**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 | Separtion 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* | Foundation Course I | Modern Pharmaceutical Analytical Techniques | 25 | 75 | 4 | -- | 4 |
| *5* | Optional Elective | 1. Stability of Drugs and Dosage Forms 2. Pharmacoepidemology, Pharmacoeconomics and Pharmacovigilance 3. Drug Regulatory Affairs 4. Pharmaceutical Management - I | 25 | 75 | 4 | -- | 4 |
| *6* | Laboratory I | Modern Pharmaceutical Analytical Techniques Lab | 25 | 75 | -- | 6 | 3 |
| *7* | Laboratory II | Advanced Pharmaceutical Analysis Lab | 25 | 75 | -- | 6 | 3 |
| *8* | Seminar I |  | 50 | 50 | -- | 4 | 2 |
|  | **Total** |  | **225** | **575** | **20** | **16** | **28** |

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **II Semester** | |  | **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 VII | Quality Assurance | 25 | 75 | 4 | -- | 4 |
| *4* | Foundation Course II | Biostatistics And Research Methodology | 25 | 75 | 4 | -- | 4 |
| *5* | Optional Elective | 1. Plant Drug Analysis 2. Pharmaceutical Product development and Management 3. Screening Methods & Clinical Research 4. Pharmaceutical Market and Research Analysis | 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 | 50 | -- | 4 | 2 |
|  | **Total** | | **225** | **575** | **20** | **16** | **28** |

**II Year**

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **I Semester** | | **Int. marks** | **Ext. marks** | **L** | **P** | **C** |
|  | Comprehensive Viva | 0 | 100 | -- | -- | 4 |
|  | Seminar-I on Project Work | 25 | 75 | -- | -- | 12 |
|  | **Total** | **25** | **175** | -- | -- | **16** |

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **II Semester** | | **Int. marks** | **Ext.marks** | **L** | **P** | **C** |
| *1* | Seminar-II on Project Work | 25 | 0 | -- | -- | 16 |
| *2* | Project Evaluation | 0 | 75 | -- | -- | -- |
|  | **Total** | **25** | **75** | -- | -- | **16** |

**JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD**

**I Year – I Sem M.Pharm (PAQA/QA)**

**CORE COURSE – I SEPARATION TECHNIQUES**

**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.

**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

**JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD**

**I Year – I Sem M.Pharm (PAQA/QA)**

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

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

**UNIT I**

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

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

**UNIT II**

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

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

**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.

**Text Books**

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

**References**

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

**JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD**

**I Year – I 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

**JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD**

**I Year – I Sem M.Pharm (PAQA/QA)**

**FOUNDATION COURSE - 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

**JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD**

**I Year – I Sem M.Pharm (PAQA/QA)**

**OPTIONAL ELECTIVE – I- STABILITY OF DRUGS AND DOSAGE FORMS**

**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

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**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.

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.

**JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD**

**I Year – I Sem M.Pharm (PAQA/QA)**

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

**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.

**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

**JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD**

**I Year – I Sem M.Pharm (PAQA&QA)**

**OPEN ELECTIVES – III - DRUG REGULATORY AFFAIRS (NATIONAL AND INTERNATIONAL)**

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

**UNIT I**

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

**UNIT II**

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

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

**UNIT III**

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

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

**UNIT IV**

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

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

**UNIT V**

**Governing Regulatory Bodies across the globe.**

Country Authority Submission

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

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

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

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

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

**Outcome:**

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

**Text and reference books**

1. Original laws published by Govt. of India.

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

3. Laws of Drugs in India by Hussain.

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

**JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD**

**I Year – I Sem M.Pharm (PAQA&QA)**

**OPTIONAL ELECTIVE – IV - PHARMACEUTICAL MANAGEMENT- I**

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

**UNIT I**

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

**UNIT II**

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

**UNIT III**

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

**UNIT IV**

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

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

**UNIT V**

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

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

**Outcome**: These topics are useful for the students to know how to manage a pharma industry and its various departments viz QA, QC, RA, Production etc.

Along with this it aids the students to develop leadership qualities, communication &interpersonal skills, decisions making, motivation, organization &various managerial functions &professional skills required for a dynamic professional.

Management helps to understand the concept of managerial control, its levels &role, importance in pharma industry.

**Text and reference books**

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

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

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

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

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

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

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

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

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

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

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

**JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD**

**I Year – I 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.

**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

**JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD**

**I Year – II Sem M.Pharm (PAQA/QA)**

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

**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

**JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD**

**I Year – II Sem M.Pharm (PAQA/QA)**

**CORE COURSE – V - SPECTRAL ANALYSIS**

**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.

**References:**

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

**JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD**

**I Year – II Sem M.Pharm (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)

**JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD**

**I Year – II Sem M.Pharm (PAQA/QA)**

**FOUNDATION COURSE – 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.

**JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD**

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

**OPEN ELECTIVE – I - PLANT DRUG ANALYSIS**

**Objective:** Helps the students in getting exposed to the use of chromatographic techniques and spectroscopy for the quantitative evaluation of phytoconstituents, preparation and evaluation of plant extracts by specific methods.

**UNIT I**

Isolation and evaluation of phytochemicals using TLC, HPTLC, Flash and vacuum liquid chromatography and HPLC with details on the methodology used for different classes of compounds.

**UNIT II**

a. Preparation and standardization of extracts of guggul lipids, Garcinia, Ginger, Aloes, Momordica, *Andrographis paniculata, Picrorhiza kurroa*, Brahmi, Boswelia

b. Importance of standardization, problems encountered in standardization of plant drugs. Detailed study of WHO guidelines for quality control of herbal drugs.

**UNIT III**

Qualitative and quantitative analysis of following Phytoconstituents by various methods

Allicin, Atropine, Digoxin, Diosgenin, Ergot, Phyllanthin, Quercetin, Quinine, Taxol, Vinca alkaloids, Phenolic, Aldehyde and Ketonic substances in volatile oils.

**UNIT IV**

Structure elucidation of the following compounds by spectroscopic techniques like UV, IR, 1H NMR, 13C NMR,

1. Carvone, Citral, Menthol
2. Kaemferol, Luteolin, Luteolin 7-O- glucoside
3. Nicotine, Papaverine
4. Estrone, Progesterone

**UNIT V**

Total Quality Assurance- GMP, Plant level Documentation, Sanitation of manufacturing premises, Importance and preparation of SOP’s and control records, Packaging and labeling operations, Drug product inspections, safety and environmental protection procedures.

**Outcome:** Helps the students to understand the importance of quality control of herbal drugs using modern analytical techniques.

**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. Plant Drug Analysis by Wagner H and Bladt S.
6. New natural products and plant drugs with pharmacological, biological, therapeutic activity by H.Wagner and P.Wolff

**JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD**

**I Year – II Sem M.Pharm (PAQA/QA)**

**OPEN ELECTIVE – II - PHARMACEUTICAL PRODUCT DEVELOPMENT AND MANAGEMENT**

**Objective:**  The students shall know the molecular optimization of APIs, different physical preformulation parameters, drug excipients compatibility studies, degradation kinetics, solid state stability and shelf life. They also know the equipment design and their qualification, USFDA guidelines for GLP, silent features of ISO, NABL and also environment health and safety.

**UNIT I**

**Preformulation Studies:** Molecular optimization of APIs (drug substances), crystal morphology and variations, powder flow, structure modification, drug-excipient compatibility studies, methods of determination.

**UNIT II**

**Product Stability:** Degradation kinetics, mechanisms, stability testing of drugs and pharmaceuticals, factors influencing-media effects and pH effects, accelerated stability studies, interpretation of kinetic data (API & Formulations). Solid state stability and shelf-life assignment.

**UNIT III**

Detailed study on Equipment Design, Installation, Operational and Performance Qualification

**UNIT IV**

a. US FDA Guidelines for GLP in non-clinical testing laboratories (only salient features will be covered)

b. Organization & Functioning of Accreditation bodies- ISO-9000, ISO-14000, NABL and OSHA (ISO 18000)

**UNIT V**

1. Environment Health and Safety (EHS): Hazards- Fire, mechanical, chemical and pharmaceutical, monitoring and prevention systems, industrial effluents testing and treatment, control of environmental pollution
2. Ware housing –Design, construction, maintenance and sanitation for materials and products – good warehousing practices.

**Outcome:**  students will have knowledge about preformulation studies, product stability, USFDA guidelines, environment health and safety and warehousing procedures.

**Text books:**

1. Ira R. Berry and R.A. Nash (eds) Pharmaceutical Process Validation, Marcel Dekker Inc, New York
2. Pharmaceutical Process Validation by Loftus and Nash..
3. Remington’s Pharmaceutical Sciences, The science and practice of Pharmacy, 20th Edition, Vol. I&II,.
4. Quality Assurance of Pharmaceutical – A compendium of guidelines. – WHO publication..
5. Theory and practice of industrial practice of industrial pharmacy by Liberian and Lachman.

**References:**

1. GMP by Sidney Herbal, Willing.
2. Quality Assurance Guide Organization of Pharmaceutical products of India.
3. Drugs and Cosmetics Act 1969 and Rules 1945.
4. S.H. Willing M.M.T. Tuckerman, W.S. Hitchings IV, Good Manufacturing Practices for Pharmaceuticals, Marcel Decker Inc, M. New York.
5. P.P. Sharma, How to Practice GMP’s Vandhana Publications, Agra
6. Lippincott Williams Wilkins, Philadelphia, 2000
7. Quality assurance guide supplied by Organization of Pharmaceutical procedure of India.
8. Basic tests for Pharmaceutical Substances, WHO, Geneva, All India traveler book seller, India, 1990.
9. Handbook of Environmental Health and Safety: Principles and Practices, Herman Koren, Michel S. Bisesi, National Environmental Health Association.

**JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD**

**I Year – II Sem M.Pharm (PAQA/QA)**

**OPEN ELECTIVE – III - 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

**JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD**

**I Year – II Sem M.Pharm (PA&QA)**

**OPEN ELECTIVE – IV - PHARMACEUTICAL MARKET RESEARCH AND ANALYSIS**

**Objective:**  students shall know the overview of global pharmaceutical market, growth calculations, innovator new drug evaluation, analysis of finished dosage forms and APIs. They also know about the pharmaceutical companies, R&D strengths, case study of companies.

**UNIT I**

* Introduction and overview of global pharmaceutical market
* Growth calculations based on Therapeutic category vs regions
* Innovator new drug candidate evaluation and strategic development cycle.
* Calculation of market promotion data
* Patent extension strategies
* Return on investment and R&D pipeline

**UNIT II**

Analysis of finished dosage forms based on

* Therapy
* Product
* Companies
* Quantity
* Value
* Country wise
* Region wise etc

Analysis of Active Pharmaceutical Ingredients based on

* Product,
* Quantities
* Value

Critical evaluation of databases for the global market research

* IMS
* Newport
* Export data etc

**UNIT III**

Lead analysis of Innovator vis-à-vis with Therapeutic Category & Generic drug makers vis-à-vis with Therapeutic Category

**UNIT IV**

Pharmaceutical Companies Portfolio, financials, R&D strengths and pipeline strength analysis

**UNIT V**

Case studies- Pharma growth stories of companies

Market research using SAS programmes on market trends

Multi Variate Analysis programmes to analyse in relationship between various factors governing the market growth.

**Outcome**: Students will have knowledge about global market, growth calculations depending on regions, market promotion datas, patent extensions, analysis of finished dosage forms and APIs. They also study data base related to strategies of companies.

**Text and Reference books**

1. Principles of Pharmaceutical Marketing    by MICKEY SMITH

2. Principles and Practice of Drug Manufacturing Management by MD BURANDE

3. Pharmaceutical Market research and analysis    by Donald R. Lehmann

4. Pharmaceutical Market in 21st Century    by Mickey C. Smith

5. Pharmaceutical Marketing: A Practical Guide    by Dimitris Dogramatzis

6. Strategic management of health care organizations by Linda E. Swayne, Walter Jack Duncan,

Peter M. Ginter

7. Managing Health Care Business Strategy by George B. Moseley, III, George B. Moseley

8. Pharmaceutical Management by Sachin Atkar

**JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD**

**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)

**JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD**

**I Year – II Sem M.Pharm (PAQA/QA)**

**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.