) CE-MS  g) High Performance Thin Layer chromatography  h) Super critical fluid chromatography  i) Ion Chromatography  j) I-EC (Ion-Exclusion Chromatography)  k) Flash chromatography</td>
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</table>
a). Thermal methods of analysis
Introduction, principle, instrumentation and application of DSC, DTA and TGA.

b). Raman Spectroscopy
Introduction, Principle, Instrumentation and Applications.

c). Radio immuno assay
Biological standardization, bioassay, ELISA, Radioimmuno assay of digitalis and insulin.

REFERENCES
1. Spectrometric Identification of Organic compounds – Robert M Silverstein,
2. Principles of Instrumental Analysis – Douglas A Skoog, F. James Holler,
6. Quantitative Analysis of Drugs in Pharmaceutical formulation – P D Sethi,
7. Pharmaceutical Analysis- Modern methods – Part B – J W Munson,
   Volume 11, Marcel Dekker Series
ADVANCED ORGANIC CHEMISTRY - II  
(MPC 202T)

Scope
The subject is designed to provide in-depth knowledge about advances in organic chemistry, different techniques of organic synthesis and their applications to process chemistry as well as drug discovery.

Objectives
Upon completion of course, the student shall able to understand
- The principles and applications of Green chemistry
- The concept of peptide chemistry.
- The various catalysts used in organic reactions
- The concept of stereochemistry and asymmetric synthesis.

THEORY  60 Hrs
1. Green Chemistry:  12 Hrs
   a. Introduction, principles of green chemistry
   b. Microwave assisted reactions: Merit and demerits of its use, increased reaction rates, mechanism, superheating effects of microwave, effects of solvents in microwave assisted synthesis, microwave technology in process optimization, its applications in various organic reactions and heterocycles synthesis
   c. Ultrasound assisted reactions: Types of sonochemical reactions, homogenous, heterogeneous liquid-liquid and liquid-solid reactions, synthetic applications
   d. Continuous flow reactors: Working principle, advantages and synthetic applications.
2. Chemistry of peptides  12 Hrs
   a. Coupling reactions in peptide synthesis
   b. Principles of solid phase peptide synthesis, t-BOC and FMOC protocols, various solid supports and linkers: Activation procedures, peptide bond formation, deprotection and cleavage from resin, low and high HF cleavage protocols, formation of free peptides and peptide amides, purification and case studies, site-specific chemical modifications of peptides
   c. Segment and sequential strategies for solution phase peptide synthesis with any two case studies
   d. Side reactions in peptide synthesis: Deletion peptides, side
reactions initiated by proton abstraction, protonation, over-activation and side reactions of individual amino acids.

3 Photochemical Reactions
Basic principles of photochemical reactions. Photo-oxidation, photo-addition and photo-fragmentation.

Pericyclic reactions
Mechanism, Types of pericyclic reactions such as cyclo addition, electrocyclic reaction and sigmatropic rearrangement reactions with examples

4 Catalysis:
   a. Types of catalysis, heterogeneous and homogenous catalysis, advantages and disadvantages
   b. Heterogeneous catalysis – preparation, characterization, kinetics, supported catalysts, catalyst deactivation and regeneration, some examples of heterogeneous catalysis used in synthesis of drugs.
   c. Homogenous catalysis, hydrogenation, hydroformylation, hydrocyanation, Wilkinson catalysts, chiral ligands and chiral induction, Ziegler-Natta catalysts, some examples of homogenous catalysis used in synthesis of drugs
   d. Transition–metal and Organo–catalysis in organic synthesis: Metal–catalyzed reactions
   f. Phase transfer catalysis - theory and applications

5 Stereochemistry & Asymmetric Synthesis
   a. Basic concepts in stereochemistry – optical activity, specific rotation, racemates and resolution of racemates, the Cahn, Ingold, Prelog (CIP) sequence rule, meso compounds, pseudo asymmetric centres, axes of symmetry, Fischers D and L notation, cis–trans isomerism, E and Z notation.
   b. Methods of asymmetric synthesis using chiral pool, chiral auxiliaries and catalytic asymmetric synthesis, enantiopure separation and Stereo selective synthesis with examples.
REFERENCES
6. Organic synthesis—the disconnection approach, S. Warren, Wily India
7. Principles of organic synthesis, ROCNorman and JMCoxan, Nelson thorns
COMPUTER AIDED DRUG DESIGN
(MPC 203T)

Scope
The subject is designed to impart knowledge on the current state of the art techniques involved in computer assisted drug design.

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

- Role of CADD in drug discovery
- Different CADD techniques and their applications
- Various strategies to design and develop new drug like molecules.
- Working with molecular modeling softwares to design new drug molecules
- The in silico virtual screening protocols

Theory

1. Introduction to Computer Aided Drug Design (CADD)  
   History, different techniques and applications.  
   Quantitative Structure Activity Relationships: Basics
   History and development of QSAR: Physicochemical parameters and methods to calculate physicochemical parameters: Hammett equation and electronic parameters (sigma), lipophilicity effects and parameters (log P, pi-substituent constant), steric effects (Taft steric and MR parameters) Experimental and theoretical approaches for the determination of these physicochemical parameters.

2. Quantitative Structure Activity Relationships: Applications  
   Hansch analysis, Free Wilson analysis and relationship between them, Advantages and disadvantages; Deriving 2D-QSAR equations.  
   3D-QSAR approaches and contour map analysis.  
   Statistical methods used in QSAR analysis and importance of statistical parameters.

3. Molecular Modeling and Docking
   a) Molecular and Quantum Mechanics in drug design.
   b) Energy Minimization Methods: comparison between global
minimum conformation and bioactive conformation

c) Molecular docking and drug receptor interactions: Rigid docking, flexible docking and extra-precision docking. Agents acting on enzymes such as DHFR, HMG-CoA reductase and HIV protease, choline esterase (AchE & BchE)

4 Molecular Properties and Drug Design

a) Prediction and analysis of ADMET properties of new molecules and its importance in drug design.
b) De novo drug design: Receptor/enzyme-interaction and its analysis, Receptor/enzyme cavity size prediction, predicting the functional components of cavities, Fragment based drug design.
c) Homology modeling and generation of 3D-structure of protein.

5 Pharmacophore Mapping and Virtual Screening

Concept of pharmacophore, pharmacophore mapping, identification of Pharmacophore features and Pharmacophore modeling; Conformational search used in pharmacophore mapping.

In Silico Drug Design and Virtual Screening Techniques

Similarity based methods and Pharmacophore based screening, structure based In-silico virtual screening protocols.

REFERENCES

2. Introduction to Quantitative Drug Design by Y.C. Martin, CRC Press, Taylor & Francis group..
10. Computational and structural approaches to drug design edited by Robert M Stroud and Janet. F Moore
PHARMACEUTICAL PROCESS CHEMISTRY  
(MPC 204T)

Scope
Process chemistry is often described as scale up reactions, taking them from small quantities created in the research lab to the larger quantities that are needed for further testing and then to even larger quantities required for commercial production. The goal of a process chemist is to develop synthetic routes that are safe, cost-effective, environmentally friendly, and efficient. The subject is designed to impart knowledge on the development and optimization of a synthetic route/s and the pilot plant procedure for the manufacture of Active Pharmaceutical Ingredients (APIs) and new chemical entities (NCEs) for the drug development phase.

Objectives
At completion of this course it is expected that students will be able to understand
- The strategies of scale up process of APIs and intermediates
- The various unit operations and various reactions in process chemistry

THEORY  
60 Hrs
1. Process chemistry  
   Introduction, Synthetic strategy  
   Stages of scale up process: Bench, pilot and large scale process.  
   In-process control and validation of large scale process.  
   Case studies of some scale up process of APIs.  
   Impurities in API, types and their sources including genotoxic impurities

2 Unit operations  
   a) Extraction: Liquid equilibria, extraction with reflux, extraction with agitation, counter current extraction.  
   b) Filtration: Theory of filtration, pressure and vacuum filtration, centrifugal filtration,  
   c) Distillation: Azeotropic and steam distillation  
   d) Evaporation: Types of evaporators, factors affecting evaporation.  
   e) Crystallization: Crystallization from aqueous, non-aqueous solutions factors affecting crystallization, nucleation. Principle and general methods of Preparation of polymorphs, hydrates, solvates and amorphous APIs.
3 Unit Processes - I
   a) Nitrating: Nitrating agents, Aromatic nitration, kinetics and mechanism of aromatic nitrations, process equipment for technical nitration, mixed acid for nitration,
   b) Halogenation: Kinetics of halogenations, types of halogenations, catalytic halogenations. Case study on industrial halogenation process.
   c) Oxidation: Introduction, types of oxidative reactions, Liquid phase oxidation with oxidizing agents. Nonmetallic Oxidizing agents such as H₂O₂, sodium hypochlorite, Oxygen gas, ozonolysis.

4 Unit Processes - II
   a) Reduction: Catalytic hydrogenation, Heterogeneous and homogeneous catalyst; Hydrogen transfer reactions, Metal hydrides. Case study on industrial reduction process.
   b) Fermentation: Aerobic and anaerobic fermentation. Production of
      i. Antibiotics; Penicillin and Streptomycin,
      ii. Vitamins: B2 and B12
      iii. Statins: Lovastatin, Simvastatin
   c) Reaction progress kinetic analysis
      i. Streamlining reaction steps, route selection,
      ii. Characteristics of expedient routes, characteristics of cost–effective routes, reagent selection, families of reagents useful for scale–up.

5 Industrial Safety
   a) MSDS (Material Safety Data Sheet), hazard labels of chemicals and Personal Protection Equipment (PPE)
   b) Fire hazards, types of fire & fire extinguishers
   c) Occupational Health & Safety Assessment Series 1800 (OHSAS-1800) and ISO-14001(Environmental Management System), Effluents and its management
REFERENCES
8. P.H.Groggins: Unit processes in organic synthesis (MGH)
9. F.A.Henglein: Chemical Technology (Pergamon)
12. Lowenheim & M.K. Moran: Industrial Chemicals
17. ICH Guidelines
18. United States Food and Drug Administration official website www.fda.gov
PHARMACEUTICAL CHEMISTRY PRACTICALS – II  
(MPC 205P)

1. Synthesis of organic compounds by adapting different approaches involving (3 experiments)
   a) Oxidation
   b) Reduction/hydrogenation
   c) Nitration
2. Comparative study of synthesis of APIs/intermediates by different synthetic routes (2 experiments)
3. Assignments on regulatory requirements in API (2 experiments)
4. Comparison of absorption spectra by UV and Wood ward – Fieser rule
5. Interpretation of organic compounds by FT–IR
6. Interpretation of organic compounds by NMR
7. Interpretation of organic compounds by MS
8. Determination of purity by DSC in pharmaceuticals
9. Identification of organic compounds using FT–IR, NMR, CNMR and Mass spectra
10. To carry out the preparation of following organic compounds
13. NaBH₄ reduction of vanillin to vanillyl alcohol
14. Preparation of umbelliferone by Pechhman reaction
15. Preparation of triphenyl imidazole
16. To perform the Microwave irradiated reactions of synthetic importance  
    (Any two)
17. Determination of log P, MR, hydrogen bond donors and acceptors of 
    selected drugs using softwares
18. Calculation of ADMET properties of drug molecules and its analysis using 
    softwares
    Pharmacophore modeling
19. 2D-QSAR based experiments
20. 3D-QSAR based experiments
21. Docking study based experiment
22. Virtual screening based experiment
PHARMACEUTICAL ANALYSIS (MPA)

MODERN PHARMACEUTICAL ANALYTICAL TECHNIQUES
(MPA 101T)

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

Objectives
After completion of course student is able to know about chemicals and excipients

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

THEORY

1. a. UV-Visible spectroscopy: Introduction, Theory, Laws, 10 Hrs
   b. IR spectroscopy: Theory, Modes of Molecular vibrations, Sample handling, Instrumentation of Dispersive and Fourier – Transform IR Spectrometer, Factors affecting vibrational frequencies and Applications of IR spectroscopy, Data Interpretation.
   c. Spectrofluorimetry: Theory of Fluorescence, Factors affecting fluorescence (Characteristics of drugs that can be analysed by fluorimetry), Quenchers, Instrumentation and Applications of fluorescence spectrophotometer.

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

3  Mass Spectroscopy: Principle, Theory, Instrumentation of Mass
Spectroscopy, Different types of ionization like electron impact, chemical, field, FAB and MALDI, APCI, ESI, APPI Analyzers of Quadrupole and Time of Flight, Mass fragmentation and its rules, Meta stable ions, Isotopic peaks and Applications of Mass spectroscopy.

4 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

5 a. Electrophoresis: Principle, Instrumentation, Working conditions, factors affecting separation and applications of the following:
   a) Paper electrophoresis b) Gel electrophoresis c) Capillary electrophoresis d) Zone electrophoresis e) Moving boundary electrophoresis f) Iso electric focusing
   b. X ray Crystallography: Production of X rays, Different X ray methods, Bragg's law, Rotating crystal technique, X ray powder technique, Types of crystals and applications of X-ray diffraction


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
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.

Objective
After completion of the course students shall 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 Hrs
1. 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

2. 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.

3 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

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

5 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)

6 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
9. Methods of sampling and microbiological examination of water, first revision, BIS
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
- Carry out validation of manufacturing processes
- Apply the knowledge of validation to instruments and equipments
- Validate the manufacturing facilities

THEORY  
60 Hrs


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

5 General Principles of Intellectual Property: Concepts of Intellectual Property (IP), Intellectual Property Protection (IPP), Intellectual Property Rights (IPR); Economic importance, mechanism for protection of Intellectual Property—patents, Copyright, Trademark; Factors affecting choice of IP protection; Penalties for violation; Role of IP in pharmaceutical industry; Global ramifications 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
3. Validation Master plan by Terveeks or Deeks, Davis Harwood International publishing.
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 Hrs

1. 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.

2. 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.

   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.

4 General Analytical methods for milk, milk constituents and milk 12
products like ice cream, milk powder, butter, margarine, cheese Hrs
including adulterants and contaminants of milk.
Analysis of fermentation products like wine, spirits, beer and
vinegar.

5 Pesticide analysis: Effects of pest and insects on various food, 12
use of pesticides in agriculture, pesticide cycle, Hrs
organophosphorus and organochlorine 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, FDA and US-FDA.

REFERENCES
1. The chemical analysis of foods – David Pearson, Seventh edition,
2. Introduction to the Chemical analysis of foods – S. Nielsen, Jones &
4. Analysis of Food constituents – Multon, Wiley VCH.
5. Dr. William Horwitz, Official methods of analysis of AOAC International,
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.
9. Quantitative determination of hydroxyl group.
10. Quantitative determination of amino group
11. Colorimetric determination of drugs by using different reagents
12. Impurity profiling of drugs
13. Calibration of glasswares
14. Calibration of pH meter
15. Calibration of UV–Visible spectrophotometer
16. Calibration of FTIR spectrophotometer
17. Calibration of GC instrument
18. Calibration of HPLC instrument
19. Cleaning validation of any one equipment
20. Determination of total reducing sugar
21. Determination of proteins
22. Determination of saponification value, Iodine value, Peroxide value, Acid value in food products
23. Determination of fat content and rancidity in food products
24. Analysis of natural and synthetic colors in food
25. Determination of preservatives in food
26. Determination of pesticide residue in food products
27. Analysis of vitamin content in food products
28. Determination of density and specific gravity of foods
29. Determination of food additives
ADVANCED INSTRUMENTAL ANALYSIS
(MPIA 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, and hyphenated techniques.

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

1. 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.

2. 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.
   High performance Thin Layer 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.

4 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 (Quadrpole, 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).

5 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
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 Hrs

1. Extraction of drugs and metabolites from biological matrices: 12 Hrs
   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.

2. Biopharmaceutical Consideration: 12 Hrs

3. Pharmacokinetics and Toxicokinetics: 12 Hrs

4. Cell culture techniques 12 Hrs
   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.


Drug Product Performance, In Vivo: Bioavailability and Bioequivalence:

REFERENCES
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
1. 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.
   12 Hrs

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

3. Analysis of raw materials, finished products, packaging materials, in process quality control (IPQC), Developing specification (ICH Q6 and Q3)
   12 Hrs
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.

4. Documentation in pharmaceutical industry: Three tier documentation, Policy, Procedures and Work instructions, and records (Formats), Basic principles– How to maintain, retention and retrieval etc. Standard operating procedures (How to write), Master Formula Record, Batch Formula Record, Quality audit plan and reports. Specification and test procedures, Protocols and reports. Distribution records. Electronic data.

5. Manufacturing operations and controls: Sanitation of manufacturing premises, mix-ups and cross contamination, processing of intermediates and bulk products, packaging operations, IPQC, release of finished product, process deviations, charge in of components, time limitations on production, drug product inspection, expiry date calculation, calculation of yields, production record review, change control, sterile products, aseptic process control, packaging.

REFERENCES

7. ICH guidelines
8. ISO 9000 and total quality management
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 herbal remedies and regulations
- Analysis of natural products and monographs
- Determination of Herbal drug–drug interaction
- Principles of performance evaluation of cosmetic products.

THEORY  
60 Hrs

12 Hrs

12 Hrs

3. 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.  
12 Hrs

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.

4 Herbal drug-drug interaction: WHO and AYUSH guidelines for safety monitoring of natural medicine, Spontaneous reporting 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.

5 Evaluation of cosmetic products: Determination of acid value, ester value, saponification value, iodine value, peroxide value, 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
4. Pharmacognosy & Pharmacobiotechnology by Ashutosh Kar
5. Essential of Pharmacognosy by Dr.S.H.Ansari
8. Indian Standard specification for 28 finished cosmetics BIS, New Delhi
9. Harry’s Cosmetology 8th edition
10.Suppliers catalogue on specialized cosmetic excipients
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).
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
20. Determination of foam height and SLS content of Shampoo.
21. Determination of total fatty matter in creams (Soap, skin and hair creams)
22. Determination of acid value and saponification value.
23. Determination of calcium thioglycolate in depilatories
PHARMACEUTICAL QUALITY ASSURANCE (MQA)

MODERN PHARMACEUTICAL ANALYTICAL TECHNIQUES
(MQA 101T)

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

Objectives
After completion of course student is able to know about chemicals and excipients

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

THEORY

b. IR spectroscopy: Theory, Modes of Molecular vibrations, Sample handling, Instrumentation of Dispersive and Fourier – Transform IR Spectrometer, Factors affecting vibrational frequencies and Applications of IR spectroscopy, Data Interpretation.
c. Spectrofluorimetry: Theory of Fluorescence, Factors affecting fluorescence (Characteristics of drugs that can be analysed by fluorimetry), Quenchers, Instrumentation and Applications of fluorescence spectrophotometer.

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

60 Hrs

12 Hrs

4 Chromatography: Principle, apparatus, instrumentation, chromatographic parameters, factors affecting resolution, isolation of drug from excipients, data interpretation and applications of the following:
   - Thin Layer chromatography
   - High Performance Thin Layer Chromatography
   - Ion exchange chromatography
   - Column chromatography
   - Gas chromatography
   - High Performance Liquid chromatography
   - Ultra High Performance Liquid chromatography
   - Affinity chromatography
   - Gel Chromatography

5 a. Electrophoresis: Principle, Instrumentation, Working conditions, factors affecting separation and applications of the following:
   a) Paper electrophoresis b) Gel electrophoresis c) Capillary electrophoresis d) Zone electrophoresis e) Moving boundary electrophoresis f) Iso electric focusing
   b. X ray Crystallography: Production of X rays, Different X ray methods, Bragg's law, Rotating crystal technique, X ray powder technique, Types of crystals and applications of X-ray diffraction.

   b. 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
QUALITY MANAGEMENT SYSTEMS
(MQA 102T)

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

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

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

THEORY

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

3 Six System Inspection model: Quality Management system, Production system, Facility and Equipment system, Laboratory control system, Materials system, Packaging and labeling system. Concept of self inspection.

Quality risk management: Introduction, risk assessment, risk control, risk review, risk management tools, HACCP, risk ranking and filtering according to ICH Q9 guidelines.

5 Statistical Process control (SPC): Definition and Importance of SPC, Quality measurement in manufacturing, Statistical control charts – concepts and general aspects, Advantages of statistical control, Process capability, Estimating Inherent or potential capability from a control chart analysis, Measuring process control and quality improvement, Pursuit of decreased process variability.

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

1. Implementing Juran's Road Map for Quality Leadership: Benchmarks and Results, By Al Endres, Wiley, 2000
2. Understanding, Managing and Implementing Quality: Frameworks, Techniques and Cases, By Jiju Antony; David Preece, Routledge, 2002
QUALITY CONTROL AND QUALITY ASSURANCE  
(MQA 103T)

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

Objectives
Upon completion of this course the student should be able to
- Understand the cGMP aspects in a pharmaceutical industry
- To appreciate the importance of documentation
- To understand the scope of quality certifications applicable to Pharmaceutical industries
- To understand the responsibilities of QA & QC departments.

THEORY

1. Introduction: Concept and evolution and scopes of Quality Control and Quality Assurance, Good Laboratory Practice, GMP, Overview of ICH Guidelines – QSEM, with special emphasis on 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. CPCSEA guidelines.

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

3. Analysis of raw materials, finished products, packaging materials, in process quality control (IPQC), Developing specification (ICH Q6 and Q3), purchase specifications and maintenance of stores for raw materials.
In process quality control and finished products quality control for following dosage forms in Pharma industry according to Indian, US and British pharmacopoeias: tablets, capsules, ointments, suppositories, creams, parenterals, ophthalmic and surgical products (How to refer pharmacopoeias).

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

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

REFERENCES
7. ICH guidelines
8. ISO 9000 and total quality management
14. Packaging of Pharmaceuticals.
15. Schedule M and Schedule N.
PRODUCT DEVELOPMENT AND TECHNOLOGY TRANSFER
(MQA 104T)

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

Objectives
Upon completion of this course the student should be able to
- To understand the new product development process
- To understand the necessary information to transfer technology from R&D to actual manufacturing by sorting out various information obtained during R&D
- To elucidate necessary information to transfer technology of existing products between various manufacturing places

THEORY

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

   12 Hrs

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

   12 Hrs

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

92

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

REFERENCES

QUALITY ASSURANCE PRACTICAL - I
(MQA 105P)

PRACTICALS

1. Analysis of Pharmacopoeial compounds in bulk and in their formulations (tablet/ capsules/ semisolids) by UV Vis spectrophotometer
2. Simultaneous estimation of multi-drug component containing formulations by UV spectrophotometry
3. Experiments based on HPLC
4. Experiments based on Gas Chromatography
5. Estimation of riboflavin/quinine sulphate by fluorimetry
6. Estimation of sodium/potassium by flame photometry or AAS
7. Case studies on
   a. Total Quality Management
   b. Six Sigma
   c. Change Management/ Change control. Deviations,
   d. Out of Specifications (OOS)
   e. Out of Trend (OOT)
   f. Corrective & Preventive Actions (CAPA)
   g. Deviations
8. Development of Stability study protocol
9. Estimation of process capability
10. In process and finished product quality control tests for tablets, capsules, parenterals and semisolid dosage forms.
11. Assay of raw materials as per official monographs
12. Testing of related and foreign substances in drugs and raw materials
13. To carry out pre formulation study for tablets, parenterals (2 experiment).
14. To study the effect of pH on the solubility of drugs, (1 experiment)
15. Quality control tests for Primary and secondary packaging materials
16. Accelerated stability studies (1 experiment)
17. Improved solubility of drugs using surfactant systems (1 experiment)
18. Improved solubility of drugs using co-solvency method (1 experiment)
HAZARDS AND SAFETY MANAGEMENT  
(MQA 201T)

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

Objectives
At completion of this course it is expected that students will be able to
- Understand about environmental problems among learners.  
- Impart basic knowledge about the environment and its allied problems.  
- Develop an attitude of concern for the industry environment. 
- Ensure safety standards in pharmaceutical industry.  
- Provide comprehensive knowledge on the safety management  
- Empower an ideas to clear mechanism and management in different kinds of hazard management system  
- Teach the method of Hazard assessment, procedure, methodology for provide safe industrial atmosphere.

THEORY  60 Hrs
1. Multidisciplinary nature of environmental studies: Natural 12 
   Resources, Renewable and non-renewable resources, Natural Hrs 
   resources and associated problems, 
   a) Forest resources; b) Water resources; c) Mineral resources; d) 
   Energy resources; e) Land resources 
   Ecosystems: Concept of an ecosystem and Structure and function of an ecosystem. Environmental hazards: Hazards based on Air, Water, Soil and Radioisotopes. 

2 Air based hazards: Sources, Types of Hazards, Air circulation 12 
   maintenance industry for sterile area and non sterile area, Hrs 
   Preliminary Hazard Analysis (PHA) Fire protection system: Fire 
   prevention, types of fire extinguishers and critical Hazard 
   management system. 

3 Chemical based hazards: Sources of chemical hazards, 12 
   Hazards of Organic synthesis, sulphonating hazard, Organic Hrs 
   solvent hazard, Control measures for chemical hazards,
Management of combustible gases, Toxic gases and Oxygen displacing gases management, Regulations for chemical hazard, Management of over-Exposure to chemicals and TLV concept.

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

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

**REFERENCES**

1. Y.K. Sing, Environmental Science, New Age International Pvt, Publishers, Bangalore
3. Bharucha Erach, The Biodiversity of India, Mapin Pu blishing Pvt. Ltd., Ahmedabad – 380 013, India,
PHARMACEUTICAL VALIDATION
(MQA 202T)

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

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

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

THEORY

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

2 Qualification of manufacturing equipment: Dry Powder 10 Mixers, Fluid Bed and Tray dryers, Tablet Compression Hrs (Machine), Dry heat sterilization/Tunnels, Autoclaves, Membrane filtration, Capsule filling machine.
   Qualification of analytical instruments: UV–Visible spectrophotometer, FTIR, DSC, GC, HPLC, HPTLC, LC-MS.
3 Qualification of laboratory equipments: Hardness tester, Friability test apparatus, tap density tester, Disintegration tester, Dissolution test apparatus
Validation of Utility systems: Pharmaceutical water system & pure steam, HVAC system, Compressed air and nitrogen.

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

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

6 General Principles of Intellectual Property: Concepts of Intellectual Property (IP), Intellectual Property Protection (IPP), Intellectual Property Rights (IPR); Economic importance, mechanism for protection of Intellectual Property – patents, Copyright, Trademark; Factors affecting choice of IP protection; Penalties for violation; Role of IP in pharmaceutical industry; Global ramification and financial implications. Filing a patent 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

3. Validation Master plan by Terveeks or Deeks, Davis Harwood International publishing.
5. (Marcel Dekker).
11. Huber L. Validation and Qualification in Analytical Laboratories. Informa Healthcare
AUDITS AND REGULATORY COMPLIANCE  
(MPA 203T)

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

Objectives  
Upon completion of this course the student should be able to  
- To understand the importance of auditing  
- To understand the methodology of auditing  
- To carry out the audit process  
- To prepare the auditing report  
- To prepare the check list for auditing

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

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

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

4 Auditing of Microbiological laboratory: Auditing the manufacturing process, Product and process information, General areas of interest in the building raw materials, Water, Packaging materials.
Auditing of Quality Assurance and engineering department: 12
Quality Assurance Maintenance, Critical systems: HVAC, Water, Hrs
Water for Injection systems, ETP.

REFERENCES
1. Compliance auditing for Pharmaceutical Manufacturers. Karen Ginsbury
and Gil Bismuth, Interpharm/CRC, Boca Raton, London New York,
Washington D.C.
2. Pharmaceutical Manufacturing Handbook, Regulations and Quality by
Publications.
3. Handbook of microbiological Quality control. Rosamund M. Baird, Norman
4. Laboratory auditing for quality and regulatory compliance. Donald C.
Singer, Raluca–Ioana Stefan, Jacobus F. Van Staden. Taylor and Francis
(2005).
PHARMACEUTICAL MANUFACTURING TECHNOLOGY  
(MQA 204T)

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

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

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

THEORY  60 Hrs

1. Pharmaceutical industry developments: Legal requirements and Licenses for API and formulation industry, Plant location-Factors influencing.
   Plant layout: Factors influencing, Special provisions, Storage space requirements, sterile and aseptic area layout.
   Production planning: General principles, production systems, calculation of standard cost, process planning, routing, loading, scheduling, dispatching of records, production control.

2. Aseptic process technology: Manufacturing, manufacturing flowcharts, in process-quality control tests for following sterile dosage forms: Ointment, Suspension and Emulsion, Dry powder, Solution (Small Volume & large Volume).
   Advanced sterile product manufacturing technology: Area planning & environmental control, wall and floor treatment, fixtures and machineries, change rooms, personnel flow, utilities & utilities equipment location, engineering and maintenance.
   Process Automation in Pharmaceutical Industry: With specific reference to manufacturing of sterile semisolids, Small Volume Parenterals & Large Volume Parenterals (SVP & LVP), Monitoring of Parenteral manufacturing facility, Cleaning in Place (CIP),

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Sterilization in Place (SIP), Prefilled Syringe, Powdered Jet, Needle Free Injections, and Form Fill Seal Technology (FFS). Lyophilization technology: Principles, process, equipment.


4 Containers and closures for pharmaceuticals: Types, performance, assuring quality of glass; types of plastics used, Drug plastic interactions, biological tests, modification of plastics by drugs; different types of closures and closure liners; film wrapper; blister packs; bubble packs; shrink packaging; foil / plastic pouches, bottle seals, tape seals, breakable seals and sealed tubes; quality control of packaging material and filling equipment, flexible packaging, product package compatibility, transit worthiness of package, Stability aspects of packaging. Evaluation of stability of packaging material.

5 Quality by design (QbD) and process analytical technology (PAT): Current approach and its limitations. Why QbD is required, Advantages, Elements of QbD, Terminology: QTPP. CMA, CQA, CPP, RLD, Design space, Design of Experiments, Risk Assessment and mitigation/minimization. Quality by Design, Formulations by Design, QbD for drug products, QbD for Drug Substances, QbD for Excipients, Analytical QbD. FDA initiative on process analytical technology. PAT as a driver for improving quality and reducing costs: quality by design (QbD), QA, QC and GAMP. PAT guidance, standards and regulatory requirements.
REFERENCES
QUALITY ASSURANCE PRACTICAL – II PRACTICALS  
(MQA 205P)

1. Organic contaminants residue analysis by HPLC
2. Estimation of Metallic contaminants by Flame photometer
3. Identification of antibiotic residue by TLC
4. Estimation of Hydrogen Sulphide in Air.
6. Sampling and analysis of SO₂ using Colorimetric method
7. Qualification of following Pharma equipment
   a. Autoclave
   b. Hot air oven
   c. Powder Mixer (Dry)
   d. Tablet Compression Machine
8. Validation of an analytical method for a drug
9. Validation of a processing area
10. Qualification of at least two analytical instruments
11. Cleaning validation of one equipment
12. Qualification of Pharmaceutical Testing Equipment (Dissolution testing apparatus, Friability Apparatus, Disintegration Tester)
13. Check list for Bulk Pharmaceutical Chemicals vendors
14. Check list for tableting production.
15. Check list for sterile production area
16. Check list for Water for injection.
17. Design of plant layout: Sterile and non-sterile
18. Case study on application of QbD
19. Case study on application of PAT
PHARMACEUTICAL REGULATORY AFFAIRS (MRA)

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 Hrs

   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.

2. 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 12 Hrs


5. 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 III and other relevant CDSCO regulatory guidance documents.

REFERENCES
2. Good Pharmaceutical Manufacturing practice, Rational and compliance by John Sharp, CRC Press
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 Hrs

1. 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).


4 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).


REFERENCES
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
8. Corporate Culture and the Quality Organization By James W. Fairfield-Sonn, Quorum Books, 2001
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 Hrs
1. 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
2 Ethics in Clinical Research:
- 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

3 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)
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

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 (EMEA) 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

2. HIPAA and Human Subjects Research: A Question and Answer Reference Guide By Mark Barnes, JD, LLM and Jennifer Kulyanych, JD, PhD
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.
7. FDA regulatory affairs: a guide for prescription drugs, medical devices, and biologics; Douglas J. Pisano, David Mantus; CRC Press, USA
9. Drugs & Cosmetics Act & Rules and Amendments

RECOMMENDED WEBSITES:

8. 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

1. Biologicals & Herbals, and Food & Nutraceuticals Acts and Rules (with latest amendments): 60 Hrs
   
   1. Drugs and Cosmetics Act 1940 and Rules 1945: DPCO and NPPA 12 Hrs
   2. Other relevant provisions (rules schedules and guidelines for approval of Drugs & Cosmetics, Medical Devices, Biologicals & Herbals, and Food & Nutraceuticals in India

2 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

3 Indian Pharmacopoeia Standards, BIS standards and ISO and other relevant standards

4 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


REFERENCES


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
SEMESTER II
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

1. 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.

2. 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,

3 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

4 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)

5 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 pre-requisites 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 pre-requisites 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:

2. The Pharmaceutical Regulatory Process, Edited by Ira R. Berry Marcel Dekker Series, Vol.144
6. Drugs: From Discovery to Approval, Second Edition By Rick Ng
9. Preparation and Maintenance of the IND Application in eCTD Format By William K. Sietsema
15. Outsourcing to India: The Offshore Advantage, Mark Kobayashi-Hillary, Springer Trade performance and Regional Integration of the CIS Countries, Lev Freinkman,
139
20. Realizing the ASEAN Economic Community: A Comprehensive Assessment, Michael G Plummer (Editor), Chia Siow Yue (Editor), Instute 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

1. 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.

2. 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.

3. 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

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and clinical development considerations; stability, safety, advertising, labelling and packing of biologics in EU

4 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 Haemovigilence Network)

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

REFERENCES
2. Biological Drug Products: Development and Strategies; Wei Wang, Manmohan Singh; wiley, 2013
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 cdsco nic in
10. www.ema.europa.eu › scientific guidelines › Biologicals
11. www.fda.gov/biologicsbloodVaccines/GuidanceCompliance Regulatory Information (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

1. 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.

2. 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

60 Hrs

12 Hrs
USA: Introduction, Classification, Regulatory approval process for Medical Devices (510k) Premarket 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.


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
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
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 Hrs


3. 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.

4. 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.

REFERENCES
1. Regulation of Functional Foods and Nutraceuticals: A Global Perspective by Clare M. Hasler (Wiley Online Library)
6. Food Regulation: Law, Science, Policy and Practice by Neal D. Fortin (Wiley)
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
PHARMACEUTICAL BIOTECHNOLOGY (MPB)

MODERN PHARMACEUTICAL ANALYTICAL TECHNIQUES
(MPB 101T)

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

Objectives
After completion of course student is able to know,
- The analysis of various drugs in single and combination dosage forms
- Theoretical and practical skills of the instruments

THEORY

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

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

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4 Chromatography: Principle, apparatus, instrumentation, chromatographic parameters, factors affecting resolution and applications of the following:
a) Paper chromatography b) Thin Layer chromatography
c) Ion exchange chromatography d) Column chromatography
e) Gas chromatography f) High Performance Liquid chromatography
g) Affinity chromatography

5 a. Electrophoresis: Principle, Instrumentation, Working conditions, factors affecting separation and applications of the following:
   a) Paper electrophoresis b) Gel electrophoresis c) Capillary electrophoresis d) Zone electrophoresis e) Moving boundary electrophoresis f) Iso electric focusing
   b. X ray Crystallography: Production of X rays, Different X ray methods, Bragg’s law, Rotating crystal technique, X ray powder diffraction technique, Types of crystals and applications of X-ray diffraction.

REFERENCES
MICROBIAL AND CELLULAR BIOLOGY
(MPB 102T)

Scope
This subject is designed to provide the advanced knowledge to the biotechnology students in invaluable areas of advanced microbiology which plays a crucial role in determining its future use and applications in medicine, drug discovery and in pharmaceutical industry.

Objective
At the completion of this course it is expected that the students will get an understanding about the following aspects;

- Importance of Microorganisms in Industry
- Central dogma of molecular biology
- Structure and function of cell and cell communication
- Cell culture technology and its applications in pharmaceutical industries.
- Microbial pathogenesis and correlating it to rational use of antimicrobial agents.

THEORY 60Hrs
1. Microbiology 12 Hrs
   Introduction – Prokaryotes and Eukaryotes. Bacteria, fungi, actinomycetes and virus – structure, chemistry and morphology, cultural, physiological and reproductive features. Methods of isolation, cultivation and maintenance of pure cultures. Industrially important microorganisms – examples and applications
   Gene regulation
   Gene copy number, transcriptional control and translational control.
   RNA processing
   Modification and Maturation, RNA splicing, RNA editing, RNA amplification. Mutagenesis and repair mechanisms, types of mutants, application of mutagenesis in stain improvement, gene mapping of plasmids– types purification and application. Phage genetics, geneticorganization, phage mutation and lysogeny.
3 Cell structure and function
Cell organelles, cytoskeleton & cell movements, basic aspects of cell regulation, bioenergetics and fuelling reactions of aerobics and anaerobics, secondary metabolism & its applications. Cell communication, cell cycle and apoptosis, mechanism of cell division. Cell junctions/adhesion and extra cellular matrix, germ cells and fertilization, histology - the life and death of cells in tissues.

Cell Cycle and Cytoskeleton
Cell Division and its Regulation, G-Protein Coupled Receptors, Kinases, Nuclear receptors, Cytoskeleton & cell movements, Intermediate Filaments.

Apoptosis and Oncogenes
Programmed Cell Death, Tumor cells, carcinogens & repair.

Differentiation and Developmental Biology

4 Principles of microbial nutrition
Physical and chemical environment for microbial growth, Stability and degeneration of microbial cultures.

Growth of animal cells in culture
General procedure for cell culture, Nutrient composition, Primary, established and transformed cell cultures, applications of cell cultures in pharmaceutical industry and research. Growth of viruses in cell culture propagation and enumeration. In-vitro screening techniques- cytotoxicity, anti-tumor, anti-viral assays.

5 Microbial pathology
Identifying the features of pathogenic bacteria, fungi and viruses. Mechanism of microbial pathogenicity, etiology and pathology of common microbial diseases and currently recommended therapies for common bacterial, fungal & viral infections. Mechanism of action of antimicrobial agents and possible sites of chemotherapy.
REFERENCES
2. Prescott and Dunn, Industrial Microbiology, CBS Publishers & Distributors, Delhi.
BIOPROCESS ENGINEERING AND TECHNOLOGY  
(MPB 103T)

Scope
This paper has been designed to provide the knowledge to the biotechnology students in invaluable areas of bioprocess technology to develop skills to modify, design and operate different types of fermenters, to understand and implement various fermentation procedures, to train students in scale up fermentation operations.

Objective
At the completion of this subject it is expected that students will be able to,
- Understand basics and design of fermentation technology
- Scale up and scale down processing of fermentation technology
- Bioprocessing of the industrially important microbial metabolites in industries and R & D organizations.
- Regulation governing the manufacturing of biological products
- Understand and conduct fermentation process kinetics.

THEORY 60 Hrs
1. Introduction to fermentation technology 12 Hrs
   Basic principles of fermentation
   Study of the design and operation of bioreactor
   Ancillary parts and function, impeller design and agitation, power requirements on measurements and control of dissolved oxygen, carbon dioxide, temperature, pH and foam.
   Types of bioreactor
   CSTR, tower, airlift, bubble column, packed glass bead, hollow fiber, configuration and application
   Computer control of fermentation process
   System configuration and application

2. Mass transfer 12 Hrs
   Theory, diffusional resistance to oxygen requirements of microorganisms, measurements of mass transfer coefficients and factor affecting them, effects of aeration and agitation on mass transfer, supply of air, air compressing, cleaning and sterilization of air and plenum ventilation, air sampling and testing standards for air purity.
Rheology
Rheological properties of fermentation system and their importance in bioprocessing.

3 Scale up of fermentation process
Principles, theoretical considerations, techniques used, media for fermentation, HTST sterilization, advantage and disadvantage, liquid sterilization.
Cultivation and immobilized culture system
Cultivation system – batch culture, continuous culture, synchronous cultures, fed batch culture. Graphical plot representing the above systems.
Introduction to immobilization
Techniques, immobilization of whole cell, immobilized culture system to prepare fine chemicals. Immobilization of enzymes and their applications in the industry. Reactors for immobilized systems and perspective of enzyme engineering.

4 Scale down of fermentation process
Theory, equipment design and operation, methods of filtration, solvent extraction, chromatographic separation, crystallization turbidity analysis and cell yield determination, metabolic response assay, enzymatic assay, bioautographic techniques and disruption of cells for product recovery.
Isolation and screening
Primary and secondary, maintenance of stockculture, strain improvement for increased yield.

5 Bioprocessing of the industrially important microbial metabolites
   a) Organic solvents – Alcohol and Glycerol
   b) Organic acids – Citric acids, Lactic acids,
   c) Amino acids – Glutamic acids, Lysine, Cyclic AMP and GMP
   d) Antibiotics – Penicillin, Streptomycin, Griseofulvin,
   e) Vitamins – B12, Riboflavin and Vitamin C
Biosynthetic pathways for some secondary metabolites, microbial transformation of steroids and alkaloids
Regulation governing the manufacturing of biological products .
REFERENCES
1. Peter Stanbury, Allan Whitaker, Stephen Hall, Principles of Fermentation technology, Elsevier stores.
2. L.E. Casida, Industrial Microbiology, John Wiley & sons Inc.
ADVANCED PHARMACEUTICAL BIOTECHNOLOGY  
(MPB 104T)

Scope
This paper has been designed to provide the knowledge to the students to develop skills of advanced techniques of isolation and purification of enzymes, to enrich students with current status of development of vaccines and economic importance of biotechnology products.

Objective
At the completion of this subject it is expected that students will be able to
- Understand about the latest technology development in biotechnology technique, tools and their uses in drug and vaccine development.
- Identify appropriate sources of enzymes.
- Understand and perform genetic engineering techniques in gene manipulation, r-DNA technology and gene amplification.
- Understand the overview of pharmacogenomics.
- Learn the regulatory approval process and key regulatory agencies for new drugs, biologics, devices, and drug-device combinations.

THEORY 60 Hrs

1. Enzyme Technology 12 Hrs
Classification, general properties of enzymes, dynamics of enzymatic activity, sources of enzymes, extraction and purification, pharmaceutical, therapeutic and clinical application. Production of amyloglucosidase, glucose isomerase, amylase and trypsin.

2. Genetic Engineering 12 Hrs
Techniques of gene manipulation, cloning strategies, procedures, cloning vectors expression vectors, recombinant selection and screening, expression in E.coli and yeast. Site directed mutagenesis, polymerase chain reaction, and analysis of DNA sequences.
Gene library and cDNA
Applications of the above technique in the production of,
- Regulatory proteins - Interferon, Interleukins
- Blood products - Erythropoietin
- Vaccines - Hepatitis-B
- Hormones - Insulin
3 Therapeutic peptides
Study on controlled and site specified delivery of therapeutic peptides and proteins through various routes of administration.
Transgenic animals
Production of useful proteins in transgenic animals and gene therapy.
Human Genome
The human genome project—a brief study, Human chromosome—Structure and classification, chromosomal abnormalities—Syndromes

4 Signal transduction
Introduction, cell signaling pathways, ion channels, Sensors and effectors, ON and OFF mechanisms, Spatial and temporal aspects of signaling, cellular process, development, cell cycle and proliferation, neuronal signaling, cell stress, inflammatory responses and cell death, signaling defects and diseases.
Oncogenes
Introduction, definition, various oncogenes and their proteins.

5 Microbial Biotransformation
Biotransformation for the synthesis of chiral drugs and steroids.
Microbial Biodegradation
Biodegradation of xenobiotics, chemical and industrial wastes,
Production of single—cell protein,
Applications of microbes in environmental monitoring.
Biosensors
Definition, characteristics of ideal biosensors, types of biosensors, biological recognition elements, transducers, application of biosensors.

REFERENCES
2. Immobilization of cells and enzymes: HosevearKennadycabral& Bicker staff
5. Modern Biotechnology: S.B Primrose
PHARMACEUTICAL BIOTECHOLOGY PRACTICAL - I
(MPB 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. Isolation and Purification of microorganism from the soil
8. Microbial contamination of Water and biochemical parameters.
9. Determination of Minimum Inhibitory concentration by gradient plate technique and serial dilution method.
10. UV− survival curve and Dark repair
11. Sterility test for pharmaceutical preparations
12. Sub culturing of cells and cytotoxicity assays.
13. Construction of growth curve and determination of specific growth rate and doubling time
14. Fermentation process of alcohol and wine production
15. Fermentation of vitamins and antibiotics
16. Whole cell immobilization engineering
17. Thermal death kinetics of bacteria
18. Replica plating
20. Isolation and estimation of DNA
21. Isolation and estimation of RNA
22. Isolation of plasmids
23. Agarose gel electrophoresis.
24. Transformation techniques
25. SDS – polyacrylamide gel electrophoresis for proteins
26. Polymerase chain reaction technique.
PROTEINS AND PROTEIN FORMULATIONS  
(MPB 201T)

Scope
This course is designed to impart knowledge and skills necessary for knowing fundamental aspects of proteins and their formulations is a part of drug research and development process. Basic theoretical discussions of the principles of more integrated and coherent use of information for protein formulation and design are provided to help the students to clarify the various biological concepts of protein.

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

- Various methods of purification of proteins
- Peptides in drug development
- Protein identification and characterization
- Protein based formulations
- Sequencing proteins

THEORY 60 Hrs

1. Protein engineering 12 Hrs

2. Peptidomimetics 12 Hrs
   Introduction, classification; Conformationally restricted peptides, design, pseudopeptides, peptidomimetics and transition state analogs; Biologically active template; Amino acid replacements; Peptidomimetics and rational drug design; CADD techniques in peptidomimetics; Development of non peptide peptidomimetics.

3. Proteomics 12 Hrs
2-Dimensional gel electrophoresis
Methods including immobilized pH gradients (IPGs), resolution, reproducibility and image analysis, future developments

Protein formulation
Different strategies used in the formulation of DNA and proteins, Analytical and biophysical parameters of proteins and DNA in pre-formulation, Liposomes, Neon-spears, Neon-particulate system, PEGylation, Biological Activity, Biophysical Characterization Techniques, Forced degradation studies of protein.

Methods of protein sequencing
Various methods of protein sequencing, characterisation, Edman degradation, Tryptic and/or Chymotryptic Peptide Mapping.

REFERENCES
2. Protein Purification – Hand Book, Amersham pharmacia biotech
6. David Whitford, Proteins-Structure and Function, John Wiley & Sons Ltd.
7. James Swarbrick, Protein Formulation and Delivery Informa Healthcare USA,Inc.
IMMUNOTECHNOLOGY
(MPB 202T)

Scope
This course is designed to impart knowledge on production and engineering of antibodies, the application of antigens, the design of (recombinant) vaccines, strategies for immune intervention, etc. The Immunotechnology – based techniques will be used for therapeutics and diagnostics, industries in the production, quality control and quality assurance, and in R&D.

Objective
After this course, the students will be able to:-
- Understand the techniques like immunodiagnostic tests,
- Characterization of lymphocytes, purification of antigens and antibody, etc.
- Access health problems with immunological background;
- Develop approaches for the immune intervention of diseases

THEORY

1. Fundamental aspects of immunology
   Introduction, cells and organs of the immune system, cellular basis of Immune response, primary and secondary lymphoid organs, antigen antibody and their structure.
   Types of immune responses, anatomy of immune response.
   Overview of innate and adaptive Immunity.
   Humoral Immunity
   B – Lymphocytes and their activation. Structure and function of immunoglobulins, idiootypes and anti idiootypic antibodies.
   Cell mediated Immunity
   Thymus derived lymphocytes (T cells) – their ontogeny and types, MHC complex, antigen presenting cells (APC), mechanisms of T cell activation, macrophages, dendritic cells, langerhans cells, mechanism of phagocytosis
   12 Hrs

2 Immune Regulation and Tolerance
   Complement activation and types and their biological functions, cytokines and their role in immune response.
   Hypersensitivity
   Hypersensitivity Types I–IV, Hypersensitivity reactions and treatment
   Autoimmune diseases

60 Hrs
3 Vaccine technology
Vaccine and their types, conventional vaccines, novel methods for vaccine production, antiidiotype vaccine, DNA vaccine, genetically engineered vaccine, iscoms, synthetic peptides, and immunodiagnostics.
Stem cell technology
Stem cell technology and applications to immunology

4 Hybridoma Technology
Hybridoma techniques - fusion methods for myeloma cells and B-Lymphocytes, selection and screening techniques. Production and purification of monoclonal antibodies and their applications in Pharmaceutical industry.

5 Immunological Disorder
Autoimmune disorders and types, pathogenic mechanisms, treatment, experimental models of auto immune diseases, primary and secondary immunodeficiency disorders.
Immunodiagnosis
Antigen antibody interaction - Precipitation reaction, Agglutination reactions, Principles and applications of ELISA, Radio Immuno Assay, Western blot analysis, immune-electrophoresis, immuno fluorescence, chemiluminescence assay, complement fixation reaction.

REFERENCES
1. J. Kubey, Immunology – an Introduction.
3. Ashim Chakravarthy, Immunology and Immunotechnology, Oxford University Press.
4. E. Benjamini, Molecular Immunology.
BIOINFORMATICS AND COMPUTATIONAL BIOTECHNOLOGY
(MPB 203T)

Scope
This paper has been designed to provide the advanced knowledge to the
biotechnology students in invaluable areas of advanced bioinformatics which
plays a crucial role in determining its future use and applications in medicine,
drug discovery and in pharmaceutical industry.

Objectives
Upon completion of this course it is expected that the students will be able to
understand,
  1. Use of computers in developing a new drugs
  2. Biological concepts for bioinformatics
  3. Proteins and their diversity
  4. Various gene finding methods
  5. Searching the biological databases
  6. Target searching
  7. Various methods of drug designing

THEORY 60 Hrs
1. Introduction to Bioinformatics
   Definition and History of Bioinformatics, Internet and Bioinformatics, Introduction to Data Mining, Applications of Data Mining to Bioinformatics,
   Biological Database
   Protein and nucleic acid databases. Structural data bases. Collecting and storing the sequence and Applications of Bioinformatics.

2. Sequence analysis
   Sequence alignment, pair wise alignment techniques, multiple sequence analysis, multiple sequence alignment; Flexible sequence similarity searching with the FAST3 program package, the use of CLUSTAL W and CLUSTAL X for the multiple sequence alignment. Tools used for sequence analysis.

3. Protein informatics
   Introduction; Force field methods; Energy, buried and exposed residues, side chains and neighbours; Fixed regions, hydrogen bonds, mapping properties onto surfaces; Fitting monomers, R &
S fit of conformers, assigning secondary structures; Sequence alignment – methods, evaluation, scoring; Protein completion, backbone construction and side chain addition; Small peptide methodology, software accessibility, building peptides; Protein displays; Substructure manipulations, annealing.
Protein structure prediction

Protein folding and model generation; Secondary structure prediction, analyzing secondary structures; Protein loop searching, loop generating methods, loop analysis; Homology modeling, concepts of homology modeling, potential applications, description, methodology, homologous sequence identification; Align structures, align model sequence; Construction of variable and conserved regions, threading techniques, Topology fingerprint approach for prediction, evaluation of alternate models; Structure prediction on a mystery sequence, structure aided sequence techniques of structure prediction, structural profiles, alignment algorithms, mutation tables, prediction, validation, sequence based methods of structure prediction, prediction using inverse folding, fold prediction; Significance analysis, scoring techniques, sequence– sequence scoring.

Docking

Docking problems, methods for protein– ligand docking, validation studies and applications; Screening small molecule databases, docking of combinatorial libraries, input data, analyzing docking results.

Diversity of Genomes

Prokaryotic and Eukaryotic Gene Families. Genome Analysis: Hrs
Introduction, Gene prediction methods, Gene mapping and applications– Genetic and Physical Mapping, Integrated map, Sequence assembly and gene expression.
Completed Genomes

Bacterium, Nematode, Plant and Human Evolution of Genomes

Lateral or Horizontal Transfer among Genomes, Transcriptome and Proteome-General Account

Phylogenetic analysis

Evolutionary Change in Nucleotide Sequences, Rates and Patterns of Nucleotide Substitution, Models for Nucleotide Substitution, Construction of Phylogenetic Tree, Genome Annotation technique.
Target searching and Drug Designing

Target and lead, timeline for drug development, target discovery, target modulators, In-silico gene expression, microarray, and lead discovery, libraries of ligands, active site analysis, and prediction of drug quality.

REFERENCES
1. David W. Mount, Bioinformatics Sequence and Genome Analysis, CBS Publishers and Distributors
7. David Posada, Bioinformatics for DNA Sequence Analysis, Humana press.
BIOLOGICAL EVALUATION OF DRUG THERAPY
(MPB 204T)

Scope
This paper has been designed to provide the knowledge to the biotechnology students to understand the importance of biological and evaluation of drug therapy of biological medicines.

Objective
At the completion of this subject it is expected that students will be able to,
- Understand about the general concept of standardization of biological.
- Understand the importance of transgenic animals and knockout animals.
- Understand the biological medicines in development of various diseases.
- Learn the biological evaluation of drugs in vitro and in vivo

THEORY

1. Biological Standardization
   General principles, Scope and limitation of bio-assay, bioassay of some official drugs.
   Preclinical drug evaluation
   Preclinical drug evaluation of its biological activity, potency and toxicity—Toxicity test in animals including acute, sub-acute and chronic toxicity, ED50 and LD50 determination, special toxicity test like teratogenicity and mutagenicity.
   Guidelines for toxicity studies
   Various guidelines for toxicity studies. Animal experiments assessing safety of packaging materials.

2. Pyrogens
   Pyrogens: Sources, Chemistry and properties of bacterial pyrogens and endotoxins, Official pyrogen tests.
   Microbiological assay
   Assay of antibiotics and vitamins.
   Biological evaluation of drugs
   Screening and evaluation (including principles of screening, development of models for diseases: In vivo models / In vitro models / cell line study).

60 Hrs

12

12
3 Biologic Medicines in Development for various diseases - By Therapeutic Category

- Genetic Disorders
- Eye related Disorders
- Digestive Disorders
- Diabetes/Related Conditions
- Cardiovascular Disease
- Cancer/Related Conditions
- Blood Disorders
- Autoimmune Disorders
- Infectious Diseases
- Neurologic Disorders
- Skin Diseases
- Organe Transplantation

Biologic Medicines in Development for various diseases – by Product Category

- Antisense
- Vaccines
- Recombinant Hormones/Proteins
- Monoclonal Antibodies (mAb)
- Interferons
- Growth Factors
- Gene Therapy
- RNA Interference

4 Regulatory aspects : drugs, biologics and medical devices

An introduction to the regulations and documents necessary for approval of a medical product.
Regulatory consideration
Regulatory consideration for pre-clinical testing and clinical testing of drugs, biologics and medical devices.
New Drug Applications for Global Pharmaceutical Product Approvals

5 Bioavailability

Objectives and consideration in bio-availability studies of Biopharmaceuticals, Concept of equivalents, Measurements of bio-availability.
Determination of the rate of absorption, Bioequivalence and its importance, Regulatory aspects of bio-availability and bioequivalence studies for conventional dosage forms and controlled drug delivery systems of Biopharmaceuticals.

Pharmacokinetics

Pharmacokinetics:- Basic consideration, Pharmacokinetic models, Application of Pharmacokinetics in new drug development of Biopharmaceuticals and designing of dosage forms and Novel drug delivery systems of Biopharmaceuticals.

REFERENCES
1. Perkins F.T., Hennessen W. Standardization and Control of Biologicals Produced by Recombinant DNA Technology, International Association of Biological Standardization
2. J.H. Burn., Biological Standardization, Oxford University Press
3. Drug Discovery and Evaluation in Pharmacology assay: Vogel
4. Chow, Shein, Ching, Design and analysis of animal studies in pharmaceutical development,
1. Protein identification
2. Protein characterization
3. Protein biochemistry
4. Recombinant DNA Technology
5. Protein expression
6. Protein formulations
7. Database searching
8. Sequence analysis methods
9. Protein structure prediction
10. Gene annotation methods
11. Phylogenetic analysis
12. Protein, DNA binding studies
13. Preparation of DNA for PCR applications – Isolation, Purity and Quantification
15. Introduction to RT-PCR – working, programming.
16. Primer design using softwares.
17. Gene DNA amplification by random / specific primers.
18. Southern Hybridization
19. Western Blotting
20. Gene transformation
PHARMACY PRACTICE (MPP)

CLINICAL PHARMACY PRACTICE (MPP 101T)

Scope
This course is designed to impart the basic knowledge and skills that are required to practice pharmacy including the provision of pharmaceutical care services to both healthcare professionals and patients in clinical settings.

Objectives
Upon completion of this course it is expected that students shall be able to:
- Understand the elements of pharmaceutical care and provide comprehensive patient care services
- Interpret the laboratory results to aid the clinical diagnosis of various disorders
- Provide integrated, critically analyzed medicine and poison information to enable healthcare professionals in the efficient patient management

THEORY

1. Introduction to Clinical Pharmacy: Definition, evolution and scope of clinical pharmacy, International and national scenario of clinical pharmacy practice, Pharmaceutical care
   Clinical Pharmacy Services: Ward round participation, Drug therapy review (Drug therapy monitoring including medication order review, chart endorsement, clinical review and pharmacist interventions)

2. Clinical Pharmacy Services: Patient medication history interview, Basic concept of medicine and poison information services, Basic concept of pharmacovigilance, Hemovigilance, Materiovigilance and AEFI, Patient medication counselling, Drug utilisation evaluation, Documentation of clinical pharmacy services, Quality assurance of clinical pharmacy services.

3. Patient Data Analysis:
   Patient Data & Practice Skills: Patient's case history - its structure and significances in drug therapy management, Common medical abbreviations and terminologies used in clinical practice, Communication skills: verbal and non-verbal communications, its applications in patient care services.

60 Hrs

12 Hrs

12 Hrs

12 Hrs
Lab Data Interpretation: Hematological tests, Renal function tests, Liver function tests

4  Lab Data Interpretation: Tests associated with cardiac disorders, Pulmonary function tests, Thyroid function tests, Fluid and electrolyte balance, Microbiological culture sensitivity tests  12  Hrs

5  Medicines & Poison Information Services  12  Hrs
Medicine Information Service: Definition and need for medicine information service, Medicine information resources, Systematic approach in answering medicine information queries, Preparation of verbal and written response, Establishing a drug information centre.
Poison Information Service: Definition, need, organization and functions of poison information centre.

REFERENCES
2. Practice Standards and Definitions – The Society of Hospital Pharmacists of Australia
3. Basic skills in interpreting laboratory data – Scott LT, American Society of Health System Pharmacists Inc
4. Relevant review articles from recent medical and pharmaceutical literature.
PHARMACOTHERAPEUTICS-I
(MPP 102T)

Scope
This course aims to enable the students to understand the different treatment approaches in managing various disease conditions. Also, it imparts knowledge and skills in optimizing drug therapy of a patient by individualizing the treatment plan through evidence-based medicines.

Objectives
Upon completion of this course, it is expected that students shall be able to:

- Describe and explain the rationale for drug therapy
- Summarize the therapeutic approach for management of various disease conditions including reference to the latest available evidence
- Discuss the clinical controversies in drug therapy and evidence-based medicine
- Prepare individualized therapeutic plans based on diagnosis
- Identify the patient-specific parameters relevant in initiating drug therapy, and monitoring therapy (including alternatives, time-course of clinical and laboratory indices of therapeutic response and adverse effect/s)

THEORY

Etiopathogenesis and pharmacotherapy of diseases associated with following systems

1. Cardiovascular system: Hypertension, Congestive cardiac failure, Acute coronary syndrome, Arrhythmias, Hyperlipidemias. 12 Hrs

2. Respiratory system: Asthma, Chronic obstructive airways disease, Drug induced pulmonary diseases 12 Hrs
   Endocrine system: Diabetes, Thyroid diseases

3. Gastrointestinal system: Peptic ulcer diseases, Reflux esophagitis, Inflammatory bowel diseases, Jaundice & hepatitis 12 Hrs

4. Gastrointestinal system: Cirrhosis, Diarrhea and Constipation, Drug-induced liver disease 12 Hrs
   Hematological diseases: Anemia, Deep vein thrombosis, Drug induced hematological disorders
Bone and joint disorders: Rheumatoid arthritis, Osteoarthritis, Gout, Osteoporosis

Dermatological Diseases: Psoriasis, Eczema and scabies, impetigo, drug induced skin disorders

Ophthalmology: Conjunctivitis, Glaucoma

REFERENCES
1. Roger and Walker. Clinical Pharmacy and Therapeutics – Churchill Livingstone publication
3. Robins SL. Pathologic basis of disease –W.B. Saunders publication
5. Lloyd Young and Koda-Kimble MA Applied Therapeutics: The clinical Use of Drugs– Lippincott Williams and Wilkins
7. Carol Mattson Porth. Principles of Pathophysiology- Lippincott Williams and Wilkins
9. Relevant review articles from recent medical and pharmaceutical literature
HOSPITAL & COMMUNITY PHARMACY
(MPP 103T)

Scope
This course is designed to impart basic knowledge and skills that are required to practice pharmacy in both hospital and community settings.

Objectives
Upon completion of this course, it is expected that students shall be able to:
- Understand the organizational structure of hospital pharmacy
- Understand drug policy and drug committees
- Know about procurement & drug distribution practices
- Know the admixtures of radiopharmaceuticals
- Understand the community pharmacy management
- Know about value added services in community pharmacies

THEORY 60 Hrs

1. Introduction to Hospitals – Definition, classification, organizational structure 12 Hrs

   Hospital Pharmacy: Definition, Relationship of hospital pharmacy department with other departments, Organizational structure, legal requirements, workload statistics, infrastructural requirements, Hospital Pharmacy Budget and Hospital Pharmacy management

   Hospital Drug Policy: Pharmacy & Therapeutics Committee, Infection Control committee, Research & Ethics Committee, Management of Medicines as per NABH

2. Hospital Formulary Guidelines and its development, Developing Therapeutic guidelines, Drug procurement process, and methods of Inventory control, Methods of Drug distribution, Intravenous admixtures, Hospital Waste Management 12 Hrs

3. Education and training: Training of technical staff, training and continuing education for pharmacists, Pharmacy students, Medical staff and students, Nursing staff and students, Formal and informal meetings and lectures, Drug and therapeutics newsletter.

   Community Pharmacy Practice: Definition, roles & responsibilities of community pharmacists, and their relationship with other health care providers.
Community Pharmacy management: Legal requirements to start community pharmacy, site selection, lay out & design, drug display, super drug store model, accounts and audits, Good dispensing practices, Different softwares & databases used in community pharmacies. Entrepreneurship in community pharmacy.

4 Prescription – Legal requirements & interpretation, prescription related problems 12 Hrs
Responding to symptoms of minor ailments: Head ache, pyrexia, menstrual pains, food and drug allergy,
OTC medication: Rational use of over the counter medications
Medication counseling and use of patient information leaflets
Medication adherence – Definition, factors influencing adherence behavior, strategies to improve medication adherence
Patient referrals to the doctors
ADR monitoring in community pharmacies

5 Health Promotion – Definition and health promotion activities, 12 family planning, Health screening services, first aid, prevention of Hrs communicable and non-communicable diseases, smoking cessation, Child & mother care
National Health Programs- Role of Community Pharmacist in Malaria and TB control programs
Home Medicines review program – Definition, objectives,
Guidelines, method and outcomes
Research in community pharmacy Practice

REFERENCES
1. Hospital Pharmacy – Hassan WE. Lea and Febiger publication.
3. Avery’s Drug Treatment, Adis International Limited.
5. Remington Pharmaceutical Sciences.
6. Relevant review articles from recent medical and pharmaceutical literature
CLINICAL RESEARCH  
(MPP 104T)

Scope

This course aims to provide the students an opportunity to learn drug development process especially the phases of clinical trials and also the ethical issues involved in the conduct of clinical research. Also, it aims to imparts knowledge and develop skills on conceptualizing, designing, conducting and managing clinical trials.

Objectives

Upon completion of this course it is expected that students shall be able to:
- Know the new drug development process.
- Understand the regulatory and ethical requirements.
- Appreciate and conduct the clinical trials activities
- Know safety monitoring and reporting in clinical trials
- Manage the trial coordination process

THEORY


2. Types and Designs used in Clinical Research: Planning and execution of clinical trials, Various Phases of clinical trials, Bioavailability and Bioequivalence studies, Randomization techniques (Simple randomization, restricted randomization, blocking method and stratification), Types of research designs based on Controlling Method (Experimental, Quasi experimental, and Observational methods) Time Sequences (Prospective and Retrospective), Sampling methods (Cohort study, case Control study and cross sectional study), Health outcome measures (Clinical & Physiological, Humanistic and economic) Clinical Trial Study team: Roles and responsibilities of: Investigator, Study Coordinator, Sponsor, Monitor, Contract Research Organization.

60 Hrs

12 Hrs
Clinical trial Documents: Guidelines to the preparation of following documents: Protocols, Investigator’s Brochure, Informed Consent Form, Case report forms, Contracts and agreements, Dairy Cards
Clinical Trial Start up activities: Site Feasibility Studies, Site/Investigator selection, Pre-study visit, Investigator meeting, Clinical trial agreement execution, Ethics committee document preparation and submission

Investigational Product: Procurement and Storage of investigation product
Filing procedures: Essential documents for clinical trial, Trial Master File preparation and maintenance, Investigator Site File, Pharmacy File, Site initiation visit, Conduct, Report and Follow up Clinical Trial Monitoring and Close out:
Preparation and conduct of monitoring visit: Review of source documents, CRF, ICF, IP storage, accountability and reconciliation, Study Procedure, EC communications, Safety reporting, Monitoring visit reporting and follow-up Close-Out visit: Study related documents collection, Archival requirement, Investigational Product reconciliation and destruction, Close-Out visit report.

Quality Assurance and Quality Control in Clinical Trials:
Types of audits, Audit criteria, Audit process, Responsibilities of stakeholders in audit process, Audit follow-up and documentation, Audit resolution and Preparing for FDA inspections, Fraud and misconduct management
Data Management Infrastructure and System Requirement for Data Management: Electronic data capture systems, Selection and implementation of new systems, System validation and test procedures, Coding dictionaries, Data migration and archival
Clinical Trial Data Management: Standard Operating Procedures, Data management plan, CRF & Data base design considerations, Study set-up, Data entry, CRF tracking and corrections, Data cleaning, Managing laboratory and ADR data, Data transfer and database lock, Quality Control and Quality Assurance in CDM, Data mining and warehousing.
REFERENCES


10. Relevant review articles from recent medical and pharmaceutical literature.
PHARMACY PRACTICE PRACTICAL – I
(MPP 105P)

Pharmacy Practice practical component includes experiments covering important topics of the courses Clinical Pharmacy Practice, Pharmacotherapeutics-I, Hospital & Community Pharmacy and Clinical Research.

List of Experiments (24)
1. Treatment Chart Review (one)
2. Medication History Interview (one)
3. Patient Medication Counseling (two)
4. Drug Information Query (two)
5. Poison Information Query (one)
6. Lab Data Interpretation (two)
7. Presentation of clinical cases of various disease conditions adopting Pharmaceutical Care Plan Model (eight)
8. ABC Analysis of a given list of medications (one)
9. Preparation of content of a medicine, with proper justification, for the inclusion in the hospital formulary (one)
10. Formulation and dispensing of a given IV admixtures (one)
11. Preparation of a patient information leaflet (two)
12. Preparation of Study Protocol (one)
13. Preparation of Informed Consent Form (one)
PRINCIPLES OF QUALITY USE OF MEDICINES  
(MPP 201T)

Scope:
This course is designed to impart basic knowledge and skills that are required to practice quality use of medicines (QUM) in different healthcare settings and also to promote quality use of medicines, in clinical practice, through evidence-based medicine approach.

Objectives:
Upon completion of this course it is expected that students shall be able to:
  □ Understand the principles of quality use of medicines
  □ Know the benefits and risks associated with use of medicines
  □ Understand regulatory aspects of quality use of medicines
  □ Identify and resolve medication related problems
  □ Promote quality use of medicines
  □ Practice evidence-based medicines

THEORY 60 Hrs
1. Introduction to Quality use of medicines (QUM): Definition and Principles of QUM, Key partners and responsibilities of the partners, Building blocks in QMC, Evaluation process in QMC, Communication in QUM, Cost effective prescribing.

2. Concepts in QUM 12 Hrs
Evidence based medicine: Definition, concept of evidence based medicine, Approach and practice of evidence based medicine in clinical settings
Essential drugs: Definition, need, concept of essential drug, National essential drug policy and list
Rational drug use: Definition, concept and need for rational drug use, Rational drug prescribing, Role of pharmacist in rational drug use.

3. QUM in various settings: Hospital settings, Ambulatory care/Residential care, Role of health care professionals in promoting the QUM, Strategies to promote the QUM, Impact of QUM on E-health, integrative medicine and multidisciplinary care. QUM in special population: Pediatric prescribing, Geriatric prescribing, Prescribing in pregnancy and lactation, Prescribing in immune compromised and organ failure patients.
4 Regulatory aspects of QUM in India: Regulation including 12 scheduling, Regulation of complementary medicines, Regulation Hrs of OTC medicines, Professional responsibility of pharmacist, Role of industry in QUM in medicine development.

5 Medication errors: Definition, categorization and causes of 12 medication errors, Detection and prevention of medication errors, Role of pharmacist in monitoring and management of medication errors Pharmacovigilance: Definition, aims and need for pharmacovigilance, Types, predisposing factors and mechanism of adverse drug reactions (ADRs), Detection, reporting and monitoring of ADRs, Causality assessment of ADRs, Management of ADRs, Role of pharmacist in pharmacovigilance.

REFERENCES:
2. Andrews EB, Moore N. Mann’s Pharmacovigilance
3. Dipiro JT, Talbert RL, Yee GC. Pharmacotherapy: A Pathophysiologic Approach
4. Straus SE, Richardson WS, Glasziou P, Haynes RB. Evidence-Based Medicine: How to practice and teach it
5. Cohen MR. Medication Errors
6. Online:
7. Relevant review articles from recent medical and pharmaceutical literature.
PHARMACOTHERAPEUTICS II  
(MPP 202T)

Scope
This course aims to enable the students to understand the different treatment approaches in managing various disease conditions. Also, it imparts knowledge and skills in optimizing drug therapy of a patient by individualizing the treatment plan through evidence-based medicines.

Objectives
Upon completion of this course it is expected that students shall be able to:

- Describe and explain the rationale for drug therapy
- Summarize the therapeutic approach for management of various disease conditions including reference to the latest available evidence
- Discuss the clinical controversies in drug therapy and evidence based medicine
- Prepare individualized therapeutic plans based on diagnosis
- Identify the patient specific parameters relevant in initiating drug therapy, and monitoring therapy (including alternatives, time-course of clinical and laboratory indices of therapeutic response and adverse effect/s)

THEORY  
60 Hrs


2 Psychiatric disorders: Schizophrenia, Depression, Anxiety disorders, Sleep disorders, Drug induced psychiatric disorders Renal system: Acute renal failure, Chronic renal failure, Renal dialysis, Drug induced renal disease

3. Infectious diseases: General guidelines for the rational use of antibiotics and surgical prophylaxis, Urinary tract infections, Respiratory tract infections, Gastroenteritis, Tuberculosis, Malaria, Bacterial endocarditis, Septicemia.

REFERENCES
3. Robins SL. Pathologic basis of disease – W.B. Saunders publication
5. Lloyd Young and Koda-Kimble MA Applied Therapeutics: The clinical Use of Drugs – Lippincott Williams and Wilkins
7. Carol Mattson Porth. Principles of Pathophysiology– Lippincott Williams and Wilkins
9. Relevant review articles from recent medical and pharmaceutical literature
CLINICAL PHARMACOKINETICS AND THERAPEUTIC DRUG MONITORING  
(MPP 203T)

Scope
This course is designed to enable students to understand the basics principles and applications of pharmacokinetics in designing the individualized dosage regimen, to interpret the plasma drug concentration profile in altered pharmacokinetics, drug interactions and in therapeutic drug monitoring processes to optimize the drug dosage regimen. Also, it enables students to understand the basic concepts of pharmacogenetics, pharmacometrics for modeling and simulation of pharmacokinetic data.

Objectives
Upon completion of this course it is expected that students shall be able to:

- Design the drug dosage regimen for individual patients
- Interpret and correlate the plasma drug concentrations with patients' therapeutic outcomes
- Recommend dosage adjustment for patients with renal/ hepatic impairment
- Recommend dosage adjustment for paediatrics and geriatrics
- Manage pharmacokinetic drug interactions
- Apply pharmacokinetic parameters in clinical settings
- Interpret the impact of genetic polymorphisms of individuals on pharmacokinetics and or pharmacodynamics of drugs
- Do pharmacokinetic modeling for the given data using the principles of pharmacometrics

THEORY  60 Hrs
1. Introduction to Clinical pharmacokinetics: Compartmental and Non compartmental models, Renal and non–renal clearance, Organ extraction and models of hepatic clearance, Estimation and determinants of bioavailability, Multiple dosing, Calculation of loading and maintenance doses
   Designing of dosage regimens: Determination of dose and dosing intervals, Conversion from intravenous to oral dosing, Nomograms and Tabulations in designing dosage regimen.

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2 Pharmacokinetics of Drug Interaction: Pharmacokinetic drug interactions, Inhibition and Induction of Drug metabolism, Inhibition of Biliary Excretion
Pharmacogenetics: Genetic polymorphism in Drug metabolism: Cytochrome P-450 Isoenzymes, Genetic Polymorphism in Drug Transport and Drug Targets, Pharmacogenetics and Pharmacokinetic / Pharmacodynamic considerations
Introduction to Pharmaco metric: Introduction to Bayesian Theory, Adaptive method or Dosing with feedback, Analysis of Population pharmacokinetic Data.

3 Non Linier Mixed Effects Modelling: The Structural or Base Model, Modeling Random Effects, Modeling Covariate Relationships, Mixture Model, Estimation Methods, Model Building Techniques, Covariate Screening Methods, Testing the model assumptions, Precision of the parameter estimates and confidence intervals, Model misspecification and violation of the model assumptions, Model Validation, Simulation of dosing regimens and dosing recommendations, Pharmacometrics software.

4 Altered Pharmacokinetics: Drug dosing in the elderly, Drug dosing in the paediatrics, Drug dosing in the obese patients, Drug dosing in the pregnancy and lactation, Drug dosing in the renal failure and extracorporeal removal of drugs, Drug dosing in the in hepatic failure.

5 Therapeutic Drug monitoring: Introduction, Individualization of drug dosage regimen (Variability – Genetic, age, weight, disease and Interacting drugs), Indications for TDM, Protocol for TDM, Pharmacokinetic/Pharmacodynamic Correlation in drug therapy, TDM of drugs used in the following conditions: Cardiovascular disease: Digoxin, Lidocaine, Amiodarone; Seizure disorders: Phenytoin, Carbamazepine, Sodium Valproate; Psychiatric conditions: Lithium, Fluoxetine, Amitriptyline; Organ transplantations: Cyclosporine; Cytotoxic Agents: Methotrexate, 5-FU, Cisplatin; Antibiotics: Vancomycin, Gentamicin, Meropenem.
REFERENCES

4. Steven How–Yan Wong, Irving Sunshine. Handbook of Analytical Therapeutic Drug Monitoring and Toxicology. CRC Press, USA.
7. Malcolm Rowland, Thomas N. Tozer. Clinical Pharmacokinetics and pharmacodynamics: concepts and applications. lippincott Williams & Wilkins, USA.
9. Michael E. Winter. Basic Clinical Pharmacokinetics. lippincott Williams & Wilkins, USA.
13. Relevant review articles from recent medical and pharmaceutical literature
PHARMA COEPIDEMIOLOGY & PHARMA COECONOMICS
(MPP 204T)

Scope
This course enables students to understand various pharmacoepidemiological methods and their clinical applications. Also, it aims to impart knowledge on basic concepts, assumptions, terminology, and methods associated with Pharmacoconomics and health related outcomes, and when should be appropriate Pharmacoeconomic model should be applied for a health care regimen.

Objectives
Upon completion of this course it is expected that students shall be able to:
- Understand the various epidemiological methods and their applications
- Understand the fundamental principles of Pharmacoconomics.
- Identify and determine relevant cost and consequences associated with pharmacy products and services.
- Perform the key Pharmacoconomics analysis methods
- Understand the Pharmacoeconomic decision analysis methods and its applications.
- Describe current Pharmacoeconomic methods and issues.
- Understand the applications of Pharmacoeconomics to various pharmacy settings.

THEORY 60 Hrs
1. Introduction to Pharmacoepidemiology: Definition, Scope, Need, Aims & Applications; Outcome measurement: Outcome measures, Drug use measures: Monetary units, Number of prescriptions, units of drug dispensed, defined daily doses, prescribed daily doses, Diagnosis and Therapy surveys, Prevalence, Incidence rate, Monetary units, number of prescriptions, unit of drugs dispensed, defined daily doses and prescribed daily doses, medications adherence measurements. Concept of risk: Measurement of risk, Attributable risk and relative risk, Time– risk relationship and odds ratio

2 Pharmacoepidemiological Methods: Qualitative models: Drug Utilization Review; Quantitative models: case reports, case series, Cross sectional studies, Cohort and case control studies, Calculation of Odds’ ratio, Meta analysis models, Drug effects study in populations: Spontaneous reporting, Prescription event
monitoring, Post marketing surveillance, Record linkage systems, Applications of Pharmacoepidemiology

3 Introduction to Pharmacoconomics: Definition, history of 12 Pharmacoconomics, Need of Pharmacoeconomic studies in Hrs Indian healthcare system.
Cost categorization and resources for cost estimation: Direct costs. Indirect costs. Intangible costs.
Outcomes and Measurements of Pharmacoconomics: Types of outcomes: Clinical outcome, Economic outcomes, Humanistic outcomes; Quality Adjusted Life Years, Disability Adjusted Life Years Incremental Cost Effective Ratio, Average Cost Effective Ratio. Person Time, Willingness To Pay, Time Trade Off and Discounting.

4 Pharmacoeconomic evaluations: Definition, Steps involved, Applications, Advantages and disadvantages of the following Pharmacoeconomic models: Cost Minimization Analysis (CMA), Cost Benefit Analysis (CBA), Cost Effective Analysis (CEA), Cost Utility Analysis (CUA), Cost of Illness (COI), Cost Consequences Analysis (COA).

5 Definition, Steps involved, Applications, Advantages and disadvantages of the following:
Health related quality of life (HRQOL): Definition, Need for measurement of HRQOL, Common HRQOL measures.
Definition, Steps involved, Applications of the following:
Decision Analysis and Decision tree, Sensitivity analysis, Markov Modeling, Software used in pharmacoeconomic analysis, Applications of Pharmacoconomics.

REFERENCES
5. George E Mackinnon III. Understanding health outcomes and pharmacoeconomics.
7. Walley, Pharmacoeconomics.
8. Pharmacoeconomic – ed. by Nowakowska – University of Medical Sciences, Poznan.
9. Relevant review articles from recent medical and pharmaceutical literature
PHARMACY PRACTICE PRACTICAL - II
(MPP 205P)

Pharmacy Practice practical component includes experiments covering important topics of the courses Principles of Quality Use of Medicines, Pharmacotherapeutics-II, Clinical Pharmacokinetics & Therapeutic Drug Monitoring and Pharmacoepidemiology and Pharmacoconomics.

List of Experiments (24)
1. Causality assessment of adverse drug reactions (three)
2. Detection and management of medication errors (three)
3. Rational use of medicines in special population (three)
4. Presentation of clinical cases of various disease conditions adopting Pharmaceutical Care Plan Model (eight)
5. Calculation of Bioavailability and Bioequivalence from the given data (two)
6. Interpretation of Therapeutic Drug Monitoring reports of a given patient (three)
7. Calculation of various Pharmacoeconomic outcome analysis for the given data (two)
PHARMACOLOGY (MPL)

MODERN PHARMACEUTICAL ANALYTICAL TECHNIQUES
(MPL 101T)

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

Objectives
After completion of course student is able to know about,
- Chemicals and Excipients
- The analysis of various drugs in single and combination dosage forms
- Theoretical and practical skills of the instruments

THEORY

   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.
   Spectrofouirimetry: Theory of Fluorescence, Factors affecting fluorescence (Characterestics 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.

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

4 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

5 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
   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.

   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.
REFERENCES
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

1. General Pharmacology 12 Hrs
   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.

2. Neurotransmission 12 Hrs
   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). Co-transmission
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

3  Central nervous system Pharmacology  12
General and local anesthetics  Hrs
Sedatives and hypnotics, drugs used to treat anxiety.
Depression, psychosis, mania, epilepsy, neurodegenerative
diseases.
Narcotic and non-narcotic analgesics.

4  Cardiovascular Pharmacology  12
Diuretics, antihypertensives, antiischemics, anti-arrhythmics, Hrs
drugs for heart failure and hyperlipidemia.
Hematinics, coagulants, anticoagulants, fibrinolytics and anti-
platelet drugs

5  Autocoid Pharmacology  12
The physiological and pathological role of Histamine, Serotonin, Hrs
Kinin 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,
3. Basic and Clinical Pharmacology by B.G Katzung
5. Applied biopharmaceutics and Pharmacokinetics by Leon Shargel and
   Andrew B.C.Yu.
7. Avery Drug Treatment
10. Robbins & Cortan Pathologic Basis of Disease, 9th Ed. (Robbins Pathology)
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

1. 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

2. Preclinical screening of new substances for the pharmacological activity using in vivo, in vitro, and other possible animal alternative models.
   - General principles of preclinical screening. CNS Pharmacology: behavioral and muscle coordination, CNS stimulants and

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


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


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

Immunomodulators, Immunosuppressants and immunostimulants

General principles of immunoassay: theoretical basis and optimization of immunoassay, heterogeneous and homogenous immunoassay systems. Immunoassay methods evaluation; protocol outline, objectives and preparation. Immunoassay for digoxin and insulin

Limitations of animal experimentation and alternate animal experiments.

Extrapolation of in vitro data to preclinical and preclinical to humans
REFERENCES
1. Biological standardization by J.H. Burn D.J. Finney and I.G. Goodwin
2. Screening methods in Pharmacology by Robert Turner. A
3. Evaluation of drugs activities by Laurence and Bachrach
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.
9. Preclinical evaluation of new drugs by S.K. Guta
10. Handbook of Experimental Pharmacology, SK.Kulkarni
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 Hrs

1. Cell biology 12 Hrs
   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.

2. Cell signaling 12 Hrs
   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.

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3. Principles and applications of genomic and proteomic tools
   DNA electrophoresis, PCR (reverse transcription and real time),
   Gene sequencing, micro array technique, SDS page, ELISA and western blotting,
   Recombinant DNA technology and gene therapy
   Basic principles of recombinant DNA technology–Restriction enzymes, various types of vectors. Applications of recombinant DNA technology.
   Gene therapy– Various types of gene transfer techniques, clinical applications and recent advances in gene therapy.

4. Pharmacogenomics
   Gene mapping and cloning of disease gene.
   Genetic variation and its role in health/ pharmacology
   Polymorphisms affecting drug metabolism
   Genetic variation in drug transporters
   Genetic variation in G protein coupled receptors
   Applications of proteomics science: Genomics, proteomics, metabolomics, functionomics, nutrigenomics
   Immunotherapeutics
   Types of immunotherapeutics, humanisation antibody therapy, Immunotherapeutics in clinical practice

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

REFERENCES:
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)
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.
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 Braford/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).
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
4. Drug discovery and Evaluation by Vogel H.G.
5. Spectrometric Identification of Organic compounds – Robert M Silverstein,
6. Principles of Instrumental Analysis – Doglas 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)
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 Hrs
1. Endocrine Pharmacology 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

2. Chemotherapy 12 Hrs
   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.

3. Chemotherapy 12 Hrs
   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
4  GIT Pharmacology
   Antiulcer drugs, Prokinetics, antiemetics, anti-diarrheals and
   drugs for constipation
   and irritable bowel syndrome.
   Chronopharmacology
   Biological and circadian rhythms, applications of chronotherapy in
   various diseases like
   cardiovascular disease, diabetes, asthma and peptic ulcer
   12 Hrs

5  Free radicals Pharmacology
   Generation of free radicals, role of free radicals in etiopathology of
   various diseases
   such as diabetes, neurodegenerative diseases and cancer.
   Protective activity of certain important antioxidant
   Recent Advances in Treatment:
   Alzheimer’s disease, Parkinson’s disease, Cancer, Diabetes
   mellitus
   12 Hrs

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
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 Hrs
1. Basic definition and types of toxicology (general, mechanistic, regulatory and descriptive)  12 Hrs
   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

2 Acute, sub-acute and chronic- oral, dermal and inhalational studies as per OECD guidelines.  12 Hrs
   Acute eye irritation, skin sensitization, dermal irritation & dermal toxicity studies.
   Test item characterization- importance and methods in regulatory toxicology studies

3 Reproductive toxicology studies, Male reproductive toxicity studies, female reproductive studies (segment I and segment III), teratogenicity studies (segment II)
   Genotoxicity studies (Ames Test, in vitro and in vivo Micronucleus and Chromosomal aberrations studies)
   In vivo carcinogenicity studies

4 IND enabling studies (IND studies)- Definition of IND, importance of IND, industry perspective, list of studies needed for IND submission.
Safety pharmacology studies– origin, concepts and importance of safety pharmacology.
Tier1– CVS, CNS and respiratory safety pharmacology, HERG assay. Tier2– GI, renal and other studies

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

REFERENCES
3. Drugs from discovery to approval by Rick NG.
5. OECD test guidelines.
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 Hrs

2. Lead Identification—combinatorial chemistry & high throughput screening, in silico lead discovery techniques, Assay development for hit identification. Protein structure
   Levels of protein structure, Domains, motifs, and folds in protein structure. Computational prediction of protein structure: Threading and homology modeling methods. Application of NMR and X-ray crystallography in protein structure prediction.

3. Rational Drug Design 12 Hrs
Virtual Screening techniques: Drug likeness screening, Concept of pharmacophore mapping and pharmacophore based Screening,


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

REFERENCES
2. Darryl León. Scott Markelln. Silico Technologies in Drug Target Identification and Validation. 2006 by Taylor and Francis Group, LLC.
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

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

2. Clinical Trials: Types and Design  
   Experimental Study- RCT and Non RCT,  
   Observation Study: Cohort, Case Control, Cross sectional  
   Clinical Trial Study Team  
   Roles and responsibilities of Clinical Trial Personnel: Investigator,  
   Study Coordinator, Sponsor, Contract Research Organization and  
   its management
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


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

Methods, ADR reporting and tools used in Pharmacovigilance


Pharmacoepidemiology, pharmacoeconomics, safety pharmacology

REFERENCES


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.
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
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.
PHARMACOGNOSY (MPG)

MODERN PHARMACEUTICAL ANALYTICAL TECHNIQUES
(MPG 101T)

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

Objectives
After completion of course student is able to know,
- The analysis of various drugs in single and combination dosage forms
- Theoretical and practical skills of the instruments

THEORY 60 Hrs
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.

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

4  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

5  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

   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.


   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
SCOPE
To learn and understand the advances in the field of cultivation and isolation of drugs of natural origin, various phytopharmaceuticals, nutraceuticals and their medicinal use and health benefits.

OBJECTIVES
Upon completion of the course, the student shall be able to know the,
- advances in the cultivation and production of drugs
- various phyto-pharmaceuticals and their source, its utilization and medicinal value.
- various nutraceuticals/herbs and their health benefits
- Drugs of marine origin
- Pharmacovigilance of drugs of natural origin

THEORY


2. Marine natural products: General methods of isolation and purification, Study of Marine toxins, Recent advances in research in marine drugs, Problems faced in research on marine drugs such as taxonomical identification, chemical screening and their solution.

3. Nutraceuticals: Current trends and future scope, Inorganic mineral supplements, Vitamin supplements, Digestive enzymes, Dietary fibres, Cereals and grains, Health drinks of natural origin, Antioxidants, Polyunsaturated fatty acids, Herbs as functional foods, Formulation and standardization of nutraceuticals, Regulatory aspects, FSSAI guidelines, Sources, name of marker compounds and their chemical nature, medicinal uses and health benefits of following
4 Phytopharmaceuticals: Occurrence, isolation and characteristic features (Chemical nature, uses in pharmacy, medicinal and health benefits) of following.
   a) Carotenoids - i) α and β - Carotene ii) Xanthophyll (Lutein)
   b) Limonoids - i) d-Limonene ii) α - Terpineol
   c) Saponins - i) Shatavarins
   d) Flavonoids - i) Resveratrol ii) Rutin iii) Hesperidin iv) Naringin v) Quercetin
   e) Phenolic acids- Ellagic acid
   f) Vitamins
   g) Tocotrienols and Tocopherols
   h) Andrographolide, Glycolipids, Gugulipids, Withanolides, Vascine, Taxol
   i) Miscellaneous

5 Pharmacovigilance of drugs of natural origin: WHO and AYUSH guidelines for safety monitoring of natural medicine, Hrs Spontaneous reporting schemes for biodrug adverse reactions, bio drug-drug and bio drug-food interactions with suitable examples.

REFERENCES (Latest Editions of)
2. Pharmacognosy-Tyler, Brady, Robbers
4. Text Book of Pharmacognosy by T.E. Wallis
5. Marine Natural Products-Vol.I to IV.
PHYTOCHEMISTRY
(MPG 103T)

SCOPE
Students shall be equipped with the knowledge of natural product drug discovery and will be able to isolate, identify and extract and the phyto-constituents

OBJECTIVES
Upon completion of the course, the student shall be able to know the,
- different classes of phytoconstituents, their biosynthetic pathways, their properties, extraction and general process of natural product drug discovery
- phytochemical fingerprinting and structure elucidation of phytoconstituents.

THEORY 60 Hrs
1. Biosynthetic pathways and Radio tracing techniques: 12 Hrs
Constituents & their Biosynthesis, Isolation, Characterization and purification with a special reference to their importance in herbal industries of following phyto-pharmaceuticals containing drugs:
   a) Alkaloids: Ephedrine, Quinine, Strychnine, Piperine, Berberine, Taxol, Vinca alkoloids.
   b) Glycosides: Digitoxin, Glycyrrhizin, Sennosides, Bacosides, Quercitin.
   c) Steroids: Hecogenin, guggulosterone and withanolides
   d) Coumarin: Umbelliferone.
   e) Terpenoids: Cucurbitacins

2 Drug discovery and development: History of herbs as source of 12 Hrs
drugs and drug discovery, the lead structure selection process, structure development, product discovery process and drug registration, Selection and optimization of lead compounds with suitable examples from the following source : artemesin, andrographolides. Clinical studies emphasising on phases of clinical trials, protocol design for lead molecules.

3 Extraction and Phytochemical studies: Recent advances in 12 Hrs
extractions with emphasis on selection of method and choice of solvent for extraction, successive and exhaustive extraction and other methods of extraction commonly used like microwave
assisted extraction, Methods of fractionation. Separation of phytoconstituents by latest CCCET, SCFE techniques including preparative HPLC and Flash column chromatography.

4 Phytochemical finger printing: HPTLC and LCMS/GCMS applications in the characterization of herbal extracts. Structure elucidation of phytoconstituents.

5 Structure elucidation of the following compounds by spectroscopic techniques like UV, IR, MS, NMR (1H, 13C) Hrs
   a. Carvone, Citral, Menthol
   b. Luteolin, Kaempferol
   c. Nicotine, Caffeine iv) Glycyrrhizin.

REFERENCES (Latest Editions of)
1. Organic chemistry by I.L. Finar Vol.11
2. Pharmacognosy by Trease and Evans, ELBS.
3. Pharmacognosy by Tylor and Brady.
5. Clark’s isolation and Identification of drugs by A.C. Mottal.
9. Natural Products Chemistry Practical Manual by Anees A Siddiqui and SeemiSiddiqui
11. Chemistry of Natural Products- Vol. 1 onwards IWPAC.
12. Modem Methods of Plant Analysis- Peach & M.V. Tracey, Vol. I&II
INDUSTRIAL PHARMACOGNOSTICAL TECHNOLOGY  
(MPG 104T)

SCOPE
To understand the Industrial and commercial potential of drugs of natural origin, integrate traditional Indian systems of medicine with modern medicine and also to know regulatory and quality policy for the trade of herbals and drugs of natural origin.

OBJECTIVES
By the end of the course the student shall be able to know,
- the requirements for setting up the herbal/natural drug industry.
- the guidelines for quality of herbal/natural medicines and regulatory issues.
- the patenting/IPR of herbals/natural drugs and trade of raw and finished materials.

THEORY


5 Patents: Indian and international patent laws, proposed amendments as applicable to herbal/natural products and process. Geographical indication, Copyright, Patentable subject maters, novelty, non obviousness, utility, enablement and best mode, procedure for Indian patent filing, patent processing, grant of patents, rights of patents, cases of patents, opposition and revocation of patents, patent search and literature, Controllers of patents.

REFERENCES (Latest Editions of)
5. Indian Herbal Pharmacopoeia (2002), IDMA, Mumbai.

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PHARMACOGNOSY PRACTICAL - I
(MPG I05P)

1. Analysis of Pharmacopoeial compounds of natural origin and their formulations by UV Vis spectrophotometer
2. Analysis of recorded spectra of simple phytoconstituents
3. Experiments based on Gas Chromatography
4. Estimation of sodium/potassium by flame photometry
6. Methods of extraction
7. Phytochemical screening
8. Demonstration of HPLC- estimation of glycrrhizin
9. Monograph analysis of clove oil
10. Monograph analysis of castor oil.
11. Identification of bioactive constituents from plant extracts
12. Formulation of different dosage forms and their standardisation.
MEDICINAL PLANT BIOTECHNOLOGY
(MPG 201T)

SCOPE
To explore the knowledge of Biotechnology and its application in the improvement of quality of medicinal plants

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

- Know the process like genetic engineering in medicinal plants for higher yield of Phytopharmaceuticals.
- Use the biotechnological techniques for obtaining and improving the quality of natural products/medicinal plants

THEORY

60 Hrs

1. Introduction to Plant biotechnology: Historical perspectives, prospects for development of plant biotechnology as a source of medicinal agents. Applications in pharmacy and allied fields. Genetic and molecular biology as applied to pharmacognosy, study of DNA, RNA and protein replication, genetic code, regulation of gene expression, structure and complicity of genome, cell signaling, DNA recombinant technology.

12 Hrs


15 Hrs


15 Hrs

4. Biotransformation and Transgenesis: Biotransformation, bioreactors for pilot and large scale cultures of plant cells and retention of biosynthetic potential in cell culture. Transgenic

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plants, methods used in gene identification, localization and sequencing of genes. Application of PCR in plant genome analysis.

5 Fermentation technology: Application of Fermentation technology, Production of ergot alkaloids, single cell proteins, Hrs enzymes of pharmaceutical interest.

REFERENCES (Latest Editions of)
9. Plant tissue culture by Street.
12. Biotechnological applications to tissue culture by Shargool, Peter D, Shargool, CKC Press.
13. Pharmacognosy by Varo E. Tyler, Lynn R. Brady and James E. Robberrt, That Tjen, NGO.
ADVANCED PHARMACOGNOSY - II
(MPG 202T)

SCOPE
To know and understand the Adulteration and Deterioration that occurs in herbal/natural drugs and methods of detection of the same. Study of herbal remedies and their validations, including methods of screening.

OBJECTIVES
Upon completion of the course, the student shall be able to know the,
- validation of herbal remedies
- methods of detection of adulteration and evaluation techniques for the herbal drugs
- methods of screening of herbs for various biological properties

THEORY  
60 Hrs
1. Herbal remedies – Toxicity and Regulations: Herbs vs Conventional drugs, Efficacy of Herbal medicine products, Validation of herbal therapies, Pharmacodynamic and Pharmacokinetic issues. 12 Hrs


4. Analytical Profiles of herbal drugs: Andrographis paniculata, Boswellia serata, Coleus forskholii, Curcuma longa, Embelia officinalis, Psoralea corylifolia. 12 Hrs

5. Biological screening of herbal drugs: Introduction and Need for Phyto-Pharmacological Screening, New Strategies for evaluating. 12 Hrs

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Natural Products, In vitro evaluation techniques for Antioxidants, Antimicrobial and Anticancer drugs. In vivo evaluation techniques for Anti-inflamatory, Antiulcer, Anticancer, Wound healing, Antidiabetic, Hepatoprotective, Cardio protective, Diuretics and Antifertility, Toxicity studies as per OECD guidelines.

REFERENCES (Latest Editions of)

10. Indian Herbal Pharmacopoeia, IDMA, Mumbai.
INDIAN SYSTEMS OF MEDICINE
(MPG 203T)

SCOPE
To make the students understand thoroughly the principles, preparations of medicines of various Indian systems of medicine like Ayurveda, Siddha, Homeopathy and Unani. Also focusing on clinical research of traditional medicines, quality assurance and challenges in monitoring the safety of herbal medicines.

OBJECTIVES
After completion of the course, student is able to

- To understand the basic principles of various Indian systems of medicine
- To know the clinical research of traditional medicines, Current Good Manufacturing Practice of Indian systems of medicine and their formulations.

THEORY 60 Hrs

1. Fundamental concepts of Ayurveda, Siddha, Unani and Homeopathy systems of medicine 12 Hrs
   Different dosage forms of the ISM.
   Ayurveda: Ayurvedic Pharmacopoeia, Analysis of formulations and bio crude drugs with references to: Identity, purity and quality.
   Siddha: Gunapadam (Siddha Pharmacology), raw drugs/Dhatu Jeevam in Siddha system of medicine, Purification process (Suddhi).

2. Naturopathy, Yoga and Aromatherapy practices 12 Hrs
   a) Naturopathy – Introduction, basic principles and treatment modalities.
   b) Yoga – Introduction and Streams of Yoga. Asanas, Pranayama, Meditations and Relaxation techniques.
   c) Aromatherapy – Introduction, aroma oils for common problems, carrier oils.

3. Formulation development of various systems of medicine 12 Hrs
   Salient features of the techniques of preparation of some of the important class of Formulations as per Ayurveda, Siddha, Homeopathy and Unani Pharmacopoeia and texts. Standardization, Shelf life and Stability studies of ISM formulations.

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4. Schedule T – Good Manufacturing Practice of Indian systems of medicine
   Components of GMP (Schedule – T) and its objectives, Infrastructural requirements, working space, storage area, machinery and equipments, standard operating procedures, health and hygiene, documentation and records.
   Quality assurance in ISM formulation industry – GAP, GMP and GLP. Preparation of documents for new drug application and export registration.
   Challenges in monitoring the safety of herbal medicines: Regulation, quality assurance and control, National/Regional Pharmacopoeias.

5. TKDL, Geographical indication Bill, Government bills in AYUSH, ISM, CCRAS, CCRS, CCRH, CCRU

REFERENCES (Latest Editions of )
3. Ayurvedic System of Medicine, Kaviraj Nagendranath Sengupata, Sri Satguru Publications, New Delhi.
7. Indian Herbal Pharmacopoeia, IDMA, Mumbai.
8. British Herbal Pharmacopoeia, bRITISH Herbal Medicine Association, UK.
10. Indian System of Medicine and Homeopathy in India, Planning and Evaluation Cell, Govt. of India, New Delhi.
11. Essential of Food and Nutrition, Swaminathan, Bappco, Bangalore.

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HERBAL COSMETICS  
(MPG 204T)

SCOPE
This subject deals with the study of preparation and standardization of herbal/natural cosmetics. This subject gives emphasis to various national and international standards prescribed regarding herbal cosmeceuticals.

OBJECTIVES
After completion of the course, student shall be able to,
  ▶ understand the basic principles of various herbal/natural cosmetic preparations
  ▶ current Good Manufacturing Practices of herbal/natural cosmetics as per the regulatory authorities

THEORY

1. Introduction: Herbal/natural cosmetics, Classification & Economic aspects.
   12 Hrs

2. Commonly used herbal cosmetics, raw materials, preservatives, surfactants, humectants, oils, colors, and some functional herbs, preformulation studies, compatibility studies, possible interactions between chemicals and herbs, design of herbal cosmetic formulation.
   12 Hrs

3. Herbal Cosmetics: Physiology and chemistry of skin and pigmentation, hairs, scalp, lips and nail, Cleansing cream, Lotions, Face powders, Face packs, Lipsticks, Bath products, soaps and baby product, Preparation and standardisation of the following: Tonic, Bleaches, Dentifrices and Mouth washes & Tooth Pastes, Cosmetics for Nails.
   12 Hrs

   12 Hrs

60 Hrs
5 Analysis of Cosmetics, Toxicity screening and test methods: Quality control and toxicity studies as per Drug and Cosmetics Hrs Act.

REFERENCES (Latest Editions of)
2. Thomson EG. Modern Cosmetics, Universal Publishing Corporation, Mumbai.
7. Chattopadhyay PK. Herbal Cosmetics & Ayurvedic Medicines (EOU), National Institute of Industrial Research, Delhi.
HERBAL COSMETICS PRACTICALS
(MPG 205P)

1. Isolation of nucleic acid from cauliflower heads
2. Isolation of RNA from yeast
3. Quantitative estimation of DNA
4. Immobilization technique
5. Establishment of callus culture
6. Establishment of suspension culture
7. Estimation of aldehyde contents of volatile oils
8. Estimation of total phenolic content in herbal raw materials
9. Estimation of total alkaloid content in herbal raw materials
10. Estimation of total flavonoid content in herbal raw materials
11. Preparation and standardization of various simple dosage forms from Ayurvedic, Siddha, Homoeopathy and Unani formulary
12. Preparation of certain Aromatherapy formulations
13. Preparation of herbal cosmetic formulation such as lip balm, lipstick, facial cream, herbal hair and nail care products
14. Evaluation of herbal tablets and capsules
15. Preparation of sunscreen, UV protection cream, skin care formulations.
16. Formulation & standardization of herbal cough syrup.