**JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD**
**Course scheme for M. Pharm (Pharmaceutical Analysis) 2019-20**

**M. Pharm Sem-I.**

| Course Number | Subject | Scheme of studies Per Week | | | Credits |
|---|---|---|---|---|---|
| | | L | T | P | |
| 1MPA01 | Program core-I<br>Modern Pharmaceutical Analytical Techniques | 3 | 0 | 0 | 3 |
| 1 MPA02 | Program core-II<br>Pharmaceutical Food Analysis | 3 | 0 | 0 | 3 |
| 1 MPAPEI | Program Elective-I<br>1. Advanced Pharmaceutical Analysis<br>2. Drug Regulatory Affairs<br>3. Phytochemistry | 3 | 0 | 0 | 3 |
| 1MPAPEII | Program Elective-II<br>4. Pharmaceutical Validation<br>5. Cosmetics and Cosmeceuticals<br>6. Industrial Pharmacognostical Technology | 3 | 0 | 0 | 3 |
| 1 MPAA01 | Research Methodology & Intellectual Property Rights | 2 | 0 | 0 | 2 |
| 1 MPAA02 | Audit course | 2 | 0 | 0 | 0 |
| 1 MPAL03 | Laboratory 1- Modern Pharmaceutical Analytical Techniques lab | 0 | 0 | 4 | 2 |
| 1 MPAL04 | Laboratory 2 – Programme Elective - 1/3/5/6 | 0 | 0 | 4 | 2 |
| **Total credits:** | | | | | **18** |

**M. Pharm Sem-II**

| Course Number | Subject | Scheme of studies Per Week | | | Credits |
|---|---|---|---|---|---|
| | | L | T | P | |
| 2 MPA05 | Program core-III<br>Advanced Instrumental Analysis I | 3 | 0 | 0 | 3 |
| 2 MPA06 | Program core-IV<br>Modern Bio-analytical Techniques | 3 | 0 | 0 | 3 |
| 2 MPAPEIII | Program Elective-III<br>7. Pharmaceutical Quality Control and Quality Assurance<br>8. Herbal Cosmetics<br>9. Pharmacoepidomology and | 3 | 0 | 0 | 3 |

| | | | | | |
|---|---|---|---|---|---|
| | Pharmacoeconomics | | | | |
| 2 MPAPEIV | Program Elective-IV<br>10. Advanced Instrumental Analysis - II<br>11. Neutraceuticals<br>12. Clinical Research and Pharmacovigilance | 3 | 0 | 0 | 3 |
| 2 MPAA03 | Audit Course | 2 | 0 | 0 | 0 |
| 2 MPAL07 | Laboratory – 3 Advanced Instrumental Analysis I Lab | 0 | 0 | 4 | 2 |
| 2 MPAL08 | Laboratory – 4 Programme Elective – 7/8/10/11 | 0 | 0 | 4 | 2 |
| 2 MPA09 | Mini Project with Seminar | 2 | 0 | 0 | 2 |
| **Total credits:** | | | | | **18** |

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

**M. Pharm Sem-III**

| Course Number | Subject | Scheme of studies Per Week | | | Credits |
|---|---|---|---|---|---|
| | | L | T | P | |
| 3 MPAPEV | Program Elective-V<br>13. Biostatistics<br>14. Scale up and Technology Transfer<br>15. Production Area Design and Packaging Development | 3 | 0 | 0 | 3 |
| 3 MPAOE | Open Elective<br>1. Screening Methods in Pharmacology<br>2. Entrepreneur Management<br>3. Stability Of Drugs And Dosage Forms<br>4. Cosmetic Science<br>5. Hazards and Safety Management<br>6. Audits and Regulatory Complaince | 3 | 0 | 0 | 3 |
| 3 MPA10 | Dissertation – I / Industrial Project | 0 | 0 | 20 | 10 |
| **Total credits:** | | | | | **16** |

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

**M. Pharm Sem-IV**

| Course Number | Subject | Scheme of studies Per Week | | | Credits |
|---|---|---|---|---|---|
| | | L | T | P | |
| | Dissertation – II / Industrial Project | 0 | 0 | 32 | 16 |
| **Total credits:** | | | | | **16** |

**Audit course 1 & 2**

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

**Course No. 1MPA01**

**JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD**
**M.Pharm Sem – I (PHARMACEUTICAL ANALYSIS)**

**(Program Core - I)**

# Modern Pharmaceutical Analytical Techniques

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

**UNIT I**

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

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

**UNIT II**

a. Gas chromatography: Introduction, fundamentals, instrumentation, columns: preparation and operation, detection, derivatization.
b. HPLC: Basic parameters, Principles and instrumentation, solvents and columns used, Operational modes, detection and applications of HPLC
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 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.

**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 Principles of Instrumental Analysis - Doglas A Skoog, F. James Holler, Timothy A. Nieman, 5th edition, Eastern press, Bangalore, 1998.
3) Instrumental methods of analysis – Willards, 7th edition, CBS publishers.
4) A Text book of Pharmaceutical Analysis by Kerrenth A. Connors
5) Vogel's Text book of Quantitative Chemical Analysis by A.I. Vogel
6) Practical Pharmaceutical Chemistry by A.H. Beckett and J.B. Stenlake
7) Organic Chemistry by I. L. Finar
8) Organic spectroscopy by William Kemp
9) Quantitative Analysis of Drugs by D. C. Garrett
10) Quantitative Analysis of Drugs in Pharmaceutical Formulations by P. D. Sethi
11) Spectrophotometric identification of Organic Compounds by Silverstein
12) HPTLC by P.D. Seth
13) Indian Pharmacopoeia 2007
14) High Performance thin layer chromatography for the analysis of medicinal plants by Eike Reich, Anne Schibli
15) Introduction to instrumental analysis by Robert. D. Braun

**Course No. 1MPA02**

**JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD**
**M.Pharm Sem – I (PHARMACEUTICAL ANALYSIS)**

**(Program Core – II)**

## Pharmaceutical Food Analysis

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

**UNIT I**

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

**UNIT II**

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

**UNIT III**

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

**UNIT IV**

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

**UNIT V**

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

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

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

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

**TEXT BOOKS**


1) The chemical analysis of foods – David Pearson, Seventh edition, Churchill Livingstone, Edinburgh London, 1976
2) Introduction to the Chemical analysis of foods – S. Nielsen, Jones & Bartlett publishers, Boston London, 1994.
3) Official methods of analysis of AOAC International, sixth edition, Volume I & II, 1997.
4) Analysis of Food constituents – Multon, Wiley VCH.
5) Dr. William Horwitz, Official methods of analysis of AOAC International
6) 18th edition, 2005.Theory and Practice of Industrial Pharmacy by Lieberman and Lachman


**REFERENCE BOOKS**


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

**Course No. 1 MPAPEI**

**JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD**
**M.Pharm Sem – I (PHARMACEUTICAL ANALYSIS)**

**(Program Elective - I)**

# 1. 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

A. Non-aqueous
B. Oxidation-reduction
C. Complexometric
D. Diazotization methods
E. Neutralization
F. Acid – Base

**UNIT II**

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

A. Amines
B. Esters
C. Carbonyl compounds
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

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

**UNIT-IV**

a. **Analysis 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.

b. **Excipients of interest:** Disintegrating agents, binders, emulsifiers, viscosity modifiers and preservatives including preservative challenge test.

**UNIT-V**

a. **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..

b. **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
5. Organic spectroscopy by Y.R Sharma Principles of Instrumental Analysis - Doglas A Skoog, F. James Holler, Timothy A. Nieman, 5th edition, Eastern press, Bangalore, 1998.
6. Instrumental methods of analysis – Willards, 7th edition, CBS publishers.


**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.)

**Course No. 1MPAPEI**

**JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD**
**M.Pharm Sem – I (PHARMACEUTICAL ANALYSIS)**

**(Program Elective - I)**

## 2. Drug Regulatory Affairs

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

**UNIT I**
**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 Managemant, 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.

**Outcome:**

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

**TEXT AND REFERENCE BOOKS**


1. Original laws published by Govt. of India.
2. Text Book of Forensic Pharmacy by Mithal B. M.; VallabhPrakashan, New Delhi.
3. Laws of Drugs in India by Hussain.
4. Text Book of Forensic Pharmacy by Jain N. K.; VallabhPrakashan, New Delhi.
5. Pharmaceutical Regulatory Affairs - Selected Topics , CVS Subramanyam and J Thimmasetty, VallabhaPrakashan Delhi - 2013

**Course No. 1MPAPEI**

**JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD**
**M.Pharm Sem – I (PHARMACEUTICAL ANALYSIS)**

**(Program Elective - I)**

# 3. Phytochemistry

**Objective:** Helps the students to get exposed to natural product drug discovery and to perform quantitative and qualitative evaluation of herbal extracts. To understand the chemistry of important phyto consitituents of different categories.

**UNIT I**

Biosynthetic pathways and Radio tracing techniques: containing drugs:

a) Methods of Biogenetic Investigations, detailed study of isotropic tracer techniques.

b) Study of Biosynthetic pathways of of following phyto-pharmaceuticals :Atropine, Morphine, Cardiac glycosides and Flavonoids.

**UNIT II**

Drug discovery and development : Approaches to discovery and development of natural products as potential new drugs. Sourcing and archiving Natural products for discovery, Evaluating natural products for therapeutic properties, Identifying the biologically active Natural products, the lead structure selection process and Optimization with suitable examples from the following source: artemesin, andrographolides.

**UNIT III**

a) Extraction/Isolation methods for specific Phytochemical groups, Choice of solvents and Interfering compounds for general Isolation and purification of desired phytoconstituents.
b) Recent sophisticated extraction techniques like: Super critical fluid extraction and Ultra-sonic extraction. Separation of phytoconstituents by Vacuum and Flash column chromatography.

**UNIT IV**

Sources, Chemical structure, Identification tests, mechanism of action SAR, uses of the following phyto-pharmaceuticals:

a) Atropine, caffeine, Morphine and brief account on its derivatives and analogues
b) Camptothecin, Digoxin
c) Taxol, Podophyllotoxin

**UNIT V**

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

b. Flavours and Perfumes : Sandal wood oil, Orange oil, Lemon oil, Palmarosa oil, Geranium oil.

**Outcome:** On the basis of chemistry data of phytoconsitituents students will acquire knowledge on various types of phytoconstituents present in the plants.

**Reference books**


1) Phytochemical methods of chemical analysis by Harbone
2) Modern methods of plant analysis- peach & M.V.Tracey Vol.1 to VII
3) Pharmacognosy & Phytochemistry of medical plants by Jean Brunton
4) Thin layer chromatography by Stahl
5) Chemistry of natural products by Atur Rahman
6) Comprehensive Medicinal Chemistry, Vol 1-6, Elsevier Publication
7) Medicinal Chemistry Drug Discovery by Donald J, Abrahm,
8) Plant drug analysis by Wagner
9) Clarke's isolation & identification of drugs by AC Mottal
10) Chromatography of Alkaloids by Varpoorte Swendson
11) Jenkins Quantitative pharmaceutical chemistry by AN Kenwell
12) Standardisation of botanicals by V. Rajpal Vol 1 & 2
13) Medicinal chemistry and drug discovery by Burger's
14) Foye's Principles of medicinal chemistry .
15) Pharmacognosy and phytochemistry by Biren seth
16) Herbal Perfumes and cosmetics by Panda
17) Herbal Drug Technology by SS Agarwal
18) Pharmacognosy and Phytochemistry by VD Rangari.
19) Textbook of Pharmacognosy by G.E.Trease, W.C.Evans,ELBS

**Course No. 1MPAPEII**

**JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD**
**M.Pharm Sem – I (PHARMACEUTICAL ANALYSIS)**

**(Program Elective - II)**

# 4. Pharmaceutical Validation

**Objective**

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

**UNIT I**

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

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

**UNIT II**

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

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

**UNIT III**

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

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

**UNIT IV**

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

**UNIT V**

**Analytical method validation**: General principles, Validation of analytical method as per ICH guidelines 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,

**Course No. 1MPAPEII**

**JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD**
**M.Pharm Sem – I (PHARMACEUTICAL ANALYSIS)**

**(Program Elective - II)**

## 5. Cosmetics And Cosmeceuticals

**Objectives:** Upon completion of the course, the students shall be able to understand

- Key ingredients used in cosmetics and cosmeceuticals.
- Key building blocks for various formulations.
- Current technologies in the market
- Various key ingredients and basic science to develop cosmetics and cosmeceuticals
- Scientific knowledge to develop cosmetics and cosmeceuticals with desired Safety, stability, and efficacy.

**UNIT I**

**Cosmetics – Regulatory:** Definition of cosmetic products as per Indian regulation. Indian regulatory requirements for labeling of cosmetics Regulatory provisions relating to import of cosmetics. Misbranded and spurious cosmetics. Regulatory provisions relating to manufacture of cosmetics − Conditions for obtaining license, prohibition of manufacture and sale of certain cosmetics, loan license, offences and penalties.

**UNIT II**

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

**UNIT III**

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

**Perfumes;** Classification of perfumes. Perfume ingredients listed as allergens in EU regulation.

**Controversial ingredients:** Parabens, formaldehyde liberators, dioxane.

**UNIT IV**

**Design of cosmeceutical products:** Sun protection, sunscreens classification and regulatory aspects. Addressing dry skin, acne, sun-protection, pigmentation, prickly heat, wrinkles, body odor., dandruff, dental cavities, bleeding gums, mouth odor and sensitive teeth through cosmeceutical formulations.

**UNIT V**

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

**REFERENCES**


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

**Course No. 1MPAPEII**

**JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD**
**M.Pharm Sem – I (PHARMACEUTICAL ANALYSIS)**

**(Program Elective - II)**

## 6. INDUSTRIAL PHARMACOGNOSTICAL TECHNOLOGY

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

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

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

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

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

**UNIT V:**
**Patents:** Patenting of herbal drugs: Benefits of patent protection, Patent application, drafting and filing an application. Indian and international patent laws, proposed amendments as applicable to

herbal/natural products and process. Geographical indication, Copyright, Patentable subject maters, novelty, non obviousness, utility, patent processing and grant of patents.

**Outcome:**

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

**REFERENCES** (Latest Editions of)


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

**Course No. 1MPAL03**

**JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD**
**M.Pharm Sem – I (PHARMACEUTICAL ANALYSIS)**

# Laboratory - I
# Modern Pharmaceutical Analytical Techniques Lab

**List of experiments**

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

**Course No. 1MPAL04**

**JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD**
**M.Pharm Sem – I (PHARMACEUTICAL ANALYSIS)**

# Laboratory - 2

# 1. Advanced Pharmaceutical Analysis Lab

**List of experiments**

1) Determination of official compounds by Acid- base titrations
2) Determination of official compounds by Non-aqueous titrations
3) Determination of drugs containing di and trivalent metal ions by complexometric titrations
4) Determination of sulfa drugs by diazotization
5) Determination of Vitamin C by redox titration
6) Quantitative determination of hydroxyl group.
7) Quantitative determination of amino group
8) Colorimetric determination of drugs by using different reagents
9) Quantitative determination of pharmaceutical dosage forms belonging to alkaloids, antibiotics, vitamins, glycosides and steroids

**Course No. 1MPAL04**

**JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD**
**M.Pharm Sem – I (PHARMACEUTICAL ANALYSIS)**

## Laboratory - 2

## 3. Phytochemistry Lab

**List of experiments:**

1. Methods of extraction: Preparation of extracts of organized crude drugs / Herbs by successive solvent extraction method to record the percentage yield and physical status of the respective extracts and for subjecting them to phytochemical screening.
2. Detection of Phytoconstituents by test tubes and TLC methods, such as
   a. Alkaloids, b. Steroids, Triterpenoids and their glycosides and saponins,
   c. Anthracene glycosides d. Flavanoids and their glycosides
   e. Coumarins f. Tannins
3. a. Identification of alkaloids in a mixture by TLC
   e.g. Atropine, Caffeine, Ergot, Piperine, Quinine, Reserpine, Strychnine and Brucine
   b. Color reactions of different groups of alkaloids.
4. Isolation of the following Phytoconstituents
   a. Caffeine from Tea
   b. Caffeine from marketed product
   c. Strychnine and Brucine from Nux-Vomica by Column chromatography.
   d. Piperine from black pepper
   e. Citric acid from Lemon
   f. Nicotine from Tobacco
   g. Pectin from Orange peels
5. Detection, extraction, and estimation of volatile oils by Clevenger's method (Hydrodistillation method), TLC of volatile oils and their pure constituents.
6. Isolation of starches from potatoes and rice
7. Isolation of Bixin from *Bixa orellana*
8. Isolation of Lawsone from Henna
9. Preparation of Curcuminoids
10. Identification of bioactive constituents from plant extracts

**Course No. 1MPAL04**

**JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD**
**M.Pharm Sem – I (PHARMACEUTICAL ANALYSIS)**

# Laboratory – 2

# 4. Pharmaceutical Validation

**List of Experiments**

1. Calibration of Electronic Balance.
2. Calibration of pH meter.
3. Calibration of Friability test apparatus.
4. Calibration of Tap density tester.
5. Calibration of Disintegration tester.
6. Calibration of Dissolution test apparatus
7. Cleaning validation of **any 2** analytical instruments.
8. Analytical method development and validation of **any 2** drugs of interest.
9. Preparation of Master Formula Record.
10. Preparation of Batch Manufacturing Record.

**Course No. 1MPAL04**

**JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD**
**M.Pharm Sem – I (PHARMACEUTICAL ANALYSIS)**

# Laboratory – 2

## 5. Cosmetics and Cosmeceuticals

**List of Experiments**

1. Preparation and evaluation of Gels like Shaving gels, Anti dandruff Shampoo and Hair styling gels

2. Preparation of Mouth washes

3. Preparation and evaluation of Cold Creams, Vanishing Creams.

4. Preparation and evaluation of Calamine lotion

5. Preparation and evaluation of Face powder and Dusting Powder

6. Preparation and evaluation of Eye liners and Lip sticks

7. Preparation of Anti-Perspirants

8. Preparation of Hand and Body Lotions

9. Preparation and evaluation of Foundation Creams and Cleansing Creams

10. Preparation and Evaluation of Face Masks

11. Preparation of Hair oils to prevent hair fall

12. Preparation and evaluation of Aloe vera Gel

13. Preparation of Antiseptic cream (Turmeric)

14. Preparation and evaluation of Perfumes

15. Preparation and evaluation of Herbal Henna

**Course No. 2MPA05**

**JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD**
**M.Pharm Sem – II (PHARMACEUTICAL ANALYSIS)**

**(Program Core - III)**
## Advanced Instrumental Analysis - I

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

**UNIT-I**
**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.

**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

**Course No. 2MPA06**

**JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD**
**M.Pharm Sem - II (PHARMACEUTICAL ANALYSIS)**

**(Program Core - IV)**

# Modern Bio-Analytical Techniques

**Objectives:**
This subject is designed to provide detailed knowledge about the importance of analysis of drugs in biological matrices.

**UNIT I**
Extraction of drugs and metabolites from biological matrices: General need, principle and procedure involved in the Bioanalytical methods such as Protein precipitation, Liquid -Liquid extraction and Solid phase extraction and other novel sample 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:**

a. Types of body fluids, requirement of analysis, matrix effects, non-biological analytical samples.

b. 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**

a. **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).

b. **Drug Product Performance, In Vivo:** Purpose of Bioavailability Studies, Bioavailability and Bioequivalence Studies.

**Outcomes:**

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

1. Extraction of drugs from biological samples
2. Separation of drugs from biological samples using different techniques
3. 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, 2nd Edition, John Wiley & Sons, New Jercy. USA.
6. Chromatographic Analysis of Pharmaceuticals – John A Adamovics, 2nd Edition, 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

**Course No. 2MPAPEIII**

**JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD**

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

**(Program Elective - III)**

# 7. Pharmaceutical Quality Control and Quality Assurance

**Objectives**

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

**UNIT I**

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

**UNIT II**

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

**UNIT III**

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

**UNIT IV**

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

**UNIT V**

**Manufacture and controls on dosage forms**

a. Manufacturing documents, Master Formula, Batch Formula, Records, Standard Operating Procedures,

b. In process quality control on various dosage forms sterile and biological products, standard operating procedures for various operations like cleaning, filling, drying, compression, coating, disinfection, sterilization, membrane filtration etc.

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

**Text Books**

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

**References Books**


1. Basic Tests for Pharmaceutical Substances - WHO (1991)
2. The Drugs and Cosmetic Act 1940 by Vijay Malik
3. Q.A. Manual by D.H. Shah
4. SOP Guidelines by D.H. Shah
5. Quality Assurance Guide by OPPI
6. Good Manufacturing-Practices for Pharmaceuticals, by Graham Bunn and Joseph 6th Ed. D. Nally (Dec 26, 2006)
7. Analytical Profiles of drug substances and Excipients – Harry G Brittan, Volume 21 – 30, Elsevier, 2005.

**Course No. 2MPAPEIII**

**JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD**
**M.Pharm Sem – II (PHARMACEUTICAL ANALYSIS)**

**(Program Elective - III)**

## 8. HERBAL COSMETICS

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

**UNIT I**

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

Regulatory Provisions relation to manufacture of cosmetics: -

License, GMP, offences & Penalties, Import & Export of Herbal/natural cosmetics, Industries involved in the production of Herbal/natural cosmetics.

**UNIT II**

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

**UNIT III**

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

**UNIT IV**

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

Method of preparation, pharmaceutical and Pharmacological evaluation procedures for various formulations like Hair dyes, Creams, Oils and Shampoos. Elaborative study of five formulations under each category with regard to their composition and claims for various herbs used in them.

**UNIT IV**

**Herbs in cosmetics:**

A brief account of following herbals or herb extracts or herbal products of cosmetic importance such as Acacia concinna pods, Aloe Vera, Almond oil, Neem, Citrus aurantium peels, Henna,

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

**Outcome:**

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

**REFERENCES:**


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

**Course No. 2MPAPEIII**

**JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD**
**M.Pharm. Sem – II (PHARMACEUTICAL ANALYSIS)**

**(Program Elective - III)**

# 9. Pharmacoepidemiology & Pharmacoeconomics

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

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

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

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

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

**UNIT-V**

**Definition, Steps involved, Applications, Advantages and disadvantages of the following:**
Health related quality of life (HRQOL): Definition, Need for measurement of HRQOL, Common HRQOL measures. Definition, Steps involved, Applications of the following: Decision Analysis and Decision tree, Sensitivity analysis, Markov Modeling, Software used in Pharmacoeconomic analysis, Applications of Pharmacoeconomics.

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

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

**REFERENCES**


1. Rascati K L. Essentials of Pharmacoeconomics, Woulters Kluwe rLippincott Williams & Wilkins, Philadelphia.
2. Thomas E Getzen. Health economics. Fundamentals and Flow of Funds .John Wiley & Sons, USA.
3. Andrew Briggs, Karl Claxton, Mark Sculpher. Decision Modeling for Health Economic Evaluation, Oxford University Press, London.
4. K G Revikumar, Pharmacoepidemiology and Pharmacoeconomics Concepts and Practices.
5. Michael Drummond, Mark Sculpher, George Torrence, Bernie O'Brien and Greg Stoddart. Methods for the Economic Evaluation of Health Care Programmes Oxford University Press, London.
6. George E Mackinnon III. Understanding health outcomes and Pharmacoeconomics.
7. Graker, Dennis. Pharmacoeconomics and outcomes.
8. Walley, Pharmacoeconomics.
9. Pharmacoeconomic – ed. by Nowakowska – University of Medical Sciences, Poznan.
10. Relevant review articles from recent medical and pharmaceutical literature
11. Guru Prasad Mohanta and P K Manna, Textbook of Pharmacovigilance Concepts and Practice

**Course No. 2MPAPEIV**

**JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD**
**M.Pharm Sem – II (PHARMACEUTICAL ANALYSIS)**

**(Program Elective - IV)**

## 10. Advanced Instrumental Analysis - II

**Objectives**

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

**UNIT-I**

**Polarography** – Principle, Ilkovic equation, construction and working of dropping mercury electrode and rotating platinum electrode, applications.

**Amperometry -** Principles, instrumentation and applications including amperometric titrations.

**UNIT-II**

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

**UNIT-III**

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

**UNIT-IV**

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

**UNIT-V**

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

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

**References:**


1. Instrumental Methods of Chemical Analysis by B.K Sharma
2. Organic spectroscopy by Y.R Sharma

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

**Course No. 2MPAPEIV**

**JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD**
**M.Pharm Sem – II (PHARMACEUTICAL ANALYSIS)**

**(Program Elective - IV)**

## 11. NUTRACEUTICALS

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

**UNIT I**

a. Definitions of Functional foods, Nutraceuticals and Dietary supplements. Classification of Nutraceuticals, Health problems and diseases that can be prevented or cured by Nutraceuticals i.e. weight control, diabetes, cancer etc.

b. Source, Name of marker compounds and their chemical nature, Medicinal uses and health benefits of following used as Nutraceuticals / functional foods:
Spirulina, Soyabean, Ginseng, Garlic, Broccoli, Gingko, Flaxseeds

**UNIT II**

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

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

**UNIT III**

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

**UNIT IV**

A. Free radicals in Diabetes mellitus, Inflammation, Ischemic reperfusion injury, Cancer, Atherosclerosis, Free radicals in brain metabolism and pathology, kidney damage, muscle damage. Free radicals involvement in other disorders. Free radicals theory of ageing.

B. **Antioxidants**: Endogenous antioxidants – enzymatic and nonenzymatic antioxidant defence, Superoxide dismutase, catalase, Glutathione peroxidase, Glutathione Vitamin C, Vitamin E, α- Lipoic acid, melatonin
Synthetic antioxidants :Butylatedhydroxy Toluene, Butylatedhydroxy Anisole.

**UNIT V**

**Food Laws and Regulations**; FDA, FPO, MPO, AGMARK. HACCP and GMPs on Food Safety. Adultration of foods.
**Regulations and Claims** – Current Products: Label Claims, Nutrient Content Claims, Health Claims, Dietary Supplements Claims

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

**REFERENCES:**


1. Dietetics by Sri Lakshmi
2. Role of dietary fibres and neutraceuticals in preventing diseases by K.T Agusti and P.Faizal: BSPunblication.
3. Advanced Nutritional Therapies by Cooper. K.A., (1996).
4. The Food Pharmacy by Jean Carper, Simon & Schuster, UK Ltd., (1988).
5. Prescription for Nutritional Healing by James F.Balch and Phyllis A.Balch2$^{nd}$Edn., Avery Publishing Group, NY (1997).
6. G. Gibson and C.williams Editors *2000 Functional foods* WoodheadPubl.Co.London.
7. Goldberg, I. *Functional Foods*. 1994. Chapman and Hall, New York.
8. Labuza, T.P. 2000 Functional Foods and Dietary Supplements: Safety, Good Manufacturing Practice (GMPs) and Shelf Life Testing in *Essentials of Functional Foods* M.K. Sachmidl and T.P. Labuza eds. Aspen Press.
9. Handbook of Nutraceuticals and Functional Foods, Third Edition (Modern Nutrition)
10. Shils, ME, Olson, JA, Shike, M. 1994 *Modern Nutrition in Health and Disease*. Eighth edition. Lea and Febiger

**Course No. 2MPAPEIV**

**JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD**

**M.Pharm Sem - II (PHARMACEUTICAL ANALYSIS)**

**(Program Elective - IV)**

# 12. Clinical Research and Pharmacovigilance

**Objective:**

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

**UNIT-I**

**Regulatory Perspectives of Clinical Trials:**

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

**UNIT-II**

**Clinical Trials: Types and Design:**

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

**UNIT-III**

**Clinical Trial Documentation:**

Guidelines to the preparation of documents, Preparation of protocol, Investigator Brochure, Case Report Forms, Clinical Study Report Clinical Trial Monitoring-Safety Monitoring in CT Adverse Drug Reactions: Definition and types. Detection and reporting methods. Severity and seriousness assessment. Predictability and preventability assessment. Management of adverse drug reactions; Terminologies of ADR.

**UNIT-IV**

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

History and progress of pharmacovigilance, Significance of safety monitoring, Pharmacovigilance in India and international aspects, WHO international drug monitoring programme, WHO and Regulatory terminologies of ADR, evaluation of medication safety, Establishing pharmacovigilance centre's in Hospitals, Industry and National programmes related to pharmacovigilance. Roles and responsibilities in Pharmacovigilance.

**UNIT-V**

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

International classification of diseases, International Nonproprietary names for drugs, Passive and Active surveillance, Comparative observational studies, Targeted clinical investigations and Vaccine safety surveillance. Spontaneous reporting system and Reporting to regulatory authorities, Guidelines for ADRs reporting. Argus, Aris G Pharmacovigilance, VigiFlow, Statistical methods for evaluating medication safety data.

**Outcome:**

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

REFERENCES


1. Central Drugs Standard Control Organization- Good Clinical Practices, Guidelines for Clinical Trials on Pharmaceutical Products in India. New Delhi: Ministry of Health;2001.
2. International Conference on Harmonization of Technical requirements for registration of Pharmaceuticals for human use. ICH Harmonized Tripartite Guideline. Guideline for Good Clinical Practice.E6; May 1996.230
3. Ethical Guidelines for Biomedical Research on Human Subjects 2000.Indian Council of Medical Research, New Delhi.
4. Textbook of Clinical Trials edited by David Machin, Simon Day and Sylvan Green, March 2005, John Wiley and Sons.
5. Clinical Data Management edited by R K Rondels, S A Varley, C F Webbs. Second Edition, Jan 2000, Wiley Publications.
6. Handbook of clinical Research. Julia Lloyd and Ann Raven Ed. Churchill Livingstone.
7. Principles of Clinical Research edited by Giovanna di Ignazio, Di Giovannaand Haynes.
8. Textbook of Pharmacovigilance: Concept and Practice. G.P. Mohanta and P. K. Manna. 2016, Pharma Med Press.
9. A textbook of Clinical Pharmacy Practice: Essential Concepts and Skills. Second Edition, 2012, University Press

**Course No. 2MPAL07**

**JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD**
**M.Pharm Sem – II (PHARMACEUTICAL ANALYSIS)**

# Laboratory - 3

# Advanced Instrumental Analysis Lab

**List of Experiments**

1. Comparison of absorption spectra by UV and Wood ward – Fiesure rule
2. Determination of bulk Drugs and formulations by UV-Visible, HPLC, GC etc. methods
3. Interpretation of organic compounds by FT-IR
4. Detection and determination of preservatives, antioxidants and colourants in pharmaceutical preparations
5. Determination of chlorides and sulphates by Nephelo -Tubmidimetry
6. Determination of moisture content in official compounds (Any 4)
7. Assays of official compounds by Flourimetry
8. Determination of compounds of sodium, potassium and calcium by Flame photometry.
9. Analytical method development and validation of an official compound.

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

**Course No. 2MPAL08**

**JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD**
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## Laboratory – 4

## 7. Pharmaceutical 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.
10. Moisture content of official compounds( Any 2)

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## Laboratory – 4

## 8. Herbal Cosmetics Lab

**List of experiments :**

1. Preparation and standardization of various simple dosage forms from Ayurvedic system.
2. Preparation of certain Aromatherapy formulations
3. Preparation of herbal cosmetic formulation such as lipstick, herbal hair and nail care products
4. Evaluation of herbal tablets and capsules
5. Preparation of sunscreen, skin care formulations.
6. Preparation and evaluation of any two of each hair care and skin care products
7. Preparation and evaluation of poly herbal formulation face cream.
8. Preparation and evaluation of single herbal formulation face cream.
9. Preparation and evaluation of herbal ointments
10. Preparation and evaluation of herbal acid balanced shampoo

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# Laboratory – 4

## 10. Advanced Instrumental Analysis – II Lab

**List of Experiments**

1. Estimation of riboflavin/quinine sulphate by flourimetry
2. Estimation of sodium/potassium by flame photometry
3. Assay of official compounds by instrumental techniques **(Any 4)**
4. Assay of official compounds by potentiometric titrations **(Any 2)**
5. Assay of official compounds by conductimetric titrations **(Any 2)**
6. Demonstration on ELISA
7. Quenching of fluorescence
8. Perform phosphate interference on absorption of calcium.

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# Laboratory – 4

# 11. Neutraceuticals

**List of Experiments**

1. Preparation of Herbarium
2. Preparation of Oral rehydration Solution (ORS)
3. Preparation of Protein Powder
4. Preparation of Herbal Neutraceuticals using Ginseng, Spirulina etc.
5. Formulation of Sports food
6. Preparation of Multivitamin formulations
7. Preparation of Pediatric protein and Carbohydrate
8. Preparation of Lactobacillus
9. Preparation of Green Tea and estimation of its antioxidant activity
10. Preparation and Evaluation of Ascorbic acid tablets
11. Preparation of Iron suppliments
12. Preparation and evaluation of Calcium carbonate tablets

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**(Program Elective - V)**

## 13. Biostatistics

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

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

**UNIT II**
**Measures of central tendency**: computation of means, median and mode from grouped and ungrouped data.
**Measure of dispersion**: computation of variance, standard deviation, standard error and their coefficients.

**UNIT III**
Measures of Correlation and Regression
**Probability rules**: Binomial, Poison and Normal distribution.

**UNIT IV**
Experimental designing, planning of an experiment, replication and randomization.
**Analysis of Variance (ANOVA)**: 1-way, 2- Way

**UNIT V**
**Hypothesis testing**: Student 't' test, Chi square test,
**Non- Parametric Tests:** Sign Test, Sign Rank Test, Wilcoxon Sign Rank Test

**Outcome**: The student will be known the Biostatistics arrangement, presentation and formation of tables and charts. They also know the correlation and regression & application of different methods, analysis of data

**Reference Books**


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

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**(Program Elective - V)**

# 14. Scale Up And Technology Transfer

**Objective**

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

**UNIT I**

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

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

**UNIT II**

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

**UNIT III**

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

**UNIT IV**

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

**UNIT V**

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

**Outcome:**

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

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

**References**


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

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**(Program Elective - V)**

# 15. Production Area Design & Packaging Development

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

**UNIT I**

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

**UNIT II**

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

**UNIT III**

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

**UNIT IV**

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

**UNIT V**

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

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

**References:**


1. Leon Lachman; Lieberman Herbert A.; Kanig, Joseph L. The theory and Practice of Industrial Pharmacy.
2. Gilbert Banker and Christopher Rhodes. Modern Pharmaceutics.
3. Aulton's Pharmaceutics: The design and Manufacture of Medicine
4. D. A. Dean, Roy Evans, Ian Hall. Pharmaceutical packaging technology. Tylor and Francis.
5. Edward J. Bauer, Pharmaceutical Packaging Handbook. Bausch and Lomb, Rochester, New York, USA.
6. Wilmer A. Jenkins, Kenton R. Osborn. Packaging drugs and pharmaceuticals.
7. Remington: The Science and Practice of Pharmacy. 8. Michael E. Aulton, Kevin Tylor

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**(Open Elective)**

## 1. Screening Methods In Pharmacology

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

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

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

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

**UNIT IV**
Organization of screening for the Pharmacological activity of new substances with emphasis on the evaluation of cardiac and anti-diabetic activities.

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

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

**Text Books:**
1. Screening methods in Pharmacology, Vol.-1&2 by Robert .A. Turner and Peter Hebborn.
2. Drug discovery and evaluation by H.G.Vogel and W.H.Vogel, Springerverlag, Berlin Heideleberg.

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

**Reference Books:**

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

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**(Open Elective)**

## 2. Entrepreneurship Management

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

**UNIT I**

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

**UNIT II**

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

**UNIT III**

Launching And Organising An Enterprise: Environment scanning – Information, sources, schemes of assistance, problems. Enterprise selection, market assessment, enterprise feasibility study, SWOT Analysis. Resource mobilization -finance, technology, raw material, site and manpower. Costing and marketing management and quality control. Feedback, monitoring and evaluation.

**UNIT IV**

Growth Strategies And Networking: Performance appraisal and assessment. Profitability and control measures,demands and challenges. Need for diversification. Future Growth – Techniques of expansion and diversification, vision strategies. Concept and dynamics. Methods, Joint venture, co-ordination and feasibility study.

**UNIT V**

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

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

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

**Text and reference books**

1. Akhauri, M.M.P.(1990): Entrepreneurship for Women in India, NIESBUD, New Delhi.
2. Hisrich, R.D & Brush, C.G.(1996) The Women Entrepreneurs, D.C. Health& Co., Toranto.
3. Hisrich, R.D. and Peters, M.P. (1995): Entrepreneurship – Starting Developing and Managing a New Enterprise, Richard D., Inwin, INC, USA.
4. Meredith, G.G. etal (1982): Practice of Entrepreneurship, ILO, Geneva.
5. Patel, V.C. (1987): Women Entrepreneurship – Developing New Entrepreneurs, Ahmedabad EDII

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

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## 3. Stability of Drugs and Dosage Forms

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

**UNIT-I**

**Drug decomposition mechanisms:**

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

**UNIT-II**

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

Physical stability testing of dosage forms:

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

**UNIT-III**

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

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

**UNIT-IV**

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

**UNIT-V**

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

a) cGMP& ICH guidelines for Accelerated stability Testing.

b) Interaction of containers & closure Compatibility Testing.

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

**REFERENCE BOOKS :**


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

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# 4. Cosmetic Science

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

**UNIT I**

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

**UNIT II**

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

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

**UNIT IV**

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

**UNIT V**

Oily and dry skin, causes leading to dry skin, skin moisturization. Basic understanding of the terms comedogenic, dermatitis.

**Cosmetic problems associated with hair and scalp:** Dandruff, hair fall causes.

**Cosmetic problems associated with skin:** Blemishes, wrinkles, acne, prickly heat and body odor.

**Anti persprants and deodorants –** Actives and MOA

**Outcome:**

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

**References:**

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

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# 5. Hazards and Safety Management

**Scope**

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

**Objectives**

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

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

**UNIT I**

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

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

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

**UNIT II**

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

**UNIT III**

**Chemical based hazards**: Sources of chemical hazards, Hazards of Organic synthesis, sulphonating hazard, Organic solvent hazard, Control measures for chemical hazards,
Management of combustible gases, Toxic gases and Oxygen displacing gases management, Regulations for chemical hazard, Management of over-Exposure to chemicals and TLV concept.

**UNIT IV**

**Fire and Explosion**: Introduction, Industrial processes and hazards potential, mechanical electrical, thermal and process hazards. Safety and hazards regulations, Fire protection system:
Fire prevention, types of fire extinguishers and critical Hazard management system mechanical and chemical explosion, multiphase reactions, transport effects and global rates. Preventive and protective management from fires and explosion electricity passivation, ventilation, and sprinkling, proofing, relief systems -relief valves, flares, scrubbers.

**UNIT V**

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

**References**


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

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# 6. Audits and Regulatory Compliance

**Scope**

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

**Objectives**

Upon completion of this course the student should be able to

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

**UNIT I**

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

**UNIT II**

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

**UNIT III**

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

**UNIT IV**

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

**UNIT V**

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

**References**


1. Compliance auditing for Pharmaceutical Manufacturers. Karen Ginsbury and Gil Bismuth, Interpharm/CRC, Boca Raton, London New York, Washington D.C.
2. Pharmaceutical Manufacturing Handbook, Regulations and Quality by Shayne Cox Gad. Wiley-Interscience, A John Wiley and sons, Inc., Publications.
3. Handbook of microbiological Quality control. Rosamund M. Baird, Norman A. Hodges, Stephen P. Denyar. CRC Press. 2000.
4. Laboratory auditing for quality and regulatory compliance. Donald C. Singer, Raluca-loana Stefan, Jacobus F. Van Staden. Taylor and Francis (2005).