ANNAMACHARYA UNIVERSITY

(ESTD UNDER AP PRIVATE UNIVERSITIES (ESTABLISHMENT AND REGULATION) ACT,
(UNIVERSITY LISTED IN UGC AS PER THE SECTION 2(f) OF THE UGC ACT, 1956)

RAJAMPET, YSR District, AP – 516126, INDIA

PHARMACEUTICAL SCIENCES

Course Structure and Syllabi for Pre Ph.D. Programme

SUBJECT-1

S. No	Course Code	Title of the Course
1	26CPHP01T	Research Methodology for Pharmaceutical Sciences

SUBJECT-2

S. No	Course Code	Title of the Course
1	26CPHP02T	Research and Publications ethics for Pharmaceutical Sciences

CORE SUBJECTS

Choose any Two subjects from the following list

S. No	Course Code	Title of the Course
1.	26CPHP03T	Drug Delivery Systems
2.	26CPHP04T	Modern Pharmaceutics
3.	26CPHP05T	Molecular Pharmaceutics (Nano Technology & Targeted DDS)
4.	26CPHP06T	Computer Aided Drug Development
5.	26CPHP07T	Modern Pharmaceutical Analytical Techniques
6.	26CPHP08T	Quality Control and Quality Assurance
7.	26CPHP09T	Pharmaceutical Validation
8.	26CPHP0AT	Advanced Pharmaceutical Analysis
9.	26CPHP0BT	Food Analysis
10.	26CPHP0CT	Advanced Organic Chemistry
11.	26CPHP0DT	Advanced Medicinal Chemistry
12.	26CPHP0ET	Computer Aided Drug Design & Discovery
13.	26CPHP0FT	Chemistry of Natural Products
14.	26CPHP0GT	Pharmacological and Toxicological Screening Methods
15.	26CPHP0HT	Advanced Pharmacology – I
16.	26CPHP0IT	Advanced Pharmacology – II
17.	26CPHP0JT	Cellular and Molecular Pharmacology
18.	26CPHP0KT	Advanced Pharmacognosy - I
19.	26CPHP0LT	Phytochemistry
20.	26CPHP0MT	Industrial Pharmacognostical Technology
21.	26CPHP0NT	Medicinal Plant Biotechnology
22.	26CPHP0OT	Advanced Pharmacognosy - II
23.	26CPHP0PT	Indian Systems of Medicine
24.	26CPHP0QT	Herbal Cosmetics
25.	26CPHP0RT	Advanced Pharmacy Practice
26.	26CPHP0ST	Pharmacotherapeutics

27.	26CPHP0TT	Clinical Pharmacy
28.	26CPHP0UT	Pharmacy Management and Pharmacoepidemiology

Title of the Course : Drug Delivery Systems
Course Code : 26CPHP03T
Course offered to : Pharmaceutical Sciences
Credits : 4

Course Objectives

1. To provide comprehensive knowledge of various approaches and strategies employed in the design and development of novel drug delivery systems (NDDS).
2. To develop an understanding of the physicochemical, biopharmaceutical, and therapeutic factors involved in the selection of suitable drug candidates for NDDS.
3. To impart knowledge on the selection and characterization of polymers, excipients, and carrier systems used in novel drug delivery formulations.
4. To train scholars in the formulation, optimization, and scale-up of various novel drug delivery systems using modern pharmaceutical techniques.
5. To develop skills in the evaluation, characterization, and performance assessment of novel drug delivery systems for ensuring safety, efficacy, and product quality.

Course Outcomes:

1. Explain the principles, concepts, advantages, limitations, and mechanisms of sustained release, controlled release, and rate-controlled drug delivery systems, including the role of polymers in formulation design.
2. Analyze physicochemical, biological, and technological approaches used in developing advanced drug delivery systems such as gastro-retentive, buccal, ocular, and transdermal formulations.
3. Evaluate formulation strategies, barriers, and performance parameters involved in protein, peptide, and vaccine delivery systems for effective therapeutic outcomes.
4. Apply knowledge of personalized medicine approaches, including pharmacogenetics, customized drug delivery, bioelectronic medicines, 3D printing of pharmaceuticals, and tele pharmacy in modern healthcare practice.
5. Design and assess innovative drug delivery systems based on patient needs, drug characteristics, and therapeutic goals using scientific and regulatory considerations.

Unit 1 12

Sustained Release (SR) and Controlled Release (CR) formulations: Introduction & basic concepts, advantages/ disadvantages, factors influencing, Physicochemical & biological approaches for SR/CR formulation, Mechanism of Drug Delivery from SR/CR formulation. Polymers: introduction, definition, classification, properties and application Dosage Forms for Personalized Medicine: Introduction, Definition, Pharmacogenetics, Categories of Patients for Personalized Medicines: Customized drug delivery systems, Bioelectronic Medicines, 3D printing of pharmaceuticals, Tele pharmacy

Unit 2 12

Rate Controlled Drug Delivery Systems: Principles & Fundamentals, Types, Activation; Modulated

Drug Delivery Systems; Mechanically activated, pH activated, Enzyme activated, and Osmotic activated Drug Delivery Systems Feedback regulated Drug Delivery Systems; Principles & Fundamentals.

Unit 3 12

Gastro-Retentive Drug Delivery Systems: Principle, concepts advantages and disadvantages, Modulation of GI transit time approaches to extend GI transit. Buccal Drug Delivery Systems: Principle of muco adhesion, advantages and disadvantages, Mechanism of drug permeation, Methods of formulation and its evaluations.

Unit 4 12

Ocular Drug Delivery Systems: Barriers of drug permeation, Methods to overcome barriers.
Transdermal Drug Delivery Systems: Structure of skin and barriers, Penetration enhancers, Transdermal Drug Delivery Systems, Formulation and evaluation.

Unit 5 12

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

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

Prescribed Textbooks:

1. N.K. Jain, Controlled and Novel Drug Delivery, CBS Publishers & Distributors, New Delhi, First edition 1997 (reprint in 2001).
2. S.P.Vyas and R.K.Khar, Controlled Drug Delivery - Concepts and advances, Vallabh Prakashan, New Delhi, First edition 2002

Reference Books:

1. Y W. Chien, Novel Drug Delivery Systems, 2nd edition, revised and expanded, Marcel Dekker, Inc., New York, 1992.
2. Robinson, J. R., Lee V. H. L, Controlled Drug Delivery Systems, Marcel Dekker, Inc., New York, 1992.

Title of the Course : Modern Pharmaceutics
Course Code : 26CPHP04T
Course offered to : Pharmaceutical Sciences
Credits : 4

Course Objectives

1. To provide a comprehensive understanding of the principles and components of preformulation studies essential for successful dosage form development.
2. To impart knowledge on the development of Active Pharmaceutical Ingredients (APIs) and generic pharmaceutical products, including regulatory and quality considerations.
3. To develop an understanding of industrial pharmacy practices, Good Manufacturing Practices (GMP), and effective pharmaceutical production management.
4. To train scholars in the application of optimization techniques and pilot-scale manufacturing approaches for product development and scale-up.
5. To equip learners with knowledge and skills related to stability testing, sterilization processes, packaging systems, and quality assurance of pharmaceutical dosage forms.

Course Outcomes:

1. Explain the principles of preformulation studies, drug-excipient compatibility, stability testing, and the formulation strategies of pharmaceutical dispersions and parenteral dosage forms.
2. Apply optimization methodologies, statistical design of experiments (DoE), and response surface analysis for the development and optimization of pharmaceutical formulations and processes.
3. Demonstrate knowledge of pharmaceutical validation practices, regulatory compliance requirements, and qualification procedures for equipment, facilities, utilities, and pharmaceutical products.
4. Analyze current Good Manufacturing Practices (cGMP), industrial management principles, and Total Quality Management (TQM) approaches to ensure efficient and compliant pharmaceutical manufacturing.
5. Evaluate compression, compaction, dissolution, diffusion, and pharmacokinetic parameters using mathematical models, statistical techniques, and scientific tools for formulation development and quality assessment.

Unit 1 12

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

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

Unit 2 12

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

Unit 3 12

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

Unit 4 12

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

Unit 5 12

Study of consolidation parameters; Diffusion parameters, Dissolution parameters and Pharmacokinetic parameters, Heckel plots, Similarity factors – f2 and f1, Higuchi and Peppas plot, Linearity Concept of significance, Standard deviation, Chi square test, students t-test, ANOVA test.

Prescribed Textbooks:

1. Leon Lachman, Herbert A. Lieberman, Joseph L. Kanig. The Theory and Practice of Industrial Pharmacy.
2. Howard C. Ansel, Nicholas G. Popovich, Loyd V. Allen Jr. Pharmaceutical Dosage Forms and Drug Delivery Systems.

Reference Books:

1. Robert A. Nash, Alfred H. Wachter. Pharmaceutical Process Validation Comprehensive Medicinal Chemistry – Corwin and Hansch.
2. Michael Levin, Pharmaceutical Process Scale-Up", Drugs and Pharm. Sci. Series, Vol. 157,2nd Ed., Marcel Dekker Inc., N.Y.
3. Validation Standard Operating Procedures: A Step-by-Step Guide for Achieving Compliance in the Pharmaceutical, Medical Device, and Biotech Industries, Syed Imtiaz Haider.
4. Pharmaceutical Equipment Validation: The Ultimate Qualification Handbook, Phillip A. Cloud, Interpharm Press

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Title of the Course	**:**	Molecular Pharmaceutics (Nano Technology & Targeted DDS)
Course Code	**:**	26CPHP05T
Course offered to	**:**	Pharmaceutical Sciences
Credits	**:**	4

Course Objectives

1. To provide comprehensive knowledge of the principles, mechanisms, and biological processes involved in targeted drug delivery systems, including tumor targeting and brain-specific drug delivery.
2. To impart understanding of various targeting strategies and advanced carrier systems such as nanoparticles, liposomes, microspheres, and microcapsules used for site-specific drug delivery.
3. To develop expertise in the formulation, preparation, characterization, and evaluation of novel vesicular and colloidal drug delivery systems, including niosomes, aquasomes, phytosomes, and electrosomes.
4. To familiarize students with the design, development, and evaluation of pulmonary and intranasal drug delivery systems for local and systemic therapeutic applications.
5. To introduce emerging nucleic acid-based therapeutic delivery systems, gene therapy approaches, gene transfer technologies, biodistribution, pharmacokinetics, and future therapeutic modalities such as antisense molecules and aptamers.

Course Outcomes:

1. Explain the concepts, mechanisms, and biological barriers involved in targeted drug delivery, including tumor-specific and brain-targeted therapeutic systems.
2. Apply appropriate methods for the preparation, characterization, and evaluation of nanoparticles, liposomes, microcapsules, and microspheres used in advanced drug delivery.
3. Demonstrate knowledge of the design, formulation, and therapeutic applications of monoclonal antibodies, niosomes, aquasomes, phytosomes, and electrosomes.
4. Analyze the formulation principles, evaluation parameters, and clinical significance of pulmonary and intranasal drug delivery systems.
5. Evaluate nucleic acid-based drug delivery systems, gene therapy strategies, viral and non-viral gene transfer methods, biodistribution behavior, pharmacokinetics, and the potential of antisense and aptamer-based therapeutics.

Unit 1 12

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

Unit 2 12

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

Unit 3 12

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

Unit 4 12

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

Unit 5 12

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.

Prescribed Textbook:

1. S.P.Vyas and R.K.Khar, Controlled Drug Delivery - Concepts and advances, VallabhPrakashan, New Delhi, First edition 2002.

Reference Books:

1. Y W. Chien, Novel Drug Delivery Systems, 2nd edition, revised and expanded, Marcel Dekker, Inc., New York, 1992.
2. N.K. Jain, Controlled and Novel Drug Delivery, CBS Publishers & Distributors, New Delhi, First edition 1997 (reprint in 2001).

Title of the Course : Computer Aided Drug Development
Course Code : 26CPHP06T
Course offered to : Pharmaceutical Sciences
Credits : 4

Course Objectives

1. To understand the role of computers and statistical modeling in pharmaceutical R&D.
2. To gain knowledge of Quality-by-Design (QbD) principles in pharmaceutical development.
3. To learn computational approaches for drug disposition, formulation optimization, and product development.
4. To apply computer-aided tools in biopharmaceutics, pharmacokinetics, and clinical research.
5. To understand the applications of Artificial Intelligence, robotics, and automation in the pharmaceutical industry.

Course Outcomes:

1. Explain the applications of computer-based tools and statistical models in pharmaceutical research and development.
2. Apply QbD concepts and optimization techniques for pharmaceutical formulation and process development.
3. Analyze drug absorption, distribution, metabolism, and excretion using computational modeling approaches.
4. Evaluate biopharmaceutical, pharmacokinetic, and clinical data using simulation and computer-aided methods.
5. Assess the impact of AI, robotics, and pharmaceutical automation in modern drug development and manufacturing.

Unit 1 12

Computers in Pharmaceutical Research and Development: A General Overview: History of Computers in Pharmaceutical Research and Development. Statistical modelling in pharmaceutical research and development: Descriptive versus Mechanistic Modelling, Statistical Parameters, Estimation, Confidence Regions, Nonlinearity at the Optimum, Sensitivity Analysis, Optimal Design, Population Modelling

Quality-by-Design In Pharmaceutical Development: Introduction, ICH Q8 guideline, Regulatory and industry views on QbD, scientifically based QbD - examples of application.

Unit 2 12

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

Unit 3 12

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

Unit 4 12

Computer-aided biopharmaceutical characterization: Gastrointestinal absorption simulation. Introduction, Theoretical background, Model construction, Parameter sensitivity analysis, Virtual trial,

Fed vs. fasted state, In vitro dissolution and in vitro- in vivo correlation, Biowaiver considerations

Computer Simulations in Pharmacokinetics and Pharmacodynamics: Introduction, Computer Simulation: Whole Organism, Isolated Tissues, Organs, Cell, Proteins and Genes.

Computers in Clinical Development: Clinical Data Collection and Management, Regulation of Computer Systems

Unit 5 12

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

Prescribed Textbook:

1. Computer Applications in Pharmaceutical Research and Development, Sean Ekins, 2006, John Wiley & Sons.

Reference Books:

1. Computer-Aided Applications in Pharmaceutical Technology, 1st Edition, Jelena Djuris, Woodhead Publishing
2. Encyclopedia of Pharmaceutical Technology, Vol 13, James Swarbrick, James. G.Boylan, Marcel Dekker Inc, New York, 1996.

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Title of the Course	**:**	Modern Pharmaceutical Analytical Techniques
Course Code	**:**	26CPHP07T
Course offered to	**:**	Pharmaceutical Sciences
Credits	**:**	4

Course Objectives

1. To provide knowledge of the principles and applications of modern spectroscopic techniques used in pharmaceutical analysis.
2. To develop an understanding of structural elucidation using UV, IR, NMR, and Mass spectroscopy.
3. To impart knowledge of chromatographic and electrophoretic techniques for separation and characterization of pharmaceutical compounds.
4. To familiarize students with electroanalytical, thermal, and X-ray crystallographic methods used in drug analysis.
5. To develop skills in selecting and applying appropriate analytical techniques for qualitative and quantitative pharmaceutical analysis.

Course Outcomes:

1. Explain the principles, instrumentation, and applications of UV-Visible, IR, fluorescence, atomic absorption, and emission spectroscopic techniques.
2. Interpret NMR and mass spectral data for structural identification and characterization of pharmaceutical compounds.
3. Apply chromatographic and electrophoretic methods for separation, purification, and analysis of drug substances.
4. Evaluate pharmaceutical materials using electroanalytical, thermal, and X-ray diffraction techniques.
5. Select and utilize suitable analytical methods for the qualitative and quantitative assessment of pharmaceuticals and biological samples.

Unit 1 12

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

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

c. Spectroflourimetry: Theory of Fluorescence, Factors affecting fluorescence (Characteristics of drugs that can be analysed by fluorimetry), Quenchers, Instrumentation and Applications of fluorescence spectrophotometer.

d. Flame emission spectroscopy and atomic absorption spectroscopy: Principle, Instrumentation, Interferences and Applications.

Unit 2 12

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

Unit 3 12

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

Unit 4 12

a 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

b. 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.

Unit 5 12

a. Electroanalytical Methods: Principle, working, Ion selective Electrodes and Application of potentiometry.

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.

c. 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.

d. Immunoassays: RIA, ELISA

Prescribed Textbook:

1. Textbook of Pharmaceutical Analysis, KA. Connors, 3rd Edition, John Wiley & Sons, 1982.

Reference Books:

1. Spectrometric Identification of Organic compounds - Robert M Silverstein, Sixth edition, John Wiley & Sons, 2004.
2. Principles of Instrumental Analysis - Doglas A Skoog, F. James Holler, Timothy A. Nieman, 5th edition, Eastern press, Bangalore, 1998.
3. Instrumental methods of analysis – Willards, 7th edition, CBS publishers.

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Title of the Course	**:**	Quality Control and Quality Assurance
Course Code	**:**	26CPHP08T
Course offered to	**:**	Pharmaceutical Sciences
Credits	**:**	4

Course Objectives

1. To provide knowledge of Quality Assurance (QA), Quality Control (QC), GLP, GMP, and ICH guidelines in pharmaceutical industries.
2. To develop understanding of cGMP requirements, regulatory standards, and quality systems in pharmaceutical manufacturing.
3. To impart knowledge of quality control testing and specifications for raw materials, packaging materials, and finished dosage forms.
4. To familiarize students with pharmaceutical documentation, audits, regulatory submissions, and data management practices.
5. To understand manufacturing controls, process quality assurance, and intellectual property rights in the pharmaceutical sector.

Course Outcomes:

1. Explain the principles of QA, QC, GLP, GMP, and ICH guidelines applicable to pharmaceutical industries.
2. Apply cGMP requirements and regulatory standards to pharmaceutical manufacturing and quality systems.
3. Evaluate raw materials, in-process materials, and finished products according to pharmacopoeial specifications.
4. Prepare and manage pharmaceutical documentation, SOPs, batch records, audit reports, and regulatory submissions.
5. Analyze manufacturing operations, quality control measures, and intellectual property rights related to pharmaceutical products.

Unit 1 12

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.

Unit 2 12

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.

Unit 3 12

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).

Unit 4 12

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.

Unit 5 12

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.

Prescribed Textbooks:

1. Quality Assurance Guide by organization of Pharmaceutical Procedures of India, 3rd revised edition, Volume I & II, Mumbai, 1996.
2. 2. Good Laboratory Practice Regulations, 2nd Edition, Sandy Weinberg Vol. 69, Marcel Dekker Series, 1995.

Reference Books:

1. Quality Assurance of Pharmaceuticals- A compendium of Guide lines and Related materials Vol I & II, 2nd edition, WHO Publications, 1999.
2. How to Practice GMP's – P P Sharma, Vandana Publications, Agra, 1991.
3. The International Pharmacopoeia – vol I, II, III, IV & V - General Methods of Analysis and Quality specification for Pharmaceutical Substances, Excepients and Dosage forms, 3rd edition, WHO, Geneva, 2005.
3. 4. Good laboratory Practice Regulations – Allen F. Hirsch, Volume 38, Marcel Dekker Series, 1989.

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Title of the Course	**:**	Pharmaceutical Validation
Course Code	**:**	26CPHP09T
Course offered to	**:**	Pharmaceutical Sciences
Credits	**:**	4

Course Objectives

1. Understand the principles, concepts, and regulatory requirements of calibration, qualification, and validation in pharmaceutical industries.
2. Explain qualification procedures for pharmaceutical manufacturing equipment, analytical instruments, and laboratory systems.
3. Evaluate qualification and validation requirements for utility systems and critical pharmaceutical facilities.
4. Apply process validation and analytical method validation approaches in accordance with regulatory guidelines.
5. Develop validation strategies for cleaning processes and computerized systems to ensure compliance and product quality.

Course Outcomes:

1. Differentiate between calibration, qualification, and validation, and prepare basic validation documentation and validation master plans.
2. Perform and interpret qualification studies for pharmaceutical manufacturing equipment, analytical instruments, and laboratory instruments.
3. Assess the qualification and validation of utility systems such as HVAC, water systems, compressed air, and steam systems.
4. Design and evaluate process validation and analytical method validation protocols as per ICH, USP, and regulatory requirements.
5. Implement cleaning validation and computerized system validation practices, including compliance with 21 CFR Part 11 and GAMP guidelines.

Unit 1 12

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).

Unit 2 12

Qualification of manufacturing equipment: Dry Powder Mixers, Fluid Bed and Tray dryers, Tablet Compression (Machine), Dry heat sterilization/Tunnels, Autoclaves, Membrane filtration, Capsule filling machine.

Qualification of analytical instruments: UV-Visible spectrophotometer, FTIR, DSC, GC, HPLC, HPTLC, LC-MS.

Unit 3 12

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.

Unit 4 12

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.

Unit 5 12

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

Prescribed Textbook:

1. B. T. Loftus & R. A. Nash, "Pharmaceutical Process Validation", Drugs and Pharm Sci. Series, Vol. 129, 3rd Ed., Marcel Dekker Inc., N.Y.

Reference Books:

1. The Theory & Practice of Industrial Pharmacy, 3rd edition, Leon Lachman, Herbert A. Lieberman, Joseph. L. Kanig, Varghese Publishing House, Bombay.
2. Validation Master plan by Terveeks or Deeks, Davis Harwood International publishing.
3. Validation of Aseptic Pharmaceutical Processes, 2nd Edition, by Carleton & Agalloco, (Marcel Dekker).

Title of the Course : Advanced Pharmaceutical Analysis
Course Code : 26CPHP0AT
Course offered to : Pharmaceutical Sciences
Credits : 4

Course Objectives

1. Understand the sources, classification, and regulatory requirements of pharmaceutical impurities and stability studies.
2. Explain methodologies for identification, quantification, and control of organic, residual solvent, and elemental impurities.
3. Apply stability testing protocols and impurity profiling approaches according to ICH and WHO guidelines.
4. Evaluate stability requirements and analytical strategies for conventional and phytopharmaceutical products.
5. Understand the principles and applications of immunoassays, biological assays, and molecular techniques such as PCR.

Course Outcomes:

1. Classify and assess pharmaceutical impurities, including degradation products, residual solvents, and elemental impurities as per regulatory guidelines.
2. Design and interpret stability studies using appropriate protocols, storage conditions, and shelf-life estimation methods.
3. Perform impurity profiling, degradant characterization, and photostability evaluations in compliance with ICH and WHO requirements.
4. Evaluate stability testing approaches and analytical fingerprinting techniques for phytopharmaceutical products.
5. Apply immunoassays, biological assay methods, and PCR-based techniques for the analysis and quality evaluation of pharmaceutical and biological products.

Unit 1 12

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

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

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

Unit 2 12

Elemental impurities: Element classification, control of elemental impurities, Potential Sources of elemental Impurities, Identification of Potential Elemental Impurities, analytical procedures,

instrumentation & C, H, N and S analysis

Stability testing protocols:

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

Unit 3 12

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

Unit 4 12

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

Unit 5 12

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

b. Biological tests and assays of the following:

1. Adsorbed Tetanus vaccine
2. Adsorbed Diphtheria vaccine
3. Human anti hemophilic vaccine
4. Rabies vaccine
5. Tetanus Anti toxin
6. Tetanus Anti serum g. Oxytocin
7. Heparin sodium IP
8. Antivenom.

PCR, PCR studies for gene regulation, instrumentation (Principle and Procedures)

Prescribed Textbooks:

1. Vogel's textbook of quantitative chemical analysis - Jeffery J Bassett, J. Mendham, R. C. Denney, 5th edition, ELBS, 1991.
2. Practical Pharmaceutical Chemistry - Beckett and Stenlake, Vol II, 4th Edition, CBS publishers, New Delhi, 1997.
3. Textbook of Pharmaceutical Analysis - K A Connors, 3rd Edition, John Wiley & Sons, 1982.

Reference Books:

1. Pharmaceutical Analysis - Higuchi, Brochmman and Hassen, 2nd Edition, Wiley – Inter science Publication, 1961.
2. Quantitative Analysis of Drugs in Pharmaceutical formulation – P D Sethi, 3rd Edition, CBS Publishers New Delhi, 1997.
3. Pharmaceutical Analysis- Modern methods - J W Munson – Part B, Volume 11, Marcel Dekker Series.

Title of the Course : Food Analysis
Course Code : 26CPHP0BT
Course offered to : Pharmaceutical Sciences
Credits : 4

Course Objectives

1. Understand the chemistry, properties, metabolism, and analytical evaluation of major food constituents.
2. Explain the composition, functions, and analysis of carbohydrates, proteins, lipids, and vitamins in foods.
3. Evaluate the role and safety assessment of food additives, pigments, and synthetic dyes.
4. Apply analytical methods for quality assessment of milk, dairy products, and fermented food products.
5. Understand pesticide residue analysis and food regulatory requirements for ensuring food safety and quality.

Course Outcomes:

1. Classify and analyze food carbohydrates, proteins, lipids, and vitamins using appropriate analytical techniques.
2. Interpret digestion, metabolism, and nutritional significance of major food constituents.
3. Identify and evaluate food additives, natural pigments, synthetic dyes, and their quality control parameters.
4. Perform analytical assessment of dairy products, fermented foods, and detect adulterants or contaminants.
5. Assess pesticide residues in foods and apply national and international food quality regulations for food safety compliance.

Unit 1 12

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 fiber, Crude fiber and application of food carbohydrates

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

Unit 2 12

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

Vitamins: Classification of vitamins, methods of analysis of vitamins, Principles of microbial assay of vitamins of B-series.

Unit 3 12

Food additives: Introduction, analysis of Preservatives, antioxidants, artificial sweeteners, flavours, flavour enhancers, stabilizers, thickening and gelling agents.

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

Unit 4 12

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

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

Unit 5 12

Pesticide analysis: Effects of pest and insects on various food, use of pesticides in agriculture, pesticide cycle, 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

Prescribed Textbooks:

1. The chemical analysis of foods – David Pearson, Seventh edition, Churchill Livingstone, Edinburgh London, 1976.
2. Introduction to the Chemical analysis of foods – S. Nielsen, Jones & Bartlett publishers, Boston London, 1994.

Reference Books:

1. Official methods of analysis of AOAC International, sixth edition, Volume I & II, 1997.
2. Analysis of Food constituents – Multon, Wiley VCH.
3. Dr. William Horwitz, Official methods of analysis of AOAC International, 18th edition, 2005

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RAJAMPET, YSR District, AP – 516126, INDIA

Title of the Course : Advanced Organic Chemistry
Course Code : 26CPHP0CT
Course offered to : Pharmaceutical Sciences
Credits : 4

Course Objectives

1. Understand stereochemical concepts and the significance of chirality in organic molecules.
2. Explain the formation, stability, and reactivity of reactive intermediates and organic reaction mechanisms.
3. Analyze elimination, addition, pericyclic, and sigma tropic reactions in organic synthesis.
4. Apply important synthetic reagents for carrying out selective organic transformations.
5. Understand molecular rearrangements and their applications in organic synthesis.

Course Outcomes:

1. Interpret stereochemical features, configurational assignments, and isomerism in organic compounds.
2. Predict the behavior and reactivity of reactive intermediates in organic reaction mechanisms.
3. Differentiate and explain elimination, addition, electrocyclic, pericyclic, and sigmatropic reaction pathways.
4. Select and utilize appropriate synthetic reagents for specific organic transformations.
5. Analyze and apply various molecular rearrangement reactions in synthetic organic chemistry.

Unit 1 12

Stereochemistry: Elements of symmetry, simple axis of symmetry. Notation, relative configuration and absolute configuration. Compounds with a chiral carbon atom, compounds with other quadrivalent chiral atoms. Optical isomerism in compounds containing no chiral atom, biphenyl, allenes, compounds with exocyclic double bonds and spirans. Chirality due to helical shape. cis / trans, E – Z isomerism resulting from double bonds, monocyclic compounds, fused ring system. Racemic modifications and methods for resolution of racemic mixtures. Asymmetric synthesis and stereo – selective synthesis.

Unit 2 12

a. Reactive Intermediates: Definitions, generation, stability, structure and reactivity of free radicals carbocations, carbanions, carbenes, Nitrenes/Nitrenium ions. Concepts of aromaticity and antiaromaticity, non-benzenoid aromatic compounds.

b. Mechanisms of organic reactions: Free radical, Electrophilic, Nucleophilic reactions of aliphatic and aromatic compounds

Unit 3 12

a. Elimination Reactions: E1, E2, E1CB and E2CB mechanisms, Mechanisms and orientation in pyrolytic eliminations, effect of substrate structure, attacking base, leaving group and reaction bond, medium and reactivity addition to carbon – carbon multiple bond reactions. Mechanisms, Orientation and reactivity.

b. Electrocyclic, pericyclic and sigmotropic reactions: Introduction, terminology and mechanism, with suitable examples.

Unit 4 12

Synthetic Reagents & Applications: Lead Tetra Acetate (LTA), N- Bromosuccinimide (NBS), Osmium Tetroxide, Lithium Aluminum Hydride (LAH) and Sodium Borohydride, Dicyclohexylcarbodimide (DCC) and 2,3-dichlro-5,6-dicyano-1,4-benzoquinone (DDQ).

Unit 5 12

Molecular Rearrangements & their applications:
Wagner – Meerwin rearrangement, Claisen rearrangement and benzil – benzilic acid rearrangement, Hoffmann rearrangement, Curtius rearrangement and Lossen rearrangement, Beckman rearrangement, Bayer – Villiger oxidation , Rearrangement of hydro peroxides and Wittig rearrangement, Dieck mann condensation , Mannich rearrangement, Michael addition reactions.

Prescribed Textbooks:

1. Organic Reactions and mechanism – VK Ahluwalia, 4th Edition
2. Reactions and reagents by OP Agarwal , 6th Edition
3. A text book of organic Chemistry by Morrison & Boyed 7th Edition

Reference Books:

1. Francis A. Carey & Richard J. Sunberg, Advanced Org. Chemistry, III rd Edition, Par B; Reactions and synthesis, Plenum Press, New York, London, Latest Edition.
2. Eliel I. Ernest and Samuel h, Stereochemistry of Org. Compounds, John Wiley and sons,
3. Roland E. Lehr & Alan P Marchard, Orbital Symmetry: A Problem-Solving approach, Academic Press, New York Latest Edition.
4. J. March, Advanced Org. Chemistry, Reactions Mechanisms and Structure, 4th 6. Edition, John Wiley & Sons, New York Latest Edition
5. Herbert O. Modern Synthesis Reactions IInd Edition W.A. Beenamis Inc. Menco Park California
6. W. Carruthers, Some Modern Methods of Org. Synthesis, III rd Edition, Cambridge University Press, Cambridge.

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RAJAMPET, YSR District, AP – 516126, INDIA

Title of the Course	**:**	Advanced Medicinal Chemistry
Course Code	**:**	26CPHP0DT
Course offered to	**:**	Pharmaceutical Sciences
Credits	**:**	4

Course Objectives

1. Understand modern drug discovery approaches, target identification, and validation strategies.
2. Apply QSAR principles and rational drug design techniques for lead optimization.
3. Utilize computer-aided drug design tools for virtual screening and molecular modeling.
4. Evaluate natural products, enzyme inhibitors, and structure-based approaches in drug development.
5. Explain the design and therapeutic applications of peptidomimetics, prodrugs, and biotechnological products.

Course Outcomes:

1. Explain target validation and lead discovery strategies employed in modern drug development.
2. Apply QSAR models and rational drug design concepts to optimize drug candidates.
3. Perform virtual screening and molecular modeling studies using CADD methodologies.
4. Analyze the role of natural products, enzyme inhibitors, and structure-based drug design in therapeutic innovation.
5. Evaluate peptidomimetics, prodrugs, recombinant therapeutics, vaccines, and monoclonal antibodies for pharmaceutical applications.

Unit 1 12

Modern methods of Drug Discovery target validation: Introduction to discovery of lead molecule, methods, and rational drug discovery models. Target structure, active site identification and methods of validation. Rational Drug Design: QSAR: Parameters involved in QSAR, lipophilicity (Polarisabiltiy, electronic and steric parameters). Quantitative models. Hansch Analysis, Free Wilson Analysis and their relationships, linear relationships and applications of Hansch and Free Wilson Analysis.

Unit 2 12

Computer aided drug design (CADD): Virtual screening: concept, drug likeness screening, focused screening libraries for lead identification, pharmacophore screening, and structure based virtual screening and applications. Molecular modeling: Molecular mechanics, quantam mechanics, modeling ligands for known receptors and unknown receptors.

Unit 3 12

a. Natural Products as Leads for New Drugs: Introduction/History, approaches to discovery and development of natural products as potential new drugs, selection and optimization of lead compounds for further developments from CNS, anticancer antibiotics and cardiovascular drugs.

b. Structure based drug design: Inhibitors of HIV-I Prokinase, Structural studies of HIV-I Reverse transcriptase and implications for drug design, Bradykinin receptor antagonists, Design of purine nucleoside and Phosphorylase inhibitors, Aldose Reductase Inhibitors, Thrombin inhibitors. Rhino viral Capsid-biding Inhibitors

Unit 4 12

Enzyme Inhibitors: A detailed study of the following types of enzyme inhibitors, related drugs and their pharmaceutical significance: a) Prostaglandin Synthetase (Cycloxygenase & Lipoxygenase Inhibitors) b) Phosphodiesterase (PDE) Inhibitors c) Carbonic Anhydrase Inhibitors.
d) B- Secretase. e) Angiotensin Converting Enzyme (ACE) Inhibitors f) Acetyl Cholinesterase (Ach E) Inhibitors. g) HMG-CoA inhibitors h) Protease inhibitors

Unit 5 12

Peptidomimetic agents Prodrugs & Biotechnologically produced drugs: Physiological role of peptides, Endogenous peptide transmitters & function, cyclosporine and oxytocin Prodrugs belong to esters, Lactones, amides, hydrazides and azo compounds. Targeted prodrug, bioprecurror of prodrugs Biotechnologically produced drugs: Biotechnology of Recombinant DNA, Process of Recombinant proteins, Immunogenicity of biotechnologically produced drugs. Recombinant drug products: Hormones, cytokinins, interferons, Interleukins, enzymes, vaccines and monoclonal antibody drugs.

Prescribed Textbooks:

1. A text book of organic medicinal and Pharmaceutical chemistry, Wilson and Grswolds, 11^{th}Edition.
2. Essentials of medicinal chemistry – Andrejeous Koralkovas – 2nd Edition.

Reference Books:

1. Berger's Medicinal Chemistry and Drug Design. 6th Edition
2. William O Foye Medicinal Chemistry
3. Corwin, Hansen Comprehensive Medicinal Chemistry

Title of the Course : Computer Aided Drug Design & Discovery
Course Code : 26CPHP0ET
Course offered to : Pharmaceutical Sciences
Credits : 4

Course Objectives

1. Understand the principles and applications of molecular modeling in drug design.
2. Apply pharmacophore modeling and 3D-QSAR techniques for lead identification and optimization.
3. Analyze structure-based design approaches for enzyme, receptor, and nucleic acid targets.
4. Utilize molecular docking, molecular dynamics, and homology modeling tools in drug discovery.
5. Explain de novo drug design and informatics approaches used in modern pharmaceutical research.

Course Outcomes:

1. Apply molecular mechanics, quantum mechanics, and conformational analysis techniques to study drug molecules.
2. Develop and interpret pharmacophore models and 3D-QSAR analyses for lead optimization.
3. Evaluate drug design strategies targeting enzymes, receptors, and nucleic acids.
4. Perform molecular docking, molecular dynamics simulations, and protein structure modeling for drug discovery applications.
5. Utilize de novo drug design, bioinformatics, and chemoinformatics tools for rational drug development.

Unit 1 12

Molecular modelling: Molecular Mechanics, Quantum Mechanics, Energy minimization, geometry optimization, conformational analysis, global conformational minima determination; approaches and problems. Bioactive vs. Global minimum conformations. Automated methods of conformational search. Advantages and limitations of available software. Molecular graphics. Molecular properties, reactivity, Homo, Lumo, Electrostatic potential, Solvent accessible surface.

Unit 2 12

Pharmacophore concept: Pharmacophore mapping, methods of conformational search used in pharmacophore mapping. Comparison between the popular pharmacophore methods like Catalyst/Hip-hop, Disco Tech, GASP with practical examples, 3D QSAR Techniques. Energy Minimization Methods: comparison between global minimum conformation and bioactive conformation.

Unit 3 12

Design of drugs for the following biological targets Agent acting on enzymes: Dihydro folate reductase DHFR, HIV-protease HMG-CoA Reductase, Phosphodiesterase, ACE, Transpeptidase, β-lactamase. Agents acting on receptors: PPAR, protein kinases. Agents acting on Nucleic acids: Topoisomerase, DNA and RNA polymerase, HIV-Reverse transcriptase

Unit 4 12

Molecular docking: Rigid docking, flexible docking, manual docking. Advantages and disadvantages of Flex-X, Flex-S, Autodock and Dock softwares, with successful examples. Molecular dynamics: Dynamics of drugs, biomolecules, drug-receptor complexes, Monte Carlo simulations and Molecular dynamics in performing conformational search and docking. Estimation of free energy from dynamical methods. Homology modelling and generation of 3D-structure of protein.

Unit 5 12

De Novo drug design techniques: Receptor/enzyme cavity size prediction. Predicting the functional components of cavities, designing drugs fitting into cavity. Active site analysis structure – based drug design. Informatics methods in drug design: Informatics methods in drug design: Brief introduction to bioinformatics, chemo informatics.

Prescribed Textbooks:

1. Organic Chemistry of Drug Design and Drug Action, by R.B. Silverman
2. Practical Applications of computer aided drug design, by P.S. Charifson

Reference Books:

1. Robert GCK, ed., “Drug Action at the Molecular Level” University Prak Press Baltimore.
2. Martin YC. “Quantitative Drug Design” Dekker, New York.
3. Lien EJ. SAR “Side effects and Drug Design” Dekker, New York.
4. William H, Malick JB “Drug Discovery and Development” Humana Press Clifton.

Title of the Course : Chemistry of Natural Products
Course Code : 26CPHP0FT
Course offered to : Pharmaceutical Sciences
Credits : 4

Course Objectives

1. Understand the role of natural products as lead molecules in modern drug discovery and development.
2. Explain the chemistry, isolation, structural elucidation, and biological significance of major classes of natural products.
3. Analyze the pharmaceutical importance of alkaloids, flavonoids, terpenoids, steroids, and vitamins.
4. Understand applications of biotechnology, recombinant DNA technology, and gene therapy in drug development.
5. Apply spectroscopic techniques for structural characterization of natural and bioactive compounds.

Course Outcomes:

1. Evaluate natural product-derived drugs used in CNS, anticancer, cardiovascular, antimicrobial, and antimalarial therapies.
2. Characterize alkaloids, flavonoids, steroids, terpenoids, and vitamins based on their chemistry, isolation, and biological activities.
3. Interpret structural elucidation methods and stereochemical features of important natural products.
4. Analyze the role of recombinant DNA technology, biotechnology-derived drugs, and gene therapy in pharmaceutical sciences.
5. Utilize IR, NMR, and mass spectroscopic techniques for the structural characterization of natural compounds and drug molecules.

Unit 1 12

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)

Unit 2 12

a) 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).

Unit 3 12

a) Terpenoids: Classification, isolation, isoprene rule and general methods of structural elucidation of Terpenoids; Structural elucidation of drugs belonging to mono (citral, 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.

Unit 4 12

a) Recombinant DNA technology and drug discovery 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.

Unit 5 12

Structural Characterization of natural compounds 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

Prescribed Textbooks:

1. Organic Chemistry of Natural Products Vol I and II by O.P. Agarwal.
2. Chemistry of natural products Vol I onwards IWPAC

Reference Books:

1. Modern Methods of Plant Analysis, Peech and M.V.Tracey, Springer – Verlag, Berlin, Heidelberg.
2. Phytochemistry Vol. I and II by Miller, Jan Nostrant Rein Hld.
3. Recent advances in Phytochemistry Vol. I to IV – Scikel Runeckles, Springer Science & Business Media.
4. Natural Product Chemistry Nakanishi Gggolo, University Science Books, California.

Title of the Course : Pharmacological and Toxicological Screening Methods
Course Code : 26CPHP0GT
Course offered to : Pharmaceutical Sciences
Credits : 4

Unit 1 12

Laboratory Animals Common laboratory animals: Description, handling and applications of different species and strains of animals.
Transgenic animals: Production, maintenance and applications. Anesthesia and euthanasia of experimental animals. Maintenance and breeding of laboratory animals. CPCSEA guidelines to conduct experiments on animals.

Unit 2 12

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, CNS stimulants and depressants, anxiolytics, anti-psychotics and anti-epileptics Drugs for neurodegenerative diseases like Parkinsonism and Alzheimer. Drugs acting on Autonomic Nervous System.

Unit 3 12

Preclinical screening of new substances for the pharmacological activity using in vivo, in vitro, and other possible animal alternative models. Respiratory Pharmacology: anti-asthmatics and anti-allergics.
Reproductive Pharmacology: Aphrodisiacs and anti-fertility agents. Analgesics, anti-inflammatory and anti-pyretic agents. Gastrointestinal drugs: anti-ulcer, anti -emetic, anti-diarrheal and laxatives.

Unit 4 12

Preclinical screening of new substances for the pharmacological activity using in vivo, *in vitro*, and other possible animal alternative models. Cardiovascular Pharmacology: anti-hypertensives, anti-arrythmics, anti-ischemics, anti- atherosclerotic agents and diuretics. Drugs for metabolic disorders like anti-diabetic, anti-dyslipidemic agents. Anti-cancer agents. Hepatoprotective screening methods.

Unit 5 12

Preclinical screening of new substances for the pharmacological activity using in vivo, in vitro, and other possible animal alternative models. Immunomodulators, Immunosuppressants and immunostimulants Limitations of animal experimentation Alternate animal experiments- In silico and *in vitro* approaches
Extrapolation of *in vitro* data to preclinical and preclinical to humans.

Prescribed Textbooks:

1. Fundamentals of experimental Pharmacology by M.N.Ghosh.
2. Experimental Pharmacology by R.K.Goyal.

Reference Books:

1. Screening methods in Pharmacology by Robert Turner.
2. A Evaluation of drugs activities by Laurence and Bachrach.
3. Methods in Pharmacology by Arnold Schwartz.

Title of the Course : Advanced Pharmacology – I
Course Code : 26CPHP0HT
Course offered to : Pharmaceutical Sciences
Credits : 4

Course Objectives

1. Understand the fundamental principles of pharmacokinetics, pharmacodynamics, and drug-receptor interactions.
2. Explain neurotransmission mechanisms and pharmacology of the autonomic and central nervous systems.
3. Analyze the pharmacological actions, therapeutic uses, and adverse effects of CNS-active drugs.
4. Evaluate the pharmacology of cardiovascular and hematological agents used in major disease conditions.
5. Understand the physiological roles of autacoids and the pharmacological modulation of their actions.

Course Outcomes:

1. Apply pharmacokinetic and pharmacodynamic principles to explain drug action and therapeutic responses.
2. Interpret neurotransmitter functions and mechanisms of drugs acting on the autonomic and central nervous systems.
3. Evaluate the pharmacology and clinical applications of anesthetics, psychotropic drugs, antiepileptics, and analgesics.
4. Analyze the therapeutic roles of cardiovascular, antihyperlipidemic, anticoagulant, and hematinic agents.
5. Assess the physiological and pathological significance of autacoids and the pharmacology of antihistamines and related agents.

Unit 1 12

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

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

Unit 2 12

Neurotransmission

a. General aspects and steps involved in neurotransmission.

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

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

Unit 3 12

Central nervous system Pharmacology:

General and local anaesthetics, Sedatives and hypnotics, drugs used to treat anxiety. Depression, psychosis, mania, epilepsy, neurodegenerative diseases. Narcotic and non-narcotic analgesics.

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Unit 4

Cardiovascular Pharmacology:

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

Unit 5 12

Autacoid Pharmacology:

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

Prescribed Textbooks:

1. The Pharmacological Basis of Therapeutics, Goodman and Gillman‘s Principles of Pharmacology.
2. The Pathophysiologic basis of drug Therapy by David E Golan, Armen H, Tashjian Jr, EhrinJ, Armstrong, April W, Armstrong, Wolters, Kluwer-Lippincott Williams & Wilkins Publishers.

Reference Books:

1. Basic and Clinical Pharmacology by B. G Katzung
2. Hand book of Clinical Pharmacokinetics by Gibaldi and Prescott.
3. Applied biopharmaceutics and Pharmacokinetics by Leon Shargel and Andrew B. C. Yu.
4. Graham Smith. Oxford textbook of Clinical Pharmacology.

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RAJAMPET, YSR District, AP – 516126, INDIA

Title of the Course	**:**	Advanced Pharmacology–II
Course Code	**:**	26CPHP0IT
Course offered to	**:**	Pharmaceutical Sciences
Credits	**:**	4

Course Objectives

1. Understand hormonal regulation and the pharmacology of endocrine drugs used in major endocrine disorders.
2. Explain the mechanisms of action, resistance, and therapeutic applications of antimicrobial and anticancer agents.
3. Understand immune responses, inflammatory mediators, and pharmacological interventions in immune-related diseases.
4. Analyze the pharmacology of drugs used in gastrointestinal disorders and respiratory diseases.
5. Evaluate the role of free radicals, antioxidants, and emerging therapeutic approaches in chronic diseases.

Course Outcomes:

1. Explain the pharmacological actions, therapeutic uses, and adverse effects of endocrine drugs and hormones.
2. Analyze the mechanisms, resistance patterns, and clinical applications of antimicrobial, antiparasitic, and anticancer agents.
3. Evaluate immune and inflammatory processes and the pharmacology of immunosuppressants, immunostimulants, and anti-asthmatic drugs.
4. Assess the therapeutic roles of drugs used for gastrointestinal disorders, including ulcer, emesis, diarrhea, and constipation.
5. Interpret the role of free radicals and antioxidants in disease pathogenesis and evaluate antioxidant-based therapeutic strategies.

Unit 1 12

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

Unit 2 12

Chemotherapy 1) Cellular and molecular mechanism of actions and resistance of antimicrobial agents such as ß-lactams, aminoglycosides, quinolones, Macrolide antibiotics. Antifungal, antiviral, and anti-TB drugs.

2) Drugs used in Protozoal Infections Drugs used in the treatment of Helminthiasis Chemotherapy of cancer.

Unit 3 12

Immunopharmacology: Cellular and biochemical mediators of inflammation and immune response. Allergic or hypersensitivity reactions. Pharmacotherapy of asthma and COPD. Immunosuppressants and Immunostimulants

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Unit 4

GIT Pharmacology Antiulcer drugs, Prokinetics, anti-emetics, anti-diarrheals and drugs for constipation and irritable bowel syndrome.

Unit 5 12

Pharmacology of Free radicals 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 antioxidants. Recent Advances in antioxidant treatment of Alzheimer's disease, Parkinson's disease, Cancer, Diabetes mellitus.

Prescribed Textbooks:

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.

Reference Books:

1. Basic and Clinical Pharmacology by B.G -Katzung
2. Pharmacology by H.P. Rang and M.M. Dale.
3. Hand book of Clinical Pharmacokinetics by Gibaldi and Prescott.
4. Text book of Therapeutics, drug and disease management by E T. Herfindal and Gourley.

Title of the Course : Cellular and Molecular Pharmacology
Course Code : 26CPHP0JT
Course offered to : Pharmaceutical Sciences
Credits : 4

Course Objectives

1. Understand cellular organization, gene expression, and mechanisms regulating cell survival and death.
2. Explain receptor-mediated signaling pathways and intracellular signal transduction mechanisms.
3. Apply genomic, proteomic, and recombinant DNA technologies in biomedical and pharmaceutical research.
4. Analyze the role of pharmacogenomics, immunotherapeutics, and personalized medicine in drug therapy.
5. Understand cell culture techniques, bioassays, flow cytometry, and biosimilar development

Course Outcomes:

1. Explain cellular processes, genome organization, gene regulation, and programmed cell death mechanisms.
2. Interpret receptor functions and intracellular signaling pathways involved in cellular communication.
3. Apply genomic, proteomic, molecular biology, and gene therapy techniques in pharmaceutical sciences.
4. Evaluate genetic variations affecting drug response and the applications of pharmacogenomics and immunotherapeutics.
5. Perform and assess cell culture methods, cell-based assays, flow cytometry techniques, and biosimilar applications.

Unit 1 12

Cell biology:

Structure and functions of cell and its organelles Genome organization. Gene expression and its regulation, importance of siRNA and micro RNA, gene mapping and gene sequencing Cell cycles and its regulation. Cell death– events, regulators, intrinsic and extrinsic pathways of apoptosis. Necrosis and autophagy

Unit 2 12

Cell signaling:

Intercellular and intracellular signaling pathways. Classification of receptor family and molecular structure ligand gated ion channels; G-protein coupled receptors, tyrosine kinase receptors and nuclear receptors. Secondary messengers: cyclic AMP, cyclic GMP, calcium ion, inositol 1,4,5-trisphosphate, (IP3), NO, and diacylglycerol. Detailed study of following intracellular signaling pathways: cyclic AMP signaling pathway, mitogen-activated protein kinase (MAPK) signaling, Janus kinase (JAK)/signal transducer and activator of transcription (STAT) signaling pathway.

Unit 3 12

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.

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Unit 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.

Unit 5 12

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

Prescribed Textbooks:

1. The Cell, A Molecular Approach. Geoffrey M Cooper.
2. Pharmacogenomics: The Search for Individualized Therapies. Edited by J.Licinio and M -L. Wong.
3. Handbook of Cell Signaling (Second Edition) Edited by Ralph A. et.al

Reference Books:

1. Molecular Pharmacology: From DNA to Drug Discovery. John Dickensonet.al
2. Basic Cell Culture protocols by Cheril D.Helgason and Cindy L.Miller.
3. Basic Cell Culture (Practical Approach) by J. M. Davis (Editor)

Title of the Course : Advanced Pharmacognosy - I
Course Code : 26CPHP0KT
Course offered to : Pharmaceutical Sciences
Credits : 4

Course Objectives

1. Explain the principles of medicinal plant cultivation, collection, conservation, and quality management practices.
2. Analyze the isolation, purification, and pharmaceutical significance of marine natural products.
3. Evaluate nutraceuticals with respect to formulation, standardization, health benefits, and regulatory requirements.
4. Characterize major phytopharmaceutical constituents based on their occurrence, chemistry, and therapeutic applications.
5. Assess pharmacovigilance systems and safety monitoring practices for natural products and herbal medicines.

Course Outcomes:

1. Apply current good agricultural, cultivation, and collection practices for medicinal plant production and conservation.
2. Analyze the potential of marine natural products as sources of novel therapeutic agents.
3. Evaluate nutraceuticals based on marker compounds, health benefits, standardization, and FSSAI guidelines.
4. Characterize important phytopharmaceutical compounds and correlate their chemical nature with therapeutic uses.
5. Assess adverse reactions, herb-drug interactions, and pharmacovigilance requirements of drugs of natural origin.

Unit 1 12

Plant drug cultivation: General introduction to the importance of Pharmacognosy in herbal drug industry, Indian Council of Agricultural Research, Current Good Agricultural Practices, Current Good Cultivation Practices, Current Good Collection Practices, Conservation of medicinal plants- Ex-situ and In- situ conservation of medicinal plants.

Unit 2 12

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.

Unit 3 12

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 i)

Spirulina ii) Soya bean iii) Ginseng iv) Garlic v) Broccoli vi) Green and Herbal Tea vii) Flax seeds viii) Black cohosh ix) Turmeric.

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Unit 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

Unit 5 12

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

Prescribed Textbooks:

1. Text book of Pharmacognosy, C.K.Kokate, Purohit, Ghokhale, Nirali Prakasshan, 1996.
2. Text Book of Pharmacognosy by T.E.Wallis

Reference Books:

1. Pharmacognosy - G. E. Trease and W.C. Evans. Saunders Edinburgh, New York.
2. Pharmacognosy-Tyler, Brady, Robbers.
3. Modem Methods of Plant Analysis- Peach & M.V. Tracey, Vol. I&II

Title of the Course : Phytochemistry
Course Code : 26CPHP0LT
Course offered to : Pharmaceutical Sciences
Credits : 4

Course Objectives

1. Explain the biosynthetic pathways and phytochemical significance of major plant-derived bioactive compounds.
2. Analyze lead identification, optimization, and drug development processes from natural products.
3. Apply advanced extraction, fractionation, and purification techniques for phytoconstituents.
4. Evaluate phytochemical fingerprinting and structure elucidation techniques used in herbal drug standardization.
5. Interpret spectroscopic data for characterization of natural products and herbal constituents.

Course Outcomes:

1. Analyze the biosynthesis, isolation, purification, and pharmaceutical applications of important alkaloids, glycosides, steroids, coumarins, and terpenoids.
2. Evaluate natural products as drug leads and assess their development through preclinical and clinical stages.
3. Apply modern extraction, fractionation, and chromatographic techniques for isolation of phytoconstituents.
4. Characterize herbal extracts using phytochemical fingerprinting tools such as HPTLC, LC-MS, and GC-MS.
5. Interpret UV, IR, MS, and NMR spectral data for structural elucidation of bioactive natural compounds

Unit 1 12

Biosynthetic pathways and Radio tracing techniques: 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, Strychynine, Piperine, Berberine, Taxol, Vinca alkoloids.
b) Glycosides: Digitoxin, Glycyrrhizin, Sennosides, Bacosides, Quercitin.
c) Steroids: Hecogenin, guggulosterone and withanolides
d) Coumarin: Umbelliferone.
e) Terpenoids: Cucurbitacins

Unit 2 12

Drug discovery and development: History of herbs as source of 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.

Unit 3 12

Extraction and Phytochemical studies: Recent advances in 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.

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Unit 4

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

Unit 5 12

Structure elucidation of the following compounds by spectroscopic techniques like UV, IR, MS, NMR (^{1}H, ^{13}C)

a. Carvone, Citral, Menthol
b. Luteolin, Kaempferol
c. Nicotine, Caffeine iv) Glycyrrhizin.

Prescribed Textbooks:

1. Text book of Pharmacognosy by Wallis.
2. Chemistry of Natural Products- Vol. 1 onwards IWPAC.

Reference Books:

1. Modem Methods of Plant Analysis- Peach & M.V. Tracey, Vol. I&II
2. Pharmacognosy by Trease and Evans, ELBS.
3. Pharmacognosy by Tylor and Brady.

Title of the Course : Industrial Pharmacognostical Technology
Course Code : 26CPHP0MT
Course offered to : Pharmaceutical Sciences
Credits : 4

Course Objectives

1. Explain the infrastructure, scale-up processes, and production management practices in the herbal drug industry.
2. Analyze regulatory, quality assurance, and international trade requirements applicable to herbal products.
3. Evaluate herbal drug monographs and quality standards prescribed by national and international pharmacopoeias.
4. Apply testing and stability evaluation protocols for herbal and natural product formulations.
5. Interpret patent laws, intellectual property rights, and patent filing procedures related to herbal products.

Course Outcomes:

1. Apply principles of herbal industry management, entrepreneurship, and pilot-scale production in herbal drug development.
2. Analyze GMP, GLP, TQM, ISO standards, and regulatory requirements governing herbal drug manufacture and marketing.
3. Evaluate herbal drug monographs and WHO guidelines for quality assessment and standardization of herbal medicines.
4. Perform stability testing and quality evaluation of herbal and natural product formulations.
5. Assess patentability, intellectual property rights, patent prosecution, and legal aspects of herbal and natural products.

Unit 1 12

Herbal drug industry: Infrastructure of herbal drug industry involved in production of standardized extracts and various dosage forms. Current challenges in upgrading and modernization of herbal formulations. Entrepreneurship Development, Project selection, project report, technical knowledge, Capital venture, plant design, layout and construction. Pilot plant scale –up techniques, case studies of herbal extracts. Formulation and production management of herbals.

Unit 2 12

Regulatory requirements for setting herbal drug industry: Global marketing management. Indian and international patent law as applicable herbal drugs and natural products. Export - Import (EXIM) policy, TRIPS. Quality assurance in herbal/natural drug products. Concepts of TQM, GMP, GLP, ISO-9000.

Unit 3 12

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

Unit 4 12

Testing of natural products and drugs: Herbal medicines - clinical laboratory testing. Stability testing of natural products, protocols.

Unit 5 12

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.

Prescribed Textbooks:

1. Text book of Pharmacognosy by C.K. Kokate, Purohit, Gokhlae (1996), Nirali Prakashan, New Delhi.
2. Text book of Pharmacognosy and Phytochemistry by Vinod D. RangarI (2002), Part I & II, Career Publication, Nasik, India.

Reference Books:

1. Herbal drug industry by R.D. Choudhary (1996), Eastern Publisher, New Delhi.
2. GMP for Botanicals - Regulatory and Quality issues on Phytomedicine by Pulok K Mukharjee (2003), Ist Edition, Business horizons Robert Verpoorte, New Delhi.
3. Quality control of herbal drugs by Pulok K Mukarjee (2002), Business Horizons Pharmaceutical Publisher, New Delhi.
4. PDR for Herbal Medicines (2000), Medicinal Economic Company, New Jersey.

ANNAMACHARYA UNIVERSITY

(ESTD UNDER AP PRIVATE UNIVERSITIES (ESTABLISHMENT AND REGULATION) ACT,
(UNIVERSITY LISTED IN UGC AS PER THE SECTION 2(f) OF THE UGC ACT, 1956)

RAJAMPET, YSR District, AP – 516126, INDIA

Title of the Course : Medicinal Plant Biotechnology
Course Code : 26CPHP0NT
Course offered to : Pharmaceutical Sciences
Credits : 4

Course Objectives

1. Explain the principles of plant biotechnology, molecular biology, and recombinant DNA technology relevant to medicinal plants.
2. Apply plant tissue culture techniques for propagation and genetic improvement of medicinal plants.
3. Analyze immobilization, cloning, and secondary metabolite production strategies in plant cell cultures.
4. Evaluate biotransformation, transgenic technologies, and molecular tools used in plant biotechnology research.
5. Assess fermentation processes for the production of pharmaceutically important metabolites and biomolecules.

Course Outcomes:

1. Explain genetic, molecular, and biotechnological concepts involved in medicinal plant improvement and drug discovery.
2. Apply tissue culture, micropropagation, protoplast fusion, and gene transfer techniques in plant biotechnology.
3. Analyze the production of secondary metabolites using immobilized cells, cloning, elicitors, and precursor feeding approaches.
4. Evaluate applications of transgenic plants, PCR, gene sequencing, and bioreactor systems in pharmaceutical biotechnology.
5. Assess fermentation technologies for the production of ergot alkaloids, enzymes, and single-cell proteins of pharmaceutical importance.

Unit 1 12

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.

Unit 2 12

Different tissue culture techniques: Organogenesis and embryogenesis, synthetic seed and monoclonal variation, Protoplast fusion, Hairy root multiple shoot cultures and their applications. Micro propagation of medicinal and aromatic plants. Sterilization methods involved in tissue culture, gene transfer in plants and their applications.

Unit 3 12

Immobilisation techniques & Secondary Metabolite Production: Immobilization techniques of plant cell and its application on secondary metabolite Production. Cloning of plant cell: Different methods of cloning and its applications. Advantages and disadvantages of plant cell cloning. Secondary metabolism in tissue cultures with emphasis on production of medicinal agents. Precursors and elicitors on production of secondary metabolites.

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Unit 4

Biotransformation and Transgenesis: Biotransformation, bioreactors for pilot and large scale cultures of plant cells and retention of biosynthetic potential in cell culture. Transgenic plants, methods used in gene identification, localization and sequencing of genes. Application of PCR in plant genome analysis.

Unit 5 12

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

Prescribed Textbooks:

1. Plant tissue culture, Bhagwani, vol 5, Elsevier Publishers.
2. Plant cell and Tissue Culture (Lab. Manual), JRMM. Yeoman.
3. Elements in biotechnology by PK. Gupta, Rastogi Publications, New Delhi.

Reference Books:

1. An introduction to plant tissue culture by MK. Razdan, Science Publishers.
2. Experiments in plant tissue culture by John HD and Lorin WR., Cambridge University Press.
3. Pharmaceutical biotechnology by SP. Vyas and VK. Dixit, CBS Publishers.
4. Plant cell and tissue culture by Jeffrey W. Pollard and John M Walker, Humana press.

Title of the Course : Advanced Pharmacognosy - II
Course Code : 26CPHP0OT
Course offered to : Pharmaceutical Sciences
Credits : 4

Course Objectives

1. Analyze the efficacy, safety, toxicity, and regulatory aspects of herbal medicines.
2. Evaluate adulteration, contamination, and authentication methods for herbal drugs and formulations.
3. Interpret ethnobotanical and ethnopharmacological approaches in herbal drug discovery and development.
4. Characterize herbal drugs using analytical profiling and quality assessment techniques.
5. Apply biological screening and toxicity evaluation methods for herbal drug validation.

Course Outcomes:

1. Assess the therapeutic effectiveness, pharmacokinetic behavior, and safety concerns of herbal medicines.
2. Analyze adulteration, substitution, and contamination in herbal drugs using modern authentication techniques.
3. Evaluate the significance of ethnobotany, ethnopharmacology, bioprospecting, and reverse pharmacology in drug development.
4. Characterize medicinal plants and herbal extracts through analytical profiling and standardization methods.
5. Apply in vitro, in vivo, and OECD-guided toxicity studies for pharmacological screening of herbal drugs.

Unit 1 12

Herbal remedies – Toxicity and Regulations: Herbals vs Conventional drugs, Efficacy of Herbal medicine products, Validation of herbal therapies, Pharmacodynamic and Pharmacokinetic issues.

Unit 2 12

Adulteration and Deterioration: Introduction, Types of Adulteration/ Substitution of Herbal drugs, Causes and Measures of Adulteration, Sampling Procedures, Determination of Foreign Matter, DNA Finger printing techniques in identification of drugs of natural origin, detection of heavy metals, pesticide residues, phytotoxin, microbial contamination in herbs and their formulations.

Unit 3 12

Ethnobotany and Ethnopharmacology: Ethnobotany in herbal drug evaluation, Impact of Ethnobotany in traditional medicine, New development in herbals, Bio-prospecting tools for drug discovery, Role of Ethnopharmacology in drug evaluation, Reverse Pharmacology.

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Unit 4

Analytical Profiles of herbal drugs: Andrographis paniculata, Boswellia serata, Coleus forskholii, Curcuma longa, Embelica officinalis, Psoralea corylifolia.

Unit 5 12

Biological screening of herbal drugs: Introduction and Need for Phyto-Pharmacological Screening, New Strategies for evaluating Natural Products, In vitro evaluation techniques for Antioxidants, Antimicrobial and Anticancer drugs. In vivo evaluation techniques for Anti-inflammatory, Antiulcer, Anticancer, Wound healing, Antidiabetic, Hepatoprotective, Cardio protective, Diuretics and Antifertility, Toxicity studies as per OECD guidelines.

Prescribed Textbooks:

1. Text book of Pharmacognosy and Phytochemistry by Vinod D. RangarI, Part I & II, Career Publication, Nasik, India.
2. Text book of Pharmacognosy by C.K.Kokate, Purohit, Ghokhale, Nirali Prakashan.
3. Text Book of Pharmacognosy by T.E. Wallis, J & A Churchill Ltd., London.

Reference Books:

1. Glimpses of Indian Ethano Pharmacology by P. Pushpangadam. Ulf Nyman. V.George Tropical Botanic Garden & Research Institute.
2. Natural products: A lab guide by Raphael Ikan, Academic Press.
3. Pharmacognosy - G. E. Trease and W.C. Evans. WB. Saunders Edinburgh, New York.
4. Pharmacognosy-Tyler, Brady, Robbers, Lee & Fetiger.

Title of the Course	**:**	Indian Systems of Medicine
Course Code	**:**	26CPHP0PT
Course offered to	**:**	Pharmaceutical Sciences
Credits	**:**	4

Course Objectives

1. Explain the principles, dosage forms, and pharmacopoeial standards of Ayurveda, Siddha, Unani, and Homoeopathy systems.
2. Analyze the therapeutic applications of Naturopathy, Yoga, and Aromatherapy in health management.
3. Apply formulation development, standardization, and stability assessment techniques for ISM products.
4. Evaluate GMP, quality assurance, and regulatory requirements governing Indian Systems of Medicine.
5. Interpret intellectual property rights, traditional knowledge protection, and regulatory frameworks related to AYUSH systems.

Course Outcomes:

1. Compare the principles, dosage forms, and quality standards of Ayurveda, Siddha, Unani, and Homoeopathy systems.
2. Assess the role of Naturopathy, Yoga, and Aromatherapy in preventive and complementary healthcare.
3. Apply formulation, standardization, shelf-life determination, and stability evaluation methods for ISM formulations.
4. Analyze GMP requirements, quality assurance systems, and documentation procedures for ISM industries.
5. Evaluate the significance of TKDL, geographical indications, AYUSH regulations, and national research councils in promoting traditional medicine.

Unit 1 12

Fundamental concepts of Ayurveda, Siddha, Unani and Homoeopathy systems of medicine 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).

Unit 2 12

Naturopathy, Yoga and Aromatherapy practices:

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.

Unit 3 12

Formulation development of various systems of medicine 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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Unit 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.

Unit 5 12

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

Prescribed Textbooks:

1. Hand Book on Ayurvedic Medicines, H. Panda, National Institute of Industrial Research, New Delhi.
2. Ayurvedic System of Medicine, Kaviraj Nagendranath Sengupata, Sri Satguru Publications, New Delhi.

Reference Books:

1. Ayurvedic Pharmacopoeia, The Controller of Publications, Civil Lines, Govt. of India, New Delhi.
2. Homeopathic Pharmacopoeia. Formulary of Homeopathic Medicines, IMCOPS, Chennai.
3. Homeopathic Pharmacy : An introduction & Hand book, Steven B. Kayne, Churchill Livingstone, New York.
4. Indian Herbal Pharmacopoeia, IDMA, Mumbai.

Title of the Course	**:**	Herbal Cosmetics
Course Code	**:**	26CPHP0QT
Course offered to	**:**	Pharmaceutical Sciences
Credits	**:**	4

Course Objectives

1. Explain the principles, regulations, and industrial aspects of herbal and natural cosmetics.
2. Apply preformulation and formulation approaches for the development of herbal cosmetic products.
3. Analyze the role of herbal ingredients in skincare, haircare, oral care, and personal care formulations.
4. Evaluate the quality, safety, and efficacy of herbal cosmeceuticals and cosmetic preparations.
5. Assess analytical methods, quality control measures, and toxicity testing of cosmetic products.

Course Outcomes:

1. Interpret regulatory requirements, GMP provisions, and industrial practices related to herbal cosmetics.
2. Design herbal cosmetic formulations by selecting appropriate excipients, functional herbs, and formulation components.
3. Develop and standardize herbal cosmetic products for skin, hair, oral, and nail care applications.
4. Evaluate herbal cosmeceutical formulations based on their composition, functionality, and therapeutic benefits.
5. Perform quality control, analytical evaluation, and toxicity assessment of cosmetic products in compliance with regulatory standards.

Unit 1 12

Introduction: Herbal/natural cosmetics, Classification & Economic aspects.
Regulatory Provisions relation to manufacture of cosmetics: - License, GMP, offences & Penalties, Import & Export of Herbal/natural cosmetics, Industries involved in the production of Herbal/natural cosmetics.

Unit 2 12

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.

Unit 3 12

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.

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Unit 4

Cosmeceuticals of herbal and natural origin: Hair growth formulations, Shampoos, Conditioners, Colorants & hair oils, Fairness formulations, vanishing & foundation creams, anti-sun burn preparations, moisturizing creams, deodorants.

Unit 5 12

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

Prescribed Textbooks:

1. Panda H. Herbal Cosmetics (Hand book), Asia Pacific Business Press Inc, New Delhi.
2. Thomson EG. Modern Cosmetics, Universal Publishing Corporation, Mumbai.
3. P.P.Sharma. Cosmetics - Formulation, Manufacturing & Quality Control, Vandana Publications, New Delhi.

Reference Books:

1. Supriya K B. Handbook of Aromatic Plants, Pointer Publishers, Jaipur.
2. Skaria P. Aromatic Plants (Horticulture Science Series), New India Publishing Agency, New Delhi.
3. Kathi Keville and Mindy Green. Aromatheraphy (A Complete Guide to the Healing Art), Sri Satguru Publications, New Delhi.

Title of the Course : Advanced Pharmacy Practice
Course Code : 26CPHP0RT
Course offered to : Pharmaceutical Sciences
Credits : 4

Course Objectives

1. Analyze methods for evaluating drug effectiveness using pharmacoepidemiological study designs and real-world evidence.
2. Evaluate pharmacovigilance systems, drug safety monitoring, and risk management strategies.
3. Apply pharmacoeconomic and health technology assessment tools for healthcare decision-making.
4. Interpret evidence synthesis methods including systematic reviews, meta-analyses, and guideline development.
5. Assess healthcare databases, regulatory guidelines, and professional practices relevant to drug utilization and patient care.

Course Outcomes:

1. Evaluate drug effectiveness using observational studies, clinical trials, and real-world evidence methodologies.
2. Analyze adverse drug reactions, signal detection processes, and pharmacovigilance practices for ensuring medication safety.
3. Apply pharmacoeconomic techniques and health technology assessment methods to evaluate healthcare interventions.
4. Conduct evidence synthesis using systematic reviews, meta-analysis, network meta-analysis, and GRADE approaches.
5. Interpret healthcare databases, ethical guidelines, regulatory frameworks, and professional standards governing clinical pharmacy practice.

Unit 1 12

Drug Effectiveness Evaluation: Post-marketing surveillance, real-world evidence, observational study designs, experimental and quasi-experimental study designs, pragmatic randomized controlled trials, single-arm trials, self-controlled case-series design, case-crossover design, and mixed methods research. Confounding, biases (including immortal-time bias and channeling bias), propensity score matching, intention-to-treat analysis, per-protocol analysis, as-treated analysis, and benefit risk assessment. Importance of machine learning, artificial intelligence, and big data mining in drug discovery and development.

Unit 2 12

Drug Safety Evaluation: Pharmacovigilance methods, signal detection, risk assessment, risk management, risk communication, and drug safety evaluation in special populations. The importance of pharmacogenomics for individual variation in adverse drug reactions. Regulatory requirements for pharmacovigilance, Good Pharmacovigilance Practices (GVP), and qualified Person for pharmacovigilance. Eco pharmacovigilance, vaccine pharmacovigilance, hemovigilance, materiovigilance and pharmacovigilance of biologics.

Unit 3 12

Pharmacoeconomic Evaluation: Pharmacoeconomic methods, budget impact analysis, health status measures, decision analysis, Markov modeling, and health technology assessment in India.

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Unit 4

Evidence Synthesis: Scoping review, systematic review, meta-analysis, network meta-analysis, GRADE approach, and consensus approach.

Unit 5 12

(a) Databases, Registries, and Guidelines: Spontaneous reporting databases and insurance & claims databases. Drug & disease registries and pregnancy exposure registries. ICMR ethical guidelines for human research, Good Clinical Practice (GCP, certification is mandatory) and Good Pharmacy Practice guidelines, and Drugs, Medical Devices and Cosmetics Bill 2022.

(b) Societies and Associations: International Society for Pharmacoepidemiology (ISPE), International Society for Pharmacoeconomics and Outcomes Research (ISPOR), International Society of Pharmacovigilance (ISoP), Institute for Safe Medication Practices (ISMP), American College of Clinical Pharmacy (ACCP), American Society of Health-System Pharmacists (ASHP), and Board of Pharmacy Specialties (BPS).

Prescribed Textbooks:

1. Strom, B. L. Pharmacoepidemiology. (Wiley-Blackwell) – The gold standard for epidemiology.
2. Stephens, M. D. B. Stephens' Detection and Evaluation of Adverse Drug Reactions. (Wiley).
3. Bootman, J. L. Principles of Pharmacoeconomics. (Harvey Whitney Books).

Reference Books:

1. Cipolle, R. J., et al. Pharmaceutical Care Practice: The Patient-Centered Approach to Medication Management. (McGraw-Hill).
2. Katzung, B. G. Basic & Clinical Pharmacology (for foundational therapeutic knowledge).

Title of the Course : Pharmacotherapeutics
Course Code : 26CPHP0ST
Course offered to : Pharmaceutical Sciences
Credits : 4

Course Objectives

1. Understand the pathophysiology and pharmacotherapeutic management of gastrointestinal, hepatic, and infectious diseases.
2. Explain the etiology, clinical manifestations, and treatment approaches for musculoskeletal and renal disorders.
3. Describe the principles of cancer chemotherapy and management of dermatological and hematological diseases.
4. Interpret the pharmacotherapy of neurological, psychiatric, and ophthalmological disorders.
5. Apply evidence-based therapeutic principles in the management of cardiovascular and endocrine diseases.

Course Outcomes:

1. Explain the pathophysiology and therapeutic management of gastrointestinal, liver, and infectious diseases.
2. Evaluate treatment strategies for musculoskeletal and renal disorders, including drug-induced complications.
3. Discuss cancer chemotherapy and the management of dermatological and hematological disorders.
4. Analyze therapeutic approaches for neurological, psychiatric, and ophthalmic diseases.
5. Recommend appropriate pharmacotherapy for cardiovascular and endocrine disorders based on patient-specific needs.

Unit 1 12

a) Gastrointestinal system: Peptic ulcer disease, Gastro Esophageal Reflux Disease, Inflammatory bowel disease, Liver disorders - Alcoholic liver disease, viral hepatitis including jaundice, and Drug induced liver disorders.

b) Infectious diseases: Tuberculosis, Meningitis, Respiratory tract infections (URTI &LRTI, Asthma, Chronic obstructive airways disease, Drug induced pulmonary diseases), Gastroenteritis, Endocarditis, Septicemia, Urinary tract infections, Protozoal infection- Malaria, HIV & Opportunistic infections, Fungal infections, Viral infections, Gonorrhea and Syphilis

Unit 2 12

a) Musculoskeletal disorders: Rheumatoid arthritis, Osteoarthritis, Gout, Spondylitis, Systemic lupus erythematous

b) Renal system: Acute Renal Failure, Chronic Renal Failure, Renal Dialysis, Drug induced renal disorders

Unit 3 12

a) Oncology: Basic principles of Cancer therapy, General introduction to cancer chemotherapeutic agents, Chemotherapy of breast cancer, leukaemia. Management of chemotherapy induced nausea and emesis

b) Dermatology: Psoriasis, Scabies, Eczema, Impetigo

c) Haematological system: Anaemias, Venous thromboembolism, Drug induced blood disorders.

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Unit 4

(a) Nervous system & psychiatric disorders: Epilepsy, Parkinsonism, stroke, Alzheimer's disease, Schizophrenia, Affective disorders, anxiety disorders, sleep disorders, obsessive compulsive disorders

b) Ophthalmology: Glaucoma, Conjunctivitis- viral & bacterial.

Unit 5 12

a) Cardiovascular system: Hypertension, Congestive cardiac failure, Angina Pectoris, Myocardial infarction, Hyperlipidemia, Electrophysiology of heart and Arrhythmias.

b) Endocrine system: Diabetes, Thyroid diseases, Oral contraceptives, Hormone replacement therapy, Osteoporosis

Prescribed Textbooks:

1. Clinical Pharmacy and Therapeutics - Roger and Walker and Whittlesea, Churchill Livingstone publication
2. Pharmacotherapy: A Pathophysiologic approach - Joseph T. Dipiro et al. Appleton & Lange
3. Clinical Pharmacy and Therapeutics - Eric T. Herfindal, Williams and Wilkins Publication.
4. Applied Therapeutics: The clinical Use of Drugs. Lloyd Young and Koda-Kimble

Reference Books:

1. Pathologic basis of disease - Robbins SL, W.B.Saunders publication
2. Pathology and Therapeutics for Pharmacists - A Basis for Clinical Pharmacy Practice - Green and Harris, Chapman and Hall publication.
3. Avery's Drug Treatment - 4th Edn, 1997, Adis International Limited.

Title of the Course : Clinical Pharmacy
Course Code : 26CPHP0TT
Course offered to : Pharmaceutical Sciences
Credits : 4

Course Objectives

1. Explain the roles and responsibilities of clinical pharmacists in patient care and medication management.
2. Analyze patient-specific clinical and laboratory data for optimizing drug therapy outcomes.
3. Apply drug and poison information resources to support evidence-based clinical decision-making.
4. Demonstrate effective communication, patient counseling, and pharmaceutical care skills in clinical settings.
5. Evaluate adverse drug reactions, medication errors, and pharmacovigilance practices to promote patient safety.

Course Outcomes:

1. Perform clinical pharmacy services including medication review, ward round participation, and therapeutic monitoring.
2. Interpret clinical laboratory investigations and patient records to assess disease status and drug therapy.
3. Retrieve, evaluate, and communicate drug and poison information using appropriate information resources.
4. Apply patient counseling, medication history interviewing, and pharmaceutical care principles in clinical practice.
5. Assess adverse drug reactions, conduct causality assessments, and contribute to pharmacovigilance activities.

Unit 1 12

Definitions, development and scope of clinical pharmacy Introduction to daily activities of a clinical pharmacist

a. Drug therapy monitoring (medication chart review, clinical review, pharmacist interventions)
b. Ward round participation
c. Adverse drug reaction management
d. Drug information and poisons information
e. Medication history
f. Patient counseling
g. Drug utilization evaluation (DUE) and review (DUR)
h. Quality assurance of clinical pharmacy services

Unit 2 12

(a) Patient data analysis The patient's case history, its structure and use in evaluation of drug

therapy & understanding common medical abbreviations and terminologies used in clinical practices,

(b) Clinical laboratory tests used in the evaluation of disease states, and interpretation of test results

(i) Hematological, Liver function, renal function, thyroid function tests
(ii) Tests associated with cardiac disorders
(iii) Fluid and electrolyte balance
(iv) Microbiological culture sensitivity tests
(v) Pulmonary Function

Unit 3 12

Drug & Poison information

Introduction to drug information resources available Systematic approach in answering DI queries Critical evaluation of drug information and literature Preparation of written and verbal reports Establishing a Drug Information Centre

Poisons information- organization & information resources

12

Unit 4

Communication skills, including patient counseling techniques, medication history interview, presentation of cases.

Pharmaceutical care concepts

Critical evaluation of biomedical literature Medication errors

Unit 5 12

Pharmacovigilance

Scope, definition and aims of pharmacovigilance

Adverse drug reactions - Classification, mechanism, predisposing factors, causality assessment [different scales used], Reporting, evaluation, monitoring, preventing & management of ADRs, Role of pharmacist in management of ADR.

Prescribed Textbooks:

1. Practice Standards and Definitions, the Society of Hospital Pharmacists of Australia.
2. Basic skills in interpreting laboratory data, Scott LT, American Society of Health System Pharmacists Inc.
3. Biopharmaceutics and Applied Pharmacokinetics, Leon Shargel, Prentice Hall Publication.
4. Textbook of Clinical Pharmacy Practice; Essential concepts and skills, Dr. G.Parthasarathi, Karin Nyfort-Hansen, Milap Nahata, Orient Longman Pvt. Ltd.

Reference Books:

1. Australian drug information -Procedure manual. The Society of Hospital Pharmacists of Australia.
2. Clinical Pharmacokinetics - Rowland and Tozer, Williams and Wilkins Publication.
3. Pharmaceutical statistics. Practical and clinical applications. Sanford Bolton, Marcel Dekker, Inc.

ANNAMACHARYA UNIVERSITY

(ESTD UNDER AP PRIVATE UNIVERSITIES (ESTABLISHMENT AND REGULATION) ACT,
(UNIVERSITY LISTED IN UGC AS PER THE SECTION 2(f) OF THE UGC ACT, 1956)

RAJAMPET, YSR District, AP – 516126, INDIA

Title of the Course : Pharmacy Management and Pharmacoepidemiology
Course Code : 26CPHP0UT
Course offered to : Pharmaceutical Sciences
Credits : 4

Course Objectives

1. Explain hospital and community pharmacy management practices, including drug procurement, storage, and distribution systems.
2. Apply inventory control techniques and pharmacy management principles to optimize pharmaceutical services.
3. Demonstrate pharmaceutical care practices, patient counseling, and medication adherence strategies.
4. Analyze pharmacoepidemiological outcome measures and drug utilization indicators used in healthcare research.
5. Evaluate pharmacoepidemiological study designs for assessing drug use, effectiveness, and safety.

Course Outcomes:

1. Manage hospital and community pharmacy operations, including inventory control and drug distribution systems.
2. Apply inventory management tools such as ABC, VED, EOQ, and safety stock analysis in pharmacy practice.
3. Provide pharmaceutical care services through effective patient counseling, medication adherence monitoring, and health education.
4. Interpret pharmacoepidemiological outcome measures, incidence, prevalence, and drug utilization data.
5. Analyze pharmacoepidemiological research methods and their applications in evaluating medication use and healthcare outcomes.

Unit 1 12

Hospital pharmacy services

a) Procurement & warehousing of drugs and Pharmaceuticals

b) Inventory control: Definition, various methods of Inventory Control ABC, VED, EOQ, Lead time and safety stock

c) Drug distribution in the hospital i) Individual prescription method ii) Floor stock method iii) Unit dose drug distribution method

d) Distribution of Narcotic and other controlled substances

e) Central sterile supply services – Role of pharmacist

Unit 2 12

Community Pharmacy Management

a) Selection of site, Space layout, and design

b) Staff, Materials- coding, stocking
c) Legal requirements
d) Maintenance of various registers
e) Use of Computers: Business and health care softwares

Unit 3 12

Pharmaceutical care: Definition and Principles of Pharmaceutical care.
Patient counselling : Definition, outcomes, various stages, barriers, strategies to overcome barriers
Patient information leaflets- content, design, layouts & advisory labels
Patient medication adherence: Definition, Factors affecting medication adherence and role of pharmacist in improving the adherence

12

Unit 4

Measurement of outcomes in pharmacoepidemiology, Outcome measure and drug use measures Prevalence, incidence and incidence rate. Monetary units, number of prescriptions, units of drugs dispensed, defined daily doses and prescribed daily doses, medication adherence measurement.

Unit 5 12

Pharmacoepidemiological methods:
Includes theoretical aspects of various methods and practical study of various methods with the help of case studies for individual methods; Drug utilization review, case reports, case series, surveys of drug use, cross – sectional studies, cohort studies, case control studies, case – cohort studies, meta – analysis studies, spontaneous reporting, prescription event monitoring and record linkage system.

Prescribed Textbooks:

1. Pharmacoepidemiology and Pharmacoeconomics K.G Revikumar First edition.
2. Concept of Pharmacoepidemiology and Pharmacoeconomics Dr. Aditya Prarashar First edition

Reference Book:

1. Pharmacoepidemiology Brian L. Strom Sixth edition.