



JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY KAKINADA

KAKINADA-533003, Andhra Pradesh, India

**B.Tech PHARMACEUTICAL ENGINEERING
(R23 – IIIrd YEAR COURSE STRUCTURE & SYLLABUS)**

III YEAR I SEMESTER

S No	Category	Course Title	L	T	P	C
1	Professional Core	Managerial Economics and Financial Accountancy	3	0	0	3
2	Professional Core	Pharmaceutical Engineering – I	3	0	0	3
3	Professional Core	Biopharmaceutics and Pharmacokinetics	3	0	0	3
4	Professional Elective – I	Biostatistics	3	0	0	3
5	Open Elective-I	Quality Control and Assurance Food Processing Technology Pharmaceutical Biotechnology	3	0	0	3
6	Professional Core	OR Entrepreneurship Development & Venture Creation 1. Non-Conventional Energy Sources 2. Introduction to Data Structures 3. Design and Analysis of Experiments	3	0	0	3
7	Professional Core	Pharmaceutical Engineering – I lab	0	0	3	1.5
8	Skill Enhancement course	Statistics using R - Programming Lab	0	0	3	1.5
9	Engineering Science	Advanced Communication Skills lab	0	0	0	1.5
10		Pharma Engineering Practice-Field trip	0	0	0	2
Total Credits						24.5
MC	Minor Course (Student may select from the same specialized minors pool)		3	0	3	4.5
MC	Minor Course through SWAYAM / NPTEL (Minimum 12 Week, 3 credit course)		3	0	0	3
HC	Honors Course (Student may select from the same Honors pool)		3	0	0	3
HC	Honors Course (Student may select from the same Honors Pool)		3	0	0	3



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III-YEAR II SEMESTER

S.NO	Category	Course Title	L	T	P	C
1	Professional Core	Pharmaceutical Engineering – II	3	0	0	3
2	Professional Core	Instrumental Methods of Analysis	3	0	0	3
3	Professional Core	Principles of Transducers and Measurements	3	0	0	3
4	Professional Elective-II	Water conservation management	3	0	0	3
5	Professional Elective-III	PE 2: 1. Computer Aided Drug Design 2. Pharmaceutical Regulatory affairs 3. Novel Drug Delivery Systems	3	0	0	3
6	Open Elective – II	OE 2: 1. Hospital Management and Information Systems 2. Neural Networks and Fuzzy Logic 3. Introduction to Database Management	3	0	0	3
7	Professional Core	Instrumental Methods of Analysis Lab	0	0	3	1.5
8	Professional Core	Experimental Modeling and Simulation Lab	0	0	3	1.5
9	Skill Enhancement course	Transducers and Measurements Lab	0	1	2	2
10	Audit Course	Effluent Treatment & Pollution Control –Field trip	2	0	0	0
Total Credits						24.5
MC	Minor Course (Student may select from the same specialized minors pool)		3	0	3	4.5
MC	Minor Course through SWAYAM / NPTEL (Minimum 12 Week, 3 credit course)		3	0	0	3
HC	Honors Course (Student may select from the same Honors pool)		3	0	0	3
HC	Honors Course (Student may select from the same Honors Pool)		3	0	0	3



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III Year I Semester	MANAGERIAL ECONOMICS AND FINANCIAL ACCOUNTANCY	L	T	P	C
		3	0	0	3

COURSE OBJECTIVES:

- The Learning objectives of this paper is to understand the concept and nature of Managerial Economics and its relationship with other disciplines and also to understand the Concept of Demand and Demand forecasting, Production function, Input Output relationship, Cost-Output relationship and Cost-Volume-Profit Analysis.
- To understand the nature of markets, Methods of Pricing in the different market structures and to know the different forms of Business organization and the concept of Business Cycles.
- To learn different Accounting Systems, preparation of Financial Statement and uses of different tools for performance evaluation. Finally, it is also to understand the concept of Capital, Capital Budgeting and the techniques used to evaluate Capital Budgeting proposals.

COURSE OUTCOME:

- The Learner is equipped with the knowledge of estimating the Demand and demand elasticities for a product and the knowledge of understanding of the Input-Output-Cost relationships and estimation of the least cost combination of inputs.
- One is also ready to understand the nature of different markets and Price Output determination under various market conditions and also to have the knowledge of different Business Units.
- The Learner is able to prepare Financial Statements and the usage of various Accounting tools for Analysis and to evaluate various investment project proposals with the help of capital budgeting techniques for decision making.

UNIT-I

Introduction to Managerial Economics and demand Analysis:

Definition of Managerial Economics –Scope of Managerial Economics and its relationship with other subjects –Concept of Demand, Types of Demand, Determinants of Demand- Demand schedule, Demand curve, Law of Demand and its limitations- Elasticity of Demand, Types of Elasticity of Demand and Measurement- Demand forecasting and Methods of forecasting, Concept of Supply and Law of Supply.

UNIT – II:

Production and Cost Analyses:



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Concept of Production function- Cobb-Douglas Production function- Leontief production function - Law of Variable proportions-Isoquants and Isocosts and choice of least cost factor combination-Concepts of Returns to scale and Economies of scale-Different cost concepts: opportunity costs, explicit and implicit costs- Fixed costs, Variable Costs and Total costs – Cost – Volume-Profit analysis-Determination of Breakeven point(simple problems)- Managerial significance and limitations of Breakeven point.

UNIT – III:

Introduction to Markets, Theories of the Firm & Pricing Policies:

Market Structures: Perfect Competition, Monopoly, Monopolistic competition and Oligopoly – Features – Price and Output Determination – Managerial Theories of firm: Marris and Williamson's models – other Methods of Pricing: Average cost pricing, Limit Pricing, Market Skimming Pricing, Internet Pricing: (Flat Rate Pricing, Usage sensitive pricing) and Priority Pricing.

UNIT – IV:

Types of Business Organization and Business Cycles:

Features and Evaluation of Sole Trader, Partnership, Joint Stock Company – State/Public Enterprises and their forms – Business Cycles : Meaning and Features – Phases of a Business Cycle.

Unit – V:

Introduction to Accounting & Financing Analysis:

Introduction to Double Entry Systems – Preparation of Financial Statements-Analysis and Interpretation of Financial Statements-Ratio Analysis – Preparation of Funds flow and cash flow statements (Simple Problems)

UNIT – VI:

Capital and Capital Budgeting: Capital Budgeting: Meaning of Capital-Capitalization-Meaning of Capital Budgeting-Time value of money- Methods of appraising Project profitability: Traditional Methods(pay back period, accounting rate of return) and modern methods(Discounted cash flow method, Net Present Value method, Internal Rate of Return Method and Profitability Index)

TEXT BOOKS

1. Dr. N. AppaRao, Dr. P. Vijay Kumar: 'Managerial Economics and Financial Analysis', Cengage Publications, New Delhi – 2011
2. Dr. A. R. Aryasri – Managerial Economics and Financial Analysis, TMH 2011



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3. Prof. J.V.Prabhakararao, Prof. P. Venkatarao. ‘Managerial Economics and Financial Analysis’, Ravindra Publication.

REFERENCES:

1. Dr. B. Kuberudu and Dr. T. V. Ramana: Managerial Economics & Financial Analysis, Himalaya Publishing House, 2014.
2. V. Maheswari: Managerial Economics, Sultan Chand. 2014
3. Suma Damodaran: Managerial Economics, Oxford 2011.
4. Vanitha Agarwal: Managerial Economics, Pearson Publications 2011.
5. Sanjay Dhameja: Financial Accounting for Managers, Pearson.
6. Maheswari: Financial Accounting, Vikas Publications.
7. S. A. Siddiqui & A. S. Siddiqui: Managerial Economics and Financial Analysis, New Age International Publishers, 2012
8. Ramesh Singh, Indian Economy, 7th Edn., TMH 2015
9. Pankaj Tandon A Text Book of Microeconomic Theory, Sage Publishers, 2015
10. Shailaja Gajjala and Usha Munipalle, Universities press, 2015



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III Year – I Semester	PHARMACEUTICAL ENGINEERING -I	L	T	P	C
		3	0	0	3

COURSE OBJECTIVES: Upon completion of the course student shall be able:

1. To know various unit operations used in Pharmaceutical industries.
2. To understand the material handling techniques.
3. To perform various processes involved in pharmaceutical manufacturing process.
4. To carry out various tests to prevent environmental pollution.
5. To appreciate and comprehend significance of plant lay out design for optimum use of resources.
6. To appreciate the various preventive methods used for corrosion control in Pharmaceutical industries.

COURSE CONTENT:

UNIT-I

Flow of fluids: Types of manometers, Reynolds number and its significance, Bernoulli's theorem and its applications, Energy losses, Orifice meter, Venturimeter, Pitot tube and Rotometer.

Distillation: Basic Principles and methodology of simple distillation, flash distillation, fractional distillation, distillation under reduced pressure, steam distillation & molecular distillation

UNIT-II

Size Reduction: Objectives, Mechanisms & Laws governing size reduction, factors affecting size reduction, principles, construction, working, uses, merits and demerits of Hammer mill, ball mill, fluid energy mill, Edge runner mill & end runner mill.

Size Separation: Objectives, applications & mechanism of size separation, official standards of powders, sieves, size separation Principles, construction, working, uses, merits and demerits of Sieve shaker, cyclone separator, Air separator, Bag filter & elutriation tank.

UNIT- III

Drying: Objectives, applications & mechanism of drying process, measurements & applications of Equilibrium Moisture content, rate of drying curve. principles, construction, working, uses, merits and demerits of Tray dryer, drum dryer, spray dryer, fluidized bed dryer, vacuum dryer, freeze dryer.



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Mixing: Objectives, applications & factors affecting mixing, Difference between solid and liquid mixing, mechanism of solid mixing, liquids mixing and semisolids mixing. Principles, Construction, Working, uses, Merits and Demerits of Double cone blender, twin shell blender, ribbon blender, Sigma blade mixer, planetary mixers, Propellers, Turbines, Paddles & Silvers on Emulsifier.

UNIT-IV

Filtration: Objectives, applications, Theories & Factors influencing filtration, filter aids, filter medias. Principle, Construction, Working, Uses, Merits and demerits of plate & frame filter, filter leaf, rotary drum filter, Meta filter & Cartridge filter, membrane filters and Seidtz filter.

Centrifugation: Objectives, principle & applications of Centrifugation, principles, construction, working, uses, merits and demerits of Perforated basket centrifuge, Non-perforated basket centrifuge, semi continuous centrifuge & super centrifuge.

UNIT- V

Materials of pharmaceutical plant construction, Corrosion and its prevention: Factors affecting during materials selected for Pharmaceutical plant construction, Theories of corrosion, types of corrosion and their prevention. Ferrous and nonferrous metals, inorganic and organic non metals, basic of material handling systems.

Recommended Books: (Latest Editions)

1. Introduction to chemical engineering – Walter L Badger & Julius Banchemo, Latest edition.
2. Solid phase extraction, Principles, techniques and applications by Nigel J.K. Simpson- Latest edition.
3. Unit operation of chemical engineering – McCabe Smith, Latest edition.
4. Pharmaceutical engineering principles and practices – C.V.S Subrahmanyam et al., Latest edition.
5. Remington practice of pharmacy- Martin, Latest edition.
6. Theory and practice of industrial pharmacy by Lachmann., Latest edition.
7. Physical pharmaceuticals- C.V.S Subrahmanyam et al., Latest edition.
8. Cooper and Gunn's Tutorial pharmacy, S.J. Carter, Latest edition.



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III Year – I Semester	BIOPHARMACEUTICS AND PHARMACOKINETICS	L	T	P	C
		3	0	0	3

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

1. Understand the basic concepts in biopharmaceutics and pharmacokinetics and their significance.
2. Use of plasma drug concentration-time data to calculate the pharmacokinetic parameters to describe the kinetics of drug absorption, distribution, metabolism, excretion, elimination.
3. To understand the concepts of bioavailability and bioequivalence of drug products and their significance.
4. Understand various pharmacokinetic parameters, their significance & applications.

COURSE CONTENT:

UNIT-I

Introduction to Bio pharmaceutics: Absorption; Mechanisms of drug absorption through GIT, factors influencing drug absorption through GIT, absorption of drug from Non per oral extra-vascular routes, **Distribution** Tissue permeability of drugs, binding of drugs, apparent volume of drug distribution, plasma and tissue protein binding of drugs, factors affecting protein-drug binding. Kinetics of protein binding, Clinical significance of protein binding of drugs

UNIT- II

Elimination: Drug metabolism and basic understanding metabolic pathways, renal excretion of drugs, factors affecting renal excretion of drugs, renal clearance, Non renal routes of drug excretion

Bioavailability and Bioequivalence: Definition and Objectives of bioavailability, absolute and relative bioavailability, measurement of bioavailability, *in-vitro* drug dissolution models, *in-vitro-in-vivo* correlations, bioequivalence studies, methods to enhance the dissolution rates and bioavailability of poorly soluble drugs.

UNIT- III

Pharmacokinetics: Definition and introduction to Pharmacokinetics, Compartment models, Non compartment models, physiological models, One compartment open model. (a). Intravenous Injection (Bolus) (b). Intravenous infusion and (c) Extra vascular administrations. Pharmacokinetics parameters - K_e , $t_{1/2}$, V_d , AUC, K_a , Cl and Cl_R - definitions, methods of eliminations, understanding of their significance and application



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UNIT- IV

Multi compartment models: Two compartment open model. IV bolus Kinetics of multiple dosing, steady state drug levels, calculation of loading and maintenance doses and their significance in clinical settings.

UNIT- V

Nonlinear Pharmacokinetics: a. Introduction, b. Factors causing Non-linearity. c. Michaelis-menton method of estimating parameters, Explanation with example of drugs.

Recommended Books: (Latest Editions)

1. Biopharmaceutics and Clinical Pharmacokinetics by, Milo Gibaldi.
2. Biopharmaceutics and Pharmacokinetics; By Robert F Notari
3. Applied biopharmaceutics and pharmacokinetics, Leon Shargel and Andrew B.C.YU
4th edition, Prentice-Hall International edition, USA
4. Bio pharmaceuticals and Pharmacokinetics-A Treatise, By D. M. Brahmkar and Sunil B. Jaiswal, Vallabh Prakashan Pitampura, Delhi
5. Pharmacokinetics: By Milo Gibaldi Donald, R. Mercel Dekker Inc.
6. Hand Book of Clinical Pharmacokinetics, By Milo Gibaldi and Laurie Prescott by
ADIS Health Science Press.
7. Biopharmaceutics; By Swarbrick
8. Clinical Pharmacokinetics, Concepts and Applications: By Malcolm Rowland and
9. Thomas, N. Tozen, Lea and Febrger, Philadelphia, 1995.
10. Dissolution, Bioavailability and Bioequivalence, By Abdou H.M, Mack, Publishing
Company, Pennsylvania 1989.
11. Biopharmaceutics and Clinical Pharmacokinetics-An introduction 4th edition
Revised and expanded by Robert F Notari Marcel Dekker Inc, New York and Basel,
1987.
12. Remington's Pharmaceutical Sciences, By Mack Publishing Company, Pennsylvania



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III Year – I Semester	BIostatistics	L	T	P	C
		3	0	0	3

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

- Know the operation of M.S.Excel, R,DoE (Design of Experiment)
- Know the various statistical techniques to solve statistical problems
- Appreciate statistical techniques in solving the problems.

COURSE CONTENT:

UNIT-I

Introduction: Statistics, Biostatistics, Frequency distribution

Measures of central tendency: Mean, Median, Mode- Pharmaceutical examples

Measures of dispersion: Dispersion, Range, standard deviation, Pharmaceutical problems

Correlation: Definition, Karl Pearson's coefficient of correlation, Multiple correlation -
Pharmaceuticals examples

UNIT-II

Regression: Curve fitting by the method of least squares, fitting the lines $y = a + bx$ and $x = a + by$, Multiple regression, standard error of regression– Pharmaceutical Examples

Probability: Definition of probability, Binomial distribution, Normal distribution, Poisson's distribution, properties - problems

Sample, Population, large sample, small sample, Null hypothesis, alternative hypothesis, sampling, essence of sampling, types of sampling, type-I, type - II errors, Standard error of mean (SEM) - Pharmaceutical examples

Parametric test: t-test(Sample, Pooled or Unpaired and Paired) , ANOVA, (One way and Two way), Least Significance difference

UNIT-III

Non Parametric tests: Wilcoxon Rank Sum Test, Mann-Whitney U test, Kruskal-Wallis test, Friedman Test

Graphs: Histogram, Pie Chart, Cubic Graph, response surface plot, Counter Plotgraph.

UNIT-IV

Blocking and confounding system for Two-level factorials

Regression modeling: Hypothesis testing in Simple and Multiple regression models

Introduction to Practical components of Industrial and Clinical Trials Problems:



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Statistical Analysis Using Excel, SPSS, MINITAB[®], DESIGN OF EXPERIMENTS, R -
Online Statistical Software's to Industrial and Clinical trial approach

UNIT-V

Design and Analysis of experiments:

Factorial Design: Definition, 2^2 , 2^3 design. Advantage of factorial design **Response Surface methodology:** Central composite design, Historical design, Design Optimization Techniques

Recommended Books (Latest edition):

1. Pharmaceutical statistics- Practical and clinical applications, 5th edition, Sanford Bolton, Publisher Marcel Dekker Inc. New York.
2. Fundamental of Statistics – Himalaya Publishing House, 7th edition, S.C. Gupta.
3. Design and Analysis of Experiments – PHI Learning Private, Eastern economy edition, Limited, R. Pannerselvam.
4. Design and Analysis of Experiments– Wiley, 10th edition, Douglas C. Montgomery.



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III Year – I Semester	QUALITY CONTROL AND ASSURANCE	L	T	P	C
		3	0	0	3

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

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

COURSECONTENT:

UNIT– I

Quality Assurance and Quality Management concepts: Definition and concept of Quality control, Quality assurance and GMP

Total Quality Management (TQM): Definition, elements, philosophies

ICH Guidelines: purpose, participants, process of harmonization, Brief overview of QSEM, with special emphasison Q-series guidelines, ICH stability testing guidelines

Quality by design (QbD): Definition, overview, elements of QbD program tools

ISO 9000 & ISO14000: Overview, Benefits, Elements, steps for registration **NABLaccreditation:** Principles and procedures

UNIT-II

Organization and personnel: Personnel responsibilities, training, hygiene and personal records.

Premises: Design, construction and plant layout, maintenance, sanitation, environmental control, utilities and maintenance of sterile areas, control of contamination.

Equipments and raw materials: Equipment selection, purchase specifications, maintenance, purchase specifications and maintenance of stores for raw materials.

UNIT– III

Quality Control: Quality control test for containers, rubber closures and secondary packing material.

Good Laboratory Practices: General Provisions, Organization and Personnel, Facilities, Equipment, Testing Facilities Operation, Test and Control Articles, Protocol for Conduct of a Non clinical Laboratory Study, Records and Reports, Disqualification of Testing Facilities



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UNIT- IV

Complaints: Complaints and evaluation of complaints, Handling of returned goods, recalling and waste disposal.

Document maintenance in pharmaceutical industry: Batch Formula Record, Master Formula Record, SOP, Quality audit, Quality Review and Quality documentation, Reports and documents, distribution records.

UNIT- V

Calibration: Introduction, definition and general principles of calibration, qualification and validation. Calibration of pH meter, Qualification of UV-Visible spectrophotometer.

Warehousing: Good warehousing practice, materials management

Recommended Books:(Latest Edition)

1. Quality Assurance Guide by organization of Pharmaceutical Products of India.
2. Good Laboratory Practice Regulations, 2nd Edition, Sandy Weinberg Vol.69.
3. Quality Assurance of Pharmaceuticals-Acompendium of Guidelines and Related materials VolII WHO Publications.
4. A guide to Total Quality Management- Kushik Maitra and Sedhan KGhosh
5. How to Practice GMP's-P P Sharma.
6. ISO 9000andTotalQualityManagement-SadhankG Ghosh
7. The International Pharmacopoeia – Vol I, II, III, IV- General Methods of Analysis and Quality specification for Pharmaceutical Substances, Excipients and Dosage forms
8. Good laboratory Practices– Marcel Deckker Series
9. ICH guidelines, ISO9000 and14000 guidelines



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III Year – I Semester	FOOD PROCESSING TECHNOLOGY	L	T	P	C
		3	0	0	3

COURSE OBJECTIVES: To impart pertinent concepts about different unit operations involved in the food processing industry and preservation techniques.

COURSE OUTCOMES: The student will enable to

1. Perform material balance and energy balance calculations for food processing
2. Explain various unit operations such as fluid flow, thermal process calculations, refrigeration and dehydration in food processing.
3. Explain the theory, applications, equipment involved and hazards of microwave heating in food processing
4. Describe the different mechanical unit operations involved in food processing industry
5. Explain the various preservation techniques.

COURSE CONTENT:

UNIT-I

Food process engineering: Fundamentals of food process engineering, application of quantitative methods of material and energy balances in food engineering practices.

UNIT-II

Unit Operations in food industries: Fluid flow, thermal process calculations, refrigeration, and dehydration operations in food processing.

UNIT-III

Microwave heating: Theory of microwave heating, microwave properties of foods, comparison of microwave and conventional heating, benefits of microwave heating. Applications in food processing, microwave heating equipment, hazards of microwave heating.

UNIT-IV

Mechanical Operations in food processing: Size reduction and screening of solids, mixing and emulsification, filtration, crystallization, extraction.

UNIT-V

Preservation operations: Preservation methods & Strategies, Thermal Methods, Nabla Factor Sterilization, Types of Pasteurization, Dehydro freezing, Irradiation Dosimetry, Transport of food & Preservation strategies



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Text Books:

1. R. T. Toledo, Fundamentals of Food Process Engineering", AVI Publishing Co., 1990.
2. R. Angold G. Beech and J. Taggart, "Food Biotechnology", Cambridge University Press, 1989.
3. Fundamentals of Food Engineering. D G Rao, PHI, New Delhi, 2012.

Reference Books:

1. J.M. Jackson and B. M. Shinn. Fundamentals of Food Canning Technology", AVI Publishing Co., 1978.
2. G. Bernnan, J. P.. Butters, N. D. Cowell and AEV Lilley, "Food Engineering Operations", 2nd Edn., Applied Science, 1976. ww 3.



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III Year – I Semester	PHARMACEUTICAL BIOTECHNOLOGY	L	T	P	C
		3	0	0	3

COURSE OBJECTIVE

- Biotechnology has a long promise to revolutionize the biological sciences and technology.
- Scientific application of biotechnology in the field of genetic engineering, medicine and fermentation technology makes the subject interesting.
- Biotechnology is leading to new biological revolutions in diagnosis, prevention and cure of diseases, new and cheaper pharmaceutical drugs.
- Biotechnology has already produced transgenic crops and animals and the future promises lot more.
- It is basically a research-based subject.

COURSE OUTCOMES: Upon completion of the subject student shall be able to;

1. Understanding the importance of Immobilized enzymes in Pharmaceutical Industries
2. Genetic engineering applications in relation to production of pharmaceuticals
3. Importance of Monoclonal antibodies in Industries
4. Appreciate the use of microorganisms in fermentation technology

COURSE CONTENT:

Unit I

- a) Brief introduction to Biotechnology with reference to Pharmaceutical Sciences.
- b) Enzyme Biotechnology- Methods of enzyme immobilization and applications.
- c) Biosensors- Working and applications of biosensors in Pharmaceutical Industries.
- d) Brief introduction to Protein Engineering.
- e) Use of microbes in industry. Production of Enzymes- General consideration- Amylase, Catalase, Peroxidase, Lipase, Protease, Penicillinase.
- f) Basic principles of genetic engineering.

Unit II

- a) Study of cloning vectors, restriction endonucleases and DNA ligase.
- b) Recombinant DNA technology. Application of genetic engineering in medicine.
- c) Application of r DNA technology and genetic engineering in the production of:
 - i) Interferon ii) Vaccines- hepatitis- B iii) Hormones-Insulin.
- d) Brief introduction to PCR

Unit III

Types of immunity- humoral immunity, cellular immunity

- a) Structure of Immunoglobulins
- b) Structure and Function of MHC
- c) Hypersensitivity reactions, Immune stimulation and Immune suppressions.
- d) General method of the preparation of bacterial vaccines, toxoids, viral vaccine, antitoxins, serum-immune blood derivatives and other products relative to immunity.



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- e) Storage conditions and stability of official vaccines
- f) Hybridoma technology- Production, Purification and Applications
- g) Blood products and Plasma Substitutes.

Unit IV

- a) Immunoblotting techniques- ELISA, Western blotting, Southern blotting.
- b) Genetic organization of Eukaryotes and Prokaryotes
- c) Microbial genetics including transformation, transduction, conjugation, plasmids and transposons.
- d) Introduction to Microbial biotransformation and applications.
- e) Mutation: Types of mutation/mutants.

Unit V

- a) Fermentation methods and general requirements, study of media, equipments, sterilization methods, aeration process, stirring.
- b) Large scale production fermenter design and its various controls.
- c) Study of the production of - penicillins, citric acid, Vitamin B12, Glutamic acid, Grise of ulvin,
- d) Blood Products: Collection, Processing and Storage of whole human blood, dried human plasma, plasma Substitutes.

Recommended Books (Latest edition):

1. B.R. Glick and J.J. Pasternak: Molecular Biotechnology: Principles and Applications of Recombinant DNA: ASM Press Washington D.C.
2. RA Goldshy et. al., :Kuby Immunology.
3. J.W. Goding: Monoclonal Antibodies.
4. J.M. Walker and E.B. Gingold: Molecular Biology and Biotechnology by Royal Society of Chemistry.
5. Zaborsky: Immobilized Enzymes, CRC Press, Degrand, Ohio.
6. S.B. Primrose: Molecular Biotechnology (Second Edition) Blackwell Scientific Publication.
7. Stanbury F., P., Whitakar A., and Hall J., S., Principles of fermentation technology, 2nd edition, Aditya books Ltd., New Delhi



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III Year – I Semester	NON-CONVENTIONAL ENERGY SOURCES	L	T	P	C
		3	0	0	3

COURSE OBJECTIVES: The course will enable the student's to

1. Study the concepts of solar energy radiation, collection, storage and applications.
2. Acquire the knowledge on the windenergy, biomassenergy,
3. Students will learn the systems dimensions of the energy problems and its historical perspective on energy technology and system development.

COURSE OUTCOMES: At the end of this course, students will be able to

1. Illustrate the principles behind different non-conventional energy sources.(L2)
2. Explain the effects of the current energy systems based on fossil fuels over the environment and the society.(L3)
3. Design renewable/hybrid energy systems that meet specific energy demands, are economically feasible and have a minimal impact on the environment.(L4)
4. Summarize the wind Energy, horizontal and vertical Access wind Mills and bio-conversion.(L2)
5. Classify types of Bio-Gas digesters and Utilization for Cooking using Geothermal Energy Resources.(L3)

COURSE CONTENT:

UNITI:

Principles of Solar Radiation

Role and potential of new and renewable source, the solar energy option, Environmental impact of solar power, physics of the sun, the solar constant, extraterrestrial and terrestrial solar radiation, solar radiation on titled surface, instruments for measuring solar radiation and sun shine, solar radiation data.

UNITII:

Solar Thermal Systems

Flat plate and concentrating collectors, classification of concentrating collectors, solar ponds. Solar Applications-solar heating/cooling technique, solar distillation and drying.



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UNIT III:

Solar Photovoltaic Systems: Operating principles, Photovoltaic cell concepts, Cell, module, array, Series and parallel connections, Maximum power point tracking, Applications: Battery charging, Pumping, Lighting.

UNITIV:

Wind Energy

Sources and potentials, horizontal and vertical axis wind mills, performance characteristics, Betzcriteria.

UNITV:

Bio-Mass Energy

Operating principles. Combustion and fermentation, Anaerobic digester, Wood gasifier, Pyrolysis. Applications: Biogas, Woodstoves, Biodiesel, Combustion engine.

TEXTBOOKS:

1. Non-Conventional Energy Sources/G.D.Rai, Khanna Publishers
2. Renewable Energy Resources–Twidell &Wier,CRCPress(Taylor&Francis)

REFERENCES:

1. Renewable energy resources/Tiwariand Ghosal/Narosa.
2. Renewable Energy Technologies/Ramesh & Kumar/Narosa
3. Non-Conventional Energy Systems/KMittal/Wheeler.
4. Renewable energy sources and emerging technologies by D.P.Kothari, K.C. Singhal,P.H.I.



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B.Tech PHARMACEUTICAL ENGINEERING

(R23 – IIIrd YEAR COURSE STRUCTURE & SYLLABUS)

III Year – I Semester	INTRODUCTION TO DATA STRUCTURES	L	T	P	C
		3	0	0	3

COURSE OBJECTIVES:

The objective of the course is to

- Introduce the fundamental concept of data structures and abstract data types
- Emphasize the importance of data structures in developing and implementing efficient algorithms
- Describe how arrays, records, linked structures, stacks, queues, trees, and graphs are represented in memory and used by algorithms

COURSE OUTCOMES:

After completing this course a student will be able to:

- Summarize the properties, interfaces, and behaviors of basic abstract data types
- Discuss the computational efficiency of the principal algorithms for sorting & searching
- Use arrays, records, linked structures, stacks, queues, trees, and Graphs in writing programs
- Demonstrate different methods for traversing trees

COURSE CONTENT:

UNIT I

Data Structures - Definition, Classification of Data Structures, Operations on Data Structures, Abstract Data Type (ADT), Preliminaries of algorithms. Time and Space complexity. Searching - Linear search, Binary search, Fibonacci search. Sorting- Insertion sort, Selection sort, Exchange (Bubble sort, quick sort), distribution (radix sort), merging (Merge sort) algorithms.

UNIT II

Linked List: Introduction, Single linked list, Representation of Linked list in memory, Operations on Single Linked list-Insertion, Deletion, Search and Traversal ,Reversing Single Linked list, Applications on Single Linked list- Polynomial Expression Representation ,Addition and Multiplication, Sparse Matrix Representation using Linked List, Advantages and Disadvantages of Single Linked list, Double Linked list-Insertion, Deletion, Circular Linked list-Insertion, Deletion.



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UNIT III

Queues: Introduction to Queues, Representation of Queues-using Arrays and using Linked list, Implementation of Queues-using Arrays and using Linked list, Application of Queues-Circular Queues, Deques, Priority Queues, Multiple Queues.

Stacks: Introduction to Stacks, Array Representation of Stacks, Operations on Stacks, Linked list Representation of Stacks, Operations on Linked Stack, Applications-Reversing list, Factorial Calculation, Infix to Postfix Conversion, Evaluating Postfix Expressions.

UNIT IV

Trees: Basic Terminology in Trees, Binary Trees-Properties, Representation of Binary Trees using Arrays and Linked lists. Binary Search Trees- Basic Concepts, BST Operations: Insertion, Deletion, Tree Traversals, Applications-Expression Trees, Heap Sort, Balanced Binary Trees- AVL Trees, Insertion, Deletion and Rotations.

UNIT V

Graphs: Basic Concepts, Representations of Graphs-Adjacency Matrix and using Linked list, Graph Traversals (BFT & DFT), Applications- Minimum Spanning Tree Using Prim's & Kruskal's Algorithm, Dijkstra's shortest path, Transitive closure, Warshall's Algorithm.

Text Books:

1. Data Structures Using C. 2nd Edition. Reema Thareja, Oxford.
2. Data Structures and algorithm analysis in C, 2nd ed, Mark Allen Weiss.

Reference Books:

1. Fundamentals of Data Structures in C, 2nd Edition, Horowitz, Sahni, Universities Press.
2. Data Structures: A PseudoCode Approach, 2/e, Richard F. Gilberg, Behrouz A. Forouzan, Cengage.
3. Data Structures with C, Seymour Lipschutz TMH

e-Resources:

1. <http://algs4.cs.princeton.edu/home/>
2. https://faculty.washington.edu/jstraub/dsa/Master_2_7a.pdf



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(R23 – IIIrd YEAR COURSE STRUCTURE & SYLLABUS)

III Year – I Semester	DESIGN AND ANALYSIS OF EXPERIMENTS	L	T	P	C
		3	0	0	3

Course Objectives:

1. To identify the role of experimentations in engineering
2. To study the importance of single factor experimentation
3. To gain the concepts of multifactor experimentation
4. To use fractional factorial design of experiments
5. To understand the usage of response surface methodology
6. To study the concepts of Taguchi methods.

Course Outcomes: At the end of the course students will be able to

1. Plan an experimentation using the experimental design strategies and principles
2. Estimate model parameters and analyse the model adequacy
3. Design experimentation for a multifactor problem using factorial design
4. Compute fractional factorial design of experimentation
5. Propose design using a response surface methodology and interpret the results
6. Correlate experimentation with a Taguchi based design for a given case study

COURSE CONTENT

UNIT-I

Experimental Design Fundamental: Importance of experiments, experimental strategies, basic principles of design, terminology, ANOVA, steps in experimentation, sample size, normal probability plot, line regression model.

UNIT - II

Single Factor Experiments: Completely randomized design, Randomized block design, Latin square design Statistical analysis, estimation of model parameters, model adequacy checking, pair wise comparison tests.

UNIT-III

Multifactor Experiments: Two and three factor factorial experiments, 2^k factorial experiments, confounding and blocking designs

Fractional Factorial design: Fractional factorial design of experiments, nested designs, split plot design



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UNIT - IV

Special Experimental Design: Response Surface Methodology, experiments with random factors, rules for expected mean squares, approximate F-tests.

UNIT - V

Taguchi Methods: Steps in experimentation, design using Orthogonal Arrays, data analysis, Robust design–control and noise factors, S/Nratios, parameter design, case studies.

Text Books:

1. Design and Analysis of Experiments/ Montgomery DC/ 7th Edition/ John Wiley & Sons, NY/2008.
2. Taguchi Techniques for Quality Engineering/RossPJ / Mc Graw-Hill Book Company, NY/2nd Edition/2005.

Reference Books:

1. Doe Simplified: Practical Tools for Effective Experimentation /M.J. Anderson, and P.J.Whitcomb /3rdEdition /Productivity Press, USA/2015
2. Modern Statistics for Engineering and Quality Improvement /J.Lawson, and J.Erjavec/1stEdition/Duxbury Press/2000.
3. Statistics for Experimenters /G.E.P.Box,W.G.Hunter,andS.J.Hunter/2ndEdition/JohnWiley & SonsInc./ 2005.



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III Year – I Semester	PHARMACEUTICAL ENGINEERING LAB	L	T	P	C
		0	0	3	1.5

1. Steam distillation –To calculate the efficiency of steam distillation.
2. To determine the overall heat transfer coefficient by heat exchanger.
3. Construction of drying curves (for calcium carbonate and starch).
4. Determination of moisture content and loss on drying.
5. Determination of humidity of air – i) From wet and dry bulb temperatures ii) Dew point method.
6. Description of Construction working and application of Pharmaceutical Machinery such as rotary tablet machine, fluidized bed coater, fluid energy mill, dehumidifier.
7. Size analysis by sieving – To evaluate size distribution of tablet granulations – Construction of various size frequency curves including arithmetic and logarithmic probability plots.
8. Size reduction: To verify the laws of size reduction using ball mill and determining Kicks, Rittinger's, Bond's coefficients, power requirement and critical speed of Ball Mill.
9. Demonstration of colloid mill, planetary mixer, fluidized bed dryer, freeze dryer and such other major equipment.
10. Factors affecting Rate of Filtration and Evaporation (Surface area, Concentration and Thickness/ viscosity)
11. To study the effect of time on the Rate of Crystallization.
12. To calculate the uniformity Index for given sample by using Double Cone Blender.



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III Year – I Semester	STATISTICS USING R PROGRAMMING LAB	L	T	P	C
		0	0	3	1.5

COURSE OBJECTIVE: This course provides a solid undergraduate foundation in both probability theory and mathematical statistics and at the same time provides an indication of the relevance and importance of the theory in solving practical problems in the real world

CO1: Manipulate data within R and to create simple graphs and charts used in introductory statistics

CO2: Perform and interpret different distribution using R **CO3:** Carry out hypothesis testing and calculate confidence intervals; Perform linear regression models for data analysis

Prerequisites: Basics of Mathematics Syllabus

UNIT-1: Introduction to R Programming Installation of R- Creating workspace Environment –file systems in R.

UNIT-2: Working with R:

Summary Statistics. Loading R-Datasets- Data frames Computing descriptive structures.

Mean, Median ..etc. Simple plots. Reading own data files in C&V, TXT..etc formats

Viewing and manipulating data

- Plotting data
- reading in your own data.

UNIT- 3: Visualizing Data Tables, charts and plots. Visualising Measures of Central Tendency, Variation, and Shape. Box plots, Pareto diagrams. How to find the mean median standard deviation and quantiles of a set of observations. Students may experiment with real as well as sampled data sets.

UNIT 4: Probability Distributions.

• Generate and Visualize Discrete and continuous distributions using the statistical environment. Demonstration of CDF and PDF uniform and normal, binomial Poisson distributions.

- Students are expected to generate sampled data using various distributions and their compute distribution parameters from the sampled data and compare properties.

UNIT5: Densities of Random Variables

- Off the Shelf Distributions in R
- Matching a Density to Data
- More About Making Histograms Cycle

UNIT 6: Binomial Distribution

- Study of binomial distribution. Plots of density and distribution functions. Normal approximation to the Binomial distribution.

UNIT 7: Building Confidence in Confidence Intervals

- Populations Versus Samples
- Large Sample Confidence Intervals
- Simulating Data Sets



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- Evaluating the Coverage of Confidence Intervals Cycle

UNIT 8: Perform Tests of Hypotheses

- How to perform tests of hypotheses about the mean when the variance is known. How to compute the p-value. Explore the connection between the critical region, the test statistic, and the p-value Cycle

UNIT 9: Correlation

- How to calculate the correlation between two variables. How to make scatter plots. Use the scatter plot to investigate the relationship between two variables

UNIT 10: Estimating a Linear Relationship

- A Statistical Model for a Linear Relationship
- Least Squares Estimates
- The R Function lm
- Scrutinizing the Residuals

TEXTBOOK/S:

1. Maria Dolores Ugarte , Ana F. Militino , Alan T. Arnholt “Probability and Statistics with R”
2nd Edition on, CRC Press, 2016.
2. P. Dalgaard. Introductory Statistics with R, 2nd Edition. (Springer 2008)

REFERENCES:

1. Michael Akritas, " Probability & Statistics with R for Engineers and Scientists”,
2nd
Edition on, CRC Press, 2016.

Web Links

1. <http://nptel.ac.in/courses/106104135/48> 2. <http://nptel.ac.in/courses/110106>



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III Year – I Semester	ADVANCED COMMUNICATION SKILLS LAB	L	T	P	C
		0	0	3	1.5

UNIT I

Oral Activity: JAM, Hypothetical Situations, Self/Peer Profile Common Errors in pronunciation, Neutralising Accent

UNIT II

Oral Activity: Telephonic Etiquette, Role Plays Poster Presentations

UNIT III

Oral Activity: Oral Presentation skills, Public speaking Data Interpretation

UNIT IV

Oral Activity: Group Discussions: Do's and Don'ts- Types, Modalities

UNIT V

Oral Activity: Interview Skills: Preparatory Techniques, Frequently asked questions, Mock Interviews.

Pronunciation: Connected speech (Pausing, Tempo, Tone, Fluency etc.,)

References:

1. Infotech English, Maruthi Publications (with Compact Disc).
2. Exercises in Spoken English Part 1,2,3,4, OUP and CIEFL.
3. English Pronunciation in use- Mark Hancock, Cambridge University Press.
4. English Phonetics and Phonology-Peter Roach, Cambridge University Press.
5. English Pronunciation in use- Mark Hewings, Cambridge University Press.
6. English Pronunciation Dictionary- Daniel Jones, Cambridge University Press.
7. English Phonetics for Indian Students- P. Bala Subramanian, Mac Millan Publications.
8. Technical Communication- Meenakshi Raman, Sangeeta Sharma, Oxford University Press.
9. Technical Communication- Gajendra Singh Chauhan, SmitaKashiramka, Cengage Publications.



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III Year – I Semester	PHARMA ENGINEERING PRACTICE - FIELD TRIP	L	T	P	C
		0	0	3	2



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III Year – II Semester	PHARMACEUTICAL ENGINEERING - II	L	T	P	C
		3	0	0	3

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

1. Know the various pharmaceutical dosage forms and their manufacturing techniques.
2. Know various considerations in development of pharmaceutical dosage forms
3. Formulate solid, liquid and semisolid dosage forms and evaluate them for their quality

COURSE CONTENT:

UNIT-I

Preformulation Studies: Introduction to preformulation, goals and objectives, study of physicochemical characteristics of drug substances.

- a. Physical properties:** Physical form (crystal & amorphous), particle size, shape, flow properties, solubility profile (pKa,pH, partition coefficient), polymorphism.
- b. Chemical Properties:** Hydrolysis, oxidation, reduction, racemisation, polymerization, BCS classification of drugs &its significance Application of preformulation considerations in the development of solid, liquid oral and parenteral dosage forms and its impact on stability of dosage forms.

UNIT-II

Tablets:

- a. Introduction, ideal characteristics of tablets, classification of tablets. Excipients, Formulation of tablets, granulation methods, compression and processing problems. Equipments and tablet tooling.
- b. Tablet coating: Type of coating, coating materials, formulation of coating composition, methods of coating, equipment employed and defects in coating.
- c. Quality control tests: In process and finished product tests

Liquid orals: Formulation and manufacturing consideration of syrups and elixirs suspensions and emulsions; Filling and packaging; evaluation of liquid orals

UNIT-III

Capsules:

- a. **Hard gelatin capsules:** Introduction, Production of hard gelatin capsule shells. size of capsules, Filling, finishing and special techniques of formulation of hard gelatin capsules, manufacturing defects. In process and final product quality control tests for capsules.
- b. **Soft gelatin capsules:** Nature of shell and capsule content, size of capsules, importance of base adsorption and minim/gram factors, production, in process and final product quality control tests. Packing, storage and stability testing of soft gelatin capsules and



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their applications.

Pellets: Introduction, formulation requirements, pelletization process, equipments for manufacture of pellets

UNIT-IV

Parenteral Products

- Definition, types, advantages and limitations. Preformulation factors and essential requirements, vehicles, additives, importance of isotonicity
- Production procedure, production facilities and controls, aseptic processing
- Formulation of injections, sterile powders, large volume parenterals and lyophilized products.
- Containers and closures selection, filling and sealing of ampoules, vials and infusion fluids. Quality control tests of parenteral products.

Ophthalmic Preparations: Introduction, formulation considerations; formulation of eye drops, eye ointments and eye lotions; methods of preparation; labeling, containers; evaluation of ophthalmic preparations

UNIT-V

Cosmetics: Formulation and preparation of the following cosmetic preparations: lipsticks, shampoos, cold cream and vanishing cream, tooth pastes, hair dyes and sunscreens.

Pharmaceutical Aerosols: Definition, propellants, containers, valves, types of aerosol systems; formulation and manufacture of aerosols ; Evaluation of aerosols; Quality control and stability studies.

Packaging Materials Science: Materials used for packaging of pharmaceutical products, factors influencing choice of containers, legal and official requirements for containers, stability aspects of packaging materials, quality control tests.

Recommended Books: (Latest Editions)

1. Pharmaceutical dosage forms - Tablets, volume 1 -3 by H.A. Liberman, Leon Lachman & J.B.Schwartz
2. Pharmaceutical dosage form - Parenteral medication vol- 1&2 by Liberman & Lachman
3. Pharmaceutical dosage form disperse system VOL-1 by Liberman & Lachman
4. Modern Pharmaceutics by Gilbert S. Banker & C.T. Rhodes, 3rd Edition
5. Remington: The Science and Practice of Pharmacy, 20th edition Pharmaceutical Science (RPS)
6. Theory and Practice of Industrial Pharmacy by Liberman & Lachman.
7. Pharmaceutics- The science of dosage form design by M.E. Aulton, Churchill living stone, Latest edition.
8. Introduction to Pharmaceutical Dosage Forms by H. C.Ansel, Lea & Febiger, Philadelphia, 5th edition, 2005.
9. Drug stability Principles and practice by Cartensen& C.J. Rhodes, 3rd Edition. Marcel Dekker Series, Vol 107.



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B.Tech PHARMACEUTICAL ENGINEERING
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III Year – II Semester	INSTRUMENTAL METHODS OF ANALYSIS	L	T	P	C
		3	0	0	3

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

1. Understand the interaction of matter with electromagnetic radiations and its applications in drug analysis
2. Understand the chromatographic separation and analysis of drugs.
3. Perform quantitative & qualitative analysis of drugs using various analytical instruments.

COURSE CONTENT:

UNIT-I

UV Visible spectroscopy

Electronic transitions, chromophores, auxochromes, spectral shifts, solvent effect on absorption spectra, Beer and Lambert's law, Derivation and deviations.

Instrumentation - Sources of radiation, wavelength selectors, sample cells, detectors- Photo tube, Photomultiplier tube, Photo voltaic cell, Silicon Photodiode.

Applications - Spectrophotometric titrations, Single component and multi component analysis Fluorimetry Theory, Concepts of singlet, doublet and triplet electronic states, internal and external conversions, factors affecting fluorescence, quenching, instrumentation and applications

UNIT-II

IR spectroscopy

Introduction, fundamental modes of vibrations in poly atomic molecules, sample handling, factors affecting vibrations

Instrumentation - Sources of radiation, wavelength selectors, detectors - Golay cell, Bolometer, Thermocouple, Thermister, Pyroelectric detector and applications

Flame Photometry- Principle, interferences, instrumentation and applications

Atomic absorption spectroscopy-Principle, interferences, instrumentation and applications

Nephelo turbidometry- Principle, instrumentation and applications

UNIT-III

Introduction to chromatography

Adsorption and partition column chromatography-Methodology, advantages, disadvantages and applications.



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Thin layer chromatography-Introduction, Principle, Methodology, Rf values, advantages, disadvantages and applications.

Paper chromatography- Introduction, methodology, development techniques, advantages, disadvantages and applications

Electrophoresis- Introduction, factors affecting electrophoretic mobility, Techniques of paper, gel, capillary electrophoresis, applications

UNIT-IV

Gas chromatography - Introduction, theory, instrumentation, derivatization, temperature programming, advantages, disadvantages and applications

High performance liquid chromatography (HPLC) - Introduction, theory, instrumentation, advantages and applications.

UNIT-V

Ion exchange chromatography- Introduction, classification, ion exchange resins, properties, mechanism of ion exchange process, factors affecting ion exchange, methodology and applications

Gel chromatography-Introduction, theory, instrumentation and applications

Affinity chromatography- Introduction, theory, instrumentation and applications

References books:

1. Spectrometric Identification of Organic compounds –Robert M Silverstein, Sixth edition, John Wiley & Sons, 2004.
2. Principles of Instrumental Analysis - Douglas A Skoog, F. James Holler, Timothy A. Nieman, 5 th edition, Easternpress, Bangalore,1998.
3. Instrumental methods of analysis – Willards, 7 th edition, CBS publishers.
4. Practical Pharmaceutical Chemistry – Beckett and Stenlake, Vol II, 4th edition, CBS Publishers, New Delhi, 1997.
5. Organic Spectroscopy - William Kemp, 3rd edition, ELBS, 1991.
6. Quantitative Analysis of Drugs in Pharmaceutical formulation – PD Sethi, 3 rd Edition, CBS Publishers, New Delhi, 1997.
7. Pharmaceutical Analysis –Modern methods –Part B- JW Munson, Volume 11, Marcel Dekker Series



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B.Tech PHARMACEUTICAL ENGINEERING

(R23 – IIIrd YEAR COURSE STRUCTURE & SYLLABUS)

III Year – II Semester	PRINCIPLES OF TRANSDUCERS AND MEASUREMENTS	L	T	P	C
		3	0	0	3

COURSE OBJECTIVES:

1. To demonstrate fundamentals, basic procedures for operating, testing, calibration and the characteristics of an instrument.
2. To study different types of instruments which are used to measure different parameters like displacement, pressure, temperature.
3. To identify various types of level, flow, speed, vibration etc. and their control.
4. To know the construction details, working principle and mounting of strain gauges for measurement of bending, compressive and tensile forces.
5. To interpret working principle of various instruments used for measurement of humidity, torque and power.

COURSE OUTCOMES: At the end of the course students will be able to

1. Analyze the basic elements, characteristics and errors of an instrument.
2. Select the instrument for measurement of displacement, temperature and pressure.
3. Choose appropriate instrument to measure level and flow of fluid
4. Measure speed and vibration using different instruments
5. Illustrate the working principle of strain gauges, mounting procedures for measurement of bending, compressive, tensile forces.
6. Select appropriate instrument to measure humidity, force, torque and power for different applications.

COURSE CONTENT:

UNIT-I

Definition: Basic principles of measurement – Measurement systems, generalized configuration and functional descriptions of measuring instruments–examples. Dynamic performance characteristics–sources of error, Classification and elimination of error

UNIT-II

Measurement of Displacement: Theory and construction of various transducers to measure displacement – Piezo electric, Inductive, capacitance, resistance, ionization and Photo electric transducers- Calibration procedures



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Measurement of Temperature: Classification–Ranges– Various Principles of measurement–Expansion, Electrical Resistance–Thermister–Thermocouple–Pyrometers– Temperature Indicators

Measurement of Pressure: Units–classification–different principles used. Manometers, Piston, Bourd on pressure gauges, Bellows–Diaphragmgauges. Low pressure measurement– Thermal conductivity gauges–ionization pressure gauges, McLeod pressure gauge

UNIT–III

Measurement of Level: Direct method–Indirect methods–capacitative, ultrasonic, magnetic, cryogenic fuel level indicators–Bubler level indicators

Flow Measurement: Rotameter, magnetic, Ultrasonic, Turbine flow meter, Hot – wire anemometer, Laser Doppler Anemometer(LDA)

Measurement of Speed: Mechanical Tachometers–Electrical tachometers–Stroboscope, Non contact type of tachometer

Measurement of Acceleration and Vibration: Different simple instruments–Principles of Seismic instruments–Vibro meter and accelerometer using this principle

UNIT–IV

Stress Strain Measurements: Various types of stress and strain measurements– electrical strain gauge–gauge factor–method of usage of resistance strain gauge for bending compressive and tensile strains–usage for measuring torque, Strain gauge Rosettes. **Measurement of Humidity:** Moisture content of gases, sling psychrometer, Absorption psychrometer, Dew pointmeter

Measurement of Force, Torque and Power- Elastic force meters, load cells, Torsion meters, Dynamometers.

UNIT–V

Elements of Control Systems: Introduction, Importance–Classification–Open and closed Systems, Servo mechanisms–Examples with block diagrams–Temperature, speed & position control systems Transfer Functions- Signal flow graphs.

Text Books:

1. Mechanical Measurements/ Beckwith, T.G. and Buck, N.L /6thEdition /Narosa Publishing House/2006.
2. Experimental Methods for Engineers/J.P. Holman /8thEdition/ McGrawHill/2011.

Reference Books:

1. Principles of Industrial Instrumentation and Control Systems/ Chennakesava RAlavala/1stEdition/CengageLearning/2009.



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2. Instrumentation and Control systems/S.Bhaskar/Anuradha Agencies.
3. Instrumentation, Measurement & Analysis /B.C.Nakra& K.K Choudhary/2ndEdition/TMH/2006.
4. Measurement Systems: Applications & design/D.SKumar/6thEdition/AnuradhaAgencies/2002.
5. Mechanical and Industrial Measurements/ R.K.Jain/ 11thEdition/ Khanna Publishers/2013.
6. Mechanical Measurements /sirohi and Radha krishna /New Age International/1991.
7. Instrumentation & Mechanical Measurements/A.K.Tayal/3rdEdition/ GalgotiaPublications/2010.



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B.Tech PHARMACEUTICAL ENGINEERING

(R23 – IIIrd YEAR COURSE STRUCTURE & SYLLABUS)

III Year – II Semester	WATER CONSERVATION MANAGEMENT	L	T	P	C
		3	0	0	3

COURSE OBJECTIVE:

The student will acquire the knowledge on water conservation.

COURSE OUTCOMES:

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

1. Understand about water quality.
2. Analyze various water management techniques
- 3 Understand about Water flow measurement
4. Analyze various water testing methods
5. Conduct water audit and realize the importance water conservation.

COURSE CONTENT:

Unit. I

Introduction: water cycle, water storage, water quality. Water conservation in homes; water conservation in the work place; water management-water quality, controlling use and quality of water.

Unit-II:

Water flow measurement, flow in open channels, flow in pipes partially filled with water, flow in pipes wholly filled with water, accuracy direct flow measurement, water quality control, water quality. parameters, water quality grades, benefits of use of water and practical considerations.

Unit- III:

Water testing water salinity, preserving water quality, minimizing evaporation, water sanitation.

Unit - IV

Water audits, Introduction to water auditing and conservation, water and life, a vision for water and - world water conservation, water auditing, the water auditing process, audit preparation, resources, water flow diagram, conducting audit, the water audit report

Unit - V:

Water conservation in agriculture: water conservation in process industry, water conservation in construction industry; water conservation in service industry.

Text books:

- 1 Water Auditing, and Water Conservation, Jeff Starnian, Geert Ho, Kunivilla Mathew, 2004



III Year – II Semester	COMPUTER AIDED DRUG DESIGN	L	T	P	C
		3	0	0	3

COURSE OBJECTIVES: Upon completion of this course the student should be able to

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

COURSE CONTENT:

UNIT-I

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

UNIT-II

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

UNIT-III

Molecular Modeling and Docking A) Molecular and Quantum Mechanics in drug design B) Energy Minimization Methods: comparison between global minimum conformation and bioactive conformation C) Molecular docking and drug receptor interactions: Rigid docking, flexible docking and extra-precision docking. Agents acting on enzymes such as DHFR, HMG-CoA reductase and HIV protease, choline esterase (AchE&BchE)

UNIT-IV

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



of 3D-structure of protein

UNIT-V

Pharmacophore Mapping and Virtual Screening Concept of pharmacophore, pharmacophore mapping, identification of Pharmacophore features and Pharmacophore modeling; Conformational search used in pharmacophore mapping In Silico Drug Design and Virtual Screening Techniques Similarity based methods and Pharmacophore based screening, structure based In-silico virtual screening protocols

REFERENCES:

1. Computational and structural approaches to drug discovery, Robert M Stroud and Janet F Moore, RCS Publishers.
2. Introduction to Quantitative Drug Design by Y.C. Martin, CRC Press, Taylor & Francis group.
3. Drug Design by Ariens Volume 1 to 10, Academic Press, 1975, Elsevier Publishers.
4. Principles of Drug Design by Smith and Williams, CRC Press, Taylor & Francis.
5. The Organic Chemistry of the Drug Design and Drug action by Richard B. Silverman, Elsevier Publishers.
6. Medicinal Chemistry by Burger, Wiley Publishing Co
7. An Introduction to Medicinal Chemistry – Graham L. Patrick, Oxford University Press.
8. Wilson and Gisvold's Text book of Organic Medicinal and Pharmaceutical Chemistry, Lippincott Williams & Wilkins.
9. Comprehensive Medicinal Chemistry – Corwin and Hansch, Pergamon Publishers.
10. Computational and structural approaches to drug design edited by Robert M Stroud and Janet F Moore



III Year – II Semester	PHARMACEUTICAL REGULATORY AFFAIRS	L	T	P	C
		3	0	0	3

COURSE OBJECTIVES: Upon completion of the subject student shall be able to;

1. Know about the process of drug discovery and development
2. Know the regulatory authorities and agencies governing the manufacture and sale of pharmaceuticals
3. Know the regulatory approval process and their registration in Indian and International markets

COURSECONTENT:

Unit I

Drug Discovery and development

Stages of drug discovery, Drug development process, pre-clinical studies, non-clinical activities, clinical studies, Innovator and generics, Concept of generics, Generic drug product development.

Unit II

Regulatory Approval Process

Approval processes and time lines involved in Investigational New Drug (IND), New Drug Application (NDA), Abbreviated New Drug Application (ANDA). Changes to an approved NDA/ ANDA.

Regulatory authorities and agencies

Overview of regulatory authorities of India, United States, European Union, Australia, Japan, Canada (Organization structure and types of applications)

Unit III

Registration of Indian drug product in overseas market

Procedure for export of pharmaceutical products, Technical documentation, Drug Master Files(DMF), Common Technical Document (CTD), electronic Common Technical Document (eCTD), ASEAN Common Technical Document(ACTD) research.

Unit IV

Clinical trials

Developing clinical trial protocols, Institutional Review Board/Independent Ethics committee-formation and working procedures, Informed consent process and procedures, GC Publications of Investigators, sponsors & Monitors, Managing and Monitoring clinical trials,



Pharmacovigilance-safety monitoring in clinical trials

Unit V

Regulatory Concepts

Basic terminology, guidance, guidelines, regulations, Laws and Acts, Orange book, Federal Register, Code of Federal Regulatory, Purple book

Recommended books (Latest edition):

1. Drug Regulatory Affairs by Sachin Itkar, Dr.N.S.Vyawahare, Nirali Prakashan.
2. The Pharmaceutical Regulatory Process, Second Edition Edited by Ira R. Berry and Robert P. Martin, Drugs and the Pharmaceutical Sciences, Vol.185. Informa Healthcare Publishers.
3. New Drug Approval Process: Accelerating Global Registrations By Richard A Guarino, MD, 5th edition, Drugs and the Pharmaceutical Sciences, Vol.190.
4. Guide book for drug regulatory submissions /Sandy Weinberg. By John Wiley & Sons, Inc.
5. FDA Regulatory Affairs: a guide for prescription drugs, medical devices, and biologics/edited by Douglas J. Pisano, David Mantus.
6. Generic Drug Product Development, Solid Oral Dosage forms, Leon Shargel and Isader Kaufer, Marcel Dekker series, Vol.143
7. Clinical Trials and Human Research: A Practical Guide to Regulatory Compliance By Fay A. Rozovsky and Rodney K. Adams
8. Principles and Practices of Clinical Research, Second Edition Edited by John I. Gallin and Frederick P. Ognibene
9. Drugs: From Discovery to Approval, Second Edition By Rick Ng



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B.Tech PHARMACEUTICAL ENGINEERING

(R23 – IIIrd YEAR COURSE STRUCTURE & SYLLABUS)

III Year – II Semester	NOVEL DRUG DELIVERY SYSTEMS	L	T	P	C
		3	0	0	3

COURSE OBJECTIVES: Upon completion of the course student shall be able

1. To understand various approaches for development of novel drug delivery systems.
2. To understand the criteria for selection of drugs and polymers for the development of Novel drug delivery systems, their formulation and evaluation

COURSE CONTENT:

Unit-I

Controlled drug delivery systems: Introduction, terminology/ definitions and rationale, advantages, disadvantages, selection of drug candidate. Approaches to design controlled release formulations based on diffusion, dissolution and ion exchange principles. Physico chemical and biological properties of drugs relevant to controlled release formulations

Polymers: Introduction, classification, properties, advantages and application of polymers in formulation of controlled release drug delivery systems.

Unit-II

Microencapsulation: Definition, advantages and disadvantages, microspheres /microcapsules, micro particles, methods of micro encapsulation, applications

Mucosal Drug Delivery system: Introduction, Principles of bioadhesion /mucoadhesion, concepts, advantages and disadvantages, transmucosal permeability and formulation considerations of buccal delivery systems

Implantable Drug Delivery Systems: Introduction, advantages and disadvantages, concept of implants and osmotic pump

Unit-III

Transdermal Drug Delivery Systems: Introduction, Permeation through skin, factors affecting permeation, permeation enhancers, basic components of TDDS, formulation approaches

Gastro retentive drug delivery systems: Introduction, advantages, disadvantages, approaches for GRDDS – Floating, high density systems, inflatable and gastro adhesive systems and their applications

Nasopulmonary drug delivery system: Introduction to Nasal and Pulmonary routes of drug delivery, Formulation of Inhalers (dry powder and metered dose), nasal sprays, nebulizers



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Unit-IV

Targeted drug Delivery: Concepts and approaches, advantages and disadvantages, introduction to liposomes, niosomes, nanoparticles, monoclonal antibodies and their applications

Unit-V

Ocular Drug Delivery Systems: Introduction, intraocular barriers and methods to overcome –Preliminary study, ocular formulations and ocuserts

Intrauterine Drug Delivery Systems: Introduction, advantages and disadvantages, development of intrauterine devices (IUDs) and applications

Recommended Books:(Latest Editions)

1. YW.Chien, Novel Drug Delivery Systems, 2nd edition, revised and expanded, Marcel Dekker, Inc., New York, 1992.
2. Robinson, J. R., Lee V. H. L, Controlled Drug Delivery Systems, Marcel Dekker, Inc., New York, 1992.
3. Encyclopedia of Controlled Delivery. Edith Mathiowitz, Published by Wiley Interscience Publication, John Wiley and Sons, Inc, New York. Chichester/Weinheim
4. N.K. Jain, Controlled and Novel Drug Delivery, CBS Publishers & Distributors, New Delhi, First edition 1997 (reprint in 2001).
5. S.P. Vyas and R.K. Khar, Controlled Drug Delivery -concepts and advances, Vallabh Prakashan, New Delhi, First edition 2002.

Journals

1. Indian Journal of Pharmaceutical Sciences(IPA)
2. Indian Drugs (IDMA)
3. Journal of Controlled Release (Elsevier Sciences)
4. Drug Development and Industrial Pharmacy (Marcel & Decker)
5. International Journal of Pharmaceutics (Elsevier Sciences)



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(R23 – IIIrd YEAR COURSE STRUCTURE & SYLLABUS)

III Year – II Semester	HOSPITAL MANAGEMENT AND INFORMATION SYSTEMS	L	T	P	C
		3	0	0	3

COURSE OBJECTIVES:

1. To understand the role of IT in hospital management
2. To familiarize with the latest developments in technology with relevance to hospitals

COURSE CONTENT:

Unit I

The Information Explosion: Information is important – Impact on society – Impact on teaching and learning – Impact on Government – Impact on Healthcare – The future of healthcare technology – The future healthcare record – Preparing for the future – Summary. The world of Informatics.

Unit II

The Electronic health record: Functions of the health record –Changing functions of the patients record – Advantages of the paper record – Disadvantages of the paper record – Optically scanned records – The electronic health record – Automating the paper record – Advantages of the EHR – Disadvantages of the EHR – Bedside or point-of-care systems – Human factors and the EHR – Roadblocks and challenges to EHR implementation –The future

Unit III

Securing the Information: Privacy and confidentiality and Law – Who owns the data? – Security – Computer crime – Role of healthcare professionals – Summary. Information Systems cycle: The information systems cycle – Analysis – Design phase – Development – Implementation – Why some projects fails?

Unit IV

Electronic Communications: A bit of history – Hardware and software for connecting – Methods of accessing information – World Wide Web (WEB) – Communication Technologies **Unit V**

Telehealth– Historical perspective on telehealth – Types of Technology – Clinical initiatives – Administrative initiatives – Advantages and Barriers of telehealth – Future trends – Summary- The future of Informatics: Globalization of Information Technology – Electronic communication – Knowledge management – Genomics – Advances in public health – Speech



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recognition – Wireless computing – Security – Telehealth – Informatics Education – Barriers to Information Technology implementation

REFERENCES:

1. Kathleen M., INFORMATICS FOR HEALTHCARE PROFESSIONAL
2. James O'Brien, Tate McGraw Hill, MANAGEMENT INFORMATION SYSTEM
3. Peter Norton, INTRODUCTION TO COMPUTER, Tata McGraw Hill



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**B.Tech PHARMACEUTICAL ENGINEERING
(R23 – IIIrd YEAR COURSE STRUCTURE & SYLLABUS)**

III Year – II Semester	NEURAL NETWORKS AND FUZZY LOGIC	L	T	P	C
		3	0	0	3

COURSE OBJECTIVES: The course will enable the student's to

1. Understand the concept of Neural Networks.
2. Analyze the concepts of Fuzzy Logic.
3. Apply the concepts of neural networks and fuzzy logic to electrical applications.

COURSE OUTCOMES: At the end of this course, students will be able to

1. Identify the architectures of neural networks and the learning methodologies.(L3)
2. Examine the concepts of single and multi-layer feed forward neural networks.(L4)
3. Analyze the paradigms of associative memory and architecture of Hopfield network.(L4)
4. Illustrate the operations and relations in fuzzy set theory.(L2)
5. Apply fuzzy logic control to real time systems.(L3)

COURSE CONTENT:

UNIT-I: ARTIFICIAL NEURAL NETWORKS

Introduction- Models of Neural Networks- Architectures–Knowledge representation – Artificial Neuron Model, Types of Neuron Activation Functions, Artificial Intelligence and Neural networks –Learning process – McCulloch-Pitts Model, Hebbian learning – Supervised learning – Unsupervised learning– Reinforcement learning, Potential Applications of ANN.

UNIT-II: SINGLE AND MULTI LAYER FEED FORWARD NETWORK

Single layer and Multi-layer perceptron Networks, Limitations of the Perceptron Model, Generalized Delta Rule, ADALINE and MADLINE Networks, Back propagation Algorithm.

UNIT-III: ANNPADIGMS

Paradigms of Associative Memory, Bidirectional Associative Memory (BAM) Architecture, BAM Training Algorithms, Radial Basis Networks, Hopfield Network.

UNIT-IV: INTRODUCTION TO FUZZY LOGIC

Introduction to classical sets-properties, Operations and relations; Fuzzy versus crisp, Fuzzy sets, Membership functions, Uncertainty, Operations, properties, fuzzy



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relations.

UNIT-V: FUZZY SYSTEMS

Fuzzification, De-fuzzification methods, Applications of fuzzy logic control.

TEXTBOOKS:

1. Jack M. Jurada, –Introduction to Artificial Neural Systems, West Publishing Company.
2. S.N. Sivanandam, S.N. Deepa, –Principles of Soft Computing methods, Wiley.
3. S. Rajasekar anand G.A.V. Pai, “Neural Networks, Fuzzy Logic & Genetic Algorithms”-PHI, New Delhi, 2003.
4. Timothy J. Ross, –Fuzzy Logic with Engineering Applications, Second edition, Wiley.

REFERENCES:

1. G.J. Klir and T.A. Folger, “Fuzzy sets, Uncertainty and Information”-PHI, Pvt. Ltd, 1994.
2. P.D. Wasserman, Van Nostrand Reinhold, “Neural Computing Theory & Practice”-New York, 1989.
3. S.N. Sivanandam, S.N. Sumathi and S.N. Deepa, –Introduction to Neural Networks using MATLAB 6.0, McGraw Hill.



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**B.Tech PHARMACEUTICAL ENGINEERING
(R23 – IIIrd YEAR COURSE STRUCTURE & SYLLABUS)**

III Year – II Semester	INTRODUCTION TO DATABASE MANAGEMENT SYSTEM	L	T	P	C
		3	0	0	3

COURSE OBJECTIVES:

1. To introduce about database management systems
2. To give a good formal foundation on the relational model of data and usage of Relational Algebra
3. To introduce the concepts of basic SQL as a universal Database language
4. To demonstrate the principles behind systematic database design approaches by covering conceptual design, logical design through normalization.
5. To provide an overview of physical design of a database system, by discussing Database indexing techniques and storage techniques

COURSE OUTCOMES:

By the end of the course, the student will be able to

- Describe a relational database and object-oriented database
- Create, maintain and manipulate a relational database using SQL
- Describe ER model and normalization for database design
- Examine issues in data storage and query processing and can formulate appropriate solutions
- Outline the role and issues in management of data such as efficiency, privacy, security, ethical responsibility, and strategic advantage

COURSE CONTENT:

UNIT I

Introduction: Database system, Characteristics (Database Vs File System), Database Users(Actors on Scene, Workers behind the scene), Advantages of Database systems, Database applications. Brief introduction of different Data Models; Concepts of Schema, Instance and data independence; Three tier schema architecture for data independence; Database system structure, environment, Centralized and Client Server architecture for the database.

UNIT II

Relational Model: Introduction to relational model, concepts of domain, attribute, tuple, relation, importance of null values, constraints (Domain, Key constraints, integrity constraints) and their importance **BASIC SQL:** Simple Database schema, data types, table definitions (create, alter), different DML operations (insert, delete, update), basic SQL querying (select and project) using where clause, arithmetic & logical operations, SQL functions (Date and Time, Numeric, String conversion).

UNIT III



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Entity Relationship Model: Introduction, Representation of entities, attributes, entity set, relationship, relationship set, constraints, sub classes, super class, inheritance, specialization, generalization using ER Diagrams. SQL: Creating tables with relationship, implementation of key and integrity constraints, nested queries, sub queries, grouping, aggregation, ordering, implementation of different types of joins, view(updatable and non-updatable), relational set operations.

UNIT IV

Schema Refinement (Normalization): Purpose of Normalization or schema refinement, concept of functional dependency, normal forms based on functional dependency(1NF, 2NF and 3 NF), concept of surrogate key, Boyce-codd normal form(BCNF), Lossless join and dependency preserving decomposition, Fourth normal form(4NF), Fifth Normal Form (5NF).

UNIT V

Transaction Concept: Transaction State, Implementation of Atomicity and Durability, Concurrent Executions, Serializability, Recoverability, Implementation of Isolation, Testing for Serializability, Failure Classification, Storage, Recovery and Atomicity, Recovery algorithm.

Indexing Techniques: B+ Trees: Search, Insert, Delete algorithms, File Organization and Indexing, Cluster Indexes, Primary and Secondary Indexes , Index data Structures, Hash Based Indexing: Tree base Indexing ,Comparison of File Organizations, Indexes and Performance Tuning.

Text Books:

1. Database Management Systems, 3/e, Raghurama Krishnan, Johannes Gehrke, TMH
2. Database System Concepts,5/e, Silberschatz, Korth, TMH

Reference Books:

1. Introduction to Database Systems, 8/e C J Date, PEA.
2. Database Management System, 6/e RamezElmasri, Shamkant B. Navathe, PEA
3. Database Principles Fundamentals of Design Implementation and Management, Corlos Coronel, Steven Morris, Peter Robb, Cengage Learning.

e-Resources:

1. <https://nptel.ac.in/courses/106/105/106105175/>
2. <https://www.geeksforgeeks.org/introduction-to-nosql/>



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III Year – II Semester	INSTRUMENTAL METHODS OF ANALYSIS LAB	L	T	P	C
		0	0	3	1.5

- 1 Determination of absorption maxima and effect of solvents on absorption maxima of organic compounds
- 2 Estimation of dextrose by colorimetry
- 3 Estimation of sulfanilamide by colorimetry
- 4 Simultaneous estimation of ibuprofen and paracetamol by UV spectroscopy
- 5 Assay of pharmacopoeial drugs by UV- visible Spectrophotometry
- 6 Estimation of quinine sulfate by fluorimetry
- 7 Determination of sodium by flame photometry
- 8 Determination of potassium by flame photometry
- 9 Determination of chlorides and sulphates by nepheloturbidometry
- 10 Separation of amino acids by paper chromatography
- 11 Separation of sugars by thin layer chromatography
- 12 Separation of plant pigments by column chromatography
- 13 Demonstration experiment on HPLC
- 14 Demonstration experiment on Gas Chromatography
- 15 Separation of compounds by electrophoresis

Recommended Books (Latest Editions)

1. Instrumental Methods of Chemical Analysis by B.K Sharma
2. Organic spectroscopy by Y.R Sharma
3. Text book of Pharmaceutical Analysis by Kenneth A.Connors
4. Vogel's Textbook of Quantitative Chemical Analysis by A.I. Vogel
5. Practical Pharmaceutical Chemistry by A.H.Beckett and J.B. Stenlake
6. Organic Chemistry by I.L.Finar
7. Organic spectroscopy by William Kemp
8. Quantitative Analysis of Drugs by D.C.Garrett
9. Quantitative Analysis of Drugs in Pharmaceutical Formulations by P.D.Sethi
10. Spectrophotometric identification of Organic Compounds by Silverst



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III Year – II Semester	EXPERIMENTAL MODELING AND SIMULATION LAB	L	T	P	C
		0	0	3	1.5

1. Mass-Spring-Damper with controller
2. Double Mass-Spring- Damper
3. Simple Mechanical System
4. Mechanical System with Translational Friction
5. Mechanical System with Translational Hard stop
6. Mechanical Rotational System with stick-slip motion
7. Linkage Mechanism
8. Steering Mechanism

Softwares Used: MATLAB/SCILAB



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III Year – II Semester	TRANSDUCERS AND MEASUREMENTS LAB	L	T	P	C
		0	0	3	1.5

1. Measurement of pressure gauge.
2. Measurement of temperature using RTD.
3. Study and Measurement of LVDT transducer for displacement measurement.
4. Measurement of force using strain gauge.
5. Measurement of temperature using thermocouple.
6. Measurement of displacement using capacitive transducer.
7. Study and calibration of photo and magnetic speed pickups.
8. Study and calibration of a rotameter.
9. Study and use of a seismic pickup for the measurement of vibration amplitude of an engine bed at various loads.
10. Study and calibration of Mcleod gauge for low pressure.



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III Year – II Semester	EFFLUENT TREATMENT & POLLUTION CONTROL - FIELD TRIP	L	T	P	C
		0	0	3	2



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HONORS

S. No.	Subject name	Credits
01.	Medicinal chemistry	4
02.	Pharmacognosy & Phytochemistry	4
03.	Pharmacovigilance	4
04.	Pharma Marketing Management	4
MOOCS COURSES		
01.	Bioreactor design and analysis	2
02.	Elements of nano technology	2
03.	Basic of biology	2
04.	Basics of Nutritions	2
05.	Diet management in health and disease	2
06.	Biomolecules – Structure, function in health and disease	2



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MEDICINAL CHEMISTRY

Scope: This subject is designed to impart fundamental knowledge on the structure, chemistry and therapeutic value of drugs. The subject emphasises on modern techniques of rational drug design like quantitative structure activity relationship (QSAR), Pro drug concept, combinatorial chemistry and Computer aided drug design (CADD). The subject also emphasizes on the chemistry, mechanism of action, metabolism, adverse effects, Structure Activity Relationships (SAR), therapeutic uses and synthesis of important drugs.

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

1. Understand the importance of drug design and different techniques of drug design.
2. Understand the chemistry of drugs with respect to their biological activity.
3. Know the metabolism, adverse effects and therapeutic value of drugs.
4. Know the importance of SAR of drugs.

Course Content:

Study of the development of the following classes of drugs, Classification, mechanism of action, uses of drugs mentioned in the course, Structure activity relationship of selective class of drugs as specified in the course and synthesis of drugs superscripted by(*)

UNIT- I

Antibiotics

Historical background, Nomenclature, Stereo chemistry, Structure activity relationship, Chemical degradation classification and important products of the following classes.

β-Lactamantibiotics: Penicillin, Cephalosporins, β-Lactamaseinhibitors

Aminoglycosides: Streptomycin, Neomycin

Tetracyclines: Tetracycline, Chlortetracycline, Minocycline, Doxycycline

UNIT- II

Antibiotics

Historical background, Nomenclature, Stereochemistry, Structure activity relationship, Chemical degradation classification and important products of the following classes.

Macrolide: Erythromycin Clarithromycin, Azithromycin.

Miscellaneous: Chloramphenicol*, Clindamycin.

Prodrugs: Basic concepts and application of prodrugs design.

Antimalarials- Quinolines: SAR, Quinine sulphate, Chloroquine*, Amodiaquine, Primaquine phosphate, Pamaquine*, Quinacrine hydrochloride, Mefloquine.

Miscellaneous: Pyrimethamine, Artesunate, Artemether, Atovaquone.

UNIT- III

Anti-tubercular Agents



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Synthetic antitubercular agents: Isoniazid*, Ethionamide, Ethambutol, Pyrazinamide, Paraaminosalicylic acid.*

Anti tubercular antibiotics: Rifampicin, Rifabutin, Cycloserine, Capreomycin sulphate.

Urinary tract anti-infective agents

Quinolones: SAR of quinolones, Nalidixic Acid, Norfloxacin, Enoxacin, Ciprofloxacin*, Ofloxacin, Lomefloxacin, Sparfloxacin, Gatifloxacin, Moxifloxacin

Miscellaneous: Furazolidine, Nitrofurantoin*, Methanamine.

Antiviral agents:

Idoxuridine, Trifluoride, Acyclovir*, Gancyclovir, Zidovudine, Didanosine, Zalcitabine, Lamivudine, Loviride, Delavirdine, Ribavirin, Saquinavir, Indinavir, Ritonavir.

UNIT- IV

Antifungal agents:

Antifungal antibiotics: Amphotericin-B, Nystatin, Natamycin, Griseofulvin.

Synthetic Antifungal agents: Clotrimazole, Econazole, Butoconazole, Oxiconazole, Tioconazole, Miconazole*, Ketoconazole, Terconazole, Itraconazole, Fluconazole, Naftifine hydrochloride, Tolnaftate*.

Anti-protozoal Agents: Metronidazole*, Tinidazole, Ornidazole, Diloxanide, Iodoquinol, Pentamidine Isethionate, Atovaquone, Eflornithine.

Anthelmintics: Diethylcarbamazine citrate*, Thiabendazole, Mebendazole*, Albendazole, Niclosamide, Oxamniquine, Praziquantal, Ivermectin.



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Sulphonamides and Sulfones

Historical development, chemistry, classification and SAR of Sulfonamides: Sulphamethizole, Sulfisoxazole, Sulphamethizine, Sulfacetamide*, Sulphapyridine, Sulfamethoxazole*, Sulphadiazine, Mefenideacetate, Sulfasalazine.

Folate reductase inhibitors: Trimethoprim*, Cotrimoxazole.

Sulfones: Dapsone*.

UNIT- V

Introduction to Drug Design

Various approaches used in drug design.

Physicochemical parameters used in quantitative structure activity relationship (QSAR) such as partition coefficient, Hammett's electronic parameter, Taft's steric parameter and Hansch analysis.

Pharmacophore modeling and docking techniques.

Combinatorial Chemistry: Concept and applications chemistry: solid phase and solution phase synthesis.



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B.Tech PHARMACEUTICAL ENGINEERING

(R23 – IIIrd YEAR COURSE STRUCTURE & SYLLABUS)

PHARMACOGNOSY AND PHYTOCHEMISTRY

Scope: The subject involves the fundamentals of Pharmacognosy like scope, classification of crude drugs, their identification and evaluation, phytochemicals present in them and their medicinal properties.

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

1. to know the techniques in the cultivation and production of crude drugs
2. to know the crude drugs, their uses and chemical nature
3. to know the evaluation techniques for the herbal drugs
4. to carry out the microscopic and morphological evaluation of crude drugs

Course Content:

UNIT-I

Introduction to Pharmacognosy:

- (a) Definition, history, scope and development of Pharmacognosy
- (b) Sources of Drugs – Plants, Animals, Marine & Tissue culture
- (c) Organized drugs, unorganized drugs (dried latex, dried juices, dried extracts, gums and mucilages, oleoresins and oleo- gum -resins).

Classification of drugs:

Alphabetical, morphological, taxonomical, chemical, pharmacological, chemo and sero taxonomical classification of drugs

Quality control of Drugs of Natural Origin:

Adulteration of drugs of natural origin. Evaluation by organoleptic, microscopic, physical, chemical and biological methods and properties.

Quantitative microscopy of crude drugs including lycopodium spore method, leaf constants, camera lucida and diagrams of microscopic objects to scale with camera lucida.

UNIT-II

Cultivation, Collection, Processing and storage of drugs of natural origin:

Cultivation and Collection of drugs of natural origin, Factors influencing cultivation of medicinal plants. Plant hormones and their applications. Polyploidy, mutation and hybridization with reference to medicinal plants

Conservation of medicinal plants

UNIT-III

Plant tissue culture:

Historical development of plant tissue culture, types of cultures, Nutritional requirements, growth and their maintenance. Applications of plant tissue culture in pharmacognosy. Edible vaccines



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UNIT IV

Pharmacognosy in various systems of medicine:

Role of Pharmacognosy in allopathy and traditional systems of medicine namely, Ayurveda, Unani, Siddha, Homeopathy and Chinese systems of medicine.

Introduction to secondary metabolites:

Definition, classification, properties and test for identification of Alkaloids, Glycosides, Flavonoids, Tannins, Volatile oil and Resins

UNIT V

Study of biological source, chemical nature and uses of drugs of natural origin containing following drugs

Plant Products:

Fibers - Cotton, Jute, Hemp

Hallucinogens, Teratogens, Natural allergens

Primary metabolites:

General introduction, detailed study with respect to chemistry, sources, preparation, evaluation, preservation, storage, therapeutic uses and commercial utility as Pharmaceutical Aids and/or Medicines for the following Primary metabolites:

Carbohydrates: Acacia, Agar, Tragacanth, Honey

Proteins and Enzymes : Gelatin, casein, proteolytic enzymes (Papain, bromelain, serratiopeptidase, urokinase, streptokinase, pepsin).

Lipids (Waxes, fats, fixed oils) : Castor oil, Chaulmoogra oil, Wool Fat, Bees Wax

Marine Drugs:

Novel medicinal agents from marine sources



PHARMACOVIGILANCE

Scope:

This paper will provide an opportunity for the student to learn about development of pharmacovigilance as a science, basic terminologies used in pharmacovigilance, global scenario of Pharmacovigilance, train students on establishing pharmacovigilance programme in an organization, various methods that can be used to generate safety data and signal detection. This paper also develops the skills of classifying drugs, diseases and adverse drug reactions.

Objectives:

At completion of this paper it is expected that students will be able to (know, do, and appreciate):

1. Why drug safety monitoring is important?
2. History and development of pharmacovigilance
3. National and international scenario of pharmacovigilance
4. Dictionaries, coding and terminologies used in pharmacovigilance
5. Detection of new adverse drug reactions and their assessment
6. International standards for classification of diseases and drugs
7. Adverse drug reaction reporting systems and communication in pharmacovigilance
8. Methods to generate safety data during pre clinical, clinical and post approval phases of drugs' life cycle
9. Drug safety evaluation in paediatrics, geriatrics, pregnancy and lactation
10. Pharmacovigilance Program of India (PvPI) requirement for ADR reporting in India
11. ICH guidelines for ICSR, PSUR, expedited reporting, pharmacovigilance planning
12. CIOMS requirements for ADR reporting
13. Writing case narratives of adverse events and their quality.

Course Content

Unit I

Introduction to Pharmacovigilance

- History and development of Pharmacovigilance
- Importance of safety monitoring of Medicine
- WHO international drug monitoring programme
- Pharmacovigilance Program of India(PvPI)

Introduction to adverse drug reactions

- Definitions and classification of ADRs
- Detection and reporting
- Methods in Causality assessment
- Severity and seriousness assessment
- Predictability and preventability assessment
- Management of adverse drug reactions

Basic terminologies used in pharmacovigilance



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- Terminologies of adverse medication related events
- Regulatory terminologies

Unit II

Drug and disease classification

- Anatomical, therapeutic and chemical classification of drugs
- International classification of diseases
- Daily defined doses
- International Non proprietary Names for drugs

Drug dictionaries and coding in pharmacovigilance

- WHO adverse reaction terminologies
- MedDRA and Standardised MedDRA queries
- WHO drug dictionary
- Eudravigilance medicinal product dictionary

Information resources in pharmacovigilance

- Basic drug information resources
- Specialised resources for ADRs

Establishing pharmacovigilance programme

- Establishing in a hospital
- Establishment & operation of drug safety department in industry
- Contract Research Organisations (CROs)
- Establishing a national programme

Unit III

Vaccine safety surveillance

- Vaccine Pharmacovigilance
- Vaccination failure
- Adverse events following immunization

Pharmacovigilance methods

- Passive surveillance – Spontaneous reports and case series
- Stimulated reporting
- Active surveillance – Sentinel sites, drug event monitoring and registries
- Comparative observational studies – Cross sectional study, case control study and cohort study
- Targeted clinical investigations

Communication in pharmacovigilance

- Effective communication in Pharmacovigilance
- Communication in Drug Safety Crisis management
- Communicating with Regulatory Agencies, Business Partners, Healthcare facilities &

Media

Unit IV

Safety data generation

- Pre clinical phase



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- Clinical phase
 - Post approval phase (PMS)
- ICH Guidelines for Pharmacovigilance
- Organization and objectives of ICH
 - Expedited reporting
 - Individual case safety reports
 - Periodic safety update reports
 - Post approval expedited reporting
 - Pharmacovigilance planning
 - Good clinical practice in pharmacovigilance studies

Unit V

Pharmacogenomics of adverse drug reactions

- Genetics related ADR with example focusing PK parameters.

Drug safety evaluation in special population

- Paediatrics
- Pregnancy and lactation
- Geriatrics

CIOMS

- CIOMS Working Groups
- CIOMS Form

CDSCO (India) and Pharmacovigilance

- D&C Act and Schedule Y
- Differences in Indian and global pharmacovigilance requirements

Recommended Books (Latest edition):

1. Textbook of Pharmacovigilance: S K Gupta, Jaypee Brothers, Medical Publishers.
2. Practical Drug Safety from A to Z By Barton Cobert, Pierre Biron, Jones and Bartlett Publishers.
3. Mann's Pharmacovigilance: Elizabeth B. Andrews, Nicholas, Wiley Publishers.
4. Stephens' Detection of New Adverse Drug Reactions: John Talbot, Patrick Walle, Wiley Publishers.
5. An Introduction to Pharmacovigilance: Patrick Waller, Wiley Publishers.
6. Cobert's Manual of Drug Safety and Pharmacovigilance: Barton Cobert, Jones & Bartlett Publishers.
7. Textbook of Pharmacoepidemiology edited by Brian L. Strom, Stephen E Kimmel, Sean Hennessy, Wiley Publishers.
8. A Textbook of Clinical Pharmacy Practice -Essential Concepts and Skills: G. Parthasarathi, Karin Nyfort Hansen, Milap C. Nahata
9. National Formulary of India
10. Text Book of Medicine by Yashpal Munjal



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PHARMA MARKETING MANAGEMENT

Scope:

The pharmaceutical industry not only needs highly qualified researchers, chemists and, technical people, but also requires skilled managers who can take the industry forward by managing and taking the complex decisions which are imperative for the growth of the industry. The Knowledge and Know-how of marketing management groom the people for taking a challenging role in Sales and Product management.

Course Objective: The course aims to provide an understanding of marketing concepts and techniques and their applications in the pharmaceutical industry.

Unit I

Marketing:

Definition, general concepts and scope of marketing; Distinction between marketing & selling; Marketing environment; Industry and competitive analysis; Analyzing consumer buying behavior; industrial buying behavior.

Pharmaceutical market:

Quantitative and qualitative aspects; size and composition of the market; demographic descriptions and socio-psychological characteristics of the consumer; market segmentation & targeting. Consumer profile; Motivation and prescribing habits of the physician; patients' choice of physician and retail pharmacist. Analyzing the Market; Role of market research.

Unit II

Product decision:

Classification, product line and product mix decisions, product life cycle, product portfolio analysis; product positioning; New product decisions; Product branding, packaging and labeling decisions, Product management in pharmaceutical industry.

Unit III

Promotion:

Methods, determinants of promotional mix, promotional budget; An overview of personal selling, advertising, direct mail, journals, sampling, retailing, medical exhibition, public relations, online promotional techniques for OTC Products.



Unit IV

Pharmaceutical marketing channels:

Designing channel, channel members, selecting the appropriate channel, conflict in channels, physical distribution management: Strategic importance, tasks in physical distribution management.

Professional sales representative (PSR):

Duties of PSR, purpose of detailing, selection and training, supervising, norms for customer calls, motivating, evaluating, compensation and future prospects of the PSR.

Unit V

Pricing:

Meaning, importance, objectives, determinants of price; pricing methods and strategies, issues in price management in pharmaceutical industry. An overview of DPCO (Drug Price Control Order) and NPPA (National Pharmaceutical Pricing Authority).

Emerging concepts in marketing:

Vertical & Horizontal Marketing; Rural Marketing; Consumerism; Industrial Marketing; Global Marketing.

Recommended Books: (Latest Editions)

1. Philip Kotler and Kevin Lane Keller: Marketing Management, Prentice Hall of India, New Delhi
2. Walker, Boyd and Larreche : Marketing Strategy- Planning and Implementation, Tata MC GrawHill, New Delhi.
3. Dhruv Grewal and Michael Levy: Marketing, Tata MC GrawHill
4. Arun Kumar and N Menakshi: Marketing Management, Vikas Publishing, India
5. Rajan Saxena: Marketing Management; Tata MC Graw-Hill (India Edition)
6. Ramaswamy, U.S & Nanakamari, S: Marketing Management: Global Perspective, Indian Context, Macmillan India, New Delhi.
7. Shanker, Ravi: Service Marketing, Excell Books, New Delhi



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8. SubbaRao Changanti, Pharmaceutical Marketing in India (GIFT – Excel series)Excel Publications.

MINOR SUBJECTS (OTHER THAN PHARMACEUTICAL ENGINEERING STUDENTS)

S. No.	Subject name	Credits
01.	Physical Pharmaceutics	4
02.	Instrumental Methods of Analysis	4
03.	Quality Control and Assurance	4
04.	Pharmaceutical Regulatory Affairs	4
MOOCS COURSES		
01.	Industrial Pharmacy	2
02.	Biochemistry and Physiology	2
03.	Biostatistics and DOE	2
04.	Advance Chemical Thermodynamics and Kinetics	2
05.	Food safety and Quality Control	2
06.	General Microbiology	2



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PHYSICAL PHARMACEUTICS

Scope: The course deals with the various physical and physicochemical properties, and principles involved in dosage forms/formulations. Theory and practical components of the subject help the student to get a better insight into various areas of formulation research and development, and stability studies of pharmaceutical dosage forms.

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

1. Understand various physicochemical properties of drug molecules in the designing the dosage forms
2. Know the principles of chemical kinetics & to use them for stability testing and determination of expiry date of formulations
3. Demonstrate use of physicochemical properties in the formulation development and evaluation of dosage forms.

Course Content:

UNIT-I 07 Hours

Colloidal dispersions: Classification of dispersed systems & their general characteristics, size & shapes of colloidal particles, classification of colloids & comparative account of their general properties. Optical, kinetic & electrical properties. Effect of electrolytes, coacervation, peptization & protective action.

UNIT-II 10Hours

Rheology: Newtonian systems, law of flow, kinematic viscosity, effect of temperature, non-Newtonian systems, pseudoplastic, dilatant, plastic, thixotropy, thixotropy in formulation, determination of viscosity, capillary, falling Sphere, rotational viscometers

Deformation of solids: Plastic and elastic deformation, Heckel equation, Stress, Strain, Elastic Modulus

UNIT-III 10 Hours

Coarse dispersion: Suspension, interfacial properties of suspended particles,



settling in suspensions, formulation of flocculated and deflocculated suspensions. Emulsions and theories of emulsification, microemulsion and multiple emulsions; Stability of emulsions, preservation of emulsions, rheological properties of emulsions and emulsion formulation by HLB method.

UNIT-IV 10 Hours

Micromeritics: Particle size and distribution, mean particle size, number and weight distribution, particle number, methods for determining particle size by different methods, counting and separation method, particle shape, specific surface, methods for determining surface area, permeability, adsorption, derived properties of powders, porosity, packing arrangement, densities, bulkiness & flow properties.

UNIT-V 10 Hours

Drug stability: Reaction kinetics: zero, pseudo-zero, first & second order, units of basic rate constants, determination of reaction order. Physical and chemical factors influencing the chemical degradation of pharmaceutical product: temperature, solvent, ionic strength, dielectric constant, specific & general acid base catalysis, Simple numerical problems. Stabilization of medicinal agents against common reactions like hydrolysis & oxidation. Accelerated stability testing in expiration dating of pharmaceutical dosage forms. Photolytic degradation and its prevention

Recommended Books: (Latest Editions)

1. Physical Pharmacy by Alfred Martin, Sixth edition
2. Experimental pharmaceutics by Eugene, Parott.
3. Tutorial pharmacy by Cooper and Gunn.
4. Stock losamJ. Pharmaceutical calculations, Lea &Febiger, Philadelphia.
5. Liberman H.A, Lachman C., Pharmaceutical Dosage forms, Tablets, Volume-1 to 3, Marcel DekkarInc.
6. Liberman
H.A,LachmanC,Pharmaceuticaldosageforms.Dispersesystems,volume1, 2,
3. Marcel DekkarInc.
7. Physical Pharmaceutics by RamasamyC, and ManavalanR.



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INSTRUMENTAL METHODS OF ANALYSIS

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

1. Understand the interaction of matter with electromagnetic radiations and its applications in drug analysis
2. Understand the chromatographic separation and analysis of drugs.
3. Perform quantitative & qualitative analysis of drugs using various analytical instruments.

COURSE CONTENT:

UNIT-I

UV Visible spectroscopy

Electronic transitions, chromophores, auxochromes, spectral shifts, solvent effect on absorption spectra, Beer and Lambert's law, Derivation and deviations.

Instrumentation - Sources of radiation, wavelength selectors, sample cells, detectors- Photo tube, Photomultiplier tube, Photo voltaic cell, Silicon Photodiode.

Applications - Spectrophotometric titrations, Single component and multi component analysis

Fluorimetry

Theory, Concepts of singlet, doublet and triplet electronic states, internal and external conversions, factors affecting fluorescence, quenching, instrumentation and applications

UNIT-II

IR spectroscopy

Introduction, fundamental modes of vibrations in polyatomic molecules, sample handling, factors affecting vibrations

Instrumentation - Sources of radiation, wavelength selectors, detectors - Golay cell, Bolometer, Thermocouple, Thermister, Pyroelectric detector and applications

Flame Photometry- Principle ,interferences, instrumentation and applications

Quality Control and Assurance

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

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

COURSE CONTENT:

UNIT- I

Quality Assurance and Quality Management concepts: Definition and concept of Quality control, Quality assurance and GMP

Total Quality Management(TQM): Definition, elements, philosophies



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ICH Guidelines: purpose, participants, process of harmonization, Brief overview of QSEM, with special emphasis on Q- series guidelines, ICH stability testing guidelines

Quality by design (QbD): Definition, overview, elements of QbD program tools

ISO 9000 & ISO14000: Overview, Benefits, Elements, steps for registration **NABL**

accreditation: Principles and procedures

UNIT-II

Organization and personnel: Personnel responsibilities, training, hygiene and personal records. **Premises:** Design, construction and plant layout, maintenance, sanitation, environmental control, utilities and maintenance of sterile areas, control of contamination.

Equipments and raw materials: Equipment selection, purchase specifications, maintenance, purchase specifications and maintenance of stores for raw materials.

UNIT- III

Quality Control: Quality control test for containers, rubber closures and secondary packing material.



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PHARMACEUTICAL REGULATORY AFFAIRS

Scope: This course is designed to impart the fundamental knowledge on the regulatory requirements for approval of new drugs, and drug products in regulated markets of India & other countries like US, EU, Japan, Australia, UK etc. It prepares the students to learn in detail on the regulatory requirements, documentation requirements, and registration procedures for marketing the drug products.

Objectives: Upon completion of the subject student shall be able to; 1. Know about the process of drug discovery and development 2. Know the regulatory authorities and agencies governing the manufacture and sale of pharmaceuticals 3. Know the regulatory approval process and their registration in Indian and international markets

Course content:

Unit I

New Drug Discovery and development Stages of drug discovery, Drug development process, pre-clinical studies, non-clinical activities, clinical studies, Innovator and generics, Concept of generics, Generic drug product development.

Unit II

Regulatory Approval Process Approval processes and timelines involved in Investigational New Drug (IND), New Drug Application (NDA), Abbreviated New Drug Application (ANDA). Changes to an approved NDA / ANDA. Regulatory authorities and agencies Overview of regulatory authorities of India, United States, European Union, Australia, Japan, Canada (Organization structure and types of applications)

Unit III

Registration of Indian drug product in overseas market Procedure for export of pharmaceutical products, Technical documentation, Drug Master Files (DMF), Common Technical Document (CTD), electronic Common Technical 163 Document (eCTD), ASEAN Common Technical Document (ACTD)research.

Unit IV

Clinical trials Developing clinical trial protocols, Institutional Review Board / Independent Ethics committee - formation and working procedures, Informed consent process and procedures, GCP obligations of Investigators, sponsors & Monitors, Managing and Monitoring clinical trials, Pharmacovigilance - safety monitoring in clinical trials



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Unit V

Regulatory Concepts Basic terminology, guidance, guidelines, regulations, Laws and Acts, Orange book, Federal Register, Code of Federal Regulatory, Purple book

Recommended books (Latest edition):

1. Drug Regulatory Affairs by SachinItkar, Dr. N.S. Vyawahare, NiraliPrakashan.
2. The Pharmaceutical Regulatory Process, Second Edition Edited by Ira R. Berry and Robert P. Martin, Drugs and the Pharmaceutical Sciences, Vol.185. Informa Health care Publishers.
3. New Drug Approval Process: Accelerating Global Registrations By Richard A Guarino, MD, 5th edition, Drugs and the Pharmaceutical Sciences, Vol.190.
4. Guidebook for drug regulatory submissions / Sandy Weinberg. By John Wiley & Sons.Inc.
5. FDA Regulatory Affairs: a guide for prescription drugs, medical devices, and biologics /edited by Douglas J. Pisano, David Mantus.
6. Generic Drug Product Development, Solid Oral Dosage forms, Leon Shargel and IsaderKaufer, Marcel Dekker series, Vol.143
7. Clinical Trials and Human Research: A Practical Guide to Regulatory Compliance By Fay A. Rozovsky and Rodney K. Adams
8. Principles and Practices of Clinical Research, Second Edition Edited by John I. Gallin and Frederick P. Ognibene
9. Drugs: From Discovery to Approval, Second Edition By Rick Ng