JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD

M.PHARMACY (PHARMACEUTICAL CHEMISTRY)

R19 COURSE STRUCTURE AND SYLLABUS
Effective from Academic Year 2019-20 Admitted Batch

I YEAR I Semester

Course Code	Course Title	L	T	P	Credits
Professional Core-I	Advanced Organic Chemistry-I	3	0	0	3
Professional Core-II	Advanced Medicinal Chemistry-I	3	0	0	3
Professional Elective-I	1. Chemistry of Natural Products 2. Modern Pharmaceutical Analytical Techniques 3. Drug Regulatory Affairs	3	0	0	3
Professional Elective-II	1. Drug Discovery & Design 2. Pharmaceuticals and Food Analysis 3. Spectral Analysis	3	0	0	3
	Research methodology and IPR	2	0	0	2
Laboratory-I	Advanced Organic Chemistry – I Lab	0	0	4	2
Laboratory-II	Advanced Medicinal Chemistry – I Lab	0	0	4	2
Audit - I	Audit Course – I	2	0	0	0
	TOTAL	**16**	**0**	**8**	**18**

I YEAR II Semester

Course Code	Course Title	L	T	P	Credits
Professional Core-III	Advanced Organic Chemistry – II	3	0	0	3
Professional Core-IV	Advanced Medicinal Chemistry - II	3	0	0	3
Professional Elective-III	1. Pharmaceutical Process Chemistry 2. Quality Control and Quality Assurance 3. Clinical Research and Pharmacovigilance	3	0	0	3
Professional Elective-IV	1. Screening Methods in Pharmacology 2. Advanced Instrumental Analysis 3. Herbal Drug Technology	3	0	0	3
Laboratory-III	Advanced Organic Chemistry - II Lab	0	0	4	2
Laboratory-IV	Advanced Medicinal Chemistry - II Lab	0	0	4	2
	Mini project with Seminar	2	0	0	2
Audit - II	Audit Course - II	2	0	0	0
	TOTAL	**16**	**0**	**8**	**18**

II YEAR I Semester

Course Code	Course Title	L	T	P	Credits
Professional Elective-V	1. Biostatistics 2. Pharmaceutical Production and packaging Technology 3. Scale-up and technology transfer	3	0	0	3
Open Elective	Open Elective	3	0	0	3
Dissertation	Dissertation Work Review - II	0	0	12	6
	Total Credits	**6**	**0**	**12**	**12**

II YEAR II - SEMESTER

Course Code	Course Title	L	T	P	Credits
Dissertation	Dissertation Work Review - III	0	0	12	6
Dissertation	Dissertation Viva-Voce	0	0	28	14
	Total Credits	**0**	**0**	**40**	**20**

***For Dissertation Work Review - I, Please refer 7.8 in R19 Academic Regulations.**

Audit Courses I & II:

1. English for Research Paper Writing
2. Disaster Management
3. Sanskrit for Technological Learning
4. Value Education
5. Constitution of India
6. Pedagogy Studies
7. Stress Management by Yoga
8. Personality Development through Life Enlightenment Skills

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD
M.Pharm I Year I Sem (Pharmaceutical Chemistry)
ADVANCED ORGANIC CHEMISTRY – I (Professional Core – I)

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.
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.

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.

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.

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

ADVANCED MEDICINAL CHEMISTRY – I (Professional Core – II)

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.

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.

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.

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

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

CHEMISTRY OF NATURAL PRODUCTS (Professional Elective – I)

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.

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.

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.

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.

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD
M.Pharm I Year I Sem (Pharmaceutical Chemistry)
MODERN PHARMACEUTICAL ANALYTICAL TECHNIQUES (Professional Elective – I)

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.

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.

UNIT I

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

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

UNIT II

a. Gas chromatography: Introduction, fundamentals, instrumentation, columns: preparation and operation, detection, dramatization.
b. HPLC: ***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, 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.

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

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

DRUG REGULATORY AFFAIRS (Professional Elective – I)

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.

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.

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.

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

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

DRUG DISCOVERY AND DESIGN (Professional Elective – II)

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.

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.

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
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

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.

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

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD
M.Pharm I Year I Sem (Pharmaceutical Chemistry)
PHARMACEUTICALS AND FOOD ANALYSIS (Professional Elective – II)

Course 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.

Course 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
- Pharmaceuticals (API & Dosage forms)
- And also student shall have the knowledge on food regulations and legislations

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

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

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

UNIT - III

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

UNIT - IV

Definition, classification and principles and procedures involved in the quantitative determination of drugs from each category of both API and dosage forms (IP) of the following

a. Analgesics & Antipyretics
b. Antihypertensives
c. Antihistamines
d. Alkaloids
e. Antibiotics
f. Diuretics

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.
    - Pesticides in food
    - And also student shall have knowledge in food regulations and legislations

TEXT BOOKS:

1. The chemical analysis of foods – David Pearson, Seventh edition, Churchill Livingstone, Edinburgh London, 1976

2. Introduction to the Chemical analysis of foods – S. Nielsen, Jones & Bartlett publishers, Boston London, 1994.
3. Official methods of analysis of AOAC International, sixth edition, Volume I & II, 1997.
4. Analysis of Food constituents – Multon, Wiley VCH.
5. Dr. William Horwitz, Official methods of analysis of AOAC International
6. 18th edition, 2005.Theory and Practice of Industrial Pharmacy by Lieberman and Lachman

REFERENCE BOOKS:

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

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD
M.Pharm I Year I Sem (Pharmaceutical Chemistry)
SPECTRAL ANALYSIS (Professional Elective – II)

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

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.

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

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. Spectroscopy by Donald L Pavia, Gary M Lampman, George S Kriz, James A Vyvyan

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD
M.Pharm I Year I Sem (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

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.

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.

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

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

ADVANCED ORGANIC CHEMISTRY – I LAB (LAB – I)

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.

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

ADVANCED MEDICINAL CHEMISTRY – I LAB (LAB – II)

List of Experiments:

1. Synthesis of any two drugs from the following classes of drugs (Minimum two from each class)
    a. Analgesics, NSAIDS and antipyretics
    b. CNS and CVS drugs
2. QSAR Studies by using softwares
    a. CoMFA – 3D QSAR method,
    b. CODESSA,
    c. descriptor software (all are free online sot wares) minimum of 3 experiments
3. Docking studies of drugs by using free online softwares like
    a. AutoDock,
    b. BLAST,
    c. GPCR pred,
    d. FASTA,
    e. ATPINT,
    f. Maestro,
    g. ESLPRED2 (Minimum of 5 experiments)

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD
M.Pharm I Year II Sem (Pharmaceutical Chemistry)

ADVANCED ORGANIC CHEMISTRY - II (Professional Core – III)

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

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.

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.
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.

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.)

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD
M.Pharm I Year II Sem (Pharmaceutical Chemistry)

ADVANCED MEDICINAL CHEMISTRY – II (Professional Core – IV)

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.

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.

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) B- 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.

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.

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD
M.Pharm I Year II Sem (Pharmaceutical Chemistry)

PHARMACEUTICAL PROCESS CHEMISTRY (Professional Elective – III)

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.

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

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 H2O2, 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

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

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

Quality Control and Quality Assurance (Professional Elective – III)

Course Objective: This course deals with the various aspects of quality control and quality assurance aspects of pharmaceutical industries. It covers the important aspects like cGMP, QC tests, documentation, quality certifications, GLP and regulatory affairs.

Course Outcome: Upon completion of this course the student should be able to

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

UNIT – I

Introduction: Concept and evolution and scopes of Quality Control and Quality Assurance, Good Laboratory Practice, GMP, Overview of ICH Guidelines - QSEM, with special emphasis on Qseries guidelines. Good Laboratory Practices: Scope of GLP, Definitions, Quality assurance unit, protocol for conduct of non-clinical testing, control on animal house, report preparation and documentation. CPCSEA guidelines.

UNIT - II

cGMP guidelines according to schedule M, USFDA (inclusive of CDER and CBER) Pharmaceutical Inspection Convention (PIC), WHO and EMEA covering: Organization and personnel responsibilities, training, hygiene and personal records, drug industry location, design, construction and plant lay out, maintenance, sanitation, environmental control, utilities and maintenance of sterile areas, control of contamination and Good Warehousing Practice.

UNIT - III

Analysis of raw materials, finished products, packaging materials, in process quality control (IPQC), Developing specification (ICH Q6 and Q3), purchase specifications and maintenance of stores for raw materials. In process quality control and finished products quality control for following dosage forms in Pharma industry according to Indian, US and British pharmacopoeias: tablets, capsules, ointments, suppositories, creams, parenterals, ophthalmic and surgical products (How to refer pharmacopoeias).

UNIT - IV

Documentation in pharmaceutical industry: Three tier documentation, Policy, Procedures and Work instructions, and records (Formats), Basic principles- How to maintain, retention and retrieval etc. Standard operating procedures (How to write), Master Batch Record, Batch Manufacturing Record, Quality audit plan and reports. Specification and test procedures, Protocols and reports. Distribution records. Electronic data handling. Concepts of controlled and uncontrolled documents. Submission documents for regulators DMFs, as Common Technical Document and Electronic Common Technical Documentation (CTD, eCTD). Concept of regulated and non-regulated markets.

UNIT - V

Manufacturing operations and controls: Sanitation of manufacturing premises, mix-ups and cross contamination, processing of intermediates and bulk products, packaging operations, IPQC, release of finished product, process deviations, charge-in of components, time limitations on production, drug product inspection, expiry date calculation, calculation of yields, production record review, change control, sterile products, aseptic process control, packaging, reprocessing, salvaging, handling of

waste and scrap disposal. Introduction, scope and importance of intellectual property rights. Concept of trade mark, copyright and patents.

REFERENCE BOOKS:

1. Quality Assurance Guide by organization of Pharmaceutical Procedures of India, 3rd revised edition, Volume I & II, Mumbai, 1996.
2. Good Laboratory Practice Regulations, 2nd Edition, Sandy Weinberg Vol. 69, Marcel Dekker Series, 1995.
3. Quality Assurance of Pharmaceuticals- A compedium of Guide lines and Related materials Vol I & II, 2nd edition, WHO Publications, 1999.
4. How to Practice GMP's – P P Sharma, Vandana Publications, Agra, 1991.
5. The International Pharmacopoeia – vol I, II, III, IV & V - General Methods of Analysis and Quality specification for Pharmaceutical Substances, Excepients and Dosage forms, 3rd edition, WHO, Geneva, 2005.
6. Good laboratory Practice Regulations – Allen F. Hirsch, Volume 38, Marcel Dekker Series, 1989.
7. ICH guidelines
8. ISO 9000 and total quality management
9. The drugs and cosmetics act 1940 – Deshpande, Nilesh Gandhi, 4th edition, Susmit Publishers, 2006.
10. QA Manual – D.H. Shah, 1st edition, Business Horizons, 2000.
11. Good Manufacturing Practices for Pharmaceuticals a plan for total quality control – Sidney H. Willig, Vol. 52, 3rd edition, Marcel Dekker Series.
12. Steinborn L. GMP/ISO Quality Audit Manual for Healthcare Manufacturers and Their Suppliers, Sixth Edition, (Volume 1 - With Checklists and
13. Software Package). Taylor & Francis; 2003.
14. Sarker DK. Quality Systems and Controls for Pharmaceuticals. John Wiley & Sons; 2008.
15. Packaging of Pharmaceuticals.
16. Schedule M and Schedule N.

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD
M.Pharm I Year II Sem (Pharmaceutical Chemistry)

CLINICAL RESEARCH AND PHARMACOVIGILANCE (Professional Elective - III)

Course Objectives: 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.

Course Outcomes: 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

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 informed consent 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 Program, WHO and Regulatory terminologies of ADR, evaluation of medication safety, establishing pharmacovigilance centres in Hospitals, Industry and National Programs 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.

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 Giovanna and 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

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD
M.Pharm I Year II Sem (Pharmaceutical Chemistry)

SCREENING METHODS IN PHARMACOLOGY (Professional Elective - IV)

Course 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.

Course 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.

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.

TEXT BOOKS:

1. Screening methods in Pharmacology, Vol.-1&2 by Robert.A. Turner and Peter Hebborn.
2. Drug discovery and evaluation by H.G. Vogel and W.H. Vogel, Springerverlag, Berlin Heideleberg.
3. Handbook of experimental pharmacology by S.K. Kulkarni, Vallabh Prakashan, Delhi.

REFERENCE BOOKS:

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

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD
M.Pharm I Year II Sem (Pharmaceutical Chemistry)

ADVANCED INSTRUMENTAL ANALYSIS (Professional Elective – IV)

Course 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.

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

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, powder diffraction, structural elucidation and applications.

UNIT - II

a. **Biochromatography:** Size exclusion chromatography, ion exchange chromatography, ion pair chromatography, affinity chromatography general principles, stationary phases and mobile phases.
b. **Super critical fluid chromatography**: Principles, instrumentation, pharmaceutical applications.

UNIT - III

Capillary Electrophoresis: Overview of CE in pharmaceutical analysis, basic configuration, CE characteristics, principles of CE, methods and modes of CE. General considerations and method development in CE,

UNIT - IV

a. **DSC:** Principle, thermal transitions, instrumentation (Heat flux and power- compensation designs), Modulated DSC, Hyper DSC, experimental parameters (sample preparation, experimental conditions, calibration, heating and cooling rates, resolution, Sources of errors) and their influence, advantages and disadvantages, pharmaceutical applications.
b. **DTA**: Principle, instrumentation, advantage and disadvantage, pharmaceutical application, derivative differential thermal analysis (DDTA).
c. **TGA:** Principle, instrumentation, factors affecting results, advantages and disadvantages, pharmaceutical application.

UNIT - V

a. **Scanning electron microscope** (**SEM**): Principles, Instrumentation and applications.
b. Optical Rotatory Dispersion (ORD), Circular Dichroism, Cotton effect, Octane rule and applications.

.

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

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD
M.Pharm I Year II Sem (Pharmaceutical Chemistry)

HERBAL DRUG TECHNOLOGY (Professional Elective – IV)

Course Objectives: Helps the students in getting exposed to methods of extraction, preparation and purification of herbal extracts. To acquire knowledge on the preparation and standardization of herbal preparation. They will expose to various research institutions of natural products.

Course Out comes: Helps the students to understand the organization and research of natural products in herbal drugs industries

UNIT - I

Equipment for preparing herbal extracts: Process and equipments- Name of the equipment and its uses with merits and demerits in each of the following unit operations in the extraction process.

1. Size reduction
2. Filtration
3. Evaporation/Distillation
4. Drying of extracts
5. Solvent recovery

UNIT - II

Definition, classification of natural excipients: Sources, Chemical nature, Description parameters Pharmaceutical uses and storage conditions of following Natural excipients

Binding agents, disintegrating agents, diluents, emulsifying agents:

Acacia, Tragacanth, Alginates, CMC, Gelatin, Pectin, Lactose, Starches, Talc,

Ointment bases, suppository bases and Hardening agents: Beeswax, Cocoa butter, Lanolin, Hard paraffin

UNIT - III

Methods of preparation and Evaluation of Herbal Tablets, Capsules, Ointments and other dosage forms. Study of any three formulations under each category with respect to their formulas and claims for various herbs used in them

UNIT - IV

a. Regulations and Claims – Current Products: Label Claims, Nutrient Content Claims, health claims, Dietary Supplements Claims.
b. Food Laws and Regulations, FDA, FPO, MPO, BIS, AGMARK.

UNIT - V

a) Natural colorants: Biological Source, coloring principles, chemical nature and usage of the following Annatto, Cochineal, Caramel, Henna, Indigo, Madder, Saffron, Turmeric

b) Natural sweeteners:

1) Definition of nutritive and non-nutritive sweeteners, qualities of an ideal sweetner and sweetness potency.
2) Biological source, chemical nature, extraction details and usage of the following: Steviosides, Glycyrrhizin, Rebaudoside

REFERENCE BOOKS:

1. Textbook of Pharmacognosy by G.E. Trease, W.C. Evans, ELBS
2. Textbook of HPTLC by P.D. Seth.
3. Herbal Perfumes and cosmetics by Panda

4. Pharmacognosy by V.E Tyler, LR Brandy and JE Robbers (KM Varghese & co., Mumbai)
5. Natural Excipients by R. S Gaud, Surana.
6. Herbal Drug industry by RD Chowdary
7. Herbal Drug Technology by SS Agarwal
8. Pharmacognosy and Phytochemistry by VD Rangari.
9. Indian Pharmacopoeia
10. Dietetics by Sri Lakshmi
11. Pharmaceutical Dosage forms - Tablets (Vol I, II and III) by Lieberman, Lachman and Schwartz.
12. Pharmaceutical Dosage forms - Capsules (Vol I, II and III) by Avis, Lieberman and Lachman.

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD
M.Pharm I Year II Sem (Pharmaceutical Chemistry)

ADVANCED ORGANIC CHEMISTRY – II LAB (Lab – III)

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

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD
M.Pharm I Year II Sem (Pharmaceutical Chemistry)

ADVANCED MEDICINAL CHEMISTRY – II LAB (Lab – IV)

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.

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD
M.Pharm II Year I Sem (Pharmaceutical Chemistry)

BIOSTATISTICS (Professional Elective - V)

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

Course 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

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

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.

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD
M.Pharm II Year I Sem (Pharmaceutical Chemistry)
PHARMACEUTICAL PRODUCTION AND PACKAGING TECHNOLOGY
(Professional Elective – V)

Course 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.

Course 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.

UNIT - I
Production Area Design: Selection of plant location, Design of plant for bulk drugs and formulations (Solids, Semisolids, Injectables, Nutraceuticals 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.

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

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD
M.Pharm II Year I Sem (Pharmaceutical Chemistry)
SCALE UP AND TECHNOLOGY TRANSFER (Professional Elective - V)

Course 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.

Course Outcome: On completion of this course it is expected that students will be able to;

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

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.

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.

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD
M.Pharm (Pharmaceutical Chemistry)

ENGLISH FOR RESEARCH PAPER WRITING (Audit Course - I & II)

Prerequisite: None

Course objectives: Students will be able to:

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

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

TEXT BOOKS/ 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's book.
4. Adrian Wallwork, English for Writing Research Papers, Springer New York Dordrecht Heidelberg London, 2011

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD
M.Pharm (Pharmaceutical Chemistry)

DISASTER MANAGEMENT (Audit Course - I & II)

Prerequisite: None

Course Objectives: Students will be able to

- learn to demonstrate a critical understanding of key concepts in disaster risk reduction and humanitarian response.
- critically evaluate disaster risk reduction and humanitarian response policy and practice from multiple perspectives.
- develop an understanding of standards of humanitarian response and practical relevance in specific types of disasters and conflict situations.
- 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

UNIT-I:

Introduction:

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

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-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 Preparedness and Management:

Preparedness: Monitoring of Phenomena Triggering A Disaster or Hazard; Evaluation of Risk: Application of Remote Sensing, Data from Meteorological and Other Agencies, Media Reports: Governmental and Community Preparedness.

UNIT-IV:

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.

UNIT-V:

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.

TEXT BOOKS/ REFERENCES:

1. R. Nishith, Singh AK, “Disaster Management in India: Perspectives, issues and strategies “’New Royal book Company.
2. Sahni, Pardeep Et. Al. (Eds.),” Disaster Mitigation Experiences and Reflections”, Prentice Hall of India, New Delhi.
3. Goel S. L., Disaster Administration and Management Text and Case Studies”, Deep &Deep Publication Pvt. Ltd., New Delhi.

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD
M.Pharm (Pharmaceutical Chemistry)

SANSKRIT FOR TECHNICAL KNOWLEDGE (Audit Course - I & II)

Prerequisite: None

Course Objectives:

- To get a working knowledge in illustrious Sanskrit, the scientific language in the world
- Learning of Sanskrit to improve brain functioning
- Learning of Sanskrit to develop the logic in mathematics, science & other subjects enhancing the memory power
- The engineering scholars equipped with Sanskrit will be able to explore the huge knowledge from ancient literature

Course Outcomes: Students will be able to

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

UNIT-I:
Alphabets in Sanskrit,

UNIT-II:
Past/Present/Future Tense, Simple Sentences

UNIT-III:
Order, Introduction of roots,

UNIT-IV:
Technical information about Sanskrit Literature

UNIT-V:
Technical concepts of Engineering-Electrical, Mechanical, Architecture, Mathematics

TEXT BOOKS/ REFERENCES:

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

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD
M.Pharm (Pharmaceutical Chemistry)

VALUE EDUCATION (Audit Course - I & II)

Prerequisite: None

Course Objectives: Students will be able to

- Understand value of education and self- development
- Imbibe good values in students
- Let the should know about the importance of character

Course outcomes: Students will be able to

- Knowledge of self-development
- Learn the importance of Human values
- Developing the overall personality

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.

UNIT-IV:
Avoid fault Thinking. Free from anger, Dignity of labour. Universal brotherhood and religious tolerance. 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

TEXT BOOKS/ REFERENCES:

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

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD
M.Pharm (Pharmaceutical Chemistry)

CONSTITUTION OF INDIA (Audit Course - I & II)

Prerequisite: None

Course Objectives: Students will be able to:

- Understand the premises informing the twin themes of liberty and freedom from a civil rights perspective.
- To address the growth of Indian opinion regarding modern Indian intellectuals' constitutional role and entitlement to civil and economic rights as well as the emergence of nationhood in the early years of Indian nationalism.
- To address the role of socialism in India after the commencement of the Bolshevik Revolution in 1917 and its impact on the initial drafting of the Indian Constitution.

Course Outcomes: Students will be able to:

- Discuss the growth of the demand for civil rights in India for the bulk of Indians before the arrival of Gandhi in Indian politics.
- Discuss the intellectual origins of the framework of argument that informed the conceptualization of social reforms leading to revolution in India.
- 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.
- Discuss the passage of the Hindu Code Bill of 1956.

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, Qualification, 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: Zila Pachayat. Elected officials and their roles, CEO Zila Pachayat: 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.

TEXT BOOKS/ REFERENCES:

1. The Constitution of India, 1950 (Bare Act), Government Publication.
2. Dr. S. N. Busi, Dr. B. R. Ambedkar framing of Indian Constitution, 1st Edition, 2015.
3. M. P. Jain, Indian Constitution Law, 7th Edn., Lexis Nexis, 2014.
4. D.D. Basu, Introduction to the Constitution of India, Lexis Nexis, 2015.

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD
M.Pharm (Pharmaceutical Chemistry)

PEDAGOGY STUDIES (Audit Course - I & II)

Prerequisite: None

Course Objectives: Students will be able to:

- Review existing evidence on the review topic to inform programme design and policy making undertaken by the DfID, other agencies and researchers.
- Identify critical evidence gaps to guide the development.

Course Outcomes: Students will be able to understand:

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

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 indepth stage: quality assessment of included studies. How can teacher education (curriculum and practicum) and the scho 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.

TEXT BOOKS/ 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.
7. www.pratham.org/images/resource%20working%20paper%202.pdf.

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD
M.Pharm (Pharmaceutical Chemistry)

STRESS MANAGEMENT BY YOGA (Audit Course - I & II)

Prerequisite: None

Course Objectives:

- To achieve overall health of body and mind
- To overcome stress

Course Outcomes: Students will be able to:

- Develop healthy mind in a healthy body thus improving social health also
- Improve efficiency

UNIT-I:
Definitions of Eight parts of yog. (Ashtanga)

UNIT-II:
Yam and Niyam.

UNIT-III:
Do`s and Don't's in life.
i) Ahinsa, satya, astheya, bramhacharya and aparigraha
ii) Shaucha, santosh, tapa, swadhyay, ishwarpranidhan

UNIT-IV:
Asan and Pranayam

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

TEXT BOOKS/ REFERENCES:

1. 'Yogic Asanas for Group Tarining-Part-I": Janardan Swami Yogabhyasi Mandal, Nagpur
2. "Rajayoga or conquering the Internal Nature" by Swami Vivekananda, Advaita Ashrama (Publication Department), Kolkata

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD
M.Pharm (Pharmaceutical Chemistry)

PERSONALITY DEVELOPMENT THROUGH LIFE ENLIGHTENMENT SKILLS
(Audit Course - I & II)

Prerequisite: None

Course Objectives:

- To learn to achieve the highest goal happily
- To become a person with stable mind, pleasing personality and determination
- To awaken wisdom in students

Course Outcomes: Students will be able to

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

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)

UNIT-II:

Neetisatakam-Holistic development of personality

- Verses- 52,53,59 (dont's)
- Verses- 71,73,75,78 (do's)

UNIT-III:

Approach to day to day work and duties.

- Shrimad Bhagwad Geeta: 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-IV:

Statements of basic knowledge.

- Shrimad Bhagwad Geeta: Chapter2-Verses 56, 62, 68
- Chapter 12 -Verses 13, 14, 15, 16,17, 18
- Personality of Role model. Shrimad Bhagwad Geeta:

UNIT-V:

- Chapter2-Verses 17, Chapter 3-Verses 36,37,42,
- Chapter 4-Verses 18, 38,39
- Chapter18 – Verses 37,38,63

TEXT BOOKS/ REFERENCES:

1. "Srimad Bhagavad Gita" by Swami Swarupananda Advaita Ashram (Publication Department), Kolkata.
2. Bhartrihari's Three Satakam (Niti-sringar-vairagya) by P.Gopinath, Rashtriya Sanskrit Sansthanam, New Delhi.