# Course scheme for M. Pharm (Pharmaceutical Chemistry) 2021-23

## I YEAR I Semester

| Course Number | Subject | Scheme of studies Per Week | | | Credits | Int Marks | Ext Marks |
|---|---|---|---|---|---|---|---|
| | | L | T | P | | | |
| 1CHEPC01 | Programme core-I<br>Advanced Organic Chemistry-I | 3 | 1 | 0 | 4 | 30 | 70 |
| 1CHEPC02 | Programme core-II<br>Advanced Medicinal Chemistry-I | 3 | 1 | 0 | 4 | 30 | 70 |
| 1CHEPE03 | Programme Elective-I<br>1. Chemistry of Natural Products<br>2. Modern Pharmaceutical Analytical Techniques<br>3. Drug Regulatory Affairs | 3 | 1 | 0 | 4 | 30 | 70 |
| 1CHEPE04 | Programme Elective-II<br>1. Drug Discovery & Design<br>2. Pharmaceutical Food Analysis<br>3. Spectral Analysis | 3 | 1 | 0 | 4 | 30 | 70 |
| 1A01 | Research Methodology & Intellectual Property Rights | 2 | 0 | 0 | 2 | 30 | 70 |
| 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 |
| 1CHEL05 | Advanced Organic Chemistry – I Lab | 0 | 0 | 6 | 3 | 30 | 70 |
| 1CHEL06 | Modern Pharmaceutical Analytical Techniques lab | 0 | 0 | 6 | 3 | 30 | 70 |
| 1CHES01 | Seminar/Assignment | 0 | 0 | 4 | 2 | 30 | 70 |
| **Total credits:** | | **16** | **4** | **16** | **26** | **240** | **560** |

## I YEAR II Semester

| | | L | T | P | | | |
|---|---|---|---|---|---|---|---|
| 2CHEPC07 | Programme core-III<br>Advanced Organic Chemistry – II | 3 | 1 | 0 | 3 | 30 | 70 |
| 2CHEPC08 | Programme core-IV<br>Advanced Medicinal Chemistry – II | 3 | 1 | 0 | 3 | 30 | 70 |
| 2CHEPE09 | Programme Elective-III<br>1. Pharmaceutical Process Chemistry<br>2. Pharmaceutical Quality Control and Quality Assurance<br>3. Pharmacoepidomology and Pharmacoeconomics | 3 | 1 | 0 | 3 | 30 | 70 |
| 2 CHEPE10 | Programme Elective-IV<br>1. Advanced Instrumental Analysis – II<br>2. Neutraceuticals<br>3. Clinical Research and Pharmacovigilance | 3 | 1 | 0 | 3 | 30 | 70 |
| 2A03 | Audit Course – II<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 | 2 | 0 | 0 | 0 | 0 | 0 |

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| | 7. Stress Management by Yoga<br>8. Personality Development through Life Enlightenment Skills | | | | | | |
| 2CHEL11 | Advanced Instrumental Analysis I Lab | 0 | 0 | 6 | 3 | 30 | 70 |
| 2CHEL12 | Pharmaceutical Quality Control and Quality Assurance | 0 | 0 | 6 | 3 | 30 | 70 |
| 2CHE13 | Mini Project | 2 | 0 | 2 | 2 | 30 | 70 |
| 2CHES02 | Seminar/Assignment | 0 | 0 | 4 | 2 | 30 | 70 |
| **Total credits:** | | **16** | **4** | **16** | **26** | **240** | **560** |

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

**M. Pharm Sem-III**

| **Course Number** | **Subject** | **Scheme of studies Per Week** | | | **Credits** | **Int Marks** | **Ext Marks** |
|---|---|---|---|---|---|---|---|
| | | **L** | **T** | **P** | | | |
| 3CHEPE14 | Programme Elective-V<br>1. Biostatistics<br>2. Scale up and Technology Transfer<br>3. Production Area Design and Packaging Development | 3 | 0 | 0 | 3 | 30 | 70 |
| 3CHEOE15 | Open Elective<br>1. Screening Methods in Pharmacology<br>2. Entrepreneur Management<br>3. Stability Of Drugs And Dosage Forms<br>4. Cosmetic Science<br>5. Hazards and Safety Management<br>6. Audits and Regulatory Complaince | 3 | 0 | 0 | 3 | 30 | 70 |
| 3CHECV01 | Comprehensive Viva Voce | 0 | 0 | 8 | 4 | 30 | 70 |
| 3CHE16 | Dissertation - I | | | | | | |
| | a. Dissertation work Review -I | 0 | | | 0 | 0 | 0 |
| | b. Dissertation work Review - II | 0 | 0 | 20 | 10 | 100 | 0 |
| **Total credits:** | | **6** | **0** | **28** | **20** | **190** | **210** |

*** Students going for Industrial Project/Thesis will complete these courses through MOOC'**

**M. Pharm Sem-IV**

| **Course Number** | **Subject** | **Scheme of studies Per Week** | | | **Credits** | **Int Marks** | **Ext Marks** |
|---|---|---|---|---|---|---|---|
| | | **L** | **T** | **P** | | | |
| 4CHE17 | Dissertation Work Review – II & Viva Voce | 0 | 0 | 32 | 16 | 30 | 70 |
| **Total credits:** | | **0** | **0** | **32** | **16** | **30** | **70** |

**Course No. 1CHEPC01**

# JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD
## M.Pharm Sem – I (Pharmaceutical Chemistry)

## (Programme Core - I)
## ADVANCED ORGANIC CHEMISTRY

**Course Objectives:** The course structure is designed to give the knowledge of organic chemistry at an advanced level and mainly aimed at the stereochemistry and different organic named reactions including preparations of reactive intermediates.

**UNIT I**

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

**UNIT II**

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

**UNIT III**

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

**UNIT IV**

**Elimination Reactions**: $E_1$, $E_2$, $E_{1CB}$ and $E_{2CB}$ mechanisms, Mechanisms and orientation in pyrolytic eliminations, effect of substrate structure, attacking base, leaving group and reaction bond, medium and reactivity addition to carbon – carbon multiple bond reactions. Mechanisms, Orientation and reactivity.

**UNIT V**

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

**Course Outcome:** The student would be in position to design a stereoselective synthesis of new chemical entities (NCE) for the treatment of different diseases in new drug discovery Program.

**RECOMMENDED BOOKS:**


1. Francis A. Carey & Richard J. Sunberg, Advanced Org. Chemistry, III rd Edition, Par B; Reactions and synthesis, Plenum Press, New York, London, Latest Edition.
2. Eliel I. Ernest and Samuel h, Stereochemistry of Org. Compounds, John Wiley and sons, New York, 2003 Edition.
3. Roland E. Lehr & Alan P Marchard, Orbital Symmetry: A Problem-Solving approach, Academic Press, New York Latest Edition.
4. J. March, Advanced Org. Chemistry, Reactions Mechanisms and Structure, 4th
5. Edition, John Wiley & Sons, New York Latest Edition
6. I. L. Finar, Organic Chemistry, ELBS
7. Herbert O. Modern Synthesis Reactions IInd Edition W.A. Beenamis Inc. Menco Park California
8. W. Carruthers, Some Modern Methods of Org. Synthesis, III rd Edition, Cambridge University Press, Cambridge.

**Course No. 1CHEPC02**

**JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD**
**M.Pharm Sem – I (Pharmaceutical Chemistry)**

**(Programme Core - II)**
**ADVANCED MEDICINAL CHEMISTRY – I**

**Course Objectives:** The course contents are mainly aimed to have advanced knowledge of rational drug design including QSAR and molecular modeling and also aimed at the identification of lead molecule from natural sources for the development of new drugs.

**UNIT I**

**Modern methods of Drug Discovery target validation:** Introduction to discovery of lead molecule, methods, rational drug discovery models. Target structure, active site identification and methods of validation.

**UNIT II**

**Rational Drug Design**: QSAR: Parameters involved in QSAR, lipophilicity (Polarisabiltiy, electronic and steric parameters). Quantitative models. Hansch Analysis, Free Wilson Analysis and their relationships, linear relationships and applications of Hansch and Free Wilson Analysis.

**UNIT III**

a. **Computer aided drug design (CADD):**
   **Virtual screening:** concept, drug likeness screening, focused screening libraries for lead identification, pharmacophore screening, structure based virtual screening and applications.
   **Molecular modeling:** Molecular mechanics, quantam mechanics, modeling ligands for known receptors and unknown receptors.
b. **Drug Design:** Introduction, Pharmacophase – based drug design, Known receptors, structure – based drug design, homology modeling, unknown receptors.

**UNIT IV**

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

**UNIT V**

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

**Course Outcome:** The student would be in a position to have detailed knowledge of computer aided drug design which is useful to involve in new drug discovery Program by the utilization of natural leads and also with the help of structure-based drug design

**RECOMMENDED BOOKS:**


1. Berger's Medicinal Chemistry and Drug Design. 6th Edition.
2. Korolkovas Essentials of Medicinal Chemistry
3. Purcell Strategies of Drug Design
4. Corwin, Hansen Comprehensive Medicinal Chemistry
5. William O Foye Medicinal Chemistry
6. Structure based Drug Design by Pandi Veerapandion.
7. Stenlake, Foundation of Molecular Pharmacology- Pharma Med Press, volume I &II

**Course No. 1CHEPE03**

**JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD**
**M.Pharm Sem – I (Pharmaceutical Chemistry)**

**(Programme Elective - I)**
**1. CHEMISTRY OF NATURAL PRODUCTS**

**Course Objective:** The contents of Unit I mainly aimed to identify lead molecules from the natural sources. The contents of Unit II &III are mainly designed to have the knowledge of alkaloids and steroids especially structural elucidation of few important compounds. The contents of Unit IV and V are to offer an understanding of utilization of natural products for the preparation of new molecules for the treatment of different diseases like cancer, malaria etc.

**UNIT I**

**Natural products as leads for new drugs:** Introduction/history, approaches to discovery and development of natural products as potential new drugs selection and optimization of lead compounds for further development with suitable examples from antibiotics, CNS, and cardiovascular agents.

**UNIT II**

**Alkaloids:** Introduction and general methods of structure elucidation.
From opium: morphine-structure elucidation, development of morphine analogues and morphine antagonists.
From Rauwolfia: Reserpine-structure eludication, structural modifications and uses.
From vinca rosea: vincristine and vinblastine - structural modification, semisynthetic derivatives and uses.

**UNIT III**

**Steroids:** Introduction, nomenclature, stereochemistry of steroids. Source and structure elucidation of cholesterol and diosgenin.
Structures, structure modifications and therapeutic uses of steroidal anti-inflammatory agents and antifertility agents.

**UNIT IV**

**Polypeptides and proteins:** introduction and general methods of separation, general methods of degradation and end group analysis, general methods of synthesis of peptides. Primary, secondary, tertiary and quaternary structure of proteins; chemistry of insulin.

**UNIT V**

**Compounds of medicinal Interest:** Structure, structural modifications, mechanism of action and therapeutic uses of a) taxanes b) camptothecin c) artemisinin e) ginkgolides and f) gymnemic acids.

**Course Outcome:** The student would be in a position to explore the natural lead compounds for the treatment of different diseases like cancer, malaria, diabetes etc.

**RECOMMENDED BOOKS:**


1. Finar IL. Organic Chemistry-stereochemistry and the chemistry of natural products. 5th ed. vol 2. Delhi: Dorling Kindersley (India) Pvt. Ltd., 2006.
2. Morrison RT, Boyd RN. Organic Chemistry. 6th ed. Delhi: Pearson education Pvt. Ltd., 2003.
3. Pelletier SW. Alkaloids-chemical & biological perspectives. vol 1-15. London: Pergamon; 2001.
4. Steroids by Fischer & Fischer.
5. Evans WC. Trease and evans pharmacognosy. 15th ed. Edinburgh: Saunders. 2004.
6. Ataur Rahman. Chemistry of natural products
7. Bhat SV, Nagasampagi BA, Sivakumar M. Chemistry of natural products. New Delhi: Narosa Publishing House; 2005.

8. Agrawal OP. Organic chemistry-natural products. 30th ed. vol 1-2. Meerut: Goel Publishing House; 2006.
9. Wallis TE. Textbook of pharmacognosy. 5th ed. New Delhi: CBS Publishers & Distributors; 2002.
10. Abraham DJ, editor. Burger's medicinal chemistry and drug discovery. 6th ed. vol 1-6, Singapore: John Wiley & Sons, 2007.
11. Lemke TL, Williams DA, Roche VF, Zito SW. Foye's principles of medicinal chemistry. 6th ed. New Delhi: Wolters Kluwer/ Lippincott Williams & Wilkins. 2008.
12. Block JH, Beale JM, editor. Wilson and Gisvold's textbook of organic medicinal and pharmaceutical chemistry. 11th ed. Baltimore: Lippincott Williams & Wilkins; 2004.
13. Jerry M. Advanced organic chemistry-reactions, mechanisms, and structure. 4th ed. Kundli: Replika Press Pvt. Ltd; 2003.
14. Murray RK, Granner DK, Mayes PA, Rodwell VW. Harper's Illustrated biochemistry. 26th ed. New Delhi: Mc Graw Hill, 2003.
15. Rama Rao AVSS. A text book of biochemistry. 9th ed. Delhi: Rajkamal electric press, 2004.
16. Remington: The science and practice of pharmacy. 21st ed., vol. I & II, Lippincatt Willams & Wilkings, New Delhi, 2005.

**Course No. 1CHEPE03**

**JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD**
**M.Pharm Sem – I (Pharmaceutical Chemistry)**

**(Programme Elective - I)**

## 2. MODERN PHARMACEUTICAL ANALYTICAL TECHNIQUES

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

**UNIT I**

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

a. Column Chromatography: Adsorption and partition, theory, preparation, procedure and methods of detection
b. Thin Layer Chromatography: Theory, preparation, procedures, detection of compounds
c. Paper Chromatography: Theory, different techniques employed, filter papers used, qualitative and quantitative detection

**UNIT II**

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

**UNIT III**

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

**UNIT IV**

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

**UNIT V**

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

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

methods for the determination and validate the procedures.

**REFERENCES:**


1. Instrumental Methods of Chemical Analysis by B.K Sharma
2. Organic spectroscopy by Y.R Sharma
3. A Text book of Pharmaceutical Analysis by Kerrenth A. Connors
4. Vogel's Text book of Quantitative Chemical Analysis by A.I. Vogel
5. Practical Pharmaceutical Chemistry by A.H. Beckett and J.B. Stenlake
6. Organic Chemistry by I. L. Finar
7. Organic spectroscopy by William Kemp
8. Quantitative Analysis of Drugs by D. C. Garrett
9. Quantitative Analysis of Drugs in Pharmaceutical Formulations by P. D. Sethi
10. Spectrophotometric identification of Organic Compounds by Silverstein
11. HPTLC by P.D. Seth
12. Indian Pharmacopoeia 2007
13. High Performance thin layer chromatography for the analysis of medicinal plants by Eike Reich, Anne Schibli
14. Introduction to instrumental analysis by Robert. D. Braun

**Course No. 1CHEPE03**

**JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD**
**M.Pharm Sem – I (Pharmaceutical Chemistry)**

**(Programme Elective - I)**
**3. DRUG REGULATORY AFFAIRS**

**Course 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**

**Drug Regulatory Aspects (India)**

1. Indian drug regulatory authorities, Central and State regulatory bodies (FDA)
2. Drugs and Cosmmetics Act and Rules with latest Amendments (Selective)
3. Special emphasis – Schedule M and Y
4. New drugs – Importation, Registration, development, Clinical Trials, BE NOC & BE studies
5. Various Licences – Test Lic., Import lic., for testing of drugs and API's, Manufacturing Contract and Loan licence manufacturing.

**UNIT II**

**Good Manufacturing Practices (GMP)**

1. Indian GMP certification, WHO GMP certification.
2. ICH guidelines for stability testing and other relevant ones (Q1-Q10)
3. Export permissions and manufacturing for semi-regulated countries
4. Understanding of the plant layouts with special emphasis on the environment & safety (HVAC, Water Systems, Stores Management, Effluent etc.)
5. Quality Assurance and Qulaity Control – Basic understanding for in-built quality.

**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.S Food & Drug Administration USDMF
b. Canada Therapeutic 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.

3) MHRA – Medicines and Health Care Products Regulatory Agency

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.

**Course Outcome:**

- Students will come to know the different competent regulatory authorities globally.
- Students be aware of technical aspects pertaining to the marketing authorization 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.; Vallabh Prakashan, New Delhi.
3. Laws of Drugs in India by Hussain.
4. Text Book of Forensic Pharmacy by Jain N. K.; Vallabh Prakashan, New Delhi.
5. Pharmaceutical Regulatory Affairs - Selected Topics, CVS Subramanyam and J Thimmasetty, Vallabh Prakashan Delhi - 2013

**Course No. 1CHEPE04**

**JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD**
**M.Pharm Sem – I (Pharmaceutical Chemistry)**

**(Programme Elective - II)**

## 1. DRUG DISCOVERY AND DESIGN

**Course Objective:** The topics are framed to enhance the student's knowledge in the various areas of molecular modelling, molecular docking, pharmacophore concepts, drug design techniques with detail concepts of all the mentioned areas.

**UNIT - I**

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

**UNIT - II**

Pharmacophore concept: Pharmacophore mapping, methods of conformational search used in pharmacophore mapping. Comparison between the popular pharmacophore methods like Catalyst/HipHop, DiscoTech, GASP with practical examples, 3D QSAR Techniques.

**UNIT - III**

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

b. Introduction to Corona virus. Latest approaches in the treatment of COVID-19.

**UNIT - IV**

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

**UNIT - V**

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

**Course Outcome:** This enables the students to get a broad idea on the drug discovery mechanisms, its related terms and concepts of designing of drugs.

**REFERENCES:**


1. Robert GCK, ed., "Drug Action at the Molecular Level" University Prak Press Baltimore.
2. Martin YC. "Quantitative Drug Design" Dekker, New York.
3. Lien EJ. SAR "Side effects and Drug Design" Dekker, New York.
4. William H, Malick JB "Drug Discovery and Development" Humana Press Clifton.
5. Molecular Modelling, by A. R. Leach
6. Organic Chemistry of Drug Design and Drug Action, by R.B. Silverman

7. Practical Applications of computer aided drug design, by P.S. Charifson
8. Molecular modeling in Drug Design, by C. Cohen
9. Chemical Applications of Molecular modeling, by J. Goodman
10. Pharmacophore perception, by O.F. Guner

**Course No. 1CHEPE04**

**JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD**
**M.Pharm Sem – I (Pharmaceutical Chemistry)**

**(Programme Elective - II)**
**2. 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 & REFERENCE 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
7. Remington's Pharmaceutical Sciences by Alfonso and Gennaro
8. David Pearson. The Chemical Analysis of Foods, 7thed., Churchill Livingstone, Edinburgh, 1976.
9. Nielsen S. Introduction to the chemical analysis of foods. Jones & Bartlett Publishers, Boston, 1974
10. Indian Pharmacopoeia 2012

**Course No. 1CHEPE04**

**JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD**
**M.Pharm Sem – I (Pharmaceutical Chemistry)**

**(Programme Elective - II)**
**3. SPECTRAL ANALYSIS**

**Course Objective:** The students will acquire the knowledge about the various aspects of X-Ray diffraction methods, all types of IR methods, particle sizing methods, also DSC, DTA, TGA etc

**UNIT - I**

**X-Ray diffraction methods:** Origin of X-rays, basic aspects of crystals, X-ray crystallography, miller indices, rotating crystal techniques, single crystal diffraction, power diffraction, structural elucidation and applications.

**UNIT - II**

a) **FT-NIR:** Principle (overtones, combinations, fermi resonance, interferences etc.), instrumentation (dispersion spectrometer and FT-NIR), advantage and disadvantage, qualitative and quantitative applications, including PAT and non-destructive analysis.
b) **ATR:** Principle (total internal reflection, evanescent wave, etc.), instrumentation (ATR crystal, IR beam), advantages and disadvantages, pharmaceutical applications.

**UNIT - III**

**ELECTROMETRIC TECHNIQUES:** Principle, instrumentation and applications of Potentiometer, Amperometer, Conductometer and Polarography.

**UNIT - IV**

a) **Spectroflourimetry:** Theory of Fluorescence, Factors affecting fluorescence (Characteristics of drugs that can be analysed by flourimetry), Quenchers, Instrumentation and Applications of fluorescence spectrophotometer.
b) **Flame emission spectroscopy and Atomic absorption spectroscopy:** Principle, Instrumentation, Interferences and applications.

**UNIT - V**

**FT-Raman**: Principle (absorption, diffraction, scattering and emission of wave, molecular interaction), instrumentation (Dispersive Raman, FT-Raman), advantage and disadvantage, pharmaceutical applications including detection of counterfeit

**Course Outcome:** By the completion of topics the students will come out with the thorough knowledge of various spectral aspects of X-Ray, IR, SEM, ORD etc which help them in further projects works and also industrial opportunities.

**REFERENCES:**


1. Instrumental Methods of Chemical Analysis by B.K Sharma
2. Organic spectroscopy by Y.R Sharma
3. A Text book of Pharmaceutical Analysis by Kerrenth A. Connors
4. Vogel's Text book of Quantitative Chemical Analysis by A.I. Vogel
5. Practical Pharmaceutical Chemistry by A.H. Beckett and J.B. Stenlake
6. Organic Chemistry by I. L. Finar
7. Quantitative Analysis of Drugs by D. C. Garrett
8. Quantitative Analysis of Drugs in Pharmaceutical Formulations by P. D. Sethi
9. Spectrophotometric identification of Organic Compounds by Silverstein
10. HPTLC by P.D. Seth
11. Spectroscopy by Donald L Pavia, Gary M Lampman, George S Kriz, James A Vyvyan

**Course No. 1A01**

**JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD**
**M.Pharm Sem – I (Pharmaceutical Chemistry)**

## RESEARCH METHODOLOGY AND IPR

**Course Objectives:**

- To understand the research problem
- To know the literature studies, plagiarism and ethics
- To get the knowledge about technical writing
- To analyze the nature of intellectual property rights and new developments
- To know the patent rights

**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

**UNIT - III**

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 - IV**

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-V:**

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

- Understand research problem formulation.
- Analyze research related information
- Follow research ethics
- Understand that today's world is controlled by Computer, Information Technology, but tomorrow world will be ruled by ideas, concept, and creativity.
- 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.
- 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.

**TEXT BOOKS:**


1. Stuart Melville and Wayne Goddard, “Research methodology: an introduction for science &engineering students’”
2. Wayne Goddard and Stuart Melville, “Research Methodology: An Introduction”


**REFERENCES:**


1. Ranjit Kumar, 2nd Edition, “Research Methodology: A Step by Step Guide for beginners”
2. Halbert, “Resisting Intellectual Property”, Taylor & Francis Ltd ,2007.
3. Mayall, “Industrial Design”, McGraw Hill, 1992.
4. Niebel, “Product Design”, McGraw Hill, 1974.
5. Asimov, “Introduction to Design”, Prentice Hall, 1962.
6. Robert P. Merges, Peter S. Menell, Mark A. Lemley, “Intellectual Property in New Technological Age”, 2016.
7. T. Ramappa, “Intellectual Property Rights Under WTO”, S. Chand, 2008

**Course No. 1CHEL05**

**JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD**
**M.Pharm Sem – I (Pharmaceutical Chemistry)**

**Laboratory -I**
**ADVANCED ORGANIC CHEMISTRY – I LAB**

**List of Experiments: (Minimum of 10 experiments shall be conducted)**

1. Synthesis and characterization of the following drugs:

   a. Benzanilide by Beckmann rearrangement
   b. 4-Benzylidene-2-methyloxazol-5-one (or) azalactone
   c. N-(m-Nitrobenzyl) aniline from m-nitrobenzaldehyde
   d. 2, 3-Diphenyl quinoxaline
   e. 1H-Indole-3-carboxaldehyde
   f. 3, 4-Dihydropyrimidin-2(1H)-one from benzaldehyde, ethyl acetoacetate and urea in presnce of $CaCl_2$ (catalyst).
   g. Schiff base by microwave irradiation
   h. Cinnamic acid by Perkin reaction
   i. β-Ddimethylaminopropiophenone hydrochloride (Mannich base)
   j. 2-Phenyl indole
   k. Dimedone (5,5-dimethyl cyclohexane-1,3-dione)
   l. 3-Bromo cyclohexene from cyclohexene using NBS.
   m. p-Amino benzyl alcohol from p-amino benzaldehyde using sodium borohydride.
   n. Cyclohexane-2,5-dicarboxylic acid from benzoic acid (hydrogenation).

2. Any other relevant experiments based on theory.

**REFERENCES:**


1. Roth HJ, Kleemann A. Pharmaceutical Chemistry. Vol-I. Drug synthesis. New York: Ellis Horwood Limited; 1988.
2. Mann FG, Saunders BC. Practical organic chemistry. 4th ed. New Delhi: Orient Longman; 2005.
3. Furniss BS, Hanaford AJ, Smith PWG, Tatchell AR. Vogel's textbook of practical organic chemistry. 5th ed. Singapore: Longman Singapore Publishers P Ltd; 1989.
4. Vogel A. Elementary practical organic chemistry. Part 1: Small scale preparations. 2nd ed. New Delhi: CBS publishers and distributors; 2004.
5. Bansal RK. Laboratory manual of organic chemistry. 4th ed. New Delhi: New Age International (P) limited; 2005.
6. Kar A. Advanced Practical Medicinal Chemistry. New Delhi: New Age International (P) limited; 2006.

**Course No. 1CHEL06**

**JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD**
**M.Pharm Sem – I (Pharmaceutical Analysis)**

**Laboratory - I**
**Modern Pharmaceutical Analytical Techniques Lab**

## List of experiments

1. Colorimetry / UV / Visible, Spectroscopy, scanning of few compounds for UV-absorption, calculation of Assay / content uniformity / % of drug release (2-3 experiments.)
2. Simultaneous estimation of multi component containing formulations by UV spectrophotometry
3. Experiment base on HPLC (Isocratic and gradient) Techniques – (2 experiments)
4. Incompatibility studies, identification and functional groups – Determination by FTIR (2 experiments)
5. Separation and calculation of Rf values by using paper chromatography, TLC, HPTLC Technique (2-3 experiments)
6. Calibration of glasswares
7. Calibration of pH meter
8. Calibration of UV-Visible spectrophotometer
9. Calibration of FTIR spectrophotometer
10. Calibration of HPLC instrument

**Course No. 2CHEPC07**

**JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD**
**M.Pharm Sem – I (Pharmaceutical Chemistry)**

**(Programme Core - III)**
**ADVANCED ORGANIC CHEMISTRY - II**

**Course Objective:** The content of Unit I and II are mainly aimed at utilization of different synthetic reagents used in the preparation of intermediates and final compounds and also aimed at the principles of green chemistry. Unit III and IV contents are mainly aimed at scale of processes for the preparation of new pharmaceutical agents and also to design different synthetic strategies. Unit V is mainly aimed to utilize the knowledge of chemical library for drug design

**UNIT - I**

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

**UNIT - II**

**Catalysis:**

a. Types of catalysis, heterogeneous and homogenous catalysis, advantages and disadvantages
b. Heterogeneous catalysis – preparation, characterization, kinetics, supported catalysts, catalyst deactivation and regeneration, some examples of heterogeneous catalysis used in synthesis of drugs.
c. Homogenous catalysis, hydrogenation, hydroformylation, hydrocyanation, Wilkinson catalysts, chiral ligands and chiral induction, Ziegler-Natta catalysts, some examples of homogenous catalysis used in synthesis of drugs
d. Transition-metal and Organo-catalysis in organic synthesis: Metal-catalyzed reactions
e. Biocatalysis: Use of enzymes in organic synthesis, immobilized enzymes/cells in organic reaction.
f. Phase transfer catalysis -theory and applications

**UNIT - III**

Molecular Rearrangements & their applications:

1. **Carbon to Carbon Migration:** Wagner – Meerwin rearrangement, Claisen rearrangement and benzil – benzilic acid rearrangement.
2. **Carbon to Nitrogen Migration:** Hoffmann rearrangement, Curtius rearrangement and Lossen rearrangement, Beckman rearrangement, Mannich reaction and Sandmeyer reaction.
3. **Carbon to Oxygen Migration:** Bayor – Villiger rearrangement, Rearrangement of hydro peroxides and Wittig rearrangement.

**UNIT - IV**

**Chemistry of peptides**

a. Coupling reactions in peptide synthesis
b. Principles of solid phase peptide synthesis, t-BOC and FMOC protocols, various solid supports and linkers: Activation procedures, peptide bond formation, deprotection and cleavage from resin, low and high HF cleavage protocols, formation of free peptides and peptide amides, purification and case studies, site-specific chemical modifications of peptides

c. Segment and sequential strategies for solution phase peptide synthesis with any two case studies
d. Side reactions in peptide synthesis: Deletion peptides, side reactions initiated by proton abstraction, protonation, overactivation and side reactions of individual amino acids.

**UNIT - V**

**Combinatorial Chemistry**: Introduction, solid phase techniques, parallel synthesis, mixed combinatorial chemistry, diconvulution techniques, tagging, photolithography, limitations of combinatorial chemistry, planning and designing of combinatorial synthesis.

**Course Outcome:** The student would be in a position to have advanced knowledge of different synthetic reagents and reaction processes, synthetic routes by involving green chemistry principles. The student would also have techniques to utilize the chemical library of combinatorial chemistry.

**RECOMMENDED BOOKS:**


1. W. Carruthers, Some Modern Methods of Org. Synthesis, III rd Edition, Cambridge University Press, Cambridge (1988)
2. Gorgy Keri and Istarian Toth, Molecular Patho-mechanisms and New Trends in Drug Research – Taylor and Francis Group, London 2003
3. R. K. Mackie, A Guidebook to Organic Thesis – Prentice Hall
4. T.W. Greene and PGM Warts, Protecting Groups – John Willey
5. Michael B. Smith, Organic Synthesis
6. Organic synthesis- Special techniques VK Ahluwalia and R Aggarwal, Narosa Publishers.
7. “Organic Chemistry” Vol I and II. I.L. Finar. ELBS, Sixth ed., 1995.
8. “Advanced Organic chemistry, Reaction, mechanisms and structure”, J March, John Wiley and sons, New York.
9. Principles of organic synthesis, ROC Norman and JM Coxan, Nelson thorns
10. Carey, Organic chemistry, 5th edition (Viva Books Pvt. Ltd.)

**Course No. 2CHEPC08**

**JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD**
**M.Pharm Sem – I (Pharmaceutical Chemistry)**

**(Programme Core - IV)**
**ADVANCED MEDICINAL CHEMISTRY – II**

**Course Objective:** The course contents of Unit I and Unit II are mainly aimed at enzyme inhibitors for the treatment of different CNS and CVS diseases. Unit III contents are aimed to have advanced knowledge of the developments of antipsychotic agents. The remaining contents are aimed to design prodrugs, peptidomimetic agents and recombinant DNA products.

**UNIT - I**

**Enzyme Inhibitors I**: A detailed study of the following types of enzyme inhibitors, related drugs and their pharmaceutical significance:

a) Prostaglandin Synthetase (Cycloxygenase & Lipoxygenase Inhibitors)
b) Phosphodiesterase (PDE) Inhibitors
c) Carbonic Anhydrase Inhibitors.
d) β- Secretase.

**UNIT - II**

**Enzyme Inhibitors II**:

a) Angiotensin Converting Enzyme (ACE) Inhibitors
b) Acetyl Cholinesterase (Ach E) Inhibitors.
c) HMG-CoA inhibitors
d) Protease inhibitors

**UNIT - III**

**Antipsychotic Agents**: Role of Dopamine, Serotonin, Glutamate and their receptors. SAR and Pharmacokinetics of Ticyclic Neuroleptics, Butyrophenones and Benzamides. A brief account of non – benzodiazepine agonist.

**UNIT - IV**

**Peptidmimetic agents & Prodrugs**

a) Physiological role of peptids, Endogenous peptide transmitters & function, cyclosporin and oxytocin
b) Prodrugs belong to esters, Lactones, amides, hydrazides and azo compounds. Targettedprodrug, bioprecurror of prodrugs

**UNIT - V**

**Biotechnologically produced drugs:** Biotechnology of Recombinant DNA, Process of Recombinant proteins, Immunogencity of biotechnologically produced drugs.

**Recombinant drug products:** Hormones, cytokinins, interferons, Interleukins, enzymes, vaccines and monoclonal antibody drugs.

**Course Outcome:** The student would be in a position to involve in the development of different enzyme inhibitors, prodrugs and also equipped with different biotechnological techniques of recombinant DNA products.

**RECOMMENDED BOOKS:**


1. Berger's Medicinal Chemistry and Drug Design. 6th Edition
2. Korolkovas Essentials of Medicinal Chemistry
3. William O Foye Medicinal Chemistry
4. Lednicer, Organic Chemistry of Drug Synthesis

5. Ariens, Drug Design, Academic Press
6. Purcell Strategies of Drug Design
7. Corwin, Hansen Comprehensive Medicinal Chemistry
8. Richard B. Silvermann, Org. Chemistry of Drug Design and drug Action
9. Smith and Williams, Introduction to principles of Drug Design – Harwood Academy Press
10. Gyorgy Keri & Istdan Toth Molecular Pathomechanism and New Trends in Drug Research, Taylor & Francis Pub
11. Thomas Nogrady, Medicinal Chemistry. A biochemical Approach, Oxford Univ. Press.

**Course No. 2CHEPE09**

**JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD**
**M.Pharm Sem – I (Pharmaceutical Chemistry)**

**(Programme Elective - III)**
**PHARMACEUTICAL PROCESS CHEMISTRY**

**Course Objectives:** The goal of a process chemist is to develop synthetic routes that are safe, cost-effective, environmentally friendly, and efficient. The subject is designed to impart knowledge on the development and optimization of a synthetic route/s and the pilot plant procedure for the manufacture of Active Pharmaceutical Ingredients (APIs) and new chemical entities (NCEs) for the drug development phase.

**UNIT - I**

Process chemistry; Introduction, Synthetic strategy Stages of scale up process: Bench, pilot and large-scale process. In-process control and validation of large-scale process. Case studies of some scale up process of APIs. Impurities in API, types and their sources including genotoxic impurities

**UNIT - II**

**Unit operations**

a) Extraction: Liquid equilibria, extraction with reflux, extraction with agitation, counter current extraction.
b) Filtration: Theory of filtration, pressure and vacuum filtration, centrifugal filtration,
c) Distillation: azeotropic and steam distillation
d) Evaporation: Types of evaporators, factors affecting evaporation.
e) Crystallization: Crystallization from aqueous, nonaqueous solutions factors affecting crystallization, nucleation. Principle and general methods of Preparation of polymorphs, hydrates, solvates and amorphous APIs.

**UNIT - III**

**Unit Processes - I**

a) Nitration: Nitrating agents, Aromatic nitration, kinetics and mechanism of aromatic nitration, process equipment for technical nitration, mixed acid for nitration,
b) Halogenation: Kinetics of halogenations, types of halogenations, catalytic halogenations. Case study on industrial halogenation process.
c) Oxidation: Introduction, types of oxidative reactions, Liquid phase oxidation with oxidizing agents. Nonmetallic Oxidizing agents such as $H_2O_2$, sodium hypochlorite, Oxygen gas, ozonolysis.

**UNIT - IV**

**Unit Processes - II**

a) Reduction: Catalytic hydrogenation, Heterogeneous and homogeneous catalyst; Hydrogen transfer reactions, Metal hydrides. Case study on industrial reduction process.
b) Fermentation: Aerobic and anaerobic fermentation.
Production of
    i. Antibiotics; Penicillin and Streptomycin,
    ii. Vitamins: B2 and B12
    iii. Statins: Lovastatin, Simvastatin
c) Reaction progress kinetic analysis
    i. Streamlining reaction steps, route selection,

ii. Characteristics of expedient routes, characteristics of cost-effective routes, reagent selection, families of reagents useful for scale-up.

**UNIT - V**

**Industrial Safety**

a) MSDS (Material Safety Data Sheet), hazard labels of chemicals and Personal Protection Equipment (PPE)
b) Fire hazards, types of fire & fire extinguishers
c) Occupational Health & Safety Assessment Series 1800(OHSAS-1800) and ISO-14001(Environmental Management System), Effluents and its management

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

- The strategies of scale up process of apis and intermediates
- The various unit operations and various reactions in process chemistry

**REFERENCES:**


1. Process Chemistry in the Pharmaceutical Industry: Challenges in an Ever- Changing Climate- An Overview; K. Gadamasetti, CRC Press.
2. Pharmaceutical Manufacturing Encyclopedia, 3rd edition, Volume 2.
3. Medicinal Chemistry by Burger, 6th edition, Volume 1-8.
4. W.L. McCabe, J.C Smith, Peter Harriott. Unit operations of chemical engineering, 7th edition, McGraw Hill
5. Polymorphism in Pharmaceutical Solids. Dekker Series Volume 95 Ed: H G Brittain (1999)
6. Regina M. Murphy: Introduction to Chemical Processes: Principles, Analysis, Synthesis
7. Peter J. Harrington: Pharmaceutical Process Chemistry for Synthesis: Rethinking the Routes to Scale-Up
8. P.H. Groggins: Unit processes in organic synthesis (MGH)
9. F.A. Henglein: Chemical Technology (Pergamon)
10. M. Gopal: Dryden's Outlines of Chemical Technology, WEP East-West Press
11. Clausen, Mattson: Principle of Industrial Chemistry, Wiley Publishing Co.,
12. Lowenheim & M.K. Moran: Industrial Chemicals
13. S.D. Shukla & G.N. Pandey: A text book of Chemical Technology Vol. II, Vikas Publishing House
14. J.K. Stille: Industrial Organic Chemistry (PH)
15. Shreve: Chemical Process, McGraw-Hill.
16. B.K. Sharma: Industrial Chemistry, Goel Publishing House
17. ICH Guidelines
18. United States Food and Drug Administration official website www.fda.gov

**Course No. 2CHEPE09**

**JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD**
**M.Pharm Sem – I (Pharmaceutical Chemistry)**

**(Programme Elective - III)**
## Pharmaceutical Quality Control and Quality Assurance

**Objectives**
This course deals with the various aspects of quality control and qualityassurance aspects of pharmaceutical industries. It covers the important aspectslike cGMP, QC tests, documentation, quality certifications, GLP and regulatoryaffairs.

**UNIT I**
a. **Impurity and stability studies:** Definition, classification of impurities in drug Substance or Active Pharmaceutical Ingredients and quantification of impurities as per ICH guidelines.
b. **Impurities in new drug products**: Rationale for the reporting and control of degradation products, reporting degradation products content of batches, listing of degradation products in specifications, qualification of degradation products
c. **Impurities in residual solvents:** General principles, classification of residual solvents, Analytical procedures, limits of residual solvents, reporting levels of residual solvents.

**UNIT II**
a. Concepts of Quality Assurance, Total Quality Management, Philosophy of GMP and cGMP
b. Guidelines for Quality Assurance of Human Blood Products and large volume parenterals.

**UNIT III**
a. Organization and personnel, responsibilities, training hygiene
b. **Premises**: Location, design, plan Layout, construction, maintenance and sanitations, environmental control, sterile areas, control of contamination.
c. **Equipments:** Selection, purchase specifications, maintenance, clean in place, sterilize in place – Raw – materials: Purchase specifications, maintenance of stores, selection of vendors, controls and raw materials.

**UNIT IV**
a. Packaging and labeling controls, line clearance and other packaging materials.
b. Quality Control Laboratory: Responsibilities, good laboratory practices, routine controls, instruments, protocols, non-clinical testing, controls on animal house, data generation and storage.

**UNIT V**
**Manufacture and controls on dosage forms**
a. Manufacturing documents, Master Formula, Batch Formula, Records, Standard Operating Procedures,
b. In process quality control on various dosage forms sterile and biological products, standard operating procedures for various operations like cleaning, filling, drying, compression, coating, disinfection, sterilization, membrane filtration etc.

**Outcome:** The study of this subject builds the confidence in the minds on the students to develop and formulate high quality pharmaceutical products.

**Text Books**
1. The International Pharmacopoeia Vol 1,2,3,4, 3rd edition General Methods of Analysis Quality Specifications for Pharmaceutical Substances, Excipients, Dosage Forms.
2. Quality Assurance of Pharmaceuticals. A Compendium of Guidelines and Related Material Vol. 1 and Vol. 2, WHO 2007)
3. GMP by Mehra
4. Pharmaceutical Process Validation by Berry and Nash
5. How to Practice GMP's – P.P. Sharma

**References Books**
1. Basic Tests for Pharmaceutical Substances - WHO (1991)
2. The Drugs and Cosmetic Act 1940 by Vijay Malik
3. Q.A. Manual by D.H. Shah
4. SOP Guidelines by D.H. Shah

5. Quality Assurance Guide by OPPI
6. Good Manufacturing-Practices for Pharmaceuticals, by Graham Bunn and Joseph 6th Ed. D. Nally (Dec 26, 2006)
7. Analytical Profiles of drug substances and Excipients – Harry G Brittan, Volume 21 – 30, Elsevier, 2005.

**Course No. 2CHEPE09**

**JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD**
**M.Pharm Sem – I (Pharmaceutical Chemistry)**

**(Programme Elective - III)**

## 3. Pharmacoepidemiology & Pharmacoeconomics

**Objective:**
This course enables students to understand various pharmacoepidemiological methods and their clinical applications. Also, it aims to impart knowledge on basic concepts, assumptions, terminology, and methods associated with Pharmacoeconomics and health related outcomes, and when should be appropriate Pharmacoeconomic model should be applied for a health careregimen.

**UNIT-I**
**Introduction to Pharmacoepidemiology:**
Definition, Scope, Need, Aims & Applications; Outcome measurement: Outcome measures, Drug use measures: Monetary units, Number of prescriptions, units of drug dispensed, defined daily doses, prescribed daily doses, Diagnosis and Therapy surveys, Prevalence, Incidence rate, Monetary units, number of prescriptions, unit of drugs dispensed, defined daily doses and prescribed daily doses, medications adherence measurements. Concept of risk: Measurement of risk, Attributable risk and relative risk, Time- risk relationship and odds ratio

**UNIT-II**
**Pharmacoepidemiological Methods:**
Qualitative models: Drug Utilization Review; Quantitative models: case reports, case series, Cross sectional studies, Cohort and case control studies, Calculation of Odds' ratio, Meta analysis models, Drug effects study in populations: Spontaneous reporting, Prescription event monitoring, Post marketing surveillance, Record linkage systems, Applications of Pharmacoepidemiology

**UNIT-III**
**Introduction to Pharmacoeconomics:**
Definition, history of Pharmacoeconomics, Need of Pharmacoeconomic studies in Indian healthcare system. Cost categorization and resources for cost estimation: Direct costs. Indirect costs. Intangible costs. Outcomes and Measurements of Pharmacoeconomics: Types of outcomes: Clinical outcome, Economic outcomes, Humanistic outcomes; Quality Adjusted Life Years, Disability Adjusted Life Years Incremental Cost Effective Ratio, Average Cost Effective Ratio. Person Time, Willingness To Pay, Time Trade Off and Discounting.

**UNIT-IV**
**Pharmacoeconomic evaluations:**
Definition, Steps involved, Applications, Advantages and disadvantages of the following Pharmacoeconomic models: Cost Minimization Analysis (CMA),Cost Benefit Analysis (CBA), Cost Effective Analysis (CEA), Cost Utility Analysis (CUA), Cost of Illness (COI), Cost Consequences Analysis (COA).

**UNIT-V**
Definition, Steps involved, Applications, Advantages and disadvantages of the following:
Health related quality of life (HRQOL): Definition, Need for measurement of HRQOL, Common HRQOL measures. Definition, Steps involved, Applications of the following: Decision Analysis and Decision tree, Sensitivity analysis, Markov Modeling, 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 Kluwe rLippincott 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 Modeling for Health Economic 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 and Greg Stoddart. Methods for the Economic Evaluation of Health Care Programmes Oxford University Press, London.
6. George E Mackinnon III. Understanding health outcomes and Pharmacoeconomics.
7. Graker, Dennis. Pharmacoeconomics and outcomes.
8. Walley, Pharmacoeconomics.
9. Pharmacoeconomic – ed. by Nowakowska – University of Medical Sciences, 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 No. 2CHEPE10**

**JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD**
**M.Pharm Sem – II (Pharmaceutical Chemistry)**

**(Programme Elective - IV)**
**1. Advanced Instrumental Analysis - II**

**Objectives**
This subject deals with various hyphenated analytical instrumental techniques for identification, characterization and quantification of drugs. Instruments dealt are LC-MS, GC-MS, and hyphenated techniques.

**UNIT-I**
**Polarography** – Principle, Ilkovic equation, construction and working of dropping mercury electrode and rotating platinum electrode, applications.
**Amperometry -** Principles, instrumentation and applications including amperometric titrations.

**UNIT-II**
a. **Potentiometry** – Electrochemical cell, construction and working of reference (Standard hydrogen, silver chloride electrode and calomel electrode) and indicator electrodes (metal electrodes and glass electrode), methods to determine end point of potentiometric titration and applications.
b. **Conductometry**– Introduction, Conductivity cell, Conductometric titrations, applications

**UNIT-III**
**Spectroflourimetry:** Theory of Fluorescence, Factors affecting fluorescence (Characteristics of drugs that can be analyzed by flourimetry), Quenchers, Instrumentation and Applications of fluorescence spectrophotometer.

**UNIT-IV**
**Flame emission spectroscopy and Atomic absorption spectroscopy:** Principle, Instrumentation, Interferences and Applications.

**UNIT-V**
a. **Radio chemical methods including RIA**: Radio Active Isotopes, tagging of compounds, Labeled Reagents, Isotope dilution Analysis, Scintillation counter, RIA.
b. **ELISA**: Principle, types and application of ELISA

**Outcome:** By the completion of topics the students will come out with the thorough knowledge of various electrochemical methods, flourimetry, AAS, RIA, ELISA etc. which help them in further projects works and also industrial opportunities.

**References:**

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

**Course No. 2CHEPE10**

**JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD**
**M.Pharm Sem – II (Pharmaceutical Chemistry)**

**(Programme 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.Balch2ndEdn., Avery Publishing Group, NY (1997).

6. G. Gibson and C.williams Editors 2000 Functional foods WoodheadPubl.Co.London.
7. Goldberg, I. Functional Foods. 1994. Chapman and Hall, New York.
8. Labuza, T.P. 2000 Functional Foods and Dietary Supplements: Safety, Good Manufacturing Practice (GMPs) and Shelf Life Testing in Essentials of Functional Foods M.K. Sachmidl and T.P. Labuza eds. Aspen Press.
9. Handbook of Nutraceuticals and Functional Foods, Third Edition (Modern Nutrition)
10. Shils, ME, Olson, JA, Shike, M. 1994 Modern Nutrition in Health and Disease. Eighth edition. Lea and Febiger

**Course No. 2CHEPE10**

**JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD**
**M.Pharm Sem - II (Pharmaceutical Chemistry)**

**(Programme Elective - IV)**

## 3. Clinical Research and Pharmacovigilance

**Objective:**
This subject will provide a value addition and current requirement for the students in clinical research and pharmacovigilance. It will teach the students on conceptualizing, designing, conducting, managing and reporting of clinical trials. This subject also focuses on global scenario of pharmacovigilance in different methods that can be used to generate safety data. It will teach the students in developing drug safety data in pre-clinical, clinical phases of drug development and post market surveillance.

**UNIT-I**
**Regulatory Perspectives of Clinical Trials:**
Origin and Principles of International Conference on Harmonization - Good Clinical Practice (ICH-GCP) guidelines Ethical Committee: Institutional Review Board, Ethical Guidelines for Biomedical Research and Human Participant-Schedule Y, ICMR, Informed Consent Process: Structure and content of an Informed Consent Process Ethical principles governing inform edconsent process

**UNIT-II**
**Clinical Trials: Types and Design:**
Experimental Study- RCT and Non RCT, Observation Study: Cohort, Case Control, Cross sectional, Clinical Trial Study Team Roles and responsibilities of Clinical Trial Personnel: Investigator, Study Coordinator, Sponsor, Contract Research Organization and its management.

**UNIT-III**
**Clinical Trial Documentation:**
Guidelines to the preparation of documents, Preparation of protocol, Investigator Brochure, Case Report Forms, Clinical Study Report Clinical Trial Monitoring-Safety Monitoring in CT Adverse Drug Reactions: Definition and types. Detection and reporting methods. Severity and seriousness assessment. 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 safety monitoring, Pharmacovigilance in India and international aspects, WHO international drug monitoring programme, WHO and Regulatory terminologies of ADR, evaluation of medication safety, Establishing pharmacovigilance centre's in Hospitals, Industry and National programmes related to pharmacovigilance. Roles and responsibilities in Pharmacovigilance.

**UNIT-V**
**Methods, ADR reporting and tools used in pharmacovigilance:**
International classification of diseases, International Nonproprietary names for drugs, Passive and Active surveillance, Comparative observational studies, Targeted clinical investigations and Vaccine safety surveillance. Spontaneous reporting 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. New Delhi: Ministry of Health;2001.
2. International Conference on Harmonization of Technical requirements for registration of Pharmaceuticals for human use. ICH Harmonized Tripartite Guideline. 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 Sylvan Green, 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. Churchill Livingstone.
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, Pharma Med Press.
9. A textbook of Clinical Pharmacy Practice: Essential Concepts and Skills. Second Edition, 2012, University Press

**Course No. 2CHEL11**

**JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD**
**M.Pharm Sem - II (Pharmaceutical Chemistry)**

**Laboratory 3**
**ADVANCED ORGANIC CHEMISTRY – II LAB**

**List of Experiments:**

1. Analysis of Pharmacopoeial compounds and their formulations by UV Vis spectrophotometer, RNA & DNA estimation
2. Simultaneous estimation of multi component containing formulations by UV spectrophotometry
3. Experiments based on Column chromatography
4. Experiments based on HPLC
5. Experiments based on Gas Chromatography
6. Estimation of riboflavin/quinine sulphate by fluorimetry
7. Estimation of sodium/potassium by flame photometry
8. To perform the following reactions of synthetic importance Purification of organic solvents, column chromatography

a. Claisen-schimidt reaction.
b. Benzyllic acid rearrangement.
c. Beckmann rearrangement.
d. Hoffmann rearrangement
e. Mannich reaction

9. Synthesis of medicinally important compounds involving more than one step along with purification and Characterization using TLC, melting point and IR spectroscopy (4 experiments)
10. Estimation of elements and functional groups in organic natural compounds Isolation, characterization like melting point, mixed melting point, molecular weight determination, functional group analysis, co-chromatographic technique for identification of isolated compounds and interpretation of UV and IR data.
11. Some typical degradation reactions to be carried on selected plant constituents

**Course No. 2CHEL12**

**JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD**
**M.Pharm Sem - II (Pharmaceutical Chemistry)**

**Laboratory 4**
**ADVANCED MEDICINAL CHEMISTRY – II LAB**

**List of Experiments: (Minimum of 10 experiments shall be conducted)**

1. Synthesis and characterization of the following drugs:
    a. Phenacetin
    b. Antipyrin
    c. Benzocaine
    d. Uramil
    e. Tolbutamide
    f. Phenothiazine
    g. Isoniazid
    h. Sulphasalazine
    i. aspirin from salicylic acid
    j. paracetamol from p-aminophenol

2. Determination of partition coefficient of any medicinal compound by shake flask method.
3. Any other relevant experiments based on theory.

**REFERENCES:**


1. Lednicer D, Mitscher LA, The organic chemistry of drug synthesis, Volume-1-6. New York: A wiley-interscience publication; 2005.
2. Mann FG, Saunders BC. Practical organic chemistry. 4th ed. New Delhi: Orient Longman; 2005.
3. Furniss BS, Hanaford AJ, Smith PWG, Tatchell AR. Vogel's textbook of practical organic chemistry. 5th ed. Singapore: Longman Singapore Publishers P Ltd; 1989.
4. Vogel A. Elementary practical organic chemistry. Part 1: Small scale preparations. 2nd ed. New Delhi: CBS publishers and distributors; 2004.
5. Bansal RK. Laboratory manual of organic chemistry. 4th ed. New Delhi: New Age International (P) limited; 2005.
6. Kar A. Advanced Practical Medicinal Chemistry. New Delhi: New Age International (P) limited; 2006.
7. Indian Pharmacopoeia. Controller of Publication. Delhi, 1996.
8. British Pharmacopoeia. British Pharmacopoeia Commission Office, London, 2008.
9. United States Pharmacopoeia. United States Pharmacoepial Convention, Inc, USA, 2003.

**Course No. 2CHEPE14**

**JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD**
**M.Pharm Sem - II (Pharmaceutical Chemistry)**

**(Programme Elective - IV)**

# 1. 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. 3CHEPE14**

**JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD**

**M.Pharm Sem - III (Pharmaceutical Chemistry)**

**(Programme Elective - V)**

## 2. 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. 3CHEPE14**

**JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD**

**M.Pharm Sem - III (Pharmaceutical Chemistry)**

**(Programme Elective - V)**

## 3. 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. 3CHEOE15**

**JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD**

**M.Pharm Sem - III (Pharmaceutical Chemistry)**

**(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.

**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.

**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.

**Course No. 3CHEOE15**

**JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD**

**M.Pharm Sem - III (Pharmaceutical Chemistry)**

**(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

**Course No. 3CHEOE15**

**JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD**

**M.Pharm Sem - III (Pharmaceutical Chemistry)**

**(Open Elective)**

## 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. 3CHEOE15**

**JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD**

**M.Pharm Sem - III (Pharmaceutical Chemistry)**

**(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. 3CHEOE15**

**JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD**

**M.Pharm Sem - III (Pharmaceutical Chemistry)**

**(Open Elective)**

## 5. Hazards and Safety Management

**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. 3CHEOE15**

**JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD**

**M.Pharm Sem - III (Pharmaceutical Chemistry)**

**(Open Elective)**

## 6. Audits and Regulatory Compliance

**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 Semester - III (Pharmaceutical Chemistry)**

## 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

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## 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.

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**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.

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**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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## 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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## 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:**


1. Ackers J, Hardman F (2001) Classroom interaction in Kenyan primary schools, Compare, 31 (2): 245-261.
2. Agrawal M (2004) Curricular reform in schools: The importance of evaluation, Journal of Curriculum Studies, 36 (3): 361-379.
3. Akyeampong K (2003) Teacher training in Ghana-does it count? Multi-site teacher education research project (MUSTER) country report 1. London: DFID.
4. 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.
5. Alexander RJ (2001) Culture and pedagogy: International comparisons in primary education. Oxford and Boston: Blackwell.
6. 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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**AUDIT COURSE**

## 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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## 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 of students.

**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.