CENTRE FOR PHARMACEUTICAL SCIENCES

PHARMACEUTICAL ANALYSIS

&

QUALITY ASSURANCE



INSTITUTE OF SCIENCE AND TECHNOLOGY

(AUTONOMOUS)

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY

Kukatpally, Hyderabad-500 085, Telangana State, INDIA.

**COURSE STRUCTURE FOR P.G. PROGRAMMES**

**PHARMACEUTICAL ANALAYSIS AND QUALITY ASSURANCE / QA**

**I Year**

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **I Semester** | | **New Title** | **Int. marks** | **Ext. marks** | **L** | **P** | **C** |
| 1 | Core Course I | Separation Techniques | 25 | 75 | 4 | -- | 4 |
| *2* | Core Course II | Advanced Pharmaceutical Analysis – I | 25 | 75 | 4 | -- | 4 |
| *3* | Core Course III | Quality Control of Bulk Drugs and Formulations | 25 | 75 | 4 | -- | 4 |
| *4* | Core Elective I | 1. Modern Pharmaceutical Analytical Techniques  2. Intellectual Property Rights and Regulatory Affairs | 25 | 75 | 4 | -- | 4 |
| *5* | Optional Elective | 1. Herbal Cosmetic Technology   2. Pharmacoepidemiology, Pharmacoeconomics  and Pharmacovigilance  3. Advanced Pharmaceutical Technology – I  4. Advanced Pharmacognosy - I | 25 | 75 | 4 | -- | 4 |
| *6* | Laboratory I | Modern Pharmaceutical Analytical Techniques Lab | 25 | 75 | -- | 6 | 3 |
| *7* | Laboratory II | Advanced Pharmaceutical Analysis Lab - I | 25 | 75 | -- | 6 | 3 |
| *8* | Seminar I |  | 50 | -- | -- | 4 | 2 |
|  | **Total** |  | **225** | **525** | **20** | **16** | **28** |

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **II Semester** | | **New Title** | **Int. marks** | **Ext. marks** | **L** | **P** | **C** |
| 1 | Core Course IV | Advanced Pharmaceutical Analysis – II | 25 | 75 | 4 | -- | 4 |
| *2* | Core Course V | Spectral Analysis | 25 | 75 | 4 | -- | 4 |
| *3* | Core Course VI | Quality Assurance | 25 | 75 | 4 | -- | 4 |
| *4* | Core Elective II | 1. Biostatistics And Research Methodology  2. Screening Methods & Clinical Research |  |  |  |  |  |
| 25 | 75 | 4 | -- | 4 |
| *5* | Optional Elective | 1. Stability of Drugs and Dosage Forms 2. Nano based Drug Delivery Systems   3. Advanced Pharmaceutical Technology – II  4. Advanced Pharmacognosy - II | 25 | 75 | 4 | -- | 4 |
| *6* | Laboratory III | Advanced Pharmaceutical Analysis – II Lab | 25 | 75 | -- | 6 | 3 |
| *7* | Laboratory IV | Spectral Analysis Lab | 25 | 75 | -- | 6 | 3 |
| *8* | Seminar II |  | 50 | -- | -- | 4 | 2 |
|  | **Total** | | **225** | **525** | **20** | **16** | **28** |

**II Year**

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **I Semester** | | **Int. marks** | **Ext. marks** | **L** | **P** | **C** |
|  | Comprehensive Viva | 0 | 100 | -- | -- | 4 |
|  | Seminar-I on Project Work | 50 | -- | -- | 24 | 12 |
|  | **Total** | **50** | **100** | -- | 24 | **16** |

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **II Semester** | | **Int. marks** | **Ext.marks** | **L** | **P** | **C** |
| 1 | Project Work Review II and Project Evaluation (Vivavoce) | 50 | 150 | -- | 32 | 16 |
|  | **Total** | **50** | **150** | -- | 32 | **16** |

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**JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD**

**I Year – I Sem M.Pharm (PAQA/QA)**

**CORE COURSE – I SEPARATION TECHNIQUES**

**Objectives:** The course is designed to import knowledge in the field of various separation techniques in the context of their applications both at laboratory and industry level. The techniques such as GC, HPLC, Electrophoresis etc. Methods allow qualitative and quantitative estimations and thus demand for the development and validation of methods.

**UNIT: I**

1. **Column Chromatography and Short column chromatography**: Column packing, sample loading, column development, detection.
2. **Flash chromatography and Vacuum liquid chromatography:** Objectives, optimization studies, selecting column and stationary phases, selecting suitable mobile phases, automated flash chromatography, and reverse phase flash chromatography.

**UNIT-II**

**Sample Preparation -** Analysis of drugs from formulations and biological samples including, selection of biological sample, extraction of drugs by various methods such as Liquid Liquid Extraction (LLE), Solid Phase Extraction (SPE) and Membrane filtration.

**UNIT: III**

1. **HPLC:** Principles, basic parameters Retention factor, Capacity factor, Selectivity factor, plate number, plate height, resolution, peak shapes, band broadening, van Deemter equation and curve. Column selection and optimization, column problems, solvents, trouble shooting, sample preparation.
2. **Method Development and validation:** Introduction, Forced Degradation Studies -Experimental Approach to Forced Degradation Studies. Stability Indicating HPLC Method Development - Method Scope, Preliminary Requirements, Method Development Approach, Method Optimization and validation.

**UNIT-IV**

1. **Gas Chromatography:** Principles, split-splitless injector, head space sampling, columns for GC, detectors, quantification, derivatization techniques.
2. **Hyphenated techniques:** Introduction to GC-MS and LC-MS techniques and their applications.

**UNIT-V**

1. Electrophoresis: Capillary electrophoresis: Basic principle (zeta potential), instrumentation, different modes of CE, advantages and disadvantages, pharmaceutical applications.
2. **Counter current chromatography:** Basic principles, droplet counter current chromatography, centrifugal partition chromatography, choice of solvents for SP and MP.

**Out come :** The students should describe the separation techniques of choromatography (GC, HPLC) with principles, instrumentation, identification, development of methodology specific to the components of the mixure, including the method validation. The students should be able to explain the separation principles using the advanced techniques such as Flash chromatography and highphenated techniques.

**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. Methods in Biotechnology, Natural Product Isolation by Sarker, Latif, Gray
13. Methods in Biotechnology, Natural Product Isolation by Richard Canell
14. Various Reviews and Research Papers

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**I Year – I Sem M.Pharm (PAQA/QA)**

**CORE COURSE – II - ADVANCED PHARMACEUTICAL ANALYSIS – I**

**Objective:** The principles and procedures for the evaluation of pharmaceutical bulk drugs and their formulations are essential in the production and for safe use. The techniques such as AAS, RIA, Microbiological and Dissolution methods are few that highlight the utility. A few important general and specific reagents illustrate thair applications in Advanced Pharmaceutical Analysis – I.

**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

**UNIT III**

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 -* Chloroquinone Chlorimide
6. *N* - (1-naphthyl) ethylenediamine dihydrochloride (B.M. Reagent)

**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 Method Development:** Physical and Chemical Properties of API, Dissolution Apparatus Selection, Dissolution Medium Selection, Key Operating Parameters, Method Optimization, Validation, Automated Systems.
2. **Microbiological assays and Biological tests:** Antimicrobial effectiveness testing, microbial limit tests, sterility test. Antibiotics-microbial assays, bacterial endotoxins test.

**Out come :** The student should be able to identify the reagents for the evaluation of bulk drugs and functional groups with principles and relative advantages. The student should explain the principles instrumentation and their utility in the evaluation of bulk drug and formulations as per the advances in Pharmaceutical Analysis – I.

**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.)

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**I Year – I Sem M.Pharm (PAQA/QA)**

**CORE COURSE – III - QUALITY CONTROL OF BULK DRUGS & FORMULATIONS**

**Objective:** The quality control aspects like in process quality control tests, impurity profiles, quality control of nutraceuticalsand excipients.

**UNIT I**

**Impurity Profiling of Pharmaceuticals**: Sources of impurities, their effect on drug stability and therapeutic actions. Determination of impurities in bulk drugs and Formulations: Isolation, characterization and analytical methods.

**UNIT II**

In process quality control tests carried on the following dosage forms

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

**UNIT III**

**Quality Control of Excipients:** Tests related to excipients such as bulk density, tapped density, particle size distribution, pH, moisture content, viscosity (dynamic), gelling temperature, swelling temperature, loss on drying, residue on ignition, conductivity, congealing range, readily carbonizable substances and readily oxidizable substances, melting point and melting range. Excipients of interest: disintegrating agents, binders, emulsifiers, viscosity modifiers and preservatives including preservative challenge test.

**UNIT IV**

**Quality Control of Nutraceuticals**: Vitamins (A, B1, B2, B12, C, D, E and K), micro nutrients and health supplements including free radical scavengers.

**UNIT V**

**Quality Control of Food Constituents**: Carbohydrates, proteins and fats with emphasis in the determination of moisture, ash, nitrogen and physical constituents. Analytical methods for milk

**Outcome:** The quality aspects bulk drugs, excipients nutraceuticals etc. and their control is clearly understood. The precautions to be taken during the process of manufacturing the formulations are also learned.

**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, 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

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**I Year – I Sem M.Pharm (PAQA/QA)**

**CORE ELECTIVE - 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**

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, dramatization.
2. HPLC: Principles and instrumentation, solvents and columns used, detection and applications
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

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**I Year – I Sem M.Pharm (PAQA / QA)**

**CORE ELECTIVES – I - INTELLECTUAL PROPERTY RIGHTS AND REGULATORY AFFAIRS**

**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.

**Intellectual Property Rights:**

**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

**Regulatory Affairs**

**Unit IV**

a. National Drug Regulatory requirements, National Drug Policy, Drugs and Cosmetics Act and its   
 amendments, overview of schedules, detail study of schedule M and Schedule Y.

b. USFDA, FDA guidelines on IND, NDA and ANDA approvals, and SUPAC changes and

understanding on 505 (b) (2) applications

**Unit V**

a. Requirement of GLP Guidance and recommendation on Dissolution and Bio-equivalence requirement. Types of ANDA filing (Para I, II, III, IV filing). Exclusivities (NCE, NS, NP, NDF, PED, ODE, PC)

b. ICH objectives and Guidelines- stability testing, WHO guidelines, ISOs- Production design, certification. ICH 8(QbD), ICH Q9 and ICHQ10

**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, Neena Sondhi
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. Phamraceutical Regulatory Affairs - Selected Topics , CVS Subramanyam and J Thimmasetty, Vallabha Prakashan Delhi - 2013
6. Protection of Industrial Property rights by P.Das and Gokul Das
7. Law and Drugs, Law Publications by S.N. Katju
8. Laws of drugs in India, Hussain
9. New drug approval process,5th edition, by Guarino
10. Commercial Manual on Drugs and Cosmetics 2004, 2nd edition
11. Drugs and Cosmetics act by Vijay Malik
12. Good Manufacturing Practices for Pharmaceuticals, S.H. Wiling, Vol. 78, Marcel Decker.
13. fda.org,wipo.int,patentlawlinks.com, hc-sc.gc.ca,ich.org,cder.org
14. Current good manufacturing practices for pharmaceuticals by Manohar A.Potdar

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**I Year – I Sem M.Pharm (PAQA / QA)**

**OPTIONAL ELECTIVES – I – HERBAL COSMETICS TECHNOLGY**

**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

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**I Year – I Sem M.Pharm (PAQA/QA)**

**OPTIONAL ELECTIVES –II- PHARMACOEPIDEMIOLOGY, PHARMACOECONOMICS AND PHARMACOVIGILANCE**

**Objective**: This course is designed to impart knowledge and skills in epidemiology, economics and vigilance of various diseases. This will enable the students to understand cost effectiveness in the management of disease and ADRS.

**Unit-I**

Pharmacoepidemiology :

**Definition and scope:**

Origin and evaluation of pharmacoepidemiology, need for pharmacoepidemiology, aims and applications.

**Measurement of outcomes in pharmacoepidemiology** Outcome measures and drug use measures Prevalence, incidence and incidence rate. Monetary units, number of prescriptions, units of drugs dispensed, defined daily doses and prescribed daily doses, medication adherence measurement.

**Unit-II**

**Concept of risk in pharmacoepidemiology,** Measurement of risk, attributable risk and relative risk, time-risk relationship and odds ratio

**Pharmacoepidemiological methods:** Includes theoretical aspects of various methods and practical study of various methods with the help of case studies for individual methods Drug utilization review, case reports, case series, surveys of drug use, cross–sectional studies, cohort studies, case control studies, case–cohort studies, meta–analysis studies, spontaneous reporting, prescription event monitoring and record linkage system.

**Unit-III**

**Sources of data for pharmacoepidemiological studies** Adhoc data sources and automated data systems.

**Selected special applications of pharmacoepidemiology** Studies of vaccine safety, hospital pharmacoepidemiology, pharmacoepidemiology and risk management, drug induced birth defects.

**Unit-IV**

**Phrmacoeconomics:**

**Definition, history, need of pharmacoeconomic evaluations** Role in formulary management decisions.

**Pharmacoeconomic evaluation** Outcomes assessment and types of evaluation, includes theoretical aspects of various methods and practical study of various methods with the help of case studies for individual methods: Cost – minimization, cost- benefit, cost – effectiveness, cost utility

**Applications of Pharmacoeconomics,** Softwares used and case studies

**Unit-V**

* 1. Scope, definition and aims of Pharmacovigilance
  2. Adverse drug reactions - Classification, Mechanism, predisposing factors, causualilty assessment (different scales used)
  3. Reporting, evaluation, monitoring and management of ADRs
  4. Role of pharmacist in management of ADRs.

**Outcome**: At completion of this subject, the students are expected to understand risk of pharmacoepidemiology history and need of pharmacoeconomics and assessment of pharmocovigilance.

**REFERENCES:**

1. Roger Walker, Clive Edward, Clinical pharmacy & therapeutics, Churchill Livingstone, New York.
2. Principles of drug action the basis of Pharmacology by Goldstein A, Arrow L. and Kalman ,S.M. 2nd edition. John Wiley & Sons. Incl. New York. 1974 Edition. McGraw Hill.
3. G Katzung, Basic and Clinical Pharmacology. Bertram, 9th edn Lange Publications, 2004
4. Goodman & Gilman’s The Pharmcological basis of Therapeutics Ed. J.G. Hardman, L.E. Limbird, P.B. Molinoff and R. W. Ruddon. International Edition. McGraw Hil

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**I Year – I Sem M.Pharm (PAQA/QA)**

**OPTIONAL ELECTIVE –III - ADVANCED PHARMACEUTICAL TECHNOLOGY-I**

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

**UNIT 1**

**Preformulation studies:** Goals of Preformulation, preformulation parameters, polymorphs and amorphous forms, selection of drugs- solubility, partition coefficient, salt forms, humidity, solid state properties, Particle Size Analysis (Laser Diffraction and Dynamic Light Scattering) drug-excipient compatibility, flow properties, format and content of reports of preformulation, preformulation stability studies (ICH**).**

**UNIT II**

**Formulation development of solid dosage forms – I:** New materials, excipients science - diluents, disintegrants, superdisintegrants, etc, evaluation of functional properties of excipients, co-processed materials, methods of preparation and evaluation.

**UNIT III**

**Formulation development of solid dosage forms** **– II:** Coating, coating machines, coating techniques in tablet technology for product development, computerization, inprocess control of tablets, formulation development and manufacture of powder dosage forms for internal use.

**Microencapsulation**- Types, methodology, problems encountered.

**UNIT IV**

**Formulation development of soft and hard gelatin capsules :** Introduction, production and methods of manufacture, filling equipment and filling operations, formulations, finishing, special techniques, advances in capsule manufacture, machines, processing and control including pharmaceutical aspects, physical stability and packaging.

**UNIT V**

**Optimization techniques in pharmaceutical formulation and processing:** Introduction, optimization parameters, statistical design, response surface method, contour diagrams, factorial design, partial factorial design, simplex methods, mixture designs, Placket Burman method, Box Benken method, applications in pharmaceutical formulation.

**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.

**Text Books**

1. Pharmaceutics - The Science of Dosage form design by ME Aulton.
2. Pharmaceutical Dosage forms - Tablets (Vol I, II and III) by Lieberman, Lachman and Schwartz.
3. Pharmaceutical Dosage forms - Capsules (Vol I, II and III) by Avis, Lieberman and Lachman.
4. Pharmaceutical Dosage forms – Disperse systems (Vol I, II and III) by Avis, Lieberman and Lachman.
5. Modern Pharmaceutics by Gilbert S. Banker and Christopher T. Rhodes.
6. Pharmaceutical statistics by Bolton
7. Industrial Pharmacy - Selected Topics , CVS Subramanyam and J Thimmasetty, Vallabha Prakashan Delhi - 2013

**Recommended Books:**

1. The Theory and Practice of industrial Pharmacy by Leon Lachman, Herbert A. Lieberman.
2. Remington’s Science and Practice of Pharmacy by A. Gennaro.
3. Ansel’s Pharmaceutical Dosage form and Drug delivery system by Loyd V. Allen, Jr. Nicholas G. Popovich, Howard C. Ansel.
4. Generic Drug Product Development by Leon Shargel and Isadore Kanfer.
5. Dispensing for Pharmaceutical Students by SJ Carter.

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**I Year – I Sem M.Pharm (PA & QA/QA)**

**OPTIONAL ELECTIVE –IV - ADVANCED PHARMACOGNOSY-I**

**Objective:** To provide an opportunity for the students to understand the cultivation and utilization aspects of drugs falling under this chapter. Helps the students to get exposed to various techniques of plant tissue culture and explore marine origin natural products

**UNIT I**

Good agricultural and collection practices for medicinal plants :Identification/authentication of cultivated medicinal plants, Seeds and other propagation methods, cultivation, Permission to collect, Technical planning, selection and collection of medicinal plants and post harvesting processing.

**UNIT-II**

Present status and future prospects of medicinal and aromaticPlantsCommercial cultivation, post harvesting techniques and utilization of the following Medicinal and Aromatic plants: Ashwagandha, Guggal Opium,saffron Safed musli, Davana, Pachouli and Lemon grass.Weed management and control, Pest control and study of pesticides with special importance to natural pesticides

A brief account on Chemical and Pharmacological aspects and uses of the following medicinal plants-

**(UNIT III and UNIT IV)**

**UNIT III**

1. Immunomodulators
2. *Asparagus racemosa*
3. *Withania somnifera*
4. Antioxidants
5. *Gingko biloba*
6. *Artemesia annua*
7. Antidiabetics
8. *Gymnema sylvestera*
9. *Momordica charantia*

**UNIT IV**

1. Hepatoprotectives
2. *Phyllanthus amarus*
3. *Silybum marianum*
4. Cardioprotectives
5. *Coleus forskolin*
6. *Allium sativum*
7. Insecticides and Insect repellants
8. *Azadirachta indica*
9. *Chrysanthemum cinerarifolium*

**UNIT V**

Plant Tissue Culture :

a) Types, Techniques, Nutritional requirements. Preparation and sterilization of media,   
 preparation of explants, Measurement of growth parameters ,Micro propagation of medicinal and aromatic plants, Organogenesis and Embryogenesis.

b i) A brief account of immobilization of plant cells, techniques and its effect on   
 secondary metabolism

ii) A brief account of biotransformation by plant cell culture and secondary metabolites   
 of medicinal importance involved in biotransformation

iii) A Brief account on Hairy root culture and their applications

**Outcome:** the students will gain applicable knowledge about the traditional/ ethno medicinal plants which helps them to work upon them for proving their use scientifically.

**Recommended / Reference books**

1. Cultivation of medical plants by Ck Atal and BM Kapoor.
2. Cultivation of medical and aromatic crops by AA Farooqi and BS sreeramu, universities press.
3. Textbook of Pharmacognosy by Mohammad Ali.
4. Herbal drug industry by R.D Choudhary, 1stedition eastern publisher
5. Introduction to plant tissue culture by M.K.Razadan
6. Advanced methods in plant breeding & biotechnology by David R Mirray
7. Pharmaceuticals biotechnology by S.P. Vyas & V.K.Dixit
8. Plant tissue culture by Street
9. Medicinal natural products – A biosynthetic approach by Paul M, Dewick, John Wiley
10. Herbal harvest by Grag Whitten, CBS Medicinal plants
11. Medicinal plant biotechnology by Ciddi Veeresham

**INSTITUTE OF SCIENCE & TECHNOLOGY**

**JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD**

**I Year – I Sem M.Pharm (PAQA/QA)**

**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. Estimation of multi components formulation by UV of two different methods
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. Interpretation of spectra and structure determination of Mass Spectroscopy
3. Separation of protein drug substances by electrophoresis.
4. Workshop on IR and NMR interpretation
5. Development and evaluation of drugs by derivative spectroscopy.

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**JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD**

**I Year – I Sem M.Pharm (PAQA/QA)**

**LABORATORY – II - ADVANCED PHARMACEUTICAL ANALYSIS - I 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 hydroxy, carboxyl. amino and carbonyl groups present in drugs
6. Quantitative determination of suitable drugs using the reagents mentioned in Unit III
7. Quantitative determination of pharmaceutical dosage forms belonging to alkaloids, antibiotics, vitamins, glycosides and steroids

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**JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD**

**I Year – II Sem M.Pharm (PAQA/QA)**

**CORE COURSE – IV - ADVANCED PHARMACEUTICAL ANALYSIS-II**

**Objectives:** The course is aimed to study the calibration of instruments, qualification of equipment and method validation procedures for general facilities (air handling, water, etc.) and specific needs of industry. The student acquires the knowledge with reference to bio analysis and bio analytical method validation, automation and computer aided analysis.

**UNIT-I**

**Calibration and qualification of equipment:** Difference of definitions, calibration standards, calibration frequency, examples of calibration of pH meter, FTIR and a UV Spectrophotometer. Definition of qualification process involving DQ, IQ, OQ, CQ and PQ. Brief discussion on protocol of each.

**UNIT-II**

**Validation methods of**

* + - 1. Equipment and Processing Techniques for mixing, granulation, drying, compression, filtration and filling.
      2. Methods and equipment for sterilization, autoclaving and membrane filtration.
      3. Air handling equipment and facilities in zones
      4. Water purification systems, deionised and distilled water and water for injection

**UNIT-III**

**Bioanalysis and bioanalytical method validation:** Types of body fluids, requirement of analysis, matrix effects, sample preparation, non-biological analytical samples. Acceptance criteria in comparison to non-biological samples.

**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).

**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.

Regulatory Requirements - Impurities in New Drug Substances Q3A & New Drug Products.Q3B (R2).

**UNIT-V**

**Analytical Method Validation**

General principles of analytical method validation, Validation of following analytical Instruments

- U.V/Visible spectrophotometers, FTIR, HPLC and GC. Dissolution test apparatus.

**Out come:** The students should be express the procedures for qualification, calibration of instruments and also formulate the protocol systems for the above procedures. The students should develop bio Analysis and Method validation with the reference to Biochemical fluids including automatic and computer aid analysis.

**Text books:**

1) Remington’s Pharmaceutical Sciences by Alfonso and Gennaro

2) Quantitative Analysis of Drugs in Pharmaceutical Formulations by P.D. Sethi

3) Pharmaceutical Analysis by Higuchi, Bechmman and Hassan

4) Instrumental Methods of Chemical Analysis By B.K. Sharma

5) A Text Book of Pharmaceutical Analysis by Kennenth A. Conners

6) Skoog, DA, Holler, FJ, Crouch, SR. Principles of instrumental analysis. 6th ed., Baba Barkha Nath Printers, Haryana, 2007

**Reference books:**

1) Willard HH, Merritt LL, Dean JA, Settle FA. Instrumental methods of analysis, 7th ed., CBS Publishers & Distributors, New Delhi, 1986

2) Quality Assurance of Pharmaceuticals (A Compendium of Guidelines and Selected Materials),

Vol. I & II (Pharma. Book Syndicate, Book Street, Hyderabad)

3)Quantitative Chemical Analysis, Daniel C. Harris, 8th Edition, 2011

4) Indian Pharmacopoeia 2010

6) Journals like Indian Drugs, IJPS etc.

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**JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD**

**I Year – II Sem M.Pharm (PAQA/QA)**

**CORE COURSE – V - SPECTRAL ANALYSIS**

**Objectives :** The course is design to import knowledge and new and advanced techniques that permit the identification, purity, incompatability, evaluation of drugs and excipients in addition to evaluate the inprocess parameters inprocess industry (Bulk drugs and pharmaceuticals). Spectral analytical techniques such as NIR, x-ray difraction, thermal methods, visual methods (SEM) etc. are relevant, which needs the study of principles, advantages, utility, spectal analysis for decision making.

**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. **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.
2. **ATR:** Principle (total internal reflection, evanescent wave, etc.), instrumentation (ATR crystal, IR beam), advantages and disadvantages, pharmaceutical applications.
3. **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

**UNIT-III**

**Particle sizing:** Light interaction methods: Rayleigh or static laser light scattering, photon

correlation spectroscopy or dynamic laser light scattering, single particle light scattering,

multi-angle light scattering.

**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** : The students should be able to describe the principles, instruments, obtaining the spectra, spectal interpretation and analysis. The student should highlight the novelty of the technique for specified purpose.

**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

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**JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD**

**I Year – II Sem M.Pharm (PAQA/QA)**

**CORE COURSE – VI - QUALITY ASSURANCE**

**Objective:** The concepts of quality assurance and validation, the aspects of quality in the organization, personnel and the controls in packaging as well as manufacturing are explained.

**UNIT I**

**a.** Concepts of Quality Assurance, Total Quality Management, Philosophy of GMP and cGMP

b. Preparation of audit, Conducting audit, Audit Analysis, Audit Report and Audit follow up

**UNIT II**

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 III**

a. Concepts of Validation: Types of validation, Master plan, protocol for process validation, cleaning validation, validation of air handling, validation of equipment and facilities in sterile and non-sterile areas.

b. Prevalidation activities, Protocol preparation, Protocol execution, Deviations and change controls, summary and certification. Revalidation

**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.

c. Guidelines for Quality Assurance of Human Blood Products and large volume parenterals.

**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)

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**JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD**

**I Year – II Sem M.Pharm (PAQA/QA)**

**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:** Experimental designing, planning of an experiment, replication and randomization. Probit analysis.

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

**Hypothesis testing:** Student ‘t’ test, Chi square test, Analysis of Variance (ANOVA): 1-way, 2-way, 3-ways

**UNIT IV**

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.

**UNIT V**

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 Neena Sondhi, 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. Remington”s Pharmaceutical Sciences
2. Theory & Practice of Industrial Pharmacy by Lachman
3. Statistics for business and economics 3rd edition by Vikas books publications
4. Biostatistics & Computer applications by GN Rao and NK Tiwari
5. Sokal, R.R. and Rohlf, F.J. 1987. An Introduction to Biostatistics. W.H. Freeman and Company.
6. Bailey, N.T.J. 1981. Statistical Methods in Biology. English University Press.
7. Mitchell, K. and Glover, T. 2001. Introduction to Biostatistics. McGraw Hill, Publishing Co.
8. Biostatistics and Computer Applications by G.N. Rao and N.K. Tiwari
9. Fundamentals of Biostatistics by Khan and Khanum
10. Research Methodology by RK Khanna bis and Suvasis Saha
11. Research methods and Quantity methods by G.N.Rao
12. A practical approach to PG dissertation.

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**JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD**

**I Year – II Sem M.Pharm (PAQA/QA)**

**CORE 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, subacute and chronic toxicity studies.

**UNIT IV**

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

**UNIT V**

Clinical evaluation of new drugs, Phases of clinical trial, protocol design, 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.
5. Principles of clinical research edited by Giovanna di ignazio, Di Giovanna and Haynes

**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 trails on pharmaceutical products in India, Central drug standard control organization, New Delhi, Minister of Health- 2001

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**JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD**

**I Year – I Sem M.Pharm (PAQA/QA)**

**OPTIONAL ELECTIVE – I - 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.

1. cGMP & ICH guidelines for Accelerated stability Testing.
2. 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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**JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD**

**I Year – II Sem M.Pharm (PAQA / QA)**

**OPEN ELECTIVE – 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 nanoemulsions

**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, paul V.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

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**JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD**

**I Year – II Sem M.Pharm (PAQA / QA)**

**OPEN ELECTIVE – III – ADVANCED PHARMACEUTICAL TECHNOLOGY-II**

**Objective:** The students shall understand about the pilot plant and their scale up techniques for manufacturing of tablets capsules, suspensions, emulsions and semisolids. The students also learn the filling of capsules, compression machines, sterilizers for formulation of parenterals and also understand the properties of propellants, DPI, MDI and their quality control. The students also understand about the cosmetics and neutraceuticals.

**UNIT I**

**Pilot plant scale-up techniques used in pharmaceutical manufacturing**

* 1. **Pilot plant:** Technology transfer from R&D to pilot plant to pilot scale considerations of steps involved with manufacture, layout design, facility, equipment selection of tablets, capsules, suspensions, emulsions & semisolids.
  2. **Scale up:** Importance, Scale up process-size reduction, mixing, blending, granulation, compression, coating involved in tablets, capsules & liquid-liquid mixing.

**UNIT II**

**Formulation development of parenteral dosage forms:** Advances in materials and production techniques, filling machines, sterilizers, product layout.

**UNIT III**

**Pharmaceutical Aerosols:** Advances in propellants, metered dose inhaler designs, dry powder inhalers, selection of containers and formulation aspects in aerosols formulation, manufacture and quality control.

**UNIT IV**

* 1. **Cosmetics:** Formulation approaches, preparation & method of manufacturing labeling & Q.C. of anti ageing products, sun screen lotion and fairness creams.
  2. **Nutraceuticals:**
     + 1. Introduction, source, manufacture and analysis of glucosamine and cartinine.
       2. Monographs: General and specific properties of glucosamine & cartinine.
       3. A brief overview of role of nutraceuticals in cancer prevention & cardio vascular disorders.

**UNIT V**

**Aseptic processing operation**

1. Introduction, contamination control, microbial environmental monitoring, microbiological testing of water, microbiological air testing, characterization of aseptic process, media and incubation condition, theoretical evaluation of aseptic operations.
2. Air handling systems: Study of AHUs, humidity & temperature control.

**Outcomes:** students will understand the planning of pilot plant techniques used for all pharmaceutical dosage forms such as tablets, capsules, parenterals, aerosols, cosmetics and neutraceuticals and their scale up.

**Text Books**

* 1. Pharmaceutics - The Science of Dosage form design by ME Aulton.
  2. The Theory and Practice of industrial Pharmacy by Leon Lachman, Herbert A. Lieberman.
  3. Remington’s Science and Practice of Pharmacy by A. Gennaro.
  4. Ansel’s Pharmaceutical Dosage form and Drug delivery system by Loyd V. Allen, Jr. Nicholas G. Popovich, Howard C. Ansel.
  5. Pharmaceutical Dosage forms - Parenterals (Vol I, II and III) by Avis, Lieberman and Lachman.
  6. Scale up techniques – Pharmaceutical process by Michael Levin, Marcel Dekker

**Recommended Books**

* + 1. Bentley`s Text Book of Pharmaceutics by EA Rawlins.
    2. Generic Drug Product Development by Leon Shargel.
    3. Dispensing for Pharmaceutical Students by SJ Carter.
    4. Modern Pharmaceutics by Gilbert S. Banker and Christopher T. Rhodes.
    5. Nutraceuticals, 2nd edition by Brian lock wood.
    6. Industrial Pharmacy - Selected Topics , CVS Subramanyam and J Thimmasetty, Vallabha Prakashan Delhi - 2013

**INSTITUTE OF SCIENCE AND TECHNOLOGY**

**JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD**

**I Year – II Sem M.Pharm (PAQA / QA)**

**OPEN ELECTIVE - IV ADVANCED PHRMACOGNOSY - II**

**Objective:** The students shall know about the importance of Nutraceuticals in various health conditions and general method of preparation and evaluation of Herbal Cosmetics and get exposed to marine origin drugs.

**UNIT I**

1. Definitions of Functional foods, Nutraceuticals and Dietary supplements. Classification of Neutraceuticals, Health problems and diseases that can be prevented or cured by Nutraceuticals i.e. weight control, diabetes, cancer etc.
2. Source, Name of marker compounds and their chemical nature, Medicinal uses and health benefits of following used as neutraceuticals like Spirulina, Soyabean, Ginseng, Garlic, Bracoli, Ginko, Flaxseeds, Black cohosh

**UNIT II**

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

1. Carotenoids- α and β-Carotene, Lycopene, Xanthophylls
2. Polyphenolics: Reservetrol
3. Flavonoids- Rutin , Naringin, Quercitin
4. Tocopherols

**UNIT III**

a) **Vegetable bitters:** Biological source, Chemical Nature and description of bitter principles, and of the following – Chirata, Quassia, Calumba, Calamus, Cusparia, Serpentaria

b**) Vegetable Laxatives:** Biological source, Chemical Nature and description of purgation actions and therapeutics of the following: Senna, Cascara, Rubarb, Aloes, Isapgul, agar, castor oil

**UNIT IV**

**Herbal cosmetics:** General method of preparation and evaluation of Herbal Cosmetics such as

1. Skin care products b. Hair care preparations with examples and claims for the various herbal materials used in them.
2. A brief account of following herbals or herb extracts or herbal products of cosmetic importance such as *Acacia*  pods, Aloe Vera, Almond oil, Neem, Henna, Liquorice, Olive oil, Sandal wood, tea tree oil and wheat germ oil with special emphasis on their source, active principles and cosmetic properties.

**UNIT V**

**Marine Pharmacognosy:** A brief account of natural products derived from Marine sources with special reference to Cardiovascular, anti-cancer, anti-viral, anti-microbial, anti-parasitic, anticoagulant and anti-inflammatory agents

**Outcome:** Helps the students to know about the Nutraceuticals and the herbal cosmetic formulations and marine origin drugs.

**Recommended/ Reference books**

1. Quality control of herbal drugs by P.K. Mukherjee
2. Phytochemical methods of chemical analysis by Harbone
3. Indian herbal Pharmacopoeia
4. Standardization of botanicals by V. Rajpal, Vol I &II
5. Dietetics by Sri Lakshmi
6. Herbal Drug industry by Chowdary
7. Herbal Drug industry by Paridhavi

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**I Year – II Sem M.Pharm (PAQA/QA)**

**LABORATORY – III - Advanced Pharmaceutical Analysis - II 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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**LABORATORY – IV - SPECTRAL ANALYSIS 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.