# JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD

**PHARMACEUTICAL ANALYSIS& QUALITY ASSURANCE**

**COURSE STRUCTURE AND SYLLABUS**

**I Year – I Semester**

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Category** | **Course Title** | **Int. marks** | **Ext. marks** | **L** | **P** | **C** |
| Core Course I | Advanced Pharmaceutical Analysis | 25 | 75 | 4 | -- | 4 |
| Core Course II | Food Analysis | 25 | 75 | 4 | -- | 4 |
| Core Course III | Modern Pharmaceutical Analytical Techniques | 25 | 75 | 4 | -- | 4 |
| Core Elective I | 1. Pharmaceutical Validation 2. Intellectual Property Rights | 25 | 75 | 4 | -- | 4 |
| Open Elective I | 1. Drug Regulatory Affairs 2. Pharmacoepidemiology and Pharmacoeconomics 3. Pharmaceutical Management 4. Herbal Cosmetics Technology 5. Pharmaceutical Formulation Technology | 25 | 75 | 4 | -- | 4 |
| Laboratory I | Modern Pharmaceutical Analytical Techniques Lab | 25 | 75 | - | -6 | 3 |
| Laboratory II | Advanced Pharmaceutical Analysis Lab | 25 | 75 | -- | 6 | 3 |
| Seminar I | Seminar | 50 | -- | -- | 4 | 2 |
| **Total Credits** | |  |  | **20** | **16** | **28** |

**I Year – II Semester**

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Category** | **Course Title** | **Int. marks** | **Ext. marks** | **L** | **P** | **C** |
| Core Course IV | Advanced Instrumental Analysis | 25 | 75 | 4 | -- | 4 |
| Core Course V | Quality Control and Quality Assurance | 25 | 75 | 4 | -- | 4 |
| Core Course VI | Modern Bio analytical Techniques | 25 | 75 | 4 | -- | 4 |
| Core Elective II | 1. Biostatistics And Research Methodology 2. Spectral Analysis | 25 | 75 | 4 | -- | 4 |
| Open Elective II | 1. Screening Methods and Clinical Research 2. Stability of Drugs and Dosage Forms 3. Entrepreneurship management 4. Nano Based Drug Delivery Systems 5. Herbal & Cosmetics Analysis | 25 | 75 | 4 | -- | 4 |
| Laboratory III | Advanced Instrumental Analysis Lab | 25 | 75 | - | 6 | 4 |
| Laboratory IV | Quality Control and Quality Assurance Lab | 25 | 75 | -- | 6 | 2 |
| Seminar II | Seminar | 50 | -- | -- | 4 | 2 |
| **Total Credits** |  |  |  | **20** | **16** | **28** |

**II Year - I Semester**

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

**II Year - II Semester**

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

**JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD**

**I Year – I SemM.Pharm (PAQA/QA)** (**Core course–I)**

**ADVANCED PHARMACEUTICAL ANALYSIS**

**Objective:** The principles and procedures for the determination of various pharmaceutical bulk drugs and their formulations belonging to different categories are discussed in detail. The applications of the important reagents like MBTH, FC, PDAB etc. in the determination of the pharmaceuticals are also discussed.

**UNIT I**

Principles and procedures involved in the determination of the official compounds in IP with the following analytical techniques

* 1. Non-aqueous C. Complexometric
  2. Oxidation-reduction D. Diazotization methods

**UNIT II**

A detailed study of the principles and procedures involved in the quantitative determination of the following organic functional groups

* + 1. Amines C. Carbonyl compounds
    2. Esters D. Hydroxy and carboxyl

E. Amino Acids

**UNIT III**

**a. ReferenceStandards:**Types, preparation methods and uses.

b. Principles and procedures involved in using the following reagents in the determination of pharmaceutical dosage forms official in IP

1. MBTH (3-methyl-2-benzothiazolone hydrazone)
2. F.C. Reagent (Folin-Ciocalteu)
3. PDAB (*para-*Dimethyl Amino Benzaldehyde)
4. 2, 3, 5 - *tri*Phenyltetrazolium salt
5. 2,6 *di -*ChloroquinoneChlorimide
6. *N* - (1-naphthyl) ethylenediaminedihydrochloride (B.M. Reagent)
7. Carr – Price Reagent
8. 2,4 - DNP

**UNIT-IV**

1. **Atomic Absorption Spectrometry (AAS):** Principle, instrumentation, sample automization techniques, interferences. Elemental analysis such as determination of Sodium, Potassium, Calcium, Chlorine, Bromine and Iodine.
2. **Radio chemical methods including RIA:** Radio Active Isotopes, tagging of compounds, Labeled Reagents, Isotope dilution Analysis, Scintillation counter, RIA.

**UNIT-V**

1. **Dissolution Tests :** Types of Dissolution apparatus, dissolution test requirements for immediate release, delayed release, extended release dosage forms, coated ,uncoated, enteric coated, gelatin capsules etc..
2. **Microbiological assays and Biological tests:** Antimicrobial effectiveness testing, microbial limit tests, sterility test. Antibiotics-microbial assays, bacterial endotoxins test.

**Outcome:** The quantitative determination of various organic compounds is clearly understood. The spectral analysis, dissolution parameters and microbial assays are also learned.

**TEXT BOOKS**

1. Pharmaceutical Chemistry by Becket and Stanlake
2. Pharmaceutical Analysis by Higuchi, Bechmman and Hassan
3. Instrumental Methods of Chemical Analysis By B.K. Sharma
4. A Text Book of Pharmaceutical Analysis by Kennenth A. Conners

**REFERENCES**

1. Remington’s Pharmaceutical Sciences by Alfonso and Gennaro
2. Quantitative Analysis of Drugs in Pharmaceutical Formulations by P.D. Sethi
3. Indian Pharmacopoeia 2010
4. Journals (Indian Drugs, IJPS etc.)

**JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD**

**I Year – I SemM.Pharm (PAQA/QA) (Core course–II)**

**Food Analysis**

**Objective**

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

**UNIT I**

1. **Carbohydrates:** Classification and properties of foodcarbohydrates, General methods of analysis of foodcarbohydrates,
2. **Proteins**: Chemistry and classification of amino acids andproteins, Physico-Chemical properties of protein and theirstructure, general methods of analysis of proteins and amino acids

**UNIT II**

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

**UNIT III**

1. **Quality Control of Excipients:** Tests related to excipients such as bulk density, tapped density, particle size distribution, pH, moisture content, viscosity (dynamic), loss on drying, ash content, conductivity.
2. **Excipients of interest:** disintegrating agents, binders, emulsifiers, viscosity modifiers and preservatives including preservative challenge test.

**UNIT IV**

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

**UNIT V**

In process quality control tests carried on the following dosage forms

A. Tablets B. Capsules C. Parenterals D. Liquid Orals

**Outcome:**

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

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

**TEXT BOOKS**

* 1. Pharmaceutical Chemistry by Beckett and Stanlake
  2. Quantitative Analysis of Drugs in Pharmaceutical Formulations by P.D.Sethi
  3. Pharmaceutical Analysis by Higuchi, Bechmman and Hassan
  4. Theory and Practice of Industrial Pharmacy by Lieberman and Lachman
  5. Ahuja S, Alsante KM. Handbook of isolation and characterization of impurities in pharmaceuticals. Academic press, California, 2003

**REFERENCE BOOKS**

1. Remington’s Pharmaceutical Sciences by Alfonso and Gennaro
2. David Pearson. The Chemical Analysis of Foods, 7thed., 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**

**I Year – I SemM.Pharm (PAQA/QA) (Core course–III)**

**MODERN PHARMACEUTICAL ANALYTICAL TECHNIQUES**

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

**UNIT I**

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

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

**UNIT II**

1. Gas chromatography: Introduction, fundamentals, instrumentation, columns: preparation and operation, detection, derivatization.
2. HPLC: Basic parameters, Principles and instrumentation, solvents and columns used, Operational modes, detection and applications of HPLC
3. HPTLC: Theory and principle, instrumentation, elution techniques and pharmaceutical applications

**UNIT III**

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

**UNIT IV**

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

**UNIT V**

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

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

**REFERENCES :**

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

**JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD**

**I Year – I SemM.Pharm (PAQA/QA)**

(Core Elective I)

**PharmaceuticalValidation**

**Objective**

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

**UNIT I.**

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

**UNIT II**

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

**UNIT III**

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

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

**UNIT IV**

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

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

**UNIT V**

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

**Outcome:**

Upon completion of the subject student shall be able to

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

**REFERENCES:**

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

**JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD**

**I Year – I SemM.Pharm (PAQA/QA)**

**(Core Elective-I)**

**INTELLECTUAL PROPERTY RIGHTS**

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

**UNIT I**

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

**UNIT II**

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

**UNIT III**

a.Salient features of Indian Patents (Amendments) Act 1999, 2002 and 2005. US and European Patent System,

b. Background, Salient Features and Impact of International Treaties / Conventions like

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

**UNIT IV**

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

**UNIT V**

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

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

**RECOMMENDED BOOKS:**

1. Research Methodology concepts and cases by Depak Chawla, NeenaSondhi
2. Draft manual of Patent Practice and Procedure -2008 , The Patent Office, India
3. Manual of Patent Office Practice and Procedure -2010
4. Original Laws Published by Govt. of India
5. Protection of Industrial Property rights by P.Das and Gokul Das
6. Law and Drugs, Law Publications by S.N. Katju
7. Laws of drugs in India, Hussain
8. New drug approval process,5th edition, by Guarino
9. Commercial Manual on Drugs and Cosmetics 2004, 2nd edition
10. Drugs and Cosmetics act by Vijay Malik
11. Good Manufacturing Practices for Pharmaceuticals, S.H. Wiling, Vol. 78, Marcel Decker.
12. fda.org,wipo.int,patentlawlinks.com, hc-sc.gc.ca,ich.org,cder.org
13. Current good manufacturing practices for pharmaceuticals by ManoharA.Potdar
14. Pharmaceutical Regulatory affairs –selected topics. CVS subhramanyam and J Thimma settee. Delhi, VallabhaPrakasham, 2012.

**JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD**

**I Year – I SemM.Pharm (PAQA/QA)**

**(Open Elective I)**

**DRUG REGULATORY AFFAIRS**

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

**UNIT I**

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

**UNIT II**

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

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

**UNIT III**

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

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

**UNIT IV**

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

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

**UNIT V**

**Governing Regulatory Bodies across the globe.**

Country Authority Submission

1. U.S Food & Drug Administration USDMF
2. Canada Therapeutic Product Directorate DMF
3. Europe

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

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

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

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

**Outcome:**

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

**TEXT AND REFERENCE BOOKS**

1. Original laws published by Govt. of India.

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

3. Laws of Drugs in India by Hussain.

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

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

**JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD**

**I Year – I SemM.Pharm (PAQA/QA)**

**(Open Elective I)**

**PHARMACOEPIDEMIOLOGY & PHARMACOECONOMICS**

**Objective:**

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

appropriatePharmacoeconomic model should be applied for a health careregimen.

**UNIT-I**

**Introduction to Pharmacoepidemiology:**

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

**UNIT-II**

**Pharmacoepidemiological Methods:**

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

**UNIT-III**

**Introduction to Pharmacoeconomics:**

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

**UNIT-IV**

**Pharmacoeconomic evaluations:**

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

**UNIT-V**

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

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

**Outcome:**

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

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

**REFERENCES**

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

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

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

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

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

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

7. Graker, Dennis. Pharmacoeconomics and outcomes.

8. Walley, Pharmacoeconomics.

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

10. Relevant review articles from recent medical and pharmaceutical literature

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

**JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD**

**I Year – I SemM.Pharm (PAQA&QA) (Open Elective I)**

**PHARMACEUTICAL MANAGEMENT**

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

**UNIT I**

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

**UNIT II**

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

**UNIT III**

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

**UNIT IV**

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

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

**UNIT V**

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

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

**Outcome:**

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

**TEXT AND REFERENCE BOOKS**

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

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

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

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

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

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

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

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

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

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

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

**JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD**

**I Year – I SemM.Pharm (PAQA/QA)**

**(Open Elective I)**

**HERBAL COSMETICS TECHNOLOGY**

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

**UNIT I**

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

**UNIT II**

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

**UNIT III**

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

**UNIT IV**

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

**UNIT V**

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

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

**REFERENCES:**

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

**JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD**

**I Year – I SemM.Pharm (PAQA/QA) (Open Elective I)**

**PHARMACEUTICAL FORMULATION TECHNOLOGY**

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

**Unit I:**

**Preformulation:** Goals of preformulation, solid state manipulation and characterization. pH dependent solubility of drug, equilibrium solubility, intrinsic dissolution of drug, particle size distribution.

Flow of Powders: Physical properties and importance. Angle of repose, Cars index, compressibility, bulk density, tapped density.

**Unit II:**

Excipients used in various dosage forms like tablets, capsules, emulsions, suspensions, semisolids and sterile products. Knowledge of packing materials. Drug- excipient compatibility- Drug stability, factors affecting stability, stabilization methods.

**Unit III:**

**Tablets:** Types of tablets, granulation methods, highlighting operations such as mixing, drying, milling, blending, lubrication and compression.

Tablet coating: Types of coating, steps involved in coating process- pan coating and fluid bed coating and problems associated with coating.

Hard Gelatin Capsules: General principles and steps involved in the production of drug loaded hard gelatin capsules, filling operation, filling of powders, granules and pellets.

**Unit IV:**

**Dissolution:** Principles of dissolution, factors influencing dissolution, official methods and apparatus. Dissolution of immediate release, controlled release and delayed release products.

**Unit V:**

**Stability testing:** Chemical degradation and preventive measures. Various stability testing conditions and use of stabilizers in packing

**Outcome:** Students shall explain thepreformulation parameters, apply ICH guidelines and evaluate drug, drug excipients compatibility. Students also explain about formulation and development, use of excipients in tablets, powders, capsules, micro-encapsules and coating techniques. They also learn and apply the statistical design in different formulations.

**JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD**

**I Year – I SemM.Pharm (PAQA/QA)**

**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)

1. Separation and calculation of Rf values by using paper chromatography, TLC, HPTLC Technique (2-3 experiments)
2. Calibration of glasswares
3. Calibration of pH meter
4. Calibration of UV-Visible spectrophotometer
5. Calibration of FTIR spectrophotometer
6. Calibration of HPLC instrument

**JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD**

**I Year – I SemM.Pharm (PAQA/QA)**

**ADVANCED PHARMACEUTICAL ANALYSIS LAB**

**List of experiments**

1. Determination of official compounds by Non-aqueous titrations
2. Determination of drugs containing di and trivalent metal ions by complexometric titrations
3. Determination of sulfa drugs by diazotization
4. Determination of Vitamin C by redox titration

5. Quantitative determination of hydroxyl group.

6. Quantitative determination of amino group

7. Colorimetric determination of drugs by using different reagents

8. Quantitative determination of pharmaceutical dosage forms belonging to alkaloids, antibiotics,   
vitamins, glycosides and steroids

**JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD**

**I Year – II Sem M.Pharm (PHARMACEUTICAL ANALYSIS)**

**(Core course IV)**

**ADVANCED INSTRUMENTAL ANALYSIS**

**Objectives**

This subject deals with various hyphenated analytical instrumental techniquesfor identification, characterization and quantification of drugs. Instruments dealtare LC-MS, GC-MS, and hyphenated techniques.

**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**

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

**UNIT-III**

**Capillary Electrophoresis**: Overview of CE in pharmaceuticalanalysis, basic configuration, CE characteristics, principles of CE,methods and modes of CE. General considerations and method

development in CE,

**UNIT-IV**

1. **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.
2. **DTA**: Principle, instrumentation, advantage and disadvantage, pharmaceutical application, derivative differential thermal analysis (DDTA).
3. **TGA:** Principle, instrumentation, factors affecting results, advantages and disadvantages, pharmaceutical application.

**UNIT-V**

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

**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. 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**

**I Year – II Sem M.Pharm (PHARMACEUTICAL ANALYSIS)**

**(Core course V)**

**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**

* 1. **Impurity and stability studies:** Definition, classification of impurities in drug Substance or Active Pharmaceutical Ingredients and quantification of impurities as per ICH guidelines.
  2. **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
3. Vol. 1 and Vol. 2, WHO 2007)
4. GMP by Mehra
5. Pharmaceutical Process Validation by Berry and Nash
6. 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.

**JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD**

**I Year – II Sem M.Pharm (PHARMACEUTICAL ANALYSIS)**

**(Core course VI)**

**MODERN BIO-ANALYTICAL TECHNIQUES**

**Objectives:**

This subject is designed to provide detailed knowledge about the importance ofanalysis of drugs in biological matrices.

**UNIT I**

Extraction of drugs and metabolites from biological matrices:General need, principle and procedure involved in theBioanalytical methods such as Protein precipitation, Liquid -Liquid extraction and Solid phase extraction and other novelsample preparation approach.

**UNIT II**

**Biopharmaceutical Consideration:**Introduction, Biopharmaceutical Factors Affecting Drug

Bioavailability, In Vitro: Dissolution and Drug Release Testing,Alternative Methods of Dissolution Testing Transport models,Biopharmaceutics Classification System. Solubility: Experimental

methods. Permeability: In-vitro, in-situ and In-vivo methods.

**UNIT III**

**Bioanalysis and bioanalytical method validation:**

1. Types of body fluids, requirement of analysis, matrix effects, non-biological analytical samples.
2. Bioanalytical method validation: USFDA and EMEA guidelines. Acceptance criteria in comparison to non-biological samples.

**UNIT-IV**

**Pre-Formulation:**

A consideration of following characteristics of medicinal agents in their dosage form:

**Physical characteristics-**

Particle size, polymorphism, crystal form, solubility, Interfacial tension, Salt formation,

wetting of solids, flow characteristics, compressibility and Partition coefficient.

**Chemical Characteristics-**

**Degradation:** Hydrolytic, oxidative, reductive and photolytic, Drug - Excipient

compatibility studies.

**UNIT V**

1. **Automation and computer-aided analysis, LIMS**: The concept of auto samplers and high throughput analysis, computer controlled instrumentation and networked laboratory. Peculiarities of laboratory information management systems (LIMS).
2. **Drug Product Performance, In Vivo:**: Purpose of Bioavailability Studies, Bioavailability and Bioequivalence Studies, Clinical Significance of Bioequivalence Studies.

**Outcomes:**

Upon completion of the course, the student shall be able to understand

Extraction of drugs from biological samples

Separation of drugs from biological samples using different techniques

Guidelines for BA/BE studies

**REFERENCES**

1. Analysis of drugs in Biological fluids - Joseph Chamberlain, 2nd Edition.CRC Press, Newyork. 1995.

2. Principles of Instrumental Analysis - Doglas A Skoog, F. James Holler,Timothy A. Nieman, 5th edition, Eastern press, Bangalore, 1998.

3. Pharmaceutical Analysis - Higuchi, Brochmman and Hassen, 2nd Edition,Wiley – Interscience Publications, 1961.

4. Pharmaceutical Analysis- Modern methods – Part B - J W Munson,Volume 11, Marcel Dekker Series

5. Practical HPLC method Development – Snyder, Kirkland, Glaich, 2ndEdition, John Wiley & Sons, New Jercy. USA.

6. Chromatographic Analysis of Pharmaceuticals – John A Adamovics, 2ndEdition, Marcel Dekker, Newyork, USA. 1997.

7. Chromatographic methods in clinical chemistry & Toxicology – Roger LBertholf, Ruth E Winecker, John Wiley & Sons, New Jercy, USA. 2007.

8. Good Laboratory Practice Regulations, 2nd Edition, Sandy Weinberg Vol.69, Marcel Dekker Series, 1995.

9. Good laboratory Practice Regulations – Allen F. Hirsch, Volume 38,Marcel Dekker Series, 1989.

10. ICH, USFDA & CDSCO Guidelines

11. Palmer

**JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD**

**I Year – II Sem M.Pharm (PHARMACEUTICAL ANALYSIS)**

(**Core Elective –II)**

**BIOSTATISTICS AND RESEARCH METHODOLOGY**

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

**UNIT I**

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

**UNIT II**

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

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

**UNIT III**

**Measures of Correlation and Regression**

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

**Hypothesis testing:** Student ‘t’ test, Chi square test,

**UNIT IV**

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

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

**UNIT V**

Developing a research question, Resources for research question,

Literature Review: Traditional Qualitative Review,

Meta-Analysis—A Quantitative Review

Preparation of Research Proposal

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

The research report paper writing/ thesis writing:

Different parts of the research paper

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

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

**Text Books**

1. Deepak Chawla NeenaSondhi, Research Methodology Concepts and Cases, Vikas books publishers
2. Donald H. McBurney -Theresa L. White “Research Methods” ( Cengage learning India Pvt. Ltd)

**Reference Books**

1. 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.
6. Biostatistics and Computer Applications by G.N. Rao and N.K. Tiwari
7. Fundamentals of Biostatistics by Khan and Khanum
8. Research Methodology by RK Khanna bis and SuvasisSaha
9. Research methods and Quantity methods by G.N.Rao
10. A practical approach to PG dissertation.

**JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD**

**I Year – II Sem M.Pharm (PHARMACEUTICAL ANALYSIS)**

**(Core Elective II)**

**SPECTRAL ANALYSIS**

**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 (Characterestics 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

**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. 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**

**I Year – II Sem M.Pharm (PHARMACEUTICAL ANALYSIS)**

(Open Elective- II)

**SCREENING METHODS AND CLINICAL RESEARCH**

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

**UNIT I**

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

**UNIT II**

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

**UNIT III**

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

**UNIT IV**

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

**UNIT V**

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

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

**Text Books:**

1. Screening methods in Pharmacology, Vol.-1&2 by Robert .A. Turner and Peter Hebborn.

2. Drug discovery and evaluation by H.G.Vogel and W.H.Vogel, Springerverlag, Berlin Heideleberg.

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

4. Textbook of clinical trials edited by David Machin, Simon Day and Sylvan green.

, VallabhPrakashan, Delhi.

**Reference Books:**

1. ICH of technical requirements for registration of pharmaceuticals for human use, ICH harmonized tripartite guidelines - Guidelines for good clinical practice, E6, May 1996.

2. Good clinical practice - Guidelines for Clinical trials on pharmaceutical products in India, Central drug standard control organization, New Delhi, Minister of Health- 2001.

**JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD**

**I Year – II Sem M.Pharm(PHARMACEUTICAL ANALYSIS)**

**(Open Elective- II)**

**STABILITY OF DRUGS AND DOSAGE FORMS**

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

**UNIT-I**

**Drug decomposition mechanisms:**

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

**UNIT-II**

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

Physical stability testing of dosage forms:

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

**UNIT-III**

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

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

**UNIT-IV**

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

**UNIT-V**

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

Stability studies: Concept of stability studies.

a) cGMP& ICH guidelines for Accelerated stability Testing.

b) Interaction of containers & closure Compatibility Testing.

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

**REFERENCE BOOKS :**

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

**JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD**

**I Year –II Sem M.Pharm(PHARMACEUTICAL ANALYSIS)**

**(Open Elective- II)**

**ENTREPRENEURSHIP MANAGEMENT**

**Objective:** This course is designed to impart knowledge and skills necessary to train the students on entrepreneurship management.

**UNIT I**

Conceptual Frame Work: Concept need and process inentrepreneurship development. Role of enterprise in national 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 mobilisation -finance, technology, raw material, site and manpower. Costing

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

**UNIT IV**

Growth Strategies And Networking: Performance appraisal 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 mobilisation 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 NewEntrepreneurs, Ahmedabad EDII

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

**JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD**

**I Year – II Sem M.Pharm (PHARMACEUTICAL ANALYSIS)**

**(OpenElective–II)**

**NANO BASED DRUG DELIVERY SYSTEMS**

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

**UNIT I – Introduction to Nanotechnology**

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

**UNIT II – Synthesis of Nanomaterials**

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

**UNIT III – Biomedical applications of Nanotechnology**

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

**Unit IV**

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

**Unit V**

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

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

**Recommended Books:**

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

**JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD**

**I Year –II Sem M.Pharm (PHARMACEUTICAL ANALYSIS)**

**(Open Elective- II)**

**HERBAL AND COSMETIC ANALYSIS**

**Objectives**

This course is designed to impart knowledge on analysis of herbal products.Regulatory requirements, herbal drug interaction with monographs.Performance evaluation of cosmetic products is included for the betterunderstanding of the equipments used in cosmetic industries for the purpose.

**UNIT I**

Herbal remedies- Toxicity and Regulations: Herbals vsConventional drugs, Efficacy of herbal medicine products,Validation of Herbal Therapies, Pharmacodynamic andPharmacokinetic issues. Herbal drug standardization: WHO andAYUSH guidelines.

**UNIT II**

Adulteration and Deterioration: Introduction, types ofadulteration/substitution of herbal drugs, Causes and Measure ofadulteration, Sampling Procedures, Determination of ForeignMatter, DNA Finger printing techniques in identification of drugs ofnatural origin, heavy metals, pesticide residues, phototoxin andmicrobial contamination in herbal formulations.

Regulatory requirements for setting herbal drug industry:Global marketing management, Indian and international patentlaw as applicable herbal drugs and natural products and itsprotocol.

**UNIT III**

Testing of natural products and drugs: Effect of herbal medicine on clinical laboratory testing, Adulterant Screening usingmodern analytical instruments, Regulation and dispensing ofherbal drugs, Stability testing of natural products, protocol.Monographs of Herbal drugs: Study of monographs of herbal

drugs and comparative study in IP, USP, Ayurvedic Pharmacopoeia, American herbal Pharmacopoeia, British herbalPharmacopoeia, Siddha and Unani Pharmacopoeia, WHOguidelines in quality assessment of herbal drugs.

**UNIT IV**

Herbal drug-drug interaction: WHO and AYUSH guidelines forsafety monitoring of natural medicine, Spontaneous reportingschemes for bio drug adverse reactions, bio drug-drug and biodrug-food interactions with suitable examples. Challenges inmonitoring the safety of herbal medicines.

**UNIT V**

Evaluation of cosmetic products: Determination of acid value,ester value, saponification value, iodine value, peroxide value,rancidity, moisture, ash, volatile matter, heavy metals, fineness ofpowder, density, viscosity of cosmetic raw materials and finishedproducts. Study of quality of raw materials and general methods of analysis of raw material used in cosmetic manufacture as perBIS.

Indian Standard specification laid down for sampling and testingof various cosmetics in finished forms such as baby careproducts, skin care products, dental products, personal hygienepreparations, lips sticks. Hair products and skin creams by theBureau Indian Standards.

**Outcomes**

At completion of this course student shall be able to understand

* Determination of herbal remedies and regulations
* Analysis of natural products and monographs
* Determination of Herbal drug-drug interaction
* Principles of performance evaluation of cosmetic products.

**REFERENCES**

1. Pharmacognosy by Trease and Evans

2. Pharmacognosy by Kokate, Purohit and Gokhale

3. Quality Control Methods for Medicinal Plant, WHO, Geneva

4. Pharmacognosy&Pharmacobiotechnology by AshutoshKar

5. Essential of Pharmacognosy by Dr.S.H.Ansari

6. Cosmetics – Formulation, Manufacturing and Quality Control, P.P.

Sharma, 4th edition, Vandana Publications Pvt. Ltd., Delhi

7. Indian Standard specification, for raw materials, BIS, New Delhi.

8. Indian Standard specification for 28 finished cosmetics BIS, New Delhi

9. Harry’s Cosmeticology 8th edition

10. Suppliers catalogue on specialized cosmetic excipients

11. Wilkinson, Moore, seventh edition, George Godwin. Poucher’s Perfumes,

Cosmetics and Soaps

12. Hilda Butler, 10th Edition, Kluwer Academic Publishers. Handbook of

Cosmetic Science and Technology, 3rd Edition,

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**I Year – II Sem M.Pharm (PHARMACEUTICAL ANALYSIS)**

**ADVANCED INSTRUMENTAL ANALYSIS LAB**

**List of Experiments**

1. Determination of bulk Drugs and formulations by UV-Visible, HPLC, GC etc. methods
2. Determination of total chloride in thiamine HCl
3. Detection and determination of preservatives, antioxidants and colourants in pharmaceutical   
    preparations
4. Determination of chlorides and sulphates by Nephelo -Tubmidimetry
5. Determination of moisture content in sorbitol, sodium citrate, ampicillin etc.
6. Assays of official compounds by Flourimetry
7. Determination of compounds of sodium, potassium and calcium by Flame photometry.

(Note: Minimum of two experiments covering each of the above mentioned topics)

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**QUALITY CONTROL AND QUALITY ASSURANCE LAB**

**List of Experiments**

1. QC tests for tablets and capsules (minimum 3 experiments)
2. QC tests for oral liquids and parenterals (minimum 3 experiments)
3. Forced degradation studies of some drugs.
4. Interpretation of spectras by IR, NMR and MASS
5. Estimation of drugs by specified colorimetric reagents
6. Assay of drug formulations using UV-Spectrophotometer (Any four)
7. Demonstration of functional groups of the given samples by IR Spectrophotometer.
8. Physicochemical tests for water
9. Solubility studies of weakly acidic and weakly basic drugs.