

Nirma University
Institute of Pharmacy
Programme: M. Pharm – Clinical Pharmacy

Nirma University
Institute of Pharmacy
M. Pharm. Semester – I
COURSE NAME: ADVANCED INSTRUMENTAL METHODS

Learning outcomes:

After successful completion of the course, student will be able to:

- Understand the fundamentals of spectroscopy and chromatographic techniques.
- Use spectroscopy for the quantitative and qualitative analysis of drugs.
- Predict the structure of unknown compounds.

Theory (Detailed Syllabus)

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Applications and recent trends in the modern methodology used for the analysis of drugs and their metabolites of the following techniques

A) Spectroscopic Techniques

UV-Visible spectrophotometry: Theory of electronic spectroscopy, absorption by organic molecules, choice of solvent and solvent effect, applications of UV-Visible spectroscopy, Woodward – Fischer rules for calculating absorption maximum, photometric titrations and its applications

Infra-red spectrophotometry: Absorption in the infrared region, factors influencing molecular vibrations, Calculation of vibrational frequencies, applications, interpretation of infra red spectra, FTIR- Theory, Instrumentation, Attenuated Total reflectance spectroscopy (ATR)

Nuclear Magnetic Resonance Spectroscopy: Basic principles, theory of PMR spectroscopy, Instrumentation, applications, Chemical shift, spin-spin coupling, factors affecting chemical shift and spin coupling, ¹³C NMR spectroscopy, interpretation of NMR spectra, 2D NMR spectroscopy
Mass spectroscopy : Basic principles, ion formation and types, Fragmentation rules, recognition of molecular ion peak, Tandem mass spectroscopy, MALDI, FAB, SIMS, Structure elucidation of pharmaceutical compounds using different spectroscopic Techniques like UV-Visible, IR, NMR, MASS etc.,]

B) Separation Techniques

Classification of chromatographic methods based upon mechanism of separation, mode of separation, ion pair chromatography and applications

1. High Pressure Liquid Chromatography: RP-HPLC, chiral, Hydrophobic interaction, Size exclusion, Ion exchange, Affinity chromatography, ion chromatography
2. Gas chromatography: column operation, derivatization methods
3. Hyphenated techniques: LC-MS, LC-MS/MS, GC-MS, tandem mass spectroscopy
4. HPTLC
5. Super Critical Fluid Chromatography: Basic Principles, Instrumentation

Practical

- 1 Analysis of drugs and raw materials using official pharmacopoeial methods based on modern instrumental techniques.
- 2 Testing of related substances and foreign substances in raw materials as per I.P.

- 3 Assay for the raw materials, calculated either on anhydrous or hydrous basis as per I.P.
- 4 Interpretation of UV, IR, NMR and Mass spectra and its use in structure elucidation.

Books Recommended

1. R. M. Silverstein, G. C. Bassler and T. C. Morrill, Spectrometric Identification of Organic Compounds, 6th edn, John Wiley, New York, 1998.
2. P. S. Kalsi, Spectroscopy of Organic Compounds, New Age Publication, 2002.
3. D. A. Skoog, E. J. Holler and T. A. Nieman, Principles of Instrumental Analysis, Harcourt Asia Pte Ltd, 2001.
4. S. Lindsay, High Performance Liquid Chromatography, Analytical Chemistry by Open Learning (ACOL), Wiley, 1987.
5. Sethi, P.D., High performance thin layer chromatography: Quantitative analysis of pharmaceutical formulations, 1996.

**Nirma University
Institute of Pharmacy**

M. Pharm. [Clinical Pharmacy] Semester – I

COURSE NAME: CLINICAL PHARMACY-I [3PP101]

Learning outcomes:

After successful completion of the course, student will be able to

- Understand about role of clinical pharmacist as a better healthcare provider.
- Learn about the requirement of a particular drug to the patient along with its dose adjustment, side effects, interaction with other drugs / food etc. which will aid in betterment of healthcare system.
- Participate in hospital setting as a clinical pharmacist.

Theory (Detailed Syllabus)

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- 1) **Definitions, Development and Scope of Clinical Pharmacy Practice**
- 2) **Clinical Toxicology**
 - a) General principles involved in the management of poisoning
 - b) Antidotes and their clinical applications
 - c) Supportive care in clinical toxicology
 - d) Clinical symptoms and management of acute poisoning with the following agents: Pesticide poisoning: organophosphorus compounds, carbamates, organochlorines, pyrethroids Opiate overdose, Antidepressants, Barbiturates and benzodiazepines, Alcohol: ethanol, methanol, Paracetamol and salicylates, Non steroidal antiinflammatory drugs, Radiation poisoning, Heavy metals: Arsenic, lead, mercury, iron, copper
- 3) **Clinical Pharmacokinetics**
 - a) Clinical significance of drug absorption, distribution, metabolism and excretion process
 - b) Clinical Pharmacokinetic models
 - c) Physiological determination of drug clearance and volume of distribution
 - d) Estimation and determination of bioavailability
 - e) Multiple dosing
 - f) Calculation of loading and maintenance dose
 - g) Dose adjustment in renal failure, hepatic dysfunction, geriatric and pediatric patients
 - h) Therapeutic drug monitoring
 - i) Clinical pharmacokinetic study for different drug therapy like aminoglycosides, antiepileptics, digoxin, theophylline, lithium and vancomycin
- 4) **Drug Interactions**
 - a) Introduction, mechanism of drug interaction, drug-drug interaction, drug-food interactions.
- 5) **Rational use of drugs**
 - a) Importance of rational drug use.
 - b) Pharmacists role
 - c) Drug use indicators
 - d) Guidelines for rational prescribing
 - e) Iatrogenic diseases.
- 6) **Medication error and medication adherence**
 - a) Categories and causes of medication error
 - b) Tools to measure the performance of medication use process
 - c) Categories of medication non-adherence
 - d) Role of pharmacist in medication error and medication non-adherence
 - e) Patient counseling (to improve patient compliance on appropriate drug use)

Practicals

Students should be trained in the following aspects of services provided at the hospital:

1. Answering drug information queries
2. Patient medication counseling
3. Case studies related to laboratory investigations
4. Patient medication history interview
5. Case studies related to medication errors
6. Appraisal of recently published articles in the biomedical literature which deals with a drug or therapeutic issues.
7. Practicals related to the topics covered in theory.

Books Recommended

1. Basic Skills in interpreting laboratory data – Scott LT, American Society of Health System Pharmacists Inc.USA.
2. Biopharmaceutics and Applied Pharmacokinetics – Leon Shargel, Prentice Hall Publication, USA.
3. Clinical Pharmacokinetics: Rowland and Tozer, Williams and Wilkins Publication, London.
4. Clinical Laboratory Tests: Values and Implications; Spring House, Pennsylvania, USA.

M. Pharm. [Clinical Pharmacy] Semester – I

COURSE NAME: APPLIED PHARMACOTHERAPEUTICS-I [3PP102]

Learning outcomes:

After successful completion of the course, student will be able to

- Understand the pathogenesis and the therapeutic management for the disorders mentioned in the syllabus
- Apply the knowledge and skill for the management of the respective disorders.

Theory (Detailed Syllabus)

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Etiopathogenesis and pharmacotherapy of following diseases

- 1) **Cardiovascular disorders**
Hypertension, Congestive cardiac failure, Arrhythmias, Ischemic Heart diseases, Hyperlipidemias
- 2) **Respiratory disorders**
Asthma, Chronic obstructive airway diseases, cystic fibrosis
- 3) **Hematological disorders**
Anemia, Coagulation disorders
- 4) **Arthritic disorders**
Rheumatoid arthritis, Osteoarthritis, Gout and Hyperuricemia, Systemic Lupus Erythematosus.
- 5) **Gastrointestinal disorders**
Peptic ulcer disease, Gastroesophageal Reflux disease, Inflammatory Bowel disease, Hepatitis, Cirrhosis, Diarrhea, Constipation
- 6) **Pain Management**
Neuralgias including herpetic, trigeminal and glossopharyngeal neuralgia
- 7) **Immunology Autoimmune disease**
- 8) **Disease of ageing**

Practicals

Hospital posting in various departments designed to complement the lectures by providing practical clinical discussion, attending ward rounds, follow up the progress and changes made in drug therapy in allotted patients, case presentation, upon discharge. Students are required to maintain a record of case presented and the same should be submitted at the end of the course evaluation.

Books Recommended

1. Clinical Pharmacy and Therapeutics – Roger and Walker, Churchill Livingstone Publications, Philadelphia USA.
2. Applied Therapeutics - The clinical use of Drugs. Lloyd Young and Koda-Kimble MA. Philadelphia USA.

3. Avery's Drug Treatment, Adis International Limited. Netherland
4. Textbook of Therapeutics: Drug and Disease Management. Editors - Eric T. Herfindal and Dick. R. Gourley, Williams and Wilkins, USA.
5. Pharmacotherapy: A Pathophysiologic Approach. Joseph T. DiPiro, Robert L. Talbert, Gary C. Yee, Gary R. Matzke, Barbara G. Wells, L. Michael Posey. MCGRAW-HILL Publication, USA.

COURSE NAME : APPROACHES TO PHARMACEUTICAL RESEARCH

Learning Outcomes:

After successful completion of the course student will be able to :

- Understand the research process, research design and various aspects related to pharmaceutical research.
- Recall the brilliant discoveries done in past from some of the top pharmaceutical industries through case studies.
- Identify the various governmental and non-governmental funding agencies with their basic criterion for getting research grants.
- Apply the concepts of bio-statistics and its role in the pharmaceutical research.

Theory (Detailed Syllabus)

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I. Research

- Aim objective & purpose and need for Research,
- Types of Research
- Selecting a problem and preparing a research proposal,
- Methods, Design and Tools used in research
- Literature Survey, Printing & Secondary Sources of Information
- E-Resources
- Documentation – How, techniques, importance and uses of computers
- The research Report/Paper writing/thesis writing and Scientific Writing
- Patent Search and Reading of Patents

II. Presentation of Experimental Data

III. Ethics in Research & Publication

IV. Procurement of Research Grants from various agencies, International Agencies, Government bodies and Private bodies.

V. Industry - Institute Interaction & Interaction with Research Organization. Case studies of development of pharmaceuticals from Lab sources to the market.

VI. Biostatistics:

Probability theory and distributions, sampling distributions and the central limit theorem. Population parameters and their sample estimates; descriptive statistics for central tendency and dispersion; hypothesis testing and confidence intervals for means, variances, and proportions; the chi-square statistic; categorical data analysis; linear correlation and regression model; analysis of variance; and nonparametric methods, application in pharmaceutical research

Tutorial

1. Case studies of the above topics mentioned in the theory section.
2. Assignments based on the above syllabus. 3. Writing applications to agencies for Research Grants.

Books Recommended

1. Research In education : John V. Best, James V. Kahn
2. Presentation Skills- Michael Halton- Indian Society for Institute Education
3. A practical Introduction to copyright- Gravin Mcfarlane

4. Thesis Projects in science and Engineering _ Richard M. Davis
5. Scientists in legal System- Ann Labor Science
6. Thesis and Assignment Writing- Jonathan Anderson

M. Pharm. Semester – I

COURSE NAME: COMMUNICATION SKILLS FOR PHARMACISTS

Learning Outcomes:

After successful completion of the course student will be able to :

- Use appropriate vocabulary for fluent and confident oral communication
- Recognize and understand important aspects of non-verbal communication
- Demonstrate communication capacities in speaking, writing, listening and narrating in English
- Prepare curriculum vitae and job application

Tutorial (Detailed Syllabus)

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Practice Assignments based on the following topics will be conducted

1. Non-verbal communication

Meaning and process of pharmaceutical communication kinesics, types of communication, psychological and social aspects of communication, barriers to effective communication.

2. Oral communication (verbal communication)

Effective presentation skills, group discussion dynamics, personal interview techniques, seminar presentation, media choice for oral presentation, active listening through recorded speech. correct pronunciation, group discussion. delivering the speech or presentation, traditional text based oral presentation. visual element of texts, tables, figures, charts, etc.

3. Written communication

Technical – writing and discussion, technical instructions, writing research papers, paragraph development, curriculum vitae and job application.

4. Mechanics of language and vocabulary building

5. Listening skills

Types of listening, barriers to effective listening, tips to improve listening skills.

Books Recommended

1. Tindall W.N, Beardsley R.S., Kimberlin C.L., Communication Skills in Pharmacy Practice: A Practical Guide for Students and Practitioners, Lippincott Williams & Wilkins.
2. J. R. Matthews and R.W. Matthews, Successful Scientific Writing, Cambridge University Press Singapore.
3. R. A. Day, How to write and publish a scientific paper, Cambridge University Press Singapore.
4. A. J. Rutherford , Basic Communication Skills for Technology, Pearson.
5. R.C. Sharma and K. Mohan Business Correspondence and Report Writing Tata McGraw

M. Pharm. [Clinical Pharmacy] Semester – II

COURSE NAME: CLINICAL PHARMACY –II [3PP201]

Learning outcomes:

After successful completion of the course, student will be able to

- Understand about setting-up and management of a new hospital pharmacy.
- Apply the knowledge of pharmacoepidemiology and pharmacoeconomics in clinical studies
- Assist in the management of critical care unit and thus contribute to the patient healthcare system.

Theory (Detailed Syllabus)

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1) Hospital Pharmacy

- a) Hospital Pharmacy – Organization and Management:
- b) Organization of hospital & hospital pharmacy, Roles & responsibilities of hospital pharmacist, Budget preparation & implementation
- c) Pharmacy and Therapeutic Committee:
- d) Objectives, organization, functions & limitations
- e) Hospital formulary
- f) Contents, preparation & Revision of formulary
- g) Other hospital committees like infection control committee and research and ethics committee.
- h) Hospital Pharmacy management
- i) Staff (professional and Non-professional), Materials (drugs, non-drugs and consumables), Financial (drug budget, cost centers, sources of revenue, revenue collection), Policy and Planning, Infrastructure requirements (building, furniture and fittings, specialized equipments, maintenance and repairs), Workload statistics.
- j) Hospital Pharmacy services
- k) Inventory control, purchasing, storage, stability and safety of drugs, special pharmaceutical products including, radiopharmaceuticals, biotech products and vaccines. Drug distribution IV additive services and total parenteral nutrition.
- l) Regulatory guidelines for hospital pharmacy of different countries.

2) Pharmacoepidemiology

- a) Definitions and scope
- b) Methods (qualitative, quantitative and meta-analysis models)
- c) System of monitoring drug effects
- d) Advantages and disadvantages of Pharmacoepidemiology

3) Pharmacoeconomics

- a) Definitions and scope
- b) Types of economic evaluation
- c) Cost models and cost effectiveness analysis.
- d) Business models of different pharmacy store.

4) Critical Care and Emergency Medicine:

- a) Basic principles of specific critical care disease states & their treatment (i.e. managing ICUs and monitoring emergency department patients)

Practicals

Students are expected to:

1. Participate in activity sessions involving issues regarding pharmacy and therapeutics committee
2. Preparation of model monograph for a drug formulary
3. Analysis of the given data on hospital pharmacy budget, work flow patterns etc.
4. Preparation of drug profiles on new drugs

Books Recommended

1. Pharmacoeconomics by J. Lyle Bootman, Roymond J. Townsend, William F. Mc Gham-Netherlands, France.
2. Pharmacoeconomics, by Tom Walley, Alan Haycox and Angela Boland. London: Elsevier.
3. Stephens, Martin, Hospital Pharmacy edited by Pharmaceutical Press, London.
4. Boh, Larry E. E., Young, Lloyd Y., Pharmacy Practice Manual, Lippincott Williams & Wilkins, New York.

M. Pharm. [Clinical Pharmacy] Semester – II COURSE NAME: APPLIED PHARMACOTHERAPEUTICS-II [3PP202]

Learning outcomes:

After successful completion of the course, student will be able to

- Understand the pathogenesis and the therapeutic management for the disorders mentioned in the syllabus
- Apply the knowledge and skill for the management of the respective disorders.

Theory (Detailed Syllabus)

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Etiopathogenesis and Pharmacotherapeutic management of following diseases:

1) **Renal disorders:**

Acute Renal failure, Chronic Renal failure, End stage renal failure

2) **Endocrine disorders:**

Diabetes Mellitus, Thyroid & Parathyroid diseases, Adrenocortical dysfunction

3) **Psychiatric and Neurologic Disorders:**

Epilepsy, Parkinsonism, Schizophrenia, Depression and Mania, Anxiety, Insomnia, Alzheimer's disease, Migraine, Drug addiction

4) **Infectious Diseases:**

Urinary Tract Infections, Enteric infections, Respiratory tract infections, Tuberculosis, Central nervous system infections, Bone and joint infections, Sexually Transmitted Diseases.

5) **Oncologic diseases:**

Acute and chronic leukemia, Lymphomas, Gastrointestinal and liver cancers, Lung cancers, prostate and Gynecologic cancers, Melanomas and Breast cancer.

6) **Ophthalmologic disorders:**

Glaucoma, Cataract.

7) **Skin diseases**

Contact Dermatitis, Acne, Burns

Practicals

Hospital posting in various departments designed to complement the lectures by providing practical clinical discussion, attending ward rounds, follow up the progress and changes made in drug therapy in allotted patients, case presentation, upon discharge. Students are required to maintain a record of case presented and the same should be submitted at the end of the course evaluation.

Books Recommended

1. Clinical Pharmacy and Therapeutics – Roger and Walker, Churchill Livingstone Publications, Philadelphia USA.
2. Applied Therapeutics - The clinical use of Drugs. Lloyd Young and Koda-Kimble MA, Philadelphia USA.
3. Avery's Drug Treatment, Adis International Limited, Netherlands.
4. Textbook of Therapeutics: Drug and Disease Management. Edited by - Eric T. Herfindal and Dick. R. Gourley, Williams and Wilkins.

M. Pharm. [Clinical Pharmacy] Semester – III

COURSE NAME: CLINICAL PHARMACY-III [3PP301] (Self-Study Course)

Learning outcomes:

After successful completion of the course, student will be able to

- Play a key role as clinical pharmacist and carry out review of medication history, participate in ward rounds and assists in drug utilization review processes.
- Understand the details of drug and poison information centers, design clinical trial protocols and assist in pharmacovigilance programmes.

Theory (Detailed Syllabus)

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- 1) **Introduction to daily activities of a Clinical Pharmacist**
 - a) Medication chart review, clinical review, pharmacist interventions
 - b) Ward round participation
 - c) Medication histories
 - d) Pharmaceutical care concepts
 - e) Drug utilization evaluation (DUE) and review (DUR)
- 2) **Patient Data Analysis**
 - a) Understanding common medical abbreviations and terminologies used in clinical practices.
 - b) Diagnosis and routine tests for diagnosis, common sources of laboratory errors and role of pharmacists.
 - c) Physiological parameters and interpretation of clinical laboratory tests:
 - d) Blood chemistry, Urinalysis, Stool, Sputum, and CSF examination.
 - e) Hematological, liver function, Renal function, thyroid function tests
 - f) Tests associated with cardiac disorders
 - g) Fluid and electrolyte balance
 - h) Microbiological culture sensitivity tests
 - i) Pulmonary Function Tests
- 3) **Drug and Poison information**
 - a) Introduction to drug information resources available
 - b) Systematic approach in answering DI queries.
 - c) Critical evaluation of drug information and literature
 - d) Preparation of written and verbal reports
 - e) Establishing a Drug Information Centre
 - f) Poisons information-organization & information resources.
 - g) Management of habit forming drugs and drugs of abuse
- 4) **Research design and conduct of clinical trials**
 - a) Role of pharmacist in clinical trial.
 - b) Various phases of clinical trials
 - c) Planning and execution of clinical trials
 - d) Guidelines of good clinical research practice and ethical requirements
 - e) Monitoring and auditing of clinical trials
- 5) **Pharmacovigilance**
 - a) Scope, definition and aims.
 - b) Adverse Drug Reactions (ADRs): Classification, mechanism, predisposing factors, causality assessment
 - c) Reporting, evaluation, monitoring, preventing and management of ADRs
 - d) Role of pharmacists in management of ADR
 - e) Counterfeit medicines

Books Recommended

1. Rowland M., Tozer N., Thomas, Clinical Pharmacokinetics- Concepts and Application by Tozer, B. I. Waverly Pvt. Ltd., New Delhi.
2. Dhillon S., Kostrzewski, A., Clinical Pharmacokinetics, Pharmaceutical Press, London.
3. Dipiro, J., Spruill, W., Wade, W., Blouin, R., Pruemer, J., Concepts in clinical pharmacokinetics, American society of health-system pharmacists, Inc.USA.
4. Burton, M., Shaw, L., Schentag, J., Evans, W., Applied pharmacokinetics & pharmacodynamics, Lippincott Williams & Wilkins, Philadelphia
5. Shargel L., Applied Biopharmaceutics and Pharmacokinetics and Mc-Graw Hill, New York.
6. Kimki C., Hui, Duffull B., Stephen, Simulation for the designing clinical trials by Marcel Dekker Inc., New York.
7. Notari, E., Robert, Biopharmaceutics and Clinical Pharmacy- An Introduction by Marcel Dekker Inc., New York.
8. Fundamental of Clinical Trials. Lawrence M. Friedman, Curt D. Furberg and David L. DeMets. Springer verlag, New York, Inc. (Latest Edition)
9. Clinical Trials, A Practical Approach. Stuart J. Pocock. John Wiley & Sons, Ltd. (Latest Edition), London.
10. Clinical Trials, A Methodologic Perspective. Steven Piantadosi. John Wiley & Sons, Inc, NZ.
11. Clinical Trials in oncology, Stephanie Green, Jacqueline Benedetti, John Crowley, Chapman & Hall/CRC, London.

M.Pharm. [Clinical Pharmacy]

SEMESTER- III

COURSE NAME: MAJOR PROJECT PART – I [3PP302]

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M. Pharm. [Clinical Pharmacy] Semester – III

COURSE NAME: SUBJECT SEMINAR [3PP103]

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M.Pharm. [Clinical Pharmacy]

SEMESTER- IV

COURSE NAME: MAJOR PROJECT PART – II [3PP401]

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**COURSE NAME : SOCIAL EXTENSION ACTIVITIES
(SUPPLEMENTARY COURSE)**

Learning outcome:

After successful completion of the course student will be able to:

- Develop competence required for team work and sense of social responsibility
- Understand the community where we live in
- Identify needs and problems of community

Theory (Detailed Syllabus)

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- 1 Introduction of areas where social services is needed.
 - a. Children: Education, health awareness and basic needs
 - b. Women : Domestic violence and self-dependency
 - c. Physically handicapped : social, economical and mental support
- 2 Identification of Non-government Organisation working for noble cause and in association with them provides services to society. 2
- 3 Piggy bank for needy children: students should save some money every month. At the end of month, things will be purchased and distributed to needy children.

Books Recommended

1. Batra, Nitin (2004) Dynamics of Social Work in India, Raj Publishing House, Jaipur
2. Bhose, S.G.R. Joel (2003) NGOs and Rural Development, Concept Publishing Company, New Delhi
3. Prasad, B.K. (2003) Rural Development: Concept, Approach and Strategy, Sarup and Sons, New Delhi

COURSE NAME: REGULATORY GUIDELINES & INTELLECTUAL PROPERTY RIGHTS

COURSE CODE: 3EP2H19

Learning Outcomes

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

- Understand the regulatory guidelines at national as well as world wide.
- Prepare documents necessary for import, Export, manufacturing and distribution of drugs.
- Express guidelines required to carry out Toxicity studies carcinogenicity & teratogenicity studies.
- Discuss IPR issues, patent filing in India and foreign countries.

Theory (Detailed Syllabus)

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1. R Regulatory Guidelines

• P Pharmaceutical Legislation

Regulatory Bodies of different

- Indian Regulatory Authorities
- Regulatory guidelines of India, ICH guidelines
Guidelines for Import, Export, Manufacturing and distribution of drugs
- Brief study of various Regulatory Guidelines of other countries mainly USA and Europe. Variation filing for changes as per regulatory guidelines
- Basics of Clinical trials and Clinical Research, Features of Clinical Trials, Good Clinical Practices, Bioavailability studies, Clinical trials Regulatory affairs.
- Guidelines required to carry out toxicity studies carcinogenicity & teratogenicity studies.
- Pharmacovigilance
- ADR reporting.
- Orphan drug indications.

2. Intellectual Property Rights:

- Intellectual Property Rights, TRIPS and GATT agreement, Patent, Copyright and Trademarks, Exclusive Marketing Rights
- Patent system in India: Types of patent, patent rights, claims, patent infringement, forms & filings
- Patent applications in foreign countries

Books Recommended

1. Regulation of Medical Products edited by J P Griffin and J O'Grady, BMJ Books Publications, 2003
2. International IT Regulations and compliance Quality standards in the pharmaceutical and regulated Industries, Siri H. Segalsatd. A John Wiley and Sons. Ltd, Publication.
3. Official websites related to various guidelines.
4. Drug & Cosmetic Act, 1940, Controller of Public ations, India.
5. Encyclopaedia of clinical pharmacy, Edited by Joseph T. Dipiro, Marcel Dekker.
6. IPR Handbook for Pharma Students and researchers, Parikshit Bansal, Pharma Book Syndicate.
7. The law of patents with special focus on pharmaceuticals in India, Feroz-Ali Khader.

COURSE NAME: MODERN CONCEPTS IN PHARMACOLOGY

Course Code: 3EP2L14

Learning Outcomes:

After successful completion of course, students will be able to:

- Explain pathophysiology and clinical manifestations of disorders pertaining to autonomic nervous system, central nervous system, renal and cardiovascular systems, cancer and inflammatory disorders
- Apply their knowledge for clinical management of the above disorders .

Theory (Detailed Syllabus)

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- !Drug actions influencing the autonomic nervous system
- Drugs acting on the Central nervous system
 - a. Neurotransmission in CNS
 - b. Psychopharmacological agents
 - c. Anti-epileptic agents
 - d. Anti-parkinsonian agents
 - e. Opioid analgesics
- Drugs acting on Renal and cardiovascular system
 - a. Diuretics
 - b. Anti-hypertensives
 - c. Anti-anginal and drugs used in acute coronary syndrome
 - d. Cardiotonics
 - e. Anti-arrhythmics
 - f. Drug used in Hyper lipoproteinemias
- Anti- asthmatics and anti-inflammatory drugs
- Anti-neoplastic agents

Books Recommended

1. Goodman Gilman A., Rall T.W., Nies A.I.S. and Taylor, P. Goodman and Oilman ' s The pharmacological Basis of therapeutics, Mc Graw Hill, Pergamon Press.
2. Rang, H.P. and Dale, M.M. Pharmacology, Churchil Livingstone
3. Katzung, B.G. Basic and Clinical Pharmacology, McGraw Hill, New York.
4. Ghosh, M.N. Fundamentals of experimental pharmacology, Scientific Book agency, Kolkata
5. Macleod, L.J. Pharmacological experiments on isolated preparations, Elsevier Health Sciences.

COURSE NAME: APPLIED INDUSTRIAL PHARMACOLOGY

COURSE CODE: 3EP2L26

Learning Outcomes:

After successful completion of course, students will be able to:

- Design protocols for new drug developments as per national and international regulatory guidelines.
- Apply the principles of clinical pharmacokinetics for management of the diseases.

Theory (Detailed Syllabus)

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- 1 Clinical Pharmacology, Clinical Pharmacokinetics, Therapeutic drug monitoring: Concepts and Applications re-clinical Testing strategy vis a vis envisaged clinical studies
Design and organization of Phase-I to Phase-IV clinical studies. GCP, ICH and WHO guidelines.
- 4) General principles of toxicology and pre-clinical toxicity studies in accordance with Schedule Y and ICH guidelines etc.
- 5) Regulatory Protocol & Guidelines

Books Recommended

1. Dhillon S., Kostrzewski, A., Clinical Pharmacokinetics, Pharmaceutical Press, London.
2. Dipiro, J., Spruill, W., Wade, W., Blouin, R., Pruemer, J., Concepts in clinical pharmacokinetics, American society of health-system pharmacists, Inc.
3. Burton, M., Shaw, L., Schentag, J., Evans, W., Applied pharmacokinetics & pharmacodynamics, Lippincott Williams & Wilkins, Philadelphia
4. Kimki C., Hui, Duffull B., Stephen, Simulation for the designing clinical trials by Marcel Dekker Inc., New York.
5. Tom Walley, Alan Haycox and Angela Boland, Pharmacoeconomics, Elsevier.
6. Bootman JL, Townsend RJ, McGhan WF, Principles of Pharmacoeconomics, Harvey Whitney Books Company, Cincinnati, OH
7. Bryan Ballantyne, Timothy marris, Paul Turner. General & Applied Toxicology by Stockton press

COURSE NAME: BIO-AVAILABILITY & BIOEQUIVALENCE TESTING

Course Code: 3EP2T23

Learning Outcomes:

After successful completion of course, students will be able to:

- Understand the concept and significance of Bioavailability and Bioequivalence study in various dosage forms.
- Apply statistical concepts and methodology in BA-BE study design.
Correlate the regulatory requirements and procedures for BA-BE studies.

Theory (Detailed Syllabus)

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- 1) Bioavailability:
Absorption of drugs and dosage forms, factors influencing bioavailability, evaluation of bioavailability of drugs and dosage forms.
- 2) Bioequivalence:
Absolute, relative, using IV & urinary data, for modified release dosage forms.
- 3) Bioavailability study protocol, Study designs for new and approved drugs
- 4) Statistical concepts used in estimation of bioavailability and bioequivalence studies.
- 5) In vivo in vitro correlation models in determining bioavailability
- 6) Regulatory agencies and procedures for Bioavailability & Bioequivalence testing

Books Recommended

1. Applied Biopharmaceutics and Pharmacokinetics, by Shargel L., Mc-Graw Hill, New York.
2. Clinical Pharmacokinetics - Concepts and Application by Rowland M., Tozer N., Thomas, B. I. Waverly Pvt. Ltd., New Delhi.
3. Pharmacokinetic and Clinical Calculation by Khan A., Mansor, Reddy K., Indra, Technomic Publishing Company Inc., Pennsylvania, USA.
4. Simulation for the designing clinical trials by Kimki C., Hui, Duffull B., Stephen, Marcel Dekker, New York.
5. Biopharmaceutics and Pharmacokinetics by P. L. Madan, Jaypee Brothers Medical Publication, India
6. Clinical Pharmacokinetics Handbook by Larry A. Bauer, McGraw-Hill, New York

