# JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD
## M.Pharmacy (PHARMACEUTICS / PHARMACEUTICAL TECHNOLOGY)
## Course Scheme & Syllabus (2022-24)

**M.Pharm Semester-I**

| Course Number | Subject | Scheme of Studies per week | | | Credits | Int Marks | Ext Marks |
|---|---|---|---|---|---|---|---|
| | | L | T | P | | | |
| 1CEU01 | Program Core-I<br>Modern Pharmaceutics-I | 3 | 1 | 0 | 4 | 25 | 75 |
| 1CEU02 | Program Core-II<br>Applied Biopharmaceutics and Pharmacokinetics | 3 | 1 | 0 | 4 | 25 | 75 |
| 1CUEPE03 | Program Elective-I<br>1. Advanced Physical Pharmaceutics<br>2. Drug Regulatory affairs<br>3. Pharmaceutical Food Analysis | 3 | 1 | 0 | 4 | 25 | 75 |
| 1CUEPE04 | Program Elective-II<br>1. Cosmetics and Cosmeceuticals<br>2. Pharmaceutical Validation<br>3. Industrial Pharmacognostical Technology | 3 | 1 | 0 | 4 | 25 | 75 |
| 1A01 | Research methodology and IPR | 2 | 0 | 0 | 2 | 25 | 75 |
| 1A02 | Audit Course – I<br>1. English for Research Paper Writing<br>2. Disaster Management<br>3. Sanskrit for Technical Knowledge<br>4. Value Education<br>5. Constitution of India<br>6. Pedagogy Studies<br>7. Stress Management by Yoga<br>8. Personality Development through Life Enlightenment Skills | 2 | 0 | 0 | 0 | 0 | 0 |
| 1CEUL05 | Applied Biopharmaceutics and Pharmacokinetics Lab | 0 | 0 | 6 | 3 | 25 | 75 |
| 1CEUL06 | Advanced Physical Pharmaceutics Lab | 0 | 0 | 6 | 3 | 25 | 75 |
| 1CEUS01 | Seminar/Assignment | 0 | 0 | 4 | 2 | 100 | 0 |
| | **Total Credits** | **16** | **4** | **16** | **26** | **275** | **525** |

**M.Pharm Semester-II**

| Course Number | Subject | Scheme of Studies per week | | | Credits | Int Marks | Ext Marks |
|---|---|---|---|---|---|---|---|
| | | L | T | P | | | |
| 2CEUPC07 | Program Core-III<br>Modern Pharmaceutics-II | 3 | 1 | 0 | 4 | 25 | 75 |
| 2CEUPC08 | Program Core-IV<br>Advanced drug delivery systems | 3 | 1 | 0 | 4 | 25 | 75 |
| 2CEUPE09 | Program Elective-III<br>1.Industrial Pharmacy<br>2.Herbal Cosmetics<br>3. Pharmacoepidemology and Pharmacoeconomics | 3 | 1 | 0 | 4 | 25 | 75 |
| 2CEUPE10 | Program Elective-IV<br>1. Nano based Drug Delivery Systems<br>2. Neutraceuticals<br>3.Clinical Research and Pharmacovigilance | 3 | 1 | 0 | 4 | 25 | 75 |
| 2A03 | Audit Course –II<br>1. English for Research Paper Writing | 2 | 0 | 0 | 0 | 0 | 0 |

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| | 2. Disaster Management<br>3. Sanskrit for Technical Knowledge<br>4. Value Education<br>5. Constitution of India<br>6. Pedagogy Studies<br>7. Stress Management by Yoga<br>8. Personality Development through Life Enlightenment Skills | | | | | | |
| 2CEUL11 | Advanced Drug Delivery Systems Lab | 0 | 0 | 6 | 3 | 25 | 75 |
| 2CEUL12 | Industrial Pharmacy Lab | 0 | 0 | 6 | 3 | 25 | 75 |
| 2CEU13 | Mini project | 2 | 0 | 2 | 2 | 25 | 75 |
| 2CEUS02 | Seminar/Assignment | 0 | 0 | 4 | 2 | 100 | 0 |
| | **Total Credits** | **16** | **4** | **16** | **26** | **275** | **525** |

***Students be encouraged to go to Industrial Training/ Internship for atleast 2-3 months during semester break.**

**M.Pharm Semester-III**

| Course Number | Subject | Scheme of studies per week | | | Credits | Int Marks | Ext Marks |
|---|---|---|---|---|---|---|---|
| | | L | T | P | | | |
| 3CEUPE14 | Program Elective – V<br>1. Scale up and Technology Transfer<br>2. Production Area Design and Packaging Development<br>3. Stability of Drugs and Dosage Forms | 3 | 1 | 0 | 4 | 25 | 75 |
| 3CEUOE15 | Open Elective<br>1. Screening Methods in Pharmacology<br>2. Entrepreneur Management<br>3. Biostatistics<br>4. Cosmetic Science<br>5. Hazards and Safety Management<br>6. Audits and Regulatory Complaints | 3 | 1 | 0 | 4 | 25 | 75 |
| 3CEUCV01 | Comprehensive Viva voce | 0 | 0 | 8 | 4 | 0 | 100 |
| | Dissertation-I | | | | | | |
| | a. Dissertation work Review -I | 0 | | | 0 | 0 | 0 |
| 3CEU16 | b. Dissertation work Review - II | 0 | 0 | 24 | 12 | 100 | 0 |
| | **Total Credits** | **6** | **2** | **32** | **24** | **150** | **250** |

*Students going for industrial project/Thesis will complete/ these courses through MOOCs.

**M.Pharm Semester-IV**

| Course Number | Subject | Scheme of studies Per Week | | | Credits | Int Marks | Ext Marks |
|---|---|---|---|---|---|---|---|
| | | L | T | P | | | |
| 4CEU17 | Dissertation – II (Project work Review – III<br>Project Evaluation viva voce | 0<br>0 | 0<br>0 | 24<br>20 | 12<br>10 | 100<br>0 | 0<br>100 |
| | **Total credits:** | **0** | **0** | **44** | **22** | **100** | **100** |

**Course No: 1CEUPC01**

**JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD**
**M.Pharm Sem-I(Pharmaceutics/Pharmaceutical Technology)**

**(Program Core-I)**
**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

**Course No: 1CEUPC02**

**JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD**

**M.Pharm Sem-I(Pharmaceutics/Pharmaceutical Technology)**

**(Program Core-II)**

## CORE COURSE – I - APPLIED BIOPHARMACEUTICS AND PHARMACOKINETICS

**Unit I**

1. **Bioavailability:** definition and importance. Biological and Formulation factors affecting Bioavailability. Methods to enhance dissolution and bioavailability. Techniques of enhancing dissolution.

2. **Bioequivalence:** important equivalency concepts, study designs, protocol, statistical designs, Biopharmaceutical classification system, biowaivers.

**Unit II**

1. **Mathematical fundamentals in pharmacokinetics –** graphs, mathematical expressions and units, units for expressing blood concentrations, rates and order of reactions. Problems related to the above topics
2. **Introduction to pharmacokinetics –** pharmacokinetic modelling, compartmental modelling, apparent volume of distribution.

3. **One compartment open Intravenous bolus administration –** Pharmacokinetics of i.v bolus administration, Elimination rate constant, calculation of elimination rate constant from urinary excretion data, Clinical applications. Problems related to i.v. bolus.

**Unit III**

1. **One compartment open Intravenous infusion –** Pharmacokinetics of i.v infusion, Elimination rate constant, Steady state concentration, AUC, Loading dose, Loading dose plus I V infusion, Clinical applications. Problems related.
2. **One compartment extravascular administration –** oral absorption, pharmacokinetics of oral administration, determination of absorption rate constant, determination of elimination rate constant by Wagner Nelson methods, method of residuals. Problems related.
3. **Two compartmental pharmacokinetic model**- IV Bolus, IV infusion and extravascular administration.

**Unit IV**

1. **Non Linear Pharmacokinetics –** linear and non linear pharmacokinetics, causes of nonlinearity, Michaelis – Menten equation, graphs of equation

2. **Concept of clearance:** organ clearance, hepatic clearance, lung clearance and renal clearance. total clearance

3. **Clinical Pharmacokinetics:** altered pharmacokinetics in disease conditions like renal failure, hepatic failure, gastric and pulmonary diseases. Altered kinetics in paediatrics, geriatrics, and pregnancy.

**Unit V**

1. **Time dependent pharmacokinetics:** Introduction, classification, physiologically induced time dependency: Chronopharmacokinetics - principles, drugs– (amino glycosides, NSAIDS, antihypertensive drug
2. **Kinetics of Drug Interactions:** 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

**Course No: 1CEUPE03**

**JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD**
**M.Pharm Sem-I(Pharmaceutics/Pharmaceutical Technology)**

**(Program Elective-I)**
## 1. ADVANCED PHYSICAL PHARMACEUTICS

**Objectives:** 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, mechanisms of polymerization, methods of polymerization and characterization of polymers. Application of polymers in pharmaceutical formulations. Mechanism of biodegradation of biodegradable polymers in drug delivery systems.

**UNIT II**
**Physics of tablet compression:** Compression and consolidation, Stages of tablet compaction, mechanism of tablet compaction, effect of friction, force volume relationships, Heckel plots, compaction profiles. Properties of tablets influenced by compression force. Similarity factors calculations.

**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**
**Characterization of API and excipients:**
Differential Scanning Calorimetry: Principle, thermal transitions, advantages, disadvantages, instrumentation, applications, and interpretations. Thermogravimetric analysis and Differential thermal analysis.
X Ray Diffraction methods: Origin of x-rays, applications, advantages, disadvantages, instrumentation, applications, and interpretations.

**UNIT V**
**Dissolution and solubility**: Solubility parameters based on BCS guidelines 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 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

**Course No: 1CEUPE03**

**JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD**
**M.Pharm Sem-I(Pharmaceutics/Pharmaceutical Technology)**

**(Program Elective-I)**
## 2. 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

a. U.SFood& Drug Administration USDMF
b. CanadaTherapeutic Product Directorate DMF
c. Europe
    1) European Medicines Agency (EMEA/ National Authorities) EDMF
    2) European Directorate for Quality of Medicines CEP/COS& Health Care Products
d. Product Filing
e. Responding Regulatory Deficiencies
f. 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

**Course No: 1CEUPE03**

**JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD**

**M.Pharm Sem-I(Pharmaceutics/Pharmaceutical Technology)**

**(Program Elective-I)**

# 3. Pharmaceutical Food Analysis

**Objective**

This course is designed to impart knowledge on analysis of food constituents and finished food products. The course includes application of instrumental analysis in the determination of pesticides in variety of food products.

**UNIT I**

a. **Carbohydrates:** Classification and properties of food carbohydrates, General methods of analysis of food carbohydrates,
b. **Proteins**: Chemistry and classification of amino acids and proteins, Physico-Chemical properties of protein and their structure, general methods of analysis of proteins and amino acids

**UNIT II**

**Probiotics:** Definition, history, importance, mode of action, identification advantages and disadvantages of probiotics. Applications of Probiotics

**UNIT III**

**Lipids:** Classification, general methods of analysis, refining of fats and oils; hydrogenation of vegetable oils, Determination of adulteration in fats and oils.

**UNIT IV**

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

**UNIT V**

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

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

**Outcome:**

At completion of this course student shall be able to understand various analytical techniques in the determination of

- Food constituents
- Food additives
- Finished food products
- Pesticides in food
- And also student shall have the knowledge on food regulations and legislations

**TEXT BOOKS**


1) The chemical analysis of foods – David Pearson, Seventh edition, Churchill Livingstone, Edinburgh London, 1976
2) Introduction to the Chemical analysis of foods – S. Nielsen, Jones & Bartlett publishers, Boston London, 1994.
3) Official methods of analysis of AOAC International, sixth edition, Volume I & II, 1997.
4) Analysis of Food constituents – Multon, Wiley VCH.

5) Dr. William Horwitz, Official methods of analysis of AOAC International
6) 18th edition, 2005.Theory and Practice of Industrial Pharmacy by Lieberman and Lachman

**REFERENCE BOOKS**

1) Remington's Pharmaceutical Sciences by Alfonso and Gennaro
2) David Pearson. The Chemical Analysis of Foods, 7th ed., Churchill Livingstone, Edinburgh, 1976.
3) Nielsen S. Introduction to the chemical analysis of foods. Jones & Bartlett Publishers, Boston, 1974
Indian Pharmacopoeia 2012

**Course No: 1CEUPE04**

**JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD**
**M.Pharm Sem-I(Pharmaceutics/Pharmaceutical Technology)**

**(Program Elective-II)**
**1. Cosmetics and Cosmeceuticals**

**Objectives:**
Upon completion of the course, the students shall be able to understand key ingredients used in cosmetics and cosmeceutical. Key building blocks for various formulations. Current technologies in the market, and basic science to develop cosmetics and cosmeceuticals. Scientific knowledge to develop cosmetics and cosmeceuticals with desired safety, stability and efficacy.

**UNIT-I**
Cosmetics- Regulatory: Definition of cosmetics as per Indian regulation. Indian regulatory requirements for labelling of cosmetics. Regulatory provisions relating to import of cosmetics.
Misbranded and spurious cosmetics. Regulatory provisions relating manufacture of cosmetics-Conditions for obtaining license, prohibition of manufacture and sale of certain cosmetics, loan license, offences and penalities.

**UNIT-II**
Cosmetics-Biological aspects : Structure of skin relating to problems like dry skin, acne, pigmentation, prickly heat, wrinkles and body odor. Structure of hair and hair growth cycle. Common problems associated with oral cavity. Cleansing and care needs for face, eye lids, lips, hands, feet, nail, scalp, neck, body and under-arm.

**UNIT-III**
Formulation Building blocks: Building blocks for different product formulations of cosmetics/cosmeceuticals. Surfactants – Classification and application. Emollients, rheological additives: classification and application. Antimicrobial used as preservatives, their merits and demerits. Factors affecting microbial preservative efficacy. Building blocks for formulation of a moisturizing cream, vanishing cream, cold cream, shampoo and toothpaste. Soaps.

**UNIT-IV**
Design and evaluation of cosmeceutical products: Creams, Lipsticks, Sun screens, Shampoos, Hair preparations and dental preparations.

**UNIT-V**
Herbal Cosmetics: Herbal ingredients used in Hair care, skin care and oral care. Review of guidelines for herbal cosmetics by private bodies like cosmos with respect to preservatives, emollients, foaming agents, emulsifiers and rheology modifiers. Challenges in formulating herbal cosmetics.

**Outcome:** The students will learn the use of different ingredients in cosmetics products. They will know the manufacturing of cosmetics and its application. They will learn about the regulatory requirements of cosmetic products.

**REFERENCES**


1. Harry's Cosmeticology. 8th edition.
2. Poucher'sperfumecosmeticsandSoaps,10th edition.
3. Cosmetics - Formulation, Manufacture and quality control, PP.Sharma,4th edition
4. Handbook of cosmetic science and Technology A.O.Barel, M.Paye and H.I. Maibach. 3 rd edition
5. Cosmetic and Toiletries recent suppliers catalogue.

**Course No: 1CEUPE04**

**JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD**
**M.Pharm Sem-I(Pharmaceutics/Pharmaceutical Technology)**

**(Program Elective-II)**

# 2. Pharmaceutical Validation

**Objective**

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

**UNIT I**

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

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

**UNIT II**

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

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

**UNIT III**

**Qualification of laboratory equipments:** Hardness tester, Friability test apparatus, tap density tester, Disintegration tester, Dissolution test apparatus.

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

**UNIT IV**

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

**UNIT V**

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

**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 byChurg Chan, Heiman Lam,

**Course No: 1CEUPE04**

**JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD**
**M.Pharm Sem-I(Pharmaceutics/Pharmaceutical Technology)**

**(Program Elective-II)**

## 3. INDUSTRIAL PHARMACOGNOSTICAL TECHNOLOGY

**OBJECTIVES**
To understand the Industrial and commercial potential of drugs of natural origin, integrate traditional Indian systems of medicine with modern medicine and also to know regulatory and quality policy for the trade of herbals and drugs of natural origin.

**UNIT I:**
**Herbal drug industry:**
a) Study of infrastructure, staff requirements, project profile, plant and equipment applicable to herbal drug industry. Plant design, layout and construction. Pilot plant scale –up techniques.
b) GMP and GLP

**UNIT II**:
**Regulatory requirements for setting herbal drug industry:**
Global marketing management. Regulatory requirements
Export - Import (EXIM) policy. TRIPS
Quality assurance in herbal/ natural drug products. Concepts of TQM, ISO-9000.
Recent guidelines of DCGI on herbal formulations.

**UNIT III:**
a) A brief account of companies making herbal drug formulations: List of formulations containing single herbal powder/extract, poly herbal powder/ extracts and their composition and uses.
b) Monographs of herbal drugs: General parameters of monographs of herbal drugs in Ayurvedic Pharmacopoeia, herbal pharmacopoeia.

**UNIT IV:**
a) Testing of natural products and drugs: Herbal medicines - clinical laboratory testing.
b) Stability testing of natural products: Indicative substances for quality assurance, GMP and HACCP in traditional system of medicine, methods of stabilization validation of analytical procedures.

**UNIT V:**
**Patents:** Patenting of herbal drugs: Benefits of patent protection, Patent application, drafting and filing an application. Indian and international patent laws, proposed amendments as applicable to herbal/natural products and process. Geographical indication, Copyright, Patentable subject maters, novelty, non obviousness, utility, patent processing and grant of patents.

**Outcome:**

By the end of the course the student shall be able to know: The requirements for setting up the herbal/natural drug industry. The guidelines for quality of herbal/natural medicines and regulatory issues.The patenting/IPR of herbals/natural drugs and trade of raw and finished materials.

**REFERENCES** (Latest Editions of)


1. Herbal drug industry by R.D. Choudhary (1996), Eastern Publisher, New Delhi.
2. GMP for Botanicals - Regulatory and Quality issues on Phytomedicine by Pulok K Mukharjee (2003) 1st Edition, Business horizons Robert Verpoorte, New Delhi.
3. Quality control of herbal drugs by Pulok K Mukarjee (2002), Business Horizons Pharmaceutical Publisher, New Delhi.
4. PDR for Herbal Medicines (2000), Medicinal Economic Company, New Jersey.
5. Text book of Pharmacognosy and Phytochemistry by Vinod D. RangarI (2002), Part I & II, Career Publication, Nasik, India.
6. Quality control of herbal drugs by P.K. Mukherjee
7. Herbal Drug Technology by SS Agarwal and paridhavi
8. Herbal Drugs Quality and Chemistry by D. D. Joshi

**Course No: 1A01**

**JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD**
**M.Pharm Sem-I (Pharmaceutics/Pharmaceutical Technology)**

## RESEARCH METHODOLOGY AND IPR

**Unit I:**

Meaning of research problem, Sources of research problem, Criteria Characteristics of a good research problem, Errors in selecting a research problem, Scope and objectives of research problem.Approaches of investigation of solutions for research problem, data collection, analysis, interpretation, Necessary instrumentations

**Unit II:**

Effective literature studies approaches, analysis Plagiarism, Research ethics, Effective technical writing, how to write report, Paper Developing a Research Proposal, Format of research proposal, a presentation and assessment by a review committee

**Unit III:**

Nature of Intellectual Property: Patents, Designs, Trade and Copyright. Process of Patenting and Development: technological research, innovation, patenting, development. International Scenario: International cooperation on Intellectual Property. Procedure for grants of patents, Patenting under PCT.

**Unit IV:**

Patent Rights: Scope of Patent Rights. Licensing and transfer of technology. Patent information and databases. Geographical Indications.

**Unit V:**

New Developments in IPR: Administration of Patent System. New developments in IPR; IPR of Biological Systems, Computer Software etc. Traditional knowledge Case Studies, IPR and IITs.

**Course Outcomes:**

At the end of this course, students will be able to CO1 Understand research problem formulation. CO2 Analyze research related information and Follow research ethics, CO3 Understand that today's world is controlled by Computer, Information Technology, but tomorrow world will be ruled by ideas, concept, and creativity. CO4 Understanding that when IPR would take such important place in growth of individuals & nation, it is needless to emphasis the need of information about Intellectual Property Right to be promoted among students in general & engineering in particular. CO5 Understand that IPR protection provides an incentive to inventors for further research work and investment in R & D, which leads to creation of new and better products, and in turn brings about, economic growth and social benefits.

REFERENCES:


1. Stuart Melville and Wayne Goddard,"Research methodology: an introduction for science & engineering students'"
2. Wayne Goddard and Stuart Melville,"Research Methodology: An Introduction"
3. Ranjit Kumar, 2nd Edition, "Research Methodology: A Step by Step Guide for beginners"
4. Halbert, "Resisting Intellectual Property", Taylor & Francis Ltd , 2007.
5. Mayall, "Industrial Design", McGraw Hill, 1992.
6. Asimov, "Introduction to Design", Prentice Hall, 1962.
7. Robert P. Merges, Peter S. Menell, Mark A. Lemley, " Intellectual Property in New Technological Age", 2016.
8. T. Ramappa, "Intellectual Property Rights Under WTO", S. Chand, 2008

**Course Number: 1CEUL05**

**JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD**
**M.Pharm Sem-I(Pharmaceutics/Pharmaceutical Technology)**

## Laboratory-1
## 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 $K_a$(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 IVIVC 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.

**Course Number: 1CEUL06**

**JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD**
**M.Pharm Sem-I(Pharmaceutics/Pharmaceutical Technology)**

## Laboratory-2
## Advanced Physical Pharmaceutics Lab

**List of experiments**

1. Determination 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 $1^{st}$ order and $2^{nd}$ 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

**Course Number: 2CEUPC07**

**JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD**
**M.Pharm Sem-II(Pharmaceutics/Pharm Tech)**

**(Program Core III)**
**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**

**a.** **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.
**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**

**Respiratory products:** Aerosols-Advances in propellants, naming of propellants, selection of containers and formulation aspects in aerosols formulation, manufacture and quality control. Metered dose inhalers and dry powder inhalers.

**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.

**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

**Course Number: 2CEUPC08**

**JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD**
**M.Pharm Sem-II(Pharmaceutics/Pharm Tech)**

**(Program Core 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, 2nd ed, by AukunuruJithan

**Course Number: 2CEUPE09**

**JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD**

**M.Pharm Sem-II(Pharmaceutics/Pharm Tech)**

**(Program Elective III)**

# 1. 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**

**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.

**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 feature1s 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

**Course Number: 2CEUPE09**

**JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD**

**M.Pharm Sem-II(Pharmaceutics/Pharm Tech)**

**(Program Elective III)**

## 2. HERBAL COSMETICS

**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**

Introduction: Herbal/ natural cosmetics, Classification & Economic aspects.

Regulatory Provisions relation to manufacture of cosmetics: -

License, GMP, offences & Penalties, Import & Export of Herbal/natural cosmetics,

Industries involved in the production of Herbal/natural cosmetics.

**UNIT II**

a) Commonly used herbal cosmetics raw materials –water, preservatives, surfactants, oils /waxes, colors, and some functional herbs
b) Processes used in the manufacture of cosmetics-Emulsification, Mixing, compaction, Molding, Packing.
c) General principles of quality control of herbal cosmetics

**UNIT III**

**Skin care Products:** Physiology and chemistry of skin, 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 IV**

**Hair care Products:** Hair structure and its chemistry

Method of preparation, pharmaceutical and Pharmacological evaluation procedures for various formulations like Hair dyes, Creams, 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**

**Herbs in cosmetics:**

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, Liquorices, Olive oil, tea tree oil and wheat germ oil with special emphasis on their source, active principles and cosmetic properties.

**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

**Course Number: 2CEUPE09**

**JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD**

**M.Pharm Sem-II(Pharmaceutics/Pharm Tech)**

**(Program Elective III)**

## 3. 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

**Course Number:2CEUPE10**

**JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD**
**M.Pharm Sem-II(Pharmaceutics/Pharm Tech)**

**(Program Elective IV)**
**1. 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**

a) Definition of nanotechnology
b) History of nanotechnology
c) Unique properties of nanomaterials
d) Role of size and size distribution of nanoparticles properties, classification.

**UNIT II – Synthesis of Nanomaterials**

a) Physical, chemical and biological Methods
b) Methods for synthesis of
- Gold nanoparticles
- Magnetic nanoparticles
- Polymeric nanoparticles
- Self – assembly structures such as liposomes, micelles, aquasomes and nanoemulsions

**UNIT III -Biomedical applications of Nanotechnology**

a) Nanotechnology products used for in vitro diagnostics
b) Improvements to medical or molecular imaging using nanotechnology
c) 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, stability 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

**Course Number:2CEUPE10**

**JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD**

**M.Pharm Sem-II(Pharmaceutics/Pharm Tech)**

**(Program Elective IV)**

## 2. 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

a. 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.

b. 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

a) Carotenoids- α and β-Carotene, Lycopene, Xanthophylls, lutein
b) Sulfides: Diallylsulfides, Allyltrisulfide.
c) Polyphenolics: Reservetrol
d) Flavonoids- Rutin , Naringin, Quercitin, Anthocyanidins, catechins, Flavones
e) Prebiotates / Probiotics.: Fructo oligosaccharides, Lacto bacillum
f) Phytoestrogens : Isoflavones, daidzein, Geebustin, lignans
g) Tocopherols

### UNIT III

a) 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.
b) Measurement of free radicals: Lipid peroxidation products, lipid hydroperoxide,malondialdehyde.

### UNIT IV

a. 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.
b. 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.Balch2nd Edn., 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

**Course Number:2CEUPE10**

**JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD**

**M.Pharm Sem-II(Pharmaceutics/Pharm Tech)**

**(Program Elective IV)**

## 3. 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

**Course Number:2CEUL11**

**JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD**

**M.Pharm Sem-II(Pharmaceutics/Pharm Tech)**

## Laboratory-3
## 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)

**Course Number:2CEUL12**

**JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD**

**M.Pharm Sem-II (Pharmaceutics/Pharm Tech)**

## Laboratory-4
## Industrial Pharmacy

**List of Experiments**

1. Effect of filter aids on rate of filtration
2. Solid-solid, Solid-liquid, Liquid-liquid mixing
3. Drying curve- porous and non porous powders
4. Factors effecting milling
5. Size separation by sieve analysis- granulation
6. Blending and Lubrication
7. Effect of hardness on Dissolution
8. Effect of disintegrating agents on dissolution
9. Preparation and evaluation of Suspension
10. Preparation of QC charts with data (IQ and PQ)
11. Evaluation of primary and secondary packaging
12. Photo stability- Drug release
13. Preparation and evaluation of Parentrals

**Course No. 3CEUPE14**

**JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD**

**M.Pharm Sem - III (Pharmaceutics/Pharm Tech)**

**(Programme Elective - V)**

# 1. SCALE UP AND TECHNOLOGY TRANSFER

**Objective**

This course is designed to impart knowledge and skills necessary to train the students to be on scale up, technology transfer process and industrial safety issues.

**UNIT I**

**Pilot plant design**: Basic requirements for design, facility, equipment selection, for tablets, capsules, liquid orals, parentral and semisolid preparations.

**Scale up**: Importance, Technology transfer from R & D to pilot plant to plant scale, process scale up for tablets, capsules, liquid orals, semisolids, parentral, NDDS products – stress on formula, equipments, product uniformity, stability, raw materials, physical layout, input, in-process and finished product specifications, problems encountered during transfer of technology

**UNIT II**

**Validation:** General concepts, types, procedures & protocols, documentation, VMF. Analytical method validation, cleaning validation and vender qualification.

**UNIT III**

**Equipment Qualification**: Importance, IQ, OQ, PQ for equipments – autoclave, DHS, membrane filter, rapid mixer granulator, cone blender, FBD, tablet compression machine, liquid filling and sealing machine. Aseptic room validation.

**UNIT IV**

**Process validation**: Importance, validation of mixing, granulation, drying, compression, tablet coating, liquid filling and sealing, sterilization, water process systems, environmental control.

**UNIT V**

Industrial safety: Hazards – fire, mechanical, electrical, chemical and pharmaceutical, Monitoring & prevention systems, industrial effluent testing & treatment. Control of environmental pollution.

**Outcome:**

On completion of this course it is expected that students will be able to understand,

- Manage the scale up process in pharmaceutical industry.
- Assist in technology transfer.
- To establish safety guidelines, which prevent industrial hazards

**REFERENCES**

1. Pharmaceutical process validation, JR Berry, Nash, Vol 57, Marcel Dekker, NY.
2. Pharmaceutical Production facilities, design and applications, by GC Cole, Taylor and Francis.
3. Pharmaceutical project management, T.Kennedy, Vol 86, Marcel Dekker, NY.
4. The theory & Practice of Industrial Pharmacy, L.Lachman, H.A.Lieberman, Varghese Publ.
Bombay.
5. Tablet machine instruments in pharmaceuticals, PR Watt, John Wiloy. 6. Pharmaceutical dosage forms, Tablets, Vol 1, 2, 3 by Lachman, Lieberman, Marcel Dekker, NY.
7. Pharmaceutical dosage forms, Parentral medications, Vol 1, 2 by K.E. Avis, Marcel Dekker,
NY.
8. Dispersed system Vol 1, 2, 3 by Lachman, Lieberman, Marcel Dekker, NY.
9. Subrahmanyam, CVS, Pharmaceutical production and Management, 2007, Vallabh Prakashan,Dehli.

**Course No. 3CEUPE14**

**JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD**

**M.Pharm Sem - III (Pharmaceutics/Pharm Tech)**

**(Programme Elective - V)**

## 2. PRODUCTION AREA DESIGN & PACKAGING DEVELOPMENT

**Objectives:** The student shall learn about Industrial area design, Current good manufacturing practices. They also learn about packaging components, polymers and metals used in packaging. They also understand about the storage conditions of different formulations and their stability evaluations.

**UNIT I**

Production Area Design: Selection of plant location, Design of plant for bulk drugs and formulations(Solids, Semisolids, Injectables, Neutraceuticals etc.), General utilities such as purified water, portable water, water for injection, Air handling units-Relative humidity and Temperature control, Material and personnel movement. Warehouse handling-API, Excipients, packaging materials and solvents.

**UNIT II**

**Current Good Manufacturing Practices:** GMP design for buildings & facilities. GMP layout design. Clean room classifications. Segregation & cross contamination control. HVAC (heating, ventilation & air-conditioning) systems. Clean room environment control. Documentation and record keeping: Specifications and testing procedures, Specifications for finished products, Master Formulae, Packaging instructions. Batch processing records, Standard operating procedures.

**UNIT III**

**Pharmaceutical packaging and Design**: Introduction, Packaging system, Components of packaging, Symbols used on packages and labels. Package development and Design research. Packaging materials- Polymers and Plasters, Glass, Metal and Blister and strip packaging.

**UNIT IV**

**Stability of Packaging:** Introduction, Legislation, Regulation, Pharmaceutical Stability Testing in Climatic Cabinets, Pharmaceutical Stability Testing Conditions, Photo-Stability Testing, Review of Pharmaceutical Product Stability, Packaging and the ICH Guidelines.

**UNIT V**

**Packaging of Solids, Semisolids, Parenterals, Ophthalmic and Aerosols**: Introduction, Packaging of Solid and semisolids, Packaging of Sterile Pharmaceuticals, Packaging Components, Inspection of Filled Injectable Products, Storage and Labelling, Packaging of Ophthalmics, Selection of Packaging Materials, Packaging of Aerosols.

**Outcome:** At the end of the semester student will get an idea about Industrial area design and packaging of different formulations and its stability conditions.

**REFERENCES:**


1. Leon Lachman; Lieberman Herbert A.; Kanig, Joseph L. The theory and Practice of Industrial Pharmacy.
2. Gilbert Banker and Christopher Rhodes. Modern Pharmaceutics.
3. Aulton's Pharmaceutics: The design and Manufacture of Medicine

4. D. A. Dean, Roy Evans, Ian Hall. Pharmaceutical packaging technology. Tylor and Francis.
5. Edward J. Bauer, Pharmaceutical Packaging Handbook. Bausch and Lomb, Rochester, New York, USA.
6. Wilmer A. Jenkins, Kenton R. Osborn. Packaging drugs and pharmaceuticals.
7. Remington: The Science and Practice of Pharmacy. 8. Michael E. Aulton, Kevin Tylor

**Course No. 3CEUPE14**

**JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD**

**M.Pharm Semester - III (Pharmaceutics/Pharm Tech)**

**(Programme Elective - V)**

# 3. 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's Cosmeticology; 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.

**Course No. 3CEUOE15**

**JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD**

**M.Pharm Semester - III (Pharmaceutics/Pharm Tech)**

**(Open Elective)**

# 1. 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.

**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.


**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, VallabhPrakashan, Delhi.

**Course No. 3CEUOE15**

**JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD**

**M.Pharm Semester - III (Pharmaceutics/Pharm Tech)**

**(Open Elective)**

# 2. 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 and global 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 of motivation. Entrepreneurial competency – Concepts. Developing Entrepreneurial competencies - requirements and understanding the process of entrepreneurship development, self-awareness, interpersonal skills, creativity, assertiveness, achievement, factors affecting entrepreneur role.

**UNIT III**

Launching And Organising An Enterprise: Environment scanning – Information, sources, schemes of assistance, problems. Enterprise selection, market assessment, enterprise feasibility study, SWOT Analysis. Resource mobilization -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 and assessment. Profitability and control measures,demands and challenges. Need for diversification. Future Growth – Techniques of expansion and diversification, vision strategies. Concept and dynamics. Methods, Joint venture, co-ordination and feasibility study.

**UNIT V**

Preparing Project Proposal to Start on New Enterprise Project work – Feasibility report; Planning, resource mobilization and implementation.

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

- 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 New Entrepreneurs, Ahmedabad EDII

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

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**JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD**

**M.Pharm Semester - III (Pharmaceutics/Pharm Tech)**

**(Open Elective)**

# 3. BIOSTATISTICS

**Objective:** The student shall know the introduction, scope of biostatistics and Research work, calculation and present of the data

**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

**Probability rules**: Binomial, Poison and Normal distribution.

**UNIT IV**

Experimental designing, planning of an experiment, replication and randomization.

**Analysis of Variance (ANOVA)**: 1-way, 2- Way

**UNIT V**

**Hypothesis testing**: Student 't' test, Chi square test,

**Non- Parametric Tests:** Sign Test, Sign Rank Test, Wilcoxon Sign Rank Test

**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

**REFERENCE BOOKS**


1. Statistics for business and economics 3rd edition by Vikas books publications
2. Biostatistics & Computer applications by GN Rao and NK Tiwari
3. Sokal, R.R. and Rohlf, F.J. 1987. An Introduction to Biostatistics. W.H. Freeman and Company.
4. Bailey, N.T.J. 1981. Statistical Methods in Biology. English University Press.
5. Mitchell, K. and Glover, T. 2001. Introduction to Biostatistics. McGraw Hill, Publishing Co.

**Course No. 3CEUOE15**

**JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD**

**M.Pharm Semester - III (Pharmaceutics/Pharm Tech)**

**(Open Elective)**

## 4. COSMETIC SCIENCE

**Objective**: These topics are designed impart a specialized knowledge to know various cosmetics, their preparation, properties, MOA, uses etc. The understanding of properties and evaluation of these cosmetics by analytical methods.

### UNIT I

**Classification of cosmetics and cosmeceutical products.**
Definition of cosmetics as per Indian and EU regulations, Evolution of cosmeceuticals from cosmetics, cosmetics as quasi and OTC drugs.
**Cosmetic excipients**: Surfactants, rheology modifiers, humectants, emollients, preservatives, classification and application.
**Skin**: Basic structure and function of skin.
**Hair**: Basic structure of hair, hair growth cycle.
**Oral Cavity**: Common problem associated with teeth and gems.

### UNIT II

**Principles of formulation and building blocks of skin care products:** Face cream, Moisturizing cream, Cold cream, Vanishing cream and their advantages and dis advantages. Application of these products in formulation of cosmeceuticals.
**Anti perspants and Deodrants:** Actives and MOA.
**Principles of formulation and building blocks of hair care products:** Conditioning shampoo, hair conditioner, anti – dandruff shampoos, hair oils.
Chemistry and formulation of Para-phylene di amine based hair dye.
**Principles of formulation and building blocks of oral care products:** Tooth paste for bleeding gums, sensitive teeth, teeth whitening, mouth wash.

### UNIT III

Sun protection, classification of sunscreens and SPF.
**Role of herbs in cosmetics:**
Skin care – Aloe and turmeric
Hair care – Henna and amla
Oral care – Clove and neem
**Analytical Cosmetics:** BIS specification and analytical method for shampoo, skin cream and tooth paste.

### UNIT IV

**Principle of cosmetic evaluation –** Principle of sebumeter, corneometer. Measurement of tewl, skin color, hair tensile strength, hair combing properties. Soaps and Syndet bars, evaluation and skin benefits.

### UNIT V

Oily and dry skin, causes leading to dry skin, skin moisturization. Basic understanding of the terms comedogenic, dermatitis.
**Cosmetic problems associated with hair and scalp:** Dandruff, hair fall causes.

**Cosmetic problems associated with skin:** Blemishes, wrinkles, acne, prickly heat and body odor.
**Anti persprants and deodorants –** Actives and MOA

**Outcome:**
The students should describe the properties and uses of various cosmetics on various parts of the body. The students should be able to suggest the proper usage of cosmetics.

**REFERENCES:**
1. Harry's cosmeticology, Wilkinson, Moore, 7th edition, George Godwin.
2. Cosmetics – Formulation, Manufacturing and Quality control, P.P. Sharma, 4th edition, Vandana Publications Pvt. Ltd. Delhi.
3. Text book of cosmeticology by Sanju Nanda & Roop K. Khar, Tata Publishers.

**Course No. 3CEUOE15**

**JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD**

**M.Pharm Semester - III (Pharmaceutics/Pharm Tech)**

**(Open Elective)**

# 5. HAZARDS AND SAFETY MANAGEMENT

## Scope

This course is designed to convey the knowledge necessary to understand issues related to different kinds of hazard and their management. Basic theoretical and practical discussions integrate the proficiency to handle the emergency situation in the pharmaceutical product development process and provides the principle based approach to solve the complex tribulations.

## Objectives

At completion of this course it is expected that students will be able to

- Understand about environmental problems among learners.
- Impart basic knowledge about the environment and its allied problems.
- Develop an attitude of concern for the industry environment.
- Ensure safety standards in pharmaceutical industry
- Provide comprehensive knowledge on the safety management
- Empower an ideas to clear mechanism and management in different kinds of hazard management system
- Teach the method of Hazard assessment, procedure, methodology for provide safe industrial atmosphere.

## UNIT I

**Multidisciplinary nature of environmental studies**: Natural Resources, Renewable and non-renewable resources, Natural resources and associated problems, Human and health safety measures.

a) Forest resources b) Water resources c) Mineral resources d) Energy resources e) Land resources

**Ecosystems**: Concept of an ecosystem and Structure and function of an ecosystem. Environmental hazards: Hazards based on Air, Water, Soil and Radioisotopes.

## UNIT II

**Air based hazards**: Sources, Types of Hazards, Air circulation maintenance industry for sterile area and non sterile area, Preliminary Hazard Analysis (PHA) Fire protection system: Fire
prevention, types of fire extinguishers and critical Hazard management system.

## UNIT III

**Chemical based hazards**: Sources of chemical hazards, Hazards of Organic synthesis, sulphonating hazard, Organic solvent hazard, Control measures for chemical hazards,

Management of combustible gases, Toxic gases and Oxygen displacing gases management, Regulations for chemical hazard, Management of over-Exposure to chemicals and TLV concept.

**UNIT IV**

**Fire and Explosion**: Introduction, Industrial processes and hazards potential, mechanical electrical, thermal and process hazards. Safety and hazards regulations, Fire protection system:

Fire prevention, types of fire extinguishers and critical Hazard management system mechanical and chemical explosion, multiphase reactions, transport effects and global rates. Preventive and protective management from fires and explosion electricity passivation, ventilation, and sprinkling, proofing, relief systems -relief valves, flares, scrubbers.

**UNIT V**

**Hazard and risk management**: Self-protective measures against workplace hazards. Critical training for risk management, Process of hazard management, ICH guidelines on risk assessment and Risk management methods and Tools Factory act and rules, fundamentals of accident prevention, elements of safety programme and safety management, Physicochemical measurements of effluents, BOD, COD, Determination of some contaminants, Effluent treatment

procedure, Role of emergency services.

**REFERENCES**


1. Y.K. Sing, Environmental Science, New Age International Pvt, Publishers, Bangalore
2. "Quantitative Risk Assessment in Chemical Process Industries" American Institute of Chemical Industries, Centre for Chemical Process safety.
3. Bharucha Erach, The Biodiversity of India, Mapin Pu blishing Pvt. Ltd., Ahmedabad – 380 013, India,
4. Hazardous Chemicals: Safety Management and Global Regulations, T.S.S. Dikshith, CRC press

**Course No. 3CEUOE15**

**JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD**

**M.Pharm Semester - III (Pharmaceutics/Pharm Tech)**

**(Open Elective)**

# 6. AUDITS AND REGULATORY COMPLIANCE

## Scope

This course deals with the understanding and process for auditing in pharmaceutical industries. This subject covers the methodology involved in the auditing process of different in pharmaceutical industries.

## Objectives

Upon completion of this course the student should be able to

- To understand the importance of auditing
- To understand the methodology of auditing
- To carry out the audit process
- To prepare the auditing report
- To prepare the check list for auditing

## UNIT I

**Introduction**: Objectives, Management of audit, Responsibilities, Planning process, information gathering, administration, Classifications of deficiencies

## UNIT II

**Role of quality systems and audits in pharmaceutical manufacturing environment**: cGMP Regulations, Quality assurance functions, Quality systems approach, Management responsibilities, Resource, Manufacturing operations, Evaluation activities, Transitioning to quality system approach, Audit checklist for drug industries.

## UNIT III

Auditing of vendors and production department: Bulk Pharmaceutical Chemicals and packaging material Vendor audit, Warehouse and weighing, Dry Production: Granulation, tableting,
coating, capsules, sterile production and packaging.

## UNIT IV

Auditing of Microbiological laboratory: Auditing the manufacturing process, Product and process information, General areas of interest in the building raw materials, Water, Packaging materials.

## UNIT V

Auditing of Quality Assurance and engineering department: Quality Assurance Maintenance, Critical systems: HVAC, Water, Water for Injection systems, ETP.

**REFERENCES**


1. Compliance auditing for Pharmaceutical Manufacturers. Karen Ginsbury and Gil Bismuth, Interpharm/CRC, Boca Raton, London New York, Washington D.C.

2. Pharmaceutical Manufacturing Handbook, Regulations and Quality by Shayne Cox Gad. Wiley-Interscience, A John Wiley and sons, Inc., Publications.

3. Handbook of microbiological Quality control. Rosamund M. Baird, Norman A. Hodges, Stephen P. Denyar. CRC Press. 2000.

4. Laboratory auditing for quality and regulatory compliance. Donald C. Singer, Raluca-loana Stefan, Jacobus F. Van Staden. Taylor and Francis (2005).

**Course No. 1A02**

**JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD**

**M.Pharm Sem I & II (Pharmaceutics/Pharm Tech)**

**AUDIT COURSE**

## 1. ENGLISH FOR RESEARCH PAPER WRITING

**UNIT I:**

Planning and Preparation, Word Order, Breaking up long sentences, Structuring Paragraphs and Sentences, Being Concise and Removing, Redundancy, Avoiding Ambiguity and Vagueness.

**UNIT II:**

Clarifying Who Did What, Highlighting Your Findings, Hedging and Criticizing, Paraphrasing and Plagiarism, Sections of a Paper, Abstracts, Introduction.

**UNIT III:**

Review of the Literature, Methods, Results, Discussion, Conclusions, The Final Check.

**UNIT IV:**

Key skills are needed when writing a Title, key skills are needed when writing an Abstract, key skills are needed when writing an Introduction, skills needed when writing a Review of the Literature.

**UNIT V:**

Skills are needed when writing the Methods, skills needed when writing the Results, skills are needed when writing the Discussion, skills are needed when writing the Conclusions, useful phrases, how to ensure paper is as good as it could possibly be the first- time submission

**COURSE OUTCOMES**:

Students will be able to:

1. Understand that how to improve your writing skills and level of readability
2. Learn about what to write in each section
3. Understand the skills needed when writing a Title Ensure the good quality of paper at very first-time submission

REFERENCES:


1. Goldbort R (2006) Writing for Science, Yale University Press (available on Google Books
2. Day R (2006) How to Write and Publish a Scientific Paper, Cambridge University Press
3. Highman N (1998), Handbook of Writing for the Mathematical Sciences, SIAM. Highman'sbook.


TEXT BOOKS:


1. Adrian Wallwork, English for Writing Research Papers, Springer New York Dordrecht Heidelberg London, 2011

**Course No. 1A02**

**JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD**

**M.Pharm Sem I & II (Pharmaceutics/Pharm Tech)**

**AUDIT COURSE**

## 2. DISASTER MANAGEMENT

**UNIT I:**

Introduction Disaster: Definition, Factors And Significance; Difference Between Hazard And Disaster; Natural And Manmade Disasters: Difference, Nature, Types And Magnitude.

**UNIT II :**

Repercussions Of Disasters And Hazards: Economic Damage, Loss Of Human And Animal Life, Destruction Of Ecosystem. Natural Disasters: Earthquakes, Volcanisms, Cyclones, Tsunamis, Floods, Droughts And Famines, Landslides And Avalanches, Man-made disaster: Nuclear Reactor Meltdown, Industrial Accidents, Oil Slicks And Spills, Outbreaks Of Disease And Epidemics, War And Conflicts.

**UNIT III:**

Disaster Prone Areas In India Study Of Seismic Zones; Areas Prone To Floods And Droughts, Landslides And Avalanches; Areas Prone To Cyclonic And Coastal Hazards With Special Reference To Tsunami; Post-Disaster Diseases And Epidemics.

**UNIT IV:**

Disaster Preparedness And Management Preparedness: Monitoring Of Phenomena Triggering A Disaster Or Hazard; Evaluation Of Risk :Application Of Remote Sensing DataFrom Meteorological And Other Agencies, Media Reports: Governmental And Community Preparedness.

**UNIT V:**

Risk Assessment

Disaster Risk: Concept And Elements, Disaster Risk Reduction, Global And National Disaster Risk Situation. Techniques Of Risk Assessment, Global Co-Operation In Risk Assessment And Warning, People's Participation In Risk Assessment. Strategies for Survival. Disaster Mitigation Meaning, Concept And Strategies Of Disaster Mitigation, Emerging Trends In Mitigation. Structural Mitigation And Non-Structural Mitigation, Programs Of Disaster Mitigation In India.

**COURSE OUTCOMES**:

Students will be able to:

1. Learn to demonstrate a critical understanding of key concepts in disaster risk reduction and humanitarian response.
2. Critically evaluate disaster risk reduction and humanitarian response policy and practice from multiple perspectives.
3. Develop an understanding of standards of humanitarian response and practical relevance in specific types of disasters and conflict situations.

4. Critically understand the strengths and weaknesses of disaster management approaches, planning and programming in different countries, particularly their home country or the countries they work in.

**REFERNCES:**


1. R. Nishith, Singh AK, "Disaster Management in India: Perspectives, issues and strategies "'New Royal book Company.
2. Sahni, PardeepEt.Al. (Eds.)," Disaster Mitigation Experiences And Reflections", Prentice Hall Of India, New Delhi.


**TEXT BOOKS:**


1. Goel S. L., Disaster Administration And Management Text And Case Studies",Deep &Deep Publication Pvt. Ltd., New Delhi.

**Course No. 1A02**

**JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD**

**M.Pharm Sem I & II (Pharmaceutics/Pharm Tech)**

**AUDIT COURSE**

## 3. SANSKRIT FOR TECHNICAL KNOWLEDGE

**UNIT I:**

Alphabets in Sanskrit, Past/Present/Future Tense, Simple Sentences

**UNIT II:**

Order Introduction of roots Technical information about Sanskrit Literature

**UNIT III:**

Technical concepts of Engineering-Electrical, Mechanical, Architecture, Mathematics

## COURSE OUTCOMES:

Students will be able to

4. Understanding basic Sanskrit language
5. Ancient Sanskrit literature about science & technology can be understood
6. Being a logical language will help to develop logic in students

## REFERENCES:


1. "Abhyaspustakam" – Dr.Vishwas, Samskrita-Bharti Publication, New Delhi
2. "Teach Yourself Sanskrit" Prathama Deeksha-VempatiKutumbshastri, Rashtriya Sanskrit Sansthanam, New Delhi Publication
3. "India's Glorious Scientific Tradition" Suresh Soni, Ocean books (P) Ltd., New Delhi.

**Course No. 1A02**

# JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD

## M.Pharm Sem I & II (Pharmaceutics/Pharm Tech)

## AUDIT COURSE

## 4. VALUE EDUCATION

**Unit I:**

Values and self-development–Social values and individual attitudes. Work ethics, Indian vision of humanism. Moral and non-moral valuation. Standards and principles. Value judgements.

**Unit II:**

Importance of cultivation of values. Sense of duty. Devotion, Self-reliance. Confidence, Concentration. Truthfulness, Cleanliness. Honesty, Humanity. Power of faith, National Unity. Patriotism. Love for nature, Discipline.

**Unit III:**

Personality and Behavior Development-Soul and Scientific attitude. Positive Thinking. Integrity and discipline. Punctuality, Love and Kindness. Avoid fault Thinking. Free from anger, Dignity of labour. Universal brotherhood and religious tolerance.

**Unit IV:**

True friendship. Happiness Vs suffering, love for truth. Aware of self-destructive habits. Association and Cooperation. Doing best for saving nature.

**Unit V:**

Character and Competence –Holy books vs Blind faith. Self-management and Good health. Science of reincarnation. Equality, Nonviolence,Humility, Role of Women. All religions and same message. Mind your Mind, Self-control. Honesty, Studying effectively.

**COURSE OUTCOMES**

Students will be able to

1. Knowledge of self-development
2. Learn the importance of Human values
3. Developing the overall personality

**REFERENCES:**

1. Chakroborty, S.K. “Values and Ethics for organizations Theory and practice”, Oxford University Press, New Delhi.

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# JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD
## M.Pharm Sem I & II (Pharmaceutics/Pharm Tech)
## AUDIT COURSE

## 5. CONSTITUTION OF INDIA

**Unit I:**

**History of Making of the Indian Constitution:** History Drafting Committee, (Composition & Working). Philosophy of the Indian Constitution: Preamble Salient Features.

**Unit II:**

**Contours of Constitutional Rights & Duties:** Fundamental Rights. Right to Equality. Right to Freedom. Right against Exploitation. Right to Freedom of Religion. Cultural and Educational Rights. Right to Constitutional Remedies. Directive Principles of State Policy. Fundamental Duties.

**Unit III:**

**Organs of Governance:** Parliament. Composition. Qualifications and Disqualifications. Powers and Functions. Executive. President. Governor. Council of Ministers. Judiciary, Appointment and Transfer of Judges, Qualifications Powers and Functions.

**Unit IV:**

**Local Administration:** District's Administration head: Role and Importance. Municipalities: Introduction, Mayor and role of Elected Representative CEO of Municipal Corporation. Pachayati raj: Introduction, PRI: ZilaPachayat. Elected officials and their roles, CEO ZilaPachayat: Position and role. Block level: Organizational Hierarchy (Different departments). Village level: Role of Elected and Appointed officials, Importance of grass root democracy.

**Unit V:**

**Election Commission:** Election Commission: Role and Functioning. Chief Election Commissioner and Election Commissioners. State Election Commission: Role and Functioning. Institute and Bodies for the welfare of SC/ST/OBC and women.

**COURSE OUTCOMES:**

**Students will be able to:**

1. Discuss the growth of the demand for civil rights in India for the bulk of Indians before the arrival of Gandhi in Indian politics.
2. Discuss the intellectual origins of the framework of argument that informed the conceptualization of social reforms leading to revolution in India.
3. Discuss the circumstances surrounding the foundation of the Congress Socialist Party [CSP] under the leadership of Jawaharlal Nehru and the eventual failure of the proposal of direct elections through adult suffrage in the Indian Constitution.
4. Discuss the passage of the Hindu Code Bill of 1956.

**REFERENCES:**


1. Dr. S. N. Busi, Dr. B. R. Ambedkar framing of Indian Constitution, 1st Edition, 2015.
2. M. P. Jain, Indian Constitution Law, 7th Edn., Lexis Nexis, 2014.
3. D.D. Basu, Introduction to the Constitution of India, Lexis Nexis, 2015.


**TEXT BOOKS:**


1. The Constitution of India, 1950 (Bare Act), Government Publication.

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# JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD
## M.Pharm Sem I & II (Pharmaceutics/Pharm Tech)
## AUDIT COURSE

## 6. PEDAGOGY STUDIES

**Unit I:**

**Introduction and Methodology:** Aims and rationale, Policy background, Conceptual framework and terminology**.** Theories of learning, Curriculum, Teacher education. Conceptual framework, Research questions**.** Overview of methodology and Searching.

**Unit II:**

Thematic overview: Pedagogical practices are being used by teachers in formal and informal classrooms in developing countries. Curriculum, Teacher education.

**Unit III:**

Evidence on the effectiveness of pedagogical practices. Methodology for the in depth stage: quality assessment of included studies. How can teacher education (curriculum and practicum) and the school curriculum and guidance materials best support effective pedagogy? Theory of change. Strength and nature of the body of evidence for effective pedagogical practices. Pedagogic theory and pedagogical approaches. Teachers' attitudes and beliefs and Pedagogic strategies.

**Unit IV:**

Professional development: alignment with classroom practices and follow-up support. Peer support. Support from the head teacher and the community. Curriculum and assessment. Barriers to learning: limited resources and large class sizes.

**Unit V:**

**Research gaps and future directions:** Research design Contexts. Pedagogy. Teacher education. Curriculum and assessment. Dissemination and research impact.

**COURSE OUTCOMES**

Students will be able to understand:

1. What pedagogical practices are being used by teachers in formal and informal classrooms in developing countries?
2. What is the evidence on the effectiveness of these pedagogical practices, in what conditions, and with what population of learners?
3. How can teacher education (curriculum and practicum) and the school curriculum and guidance materials best support effective pedagogy?

**REFERENCES:**Ackers J, Hardman F (2001) Classroom interaction in Kenyan primary schools, Compare, 31 (2): 245-261.

1. Agrawal M (2004) Curricular reform in schools: The importance of evaluation, Journal of Curriculum Studies, 36 (3): 361-379.
2. Akyeampong K (2003) Teacher training in Ghana-does it count? Multi-site teacher education research project (MUSTER) country report 1. London: DFID.
3. Akyeampong K, Lussier K, Pryor J, Westbrook J (2013) Improving teaching and learning of basic maths and reading in Africa: Does teacher preparation count? International Journal Educational Development, 33 (3): 272–282.
4. Alexander RJ (2001) Culture and pedagogy: International comparisons in primary education. Oxford and Boston: Blackwell.
5. Chavan M (2003) Read India: A mass scale, rapid, 'learning to read' campaign. www.pratham.org/images/resource%20working%20paper%202.pdf.

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## 7.STRESS MANAGEMENT BY YOGA

**Unit I:**

Definitions of Eight parts of yog (Ashtanga).

**Unit II:**

Yam and Niyam. Do`s and Don't's in life.

i) Ahinsa, satya, astheya, bramhacharya and aparigraha.
ii) Shaucha, santosh, tapa, swadhyay, ishwarpranidhan.

**Unit III:**

Asan and Pranayam

i) Various yog poses and their benefits for mind & body.
ii) Regularization of breathing techniques and its effects-Types of pranayam.

**COURSE OUTCOMES:**

Students will be able to:

1. Develop healthy mind in a healthy body thus improving social health also
2. Improve efficiency.

**REFERENCES:**

1. 'Yogic Asanas for Group Tarining-Part-I":Janardan Swami Yogabhyasi Mandal, Nagpur.

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**AUDIT COURSE**

## 8.PERSONALITY DEVELOPMENT THROUGH LIFE ENLIGHTENMENT SKILLS

**Unit I:**

Neetisatakam-Holistic development of personality; Verses- 19,20,21,22 (wisdom). Verses-29,31,32 (pride & heroism). Verses- 26,28,63,65 (virtue). Verses- 52,53,59 (dont's). Verses-71,73,75,78 (do's).

**Unit II:**

Approach to day to day work and duties. Shrimad BhagwadGeeta: Chapter 2-Verses 41, 47,48. Chapter 3-Verses 13, 21, 27, 35. Chapter 6-Verses 5,13,17, 23, 35. Chapter 18-Verses 45, 46, 48.

**Unit III:**

Statements of basic knowledge. Shrimad BhagwadGeeta: Chapter2-Verses 56, 62, 68. Chapter 12 - Verses 13, 14, 15, 16,17, 18. Personality of Role model. Shrimad Bhagwad Geeta: Chapter2-Verses 17. Chapter 3-Verses 36,37,42. Chapter 4-Verses 18, 38,39. Chapter18 – Verses 37,38,63.

**COURSE OUTCOMES**

Students will be able to

1. Study of Shrimad-Bhagwad-Geeta will help the student in developing his personality and achieve the highest goal in life
2. The person who has studied Geeta will lead the nation and mankind to peace and prosperity
3. Study of Neetishatakam will help in developing versatile personality ofstudents.

**REFERENCES:**


1. "Srimad Bhagavad Gita" by Swami SwarupanandaAdvaita Ashram (Publication Department), Kolkata.
2. Bhartrihari's Three Satakam (Niti-sringar-vairagya) by P.Gopinath


**TEXT BOOKS:**


1. Rashtriya Sanskrit Sansthanam, New Delhi.