



JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD

PHARMACEUTICAL ANALYSIS AND QUALITY ASSURANCE / QA

COURSE STRUCTURE AND SYLLABUS

I Year – I Semester

Category	Course Title	Int. marks	Ext. marks	L	P	C
Core Course I	Separation Techniques	25	75	4	--	4
Core Course II	Advanced Pharmaceutical Analysis – I	25	75	4	--	4
Core Course III	Quality Control of Bulk Drugs and Formulations	25	75	4	--	4
Core Elective I	1. Modern Pharmaceutical Analytical Technique 2. Intellectual Property Rights and Regulatory Affairs	25	75	4	--	4
Open Elective I	1. Pharmacoepidemiology, Pharmacoeconomics and Pharmacovigilance 2. Drug Regulatory Affairs (National And International) 3. Herbal Cosmetics Technology 4. Pharmaceutical Management – I 5. Advanced Physical Pharmaceutics	25	75	4	--	4
Laboratory I	Modern Pharmaceutical Analytical Techniques Lab	25	75	4	--	4
Laboratory II	Advanced Pharmaceutical Analysis-I Lab	25	75	--	4	2
Seminar I	Seminar	50	--	--	4	2
Total Credits				24	8	28

I Year – II Semester

Category	Course Title	Int. marks	Ext. marks	L	P	C
Core Course IV	Advanced Pharmaceutical Analysis – II	25	75	4	--	4
Core Course V	Spectral Analysis	25	75	4	--	4
Core Course VI	Quality Assurance	25	75	4	--	4
Core Elective II	1. Biostatistics And Research Methodology 2. Screening Methods & Clinical Research	25	75	4	--	4
Open Elective II	1. Stability of Drugs and Dosage Forms 2. Nano Based Drug Delivery Systems 3. Nutraceuticals 4. Pharmaceutical Product development and Management 5. Pharmaceutical Management-II	25	75	4	--	4
Laboratory III	Advanced Pharmaceutical Analysis – II Lab	25	75	4	--	4
Laboratory IV	Spectral Analysis Lab	25	75	--	4	2
Seminar II	Seminar	50	--	--	4	2
Total Credits				24	8	28

II Year - I Semester

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

II Year - II Semester

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



JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD
I Year – I Sem M.Pharm (PAQA/QA)

SEPARATION TECHNIQUES

Objective: The topics of various chromatographic methods from simple to advanced techniques are discussed in detail. The principles, instrumentation and method development parameters are discussed.

UNIT: I

- a. **Column Chromatography and Short column chromatography:** Column packing, sample loading, column development, detection.
- b. **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

- a. **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.
- b. **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

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

UNIT-V

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

Outcome: The students will learn the every aspect of separation methods, also sample preparation and method validation process. They will come out with full knowledge of various methods including the instrumentation, handling and uses.

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. Sethi
- 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)

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

- | | |
|------------------------|--------------------------|
| A. Non-aqueous | C. Complexometric |
| B. 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

- | | |
|-----------|-------------------------|
| A. Amines | C. Carbonyl compounds |
| B. 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

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

UNIT-IV

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

UNIT-V

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

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

TEXT BOOKS

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

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)

QUALITY CONTROL OF BULK DRUGS & FORMULATIONS

Objective: The quality control aspects like in process quality control tests, impurity profiles, quality control of nutraceuticals and 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

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

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.

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)

MODERN PHARMACEUTICAL ANALYTICAL TECHNIQUES
(Core Elective-I)

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

UNIT I

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

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

UNIT II

- a. Gas chromatography: Introduction, fundamentals, instrumentation, columns: preparation and operation, detection, dramatization.
- b. HPLC: Principles and instrumentation, solvents and columns used, detection and applications
- c. HPTLC: Theory and principle, instrumentation, elution techniques and pharmaceutical applications

UNIT III

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

UNIT IV

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

UNIT V

NMR: Theory, instrumentation, chemical shift, shielding and deshielding effects, splitting of signals, spin-spin coupling, proton exchange reactions, coupling constant(J), nuclear overhauser effect(NOE), 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)

INTELLECTUAL PROPERTY RIGHTS AND REGULATORY AFFAIRS
(Core Elective-I)

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

- a. 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).
- b. 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
- c. Opposition- pre-grant opposition and post-grant opposition, Anticipation, Infringement, Compulsory Licensing, revocation of patents, and power of Controller.
- d. 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
 - i. Paris Convention, Berne convention
 - ii. World Trade Organization (WTO)
 - iii. World Intellectual Property Organization (WIPO)
 - iv. Trade Related Aspects of Intellectual Property Rights (TRIPS)
 - v. Patent Co-operation Treaty (PCT), Madrid 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. Protection of Industrial Property rights by P.Das and Gokul Das
6. Law and Drugs, Law Publications by S.N. Katju
7. Laws of drugs in India, Hussain
8. New drug approval process, 5th edition, by Guarino
9. Commercial Manual on Drugs and Cosmetics 2004, 2nd edition
10. Drugs and Cosmetics act by Vijay Malik
11. Good Manufacturing Practices for Pharmaceuticals, S.H. Wiling, Vol. 78, Marcel Decker.
12. fda.org, wipo.int, patentlawlinks.com, hc-sc.gc.ca, ich.org, cder.org
13. Current good manufacturing practices for pharmaceuticals by Manohar A.Potdar



JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD
I Year – I Sem M.Pharm (PAQA/QA)

PHARMACOEPIDEMOLOGY, PHARMACOECONOMICS AND PHARMACOVIGILANCE
(Open Elective I)

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

Pharmacoeconomics: 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

- a. Scope, definition and aims of Pharmacovigilance
- b. Adverse drug reactions - Classification, Mechanism, predisposing factors, causality assessment (different scales used)
- c. Reporting, evaluation, monitoring and management of ADRs
- d. 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 pharmacovigilance.

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 Pharmacological basis of Therapeutics Ed. J.G. Hardman, L.E. Limbird, P.B. Molinoff and R. W. Ruddon. International Edition. McGraw Hill



JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD
I Year – I Sem M.Pharm (PAQA/QA)

DRUG REGULATORY AFFAIRS (NATIONAL AND INTERNATIONAL)
(Open Elective I)

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

- a. U.S Food & Drug Administration USDMF
- b. Canada Therapeutic Product Directorate DMF
- c. Europe
 - 1) European Medicines Agency (EMA/ National Authorities) EDMF
 - 2) European Directorate for Quality of Medicines CEP/COS & Health Care
- d. Products
- d. Product Filing
- e. Responding Regulatory Deficiencies
- f. Final Approval Procedure

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

Outcome:

1. Students will come to know the different competent regulatory authorities globally.
2. Students be aware of technical aspects pertaining to the marketing authorization application(MAA)

The regulatory guidelines and directions framed by the regulatory authorities will be helpful to place the drug products in market for marketing approvals

TEXT AND REFERENCE BOOKS

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



JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD
I Year – I Sem M.Pharm (PAQA/QA)

HERBAL COSMETICS TECHNOLOGY
(Open Elective I)

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

- a) Introduction, historical background and present status of Herbal cosmetics
- b) Processes used in the manufacture of cosmetics-Emulsification, Mixing, compaction, Moulding, Packing. Raw materials used in preparation of herbal cosmetics
- c) Machinery and Equipment for Cosmetics: Cream, Liquid, Powder and emulsion making machinery
- d) 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

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

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

REFERENCES:

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



JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD
I Year – I Sem M.Pharm (PAQA&QA)

PHARMACEUTICAL MANAGEMENT-I
(Open Elective 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 Managers; 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 BOOKS 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 Vth Edition Richard. H. Hall
9. Principles and Methods of Pharmacy Management IIIrd Edition Harry A. Smith.
10. Management “Global Perspective Heinz Wehrich, 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)

ADVANCED PHYSICAL PHARMACEUTICS
(Optional Elective –I)

Objective: the students shall know about particle science, polymer science and its use in pharmaceutical dosage forms. They also know the compression and consolidation parameters for powders and granules. Students also know about the rheology, disperse systems, dissolution and solubility parameters for dosage forms.

UNIT I

Polymer science: Classification, properties and characterization of polymers, phase separation, polymers in solid state, preparation of polymer solution, application of polymers in pharmaceutical formulations. Mechanism of biodegradation of biodegradable polymers including controlled drug delivery systems, Mucoadhesive, Hydrodynamically balanced and Transdermal Systems.

UNIT II

Physics of tablet compression: Basic principles of interactions, compression and consolidation, compression and consolidation under high loads, effect of friction, distribution of forces in compaction, force volume relationships, Heckel plots, compaction profiles, energy involved in compaction, Measurement of compression with strain gauges, compression pressure-QA parameters.

UNIT III

Kinetics and drug stability: Stability calculations, rate equations, complex order kinetics, Factors influencing stability, strategy of stability testing, method of stabilization, method of accelerated stability testing in dosage forms, temperature and humidity control, physical stability testing of pharmaceutical products. Photodecomposition, Method, solid state decomposition.

UNIT IV

Theories on stability of disperse systems: Adsorption, wetting, crystal growth mechanisms, physical stability of suspensions and emulsions, drug release from suspension and emulsion formulations. Accelerated stability evaluation of physical stability. Microemulsions & multiple emulsions, types of viscometer-principle & working.

Viscoelasticity: Theoretical consideration, instrumentation, rheological properties of disperse systems and semisolids. Oscillatory testing, Creep measurement.

UNIT V

Dissolution and solubility: Solubility and solubilization of nonelectrolytes, solubilization by the use of surfactants, cosolvents, complexation, drug derivatisation and solid state manipulation, Mechanisms of Drug release - dissolution, diffusion (Matrix and Reservoir) and swelling controlled (Peppas Model) and dissolution equipment.

Outcome: The students will know particle size analysis method, solid dispersion, physics of tablets, polymer classification and its applications, student will also know the stability calculations, shelf life calculations and accelerated stability studies. They also know the rheology, absorption related to liquids and semi-solid dosage forms. They also know the factors affecting the dissolution and solubility in related to *invitro/invivo* correlations.

TEXT BOOKS

1. Physical Pharmacy, 4th Edition by Alfred Martin.
2. Theory and Practice of Tablets – Lachman Vol.4
3. Pharmaceutical Dosage forms – Disperse systems Vol. I & II
4. Cartenson “Drug Stability, Marcel Decker Solid state properties, Marcel Dekker.
5. Industrial Pharmacy - Selected Topics, CVS Subramanyam and J Thimmasetty, VallabhaPrakashan Delhi - 2013

REFERENCE BOOKS

1. Dispersive systems I, II, and III
2. Robinson. Controlled Drug Delivery Systems



JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD
I Year – I Sem M.Pharm (PAQA/QA)

MODERN PHARMACEUTICAL ANALYTICAL TECHNIQUES LAB

List of experiments

1. Colorimetry / UV / Visible, Spectroscopy, scanning of few compounds for UV-absorption, calculation of Assay / content uniformity / % of drug release (2-3 experiments.)
2. 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)
5. Separation and calculation of R_f values by using paper chromatography, TLC, HPTLC Technique (2-3 experiments)
6. Interpretation of spectra and structure determination of Mass Spectroscopy
7. Separation of protein drug substances by electrophoresis.
8. Workshop on IR and NMR interpretation
9. Development and evaluation of drugs by derivative spectroscopy.



JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD
I Year – I SemM.Pharm (PAQA/QA)

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