

M. PHARM. (PHARMACEUTICS / PHARMACEUTICAL TECHNOLOGY)-R13 Regulations**JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD***(Established by an Act No.30 of 2008 of A.P. State Legislature)***Kukatpally, Hyderabad – 500 085, Andhra Pradesh (India)****M. PHARM. (PHARMACEUTICS / PHARMACEUTICAL TECHNOLOGY)
(R13) COURSE STRUCTURE AND SYLLABUS****I YEAR I SEMESTER**

Code	Group	Subject	L	P	Credits
		Modern Pharmaceutical Analytical Techniques	3	0	3
		Advanced biostatistics and research methods	3	0	3
		Biopharmaceutics and Pharmacokinetics	3	0	3
		Advanced Physical Pharmaceutics	3	0	3
		Advanced pharmaceutical technology-I	3	0	3
	Lab	Modern Pharmaceutical Analytical Techniques Lab	0	3	2
	Lab	Advanced Physical pharmaceutics Lab	0	3	2
		Seminar	-	-	2
		Total Credits	15	6	21

I YEAR II SEMESTER

Code	Group	Subject	L	P	Credits
		Intellectual Property Rights and Drug Regulatory Affairs	3	0	3
		Pharmacological Screening methods and clinical research	3	0	3
		Advances in Drug Delivery Systems	3	0	3
		Industrial Pharmacy	3	0	3
		Advanced Pharmaceutical Technology- II	3	0	3
	Lab	Advances in Drug Delivery Systems Lab	0	3	2
	Lab	Advanced Pharmaceutical Technology Lab	0	3	2
		Seminar	-	-	2
		Total Credits	15	6	21

II YEAR - I Semester

Code	Group	Subject	L	P	Credits
		Comprehensive Viva	-	-	2
		Project Seminar	0	3	2
		Project work	-	-	18
		Total Credits	-	3	22

II YEAR - II Semester

Code	Group	Subject	L	P	Credits
		Project work and Seminar	-	-	22
		Total Credits	--	-	22

M. PHARM. (PHARMACEUTICS / PHARMACEUTICAL TECHNOLOGY)-R13 Regulations**JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD****I Year – I Sem M.Pharm (Pharmaceutics/Pharmaceutical Technology)****MODERN PHARMACEUTICAL ANALYTICAL TECHNIQUES**

Objective: The course is designed to impart the knowledge in the field of Pharmaceutical Analysis. The various modern analytical techniques like UV-Visible, IR, NMR, Mass, GC, HPLC, different chromatographic methods and other important topics are taught to enable the students to understand and apply the principles involved in the determination of different bulk drugs and their formulation. In addition to the theoretical aspects, the basic practical knowledge relevant to the analysis is also imparted.

UNIT I**Introduction to chromatography and classification of chromatographic methods based on the mechanism of separation**

- a. Column Chromatography: Adsorption and partition, theory, preparation, procedure and methods of detection
- b. Thin Layer Chromatography: Theory, preparation, procedures, detection of compounds
- c. Paper Chromatography: Theory, different techniques employed, filter papers used, qualitative and quantitative detection
- d. Counter – current extraction, solid phase extraction techniques, gel filtration

UNIT II

- a. Gas chromatography: Introduction, fundamentals, instrumentation, columns: preparation and operation, detection, dramatization.
- b. HPLC: Principles and instrumentation, solvents and columns used, detection and applications
- c. HPTLC: Theory and principle, instrumentation, elution techniques and pharmaceutical applications

UNIT III

- a. UV-Visible spectroscopy: Introduction, electromagnetic spectrum, absorbance laws and limitations, instrumentation-design and working principle, chromophore concept, auxochromes, Wood-Fisher rules for calculating absorption maximum, applications of UV-Visible spectroscopy
- b. IR spectroscopy: Basic principles-Molecular vibrations, vibrational frequency, factors influencing vibrational frequencies, sampling techniques, instrumentation, interpretation of spectra, FT-IR, theory and applications

UNIT IV

Mass spectroscopy: Theory, ionization techniques: electron impact ionization, chemical ionization, field ionization, fast atom bombardment, plasma desorption, fragmentation process: types of fission, resolution, GC/MS, interpretation of spectra and applications for identification and structure determination

UNIT V

NMR: Theory, instrumentation, chemical shift, shielding and deshielding effects, splitting of signals, spin-spin coupling, proton exchange reactions, coupling constant(J), nuclear overhauser effect(NOE), ¹³C NMR spectra and its applications, 2D-NMR, COSY and applications in pharmacy

Outcome: The appreciable knowledge will be gained by the students in the Modern Analytical Techniques and can apply the theories in the Analysis of various bulk drugs and their formulations. The students will also be in a position to apply their knowledge in developing the new methods for the determination and validate the procedures.

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- 1) Instrumental Methods of Chemical Analysis by B.K Sharma
- 2) Organic spectroscopy by Y.R Sharma
- 3) A Text book of Pharmaceutical Analysis by Kerrenth A. Connors
- 4) Vogel's Text book 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 Silverstein
- 11) HPTLC by P.D. Seth
- 12) Indian Pharmacopoeia 2007
- 13) High Performance thin layer chromatography for the analysis of medicinal plants by Eike Reich, Anne Schibli
- 14) Introduction to instrumental analysis by Robert. D. Braun

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Objective: The student shall know the introduction, scope of biostatistics and Research work, calculation and present of the data. It also informs the students, how the present research work writing and correlating.

UNIT I

Introduction and scope of biostatistics: Use of statistics in Pharmacy. Population and Sample collection. Stages of research, types of data and methods of data collections. Data arrangement and presentation, formation of table and charts.

UNIT II

Measures of central tendency: computation of means, median and mode from grouped and ungrouped data.

Measure of dispersion: computation of variance, standard deviation, standard error and their coefficients.

UNIT III

Measures of Correlation and Regression: Experimental designing, planning of an experiment, replication and randomization. Probit analysis.

Probability rules: Binomial, Poisson and Normal distribution.

Hypothesis testing: Student't' test, Chi square test, Analysis of Variance (ANOVA): 1-way, 2-way, 3-ways

UNIT IV

Developing a research question, Resources for research question,

Literature Review: Traditional Qualitative Review,

Meta-Analysis—A Quantitative Review

Preparation of Research Proposal

Variables—Definition of Variable, Types of variables (Dependent and Independent variables, Confounded variables), Measurement of variables, Types of measurement scales and their comparison. Reliability and Validity of Measurements.

UNIT V

The research report paper writing/ thesis writing

Different parts of the research paper

1. Title-Title of project with authors' name
2. Abstract – Statement of the problem, Background list in brief and purpose and scope
3. Key words
4. Methodology- subject, apparatus, instrumentation and procedure
5. Results – tables, graphs figure and statistical presentation
6. Discussion support or non-support of hypothesis, practical and theoretical implications
7. Conclusion
8. Acknowledgements
9. References
10. Errata
11. Importance of Spell check for entire projects
12. Uses of footnotes

Outcome: The student will be known the Biostatistics arrangement, presentation and formation of tables and charts. They also know the correlation and regression & application of different methods, analysis of data and also learn how to write dissertation, thesis and Research paper.

Text Books

1. Deepak Chawla Neena Sondhi, Research Methodology Concepts and Cases, Vikas books publishers

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2. Donald H. McBurney -Theresa L. White "Research Methods" (Cengage learning India Pvt. Ltd)

Reference Books

1. Remington's Pharmaceutical Sciences
2. Theory & Practice of Industrial Pharmacy by Lachman
3. Statistics for business and economics 3rd edition by Vikas books publications
4. Biostatistics & Computer applications by GN Rao and NK Tiwari
5. Sokal, R.R. and Rohlf, F.J. 1987. An Introduction to Biostatistics. W.H. Freeman and Company.
6. Bailey, N.T.J. 1981. Statistical Methods in Biology. English University Press.
7. Mitchell, K. and Glover, T. 2001. Introduction to Biostatistics. McGraw Hill, Publishing Co.
8. Biostatistics and Computer Applications by G.N. Rao and N.K. Tiwari
9. Fundamentals of Biostatistics by Khan and Khanum
10. Research Methodology by RK Khanna bis and Suvasis Saha
11. Research methods and Quantity methods by G.N.Rao
12. A practical approach to PG dissertation.

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Objective: The student shall know about bioavailability, bioequivalence and factor affecting bioavailability. They also know the pharmacokinetic parameter like drug disposition, absorption, non-linear and time dependant pharmacokinetics. They also know about the drug interactions & problems associated in pharmacokinetic parameters calculations.

UNIT I

1. Biological and metabolic factors affecting bioavailability, complexation, dissolution - techniques of enhancing dissolution.
2. Formulation factors affecting bioavailability of drugs in dosage forms of tablets, capsules, parenterals, liquid orals and topical dosage forms.
3. **Bioavailability** :Importance, dose dependency, AUC, rate and extent, assessment, blood and urine samples, single dose and multiple dose studies.
4. **Bioequivalence**: Importance equivalency concepts, biowaivers, study designs, protocol, transformation of data.

UNIT II

Pharmacokinetics – Drug Disposition: compartment models: One, two and non-compartmental approaches to pharmacokinetics. Recent trends, merits and limitations of these approaches. Application of these models to determine the various pharmacokinetic parameters pertaining to:

- a. Distribution: Apparent volume of distribution and its determination. factors affecting.
 - b. Metabolism: Metabolic rate constant, Factors affecting Metabolism
 - c. Elimination: Over all apparent elimination rate constant, and half life.
- All the above under the following conditions:
1. Intravenous bolus injection
 2. Intravenous infusion
 3. Multiple dose injections
- d. Noninvasive methods of estimating pharmacokinetics parameters with emphasis on salivary and urinary samples.
 - e. Concept of clearance: organ, total clearance, hepatic clearance, lung clearance and renal clearance.

UNIT III

Pharmacokinetics – Absorption: Rate constants – Zero order, first order, Models of experimental study of absorption (in silico, in vitro, in situ and in vivo) – Absorption half lives, method of residuals, Wagner – Nelson method, Loo - Reigleman method, Analysis of kinetics from urine samples. Pharmacokinetic parameters determination pertaining to: Multiple dosage oral administration

UNIT IV

Non-linear pharmacokinetics: Concepts of linear and non-linear pharmacokinetics, Michaelis-Menton kinetics characteristics. Basic kinetic parameters, possible causes of non-induction, non-linear binding, and non-linearity of pharmacological responses.

Clinical Pharmacokinetics: Altered kinetics in pregnancy, child birth, infants and geriatrics. kinetics in GI disease, malabsorption syndrome, liver, cardiac, renal and pulmonary disease states.

UNIT V

Time dependent pharmacokinetics: Introduction, classification, physiologically induced time dependency: Chronopharmacokinetics - principles, drugs– (amino glycosides, NSAIDS, antihypertensive drug) chemically induced dependency.

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Drug Interactions: Kinetics of drug interaction, study of drug-drug interaction mediated through absorption, distribution, metabolism and elimination, mechanisms of interaction and consequence.

- ❖ Numerical problems associated with all units, if any.

Outcome: students will be able to tell factors affecting the bioavailability and stability of dosage form; they also know the bioequivalence studies and protocols for bioequivalent studies. They also know the parameters for the disposition, absorption and Michaelis-Menton constants for non-linear kinetics.

Text Books

1. Biopharmaceutics and Clinical Pharmacokinetics by Milo Gibaldi.
2. Learn Shargel and ABC yu, Applied Biopharmacokinetics and
3. Biopharmaceutics and Pharmacokinetics by C.V.S. Subrahmanyam, Vallabh Prakashan.2010.
4. Basic biopharmaceutics, Sulnil S. Jambhekar and Philip J Brean.
5. Text book of Biopharmaceutics and Clinical Pharmacokinetics by Niazi Sarfaraz

Recommended Books

1. Bio-Pharmaceutics and Pharmacokinetics by V.Venkateshwarlu.
2. Pharmacokinetics.Biopharmaceutics and Clinical pharmacy by Robert E. Notari.
3. Biopharmaceutics and Clinical Pharmacokinetics - An Introduction by Robert E. Notari.
4. Drug drug interactions, scientific and regulatory perspectives by Alber P. G

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Objective: the students shall know about particle science, polymer science and its use in pharmaceutical dosage forms. They also know the compression and consolidation parameters for powders and granules. Students also know about the rheology, disperse systems, dissolution and solubility parameters for dosage forms.

UNIT I

Particle science and powder technology: Crystal structure, amorphous state polymorphism, particle size analysis methods, solid dispersions/ solid solutions.

Polymer science: Classification, properties of polymers, phase separation, polymers in solid state, preparation of polymer solution, application of polymers in pharmaceutical formulations. Mechanism of biodegradation of biodegradable polymers including controlled drug delivery systems.

UNIT II

Physics of tablet compression: Basic principles of interactions, compression and consolidation, compression and consolidation under high loads, effect of friction, distribution of forces in compaction, force volume relationships, Heckel plots, compaction profiles, energy involved in compaction, Measurement of compression with strain gauges, compression pressure-QA parameters.

UNIT III

Kinetics and drug stability: Stability calculations, rate equations, complex order kinetics, Factors influencing stability, strategy of stability testing, method of stabilization, method of accelerated stability testing in dosage forms, temperature and humidity control, physical stability testing of pharmaceutical products. Photodecomposition, Method, solid state decomposition.

UNIT IV

Theories on stability of disperse systems: Adsorption, wetting, crystal growth mechanisms, physical stability of suspensions and emulsions, drug release from suspension and emulsion formulations. Accelerated stability evaluation of physical stability. Microemulsions & multiple emulsions, types of viscometer-principle & working.

Rheology: Theoretical consideration, instrumentation, rheological properties of disperse systems and semisolids. Thixotropy-determination & applications

UNIT V

Dissolution and solubility: Solubility and solubilization of nonelectrolytes, solubilization by the use of surfactants, cosolvents, complexation, drug derivatisation and solid state manipulation, dissolution rates of solids in liquids, theories of dissolution, dissolution equipment, measurement, In vitro/In vivo correlation-analysis, levels of correlations..

Outcome: The students will know particle size analysis method, solid dispersion, physics of tablets, polymer classification and its applications, student will also know the stability calculations, shelf life calculations and accelerated stability studies. They also know the rheology, absorption related to liquids and semi-solid dosage forms. They also know the factors affecting the dissolution and solubility in related to *invitro/invivo* correlations.

Text Books

1. Physical Pharmacy , 4th Edition by Alfred Martin.
2. Theory and Practice of Tablets – Lachman Vol.4
3. Pharmaceutical Dosage forms – Dispasystems Vol. I & II
4. Cartenson “Drug Stability, Marcel Decker Solid state properties, Marcel Dekker.

Reference Books

1. Dispersive systems I, II, and III
2. Robinson. Controlled Drug Delivery Systems

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Objectives: Students will know the Preformulation studies, methodology, different excipients used in solid dosage forms and their evaluation. The students also know the optimization techniques and their applications in pharmaceutical industries.

UNIT 1

Preformulation studies: Goals of Preformulation, preformulation parameters, selection of drugs-solubility, partition coefficient, salt forms, humidity, methodology, solid state properties, drug-excipient compatibility, flow properties, format and content of reports of preformulation, preformulation stability studies (ICH)

UNIT II

Formulation development of solid dosage forms – I: New materials, excipients science - diluents, disintegrants, superdisintegrants, etc, evaluation of functional properties of excipients, co-processed materials, methods of preparation and evaluation.

UNIT III

Formulation development of solid dosage forms – II: Coating, coating machines, coating techniques in tablet technology for product development, computerization, inprocess control of tablets, formulation development and manufacture of powder dosage forms for internal use.

Microencapsulation- types, methodology, problems encountered.

UNIT IV

Formulation development of soft and hard gelatin capsules : Introduction, production and methods of manufacture, filling equipment and filling operations, formulations, finishing, special techniques, advances in capsule manufacture, machines, processing and control including pharmaceutical aspects, physical stability and packaging.

UNIT V

Optimization techniques in pharmaceutical formulation and processing: Introduction, optimization parameters, statistical design, response surface method, contour diagrams, factorial design, partial factorial design, simplex methods, mixture designs, Placket Burhan method, Box Benken method, applications in pharmaceutical formulation.

Outcome: Students shall know the preformulation parameters, ICH guidelines, drug excipients compatibility studies. Students also know about formulation and development, use of excipients in tablets, powders, capsules, micro-encapsules and coating techniques. They also know the statistical design in different formulations.

Text Books

1. Pharmaceutics - The Science of Dosage form design by ME Aulton.
2. Pharmaceutical Dosage forms - Tablets (Vol I, II and III) by Lieberman, Lachman and Schwartz.
3. Pharmaceutical Dosage forms - Capsules (Vol I, II and III) by Avis, Lieberman and Lachman.
4. Pharmaceutical Dosage forms – Disperse systems (Vol I, II and III) by Avis, Lieberman and Lachman.
5. Modern Pharmaceutics by Gilbert S. Banker and Christopher T. Rhodes.
6. Pharmaceutical statistics by Bolton

Recommended Books:

1. The Theory and Practice of industrial Pharmacy by Leon Lachman, Herbert A. Lieberman.
2. Remington's Science and Practice of Pharmacy by A. Gennaro.
3. Ansel's Pharmaceutical Dosage form and Drug delivery system by Loyd V. Allen, Jr. Nicholas G. Popovich, Howard C. Ansel.
4. Generic Drug Product Development by Leon Shargel and Isadore Kanfer.
5. Dispensing for Pharmaceutical Students by SJ Carter.

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1. Colorimetry / UV / Visible, Spectroscopy, scanning of few compounds for UV-absorption, calculation of Assay / content uniformity / % of drug release (2-3 experiments.)
2. Estimation of multi components formulation by UV of two different methods
3. Experiment base on HPLC (Isocratic and gradient) Techniques – (2 experiments)
4. Incompatibility studies, identification and functional groups – Determination by FTIR (2 experiments)
5. Separation and calculation of R_f values by using paper chromatography, TLC, HPTLC Technique (2-3 experiments)
6. Interpretation of spectra and structure determination of Mass Spectroscopy
7. Separation of protein drug substances by electrophoresis.
8. Workshop on IR and NMR interpretation
9. Development and evaluation of drugs by derivative spectroscopy.

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1. Determinates of molecular weight of some selected polymers.
2. Preparation and evaluation of solid dispersions (Immediated release and sustained release)
3. Accelerated stability testing of Aspirin Tablets
4. Stability evaluation of Aspirin at various pH and temperature conditions
5. Determination of 1st order and 2nd order rate constant. Half life by Acid / Alkali hydrolysis
6. Preparation and evaluation of multiple emulsions
7. Preparation and evaluation of β -cyclodextrin complexes of some drugs.
8. Generation of dissolution profiles of few dosage forms and application of the data into various kinetic equations. Calculation of Hixon-crowell dissolution rate constant
9. Preparation and dissolution study of paracetamol tablets and comparison with the marketed product.
10. Study of solubility and dissolution for few drugs and their respective salts.
11. Study of drug release from commercial suspension and emulsion dosage forms
12. Viscosity measurement of Newtonian and Non-newtonian liquids
13. Evaluation of drug-protein binding analysis
14. Assignment of numerical problems, one compartment and two compartment disposition, method of residuals, AUC and evaluation of pharmacokinetic parameters.

1.8 SEMINAR - I

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Objective: Various types of Intellectual Property Rights Patentable Subject History of Indian Patent Protection, Patent filing procedure in India, Opposition- pre-grant opposition and post-grant opposition, Patent filing procedure under PCT, advantages, patent search and literature and Salient features of Indian Patents are discussed in detail.

Intellectual Property Rights:**UNIT I**

Introduction, Types of Intellectual Property Rights (Patents, Trademarks, Copyrights, Geographical Indications Industrial Designs and Trade secrets), Patentable Subject Matter (Novelty, Non-Obviousness, Utility, enablement and Best mode),

UNIT II

- a. History of Indian Patent Protection, Rationale behind Patent System, Objectives and Advantages of Patent System, and future challenges. Indian Patents Act 1970, Definitions and Key Terminology, Types of Patent applications, Inventions not patentable (section 3 and 4).
- b. Patent filing procedure in India (Patent Prosecution), Specifications (Provisional and Complete), Claims- types of claims and legal importance of claims, Grant of patent, Rights of Patentee and co-owners
- c. Opposition- pre-grant opposition and post-grant opposition, Anticipation, Infringement, Compulsory Licensing, revocation of patents, and power of Controller.
- d. Patent filing procedure under PCT, advantages, patent search and literature

UNIT III

- a. Salient features of Indian Patents (Amendments) Act 1999, 2002 and 2005. US and European Patent System,
- b. Background, Salient Features and Impact of International Treaties / Conventions like
 - i. Paris Convention, Berne convention
 - ii. World Trade Organization (WTO)
 - iii. World Intellectual Property Organization (WIPO)
 - iv. Trade Related Aspects of Intellectual Property Rights (TRIPS)
 - v. Patent Co-operation Treaty (PCT), Madrid Protocol

Regulatory Affairs**UNIT IV**

- a. National Drug Regulatory requirements, National Drug Policy, Drugs and Cosmetics Act and its amendments, overview of schedules, detail study of schedule M and Schedule Y.
- b. USFDA, FDA guidelines on IND, NDA and ANDA approvals, and SUPAC changes and understanding on 505 (b) (2) applications

UNIT V

- a. Requirement of GLP Guidance and recommendation on Dissolution and Bio-equivalence requirement. Types of ANDA filing (Para I, II, III, IV filing). Exclusivities (NCE, NS, NP, NDF, PED, ODE, PC)
- b. ICH objectives and Guidelines- stability testing, WHO guidelines, ISOs- Production design, certification.

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ICH 8(QbD), ICH Q9 and ICHQ10.

Outcome: The clear information about the patent laws, intellectual property rights and drug regulation in India and abroad is gained by the students.

Recommended Books:

1. Deepak Chawla Neena Sondhi, Research Methodology Concepts and Cases, Vikas books publishers
2. Draft manual of Patent Practice and Procedure -2008 , The Patent Office, India
3. Manual of Patent Office Practice and Procedure -2010
4. Original Laws Published by Govt. of India
5. Protection of Industrial Property rights by P.Das and Gokul Das
6. Law and Drugs, Law Publications by S.N. Katju
7. Laws of drugs in India, Hussain
8. New drug approval process, 5th edition, by Guarino
9. Commercial Manual on Drugs and Cosmetics 2004, 2nd edition
10. Drugs and Cosmetics act by Vijay Malik
11. Good Manufacturing Practices for Pharmaceuticals, S.H. Wiling, Vol. 78, Marcel Decker.
12. fda.org, wipo.int, patentlawlinks.com, hc-sc.gc.ca, ich.org, cder.org
13. Current good manufacturing practices for pharmaceuticals by Manohar A. Potdar

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Objective: The students is going to study about various techniques for screening of drugs for various pharmacological activities and guide lines for handling animals and human and animal ethics for screening of drugs.

UNIT I

Care Handling and breeding techniques of laboratory animals, Regulations for laboratory animals, CPCSEA guidelines, alternatives to animal studies, Good laboratory Practices.

UNIT II

Bioassays: Basic principles of Biological standardization: Methods used in the bio-assay of Rabbis Vaccine, Oxytocin, Tetanus Antitoxin and Diphtheria Vaccine. Test for pyrogens.

UNIT III

Toxicity tests: OECD guidelines, determination of LD50, acute, sub-acute and chronic toxicity studies.

UNIT IV

Organization of screening for the Pharmacological activity of new substances with emphasis on the evaluation cardiac, psychopharmacological, anti-inflammatory, analgesic and anti-diabetic.

UNIT V

Clinical evaluation of new drugs, Phases of clinical trial, protocol design, Ethics in human research.

Outcome: The expected outcomes are student will know how to handle animals and know about various techniques for screening drugs for different pharmacological activities and guidelines and regulations for screening new drug molecules on animals and human volunteers.

Text Books:

1. Screening methods in Pharmacology, Vol.-1&2 by Robert .A. Turner and Peter Hebborn.
2. Drug discovery and evaluation by H.G.Vogel and W.H.Vogel, Springerverlag, Berlin Heideleberg.
3. Handbook of experimental pharmacology by S.K. Kulkarni, Vallabh Prakashan, Delhi.
4. Textbook of clinical trials edited by David Machin, Simon Day and Sylvan green.
5. Principles of clinical research edited by Giovanna di ignazio, Di Giovanna and Haynes

Reference Books:

1. ICH of technical requirements for registration of pharmaceuticals for human use, ICH harmonized tripartite guidelines - Guidelines for good clinical practice, E6, May 1996.
2. Good clinical practice - Guidelines for Clinical trials on pharmaceutical products in India, Central drug standard control organization, New Delhi, Minister of Health- 2001.

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Objective: The students shall know the pharmacokinetic and pharmacodynamic on the basis of CDDS. They also know the design evaluation and application related to oral, parenteral, transdermal, implants, bioadhesives and targeted drug delivery systems.

UNIT 1

Fundamentals of controlled drug delivery systems, pharmacokinetic and pharmacodynamic basis of controlled drug delivery. Design, fabrication, evaluation and applications of the following controlled releasing systems

- a. Controlled release oral drug delivery systems
- b. Parenteral controlled release drug delivery systems

UNIT II

Design, fabrication, evaluation and applications of the following

- a. Implantable Therapeutic systems
- b. Transdermal delivery systems
- c. Ocular and Intrauterine delivery systems
- d. Vaccine delivery : Delivery systems used to promote uptake, absorption enhancers, oral immunization, controlled release microparticles form vaccine development

UNIT III

Biochemical and molecular biology approaches to controlled drug delivery of

- a. Bioadhesive drug delivery systems
- b. Nasal drug delivery systems
- c. Drug delivery to Colon

UNIT IV

Biochemical and molecular biology approaches to control drug delivery of

- a. Liposomes
- b. Niosomes
- c. Microspheres
- d. Nanoparticles
- e. Resealed erythrocytes

UNIT V

Drug targeting to particular organs

- a. Delivery to lungs
- b. Delivery to the brain and problems involved
- c. Drug targeting in neoplasms

Outcomes: Students will know the fabrication, design, evaluation and application of above drug delivery systems.

Text Books

1. Novel Drug Delivery System by Yie W. Chien.
2. Controlled Drug Delivery by Joseph R. Robinson and Vincent H. L. Lee.
3. Controlled and Novel Drug Delivery Systems by N. K. Jain.
4. Targeted and Controlled Drug Delivery (Novel carrier systems) by S. P. Vyas and Khar.
5. Modern Pharmaceutics by Gilbert S. Banker and Christopher T. Rhodes..
6. Advances in Drug Delivery, Vol 1, 2, 3 by Y.Madhusudan Rao, A.V. Jithan
7. Oral Drug Delivery Technology, 2nd ed, by Aukunuru Jithan

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Objectives: The students shall know about the machinery and theory of unit operations, materials of constructions, qualification of equipments and its applications. The students shall also know about the objectives and principles of GMP, TQM and effluent analysis and specifications. They also know about the regulatory basis for the validation of analytical methods related to solid, sterile and liquid dosage forms.

UNIT I

Pharmaceutical unit operations: A detailed study involving machinery and theory of Pharmaceutical unit operations like milling, mixing, filtration, and drying.

UNIT II

- a. Materials of construction of pharmaceutical equipment and packaging materials: Study of the principles, production techniques in the large scale production of tablets, capsules, suspensions, liquid pharmaceuticals, ophthalmic products and sterile products.
- b. Qualification of equipment (IQ, OQ, PQ)

UNIT III

Production management: Production organization, objectives and policies of good manufacturing practices, layout of buildings, services, equipments and their maintenance, material management, handling and transportation, inventory management and control, production and planning control, Sales forecasting, budget and cost control, industrial and personal relationship. Total Quality Management (TQM)

UNIT IV

Effluent Treatment: Effluent analysis, specifications and preventive measures water pollution, solid pollution, air pollution, sound pollution.

UNIT V

Validation: Regulatory basis, validation of analytical methods, and process, in solid dosage forms, sterile products, and liquid dosage forms.

Outcome: The students will know the machinery involved in milling, mixing, filtration, drying and packing material constructions. They also know salient features of GMP, TQM applicable in industry. They also know about the effluent treatment, prevent the pollution and validation of analytical methods.

Text Books

1. The Theory and Practice of industrial Pharmacy by Leon Lachman, Herbert A. Lieberman.
2. Good Manufacturing Practice for Pharmaceuticals by Sidney H. Willig.
3. Pharmaceutical Process validation by Robert A. Nash, Alfred H. Wachter.
4. Modern Pharmaceutics by Gilbert S. Banker and Christopher T. Rhodes.
5. Pharmaceutical production management, C.V.S. Subrahmanyam, Vallabh Prakash.

Recommended Text Books

1. Unit operations of Chemical Engineering by Warren L. McCabe, Julian C. Smith, Peter Harriott.
2. Remington's Science and Practice of Pharmacy by A. Gennaro.
3. Bentley's Text book of Pharmaceutics by EA Rawlins.
4. CGMP, H.P.P. Sharma

M. PHARM. (PHARMACEUTICS / PHARMACEUTICAL TECHNOLOGY)-R13 Regulations**JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD****I Year –II Sem M.Pharm (Pharmaceutics/Pharmaceutical Technology)****ADVANCED PHARMACEUTICAL TECHNOLOGY-II**

Objective: the students shall know about the pilot plant scale up techniques for manufacturing of tablets capsules, suspensions, emulsions and semisolids. The students also know about the filling of capsules, compression machines, sterilizers for formulation of parenterals and also know about the propellants, DPI, MDI and their quality control. The students also know about the cosmetics and nutraceuticals.

UNIT I**Pilot plant scale-up techniques used in pharmaceutical manufacturing**

- a. **Pilot plant:** Technology transfer from R&D to pilot plant to pilot scale considerations of steps involved with manufacture (design, facility, equipment selection) of tablets, capsules, suspensions, emulsions & semisolids.
- b. **Scale up:** Importance, Scale up process-size reduction, mixing, blending, granulation, compression, coating involved in tablets, capsules & liquid-liquid mixing.

UNIT II

Formulation development of parenteral dosage forms: Advances in materials and production techniques, filling machines, sterilizers, product layout.

UNIT III

Pharmaceutical Aerosols: Advances in propellants, metered dose inhaler designs, dry powder inhalers, selection of containers and formulation aspects in aerosols formulation, manufacture and quality control.

UNIT IV

- a. **Cosmetics:** Formulation approaches, preparation & method of manufacturing labeling & Q.C. of anti ageing products, sun screen lotion and fairness creams.
- b. **Nutraceuticals:**
 1. Introduction, source, manufacture and analysis of glucosamine and cartinine.
 2. Monographs: General and specific properties of glucosamine & cartinine.
 3. A brief overview of role of nutraceuticals in cancer prevention & cardio vascular disorders.

UNIT V**Aseptic processing operation**

- a. Introduction, contamination control, microbial environmental monitoring, microbiological testing of water, microbiological air testing, characterization of aseptic process, media and incubation condition, theoretical evaluation of aseptic operations.
- b. Air handling systems: Study of AHUs, humidity & temperature control, air filtration systems, dust collectors.

Outcomes: students will know about the scale up and pilot plant techniques used for all pharmaceutical dosage forms like tablets, capsules, parenterals, aerosols, cosmetics and nutraceuticals.

Text Books

1. Pharmaceutics - The Science of Dosage form design by ME Aulton.
2. The Theory and Practice of industrial Pharmacy by Leon Lachman, Herbert A. Lieberman.
3. Remington's Science and Practice of Pharmacy by A. Gennaro.
4. Ansel's Pharmaceutical Dosage form and Drug delivery system by Loyd V. Allen, Jr. Nicholas G. Popovich, Howard C. Ansel.
5. Pharmaceutical Dosage forms - Parenterals (Vol I, II and III) by Avis, Lieberman and Lachman.
6. Scale up techniques – Pharmaceutical process by Michael Levin, Marcel Dekker

Recommended Books

1. Bentley's Text Book of Pharmaceutics by EA Rawlins.
2. Generic Drug Product Development by Leon Shargel.
3. Dispensing for Pharmaceutical Students by SJ Carter.
4. Modern Pharmaceutics by Gilbert S. Banker and Christopher T. Rhodes.
5. Nutraceuticals, 2nd edition by Brian lock wood.

M. PHARM. (PHARMACEUTICS / PHARMACEUTICAL TECHNOLOGY)-R13 Regulations**JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD****I Year –II Sem M.Pharm (Pharmaceutics/Pharmaceutical Technology)****ADVANCES IN DRUG DELIVERY SYSTEMS LAB****List of Experiments**

- | | |
|---|-----------------|
| 1. Study on diffusion of drugs through various polymeric membranes | (2 experiments) |
| 2. Formulation and evaluation of sustained release oral matrix tablet | (2 experiments) |
| 3. Formulation and evaluation of sustained release oral reservoir system. | (2 experiments) |
| 4. Formulation and evaluation of microspheres / microencapsules | (2 experiments) |
| 5. Study of in-vitro dissolution of various SR products in market | (2 experiments) |
| 6. Formulation and evaluation of transdermal films | (2 experiments) |
| 7. Formulation and evaluation mucoadhesive system | (2 experiments) |
| 8. Preparation and evaluation enteric coated pellets / tablets. | (2 experiments) |

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M. PHARM. (PHARMACEUTICS / PHARMACEUTICAL TECHNOLOGY)-R13 Regulations

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD
I Year –II Sem M.Pharm (Pharmaceutics/Pharmaceutical Technology)

ADVANCED PHARMACEUTICAL TECHNOLOGY LAB**List of Experiments**

1. Preparation of four different types of semisolid forms and evaluation of their performance using in vitro diffusion method
2. Evaluation of test sterility for commercial preparations including sterile water for injection and antibiotic injection.
3. Collecting samples of environment of aseptic room and counting the colonies
4. Validation of one unit operation (eg. Mixing) and development of protocol.
5. Comparative evaluation of different marketed products (tablets) of the same API
6. Dissolution studies of drug in three different bio relevant dissolution media
7. Stability study testing of tablet dosage forms (Any two products)

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