# JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD

**M.Pharmacy (PHARMACEUTICS / PHARMACEUTICAL TECHNOLOGY)**

**COURSE STRUCTURE AND SYLLABUS**

**I Year – I Semester**

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Category**  | **Course Title** | **Int. marks** | **Ext. marks** | **L** | **P** | **C** |
| Core Course I | Advanced Physical Pharmaceutics | 25 | 75 | 4 | -- | 4 |
| Core Course II | Modern Pharmaceutics-I | 25 | 75 | 4 | -- | 4 |
| Core Course III | Applied Biopharmaceutics and Pharmacokinetics | 25 | 75 | 4 | -- | 4 |
| Core Elective I | 1.Modern Pharmaceutical Analytical Techniques2.Intellectual Property Rights  | 25 | 75 | 4 | -- | 4 |
| Open Elective I | 1. Pharmacoepidemiology and Pharmacoeconomics
2. Drug Regulatory Affairs
3. Herbal Cosmetic Technology
4. Pharmaceutical Validation
5. Pharmaceutical Management
 | 25 | 75 | 4 | -- | 4 |
| Laboratory I | Advanced physical Pharmaceutics Lab | 25 | 75 | --- | 6 | 3 |
| Laboratory II | Applied Biopharmaceutics and PharmacokineticsLab | 25 | 75 | -- | 6 | 3 |
| Seminar I | Seminar | 50 | -- | -- | 4 | 2 |
| **Total Credits** |  |  | **20** | **16** | **28** |

**I Year – II Semester**

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Category** | **Course Title** | **Int. marks** | **Ext. marks** | **L** | **P** | **C** |
| Core Course IV | Advanced Drug Delivery Systems | 25 | 75 | 4 | -- | 4 |
| Core Course V | Industrial Pharmacy | 25 | 75 | 4 | -- | 4 |
| Core Course VI | Modern Pharmaceutics-II | 25 | 75 | 4 | -- | 4 |
| Core Elective II | 1. Biostatistics And Research Methodology
2. Stability of Drugs and Dosage Forms
 | 25 | 75 | 4 | -- | 4 |
| Open Elective II | 1. Screening Methods in Pharmacology
2. Nano Based Drug Delivery Systems
3. Nutraceuticals
4. Entrepreneurship management
5. Clinical Research AndPharmacovigilance
 | 25 | 75 | 4 | -- | 4 |
| Laboratory III | Advanced Drug Delivery Systems Lab | 25 | 75 | --- | 6 | 3 |
| Laboratory IV | Modern PharmaceuticsLab | 25 | 75 | -- | 6 | 3 |
| Seminar II | Seminar | 50 | -- | -- | 4 | 2 |
| **Total Credits** |  |  |  | **20** | **16** | **28** |

**II Year - I Semester**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Course Title** | **Int. marks** | **Ext. marks** | **L** | **P** | **C** |
| Comprehensive Viva-Voce | -- | 100 | -- | -- | 4 |
| Project work Review I | 50 | -- | -- | 24 | 12 |
| **Total Credits** |  |  | -- | 24 | **16** |

**II Year - II Semester**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Course Title** | **Int. marks** | **Ext. marks** | **L** | **P** | **C** |
| Project work Review II | 50 | -- | -- | 8 | 4 |
| Project Evaluation (Viva-Voce) | -- | 150 | -- | 16 | 12 |
| **Total Credits** |  |  | **--** | **24** | **16** |

**JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD**

I Year – I SemM.Pharm (Pharmaceutics/Pharmaceutical Technology) (Core course I)

# ADVANCED PHYSICAL PHARMACEUTICS

# Objective: The students shall apply the principles of physical and chemical properties of particle science, polymer science and their use in pharmaceutical dosage forms. They also learn the compression and consolidation parameters for powders and granules. Students also learn about the rheology, disperse systems, dissolution and solubility related parameters for dosage forms.

# UNIT I

**Polymer science:** Classification, properties and characterization 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, Mucoadhesive ,Hydrodynamically balanced and Transdermal 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 and solid state decomposition.

**UNIT IV**

**Viscoelasticity:** Theoretical consideration, instrumentation, rheological properties of disperse systems and semisolids. Oscillatory testing, Creep measurement.

**Characterization of API and excipients:**

Differential Scanning Calorimetry: Principle, thermal transitions, advantages, disadvantages, instrumentation, applications, and interpretations

X Ray Diffraction methods: Origin of x-rays, applications, advantages, disadvantages, instrumentation, applications, and interpretations..

**UNIT V**

**Dissolution and solubility**: Solubility and solubilization of nonelectrolytes, solubilization by the use of surfactants, cosolvents, complexation, drug derivatisation and solid state manipulation, Mechanisms of Drug release - dissolution, diffusion (Matrix and Reservoir) and swelling controlled (Peppas Model) and dissolution equipment.

**Outcome:** The students will learn particle size analysis method, solid dispersion, physics of tablets, polymer classification and its applications, student will also practice the stability calculations, shelf life calculations and accelerated stability studies. They also understand the rheology, absorption related to liquids and semi-solid dosage forms with advances. 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 – Disperse systems Vol. I & II

4. Cartenson “Drug Stability, Marcel Decker Solid state properties, Marcel Dekker.

5. Industrial Pharmacy - Selected Topics , CVS Subramanyam and J Thimmasetty, VallabhaPrakashan Delhi - 2013

**REFERENCE BOOKS**

1. Dispersive systems I, II, and III

2. Robinson. Controlled Drug Delivery Systems

**JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD**

**I Year – I SemM.Pharm (Pharmaceutics/Pharmaceutical Technology)** (Core course II)

**MODERN PHARMACEUTICS -I**

**Objectives**: Students will know the preformulation studies, methodology, different excipients used in solid dosage forms and their evaluation with references to production technologies. The students also know the optimization techniques and their applications in pharmaceutical industries.

**UNIT I**

**Preformulation studies:** Goals of Preformulation, preformulation parameters, Polymorphs and Amorphous forms, selection of drugs- solubility, partition coefficient, salt forms, humidity, solid state properties, Particle Size Analysis (Laser Diffraction and Dynamic Light Scattering) 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 explain the preformulation parameters, apply ICH guidelines and evaluate drug, drug excipients compatibility. Students also explain about formulation and development, use of excipients in tablets, powders, capsules, micro-encapsules and coating techniques. They also learn and apply 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 IsadoreKanfer.
5. Dispensing for Pharmaceutical Students by SJ Carter.
6. Industrial Pharmacy - Selected Topics , CVS Subramanyam and J Thimmasetty, VallabhaPrakashan Delhi - 2013

**JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD**

**I Year – I SemM.Pharm (Pharmaceutics/Pharmaceutical Technology)** (Core course III)

APPLIED BIOPHARMACEUTICS AND PHARMACOKINETICS

Objective: The student shall learn about bioavailability, bioequivalence and factor affecting bioavailability. They also learn the pharmacokinetic parameter like drug disposition, absorption, non-linear and time dependant pharmacokinetics. They also understand about the drug interactions & problems, practice 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, InvitroInvivo Correlation analysis and Levels of Correlations.
4. **Bioequivalence:** Importance equivalency concepts, biowaivers, study designs, protocol, transformation of data, Statistical Criteria as per the Regulations.

**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:

* 1. Distribution: Apparent volume of distribution and its determination. factors affecting.
	2. Metabolism: Metabolic rate constant, Factors affecting Metabolism
	3. Elimination: Over all apparent elimination rate constant, and half life.

 All the above under the following conditions:

1. Intravenous infusion
2. Multiple dose injections
	1. Noninvasive methods of estimating pharmacokinetics parameters with emphasis on salivary and urinary samples.
	2. 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.

**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 express factors affecting the bioavailability and stability of dosage form; they also learn the bioequivalence studies and protocols for bioequivalent studies. They also evaluate the parameters for the disposition, absorption and Michaelis-Menton constants for non-linear kinetics.

**TEXT BOOKS**

1. Biopharmaceutics and Clinical Pharmacokinetics by MiloGibaldi.

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 NiaziSarfaraz

**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

**JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD**

**I Year – I SemM.Pharm (Pharmaceutics/Pharmaceutical Technology)**

(Core Elective I)

**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, MS, 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**

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

**UNIT II**

1. Gas chromatography: Introduction, fundamentals, instrumentation, columns: preparation andoperation, detection, dramatization.
2. HPLC: Principles and instrumentation, solvents and columns used, detection and applications
3. HPTLC: Theory and principle, instrumentation, elution techniques and pharmaceutical applications

**UNIT III**

1. 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
2. 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), 13C­NMR 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

**REFERENCES :**

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, AnneSchibli
14. Introduction to instrumental analysis by Robert. D. Braun

**JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD**

**I Year – I SemM.Pharm(Pharmaceutics/Pharmaceutical Technology)**

**(Core Elective I)**

**INTELLECTUAL PROPERTY RIGHTS**

**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.

**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**

1. 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).
2. 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
3. Opposition- pre-grant opposition and post-grant opposition, Anticipation, Infringement, Compulsory Licensing, revocation of patents, and power of Controller.
4. 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

1. Paris Convention, Berne convention
2. World Trade Organization (WTO)
3. World Intellectual Property Organization (WIPO)
4. Trade Related Aspects of Intellectual Property Rights (TRIPS)
5. Patent Co-operation Treaty (PCT), Mandrid Protocol

**UNIT IV**

1. PCT Application procedure and review procedure
2. National phase application procedure for US& EU
3. Patent procecution procedure in US and EU
4. WIPO and its role in IPR
5. Hatch- Waxman provision for IPR

**UNIT V**

1. Patent in validation process in India, US and Europe
2. IPR related to copyright, trade mark, trade secret and geographical indication.
3. Patent application writing
4. Claim construction and claims.

**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. Research Methodology concepts and cases by Depak Chawla, NeenaSondhi
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 ManoharA.Potdar

**JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD**

**I Year – I SemM.Pharm. (Pharmaceutics/Pharmaceutical Technology)**

**(Open Elective–I)**

**PHARMACOEPIDEMIOLOGY & PHARMACOECONOMICS**

**Objective:**

This course enables students to understand various pharmacoepidemiologicalmethods and their clinical applications. Also, it aims to impart knowledge onbasic concepts, assumptions, terminology, and methods associated withPharmacoeconomics and health related outcomes, and when should be

appropriatePharmacoeconomic model should be applied for a health careregimen.

**UNIT-I**

**Introduction to Pharmacoepidemiology:**

Definition, Scope,Need, Aims & Applications; Outcome measurement: Outcomemeasures, Drug use measures: Monetary units, Number ofprescriptions, units of drug dispensed, defined daily doses,prescribed daily doses, Diagnosis and Therapy surveys,Prevalence, Incidence rate, Monetary units, number ofprescriptions, unit of drugs dispensed, defined daily doses andprescribed daily doses, medications adherence measurements.Concept of risk: Measurement of risk, Attributable risk andrelative risk, Time- risk relationship and odds ratio

**UNIT-II**

**Pharmacoepidemiological Methods:**

Qualitative models: DrugUtilization Review; Quantitative models: case reports, case series,Cross sectional studies, Cohort and case control studies,Calculation of Odds’ ratio, Meta analysis models, Drug effectsstudy in populations: Spontaneous reporting, Prescription eventmonitoring, Post marketing surveillance, Record linkage systems,Applications of Pharmacoepidemiology

**UNIT-III**

**Introduction to Pharmacoeconomics:**

Definition, history ofPharmacoeconomics, Need of Pharmacoeconomic studies inIndian healthcare system.Cost categorization and resources for cost estimation: Directcosts. Indirect costs. Intangible costs.Outcomes and Measurements of Pharmacoeconomics: Typesof outcomes: Clinical outcome, Economic outcomes, Humanisticoutcomes; Quality Adjusted Life Years, Disability Adjusted LifeYears Incremental Cost Effective Ratio, Average Cost EffectiveRatio. Person Time, Willingness To Pay, Time Trade Off andDiscounting.

**UNIT-IV**

**Pharmacoeconomic evaluations:**

Definition, Steps involved,Applications, Advantages and disadvantages of the followingPharmacoeconomic models: Cost Minimization Analysis (CMA),Cost Benefit Analysis (CBA), Cost Effective Analysis (CEA), CostUtility Analysis (CUA), Cost of Illness (COI), Cost ConsequencesAnalysis (COA).

**UNIT-V**

**Definition, Steps involved, Applications, Advantages and disadvantages of the following:**

Health related quality of life (HRQOL): Definition, Need formeasurement of HRQOL, Common HRQOL measures.Definition, Steps involved, Applications of the following:Decision Analysis and Decision tree, Sensitivity analysis, MarkovModeling, Software used in pharmacoeconomic analysis,Applications of pharmacoeconomics.

**Outcome:**

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

* + Understand the various epidemiological methods and their applications
	+ Understand the fundamental principles of Pharmacoeconomics.
	+ Identify and determine relevant cost and consequences associated with pharmacy products and services.
	+ Perform the key Pharmacoeconomics analysis methods
	+ Understand the Pharmacoeconomic decision analysis methods and its applications.
	+ Describe current Pharmacoeconomic methods and issues.
	+ Understand the applications of Pharmacoeconomics to various pharmacy settings.

**REFERENCES**

1. Rascati K L. Essentials of Pharmacoeconomics, Woulters KluwerLippincott Williams & Wilkins, Philadelphia.

2. Thomas E Getzen. Health economics. Fundamentals and Flow of Funds.John Wiley & Sons, USA.

3. Andrew Briggs, Karl Claxton, Mark Sculpher. Decision Modelling for HealthEconomic Evaluation, Oxford University Press, London.

4. K G Revikumar, Pharmacoepidemiology and Pharmacoeconomics Concepts and Practices.

5. Michael Drummond, Mark Sculpher, George Torrence, Bernie O'Brien andGreg Stoddart. Methods for the Economic Evaluation of Health CareProgrammes Oxford University Press, London.

6.. George E Mackinnon III. Understanding health outcomes andpharmacoeconomics.

7. Graker, Dennis. Pharmacoeconomics and outcomes.

8. Walley, Pharmacoeconomics.

9. Pharmacoeconomic – ed. by Nowakowska – University of MedicalSciences, Poznan.

10. Relevant review articles from recent medical and pharmaceutical literature

11. Guru Prasad Mohanta and P K Manna, Textbook of Pharmacovigilance Concepts and Practice

**JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD**

**I Year – I SemM.Pharm(Pharmaceutics/Pharmaceutical Technology)**

**(Open Elective–I)**

**DRUG REGULATORY AFFAIRS**

**Objective**: The topics which are present in the Drug regulatory affairs are very much useful which increases the knowledge regarding the regulatory aspects in the pharmaceutical industries

**UNIT I**

A study of regulatory aspects that affect drug product design, manufacture and distribution in India with special emphasis on the detailed study of the following Acts (with latest amendments)

**UNIT II**

The Drugs and Cosmetics Act, 1940 and Rules there under.Recent amendments to Drugs and Cosmetic Act and other relevant rules.

Drugs (Price Control) Order in force.Loan license (contract manufacture). Certification and licensing procedures.

**UNIT III**

A detailed study of regulatory aspects that affect drug product design, manufacture and distribution in a developed country such as USA and in a developing country such as Brazil, Hatch Waxmann Act;

Bolar Provisions and other FDA Regulations. Regulatory aspects of pharmaceutical and bulk drug manufacture, regulatory drug analysis.

**UNIT IV**

Documentation related to manufacturing, cleaning methods, retention samples and records, quality control, batch release documents, distribution records, complaints and recalls.

Quality, safety and legislation for cosmetic products and herbal products.

**UNIT V**

**Governing Regulatory Bodies across the globe.**

Country Authority Submission

1. U.SFood& Drug Administration USDMF
2. CanadaTherapeutic Product Directorate DMF
3. Europe

 1) European Medicines Agency (EMEA/ National Authorities) EDMF

 2) European Directorate for Quality of Medicines CEP/COS& Health Care Products

1. Product Filing
2. Responding Regulatory Deficiencies
3. Final Approval Procedure

Preparation, review and submission of Drug Master Files to Regulatory Authorities as per their specific requirements.

**Outcome:**

* Students will come to know the different competent regulatory authorities globally.
* Students be aware of technical aspects pertaining to the marketing authoritization application(MAA)
* The regulatory guidelines and directions framed by the regulatory authorities will be helpful to place the drug products in market for marketing approvals.

**TEXT AND REFERENCE BOOKS**

1. Original laws published by Govt. of India.

2. Text Book of Forensic Pharmacy by Mithal B. M.; VallabhPrakashan, New Delhi.

3. Laws of Drugs in India by Hussain.

4. Text Book of Forensic Pharmacy by Jain N. K.; VallabhPrakashan, New Delhi.

5. Pharmaceutical Regulatory Affairs - Selected Topics , CVS Subramanyam and J Thimmasetty, VallabhaPrakashan Delhi - 2013

**JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD**

**I Year – I SemM.Pharm (Pharmaceutics and Pharmaceutical Technology)**

**(Open Elective–I)**

**HERBAL COSMETICS TECHNOLOGY**

**Objective:** The topics helps the students to get exposed to processes involved in the manufacturing of herbal cosmetics including the skin and hair care herbal products preparation and their evaluation

**UNIT I**

1. Introduction, historical background and present status of Herbal cosmetics
2. Processes used in the manufacture of cosmetics-Emulsification, Mixing, compaction, Moulding, Packing. Raw materials used in preparation of herbal cosmetics
3. Machinery and Equipment for Cosmetics: Cream, Liquid, Powder and emulsion making machinery
4. Quality, safety and efficacy of Herbal cosmetics

**UNIT II**

**Skin care Products:** Method of preparation, pharmaceutical and Pharmacological evaluation procedures for various formulations like Creams, Lotions, Lipsticks, face packs. Elaborative study of five formulations under each category with regard to their composition and claims for various herbs used in them.

**UNIT III**

**Hair care Products:** Method of preparation, pharmaceutical and Pharmacological evaluation procedures for various formulations like hair dyes, creams, Lotions, Jels, oils and Shampoos. Elaborative study of five formulations under each category with regard to their composition and claims for various herbs used in them.

**UNIT IV**

A brief account of following herbals or herb extracts or herbal products of cosmetic importance such as *Acacia concinna* pods, Aloe Vera, Almond oil, Neem, *Citrus aurantium*peels*,* Henna, Turmeric, Liquorice, Olive oil, tea tree oil and wheat germ oil with special emphasis on their source, active principles and cosmetic properties.

**UNIT V**

1. General Principles of Quality control and standardization of cosmetics-Raw material control, Packaging material control, finished product control, Shelf testing.
2. Natural colorants : Biological Source, coloring principles, chemical nature and usage of the following Annato, Cochineal, Caramel, Henna, Indigo, Madder, Saffron , Turmeric
3. Flavors and Perfumes : Sandal wood oil, Orange oil, Lemon oil, Vanilla, Palmarosa, geranium oil

**Outcome:** Students will learn about the raw materials used in herbal cosmetics and get exposed to various preparations of herbal cosmetics.

**REFERENCES:**

1. Cosmetics- Formulation, Manufacturing and Quality control –P.P.Sharma
2. Herbal Cosmetics Hand Book- H. Panda
3. Herbal Cosmetics by P.K Chattopadhyay
4. The Complete Technology Book on Herbal Perfumes and Cosmetics by H. Panda

**JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD**

**I Year – I SemM.Pharm(PHARMACEUTICS/ PHARMACEUTICAL TECHNOLOGY)**

**(Open Elective–I)**

**PHARMACEUTICAL VALIDATION**

**Objective**

The main purpose of the subject is to understand about validation and how itcan be applied to industry and thus to improve the quality of the products. Thesubject covers the complete information about validation, types, methodologyand application.

**UNIT I.**

**Introduction**: Definition of Qualification and Validation,Advantage of Validation, Streamlining of Qualification & Validationprocess and Validation Master Plan.

**UNIT II**

**Qualification:**User Requirement Specification, DesignQualification, Factory Acceptance Test (FAT)/ Site AcceptanceTest (SAT), Installation Qualification, Operational Qualification,Performance Qualification, Re- Qualification (Maintaining status-Calibration Preventive Maintenance, Change management),Qualification of Manufacturing Equipments, Qualification ofAnalytical Instruments and Laboratory equipments.

**UNIT III**

**Qualification of analytical instruments**: Electronic balance, Phmeter, UV-Visible spectrophotometer, FTIR, GC, HPLC, HPTLC

**Qualification of Glassware**: Volumetric flask, pipette, Measuringcylinder, beakers and burette.

**UNIT IV**

**Validation of Utility systems**: Pharmaceutical Water System &pure steam, HVAC system, Compressed air and nitrogen.

**Cleaning Validation**: Cleaning Validation - Cleaning Methoddevelopment, Validation and validation of analytical method usedin cleaning. Cleaning of Equipment, Cleaning of Facilities.Cleaning in place (CIP).

**UNIT V**

**Analytical method validation**: General principles, Validation ofanalytical method as per ICH guidelines and USP.

**Outcome:**

Upon completion of the subject student shall be able to

* Explain the aspect of validation
* Carryout validation of manufacturing processes
* Apply the knowledge of validation to instruments and equipments
* Validate the manufacturing facilities

**REFERENCES:**

* 1. B. T. Loftus & R. A. Nash, "Pharmaceutical Process Validation", Drugs and
* Pharm Sci. Series, Vol. 129, 3rd Ed., Marcel Dekker Inc., N.Y.
* 2. The Theory & Practice of Industrial Pharmacy, 3rd edition, Leon Lachman,
* Herbert A. Lieberman, Joseph. L. Karig, Varghese Publishing House,
* Bombay.
* 3. Validation Master plan by Terveeks or Deeks, Davis Harwood International
* publishing.
* 4. Validation of Aseptic Pharmaceutical Processes, 2nd Edition, by Carleton
* &Agalloco, (Marcel Dekker).
* 5. Michael Levin, Pharmaceutical Process Scale-Up‖, Drugs and Pharm. Sci.
* Series, Vol. 157,2nd Ed., Marcel Dekker Inc., N.Y.
* 6. Validation Standard Operating Procedures: A Step by Step Guide for
* Achieving Compliance in the Pharmaceutical, Medical Device, and Biotech
* Industries, Syed ImtiazHaider
* 7. Pharmaceutical Equipment Validation: The Ultimate Qualification
* Handbook, Phillip A. Cloud, Interpharm Press
* 8. Validation of Pharmaceutical Processes: Sterile Products, Frederick J.
* Carlton (Ed.) and James Agalloco (Ed.), Marcel Dekker, 2nd Ed.
* 9. Analytical Method validation and Instrument Performance Verification by
* Churg Chan, Heiman Lam, Y.C. Lee, Yue. Zhang, Wiley Inter Science.

**JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD**

**I Year – I SemM.Pharm (Pharmaceutics/Pharmaceutical Technology)**

**(Open Elective–I)**

**PHARMACEUTICAL MANAGEMENT**

**Objective:** The topics which are present in the pharmaceutical management are very much useful to the students in personality development become a perfect pharma professional

**UNIT I**

Pharmaceutical Management: Meaning, Evolution-scientific, administrative and human relation approach. Process of management: Planning, organizing, staffing, directing, coordinating and controlling–a preliminary idea of concepts, processes and techniques.

**UNIT II**

Fundamental concepts of production, financial, personal, legal and marketing functions with special reference to Pharmaceutical Management. Introduction to budgeting, costing, accounting, auditing and budgetary control. Entrepreneurship development.

**UNIT III**

Understanding organizations: Meaning, process, types of organization structures and departmentation, line/staff authority, promoting organizational culture. Organizations, pharmaceutical services and functioning of hospital pharmacy, bulk drug unit, formulation unit, Ayurvedic and Unani manufacturing units and testing labs etc.

**UNIT IV**

Professional Mangers; Tasks, responsibilities and skills needed. Leadership; Styles and managing change. Decision Making; Types, procedures, evaluation and selection of alternatives, decision making under various situations. Management information and decision support systems and time management.

Personnel Management: Job Analysis, recruitment, selection, orientation and training, performance appraisal and compensation. Retrenchment, lay off and discharge.

**UNIT V**

Management of Industrial Relations: Industrial disputes, settlement of disputes through various routes such as bargaining, etc.

Motivational aspects, theories of motivation, group dynamics, rewards and incentives, interpersonal skills, significance of communication, its processes, measures for effective communication, conflict management. Stress management.

**Outcome**:

* These topics are useful for the students to know how to manage a pharma industry and its various departments viz QA, QC, RA, Production etc.
* Along with this it aids the students to develop leadership qualities, communication &interpersonal skills, decisions making, motivation, organization &various managerial functions &professional skills required for a dynamic professional.
* Management helps to understand the concept of managerial control, its levels &role, importance in pharma industry..

**TEXT AND REFERENCE BOOKS**

1. Marketing Management by Philip Kotlar; Prentice-Hall of India Ltd., New Delhi.0

2. Management and Organization by Louis A. Allen; McGraw Hill, Tokyo..

3. Corporate Strategy by Ansoff, H.T.; McGraw Hill, New York.

4. Modern Management by Hempran David R.; McGraw Hill, New York.

5. Management by Stoner and Freeman; Prentice Hall, New Delhi.

6. Motivation and Personality by Maslow, Abraham, Harper & Row, New York.

7. Management of Organizational Behavior, Utilizing the Human Resources by Harcey, Paul and Blanchard Kenneth; Prentice Hall of India, New Delhi

8. Organization Structure, Process and out comes V thEdition Richard. H. Hall

9. Principles and Methods of Pharmacy Management III rd Edition Harry A. Smith.

10. Management “Global Perspective Heinz Weihrich, Harold Koontz by Tata Mcgraw Hill”.

11. Personnel Management and Industrial Relations by P. C. Tripathi.

**JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD**

**I Year – I SemM.Pharm (Pharmaceutics/Pharmaceutical Technology)**

**ADVANCED PHYSICAL PHARMACEUTICS LAB**

**List of experiments**

1. Determinates of molecular weight of some selected polymers.
2. Preparation and evaluation of solid dispersions (Immediate 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 Ist 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

**JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD**

**I Year – I SemM.Pharm (Pharmaceutics/Pharmaceutical Technology)**

**APPLIED BIOPHARMACEUTICS AND PHARMACOKINETICS LAB**

**List of experiments**

1. Intrinsic dissolution (1 exp)
2. Analysis of dissolution by various data-kinetic modelling.
3. Dissolution of immediate release, sustained release and delayed release.
4. Evaluation of drug-protein binding analysis
5. Assignment of numerical problems, one compartment and two compartment disposition, method of residuals, AUC and evaluation of pharmacokinetic parameters.
6. Calculation of Ka(absorption rate constant ) absorption curve- Wagner nelson method , Loo-Riegel method.
7. Calculation of pharmacokinetics parameters of one compartment oral data and two compartment IV data.
8. Constuction of IVIVE from the data
9. Calculation of Urinary Pharmacokinetics
10. Permeation studies of Franz diffusion cell
11. Drug Release from semisolids by Agargel method or Franz diffusion cell.

**JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD**

**I Year –II SemM.Pharm (Pharmaceutics/Pharm Tech) (Core course IV)**

**ADVANCED DRUG DELIVERY SYSTEMS**

**Objective:** The students shall apply the pharmacokinetic and pharmacodynamic principles in the design of CDDS. They also apply the design, evaluation and applications 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 neoplasams

**Outcomes**: Students will select the drugs for CDDS design of the formulation fabrication of systems of above drug delivery systems with relevant applications.

**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, 2nded, by AukunuruJithan

**JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD**

**I Year –II SemM.Pharm(Pharmaceutics/Pharm Tech) (Core course V)**

**INDUSTRIAL PHARMACY**

**Objectives:** The students shall learn the theory of unit operations, machinery, materials of constructions, qualification of equipments and its utility. The students shall also understand about the objectives and principles of GMP, TQM and effluent analysis and specifications. They also understand the regulatory basis for the validation of analytical methods related to solids, sterile and liquid dosageforms

**UNIT I**

**Pharmaceutical unit operations:** A detailed study involving machinery and theory of

Pharmaceutical unit operations like milling, mixing, filtration, and drying.

**UNIT II**

1. 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.
2. 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 Testing and Treatment: Effluent analysis, specifications and preventive measures water of pollution, solid pollution, air pollution and 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 explain the machinery involved in milling, mixing, filteration, drying and packing material constructions used in the production of pharmaceutical materials. They also learn salient features of GMP, TQM applicable in industry. They also understand the effluent treatments and prevent the pollution. They also should evaluate the validation of analytical methods and processes

**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**

Unit operations of Chemical Engineering by Warren L. McCabe, Julian C. Smith, Peter Harriott.

1. Remington’s Science and Practice of Pharmacy by A. Gennaro.
2. Bentley’s Text book of Pharmaceutics by EA Rawlins.
3. CGMP, H.P.P. Sharma

**JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD**

**I Year –II SemM.Pharm(Pharmaceutics/Pharm Tech) (Core course VI)**

**MODERN PHARMACEUTICS-II**

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

**UNIT I**

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

* 1. **Pilot plant:** Technology transfer from R&D to pilot plant to pilot scale considerations of steps involved with manufacture, layout design, facility, equipment selection of tablets, capsules, suspensions, emulsions & semisolids.
	2. **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**

* 1. **Cosmetics:** Formulation approaches, preparation & method of manufacturing labeling& Q.C. of anti ageing products, sun screen lotion and fairness creams.
	2. **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**

1. 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.
2. Air handling systems: Study of AHUs, humidity & temperature control.

**Outcomes:** students will understand the planning of pilot plant techniques used for all pharmaceutical dosage forms such as tablets, capsules, parenterals, aerosols, cosmetics and neutraceuticals.

**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.
		6. Industrial Pharmacy - Selected Topics , CVS Subramanyam and J Thimmasetty, VallabhaPrakashan Delhi - 2013

**JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD**

**I Year – IISemM.Pharm (Pharmaceutics/Pharm Tech) (Core Elective- II)**

**BIOSTATISTICS AND RESEARCH METHODOLOGY**

**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, Poison 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 NeenaSondhi, Research Methodology Concepts and Cases, Vikas books publishers
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 SuvasisSaha
11. Research methods and Quantity methods by G.N.Rao
12. A practical approach to PG dissertation.

**JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD**

**I Year – II SemM.Pharm(Pharmaceutics/Pharm Tech)**

**(Core Elective- II)**

**STABILITY OF DRUGS AND DOSAGE FORMS**

**Objective**: These topics are designed impart a specialized knowledge to preserve the properties of drugs and dosage forms during manufacture storage and shelf life. The understanding of properties and evaluation of stability during storage, by solution and solid state against several factors of degradation

**UNIT-I**

 **Drug decomposition mechanisms:**

* 1. Hydrolysis and acyltransfers: Nature of reaction, structure and utility, stabilization of Pharmaceutical examples.
	2. Oxidation: Nature of oxidation, kinetics of oxidation, oxidation pathways of pharmaceutical, Interest Inhibition of oxidation
	3. Photolysis: Energetics of photolysis, kinetics photolysis, photolytic reactions of pharmaceutical interest, prevention of photolytic reactions.

**UNIT-II**

Solid state chemical decomposition: Kinetic of solids state decomposition, Pharmaceutical examples of solid state decomposition, Pure drugs, drug excipient and drug-drug interaction in solid state, methods of stabilization.

 Physical stability testing of dosage forms:

1. Solids – tablets, capsules, powder and granules
2. Disperse systems
3. Microbial decomposition
4. Over-view, physical stability of novel drug carriers, liposomes, niosomes, nano-particles.

**UNIT-III**

Identification and quantitative determination of preservatives, Antioxidants, colouring materials, emulsifiers and stabilizers in Pharmaceutical formulation.

Analysis of drugs from biological samples including, selection of biological sample, extraction of drugs by various methods as LLE, SPE and Membrane filtration.Factors affecting extraction of drugs.

**UNIT-IV**

General method of analysis to determine the quality of raw materials used in cosmetic industry. .. Indian Standard Specifications (ISI) laid down for sampling and testing of various cosmetics in finished form by the Bureau of Indian Standards.

**UNIT-V**

Methods of analysis to determine the quality of cosmetics in the finished forms such as Hair care products, Skin care products, Baby care products, Dental products, Personal hygiene products, Colour cosmetics, Ethnic products, Colour makeup preparation, Lipsticks, Hair setting lotions and Eye shadows. Toxicity testing in cosmetics and Safety and Legislation of Cosmetic products.

Stability studies: Concept of stability studies.

a) cGMP& ICH guidelines for Accelerated stability Testing.

b) Interaction of containers & closure Compatibility Testing.

**Outcome**: The students should describe the evaluation of stability of solutions, solids and formulations against adverse conditions. The students should be able to suggest the measures to retain stability and storage conditions for retaining the efficacy of the products.

**REFERENCE BOOKS :**

* 1. Comprehensive Pharmacy Review 5th Edition by Leon Shargel, Alan H. Mutnick, Paul F. Souney, Larry N. Sawnson – 2004.
	2. A. H. Beckett and J. B. Stenlake Practical Pharmaceutical Chemistry, Part I and Part II, 4th Edition. 3. G. H. Jeffery, J. Basset, J. Mendham, R. C. Denny (Rev. by) Vogels Text Book of Quantitative Chemical Analysis, 5th Edition 1989, ELBS.
	3. The Controller of Publications; New Delhi, Govt. of India, Indian Pharmacopoeia, Vol. I and Vol. II - 2010.
	4. J. B. Wilkinson and R. J. Moore :Herry’sCosmeticology; Longman Scientific and Technical Publishers, Singapore.
	5. P.D. Sethi; Quantitative Analysis of Drugs in Pharmaceutical Formulations, 3rd Edition - 1997,
	6. Classification of cosmetics raw materials and adjuncts IS 3958 of Indian Standards Institution (BIS).
	7. Cosmetic and toilet goods – methods of sampling IS 3958 of Indian Standards Institution (BIS).
	8. Methods of sampling and test for various cosmetics as laid down by Bureau of Indian Standards.
	9. Drug stability: Principles and practices by Jens T. Carstensen
	10. Stability Testing of Drug Products by W.Grimm. 12. Stability of Drugs and Dosage Forms by Yoshioka and Stella.

**JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD**

**I Year – II SemM.Pharm(Pharmaceutics/Pharm Tech)**

**(Open Elective- II)**

SCREENING METHODS IN PHARMACOLOGY

**Objective:**

The students are 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 of cardiac and anti-diabetic activities.

**UNIT V**

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

**Outcome:**

The expected outcomes are students will know how to handle animals and know about various techniques for screening of drugs for different pharmacological activities, guidelines and regulations for screening new drug molecules on animals.

**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, BerlinHeideleberg.

3. Handbook of experimental pharmacology by S.K. Kulkarni, VallabhPrakashan, Delhi.

**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.

**JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD**

**I Year –II SemM.Pharm (Pharmaceutics/Pharm Tech)**

**(Open Elective- II)**

**NANO BASED DRUG DELIVERY SYSTEMS**

**Objective -**  To develop expertise regarding suitability and evaluation of nanomaterials, able to apply the properties to the fabrication of nanopharmaceutical, evaluate the intensity of dosage forms and availability for targeting and controlled delivery.

**UNIT I – Introduction to Nanotechnology**

1. Definition of nanotechnology
2. History of nanotechnology
3. Unique properties of nanomaterials
4. Role of size and size distribution of nanoparticles properties, classification.

**UNIT II – Synthesis of Nanomaterials**

1. Physical, chemical and biological Methods
2. Methods for sysnthesis of
* Gold nanoparticles
* Magnetic nanoparticles
* Polymeric nanoparticles
* Self – assembly structures such as liposomes , micelles, aquasomes and nanoemulsions

**UNIT III**

**Biomedical applications of Nanotechnology**

1. Nanotechnology products used for in vitro diagnostics
2. Improvements to medical or molecular imaging using nanotechnology
3. Targeted nanomaterials for diagnostic and therapeutic purpose

**Unit IV**

Design of nanomaterials for drug delivery, pulmonary and nasal drug delivery, nanomaterials for cancer therapy and cardiovascular diseases. Localized drug delivery systems.

**Unit V**

Characterization including the principles, size reduction, analysis of nanoparticles, size, PDI, size separation, stability, methods of analysis regarding integrity and release of drugs

**Outcomes –** The students should be able to select the right kind of materials, able to develop nano formulations with appropriate technologies, evaluate the product related test and for identified diseases

**Recommended Books:**

1. Nanomedicine and Nanoproducts: Applications, Disposition and Toxicologyin the Human body, Eiki Igarashi, CRC press. 2015
2. Nanotechnology and Drug Delivery Volume one and two: Nanoplatforms in Drug Delivery, Jose L.Arias,CRC press
3. Nano: The Essentials: Understanding Nanosicence and Nanotechnology, T.Pradeep, Tata McGraw-Hill Publishing Company Limited, New Delhi, 2008.
4. Nanocrystals: Synthesis, Properties and Applications, C.N.R.Rao, P.J.Thomas and G.U. Kulakarni, Springer(2007)
5. Nanostructures and Nanomaterilas: Synthesis, Properties and Application, GuozhongGao, Imperial College Press(2004)
6. Nanochemistry:A Classical Approach to Nanomaterials – Royal Society for Chemistry, Cambridege, UK (2005)
7. Nanocomposite science and technology, pulickelM.Ajayan, Linda S.Schadler, paulV.Braun, Wiley-VCH Verlag, Weiheim (2003)
8. Nanoscale materials in chemistry, Edited by Kenneth J.Klabunde, John Wiley & Sons,2009
9. Nanoparticles as Drug carriers, Vladimir P Torchiling, Imperial College Press, USA, 2006
10. Introduction to Nano Science and Technologies, AnkaneyuluYerramilli, BS Publications.2016

**JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD**

**I Year –II SemM.Pharm (Pharmaceutics/Pharm Tech)**

**(Open Elective- II)**

**NUTRACEUTICALS**

**Objectives:** The students will expose to characteristic features of various phytochemicals as neutraceuticals in various diseased conditions and also know the role of antioxidant in free radical induced disease conditions and will expose to various food laws and regulations

**UNIT I**

1. Definitions of Functional foods, Nutraceuticals and Dietary supplements. Classification of
Nutraceuticals, Health problems and diseases that can be prevented or cured by Nutraceuticals

i.e. weight control, diabetes, cancer etc.

1. Source, Name of marker compounds and their chemical nature, Medicinal uses and health benefits of following used as nutraceuticals/functional foods:

Spirulina, Soyabean, Ginseng, Garlic, Broccoli, Gingko, Flaxseeds

**UNIT II**

Phytochemicals as neutraceuticals: Occurrence and characteristic features(chemical nature medicinal benefits) of following

1. Carotenoids- α and β-Carotene, Lycopene, Xanthophylls, lutein
2. Sulfides: Diallylsulfides, Allyltrisulfide.
3. Polyphenolics: Reservetrol
4. Flavonoids- Rutin , Naringin, Quercitin, Anthocyanidins, catechins, Flavones
5. Prebiotates / Probiotics.: Fructo oligosaccharides, Lacto bacillum
6. Phytoestrogens : Isoflavones, daidzein, Geebustin, lignans
7. Tocopherols

**UNIT III**

1. Introduction to free radicals: Free radicals, reactive oxygen species, production of free radicals in cells, damaging reactions of free radicals on lipids, proteins, Carbohydrates, nucleic acids.
2. Measurement of free radicals: Lipid peroxidation products, lipid hydroperoxide,malondialdehyde.

**UNIT IV**

1. Free radicals in Diabetes mellitus, Inflammation, Ischemic reperfusion injury, Cancer, Atherosclerosis, Free radicals in brain metabolism and pathology, kidney damage, muscle damage. Free radicals involvement in other disorders. Free radicals theory of ageing.
2. Antioxidants: Endogenous antioxidants – enzymatic and nonenzymatic antioxidant defence, Superoxide dismutase, catalase, Glutathione peroxidase, Glutathione Vitamin C, Vitamin E, α- Lipoic acid, melatonin

Synthetic antioxidants :Butylatedhydroxy Toluene, Butylatedhydroxy Anisole.

**UNIT V**

Food Laws and Regulations; FDA, FPO, MPO, AGMARK. HACCP and GMPs on Food Safety. Adultration of foods.

Regulations and Claims – Current Products: Label Claims, Nutrient Content Claims, Health Claims, Dietary Supplements Claims

**Outcome:** Helps the student to understand the importance of Neutraceuticals in various commom problems with the concept of free radicals

**REFERENCES:**

1. Dietetics by Sri Lakshmi
2. Role of dietary fibres and neutraceuticals in preventing diseases by K.T Agusti and P.Faizal: BSPunblication.
3. Advanced Nutritional Therapies by Cooper. K.A., (1996).
4. The Food Pharmacy by Jean Carper, Simon & Schuster, UK Ltd., (1988).
5. Prescription for Nutritional Healing by James F.Balch and Phyllis A.Balch2ndEdn., Avery Publishing Group, NY (1997).
6. G. Gibson and C.williams Editors *2000 Functional foods* WoodheadPubl.Co.London.
7. Goldberg, I. *Functional Foods*. 1994. Chapman and Hall, New York.
8. Labuza, T.P. 2000 Functional Foods and Dietary Supplements: Safety, Good Manufacturing Practice (GMPs) and Shelf Life Testing in *Essentials of Functional Foods* M.K. Sachmidl and T.P. Labuza eds. Aspen Press.
9. Handbook of Nutraceuticals and Functional Foods, Third Edition (Modern Nutrition)
10. Shils, ME, Olson, JA, Shike, M. 1994 *Modern Nutrition in Health and Disease*. Eighth edition. Lea and Febiger

**JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD**

**I Year –II SemM.Pharm (Pharmaceutics/Pharm Tech)(Open Elective- II)**

**ENTREPRENEURSHIP MANAGEMENT**

**Objective:**This course is designed to impart knowledge and skills necessary to train the

students on entrepreneurship management.

**UNIT I**

Conceptual Frame Work: Concept need and process inentrepreneurship development. Role of enterprise in national andglobal economy. Types of enterprise – Merits and Demerits.Government policies and schemes for enterprise development.Institutional support in enterprise development and management.

**UNIT II**

Entrepreneur: Entrepreneurial motivation – dynamics ofmotivation. Entrepreneurial competency –Concepts. DevelopingEntrepreneurial competencies - requirements and understandingthe process of entrepreneurship development, self-awareness,interpersonal skills, creativity, assertiveness, achievement, factorsaffecting entrepreneur role.

**UNIT III**

Launching And Organising An Enterprise: Environmentscanning – Information, sources, schemes of assistance,problems. Enterprise selection, market assessment, enterprisefeasibility study, SWOT Analysis. Resource mobilisation -finance, technology, raw material, site and manpower. Costing

and marketing management and quality control. Feedback,monitoring and evaluation.

**UNIT IV**

Growth Strategies And Networking: Performance appraisal andassessment. Profitability and control measures, demands andchallenges. Need for diversification. Future Growth – Techniquesof expansion and diversification, vision strategies. Concept anddynamics. Methods, Joint venture, co-ordination and feasibilitystudy.

**UNIT V**

Preparing Project Proposal to Start on New EnterpriseProject work – Feasibility report; Planning, resource mobilisationand implementation.

**Outcome**: On completion of this course it is expected that students will be able tounderstand,

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

**Text and reference books**

1. Akhauri, M.M.P.(1990): Entrepreneurship for Women in India, NIESBUD,

New Delhi.

2. Hisrich, R.D & Brush, C.G.(1996) The Women Entrepreneurs, D.C. Health

& Co., Toranto.

3. Hisrich, R.D. and Peters, M.P. (1995): Entrepreneurship – Starting,

Developing and Managing a New Enterprise, Richard D., Inwin, INC, USA.

4. Meredith, G.G. etal (1982): Practice of Entrepreneurship, ILO, Geneva.

5. Patel, V.C. (1987): Women Entrepreneurship – Developing NewEntrepreneurs, Ahmedabad EDII

6. Arya kumar.(2012): Entrepreneurship- Creating and Leading an Entrepreneurial Organization, Pearson

**JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD**

**I Year –II SemM.Pharm (Pharmaceutics/Pharm Tech)**

**(Open Elective II)**

**CLINICAL RESEARCH AND PHARMACOVIGILANCE**

**Objective:**

This subject will provide a value addition and current requirement for thestudents in clinical research and pharmacovigilance. It will teach the students onconceptualizing, designing, conducting, managing and reporting of clinical trials.This subject also focuses on global scenario of pharmacovigilance in differentmethods that can be used to generate safety data. It will teach the students indeveloping drug safety data in pre-clinical, clinical phases of drug developmentand post market surveillance.

**UNIT-I**

**Regulatory Perspectives of Clinical Trials:**

Origin and Principles of International Conference onHarmonization - Good Clinical Practice (ICH-GCP) guidelinesEthical Committee: Institutional Review Board, EthicalGuidelines for Biomedical Research and Human Participant-Schedule Y, ICMR, Informed Consent Process: Structure and content of anInformed Consent Process Ethical principles governing informedconsent process

**UNIT-II**

**Clinical Trials: Types and Design:**

Experimental Study- RCT and Non RCT,Observation Study: Cohort, Case Control, Cross sectionalClinical Trial Study TeamRoles and responsibilities of Clinical Trial Personnel: Investigator,Study Coordinator, Sponsor, Contract Research Orgization andits management.

**UNIT-III**

**Clinical Trial Documentation:**

Guidelines to the preparation of documents, Preparation of protocol, Investigator Brochure, CaseReport Forms, Clinical Study Report Clinical Trial Monitoring-Safety Monitoring in CTAdverse Drug Reactions: Definition and types. Detection andreporting methods. Severity and seriousnessassessment.predictability and preventability assessment. Management of adverse drug reactions; Terminologies of ADR.

**UNIT-IV**

**Basic aspects, terminologies and establishment of pharmacovigilance:**

History and progress of pharmacovigilance, Significance of safetymonitoring, Pharmacovigilance in India and international aspects,WHO international drug monitoring programme, WHO andRegulatory terminologies of ADR, evaluation of medication safety,Establishing pharmacovigilancecentres in Hospitals, Industry andNational programmes related to pharmacovigilance. Roles andresponsibilities in Pharmacovigilance.

**UNIT-V**

**Methods, ADR reporting and tools used in pharmacovigilance:**

International classification of diseases, International Nonproprietarynames for drugs, Passive and Active surveillance,Comparative observational studies, Targeted clinicalinvestigations and Vaccine safety surveillance. Spontaneousreporting system and Reporting to regulatory authorities,Guidelines for ADRs reporting. Argus, Aris G Pharmacovigilance,VigiFlow, Statistical methods for evaluating medication safety

data.

**Outcome:**

* Upon completion of the course, the student shall be able to,
* Explain the regulatory requirements for conducting clinical trial
* Demonstrate the types of clinical trial designs
* Explain the responsibilities of key players involved in clinical trials
* Execute safety monitoring, reporting and close-out activities
* Explain the principles of Pharmacovigilance
* Detect new adverse drug reactions and their assessment
* Perform the adverse drug reaction reporting systems and communication in pharmacovigilance

REFERENCES

1. Central Drugs Standard Control Organization- Good Clinical Practices,Guidelines for Clinical Trials on Pharmaceutical Products in India. NewDelhi: Ministry of Health;2001.

2. International Conference on Harmonization of Technical requirements forregistration of Pharmaceuticals for human use. ICH Harmonized TripartiteGuideline. Guideline for Good Clinical Practice.E6; May 1996.230

3. Ethical Guidelines for Biomedical Research on Human Subjects 2000.Indian Council of Medical Research, New Delhi.

4. Textbook of Clinical Trials edited by David Machin, Simon Day and SylvanGreen, March 2005, John Wiley and Sons.

5. Clinical Data Management edited by R K Rondels, S A Varley, C F Webbs.Second Edition, Jan 2000, Wiley Publications.

6. Handbook of clinical Research. Julia Lloyd and Ann Raven Ed. ChurchillLivingstone.

7. Principles of Clinical Research edited by Giovanna di Ignazio, Di Giovannaand Haynes.

8. Textbook of PHarmacovigilance: Concept and Practice. G.P. Mohanta and P. K. Manna. 2016, PharmaMed Press.

9. A textbook of Clinical Pharmacy Practice: Essential Concepts and Skills. Second Edition, 2012, University Press

**JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD**

**I Year –II SemM.Pharm (Pharmaceutics/Pharm Tech)**

**ADVANCED 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)

**JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD**

**I Year –II SemM.Pharm (Pharmaceutics/Pharm Tech)**

**Modern PHARMACEUTICS 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)