

## JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD

## M.PHARMACY (PHARMACEUTICS / PHARMACEUTICAL TECHNOLOGY)

**R19 COURSE STRUCTURE AND SYLLABUS**  
**Effective from Academic Year 2019-20 Admitted Batch**

**I YEAR I Semester**

Course Code	Course Title	L	T	P	Credits
Professional Core-I	Modern Pharmaceutics-I	3	0	0	3
Professional Core-II	Applied Biopharmaceutics and Pharmacokinetics	3	0	0	3
Professional Elective-I	1. Advanced Physical Pharmaceutics 2. Drug Regulatory affairs 3. Total Quality Management	3	0	0	3
Professional Elective-II	1. Cosmetics and Cosmeceuticals 2. Pharmaceutical Validation 3. Stability of Drugs and Dosage Forms	3	0	0	3
MC	Research methodology and IPR	2	0	0	2
Laboratory- I	Modern Pharmaceutics – I Lab	0	0	4	2
Laboratory- II	Applied Biopharmaceutics and Pharmacokinetics Lab	0	0	4	2
Audit	Audit Course- I	2	0	0	0
<b>TOTAL</b>		<b>16</b>	<b>0</b>	<b>8</b>	<b>18</b>

**I YEAR II Semester**

Course Code	Course Title	L	T	P	Credits
Professional Core-III	Modern Pharmaceutics-II	3	0	0	3
Professional Core-IV	Advanced Drug Delivery Systems	3	0	0	3
Professional Elective-III	1. Industrial Pharmacy 2. Herbal Cosmetics 3. Pharmaceutical Management	3	0	0	3
Professional Elective-IV	1. Nano based Drug Delivery Systems 2. Nutraceuticals 3. Clinical Research and Pharmacovigilance	3	0	0	3
Laboratory- III	Modern Pharmaceutics – II Lab	0	0	4	2
Laboratory- IV	Advanced Drug Delivery System Lab	0	0	4	2
--	Mini project with seminar	2	0	0	2
Audit	Audit Course- II	2	0	0	0
<b>Total</b>		<b>16</b>	<b>0</b>	<b>8</b>	<b>18</b>

**Audit Courses 1 & 2**

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

**JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD  
M.Pharm I Year I Sem (Pharmaceutics/Pharmaceutical Technology)**

**MODERN PHARMACEUTICS – I (Professional Core-I)**

**Course 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.

**Course Outcome:** Students shall explain the preformulation 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.

**UNIT I**

**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 Burhan method, Box Benken method, applications in pharmaceutical formulation.

**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

**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.
6. Industrial Pharmacy - Selected Topics, CVS Subramanyam and J Thimmasetty, Vallabh Prakashan Delhi – 2013

**JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD**  
**M.Pharm I Year I Sem (Pharmaceutics/Pharmaceutical Technology)**

**APPLIED BIOPHARMACEUTICS AND PHARMACOKINETICS (Professional Core – II)**

**Course Objectives:** The student shall know about bioavailability, bioequivalence and factor affecting bioavailability. They also know the pharmacokinetic parameter like drug disposition, absorption, non-linear and time dependant pharmacokinetics. They also know about the drug interactions & problems associated in pharmacokinetic parameters calculations.

**Course Outcomes:** students will be able to tell factors affecting the bioavailability and stability of dosage form; they also know the bioequivalence studies and protocols for bioequivalent studies. They also know the parameters for the disposition, absorption and Michaelis-Menton constants for non-linear kinetics.

**UNIT I**

- a. Biological and metabolic factors affecting bioavailability, complexation, dissolution - techniques of enhancing dissolution.
- b. Formulation factors affecting bioavailability of drugs in dosage forms of tablets, capsules, parenterals, liquid orals and topical dosage forms.
- c. **Bioavailability:** Importance, dose dependency, AUC, rate and extent, assessment, blood and urine samples, single dose and multiple dose studies, *Invitro- Invivo* Correlation analysis and Levels of Correlations.
- d. **Bioequivalence:** Importance equivalency concepts, biowaivers, study designs, protocol, transformation of data, Statistical Criteria as per the Regulations.

**UNIT II**

**Pharmacokinetics – Drug Disposition:** compartment models: One, two and non-compartmental approaches to pharmacokinetics. Recent trends, merits and limitations of these approaches. Application of these models to determine the various pharmacokinetic parameters pertaining to:

- a. Distribution: Apparent volume of distribution and its determination, factors affecting.
- b. Metabolism: Metabolic rate constant, Factors affecting Metabolism
- c. Elimination: Over all apparent elimination rate constant, and half life.  
All the above under the following conditions:
  1. Intravenous infusion
  2. Multiple dose injections
- d. Non-invasive methods of estimating pharmacokinetics parameters with emphasis on salivary and urinary samples.
- e. Concept of clearance: organ, total clearance, hepatic clearance, lung clearance and renal clearance.

**UNIT III**

**Pharmacokinetics – Absorption:** Rate constants – Zero order, first order, Models of experimental study of absorption (in silico, in vitro, in situ and in vivo) – Absorption half lives, method of residuals, Wagner – Nelson method, Loo - Reigleman method, Analysis of kinetics from urine samples. Pharmacokinetic parameters determination pertaining to: Multiple dosage oral administration.

**UNIT IV**

**Non-linear pharmacokinetics:** Concepts of linear and non-linear pharmacokinetics, Michaelis-Menton kinetics characteristics. Basic kinetic parameters, possible causes of non-induction, non-linear binding, and non-linearity of pharmacological responses.

**Clinical Pharmacokinetics:** Altered kinetics in pregnancy, child birth, infants and geriatrics. kinetics in GI disease, malabsorption syndrome, liver, cardiac, renal and pulmonary disease states.

#### UNIT V

**Time dependent pharmacokinetics:** Introduction, classification, physiologically induced time dependency: Chronopharmacokinetics - principles, drugs– (amino glycosides, NSAIDS, antihypertensive drug) chemically induced dependency.

**Drug Interactions:** Kinetics of drug interaction, study of drug-drug interaction mediated through absorption, distribution, metabolism and elimination, mechanisms of interaction and consequence.

❖ Numerical problems associated with all units, if any.

#### TEXT BOOKS

1. Biopharmaceutics and Clinical Pharmacokinetics by Milo Gibaldi.
2. Learn Shargel and ABC yu, Applied Biopharmacokinetics and Pharmacokinetics
3. Biopharmaceutics and Pharmacokinetics by C.V.S. Subrahmanyam, Vallabh Prakashan.2010.
4. Basic biopharmaceutics, Sunil S. Jambhekar and Philip J Breaan.
5. Text book of Biopharmaceutics and Clinical Pharmacokinetics by NiaziSarfraz

#### REFERENCE BOOKS

1. Bio-Pharmaceutics and Pharmacokinetics by V. Venkateshwarlu.
2. Pharmacokinetics, Biopharmaceutics and Clinical pharmacy by Robert E. Notari.
3. Biopharmaceutics and Clinical Pharmacokinetics - An Introduction by Robert E. Notari.
4. Drug drug interactions, scientific and regulatory perspectives by Albert P. G

**JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD**  
**M.Pharm I Year I Sem (Pharmaceutics/Pharmaceutical Technology)**

**ADVANCED PHYSICAL PHARMACEUTICS (Professional Elective – I)**

**Course Objectives:** 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.

**Course Outcomes:** 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.

**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**

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

**Characterization of API and excipients: Differential Scanning Calorimetry:** Principle, thermal transitions, advantages, disadvantages, instrumentation, applications and interpretations

**X Ray Diffraction methods:** Origin of x-rays, principle, advantages, disadvantages, instrumentation, applications and interpretations.

**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.

**TEXT BOOKS**

1. Physical Pharmacy, 4<sup>th</sup> 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, Vallabh Prakashan Delhi - 2013

**REFERENCE BOOKS**

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



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**DRUG REGULATORY AFFAIRS (Professional Elective-I)**

**Course Objectives:** 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.

**Course Outcomes:**

- Students will come to know the different competent regulatory authorities globally.
- 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.

**UNIT I**

**Drug Regulatory Aspects (India)**

1. Indian drug regulatory authorities, Central and State regulatory bodies (FDA)
2. Drugs and Cosmetics Act and Rules with latest Amendments (Selective)
3. Special emphasis – Schedule M and Y
4. New drugs – Importation, Registration, development, Clinical Trials, BE NOC & BE studies
5. Various Licences – Test Lic., Import lic., for testing of drugs and API's, Manufacturing Contract and Loan licence manufacturing.

**UNIT II**

**Good Manufacturing Practices (GMP)**

1. Indian GMP certification, WHO GMP certification.
2. ICH guidelines for stability testing and other relevant ones (Q1-Q10)
3. Export permissions and manufacturing for semi-regulated countries
4. Understanding of the plant layouts with special emphasis on the environment & safety. (HVAC, Water Systems, Stores Management, Effluent etc.)
5. Quality Assurance and Quality Control – Basic understanding for in-built quality.

**UNIT III**

A detailed study of regulatory aspects that affect drug product design, manufacture and distribution in a developed country such as USA and in a developing country such as Brazil, Hatch Waxmann Act; Bolar Provisions and other FDA Regulations. Regulatory aspects of pharmaceutical and bulk drug manufacture, regulatory drug analysis.

**UNIT IV**

Documentation related to manufacturing, cleaning methods, retention samples and records, quality control, batch release documents, distribution records, complaints and recalls.  
Quality, safety and legislation for cosmetic products and herbal products.

**UNIT V**

**Governing Regulatory Bodies across the globe.**

- Country Authority Submission
- a. U.S Food & Drug Administration USDMF
  - b. Canada Therapeutic Product Directorate DMF
  - c. Europe
    - 1) European Medicines Agency (EMA/ National Authorities) EDMF
    - 2) European Directorate for Quality of Medicines CEP/COS & Health Care Products.

3) MHRA – Medicines and Health Care Products Regulatory Agency

- d. Product Filing
- e. Responding Regulatory Deficiencies
- f. Final Approval Procedure

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

**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, Vallabh Prakashan Delhi - 2013

**JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD**  
**M.Pharm I Year I Sem (Pharmaceutics/Pharmaceutical Technology)**

**TOTAL QUALITY MANAGEMENT (Professional Elective - I)**

**Course Objectives:** Total quality management constitutes very useful chapter like –good manufacturing practices, GLP, GCP, ICH etc. Which increases the knowledge of students in various quality control & regulatory aspects.

**Course Outcomes:** Total quality management helps the students to learn the established regulatory guidelines in GMP, GCP, GLP, USFDA, WHO, ISO etc to become a perfect budding pharmacist. It is very useful to students to acquire vast knowledge regarding the quality control aspects of different regulatory bodies as per their requirements throughout the world.

**UNIT - I**

Concepts and Philosophy of TQM, GLP, GMP (orange guide).

**UNIT – II**

Drug regulatory and accrediting agencies of the world (USFDA, TGA, ICH, WHO, ISO etc.)

**UNIT - III**

Good manufacturing practices: Organization and personnel, responsibilities, training, hygiene. Premises: Location, design, plant layout, construction, maintenance and sanitation, environmental control, utilities and services like gas, water, maintenance of sterile areas, control of contamination. Equipments: Selection, purchase specifications, maintenance, clean-in-place, sterilize-in-place, methods (TP and STP). Raw materials: Purchase specifications, maintenance of stores, selection of vendors, controls on raw materials and finished dosage forms. Manufacture of and controls on dosage forms: Manufacturing documents, master formula, batch formula records, standard operating procedures, quality audits of manufacturing processes and facilities. In process quality controls on various dosage forms; sterile and non–sterile, standard operating procedures for various operations like cleaning, filling, drying, compression, coating, disinfections, sterilization, membrane filtration etc., Packaging and labelling control, line clearance, reconciliation of labels, cartons and other packaging materials. Quality Control Laboratory: Responsibilities, good laboratory practices, routine controls instruments, reagents, sampling plans, standard test procedures, protocols, non-clinical testing, controls on animal house. Data generation and storage, quality control documents, retention samples, records and audits of quality control facilities. Finished products release, quality review, quality audits, batch release document.

**UNIT - IV**

Regulatory Considerations for Pre-clinical and Clinical Evaluation: Pre-clinical requirements currently in use. Regulatory requirements of single dose and repeat dose toxicity studies. Study of specific toxicities such as mutagenicity, carcinogenicity and teratogenicity. Animal pharmacokinetics and toxicokinetics. Regulatory requirements of clinical evaluation, pharmacokinetics in man genetic polymorphism. Design and interpretation of clinical trials. Quality assurance standards as per ISO.

**UNIT - V**

Globalization of drug industry, present status and scope of pharmaceutical industry in India. WHO and NABL certification, ICH guidelines for manufacturing and quality assurance of drug formulation.

**TEXT AND REFERENCE BOOKS:**

1. Guidelines for Developing National Drug Policies; WHO Publications, 1998.

2. Quality Assurance of Pharmaceuticals—A Compendium of Guidelines and Related Materials, Vol.–1; WHO Publications.
3. A Guide to Total Quality Management by Kaushik Maitra and Sedhan K. Ghosh.
4. GMP by Mehra.
5. How to Practice GMP by P.P. Sharma.
6. ISO 9000 and Total Quality Management by Sadhan K. Ghosh.
7. Good Manufacturing Practices for Pharmaceuticals-A Plan for Total Quality Control by Sidney H. Willing & James R Stoker. (Drugs & Pharm. Sciences) Vol. 78; Marcel Dekker Inc.
8. OPPI-Quality Assurance, USP.
9. Current good manufacturing practices for pharmaceuticals by Manohar A. Potdar
10. Quality assurance and quality management in pharmaceutical industry by Y. Anjaneyulu and marayya
11. Total Quality Management, An integrated Approach by D. R. Kiran, BS Publications
12. Total Quality Management, 3rd edition by Joel E. Ross. CRC press

**JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD**  
**M.Pharm I Year I Sem (Pharmaceutics/Pharmaceutical Technology)**

**COSMETICS AND COSMECEUTICALS (Professional Elective - II)**

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

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

**Course Outcomes:** Upon completion of the subject student shall able to know Regulatory biological aspects of cosmetics, excipients used for various formulations, designing of cosmeceuticals and herbal products

**UNIT I**

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

**UNIT II**

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

**UNIT III**

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

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

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

**UNIT IV**

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

**UNIT V**

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

**REFERENCES**

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

**JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD**  
**M.Pharm I Year I Sem (Pharmaceutics/Pharmaceutical Technology)**

**PHARMACEUTICAL VALIDATION (Professional Elective - II)**

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

**Course Outcome:** Upon completion of the subject student shall be able to

- Explain the aspect of validation
- Carryout validation of manufacturing processes
- Apply the knowledge of validation to instruments and equipments

**UNIT I**

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

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

**UNIT II**

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

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

**UNIT III**

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

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

**UNIT IV**

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

**UNIT V**

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

- Validate the manufacturing facilities

**REFERENCES:**

1. T. Loftus & R. A. Nash, "Pharmaceutical Process Validation", Drugs and Pharm Sci. Series, Vol. 129, 3rd Ed., Marcel Dekker Inc., N.Y.
2. The Theory & Practice of Industrial Pharmacy, 3rd edition, Leon Lachman, Herbert A. Lieberman, Joseph. L. Karig, Varghese Publishing House, Bombay.
3. Validation Master plan by Terveeks or Deeks, Davis Harwood International publishing.

4. Validation of Aseptic Pharmaceutical Processes, 2nd Edition, by Carleton & Agalloco, (Marcel Dekker).
5. Michael Levin, Pharmaceutical Process Scale-Up, Drugs and Pharm. Sci. Series, Vol. 157, 2nd Ed., Marcel Dekker Inc., N.Y.
6. Validation Standard Operating Procedures: A Step by Step Guide for Achieving Compliance in the Pharmaceutical, Medical Device, and Biotech Industries, Syed Imtiaz Haider
7. Pharmaceutical Equipment Validation: The Ultimate Qualification Handbook, Phillip A. Cloud, Interpharm Press
8. Validation of Pharmaceutical Processes: Sterile Products, Frederick J. Carlton (Ed.) and James Agalloco (Ed.), Marcel Dekker, 2nd Ed.
9. Analytical Method validation and Instrument Performance Verification by Churg Chan, Heiman Lam



**JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD**  
**M.Pharm I Year I Sem (Pharmaceutics/Pharmaceutical Technology)**

**STABILITY OF DRUGS AND DOSAGE FORMS (Professional Elective - II)**

**Course Objectives:** 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.

**Course Outcomes:** 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.

**UNIT - I**

**Drug decomposition mechanisms:**

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

**UNIT - II**

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

Physical stability testing of dosage forms:

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

**UNIT - III**

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

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

**UNIT - IV**

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

**UNIT - V**

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

Stability studies: Concept of stability studies.

- a) cGMP & ICH guidelines for Accelerated stability Testing.
- b) Interaction of containers & closure Compatibility Testing.

**REFERENCE BOOKS:**

1. Comprehensive Pharmacy Review 5th Edition by Leon Shargel, Alan H. Mutnick, Paul F. Souney, Larry N. Sawnsen – 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.
11. Stability of Drugs and Dosage Forms by Yoshioka and Stella.

**JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD**  
**M.Pharm I Year I Sem (Pharmaceutics/Pharmaceutical Technology)**

**RESEARCH METHODOLOGY AND IPR**

**Course Objectives:**

- To understand the research problem
- To know the literature studies, plagiarism and ethics
- To get the knowledge about technical writing
- To analyze the nature of intellectual property rights and new developments
- To know the patent rights

**Course Outcomes:** At the end of this course, students will be able to

- Understand research problem formulation.
- Analyze research related information
- Follow research ethics
- Understand that today's world is controlled by Computer, Information Technology, but tomorrow world will be ruled by ideas, concept, and creativity.
- Understanding that when IPR would take such important place in growth of individuals & nation, it is needless to emphasis the need of information about Intellectual Property Right to be promoted among students in general & engineering in particular.
- Understand that IPR protection provides an incentive to inventors for further research work and investment in R & D, which leads to creation of new and better products, and in turn brings about, economic growth and social benefits.

**UNIT - I:**

Meaning of research problem, Sources of research problem, Criteria Characteristics of a good research problem, Errors in selecting a research problem, Scope and objectives of research problem. Approaches of investigation of solutions for research problem, data collection, analysis, interpretation, Necessary instrumentations

**UNIT - II:**

Effective literature studies approaches, analysis, Plagiarism, Research ethics

**UNIT - III:**

Effective technical writing, how to write report, Paper Developing a Research Proposal, Format of research proposal, a presentation and assessment by a review committee

**UNIT - IV:**

Nature of Intellectual Property: Patents, Designs, Trade and Copyright. Process of Patenting and Development: technological research, innovation, patenting, development. International Scenario: International cooperation on Intellectual Property. Procedure for grants of patents, Patenting under PCT.

**UNIT-V:**

Patent Rights: Scope of Patent Rights. Licensing and transfer of technology. Patent information and databases. Geographical Indications. New Developments in IPR: Administration of Patent System. New developments in IPR; IPR of Biological Systems, Computer Software etc. Traditional knowledge Case Studies, IPR and IITs.

**TEXT BOOKS:**

1. Stuart Melville and Wayne Goddard, "Research methodology: an introduction for science & engineering students"
2. Wayne Goddard and Stuart Melville, "Research Methodology: An Introduction"

**REFERENCES:**

1. Ranjit Kumar, 2nd Edition, "Research Methodology: A Step by Step Guide for beginners"
2. Halbert, "Resisting Intellectual Property", Taylor & Francis Ltd ,2007.
3. Mayall, "Industrial Design", McGraw Hill, 1992.
4. Niebel, "Product Design", McGraw Hill, 1974.
5. Asimov, "Introduction to Design", Prentice Hall, 1962.
6. Robert P. Merges, Peter S. Menell, Mark A. Lemley, "Intellectual Property in New Technological Age", 2016.
7. T. Ramappa, "Intellectual Property Rights Under WTO", S. Chand, 2008

**JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD**  
**M.Pharm I Year I Sem (Pharmaceutics/Pharmaceutical Technology)**

**MODERN PHARMACEUTICS – I LAB (Laboratory-I)**

**List of Experiments:**

1. To carry out the preformulation studies of solid dosage forms.
2. To study the effect of compressional force on tablet disintegration time
3. To study the micromeritic properties of powders and granules
4. To study the effect of particle size on dissolution of tablets
5. To study the effect of binders on dissolution of tablets
6. To study pharmacokinetic models, to determine similarity factors
7. Accelerated stability testing of different tablets
8. Determination of first order, second order rate constants by acid and alkaline hydrolysis
9. Preparation and evaluation of beta cyclodextrin complexes of new drugs
10. Preparation of paracetamol tablets and comparison with marketed products

**JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD**  
**M.Pharm I Year I Sem (Pharmaceutics/Pharmaceutical Technology)**

**APPLIED BIOPHARMACEUTICS AND PHARMACOKINETICS LAB (Laboratory - II)**

**List of Experiments:**

1. Analysis of dissolution by various data-kinetic modelling.
2. Calibration curve of different API's by UV/HPLC/HPTLC
3. Dissolution of immediate release, sustained release and delayed release.
4. Evaluation of drug-protein binding analysis
5. Assignment of numerical problems, one compartment and two compartment disposition, method of residuals, AUC and evaluation of pharmacokinetic parameters.
6. Calculation of  $K_a$ (absorption rate constant ) absorption curve- Wagner nelson method , Loo-Riegel method.
7. Calculation of pharmacokinetics parameters of one compartment oral data and two compartment IV data.
8. Construction of IVIVC from the data
9. Calculation of Urinary Pharmacokinetics
10. Calculation of Bioavailability and Bioequivalence Studies
11. Permeation studies of Franz diffusion cell
12. Drug Release from semisolids by Agar gel method or Franz diffusion cell.

**JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD**  
**M.Pharm (Pharmaceutics/Pharmaceutical Technology)**

**ENGLISH FOR RESEARCH PAPER WRITING (Audit Course - I & II)**

**Prerequisite:** None

**Course objectives:** Students will be able to:

- Understand that how to improve your writing skills and level of readability
- Learn about what to write in each section
- Understand the skills needed when writing a Title Ensure the good quality of paper at very first-time submission

**UNIT-I:**

Planning and Preparation, Word Order, Breaking up long sentences, Structuring Paragraphs and Sentences, Being Concise and Removing Redundancy, Avoiding Ambiguity and Vagueness

**UNIT-II:**

Clarifying Who Did What, Highlighting Your Findings, Hedging and Criticizing, Paraphrasing and Plagiarism, Sections of a Paper, Abstracts. Introduction

**UNIT-III:**

Review of the Literature, Methods, Results, Discussion, Conclusions, The Final Check.

**UNIT-IV:**

key skills are needed when writing a Title, key skills are needed when writing an Abstract, key skills are needed when writing an Introduction, skills needed when writing a Review of the Literature,

**UNIT-V:**

skills are needed when writing the Methods, skills needed when writing the Results, skills are needed when writing the Discussion, skills are needed when writing the Conclusions. useful phrases, how to ensure paper is as good as it could possibly be the first- time submission

**TEXT BOOKS/ REFERENCES:**

1. Goldbort R (2006) Writing for Science, Yale University Press (available on Google Books)
2. Day R (2006) How to Write and Publish a Scientific Paper, Cambridge University Press
3. Highman N (1998), Handbook of Writing for the Mathematical Sciences, SIAM. Highman's book.
4. Adrian Wallwork, English for Writing Research Papers, Springer New York Dordrecht Heidelberg London, 2011

**JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD**  
**M.Pharm (Pharmaceutics/Pharmaceutical Technology)**

**DISASTER MANAGEMENT (Audit Course - I & II)**

**Prerequisite:** None

**Course Objectives:** Students will be able to

- learn to demonstrate a critical understanding of key concepts in disaster risk reduction and humanitarian response.
- critically evaluate disaster risk reduction and humanitarian response policy and practice from multiple perspectives.
- develop an understanding of standards of humanitarian response and practical relevance in specific types of disasters and conflict situations.
- critically understand the strengths and weaknesses of disaster management approaches,
- planning and programming in different countries, particularly their home country or the countries they work in

**UNIT-I:**

**Introduction:**

Disaster: Definition, Factors and Significance; Difference Between Hazard and Disaster; Natural and Manmade Disasters: Difference, Nature, Types and Magnitude.

**Disaster Prone Areas in India:**

Study of Seismic Zones; Areas Prone to Floods and Droughts, Landslides and Avalanches; Areas Prone to Cyclonic and Coastal Hazards with Special Reference to Tsunami; Post-Disaster Diseases and Epidemics

**UNIT-II:**

**Repercussions of Disasters and Hazards:**

Economic Damage, Loss of Human and Animal Life, Destruction of Ecosystem. Natural Disasters: Earthquakes, Volcanisms, Cyclones, Tsunamis, Floods, Droughts and Famines, Landslides and Avalanches, Man-made disaster: Nuclear Reactor Meltdown, Industrial Accidents, Oil Slicks and Spills, Outbreaks of Disease and Epidemics, War and Conflicts.

**UNIT-III:**

**Disaster Preparedness and Management:**

Preparedness: Monitoring of Phenomena Triggering A Disaster or Hazard; Evaluation of Risk: Application of Remote Sensing, Data from Meteorological and Other Agencies, Media Reports: Governmental and Community Preparedness.

**UNIT-IV:**

**Risk Assessment Disaster Risk:**

Concept and Elements, Disaster Risk Reduction, Global and National Disaster Risk Situation. Techniques of Risk Assessment, Global Co-Operation in Risk Assessment and Warning, People's Participation in Risk Assessment. Strategies for Survival.

**UNIT-V:**

**Disaster Mitigation:**

Meaning, Concept and Strategies of Disaster Mitigation, Emerging Trends In Mitigation. Structural Mitigation and Non-Structural Mitigation, Programs of Disaster Mitigation in India.

**TEXT BOOKS/ REFERENCES:**



1. R. Nishith, Singh AK, "Disaster Management in India: Perspectives, issues and strategies "New Royal book Company.
2. Sahni, Pardeep Et. Al. (Eds.)," Disaster Mitigation Experiences and Reflections", Prentice Hall of India, New Delhi.
3. Goel S. L., Disaster Administration and Management Text and Case Studies", Deep &Deep Publication Pvt. Ltd., New Delhi.

**JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD**  
**M.Pharm (Pharmaceutics/Pharmaceutical Technology)**

**SANSKRIT FOR TECHNICAL KNOWLEDGE (Audit Course - I & II)**

**Prerequisite:** None

**Course Objectives:**

- To get a working knowledge in illustrious Sanskrit, the scientific language in the world
- Learning of Sanskrit to improve brain functioning
- Learning of Sanskrit to develop the logic in mathematics, science & other subjects enhancing the memory power
- The engineering scholars equipped with Sanskrit will be able to explore the huge knowledge from ancient literature

**Course Outcomes:** Students will be able to

- Understanding basic Sanskrit language
- Ancient Sanskrit literature about science & technology can be understood
- Being a logical language will help to develop logic in students

**UNIT-I:**

Alphabets in Sanskrit,

**UNIT-II:**

Past/Present/Future Tense, Simple Sentences

**UNIT-III:**

Order, Introduction of roots,

**UNIT-IV:**

Technical information about Sanskrit Literature

**UNIT-V:**

Technical concepts of Engineering-Electrical, Mechanical, Architecture, Mathematics

**TEXT BOOKS/ REFERENCES:**

1. "Abhyaspustakam" – Dr. Vishwas, Samskrita-Bharti Publication, New Delhi
2. "Teach Yourself Sanskrit" Prathama Deeksha-Vempati Kutumbshastri, Rashtriya Sanskrit Sansthanam, New Delhi Publication
3. "India's Glorious Scientific Tradition" Suresh Soni, Ocean books (P) Ltd., New Delhi.

**JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD**  
**M.Pharm (Pharmaceutics/Pharmaceutical Technology)**

**VALUE EDUCATION (Audit Course - I & II)**

**Prerequisite:** None

**Course Objectives:** Students will be able to

- Understand value of education and self- development
- Imbibe good values in students
- Let the should know about the importance of character

**Course outcomes:** Students will be able to

- Knowledge of self-development
- Learn the importance of Human values
- Developing the overall personality

**UNIT-I:**

Values and self-development –Social values and individual attitudes. Work ethics, Indian vision of humanism. Moral and non- moral valuation. Standards and principles. Value judgements

**UNIT-II:**

Importance of cultivation of values. Sense of duty. Devotion, Self-reliance. Confidence, Concentration. Truthfulness, Cleanliness. Honesty, Humanity. Power of faith, National Unity. Patriotism. Love for nature, Discipline

**UNIT-III:**

Personality and Behavior Development - Soul and Scientific attitude. Positive Thinking. Integrity and discipline, Punctuality, Love and Kindness.

**UNIT-IV:**

Avoid fault Thinking. Free from anger, Dignity of labour. Universal brotherhood and religious tolerance. True friendship. Happiness Vs suffering, love for truth. Aware of self-destructive habits. Association and Cooperation. Doing best for saving nature

**UNIT-V:**

Character and Competence –Holy books vs Blind faith. Self-management and Good health. Science of reincarnation, Equality, Nonviolence, Humility, Role of Women. All religions and same message. Mind your Mind, Self-control. Honesty, Studying effectively

**TEXT BOOKS/ REFERENCES:**

1. Chakroborty, S.K. "Values and Ethics for organizations Theory and practice", Oxford University Press, New Delhi

**JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD**  
**M.Pharm (Pharmaceutics/Pharmaceutical Technology)**

**CONSTITUTION OF INDIA (Audit Course - I & II)**

**Prerequisite:** None

**Course Objectives:** Students will be able to:

- Understand the premises informing the twin themes of liberty and freedom from a civil rights perspective.
- To address the growth of Indian opinion regarding modern Indian intellectuals' constitutional role and entitlement to civil and economic rights as well as the emergence of nationhood in the early years of Indian nationalism.
- To address the role of socialism in India after the commencement of the Bolshevik Revolution in 1917 and its impact on the initial drafting of the Indian Constitution.

**Course Outcomes:** Students will be able to:

- Discuss the growth of the demand for civil rights in India for the bulk of Indians before the arrival of Gandhi in Indian politics.
- Discuss the intellectual origins of the framework of argument that informed the conceptualization of social reforms leading to revolution in India.
- Discuss the circumstances surrounding the foundation of the Congress Socialist Party [CSP] under the leadership of Jawaharlal Nehru and the eventual failure of the proposal of direct elections through adult suffrage in the Indian Constitution.
- Discuss the passage of the Hindu Code Bill of 1956.

**UNIT-I:**

**History of Making of the Indian Constitution:** History Drafting Committee, (Composition & Working), **Philosophy of the Indian Constitution:** Preamble, Salient Features.

**UNIT-II:**

**Contours of Constitutional Rights & Duties:** Fundamental Rights Right to Equality, Right to Freedom, Right against Exploitation, Right to Freedom of Religion, Cultural and Educational Rights, Right to Constitutional Remedies, Directive Principles of State Policy, Fundamental Duties.

**UNIT-III:**

**Organs of Governance:** Parliament, Composition, Qualifications and Disqualifications, Powers and Functions, Executive, President, Governor, Council of Ministers, Judiciary, Appointment and Transfer of Judges, Qualification, Powers and Functions.

**UNIT-IV:**

**Local Administration:** District's Administration head: Role and Importance, Municipalities: Introduction, Mayor and role of Elected Representative, CEO of Municipal Corporation. Pachayati raj: Introduction, PRI: Zila Pachayat. Elected officials and their roles, CEO Zila Pachayat: Position and role. Block level: Organizational Hierarchy (Different departments), Village level: Role of Elected and Appointed officials, Importance of grass root democracy.

**UNIT-V:**

**Election Commission:** Election Commission: Role and Functioning. Chief Election Commissioner and Election Commissioners. State Election Commission: Role and Functioning. Institute and Bodies for the welfare of SC/ST/OBC and women.

**TEXT BOOKS/ REFERENCES:**

1. The Constitution of India, 1950 (Bare Act), Government Publication.

2. Dr. S. N. Busi, Dr. B. R. Ambedkar framing of Indian Constitution, 1st Edition, 2015.
3. M. P. Jain, Indian Constitution Law, 7th Edn., Lexis Nexis, 2014.
4. D.D. Basu, Introduction to the Constitution of India, Lexis Nexis, 2015.

**JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD**  
**M.Pharm (Pharmaceutics/Pharmaceutical Technology)**

**PEDAGOGY STUDIES (Audit Course - I & II)**

**Prerequisite:** None

**Course Objectives:** Students will be able to:

- Review existing evidence on the review topic to inform programme design and policy making undertaken by the DfID, other agencies and researchers.
- Identify critical evidence gaps to guide the development.

**Course Outcomes:** Students will be able to understand:

- What pedagogical practices are being used by teachers in formal and informal classrooms in developing countries?
- What is the evidence on the effectiveness of these pedagogical practices, in what conditions, and with what population of learners?
- How can teacher education (curriculum and practicum) and the school curriculum and guidance materials best support effective pedagogy?

**UNIT-I:**

**Introduction and Methodology:** Aims and rationale, Policy background, Conceptual framework and terminology Theories of learning, Curriculum, Teacher education. Conceptual framework, Research questions. Overview of methodology and Searching.

**UNIT-II:**

**Thematic overview:** Pedagogical practices are being used by teachers in formal and informal classrooms in developing countries. Curriculum, Teacher education.

**UNIT-III:**

Evidence on the effectiveness of pedagogical practices, Methodology for the indepth stage: quality assessment of included studies. How can teacher education (curriculum and practicum) and the scho curriculum and guidance materials best support effective pedagogy? Theory of change. Strength and nature of the body of evidence for effective pedagogical practices. Pedagogic theory and pedagogical approaches. Teachers' attitudes and beliefs and Pedagogic strategies.

**UNIT-IV:**

**Professional development:** alignment with classroom practices and follow-up support, Peer support, Support from the head teacher and the community. Curriculum and assessment, Barriers to learning: limited resources and large class sizes

**UNIT-V:**

**Research gaps and future directions:** Research design, Contexts, Pedagogy, Teacher education, Curriculum and assessment, Dissemination and research impact.

**TEXT BOOKS/ REFERENCES:**

1. Ackers J, Hardman F (2001) Classroom interaction in Kenyan primary schools, Compare, 31 (2): 245-261.
2. Agrawal M (2004) Curricular reform in schools: The importance of evaluation, Journal of Curriculum Studies, 36 (3): 361-379.
3. Akyeamong K (2003) Teacher training in Ghana - does it count? Multi-site teacher education research project (MUSTER) country report 1. London: DFID.

4. Akyeampong K, Lussier K, Pryor J, Westbrook J (2013) Improving teaching and learning of basic maths and reading in Africa: Does teacher preparation count? *International Journal Educational Development*, 33 (3): 272–282.
5. Alexander RJ (2001) *Culture and pedagogy: International comparisons in primary education*. Oxford and Boston: Blackwell.
6. Chavan M (2003) *Read India: A mass scale, rapid, 'learning to read' campaign*.
7. [www.pratham.org/images/resource%20working%20paper%202.pdf](http://www.pratham.org/images/resource%20working%20paper%202.pdf).

**JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD**  
**M.Pharm (Pharmaceutics/Pharmaceutical Technology)**

**STRESS MANAGEMENT BY YOGA (Audit Course - I & II)**

**Prerequisite:** None

**Course Objectives:**

- To achieve overall health of body and mind
- To overcome stress

**Course Outcomes:** Students will be able to:

- Develop healthy mind in a healthy body thus improving social health also
- Improve efficiency

**UNIT-I:**

Definitions of Eight parts of yog. (Ashtanga)

**UNIT-II:**

Yam and Niyam.

**UNIT-III:**

Do`s and Don`t`s in life.

- i) Ahinsa, satya, astheya, bramhacharya and aparigraha
- ii) Shaucha, santosh, tapa, swadhyay, ishwarpranidhan

**UNIT-IV:**

Asan and Pranayam

**UNIT-V:**

- i) Various yog poses and their benefits for mind & body
- ii) Regularization of breathing techniques and its effects-Types of pranayam

**TEXT BOOKS/ REFERENCES:**

1. 'Yogic Asanas for Group Training-Part-I': Janardan Swami Yogabhyasi Mandal, Nagpur
2. "Rajayoga or conquering the Internal Nature" by Swami Vivekananda, Advaita Ashrama (Publication Department), Kolkata



**JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD**  
**M.Pharm (Pharmaceutics/Pharmaceutical Technology)**

**PERSONALITY DEVELOPMENT THROUGH LIFE ENLIGHTENMENT SKILLS**  
**(Audit Course - I & II)**

**Prerequisite:** None

**Course Objectives:**

- To learn to achieve the highest goal happily
- To become a person with stable mind, pleasing personality and determination
- To awaken wisdom in students

**Course Outcomes:** Students will be able to

- Study of Shrimad-Bhagwad-Geeta will help the student in developing his personality and achieve the highest goal in life
- The person who has studied Geeta will lead the nation and mankind to peace and prosperity
- Study of Neetishatakam will help in developing versatile personality of students

**UNIT-I:**

Neetisatakam-Holistic development of personality

- Verses- 19,20,21,22 (wisdom)
- Verses- 29,31,32 (pride & heroism)
- Verses- 26,28,63,65 (virtue)

**UNIT-II:**

Neetisatakam-Holistic development of personality

- Verses- 52,53,59 (dont's)
- Verses- 71,73,75,78 (do's)

**UNIT-III:**

Approach to day to day work and duties.

- Shrimad Bhagwad Geeta: Chapter 2-Verses 41, 47,48,
- Chapter 3-Verses 13, 21, 27, 35, Chapter 6-Verses 5,13,17, 23, 35,
- Chapter 18-Verses 45, 46, 48.

**UNIT-IV:**

Statements of basic knowledge.

- Shrimad Bhagwad Geeta: Chapter2-Verses 56, 62, 68
- Chapter 12 -Verses 13, 14, 15, 16,17, 18
- Personality of Role model. Shrimad Bhagwad Geeta:

**UNIT-V:**

- Chapter2-Verses 17, Chapter 3-Verses 36,37,42,
- Chapter 4-Verses 18, 38,39
- Chapter18 – Verses 37,38,63

**TEXT BOOKS/ REFERENCES:**

1. "Srimad Bhagavad Gita" by Swami Swarupananda Advaita Ashram (Publication Department), Kolkata.
2. Bhartrihari's Three Satakam (Niti-sringar-vairagya) by P.Gopinath, Rashtriya Sanskrit Sansthanam, New Delhi.

## JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD

## M.PHARMACY (INDUSTRIAL PHARMACY)

**COURSE STRUCTURE AND SYLLABUS**  
**Effective from Academic Year 2019-20 Admitted Batch**
**I YEAR I Semester**

Course Code	Course Title	L	T	P	Credits
Professional Core-I	Advanced Physical Pharmaceutics	3	0	0	3
Professional Core-II	Pharmaceutical Formulation Development	3	0	0	3
Professional Elective-I	1. Applied Biopharmaceutics and Pharmacokinetics 2. Drug Regulatory affairs 3. Pharmaceutical Management	3	0	0	3
Professional Elective-II	1. Pharmaceutical Validation 2. Herbal Cosmetics Technology 3. Stability of Drugs and Dosage Forms	3	0	0	3
MC	Research methodology and IPR	2	0	0	2
Laboratory- I	Advanced Physical Pharmaceutics Lab	0	0	4	2
Laboratory- II	Pharmaceutical Formulation Development Lab	0	0	4	2
Audit	Audit Course - I	2	0	0	0
<b>TOTAL</b>		<b>16</b>	<b>0</b>	<b>8</b>	<b>18</b>

**I YEAR II Semester**

Course Code	Course Title	L	T	P	Credits
Professional Core-III	Advanced Drug Delivery Systems	3	0	0	3
Professional Core-IV	Pharmaceutical Production Technology	3	0	0	3
Professional Elective-III	1. Nano based Drug Delivery Systems 2. Nutraceuticals 3. Pharmaceutical Industrial Management	3	0	0	3
Professional Elective-IV	1. Quality by Design of Dosage Forms 2. Total Quality Management 3. Clinical Research and Pharmacovigilance	3	0	0	3
Laboratory- III	Advanced Drug Delivery System Lab	0	0	4	2
Laboratory- IV	Pharmaceutical Production Technology Lab	0	0	4	2
--	Mini project with seminar	2	0	0	2
Audit	Audit Course - II	2	0	0	0
<b>Total</b>		<b>16</b>	<b>0</b>	<b>8</b>	<b>18</b>

**Audit Courses 1 & 2**

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

**JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD**  
**M.Pharm I Year I Sem (Industrial Pharmacy)**

**ADVANCED PHYSICAL PHARMACEUTICS (Professional Core – I)**

**Course Objectives:** 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.

**Course Outcomes:** 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.

#### **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**

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

**Characterization of API and excipients: Differential Scanning Calorimetry:** Principle, thermal transitions, advantages, disadvantages, instrumentation, applications and interpretations

**X Ray Diffraction methods:** Origin of x-rays, principle, advantages, disadvantages, instrumentation, applications and interpretations.

#### **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.

#### **TEXT BOOKS**

1. Physical Pharmacy, 4<sup>th</sup> Edition by Alfred Martin.
2. Theory and Practice of Tablets – Lachman, Vol.4

3. Pharmaceutical Dosage forms – Dispersesystems Vol. I & II
4. Cartenson “Drug Stability, Marcel Decker Solid state properties, Marcel Dekker.
1. Industrial Pharmacy - Selected Topics, CVS Subramanyam and J Thimmasetty, Vallabh Prakashan Delhi - 2013

**REFERENCE BOOKS**

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

**JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD**  
**M.Pharm I Year I Sem (Industrial Pharmacy)**

**PHARMACEUTICAL FORMULATION DEVELOPMENT (Professional Core – II)**

**Course Objectives:** This subject is to make the student achieve different parameters and factors that influence the dosage form design. This subject also impart the knowledge about unit operations, solid dosage forms and powders.

**Course Outcomes:**

- Different machinery used for various steps in manufacture of various dosage forms.
- Formulation and evaluation of hard and soft gelatin capsules and their advantages over other dosage forms.

**UNIT I**

- a. **Preformulation studies:** Goals of preformulation, preformulation parameters, methodology, solid state manipulation and characterization, solubility and partition coefficient, drug-excipient compatibility, intrinsic dissolution.
- b. Advances in Pharmaceutical excipients. Excipients selection for capsules, tablets, suspensions and emulsions.
- c. Packaging development – selection of primary and secondary packaging materials and testing

**UNIT II**

**Pharmaceutical unit operations:** A detail study involving machinery and theory of pharmaceutical unit operations like solid orals: Wet granulation- Rapid mixer granulator and Top spray granulation, Dry granulation- Slugging and roller compaction, drying, milling, blending, filtration and sterilization.

**UNIT III**

**Formulation development of solid and powder dosage forms:** Improved production techniques for tablets, new materials, processes, equipment improvements, high shear mixers, compression machines, coating machines, coating techniques in tablet technology for product development and computerization for in process quality control of tablets. Formulation development and manufacture of powder dosage form for internal and external use including inhalation dosage forms.

**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, the nature of the capsule shell and capsule, advances in capsule manufacture, processing and control including pharmaceutical aspects, physical stability and packaging.

**UNIT V**

**Optimization techniques in pharmaceutical formulation and processing:** Quality by Design: Concept and application to formulation development. Design of experiments (DOE): Formula and process optimization statistical design, response surface method, contour diagrams, factorial design, partial factorial design, simplex methods, mixture designs, Placket Burhan method, Box Benken method, applications in pharmaceutical formulation.

**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. Hand book of Pharmaceutical excipients
7. CVS Subhramanyam & J Thimmasethy, Industrial Pharmacy, Vallabh Prakasham, Delhi, 2014

**REFERENCE 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.
6. Pharmaceutical Packaging Technology by UK Jain, DC Goupale S Nayak.

**JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD**  
**M.Pharm I Year I Sem (Industrial Pharmacy)**

**APPLIED BIOPHARMACEUTICS AND PHARMACOKINETICS (Professional Elective – I)**

**Course Objectives:** The student shall know about bioavailability, bioequivalence and factor affecting bioavailability. They also know the pharmacokinetic parameter like drug disposition, absorption, non-linear and time dependant pharmacokinetics. They also know about the drug interactions & problems associated in pharmacokinetic parameters calculations.

**Course Outcomes:** students will be able to tell factors affecting the bioavailability and stability of dosage form; they also know the bioequivalence studies and protocols for bioequivalent studies. They also know the parameters for the disposition, absorption and Michaelis-Menton constants for non-linear kinetics.

**UNIT I**

- a. Biological and metabolic factors affecting bioavailability, complexation, dissolution - techniques of enhancing dissolution.
- b. Formulation factors affecting bioavailability of drugs in dosage forms of tablets, capsules, parenterals, liquid orals and topical dosage forms.
- c. **Bioavailability:** Importance, dose dependency, AUC, rate and extent, assessment, blood and urine samples, single dose and multiple dose studies, *Invitro- Invivo* Correlation analysis and Levels of Correlations.
- d. **Bioequivalence:** Importance equivalency concepts, biowaivers, study designs, protocol, transformation of data, Statistical Criteria as per the Regulations.

**UNIT II**

**Pharmacokinetics – Drug Disposition:** compartment models: One, two and non-compartmental approaches to pharmacokinetics. Recent trends, merits and limitations of these approaches. Application of these models to determine the various pharmacokinetic parameters pertaining to:

- a. Distribution: Apparent volume of distribution and its determination, factors affecting.
- b. Metabolism: Metabolic rate constant, Factors affecting Metabolism
- c. Elimination: Over all apparent elimination rate constant, and half life.  
All the above under the following conditions:
  1. Intravenous infusion
  2. Multiple dose injections
- d. Non-invasive methods of estimating pharmacokinetics parameters with emphasis on salivary and urinary samples.
- e. Concept of clearance: organ, total clearance, hepatic clearance, lung clearance and renal clearance.

**UNIT III**

**Pharmacokinetics – Absorption:** Rate constants – Zero order, first order, Models of experimental study of absorption (in silico, in vitro, in situ and in vivo) – Absorption half lives, method of residuals, Wagner – Nelson method, Loo - Reigleman method, Analysis of kinetics from urine samples. Pharmacokinetic parameters determination pertaining to: Multiple dosage oral administration.

**UNIT IV**

**Non-linear pharmacokinetics:** Concepts of linear and non-linear pharmacokinetics, Michaelis-Menton kinetics characteristics. Basic kinetic parameters, possible causes of non-induction, non-linear binding, and non-linearity of pharmacological responses.



**Clinical Pharmacokinetics:** Altered kinetics in pregnancy, child birth, infants and geriatrics. kinetics in GI disease, malabsorption syndrome, liver, cardiac, renal and pulmonary disease states.

#### UNIT V

**Time dependent pharmacokinetics:** Introduction, classification, physiologically induced time dependency: Chronopharmacokinetics - principles, drugs– (amino glycosides, NSAIDS, antihypertensive drug) chemically induced dependency.

**Drug Interactions:** Kinetics of drug interaction, study of drug-drug interaction mediated through absorption, distribution, metabolism and elimination, mechanisms of interaction and consequence.

❖ Numerical problems associated with all units, if any.

#### TEXT BOOKS

1. Biopharmaceutics and Clinical Pharmacokinetics by Milo Gibaldi.
2. Learn Shargel and ABC yu, Applied Biopharmacokinetics and Pharmacokinetics
3. Biopharmaceutics and Pharmacokinetics by C.V.S. Subrahmanyam, Vallabh Prakashan.2010.
4. Basic biopharmaceutics, Sunil S. Jambhekar and Philip J Brean.
5. Text book of Biopharmaceutics and Clinical Pharmacokinetics by NiaziSarfraz

#### REFERENCE BOOKS

1. Bio-Pharmaceutics and Pharmacokinetics by V. Venkateshwarlu.
2. Pharmacokinetics, Biopharmaceutics and Clinical pharmacy by Robert E. Notari.
3. Biopharmaceutics and Clinical Pharmacokinetics - An Introduction by Robert E. Notari.
4. Drug drug interactions, scientific and regulatory perspectives by Albert P. G

**JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD**  
**M.Pharm I Year I Sem (Industrial Pharmacy)**

**DRUG REGULATORY AFFAIRS (Professional Elective - I)**

**Course Objectives:** 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.

**Course Outcomes:**

- Students will come to know the different competent regulatory authorities globally.
- 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.

**UNIT I**

**Drug Regulatory Aspects (India)**

1. Indian drug regulatory authorities, Central and State regulatory bodies (FDA)
2. Drugs and Cosmetics Act and Rules with latest Amendments (Selective)
3. Special emphasis – Schedule M and Y
4. New drugs – Importation, Registration, development, Clinical Trials, BE NOC & BE studies
5. Various Licences – Test Lic., Import lic., for testing of drugs and API's, Manufacturing Contract and Loan licence manufacturing.

**UNIT II**

**Good Manufacturing Practices (GMP)**

1. Indian GMP certification, WHO GMP certification.
2. ICH guidelines for stability testing and other relevant ones (Q1-Q10)
3. Export permissions and manufacturing for semi-regulated countries
4. Understanding of the plant layouts with special emphasis on the environment & safety. (HVAC, Water Systems, Stores Management, Effluent etc.)
5. Quality Assurance and Quality Control – Basic understanding for in-built quality.

**UNIT III**

A detailed study of regulatory aspects that affect drug product design, manufacture and distribution in a developed country such as USA and in a developing country such as Brazil, Hatch Waxmann Act; Bolar Provisions and other FDA Regulations. Regulatory aspects of pharmaceutical and bulk drug manufacture, regulatory drug analysis.

**UNIT IV**

Documentation related to manufacturing, cleaning methods, retention samples and records, quality control, batch release documents, distribution records, complaints and recalls.  
 Quality, safety and legislation for cosmetic products and herbal products.

**UNIT V**

**Governing Regulatory Bodies across the globe.**

- Country Authority Submission
- a. U.S Food & Drug Administration USDMF
  - b. Canada Therapeutic Product Directorate DMF
  - c. Europe
    - 1) European Medicines Agency (EMEA/ National Authorities) EDMF

- 2) European Directorate for Quality of Medicines CEP/COS & Health Care Products.
- 3) MHRA – Medicines and Health Care Products Regulatory Agency

- d. Product Filing
- e. Responding Regulatory Deficiencies
- f. Final Approval Procedure

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

#### **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, Vallabh Prakashan Delhi - 2013

**JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD  
M.Pharm I Year I Sem (Industrial Pharmacy)**

**PHARMACEUTICAL MANAGEMENT (Professional Elective – I)**

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

**Course Outcomes:**

- 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.

**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.

**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<sup>th</sup> 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**  
**M.Pharm I Year I Sem (Industrial Pharmacy)**

**PHARMACEUTICAL VALIDATION (Professional Elective – II)**

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

**Course Outcomes:** Upon completion of the subject student shall be able to

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

#### **UNIT I**

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

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

#### **UNIT II**

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

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

#### **UNIT III**

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

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

#### **UNIT IV**

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

#### **UNIT V**

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

#### **REFERENCES:**

1. B. T. Loftus & R. A. Nash, "Pharmaceutical Process Validation", Drugs and Pharm Sci. Series, Vol.129, 3rd Ed., Marcel Dekker Inc., N.Y.
2. The Theory & Practice of Industrial Pharmacy, 3rd edition, Leon Lachman, Herbert A. Lieberman, Joseph. L. Karig, Varghese Publishing House, Bombay.
3. Validation Master plan by Terveeks or Deeks, Davis Harwood International publishing.

4. Validation of Aseptic Pharmaceutical Processes, 2nd Edition, by Carleton & Agalloco, (Marcel Dekker).
5. Michael Levin, Pharmaceutical Process Scale-Up, Drugs and Pharm. Sci. Series, Vol. 157, 2nd Ed., Marcel Dekker Inc., N.Y.
6. Validation Standard Operating Procedures: A Step by Step Guide for Achieving Compliance in the Pharmaceutical, Medical Device, and Biotech Industries, Syed Imtiaz Haider
7. Pharmaceutical Equipment Validation: The Ultimate Qualification Handbook, Phillip A. Cloud, Interpharm Press
8. Validation of Pharmaceutical Processes: Sterile Products, Frederick J. Carlton (Ed.) and James Agalloco (Ed.), Marcel Dekker, 2nd Ed.
9. Analytical Method validation and Instrument Performance Verification by Churg Chan, Heiman Lam.

**JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD**  
**M.Pharm I Year I Sem (Industrial Pharmacy)**

**HERBAL COSMETIC TECHNOLOGY (Professional Elective - II)**

**Course Objectives:** 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.

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

**UNIT I**

Introduction: Herbal/ natural cosmetics, Classification & Economic aspects. Regulatory Provisions relation to manufacture of cosmetics: - License, GMP, offences & Penalties, Import & Export of Herbal/natural cosmetics, Industries involved in the production of Herbal/natural cosmetics.

**UNIT II**

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

**UNIT III**

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

**UNIT IV**

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

**UNIT IV**

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

**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**  
**M.Pharm I Year I Sem (Industrial Pharmacy)**

**STABILITY OF DRUGS AND DOSAGE FORMS (Professional Elective - II)**

**Course Objectives:** 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.

**Course Outcomes:** 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.

**UNIT - I**

**Drug decomposition mechanisms:**

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

**UNIT - II**

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

Physical stability testing of dosage forms:

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

**UNIT - III**

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

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

**UNIT - IV**

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

**UNIT - V**

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

Stability studies: Concept of stability studies.

- a) cGMP & ICH guidelines for Accelerated stability Testing.
- b) Interaction of containers & closure Compatibility Testing.

**REFERENCE BOOKS:**

1. Comprehensive Pharmacy Review 5th Edition by Leon Shargel, Alan H. Mutnick, Paul F. Souney, Larry N. Sawnsen – 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.
11. Stability of Drugs and Dosage Forms by Yoshioka and Stella.

**JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD**  
**M.Pharm I Year I Sem (Industrial Pharmacy)**

**RESEARCH METHODOLOGY AND IPR**

**Course Objectives:**

- To understand the research problem
- To know the literature studies, plagiarism and ethics
- To get the knowledge about technical writing
- To analyze the nature of intellectual property rights and new developments
- To know the patent rights

**Course Outcomes:** At the end of this course, students will be able to

- Understand research problem formulation.
- Analyze research related information
- Follow research ethics
- Understand that today's world is controlled by Computer, Information Technology, but tomorrow world will be ruled by ideas, concept, and creativity.
- Understanding that when IPR would take such important place in growth of individuals & nation, it is needless to emphasis the need of information about Intellectual Property Right to be promoted among students in general & engineering in particular.
- Understand that IPR protection provides an incentive to inventors for further research work and investment in R & D, which leads to creation of new and better products, and in turn brings about, economic growth and social benefits.

**UNIT - I:**

Meaning of research problem, Sources of research problem, Criteria Characteristics of a good research problem, Errors in selecting a research problem, Scope and objectives of research problem. Approaches of investigation of solutions for research problem, data collection, analysis, interpretation, Necessary instrumentations

**UNIT - II:**

Effective literature studies approaches, analysis, Plagiarism, Research ethics

**UNIT - III:**

Effective technical writing, how to write report, Paper Developing a Research Proposal, Format of research proposal, a presentation and assessment by a review committee

**UNIT - IV:**

Nature of Intellectual Property: Patents, Designs, Trade and Copyright. Process of Patenting and Development: technological research, innovation, patenting, development. International Scenario: International cooperation on Intellectual Property. Procedure for grants of patents, Patenting under PCT.

**UNIT-V:**

Patent Rights: Scope of Patent Rights. Licensing and transfer of technology. Patent information and databases. Geographical Indications. New Developments in IPR: Administration of Patent System. New developments in IPR; IPR of Biological Systems, Computer Software etc. Traditional knowledge Case Studies, IPR and IITs.

**TEXT BOOKS:**

1. Stuart Melville and Wayne Goddard, "Research methodology: an introduction for science & engineering students"
2. Wayne Goddard and Stuart Melville, "Research Methodology: An Introduction"

**REFERENCES:**

1. Ranjit Kumar, 2nd Edition, "Research Methodology: A Step by Step Guide for beginners"
2. Halbert, "Resisting Intellectual Property", Taylor & Francis Ltd ,2007.
3. Mayall, "Industrial Design", McGraw Hill, 1992.
4. Niebel, "Product Design", McGraw Hill, 1974.
5. Asimov, "Introduction to Design", Prentice Hall, 1962.
6. Robert P. Merges, Peter S. Menell, Mark A. Lemley, "Intellectual Property in New Technological Age", 2016.
7. T. Ramappa, "Intellectual Property Rights Under WTO", S. Chand, 2008

**JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD  
M.Pharm I Year I Sem (Industrial Pharmacy)**

**ADVANCED PHYSICAL PHARMACEUTICS LAB (Laboratory - I)**

**List of experiments**

1. Determinates of molecular weight of some selected polymers.
2. Preparation and evaluation of solid dispersions (Immediate release and sustained release)
3. Accelerated stability testing of Aspirin Tablets
4. Stability evaluation of Aspirin at various pH and temperature conditions
5. Determination of 1st order and 2nd order rate constant. Half life by Acid / Alkali hydrolysis
6. Preparation and evaluation of multiple emulsions
7. Preparation and evaluation of  $\beta$ -cyclodextrin complexes of some drugs.
8. Generation of dissolution profiles of few dosage forms and application of the data into various kinetic equations. Calculation of Hixon-crowell dissolution rate constant
9. Preparation and dissolution study of paracetamol tablets and comparison with the marketed product.
10. Study of solubility and dissolution for few drugs and their respective salts.
11. Study of drug release from commercial suspension and emulsion dosage forms
12. Viscosity measurement of Newtonian and Non-Newtonian liquids

**JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD  
M.Pharm I Year I Sem (Industrial Pharmacy)**

**PHARMACEUTICAL FORMULATION DEVELOPMENT LAB (Laboratory - II)**

**List of Experiments**

1. To carry out the preformulation studies of solid dosage forms.
2. To study the effect of compressional force on tablet disintegration time
3. To study the micromeritic properties of powders and granules
4. To study the effect of particle size on dissolution of tablets
5. To study the effect of binders on dissolution of tablets
6. To study pharmacokinetic models, to determine similarity factors
7. Accelerated stability testing of different tablets
8. Determination of first order, second order rate constants by acid and alkaline hydrolysis
9. Preparation and evaluation of beta cyclodextrin complexes of new drugs
10. Preparation of paracetamol tablets and comparison with marketed products

**JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD**  
**M.Pharm (Industrial Pharmacy)**

**ENGLISH FOR RESEARCH PAPER WRITING (Audit Course - I & II)**

**Prerequisite:** None

**Course objectives:** Students will be able to:

- Understand that how to improve your writing skills and level of readability
- Learn about what to write in each section
- Understand the skills needed when writing a Title Ensure the good quality of paper at very first-time submission

**UNIT-I:**

Planning and Preparation, Word Order, Breaking up long sentences, Structuring Paragraphs and Sentences, Being Concise and Removing Redundancy, Avoiding Ambiguity and Vagueness

**UNIT-II:**

Clarifying Who Did What, Highlighting Your Findings, Hedging and Criticizing, Paraphrasing and Plagiarism, Sections of a Paper, Abstracts. Introduction

**UNIT-III:**

Review of the Literature, Methods, Results, Discussion, Conclusions, The Final Check.

**UNIT-IV:**

key skills are needed when writing a Title, key skills are needed when writing an Abstract, key skills are needed when writing an Introduction, skills needed when writing a Review of the Literature,

**UNIT-V:**

skills are needed when writing the Methods, skills needed when writing the Results, skills are needed when writing the Discussion, skills are needed when writing the Conclusions. useful phrases, how to ensure paper is as good as it could possibly be the first- time submission

**TEXT BOOKS/ REFERENCES:**

1. Goldbort R (2006) Writing for Science, Yale University Press (available on Google Books)
2. Day R (2006) How to Write and Publish a Scientific Paper, Cambridge University Press
3. Highman N (1998), Handbook of Writing for the Mathematical Sciences, SIAM. Highman's book.
4. Adrian Wallwork, English for Writing Research Papers, Springer New York Dordrecht Heidelberg London, 2011

**JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD**  
**M.Pharm (Industrial Pharmacy)**

**DISASTER MANAGEMENT (Audit Course - I & II)**

**Prerequisite:** None

**Course Objectives:** Students will be able to

- learn to demonstrate a critical understanding of key concepts in disaster risk reduction and humanitarian response.
- critically evaluate disaster risk reduction and humanitarian response policy and practice from multiple perspectives.
- develop an understanding of standards of humanitarian response and practical relevance in specific types of disasters and conflict situations.
- critically understand the strengths and weaknesses of disaster management approaches,
- planning and programming in different countries, particularly their home country or the countries they work in

**UNIT-I:**

**Introduction:**

Disaster: Definition, Factors and Significance; Difference Between Hazard and Disaster; Natural and Manmade Disasters: Difference, Nature, Types and Magnitude.

**Disaster Prone Areas in India:**

Study of Seismic Zones; Areas Prone to Floods and Droughts, Landslides and Avalanches; Areas Prone to Cyclonic and Coastal Hazards with Special Reference to Tsunami; Post-Disaster Diseases and Epidemics

**UNIT-II:**

**Repercussions of Disasters and Hazards:**

Economic Damage, Loss of Human and Animal Life, Destruction of Ecosystem. Natural Disasters: Earthquakes, Volcanisms, Cyclones, Tsunamis, Floods, Droughts and Famines, Landslides and Avalanches, Man-made disaster: Nuclear Reactor Meltdown, Industrial Accidents, Oil Slicks and Spills, Outbreaks of Disease and Epidemics, War and Conflicts.

**UNIT-III:**

**Disaster Preparedness and Management:**

Preparedness: Monitoring of Phenomena Triggering A Disaster or Hazard; Evaluation of Risk: Application of Remote Sensing, Data from Meteorological and Other Agencies, Media Reports: Governmental and Community Preparedness.

**UNIT-IV:**

**Risk Assessment Disaster Risk:**

Concept and Elements, Disaster Risk Reduction, Global and National Disaster Risk Situation. Techniques of Risk Assessment, Global Co-Operation in Risk Assessment and Warning, People's Participation in Risk Assessment. Strategies for Survival.

**UNIT-V:**

**Disaster Mitigation:**

Meaning, Concept and Strategies of Disaster Mitigation, Emerging Trends In Mitigation. Structural Mitigation and Non-Structural Mitigation, Programs of Disaster Mitigation in India.



**TEXT BOOKS/ REFERENCES:**

1. R. Nishith, Singh AK, "Disaster Management in India: Perspectives, issues and strategies "New Royal book Company.
2. Sahni, Pardeep Et. Al. (Eds.)," Disaster Mitigation Experiences and Reflections", Prentice Hall of India, New Delhi.
3. Goel S. L., Disaster Administration and Management Text and Case Studies", Deep &Deep Publication Pvt. Ltd., New Delhi.

**JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD**  
**M.Pharm (Industrial Pharmacy)**

**SANSKRIT FOR TECHNICAL KNOWLEDGE (Audit Course - I & II)**

**Prerequisite:** None

**Course Objectives:**

- To get a working knowledge in illustrious Sanskrit, the scientific language in the world
- Learning of Sanskrit to improve brain functioning
- Learning of Sanskrit to develop the logic in mathematics, science & other subjects enhancing the memory power
- The engineering scholars equipped with Sanskrit will be able to explore the huge knowledge from ancient literature

**Course Outcomes:** Students will be able to

- Understanding basic Sanskrit language
- Ancient Sanskrit literature about science & technology can be understood
- Being a logical language will help to develop logic in students

**UNIT-I:**

Alphabets in Sanskrit,

**UNIT-II:**

Past/Present/Future Tense, Simple Sentences

**UNIT-III:**

Order, Introduction of roots,

**UNIT-IV:**

Technical information about Sanskrit Literature

**UNIT-V:**

Technical concepts of Engineering-Electrical, Mechanical, Architecture, Mathematics

**TEXT BOOKS/ REFERENCES:**

1. "Abhyaspustakam" – Dr. Vishwas, Samskrita-Bharti Publication, New Delhi
2. "Teach Yourself Sanskrit" Prathama Deeksha-Vempati Kutumbshastri, Rashtriya Sanskrit Sansthanam, New Delhi Publication
3. "India's Glorious Scientific Tradition" Suresh Soni, Ocean books (P) Ltd., New Delhi.

**JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD**  
**M.Pharm (Industrial Pharmacy)**

**VALUE EDUCATION (Audit Course - I & II)**

**Prerequisite:** None

**Course Objectives:** Students will be able to

- Understand value of education and self- development
- Imbibe good values in students
- Let the should know about the importance of character

**Course outcomes:** Students will be able to

- Knowledge of self-development
- Learn the importance of Human values
- Developing the overall personality

**UNIT-I:**

Values and self-development –Social values and individual attitudes. Work ethics, Indian vision of humanism. Moral and non- moral valuation. Standards and principles. Value judgements

**UNIT-II:**

Importance of cultivation of values. Sense of duty. Devotion, Self-reliance. Confidence, Concentration. Truthfulness, Cleanliness. Honesty, Humanity. Power of faith, National Unity. Patriotism. Love for nature, Discipline

**UNIT-III:**

Personality and Behavior Development - Soul and Scientific attitude. Positive Thinking. Integrity and discipline, Punctuality, Love and Kindness.

**UNIT-IV:**

Avoid fault Thinking. Free from anger, Dignity of labour. Universal brotherhood and religious tolerance. True friendship. Happiness Vs suffering, love for truth. Aware of self-destructive habits. Association and Cooperation. Doing best for saving nature

**UNIT-V:**

Character and Competence –Holy books vs Blind faith. Self-management and Good health. Science of reincarnation, Equality, Nonviolence, Humility, Role of Women. All religions and same message. Mind your Mind, Self-control. Honesty, Studying effectively

**TEXT BOOKS/ REFERENCES:**

1. Chakroborty, S.K. "Values and Ethics for organizations Theory and practice", Oxford University Press, New Delhi

**JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD**  
**M.Pharm (Industrial Pharmacy)**

**CONSTITUTION OF INDIA (Audit Course - I & II)**

**Prerequisite:** None

**Course Objectives:** Students will be able to:

- Understand the premises informing the twin themes of liberty and freedom from a civil rights perspective.
- To address the growth of Indian opinion regarding modern Indian intellectuals' constitutional role and entitlement to civil and economic rights as well as the emergence of nationhood in the early years of Indian nationalism.
- To address the role of socialism in India after the commencement of the Bolshevik Revolution in 1917 and its impact on the initial drafting of the Indian Constitution.

**Course Outcomes:** Students will be able to:

- Discuss the growth of the demand for civil rights in India for the bulk of Indians before the arrival of Gandhi in Indian politics.
- Discuss the intellectual origins of the framework of argument that informed the conceptualization of social reforms leading to revolution in India.
- Discuss the circumstances surrounding the foundation of the Congress Socialist Party [CSP] under the leadership of Jawaharlal Nehru and the eventual failure of the proposal of direct elections through adult suffrage in the Indian Constitution.
- Discuss the passage of the Hindu Code Bill of 1956.

**UNIT-I:**

**History of Making of the Indian Constitution:** History Drafting Committee, (Composition & Working), **Philosophy of the Indian Constitution:** Preamble, Salient Features.

**UNIT-II:**

**Contours of Constitutional Rights & Duties:** Fundamental Rights Right to Equality, Right to Freedom, Right against Exploitation, Right to Freedom of Religion, Cultural and Educational Rights, Right to Constitutional Remedies, Directive Principles of State Policy, Fundamental Duties.

**UNIT-III:**

**Organs of Governance:** Parliament, Composition, Qualifications and Disqualifications, Powers and Functions, Executive, President, Governor, Council of Ministers, Judiciary, Appointment and Transfer of Judges, Qualification, Powers and Functions.

**UNIT-IV:**

**Local Administration:** District's Administration head: Role and Importance, Municipalities: Introduction, Mayor and role of Elected Representative, CEO of Municipal Corporation. Pachayati raj: Introduction, PRI: Zila Pachayat. Elected officials and their roles, CEO Zila Pachayat: Position and role. Block level: Organizational Hierarchy (Different departments), Village level: Role of Elected and Appointed officials, Importance of grass root democracy.

**UNIT-V:**

**Election Commission:** Election Commission: Role and Functioning. Chief Election Commissioner and Election Commissioners. State Election Commission: Role and Functioning. Institute and Bodies for the welfare of SC/ST/OBC and women.

**TEXT BOOKS/ REFERENCES:**

1. The Constitution of India, 1950 (Bare Act), Government Publication.
2. Dr. S. N. Busi, Dr. B. R. Ambedkar framing of Indian Constitution, 1st Edition, 2015.
3. M. P. Jain, Indian Constitution Law, 7th Edn., Lexis Nexis, 2014.
4. D.D. Basu, Introduction to the Constitution of India, Lexis Nexis, 2015.

**JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD**  
**M.Pharm (Industrial Pharmacy)**

**PEDAGOGY STUDIES (Audit Course - I & II)**

**Prerequisite:** None

**Course Objectives:** Students will be able to:

- Review existing evidence on the review topic to inform programme design and policy making undertaken by the DfID, other agencies and researchers.
- Identify critical evidence gaps to guide the development.

**Course Outcomes:** Students will be able to understand:

- What pedagogical practices are being used by teachers in formal and informal classrooms in developing countries?
- What is the evidence on the effectiveness of these pedagogical practices, in what conditions, and with what population of learners?
- How can teacher education (curriculum and practicum) and the school curriculum and guidance materials best support effective pedagogy?

**UNIT-I:**

**Introduction and Methodology:** Aims and rationale, Policy background, Conceptual framework and terminology Theories of learning, Curriculum, Teacher education. Conceptual framework, Research questions. Overview of methodology and Searching.

**UNIT-II:**

**Thematic overview:** Pedagogical practices are being used by teachers in formal and informal classrooms in developing countries. Curriculum, Teacher education.

**UNIT-III:**

Evidence on the effectiveness of pedagogical practices, Methodology for the indepth stage: quality assessment of included studies. How can teacher education (curriculum and practicum) and the scho curriculum and guidance materials best support effective pedagogy? Theory of change. Strength and nature of the body of evidence for effective pedagogical practices. Pedagogic theory and pedagogical approaches. Teachers' attitudes and beliefs and Pedagogic strategies.

**UNIT-IV:**

**Professional development:** alignment with classroom practices and follow-up support, Peer support, Support from the head teacher and the community. Curriculum and assessment, Barriers to learning: limited resources and large class sizes

**UNIT-V:**

**Research gaps and future directions:** Research design, Contexts, Pedagogy, Teacher education, Curriculum and assessment, Dissemination and research impact.

**TEXT BOOKS/ REFERENCES:**

1. Ackers J, Hardman F (2001) Classroom interaction in Kenyan primary schools, Compare, 31 (2): 245-261.
2. Agrawal M (2004) Curricular reform in schools: The importance of evaluation, Journal of Curriculum Studies, 36 (3): 361-379.
3. Akyeamong K (2003) Teacher training in Ghana - does it count? Multi-site teacher education research project (MUSTER) country report 1. London: DFID.

4. Akyeampong K, Lussier K, Pryor J, Westbrook J (2013) Improving teaching and learning of basic maths and reading in Africa: Does teacher preparation count? *International Journal Educational Development*, 33 (3): 272–282.
5. Alexander RJ (2001) *Culture and pedagogy: International comparisons in primary education*. Oxford and Boston: Blackwell.
6. Chavan M (2003) Read India: A mass scale, rapid, 'learning to read' campaign.
7. [www.pratham.org/images/resource%20working%20paper%202.pdf](http://www.pratham.org/images/resource%20working%20paper%202.pdf).

**JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD  
M.Pharm (Industrial Pharmacy)**

**STRESS MANAGEMENT BY YOGA (Audit Course - I & II)**

**Prerequisite:** None

**Course Objectives:**

- To achieve overall health of body and mind
- To overcome stress

**Course Outcomes:** Students will be able to:

- Develop healthy mind in a healthy body thus improving social health also
- Improve efficiency

**UNIT-I:**

Definitions of Eight parts of yog. (Ashtanga)

**UNIT-II:**

Yam and Niyam.

**UNIT-III:**

Do's and Don't's in life.

- i) Ahinsa, satya, astheya, bramhacharya and aparigraha
- ii) Shaucha, santosh, tapa, swadhyay, ishwarpranidhan

**UNIT-IV:**

Asan and Pranayam

**UNIT-V:**

- i) Various yog poses and their benefits for mind & body
- ii) Regularization of breathing techniques and its effects-Types of pranayam

**TEXT BOOKS/ REFERENCES:**

1. 'Yogic Asanas for Group Training-Part-I': Janardan Swami Yogabhyasi Mandal, Nagpur
2. "Rajayoga or conquering the Internal Nature" by Swami Vivekananda, Advaita Ashrama (Publication Department), Kolkata



**JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD**  
**M.Pharm (Industrial Pharmacy)**

**PERSONALITY DEVELOPMENT THROUGH LIFE ENLIGHTENMENT SKILLS**  
**(Audit Course - I & II)**

**Prerequisite:** None

**Course Objectives:**

- To learn to achieve the highest goal happily
- To become a person with stable mind, pleasing personality and determination
- To awaken wisdom in students

**Course Outcomes:** Students will be able to

- Study of Shrimad-Bhagwad-Geeta will help the student in developing his personality and achieve the highest goal in life
- The person who has studied Geeta will lead the nation and mankind to peace and prosperity
- Study of Neetishatakam will help in developing versatile personality of students

**UNIT-I:**

Neetisatakam-Holistic development of personality

- Verses- 19,20,21,22 (wisdom)
- Verses- 29,31,32 (pride & heroism)
- Verses- 26,28,63,65 (virtue)

**UNIT-II:**

Neetisatakam-Holistic development of personality

- Verses- 52,53,59 (dont's)
- Verses- 71,73,75,78 (do's)

**UNIT-III:**

Approach to day to day work and duties.

- Shrimad Bhagwad Geeta: Chapter 2-Verses 41, 47,48,
- Chapter 3-Verses 13, 21, 27, 35, Chapter 6-Verses 5,13,17, 23, 35,
- Chapter 18-Verses 45, 46, 48.

**UNIT-IV:**

Statements of basic knowledge.

- Shrimad Bhagwad Geeta: Chapter2-Verses 56, 62, 68
- Chapter 12 -Verses 13, 14, 15, 16,17, 18
- Personality of Role model. Shrimad Bhagwad Geeta:

**UNIT-V:**

- Chapter2-Verses 17, Chapter 3-Verses 36,37,42,
- Chapter 4-Verses 18, 38,39
- Chapter18 – Verses 37,38,63

**TEXT BOOKS/ REFERENCES:**

1. "Srimad Bhagavad Gita" by Swami Swarupananda Advaita Ashram (Publication Department), Kolkata.
2. Bhartrihari's Three Satakam (Niti-sringar-vairagya) by P.Gopinath, Rashtriya Sanskrit Sansthanam, New Delhi.

## JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD

## M.PHARMACY (PHARMACEUTICAL ANALYSIS)

COURSE STRUCTURE AND SYLLABUS  
Effective from Academic Year 2019-20 Admitted Batch

## I YEAR I Semester

Course Code	Course Title	L	T	P	Credits
Professional Core-I	Modern Pharmaceutical Analytical Techniques	3	0	0	3
Professional Core-II	Pharmaceutical and Food Analysis	3	0	0	3
Professional Elective-I	1. Advanced Pharmaceutical Analysis 2. Drug Regulatory Affairs 3. Phytochemistry	3	0	0	3
Professional Elective-II	1. Quality control and Quality Assurance 2. Cosmetics and Cosmeceuticals 3. Stability of Drugs and Dosage forms	3	0	0	3
MC	Research Methodology & Intellectual Property Rights	2	0	0	2
Laboratory-I	Modern Pharmaceutical Analytical Techniques lab	0	0	4	2
Laboratory-II	Pharmaceutical and food Analysis Lab	0	0	4	2
Audit	Audit course- I	2	0	0	0
<b>TOTAL</b>		<b>16</b>	<b>0</b>	<b>8</b>	<b>18</b>

## I YEAR II Semester

Course Code	Course Title	L	T	P	Credits
Professional Core-III	Advanced Instrumental Analysis I	3	0	0	3
Professional Core-IV	Modern Bio-analytical Techniques	3	0	0	3
Professional Elective-III	1. Pharmaceutical Validation 2. Herbal Cosmetics 3. Pharmacoepidemiology and Pharmacoconomics	3	0	0	3
Professional Elective-IV	1. Advanced Instrumental Analysis - II 2. Nutraceuticals 3. Clinical Research and Pharmacovigilance	3	0	0	3
Laboratory-III	Advanced Instrumental Analysis I Lab	0	0	4	2
Laboratory-IV	Modern Bio analytical Techniques Lab	0	0	4	2
--	Mini Project with Seminar	2	0	0	2
Audit	Audit Course- II	2	0	0	0
<b>TOTAL</b>		<b>16</b>	<b>0</b>	<b>8</b>	<b>18</b>

**Audit Courses 1 & 2**

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

**JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD**  
**M.Pharm I Year I Sem (Pharmaceutical Analysis)**

**MODERN PHARMACEUTICAL ANALYTICAL TECHNIQUES (Professional Core - I)**

**Course 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.

**Course 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.

#### **UNIT I**

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

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

#### **UNIT II**

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

#### **UNIT III**

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

#### **UNIT IV**

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

#### **UNIT V**

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

**REFERENCES:**

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

**JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD**  
**M.Pharm I Year I Sem (Pharmaceutical Analysis)**

**PHARMACEUTICAL AND FOOD ANALYSIS (Professional Core – II)**

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

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

- Food constituents
- Food additives
- Finished food products
- Pesticides in food
- Pharmaceuticals (API & Dosage forms)
- And also student shall have the knowledge on food regulations and legislations

**UNIT I**

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

**UNIT II**

- a. **Lipids:** Classification, general methods of analysis, refining of fats and oils; hydrogenation of vegetable oils, Determination of adulteration in fats and oils.
- b. **Vitamins:** Classification of vitamins, methods of analysis of vitamins, Principles of microbial assay of vitamins of B-series

**UNIT III**

Definition, classification and principles and procedures involved in the quantitative determination of drugs from each category of both API and dosage forms (IP) of the following

- a. Alkaloids
- b. Antibiotics
- c. Diuretics

**UNIT IV**

Definition, classification and principles and procedures involved in the quantitative determination of drugs from each category of both API and dosage forms (IP) of the following

- a. Analgesics & Antipyretics
- b. Antihypertensives
- c. Antihistamines

**UNIT V**

- a. **General Analytical methods** for milk, milk constituents and milk products like ice cream, milk powder, butter, margarine, cheese including adulterants and contaminants of milk.
- b. **Analysis of fermentation products** like wine, spirits, beer and vinegar.

**TEXT BOOKS**

1. The chemical analysis of foods – David Pearson, Seventh edition, Churchill Livingstone, Edinburgh London, 1976

2. Introduction to the Chemical analysis of foods – S. Nielsen, Jones & Bartlett publishers, Boston London, 1994.
3. Official methods of analysis of AOAC International, sixth edition, Volume I & II, 1997.
4. Pharmaceutical Analysis – Higuchi. T
5. Analysis of Food constituents – Multon, Wiley VCH.
6. Dr. William Horwitz, Official methods of analysis of AOAC International
7. 18th edition, 2005. Theory and Practice of Industrial Pharmacy by Lieberman and Lachman

#### **REFERENCE BOOKS**

1. Remington's Pharmaceutical Sciences by Alfonso and Gennaro
2. David Pearson. The Chemical Analysis of Foods, 7<sup>th</sup> 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**  
**M.Pharm I Year I Sem (Pharmaceutical Analysis)**

**ADVANCED PHARMACEUTICAL ANALYSIS (Professional Elective - I)**

**Course 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.

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

**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 |
| E. Neutralization      | F. Acid – Base           |

**UNIT II**

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

- |                |                         |
|----------------|-------------------------|
| A. Amines      | C. Carbonyl compounds   |
| B. Esters      | D. Hydroxy and carboxyl |
| E. Amino Acids |                         |

**UNIT III**

- a. **Reference Standards:** Types, preparation methods and uses.
- b. Principles and procedures involved in using the following reagents in the determination of pharmaceutical dosage forms official in IP
  - a. MBTH (3-methyl-2-benzothiazolone hydrazone)
  - b. F.C. Reagent (Folin-Ciocalteu)
  - c. PDAB (*para*-Dimethyl Amino Benzaldehyde)
  - d. 2, 3, 5 - *tri*Phenyltetrazolium salt
  - e. 2,6 *di* -ChloroquinoneChlorimide
  - f. *N* - (1-naphthyl) ethylenediaminedihydrochloride (B.M. Reagent)
  - g. Carr – Price Reagent
  - h. 2,4 - DNP

**UNIT - IV**

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

**UNIT-V**

- a. **Dissolution Tests:** Types of Dissolution apparatus, dissolution test requirements for immediate release, delayed release, extended release dosage forms, coated, uncoated, enteric coated, gelatin capsules etc.



- b. **Microbiological assays and Biological tests:** Antimicrobial effectiveness testing, microbial limit tests, sterility test. Antibiotics-microbial assays, bacterial endotoxins test.

**TEXT BOOKS:**

1. Pharmaceutical Chemistry by Becket and Stanlake
2. Pharmaceutical Analysis by Higuchi, Bechmman and Hassan
3. Instrumental Methods of Chemical Analysis By B.K. Sharma
4. A Text Book of Pharmaceutical Analysis by Kennenth A. Conners
5. Organic spectroscopy by Y.R Sharma Principles of Instrumental Analysis - Doglas A Skoog, F. James Holler, Timothy A. Nieman, 5th edition, Eastern press, Bangalore, 1998.
6. Instrumental methods of analysis – Willards, 7th edition, CBS publishers.

**REFERENCES:**

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

**JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD**  
**M.Pharm I Year I Sem (Pharmaceutical Analysis)**

**DRUG REGULATORY AFFAIRS (Professional Elective - I)**

**Course 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.

**Course Outcome:**

- Students will come to know the different competent regulatory authorities globally.
- 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.

**UNIT I**

**Drug Regulatory Aspects (India)**

1. Indian drug regulatory authorities, Central and State regulatory bodies (FDA)
2. Drugs and Cosmetics Act and Rules with latest Amendments (Selective)
3. Special emphasis – Schedule M and Y
4. New drugs – Importation, Registration, development, Clinical Trials, BE NOC & BE studies
5. Various Licences – Test Lic., Import lic., for testing of drugs and API's, Manufacturing Contract and Loan licence manufacturing.

**UNIT II**

**Good Manufacturing Practices (GMP)**

1. Indian GMP certification, WHO GMP certification.
2. ICH guidelines for stability testing and other relevant ones (Q1-Q10)
3. Export permissions and manufacturing for semi-regulated countries
4. Understanding of the plant layouts with special emphasis on the environment & safety (HVAC, Water Systems, Stores Management, Effluent etc.)
5. Quality Assurance and Quality Control – Basic understanding for in-built quality.

**UNIT III**

A detailed study of regulatory aspects that affect drug product design, manufacture and distribution in a developed country such as USA and in a developing country such as Brazil, Hatch Waxmann Act; Bolar Provisions and other FDA Regulations. Regulatory aspects of pharmaceutical and bulk drug manufacture, regulatory drug analysis.

**UNIT IV**

Documentation related to manufacturing, cleaning methods, retention samples and records, quality control, batch release documents, distribution records, complaints and recalls.  
 Quality, safety and legislation for cosmetic products and herbal products.

**UNIT V**

**Governing Regulatory Bodies across the globe.**

- Country Authority Submission
- a. U.S Food & Drug Administration USDMF
  - b. Canada Therapeutic Product Directorate DMF
  - c. Europe
    - 1) European Medicines Agency (EMA/ National Authorities) EDMF
    - 2) European Directorate for Quality of Medicines CEP/COS & Health Care Products.

- 3) MHRA – Medicines and Health Care Products Regulatory Agency
- d. Product Filing
- e. Responding Regulatory Deficiencies
- f. Final Approval Procedure

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

**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, Vallabh Prakashan Delhi - 2013

**JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD**  
**M.Pharm I Year I Sem (Pharmaceutical Analysis)**

**PHYTOCHEMISTRY (Professional Elective - I)**

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

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

**UNIT I**

Biosynthetic pathways and Radio tracing techniques: containing drugs:

- a) Methods of Biogenetic Investigations, detailed study of isotropic tracer techniques.
- b) Study of Biosynthetic pathways of following phyto-pharmaceuticals: Atropine, Morphine, Cardiac glycosides and Flavonoids.

**UNIT II**

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

**UNIT III**

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

**UNIT IV**

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

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

**UNIT V**

- a. Natural colorants: Biological Source, colouring principles, chemical nature and usage of the following Annatto, Cochineal, Caramel, Henna, Indigo, Madder, Saffron, Turmeric
- b. Flavours and Perfumes: Sandal wood oil, Orange oil, Lemon oil, Palmarosa oil, Geranium oil.

**Reference books**

1. Phytochemical methods of chemical analysis by Harbone
2. Modern methods of plant analysis- peach & M.V. Tracey Vol. 1 to VII
3. Pharmacognosy & Phytochemistry of medical plants by Jean Brunton
4. Thin layer chromatography by Stahl
5. Chemistry of natural products by Atur Rahman
6. Comprehensive Medicinal Chemistry, Vol 1-6, Elsevier Publication
7. Medicinal Chemistry Drug Discovery by Donald J, Abrahm,
8. Plant drug analysis by Wagner

9. Clarke's isolation & identification of drugs by AC Mottal
10. Chromatography of Alkaloids by Varpoorte Swendson
11. Jenkins Quantitative pharmaceutical chemistry by AN Kenwell
12. Standardization of botanicals by V. Rajpal Vol 1 & 2
13. Medicinal chemistry and drug discovery by Burger's
14. Foye's Principles of medicinal chemistry.
15. Pharmacognosy and phytochemistry by Biren seth
16. Herbal Perfumes and cosmetics by Panda
17. Herbal Drug Technology by SS Agarwal
18. Pharmacognosy and Phytochemistry by VD Rangari.
19. Textbook of Pharmacognosy by G.E. Trease, W.C.Evans, ELBS

**JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD**  
**M.Pharm I Year I Sem (Pharmaceutical Analysis)**

**QUALITY CONTROL AND QUALITY ASSURANCE (Professional Elective - II)**

**Course Objective:** This course deals with the various aspects of quality control and quality assurance aspects of pharmaceutical industries. It covers the important aspects like cGMP, QC tests, documentation, quality certifications, GLP and regulatory affairs.

**Course Outcome: Upon completion of this course the student should be able to**

- Understand the cGMP aspects in a pharmaceutical industry
- To appreciate the importance of documentation
- To understand the scope of quality certifications applicable to
- Pharmaceutical industries
- To understand the responsibilities of QA & QC departments.

**UNIT – I**

Introduction: Concept and evolution and scopes of Quality Control and Quality Assurance, Good Laboratory Practice, GMP, Overview of ICH Guidelines - QSEM, with special emphasis on Qseries guidelines. Good Laboratory Practices: Scope of GLP, Definitions, Quality assurance unit, protocol for conduct of non-clinical testing, control on animal house, report preparation and documentation. CPCSEA guidelines.

**UNIT - II**

cGMP guidelines according to schedule M, USFDA (inclusive of CDER and CBER) Pharmaceutical Inspection Convention (PIC), WHO and EMEA covering: Organization and personnel responsibilities, training, hygiene and personal records, drug industry location, design, construction and plant lay out, maintenance, sanitation, environmental control, utilities and maintenance of sterile areas, control of contamination and Good Warehousing Practice.

**UNIT - III**

Analysis of raw materials, finished products, packaging materials, in process quality control (IPQC), Developing specification (ICH Q6 and Q3), purchase specifications and maintenance of stores for raw materials. In process quality control and finished products quality control for following dosage forms in Pharma industry according to Indian, US and British pharmacopoeias: tablets, capsules, ointments, suppositories, creams, parenterals, ophthalmic and surgical products (How to refer pharmacopoeias).

**UNIT - IV**

Documentation in pharmaceutical industry: Three tier documentation, Policy, Procedures and Work instructions, and records (Formats), Basic principles- How to maintain, retention and retrieval etc. Standard operating procedures (How to write), Master Batch Record, Batch Manufacturing Record, Quality audit plan and reports. Specification and test procedures, Protocols and reports. Distribution records. Electronic data handling. Concepts of controlled and uncontrolled documents. Submission documents for regulators DMFs, as Common Technical Document and Electronic Common Technical Documentation (CTD, eCTD). Concept of regulated and non-regulated markets.

**UNIT - V**

Manufacturing operations and controls: Sanitation of manufacturing premises, mix-ups and cross contamination, processing of intermediates and bulk products, packaging operations, IPQC, release of finished product, process deviations, charge-in of components, time limitations on production, drug product inspection, expiry date calculation, calculation of yields, production record review, change control, sterile products, aseptic process control, packaging, reprocessing, salvaging, handling of

waste and scrap disposal. Introduction, scope and importance of intellectual property rights. Concept of trade mark, copyright and patents.

**REFERENCE BOOKS:**

1. Quality Assurance Guide by organization of Pharmaceutical Procedures of India, 3rd revised edition, Volume I & II, Mumbai, 1996.
2. Good Laboratory Practice Regulations, 2nd Edition, Sandy Weinberg Vol. 69, Marcel Dekker Series, 1995.
3. Quality Assurance of Pharmaceuticals- A compedium of Guide lines and Related materials Vol I & II, 2nd edition, WHO Publications, 1999.
4. How to Practice GMP's – P P Sharma, Vandana Publications, Agra, 1991.
5. The International Pharmacopoeia – vol I, II, III, IV & V - General Methods of Analysis and Quality specification for Pharmaceutical Substances, Excipients and Dosage forms, 3rd edition, WHO, Geneva, 2005.
6. Good laboratory Practice Regulations – Allen F. Hirsch, Volume 38, Marcel Dekker Series, 1989.
7. ICH guidelines
8. ISO 9000 and total quality management
9. The drugs and cosmetics act 1940 – Deshpande, Nilesh Gandhi, 4<sup>th</sup> edition, Susmit Publishers, 2006.
10. QA Manual – D.H. Shah, 1st edition, Business Horizons, 2000.
11. Good Manufacturing Practices for Pharmaceuticals a plan for total quality control – Sidney H. Willig, Vol. 52, 3rd edition, Marcel Dekker Series.
12. Steinborn L. GMP/ISO Quality Audit Manual for Healthcare Manufacturers and Their Suppliers, Sixth Edition, (Volume 1 - With Checklists and
13. Software Package). Taylor & Francis; 2003.
14. Sarker DK. Quality Systems and Controls for Pharmaceuticals. John Wiley & Sons; 2008.
15. Packaging of Pharmaceuticals.
16. Schedule M and Schedule N.

**JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD**  
**M.Pharm I Year I Sem (Pharmaceutical Analysis)**

**COSMETICS AND COSMECEUTICALS (Professional Elective - II)**

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

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

**Course Outcomes:** Upon completion of the subject student shall able to know Regulatory biological aspects of cosmetics, excipients used for various formulations, designing of cosmeceuticals and herbal products

**UNIT I**

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

**UNIT II**

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

**UNIT III**

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

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

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

**UNIT IV**

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

**UNIT V**

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



**REFERENCES**

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

**JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD**  
**M.Pharm I Year I Sem (Pharmaceutical Analysis)**

**STABILITY OF DRUGS AND DOSAGE FORMS (Professional Elective – II)**

**Course 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.

**Course 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.

**UNIT - I**

**Drug decomposition mechanisms:**

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

**UNIT - II**

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

Physical stability testing of dosage forms:

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

**UNIT - III**

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

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

**UNIT - IV**

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

**UNIT - V**

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

Stability studies: Concept of stability studies.

- a) cGMP& ICH guidelines for Accelerated stability Testing.
- b) Interaction of containers & closure Compatibility Testing.

**REFERENCE BOOKS:**

1. Comprehensive Pharmacy Review 5th Edition by Leon Shargel, Alan H. Mutnick, Paul F. Souney, Larry N. Sawnsen – 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**  
**M.Pharm I Year I Sem (Pharmaceutical Analysis)**

**RESEARCH METHODOLOGY AND IPR**

**Course Objectives:**

- To understand the research problem
- To know the literature studies, plagiarism and ethics
- To get the knowledge about technical writing
- To analyze the nature of intellectual property rights and new developments
- To know the patent rights

**Course Outcomes:** At the end of this course, students will be able to

- Understand research problem formulation.
- Analyze research related information
- Follow research ethics
- Understand that today's world is controlled by Computer, Information Technology, but tomorrow world will be ruled by ideas, concept, and creativity.
- Understanding that when IPR would take such important place in growth of individuals & nation, it is needless to emphasis the need of information about Intellectual Property Right to be promoted among students in general & engineering in particular.
- Understand that IPR protection provides an incentive to inventors for further research work and investment in R & D, which leads to creation of new and better products, and in turn brings about, economic growth and social benefits.

**UNIT - I**

Meaning of research problem, Sources of research problem, Criteria Characteristics of a good research problem, Errors in selecting a research problem, Scope and objectives of research problem. Approaches of investigation of solutions for research problem, data collection, analysis, interpretation, Necessary instrumentations

**UNIT - II**

Effective literature studies approaches, analysis, Plagiarism, Research ethics

**UNIT - III**

Effective technical writing, how to write report, Paper Developing a Research Proposal, Format of research proposal, a presentation and assessment by a review committee

**UNIT - IV**

Nature of Intellectual Property: Patents, Designs, Trade and Copyright. Process of Patenting and Development: technological research, innovation, patenting, development. International Scenario: International cooperation on Intellectual Property. Procedure for grants of patents, Patenting under PCT.

**UNIT - V**

Patent Rights: Scope of Patent Rights. Licensing and transfer of technology. Patent information and databases. Geographical Indications. New Developments in IPR: Administration of Patent System. New developments in IPR; IPR of Biological Systems, Computer Software etc. Traditional knowledge Case Studies, IPR and IITs.

**TEXT BOOKS:**

1. Stuart Melville and Wayne Goddard, "Research methodology: an introduction for science & engineering students"
2. Wayne Goddard and Stuart Melville, "Research Methodology: An Introduction"

**REFERENCES:**

1. Ranjit Kumar, 2nd Edition, "Research Methodology: A Step by Step Guide for beginners"
2. Halbert, "Resisting Intellectual Property", Taylor & Francis Ltd ,2007.
3. Mayall, "Industrial Design", McGraw Hill, 1992.
4. Niebel, "Product Design", McGraw Hill, 1974.
5. Asimov, "Introduction to Design", Prentice Hall, 1962.
6. Robert P. Merges, Peter S. Menell, Mark A. Lemley, "Intellectual Property in New
7. Technological Age", 2016.
8. T. Ramappa, "Intellectual Property Rights Under WTO", S. Chand, 2008

**JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD  
M.Pharm I Year I Sem (Pharmaceutical Analysis)**

**MODERN PHARMACEUTICAL ANALYTICAL TECHNIQUES LAB (Laboratory – I)**

**LIST OF EXPERIMENTS:**

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

**JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD  
M.Pharm I Year I Sem (Pharmaceutical Analysis)**

**PHARMACEUTICAL FOOD ANALYSIS LAB (Laboratory – II)**

**LIST OF EXPERIMENTS:**

1. Determination of total reducing sugar
2. Determination of proteins
3. Determination of saponification value, Iodine value, Peroxide value, Acid value in food products
4. Determination of fat content and rancidity in food products
5. Analysis of natural and synthetic colors & food additives in food
6. Determination of preservatives in food
7. Determination of pesticide residue in food products
8. Assay of any two Analgesic & Antipyretic drugs (API & dosage forms) official in IP
9. Assay of any two Antihistamines (API & dosage forms) official in IP
10. Assay of any two Diuretics (API & dosage forms) official in IP
11. Microbiological assay of any two Antibiotics official in IP

**JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD  
M.Pharm (Pharmaceutical Analysis)**

**ENGLISH FOR RESEARCH PAPER WRITING (Audit Course - I & II)**

**Prerequisite:** None

**Course objectives:** Students will be able to:

- Understand that how to improve your writing skills and level of readability
- Learn about what to write in each section
- Understand the skills needed when writing a Title Ensure the good quality of paper at very first-time submission

**UNIT-I:**

Planning and Preparation, Word Order, Breaking up long sentences, Structuring Paragraphs and Sentences, Being Concise and Removing Redundancy, Avoiding Ambiguity and Vagueness

**UNIT-II:**

Clarifying Who Did What, Highlighting Your Findings, Hedging and Criticizing, Paraphrasing and Plagiarism, Sections of a Paper, Abstracts. Introduction

**UNIT-III:**

Review of the Literature, Methods, Results, Discussion, Conclusions, The Final Check.

**UNIT-IV:**

key skills are needed when writing a Title, key skills are needed when writing an Abstract, key skills are needed when writing an Introduction, skills needed when writing a Review of the Literature,

**UNIT-V:**

skills are needed when writing the Methods, skills needed when writing the Results, skills are needed when writing the Discussion, skills are needed when writing the Conclusions. useful phrases, how to ensure paper is as good as it could possibly be the first- time submission

**TEXT BOOKS/ REFERENCES:**

1. Goldbort R (2006) Writing for Science, Yale University Press (available on Google Books)
2. Day R (2006) How to Write and Publish a Scientific Paper, Cambridge University Press
3. Highman N (1998), Handbook of Writing for the Mathematical Sciences, SIAM. Highman's book.
4. Adrian Wallwork, English for Writing Research Papers, Springer New York Dordrecht Heidelberg London, 2011



**JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD**  
**M.Pharm (Pharmaceutical Analysis)**

**DISASTER MANAGEMENT (Audit Course - I & II)**

**Prerequisite:** None

**Course Objectives:** Students will be able to

- learn to demonstrate a critical understanding of key concepts in disaster risk reduction and humanitarian response.
- critically evaluate disaster risk reduction and humanitarian response policy and practice from multiple perspectives.
- develop an understanding of standards of humanitarian response and practical relevance in specific types of disasters and conflict situations.
- critically understand the strengths and weaknesses of disaster management approaches,
- planning and programming in different countries, particularly their home country or the countries they work in

**UNIT-I:**

**Introduction:**

Disaster: Definition, Factors and Significance; Difference Between Hazard and Disaster; Natural and Manmade Disasters: Difference, Nature, Types and Magnitude.

**Disaster Prone Areas in India:**

Study of Seismic Zones; Areas Prone to Floods and Droughts, Landslides and Avalanches; Areas Prone to Cyclonic and Coastal Hazards with Special Reference to Tsunami; Post-Disaster Diseases and Epidemics

**UNIT-II:**

**Repercussions of Disasters and Hazards:**

Economic Damage, Loss of Human and Animal Life, Destruction of Ecosystem. Natural Disasters: Earthquakes, Volcanisms, Cyclones, Tsunamis, Floods, Droughts and Famines, Landslides and Avalanches, Man-made disaster: Nuclear Reactor Meltdown, Industrial Accidents, Oil Slicks and Spills, Outbreaks of Disease and Epidemics, War and Conflicts.

**UNIT-III:**

**Disaster Preparedness and Management:**

Preparedness: Monitoring of Phenomena Triggering A Disaster or Hazard; Evaluation of Risk: Application of Remote Sensing, Data from Meteorological and Other Agencies, Media Reports: Governmental and Community Preparedness.

**UNIT-IV:**

**Risk Assessment Disaster Risk:**

Concept and Elements, Disaster Risk Reduction, Global and National Disaster Risk Situation. Techniques of Risk Assessment, Global Co-Operation in Risk Assessment and Warning, People's Participation in Risk Assessment. Strategies for Survival.

**UNIT-V:**

**Disaster Mitigation:**

Meaning, Concept and Strategies of Disaster Mitigation, Emerging Trends In Mitigation. Structural Mitigation and Non-Structural Mitigation, Programs of Disaster Mitigation in India.

**TEXT BOOKS/ REFERENCES:**

1. R. Nishith, Singh AK, "Disaster Management in India: Perspectives, issues and strategies "New Royal book Company.
2. Sahni, Pardeep Et. Al. (Eds.)," Disaster Mitigation Experiences and Reflections", Prentice Hall of India, New Delhi.
3. Goel S. L., Disaster Administration and Management Text and Case Studies", Deep &Deep Publication Pvt. Ltd., New Delhi.

**JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD**  
**M.Pharm (Pharmaceutical Analysis)**

**SANSKRIT FOR TECHNICAL KNOWLEDGE (Audit Course - I & II)**

**Prerequisite:** None

**Course Objectives:**

- To get a working knowledge in illustrious Sanskrit, the scientific language in the world
- Learning of Sanskrit to improve brain functioning
- Learning of Sanskrit to develop the logic in mathematics, science & other subjects enhancing the memory power
- The engineering scholars equipped with Sanskrit will be able to explore the huge knowledge from ancient literature

**Course Outcomes:** Students will be able to

- Understanding basic Sanskrit language
- Ancient Sanskrit literature about science & technology can be understood
- Being a logical language will help to develop logic in students

**UNIT-I:**

Alphabets in Sanskrit,

**UNIT-II:**

Past/Present/Future Tense, Simple Sentences

**UNIT-III:**

Order, Introduction of roots,

**UNIT-IV:**

Technical information about Sanskrit Literature

**UNIT-V:**

Technical concepts of Engineering-Electrical, Mechanical, Architecture, Mathematics

**TEXT BOOKS/ REFERENCES:**

1. "Abhyaspustakam" – Dr. Vishwas, Samskrita-Bharti Publication, New Delhi
2. "Teach Yourself Sanskrit" Prathama Deeksha-Vempati Kutumbshastri, Rashtriya Sanskrit Sansthanam, New Delhi Publication
3. "India's Glorious Scientific Tradition" Suresh Soni, Ocean books (P) Ltd., New Delhi.

**JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD**  
**M.Pharm (Pharmaceutical Analysis)**

**VALUE EDUCATION (Audit Course - I & II)**

**Prerequisite:** None

**Course Objectives:** Students will be able to

- Understand value of education and self- development
- Imbibe good values in students
- Let the should know about the importance of character

**Course outcomes:** Students will be able to

- Knowledge of self-development
- Learn the importance of Human values
- Developing the overall personality

**UNIT-I:**

Values and self-development –Social values and individual attitudes. Work ethics, Indian vision of humanism. Moral and non- moral valuation. Standards and principles. Value judgements

**UNIT-II:**

Importance of cultivation of values. Sense of duty. Devotion, Self-reliance. Confidence, Concentration. Truthfulness, Cleanliness. Honesty, Humanity. Power of faith, National Unity. Patriotism. Love for nature, Discipline

**UNIT-III:**

Personality and Behavior Development - Soul and Scientific attitude. Positive Thinking. Integrity and discipline, Punctuality, Love and Kindness.

**UNIT-IV:**

Avoid fault Thinking. Free from anger, Dignity of labour. Universal brotherhood and religious tolerance. True friendship. Happiness Vs suffering, love for truth. Aware of self-destructive habits. Association and Cooperation. Doing best for saving nature

**UNIT-V:**

Character and Competence –Holy books vs Blind faith. Self-management and Good health. Science of reincarnation, Equality, Nonviolence, Humility, Role of Women. All religions and same message. Mind your Mind, Self-control. Honesty, Studying effectively

**TEXT BOOKS/ REFERENCES:**

1. Chakroborty, S.K. "Values and Ethics for organizations Theory and practice", Oxford University Press, New Delhi

**JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD**  
**M.Pharm (Pharmaceutical Analysis)**

**CONSTITUTION OF INDIA (Audit Course - I & II)**

**Prerequisite:** None

**Course Objectives:** Students will be able to:

- Understand the premises informing the twin themes of liberty and freedom from a civil rights perspective.
- To address the growth of Indian opinion regarding modern Indian intellectuals' constitutional role and entitlement to civil and economic rights as well as the emergence of nationhood in the early years of Indian nationalism.
- To address the role of socialism in India after the commencement of the Bolshevik Revolution in 1917 and its impact on the initial drafting of the Indian Constitution.

**Course Outcomes:** Students will be able to:

- Discuss the growth of the demand for civil rights in India for the bulk of Indians before the arrival of Gandhi in Indian politics.
- Discuss the intellectual origins of the framework of argument that informed the conceptualization of social reforms leading to revolution in India.
- Discuss the circumstances surrounding the foundation of the Congress Socialist Party [CSP] under the leadership of Jawaharlal Nehru and the eventual failure of the proposal of direct elections through adult suffrage in the Indian Constitution.
- Discuss the passage of the Hindu Code Bill of 1956.

**UNIT-I:**

**History of Making of the Indian Constitution:** History Drafting Committee, (Composition & Working), **Philosophy of the Indian Constitution:** Preamble, Salient Features.

**UNIT-II:**

**Contours of Constitutional Rights & Duties:** Fundamental Rights Right to Equality, Right to Freedom, Right against Exploitation, Right to Freedom of Religion, Cultural and Educational Rights, Right to Constitutional Remedies, Directive Principles of State Policy, Fundamental Duties.

**UNIT-III:**

**Organs of Governance:** Parliament, Composition, Qualifications and Disqualifications, Powers and Functions, Executive, President, Governor, Council of Ministers, Judiciary, Appointment and Transfer of Judges, Qualification, Powers and Functions.

**UNIT-IV:**

**Local Administration:** District's Administration head: Role and Importance, Municipalities: Introduction, Mayor and role of Elected Representative, CEO of Municipal Corporation. Pachayati raj: Introduction, PRI: Zila Pachayat. Elected officials and their roles, CEO Zila Pachayat: Position and role. Block level: Organizational Hierarchy (Different departments), Village level: Role of Elected and Appointed officials, Importance of grass root democracy.

**UNIT-V:**

**Election Commission:** Election Commission: Role and Functioning. Chief Election Commissioner and Election Commissioners. State Election Commission: Role and Functioning. Institute and Bodies for the welfare of SC/ST/OBC and women.

**TEXT BOOKS/ REFERENCES:**

1. The Constitution of India, 1950 (Bare Act), Government Publication.

2. Dr. S. N. Busi, Dr. B. R. Ambedkar framing of Indian Constitution, 1st Edition, 2015.
3. M. P. Jain, Indian Constitution Law, 7th Edn., Lexis Nexis, 2014.
4. D.D. Basu, Introduction to the Constitution of India, Lexis Nexis, 2015.

**JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD**  
**M.Pharm (Pharmaceutical Analysis)**

**PEDAGOGY STUDIES (Audit Course - I & II)**

**Prerequisite:** None

**Course Objectives:** Students will be able to:

- Review existing evidence on the review topic to inform programme design and policy making undertaken by the DfID, other agencies and researchers.
- Identify critical evidence gaps to guide the development.

**Course Outcomes:** Students will be able to understand:

- What pedagogical practices are being used by teachers in formal and informal classrooms in developing countries?
- What is the evidence on the effectiveness of these pedagogical practices, in what conditions, and with what population of learners?
- How can teacher education (curriculum and practicum) and the school curriculum and guidance materials best support effective pedagogy?

**UNIT-I:**

**Introduction and Methodology:** Aims and rationale, Policy background, Conceptual framework and terminology Theories of learning, Curriculum, Teacher education. Conceptual framework, Research questions. Overview of methodology and Searching.

**UNIT-II:**

**Thematic overview:** Pedagogical practices are being used by teachers in formal and informal classrooms in developing countries. Curriculum, Teacher education.

**UNIT-III:**

Evidence on the effectiveness of pedagogical practices, Methodology for the indepth stage: quality assessment of included studies. How can teacher education (curriculum and practicum) and the scho curriculum and guidance materials best support effective pedagogy? Theory of change. Strength and nature of the body of evidence for effective pedagogical practices. Pedagogic theory and pedagogical approaches. Teachers' attitudes and beliefs and Pedagogic strategies.

**UNIT-IV:**

**Professional development:** alignment with classroom practices and follow-up support, Peer support, Support from the head teacher and the community. Curriculum and assessment, Barriers to learning: limited resources and large class sizes

**UNIT-V:**

**Research gaps and future directions:** Research design, Contexts, Pedagogy, Teacher education, Curriculum and assessment, Dissemination and research impact.

**TEXT BOOKS/ REFERENCES:**

1. Ackers J, Hardman F (2001) Classroom interaction in Kenyan primary schools, Compare, 31 (2): 245-261.
2. Agrawal M (2004) Curricular reform in schools: The importance of evaluation, Journal of Curriculum Studies, 36 (3): 361-379.
3. Akyeampong K (2003) Teacher training in Ghana - does it count? Multi-site teacher education research project (MUSTER) country report 1. London: DFID.

4. Akyeampong K, Lussier K, Pryor J, Westbrook J (2013) Improving teaching and learning of basic maths and reading in Africa: Does teacher preparation count? *International Journal Educational Development*, 33 (3): 272–282.
5. Alexander RJ (2001) *Culture and pedagogy: International comparisons in primary education*. Oxford and Boston: Blackwell.
6. Chavan M (2003) Read India: A mass scale, rapid, 'learning to read' campaign.
7. [www.pratham.org/images/resource%20working%20paper%202.pdf](http://www.pratham.org/images/resource%20working%20paper%202.pdf).



**JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD  
M.Pharm (Pharmaceutical Analysis)**

**STRESS MANAGEMENT BY YOGA (Audit Course - I & II)**

**Prerequisite:** None

**Course Objectives:**

- To achieve overall health of body and mind
- To overcome stress

**Course Outcomes:** Students will be able to:

- Develop healthy mind in a healthy body thus improving social health also
- Improve efficiency

**UNIT-I:**

Definitions of Eight parts of yog. (Ashtanga)

**UNIT-II:**

Yam and Niyam.

**UNIT-III:**

Do's and Don't's in life.

- i) Ahinsa, satya, astheya, bramhacharya and aparigraha
- ii) Shaucha, santosh, tapa, swadhyay, ishwarpranidhan

**UNIT-IV:**

Asan and Pranayam

**UNIT-V:**

- i) Various yog poses and their benefits for mind & body
- ii) Regularization of breathing techniques and its effects-Types of pranayam

**TEXT BOOKS/ REFERENCES:**

1. 'Yogic Asanas for Group Training-Part-I': Janardan Swami Yogabhyasi Mandal, Nagpur
2. "Rajayoga or conquering the Internal Nature" by Swami Vivekananda, Advaita Ashrama (Publication Department), Kolkata

**JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD**  
**M.Pharm (Pharmaceutical Analysis)**

**PERSONALITY DEVELOPMENT THROUGH LIFE ENLIGHTENMENT SKILLS**  
**(Audit Course - I & II)**

**Prerequisite:** None

**Course Objectives:**

- To learn to achieve the highest goal happily
- To become a person with stable mind, pleasing personality and determination
- To awaken wisdom in students

**Course Outcomes:** Students will be able to

- Study of Shrimad-Bhagwad-Geeta will help the student in developing his personality and achieve the highest goal in life
- The person who has studied Geeta will lead the nation and mankind to peace and prosperity
- Study of Neetishatakam will help in developing versatile personality of students

**UNIT-I:**

Neetisatakam-Holistic development of personality

- Verses- 19,20,21,22 (wisdom)
- Verses- 29,31,32 (pride & heroism)
- Verses- 26,28,63,65 (virtue)

**UNIT-II:**

Neetisatakam-Holistic development of personality

- Verses- 52,53,59 (don't's)
- Verses- 71,73,75,78 (do's)

**UNIT-III:**

Approach to day to day work and duties.

- Shrimad Bhagwad Geeta: Chapter 2-Verses 41, 47,48,
- Chapter 3-Verses 13, 21, 27, 35, Chapter 6-Verses 5,13,17, 23, 35,
- Chapter 18-Verses 45, 46, 48.

**UNIT-IV:**

Statements of basic knowledge.

- Shrimad Bhagwad Geeta: Chapter2-Verses 56, 62, 68
- Chapter 12 -Verses 13, 14, 15, 16,17, 18
- Personality of Role model. Shrimad Bhagwad Geeta:

**UNIT-V:**

- Chapter2-Verses 17, Chapter 3-Verses 36,37,42,
- Chapter 4-Verses 18, 38,39
- Chapter18 – Verses 37,38,63

**TEXT BOOKS/ REFERENCES:**

1. "Srimad Bhagavad Gita" by Swami Swarupananda Advaita Ashram (Publication Department), Kolkata.
2. Bhartrihari's Three Satakam (Niti-sringar-vairagya) by P.Gopinath, Rashtriya Sanskrit Sansthanam, New Delhi.

## JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD

## M.PHARMACY (PHARMACEUTICAL ANALYSIS)

**COURSE STRUCTURE AND SYLLABUS**  
**Effective from Academic Year 2019-20 Admitted Batch**
**I YEAR I Semester**

Course Code	Course Title	L	T	P	Credits
Professional Core-I	Modern Pharmaceutical Analytical Techniques	3	0	0	3
Professional Core-II	Pharmaceutical and Food Analysis	3	0	0	3
Professional Elective-I	1. Advanced Pharmaceutical Analysis 2. Drug Regulatory Affairs 3. Phytochemistry	3	0	0	3
Professional Elective-II	1. Quality control and Quality Assurance 2. Cosmetics and Cosmeceuticals 3. Stability of Drugs and Dosage forms	3	0	0	3
MC	Research Methodology & Intellectual Property Rights	2	0	0	2
Laboratory-I	Modern Pharmaceutical Analytical Techniques lab	0	0	4	2
Laboratory-II	Pharmaceutical and food Analysis Lab	0	0	4	2
Audit	Audit course- I	2	0	0	0
<b>TOTAL</b>		<b>16</b>	<b>0</b>	<b>8</b>	<b>18</b>

**I YEAR II Semester**

Course Code	Course Title	L	T	P	Credits
Professional Core-III	Advanced Instrumental Analysis I	3	0	0	3
Professional Core-IV	Modern Bio-analytical Techniques	3	0	0	3
Professional Elective-III	1. Pharmaceutical Validation 2. Herbal Cosmetics 3. Pharmacoepidemiology and Pharmacoeconomics	3	0	0	3
Professional Elective-IV	1. Advanced Instrumental Analysis - II 2. Nutraceuticals 3. Clinical Research and Pharmacovigilance	3	0	0	3
Laboratory-III	Advanced Instrumental Analysis I Lab	0	0	4	2
Laboratory-IV	Modern Bio analytical Techniques Lab	0	0	4	2
--	Mini Project with Seminar	2	0	0	2
Audit	Audit Course- II	2	0	0	0
<b>TOTAL</b>		<b>16</b>	<b>0</b>	<b>8</b>	<b>18</b>

**Audit Courses 1 & 2**

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

**JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD**  
**M.Pharm I Year I Sem (Pharmaceutical Analysis)**

**MODERN PHARMACEUTICAL ANALYTICAL TECHNIQUES (Professional Core - I)**

**Course 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.

**Course 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.

#### **UNIT I**

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

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

#### **UNIT II**

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

#### **UNIT III**

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

#### **UNIT IV**

Mass spectroscopy: Theory, ionization techniques: electron impact ionization, chemical ionization, field ionization, fast atom bombardment, plasma desorption, fragmentation process: types of fission, resolution, GC/MS, **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), <sup>13</sup>CNMR spectra and its applications, 2D-NMR, COSY and applications in pharmacy.

**REFERENCES:**

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

**JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD**  
**M.Pharm I Year I Sem (Pharmaceutical Analysis)**  
**PHARMACEUTICAL AND FOOD ANALYSIS (Professional Core – II)**

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

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

- Food constituents
- Food additives
- Finished food products
- Pesticides in food
- Pharmaceuticals (API & Dosage forms)
- And also student shall have the knowledge on food regulations and legislations

**UNIT - I**

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

**UNIT - II**

- a. **Lipids:** Classification, general methods of analysis, refining of fats and oils; hydrogenation of vegetable oils, Determination of adulteration in fats and oils.
- b. **Vitamins:** Classification of vitamins, methods of analysis of vitamins, Principles of microbial assay of vitamins of B-series

**UNIT - III**

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

**UNIT - IV**

Definition, classification and principles and procedures involved in the quantitative determination of drugs from each category of both API and dosage forms (IP) of the following

- |                              |                      |
|------------------------------|----------------------|
| a. Analgesics & Antipyretics | b. Antihypertensives |
| c. Antihistamines            | d. Alkaloids         |
| e. Antibiotics               | f. Diuretics         |

**UNIT - V**

- a. **General Analytical methods** for milk, milk constituents and milk products like ice cream, milk powder, butter, margarine, cheese including adulterants and contaminants of milk.
- b. **Analysis of fermentation products** like wine, spirits, beer and vinegar.
  - Pesticides in food
  - And also student shall have knowledge in food regulations and legislations

**TEXT BOOKS:**

1. The chemical analysis of foods – David Pearson, Seventh edition, Churchill Livingstone, Edinburgh London, 1976

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

**REFERENCE BOOKS:**

1. Remington's Pharmaceutical Sciences by Alfonso and Gennaro
2. David Pearson. The Chemical Analysis of Foods, 7<sup>th</sup> 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**  
**M.Pharm I Year I Sem (Pharmaceutical Analysis)**

**ADVANCED PHARMACEUTICAL ANALYSIS (Professional Elective - I)**

**Course 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.

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

**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 |
| E. Neutralization      | F. Acid – Base           |

**UNIT II**

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

- |                |                         |
|----------------|-------------------------|
| A. Amines      | C. Carbonyl compounds   |
| B. Esters      | D. Hydroxy and carboxyl |
| E. Amino Acids |                         |

**UNIT III**

- a. **Reference Standards:** Types, preparation methods and uses.
- b. Principles and procedures involved in using the following reagents in the determination of pharmaceutical dosage forms official in IP
  - a. MBTH (3-methyl-2-benzothiazolone hydrazone)
  - b. F.C. Reagent (Folin-Ciocalteu)
  - c. PDAB (*para*-Dimethyl Amino Benzaldehyde)
  - d. 2, 3, 5 - *tri*Phenyltetrazolium salt
  - e. 2,6 *di* -ChloroquinoneChlorimide
  - f. *N* - (1-naphthyl) ethylenediaminedihydrochloride (B.M. Reagent)
  - g. Carr – Price Reagent
  - h. 2,4 - DNP

**UNIT - IV**

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

**UNIT-V**

- a. **Dissolution Tests:** Types of Dissolution apparatus, dissolution test requirements for immediate release, delayed release, extended release dosage forms, coated, uncoated, enteric coated, gelatin capsules etc.

- b. **Microbiological assays and Biological tests:** Antimicrobial effectiveness testing, microbial limit tests, sterility test. Antibiotics-microbial assays, bacterial endotoxins test.

**TEXT BOOKS:**

1. Pharmaceutical Chemistry by Becket and Stanlake
2. Pharmaceutical Analysis by Higuchi, Bechmman and Hassan
3. Instrumental Methods of Chemical Analysis By B.K. Sharma
4. A Text Book of Pharmaceutical Analysis by Kennenth A. Conners
5. Organic spectroscopy by Y.R Sharma Principles of Instrumental Analysis - Doglas A Skoog, F. James Holler, Timothy A. Nieman, 5th edition, Eastern press, Bangalore, 1998.
6. Instrumental methods of analysis – Willards, 7th edition, CBS publishers.

**REFERENCES:**

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

**JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD**  
**M.Pharm I Year I Sem (Pharmaceutical Analysis)**

**DRUG REGULATORY AFFAIRS (Professional Elective - I)**

**Course 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.

**Course Outcome:**

- Students will come to know the different competent regulatory authorities globally.
- 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.

**UNIT I**

**Drug Regulatory Aspects (India)**

1. Indian drug regulatory authorities, Central and State regulatory bodies (FDA)
2. Drugs and Cosmetics Act and Rules with latest Amendments (Selective)
3. Special emphasis – Schedule M and Y
4. New drugs – Importation, Registration, development, Clinical Trials, BE NOC & BE studies
5. Various Licences – Test Lic., Import lic., for testing of drugs and API's, Manufacturing Contract and Loan licence manufacturing.

**UNIT II**

**Good Manufacturing Practices (GMP)**

1. Indian GMP certification, WHO GMP certification.
2. ICH guidelines for stability testing and other relevant ones (Q1-Q10)
3. Export permissions and manufacturing for semi-regulated countries
4. Understanding of the plant layouts with special emphasis on the environment & safety (HVAC, Water Systems, Stores Management, Effluent etc.)
5. Quality Assurance and Quality Control – Basic understanding for in-built quality.

**UNIT III**

A detailed study of regulatory aspects that affect drug product design, manufacture and distribution in a developed country such as USA and in a developing country such as Brazil, Hatch Waxmann Act; Bolar Provisions and other FDA Regulations. Regulatory aspects of pharmaceutical and bulk drug manufacture, regulatory drug analysis.

**UNIT IV**

Documentation related to manufacturing, cleaning methods, retention samples and records, quality control, batch release documents, distribution records, complaints and recalls.  
 Quality, safety and legislation for cosmetic products and herbal products.

**UNIT V**

**Governing Regulatory Bodies across the globe.**

- Country Authority Submission
- a. U.S Food & Drug Administration USDMF
  - b. Canada Therapeutic Product Directorate DMF
  - c. Europe
    - 1) European Medicines Agency (EMA/ National Authorities) EDMF
    - 2) European Directorate for Quality of Medicines CEP/COS & Health Care Products.
    - 3) MHRA – Medicines and Health Care Products Regulatory Agency

- d. Product Filing
- e. Responding Regulatory Deficiencies
- f. Final Approval Procedure

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

**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, Vallabh Prakashan Delhi - 2013

**JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD**  
**M.Pharm I Year I Sem (Pharmaceutical Analysis)**

**PHYTOCHEMISTRY (Professional Elective - I)**

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

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

**UNIT I**

Biosynthetic pathways and Radio tracing techniques: containing drugs:

- a) Methods of Biogenetic Investigations, detailed study of isotropic tracer techniques.
- b) Study of Biosynthetic pathways of following phyto-pharmaceuticals: Atropine, Morphine, Cardiac glycosides and Flavonoids.

**UNIT II**

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

**UNIT III**

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

**UNIT IV**

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

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

**UNIT V**

- a. Natural colorants: Biological Source, colouring principles, chemical nature and usage of the following Annatto, Cochineal, Caramel, Henna, Indigo, Madder, Saffron, Turmeric
- b. Flavours and Perfumes: Sandal wood oil, Orange oil, Lemon oil, Palmarosa oil, Geranium oil.

**Reference books**

1. Phytochemical methods of chemical analysis by Harbone
2. Modern methods of plant analysis- peach & M.V. Tracey Vol. 1 to VII
3. Pharmacognosy & Phytochemistry of medical plants by Jean Brunton
4. Thin layer chromatography by Stahl
5. Chemistry of natural products by Atur Rahman
6. Comprehensive Medicinal Chemistry, Vol 1-6, Elsevier Publication
7. Medicinal Chemistry Drug Discovery by Donald J, Abrahm,
8. Plant drug analysis by Wagner

9. Clarke's isolation & identification of drugs by AC Mottal
10. Chromatography of Alkaloids by Varpoorte Swendson
11. Jenkins Quantitative pharmaceutical chemistry by AN Kenwell
12. Standardization of botanicals by V. Rajpal Vol 1 & 2
13. Medicinal chemistry and drug discovery by Burger's
14. Foye's Principles of medicinal chemistry.
15. Pharmacognosy and phytochemistry by Biren seth
16. Herbal Perfumes and cosmetics by Panda
17. Herbal Drug Technology by SS Agarwal
18. Pharmacognosy and Phytochemistry by VD Rangari.
19. Textbook of Pharmacognosy by G.E. Trease, W.C.Evans, ELBS

**JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD**  
**M.Pharm I Year I Sem (Pharmaceutical Analysis)**

**QUALITY CONTROL AND QUALITY ASSURANCE (Professional Elective - II)**

**Course Objective:** This course deals with the various aspects of quality control and quality assurance aspects of pharmaceutical industries. It covers the important aspects like cGMP, QC tests, documentation, quality certifications, GLP and regulatory affairs.

**Course Outcome: Upon completion of this course the student should be able to**

- Understand the cGMP aspects in a pharmaceutical industry
- To appreciate the importance of documentation
- To understand the scope of quality certifications applicable to
- Pharmaceutical industries
- To understand the responsibilities of QA & QC departments.

**UNIT – I**

Introduction: Concept and evolution and scopes of Quality Control and Quality Assurance, Good Laboratory Practice, GMP, Overview of ICH Guidelines - QSEM, with special emphasis on Qseries guidelines. Good Laboratory Practices: Scope of GLP, Definitions, Quality assurance unit, protocol for conduct of non-clinical testing, control on animal house, report preparation and documentation. CPCSEA guidelines.

**UNIT - II**

cGMP guidelines according to schedule M, USFDA (inclusive of CDER and CBER) Pharmaceutical Inspection Convention (PIC), WHO and EMEA covering: Organization and personnel responsibilities, training, hygiene and personal records, drug industry location, design, construction and plant lay out, maintenance, sanitation, environmental control, utilities and maintenance of sterile areas, control of contamination and Good Warehousing Practice.

**UNIT - III**

Analysis of raw materials, finished products, packaging materials, in process quality control (IPQC), Developing specification (ICH Q6 and Q3), purchase specifications and maintenance of stores for raw materials. In process quality control and finished products quality control for following dosage forms in Pharma industry according to Indian, US and British pharmacopoeias: tablets, capsules, ointments, suppositories, creams, parenterals, ophthalmic and surgical products (How to refer pharmacopoeias).

**UNIT - IV**

Documentation in pharmaceutical industry: Three tier documentation, Policy, Procedures and Work instructions, and records (Formats), Basic principles- How to maintain, retention and retrieval etc. Standard operating procedures (How to write), Master Batch Record, Batch Manufacturing Record, Quality audit plan and reports. Specification and test procedures, Protocols and reports. Distribution records. Electronic data handling. Concepts of controlled and uncontrolled documents. Submission documents for regulators DMFs, as Common Technical Document and Electronic Common Technical Documentation (CTD, eCTD). Concept of regulated and non-regulated markets.

**UNIT - V**

Manufacturing operations and controls: Sanitation of manufacturing premises, mix-ups and cross contamination, processing of intermediates and bulk products, packaging operations, IPQC, release of finished product, process deviations, charge-in of components, time limitations on production, drug product inspection, expiry date calculation, calculation of yields, production record review, change control, sterile products, aseptic process control, packaging, reprocessing, salvaging, handling of waste

and scrap disposal. Introduction, scope and importance of intellectual property rights. Concept of trade mark, copyright and patents.

**REFERENCE BOOKS:**

1. Quality Assurance Guide by organization of Pharmaceutical Procedures of India, 3rd revised edition, Volume I & II, Mumbai, 1996.
2. Good Laboratory Practice Regulations, 2nd Edition, Sandy Weinberg Vol. 69, Marcel Dekker Series, 1995.
3. Quality Assurance of Pharmaceuticals- A compedium of Guide lines and Related materials Vol I & II, 2nd edition, WHO Publications, 1999.
4. How to Practice GMP's – P P Sharma, Vandana Publications, Agra, 1991.
5. The International Pharmacopoeia – vol I, II, III, IV & V - General Methods of Analysis and Quality specification for Pharmaceutical Substances, Excipients and Dosage forms, 3rd edition, WHO, Geneva, 2005.
6. Good laboratory Practice Regulations – Allen F. Hirsch, Volume 38, Marcel Dekker Series, 1989.
7. ICH guidelines
8. ISO 9000 and total quality management
9. The drugs and cosmetics act 1940 – Deshpande, Nilesh Gandhi, 4<sup>th</sup> edition, Susmit Publishers, 2006.
10. QA Manual – D.H. Shah, 1st edition, Business Horizons, 2000.
11. Good Manufacturing Practices for Pharmaceuticals a plan for total quality control – Sidney H. Willig, Vol. 52, 3rd edition, Marcel Dekker Series.
12. Steinborn L. GMP/ISO Quality Audit Manual for Healthcare Manufacturers and Their Suppliers, Sixth Edition, (Volume 1 - With Checklists and
13. Software Package). Taylor & Francis; 2003.
14. Sarker DK. Quality Systems and Controls for Pharmaceuticals. John Wiley & Sons; 2008.
15. Packaging of Pharmaceuticals.
16. Schedule M and Schedule N.



**JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD**  
**M.Pharm I Year I Sem (Pharmaceutical Analysis)**

**COSMETICS AND COSMECEUTICALS (Professional Elective - II)**

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

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

**Course Outcomes:** Upon completion of the subject student shall able to know Regulatory biological aspects of cosmetics, excipients used for various formulations, designing of cosmeceuticals and herbal products

**UNIT I**

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

**UNIT II**

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

**UNIT III**

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

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

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

**UNIT IV**

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

**UNIT V**

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

**REFERENCES**

1. Harry's Cosmeticology. 8th edition.

2. Poucher's perfume cosmetics and Soaps, 10th edition.
3. Cosmetics - Formulation, Manufacture and quality control, P. P. Sharma, 4<sup>th</sup> edition
4. Handbook of cosmetic science and Technology A.O. Barel, M. Paye and H.I. Maibach. 3 rd edition
5. Cosmetic and Toiletries recent suppliers' catalogue.
6. CTFA directory.

**JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD**  
**M.Pharm I Year I Sem (Pharmaceutical Analysis)**

**STABILITY OF DRUGS AND DOSAGE FORMS (Professional Elective – II)**

**Course 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.

**Course 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.

**UNIT - I**

**Drug decomposition mechanisms:**

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

**UNIT - II**

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

Physical stability testing of dosage forms:

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

**UNIT - III**

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

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

**UNIT - IV**

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

**UNIT - V**

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

Stability studies: Concept of stability studies.

- a) cGMP& ICH guidelines for Accelerated stability Testing.
- b) Interaction of containers & closure Compatibility Testing.

**REFERENCE BOOKS:**

1. Comprehensive Pharmacy Review 5th Edition by Leon Shargel, Alan H. Mutnick, Paul F. Souney, Larry N. Sawnsen – 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**  
**M.Pharm I Year I Sem (Pharmaceutical Analysis)**

**RESEARCH METHODOLOGY AND IPR**

**Course Objectives:**

- To understand the research problem
- To know the literature studies, plagiarism and ethics
- To get the knowledge about technical writing
- To analyze the nature of intellectual property rights and new developments
- To know the patent rights

**Course Outcomes:** At the end of this course, students will be able to

- Understand research problem formulation.
- Analyze research related information
- Follow research ethics
- Understand that today's world is controlled by Computer, Information Technology, but tomorrow world will be ruled by ideas, concept, and creativity.
- Understanding that when IPR would take such important place in growth of individuals & nation, it is needless to emphasis the need of information about Intellectual Property Right to be promoted among students in general & engineering in particular.
- Understand that IPR protection provides an incentive to inventors for further research work and investment in R & D, which leads to creation of new and better products, and in turn brings about, economic growth and social benefits.

**UNIT - I**

Meaning of research problem, Sources of research problem, Criteria Characteristics of a good research problem, Errors in selecting a research problem, Scope and objectives of research problem. Approaches of investigation of solutions for research problem, data collection, analysis, interpretation, Necessary instrumentations

**UNIT - II**

Effective literature studies approaches, analysis, Plagiarism, Research ethics

**UNIT - III**

Effective technical writing, how to write report, Paper Developing a Research Proposal, Format of research proposal, a presentation and assessment by a review committee

**UNIT - IV**

Nature of Intellectual Property: Patents, Designs, Trade and Copyright. Process of Patenting and Development: technological research, innovation, patenting, development. International Scenario: International cooperation on Intellectual Property. Procedure for grants of patents, Patenting under PCT.

**UNIT - V**

Patent Rights: Scope of Patent Rights. Licensing and transfer of technology. Patent information and databases. Geographical Indications. New Developments in IPR: Administration of Patent System. New developments in IPR; IPR of Biological Systems, Computer Software etc. Traditional knowledge Case Studies, IPR and IITs.

**TEXT BOOKS:**

1. Stuart Melville and Wayne Goddard, "Research methodology: an introduction for science & engineering students"
2. Wayne Goddard and Stuart Melville, "Research Methodology: An Introduction"

**REFERENCES:**

1. Ranjit Kumar, 2nd Edition, "Research Methodology: A Step by Step Guide for beginners"
2. Halbert, "Resisting Intellectual Property", Taylor & Francis Ltd ,2007.
3. Mayall, "Industrial Design", McGraw Hill, 1992.
4. Niebel, "Product Design", McGraw Hill, 1974.
5. Asimov, "Introduction to Design", Prentice Hall, 1962.
6. Robert P. Merges, Peter S. Menell, Mark A. Lemley, "Intellectual Property in New
7. Technological Age", 2016.
8. T. Ramappa, "Intellectual Property Rights Under WTO", S. Chand, 2008

**JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD  
M.Pharm I Year I Sem (Pharmaceutical Analysis)**

**MODERN PHARMACEUTICAL ANALYTICAL TECHNIQUES LAB (Laboratory – I)**

**LIST OF EXPERIMENTS:**

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

**JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD  
M.Pharm I Year I Sem (Pharmaceutical Analysis)**

**PHARMACEUTICAL FOOD ANALYSIS LAB (Laboratory – II)**

**LIST OF EXPERIMENTS:**

1. Determination of total reducing sugar
2. Determination of proteins
3. Determination of saponification value, Iodine value, Peroxide value, Acid value in food products
4. Determination of fat content and rancidity in food products
5. Analysis of natural and synthetic colors & food additives in food
6. Determination of preservatives in food
7. Determination of pesticide residue in food products
8. Assay of any two Analgesic & Antipyretic drugs (API & dosage forms) official in IP
9. Assay of any two Antihistamines (API & dosage forms) official in IP
10. Assay of any two Diuretics (API & dosage forms) official in IP
11. Microbiological assay of any two Antibiotics official in IP



**JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD  
M.Pharm (Pharmaceutical Analysis)**

**ENGLISH FOR RESEARCH PAPER WRITING (Audit Course - I & II)**

**Prerequisite:** None

**Course objectives:** Students will be able to:

- Understand that how to improve your writing skills and level of readability
- Learn about what to write in each section
- Understand the skills needed when writing a Title Ensure the good quality of paper at very first-time submission

**UNIT-I:**

Planning and Preparation, Word Order, Breaking up long sentences, Structuring Paragraphs and Sentences, Being Concise and Removing Redundancy, Avoiding Ambiguity and Vagueness

**UNIT-II:**

Clarifying Who Did What, Highlighting Your Findings, Hedging and Criticizing, Paraphrasing and Plagiarism, Sections of a Paper, Abstracts. Introduction

**UNIT-III:**

Review of the Literature, Methods, Results, Discussion, Conclusions, The Final Check.

**UNIT-IV:**

key skills are needed when writing a Title, key skills are needed when writing an Abstract, key skills are needed when writing an Introduction, skills needed when writing a Review of the Literature,

**UNIT-V:**

skills are needed when writing the Methods, skills needed when writing the Results, skills are needed when writing the Discussion, skills are needed when writing the Conclusions. useful phrases, how to ensure paper is as good as it could possibly be the first- time submission

**TEXT BOOKS/ REFERENCES:**

1. Goldbort R (2006) Writing for Science, Yale University Press (available on Google Books)
2. Day R (2006) How to Write and Publish a Scientific Paper, Cambridge University Press
3. Highman N (1998), Handbook of Writing for the Mathematical Sciences, SIAM. Highman's book.
4. Adrian Wallwork, English for Writing Research Papers, Springer New York Dordrecht Heidelberg London, 2011

**JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD**  
**M.Pharm (Pharmaceutical Analysis)**

**DISASTER MANAGEMENT (Audit Course - I & II)**

**Prerequisite:** None

**Course Objectives:** Students will be able to

- learn to demonstrate a critical understanding of key concepts in disaster risk reduction and humanitarian response.
- critically evaluate disaster risk reduction and humanitarian response policy and practice from multiple perspectives.
- develop an understanding of standards of humanitarian response and practical relevance in specific types of disasters and conflict situations.
- critically understand the strengths and weaknesses of disaster management approaches,
- planning and programming in different countries, particularly their home country or the countries they work in

**UNIT-I:**

**Introduction:**

Disaster: Definition, Factors and Significance; Difference Between Hazard and Disaster; Natural and Manmade Disasters: Difference, Nature, Types and Magnitude.

**Disaster Prone Areas in India:**

Study of Seismic Zones; Areas Prone to Floods and Droughts, Landslides and Avalanches; Areas Prone to Cyclonic and Coastal Hazards with Special Reference to Tsunami; Post-Disaster Diseases and Epidemics

**UNIT-II:**

**Repercussions of Disasters and Hazards:**

Economic Damage, Loss of Human and Animal Life, Destruction of Ecosystem. Natural Disasters: Earthquakes, Volcanisms, Cyclones, Tsunamis, Floods, Droughts and Famines, Landslides and Avalanches, Man-made disaster: Nuclear Reactor Meltdown, Industrial Accidents, Oil Slicks and Spills, Outbreaks of Disease and Epidemics, War and Conflicts.

**UNIT-III:**

**Disaster Preparedness and Management:**

Preparedness: Monitoring of Phenomena Triggering A Disaster or Hazard; Evaluation of Risk: Application of Remote Sensing, Data from Meteorological and Other Agencies, Media Reports: Governmental and Community Preparedness.

**UNIT-IV:**

**Risk Assessment Disaster Risk:**

Concept and Elements, Disaster Risk Reduction, Global and National Disaster Risk Situation. Techniques of Risk Assessment, Global Co-Operation in Risk Assessment and Warning, People's Participation in Risk Assessment. Strategies for Survival.

**UNIT-V:**

**Disaster Mitigation:**

Meaning, Concept and Strategies of Disaster Mitigation, Emerging Trends In Mitigation. Structural Mitigation and Non-Structural Mitigation, Programs of Disaster Mitigation in India.

**TEXT BOOKS/ REFERENCES:**

1. R. Nishith, Singh AK, "Disaster Management in India: Perspectives, issues and strategies "New Royal book Company.
2. Sahni, Pardeep Et. Al. (Eds.)," Disaster Mitigation Experiences and Reflections", Prentice Hall of India, New Delhi.
3. Goel S. L., Disaster Administration and Management Text and Case Studies", Deep &Deep Publication Pvt. Ltd., New Delhi.

**JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD**  
**M.Pharm (Pharmaceutical Analysis)**

**SANSKRIT FOR TECHNICAL KNOWLEDGE (Audit Course - I & II)**

**Prerequisite:** None

**Course Objectives:**

- To get a working knowledge in illustrious Sanskrit, the scientific language in the world
- Learning of Sanskrit to improve brain functioning
- Learning of Sanskrit to develop the logic in mathematics, science & other subjects enhancing the memory power
- The engineering scholars equipped with Sanskrit will be able to explore the huge knowledge from ancient literature

**Course Outcomes:** Students will be able to

- Understanding basic Sanskrit language
- Ancient Sanskrit literature about science & technology can be understood
- Being a logical language will help to develop logic in students

**UNIT-I:**

Alphabets in Sanskrit,

**UNIT-II:**

Past/Present/Future Tense, Simple Sentences

**UNIT-III:**

Order, Introduction of roots,

**UNIT-IV:**

Technical information about Sanskrit Literature

**UNIT-V:**

Technical concepts of Engineering-Electrical, Mechanical, Architecture, Mathematics

**TEXT BOOKS/ REFERENCES:**

1. "Abhyaspustakam" – Dr. Vishwas, Samskrita-Bharti Publication, New Delhi
2. "Teach Yourself Sanskrit" Prathama Deeksha-Vempati Kutumbshastri, Rashtriya Sanskrit Sansthanam, New Delhi Publication
3. "India's Glorious Scientific Tradition" Suresh Soni, Ocean books (P) Ltd., New Delhi.

**JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD**  
**M.Pharm (Pharmaceutical Analysis)**

**VALUE EDUCATION (Audit Course - I & II)**

**Prerequisite:** None

**Course Objectives:** Students will be able to

- Understand value of education and self- development
- Imbibe good values in students
- Let the should know about the importance of character

**Course outcomes:** Students will be able to

- Knowledge of self-development
- Learn the importance of Human values
- Developing the overall personality

**UNIT-I:**

Values and self-development –Social values and individual attitudes. Work ethics, Indian vision of humanism. Moral and non- moral valuation. Standards and principles. Value judgements

**UNIT-II:**

Importance of cultivation of values. Sense of duty. Devotion, Self-reliance. Confidence, Concentration. Truthfulness, Cleanliness. Honesty, Humanity. Power of faith, National Unity. Patriotism. Love for nature, Discipline

**UNIT-III:**

Personality and Behavior Development - Soul and Scientific attitude. Positive Thinking. Integrity and discipline, Punctuality, Love and Kindness.

**UNIT-IV:**

Avoid fault Thinking. Free from anger, Dignity of labour. Universal brotherhood and religious tolerance. True friendship. Happiness Vs suffering, love for truth. Aware of self-destructive habits. Association and Cooperation. Doing best for saving nature

**UNIT-V:**

Character and Competence –Holy books vs Blind faith. Self-management and Good health. Science of reincarnation, Equality, Nonviolence, Humility, Role of Women. All religions and same message. Mind your Mind, Self-control. Honesty, Studying effectively

**TEXT BOOKS/ REFERENCES:**

1. Chakroborty, S.K. "Values and Ethics for organizations Theory and practice", Oxford University Press, New Delhi

**JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD**  
**M.Pharm (Pharmaceutical Analysis)**

**CONSTITUTION OF INDIA (Audit Course - I & II)**

**Prerequisite:** None

**Course Objectives:** Students will be able to:

- Understand the premises informing the twin themes of liberty and freedom from a civil rights perspective.
- To address the growth of Indian opinion regarding modern Indian intellectuals' constitutional role and entitlement to civil and economic rights as well as the emergence of nationhood in the early years of Indian nationalism.
- To address the role of socialism in India after the commencement of the Bolshevik Revolution in 1917 and its impact on the initial drafting of the Indian Constitution.

**Course Outcomes:** Students will be able to:

- Discuss the growth of the demand for civil rights in India for the bulk of Indians before the arrival of Gandhi in Indian politics.
- Discuss the intellectual origins of the framework of argument that informed the conceptualization of social reforms leading to revolution in India.
- Discuss the circumstances surrounding the foundation of the Congress Socialist Party [CSP] under the leadership of Jawaharlal Nehru and the eventual failure of the proposal of direct elections through adult suffrage in the Indian Constitution.
- Discuss the passage of the Hindu Code Bill of 1956.

**UNIT-I:**

**History of Making of the Indian Constitution:** History Drafting Committee, (Composition & Working),  
**Philosophy of the Indian Constitution:** Preamble, Salient Features.

**UNIT-II:**

**Contours of Constitutional Rights & Duties:** Fundamental Rights Right to Equality, Right to Freedom, Right against Exploitation, Right to Freedom of Religion, Cultural and Educational Rights, Right to Constitutional Remedies, Directive Principles of State Policy, Fundamental Duties.

**UNIT-III:**

**Organs of Governance:** Parliament, Composition, Qualifications and Disqualifications, Powers and Functions, Executive, President, Governor, Council of Ministers, Judiciary, Appointment and Transfer of Judges, Qualification, Powers and Functions.

**UNIT-IV:**

**Local Administration:** District's Administration head: Role and Importance, Municipalities: Introduction, Mayor and role of Elected Representative, CEO of Municipal Corporation. Pachayati raj: Introduction, PRI: Zila Pachayat. Elected officials and their roles, CEO Zila Pachayat: Position and role. Block level: Organizational Hierarchy (Different departments), Village level: Role of Elected and Appointed officials, Importance of grass root democracy.

**UNIT-V:**

**Election Commission:** Election Commission: Role and Functioning. Chief Election Commissioner and Election Commissioners. State Election Commission: Role and Functioning. Institute and Bodies for the welfare of SC/ST/OBC and women.

**TEXT BOOKS/ REFERENCES:**

1. The Constitution of India, 1950 (Bare Act), Government Publication.

2. Dr. S. N. Busi, Dr. B. R. Ambedkar framing of Indian Constitution, 1st Edition, 2015.
3. M. P. Jain, Indian Constitution Law, 7th Edn., Lexis Nexis, 2014.
4. D.D. Basu, Introduction to the Constitution of India, Lexis Nexis, 2015.

**JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD**  
**M.Pharm (Pharmaceutical Analysis)**

**PEDAGOGY STUDIES (Audit Course - I & II)**

**Prerequisite:** None

**Course Objectives:** Students will be able to:

- Review existing evidence on the review topic to inform programme design and policy making undertaken by the DfID, other agencies and researchers.
- Identify critical evidence gaps to guide the development.

**Course Outcomes:** Students will be able to understand:

- What pedagogical practices are being used by teachers in formal and informal classrooms in developing countries?
- What is the evidence on the effectiveness of these pedagogical practices, in what conditions, and with what population of learners?
- How can teacher education (curriculum and practicum) and the school curriculum and guidance materials best support effective pedagogy?

**UNIT-I:**

**Introduction and Methodology:** Aims and rationale, Policy background, Conceptual framework and terminology Theories of learning, Curriculum, Teacher education. Conceptual framework, Research questions. Overview of methodology and Searching.

**UNIT-II:**

**Thematic overview:** Pedagogical practices are being used by teachers in formal and informal classrooms in developing countries. Curriculum, Teacher education.

**UNIT-III:**

Evidence on the effectiveness of pedagogical practices, Methodology for the indepth stage: quality assessment of included studies. How can teacher education (curriculum and practicum) and the scho curriculum and guidance materials best support effective pedagogy? Theory of change. Strength and nature of the body of evidence for effective pedagogical practices. Pedagogic theory and pedagogical approaches. Teachers' attitudes and beliefs and Pedagogic strategies.

**UNIT-IV:**

**Professional development:** alignment with classroom practices and follow-up support, Peer support, Support from the head teacher and the community. Curriculum and assessment, Barriers to learning: limited resources and large class sizes

**UNIT-V:**

**Research gaps and future directions:** Research design, Contexts, Pedagogy, Teacher education, Curriculum and assessment, Dissemination and research impact.

**TEXT BOOKS/ REFERENCES:**

1. Ackers J, Hardman F (2001) Classroom interaction in Kenyan primary schools, Compare, 31 (2): 245-261.
2. Agrawal M (2004) Curricular reform in schools: The importance of evaluation, Journal of Curriculum Studies, 36 (3): 361-379.
3. Akyeampong K (2003) Teacher training in Ghana - does it count? Multi-site teacher education research project (MUSTER) country report 1. London: DFID.



4. Akyeampong K, Lussier K, Pryor J, Westbrook J (2013) Improving teaching and learning of basic maths and reading in Africa: Does teacher preparation count? *International Journal Educational Development*, 33 (3): 272–282.
5. Alexander RJ (2001) *Culture and pedagogy: International comparisons in primary education*. Oxford and Boston: Blackwell.
6. Chavan M (2003) Read India: A mass scale, rapid, 'learning to read' campaign.
7. [www.pratham.org/images/resource%20working%20paper%202.pdf](http://www.pratham.org/images/resource%20working%20paper%202.pdf).

**JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD  
M.Pharm (Pharmaceutical Analysis)**

**STRESS MANAGEMENT BY YOGA (Audit Course - I & II)**

**Prerequisite:** None

**Course Objectives:**

- To achieve overall health of body and mind
- To overcome stress

**Course Outcomes:** Students will be able to:

- Develop healthy mind in a healthy body thus improving social health also
- Improve efficiency

**UNIT-I:**

Definitions of Eight parts of yog. (Ashtanga)

**UNIT-II:**

Yam and Niyam.

**UNIT-III:**

Do's and Don't's in life.

- i) Ahinsa, satya, astheya, bramhacharya and aparigraha
- ii) Shaucha, santosh, tapa, swadhyay, ishwarpranidhan

**UNIT-IV:**

Asan and Pranayam

**UNIT-V:**

- i) Various yog poses and their benefits for mind & body
- ii) Regularization of breathing techniques and its effects-Types of pranayam

**TEXT BOOKS/ REFERENCES:**

1. 'Yogic Asanas for Group Training-Part-I': Janardan Swami Yogabhyasi Mandal, Nagpur
2. "Rajayoga or conquering the Internal Nature" by Swami Vivekananda, Advaita Ashrama (Publication Department), Kolkata

**JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD**  
**M.Pharm (Pharmaceutical Analysis)**

**PERSONALITY DEVELOPMENT THROUGH LIFE ENLIGHTENMENT SKILLS**  
**(Audit Course - I & II)**

**Prerequisite:** None

**Course Objectives:**

- To learn to achieve the highest goal happily
- To become a person with stable mind, pleasing personality and determination
- To awaken wisdom in students

**Course Outcomes:** Students will be able to

- Study of Shrimad-Bhagwad-Geeta will help the student in developing his personality and achieve the highest goal in life
- The person who has studied Geeta will lead the nation and mankind to peace and prosperity
- Study of Neetishatakam will help in developing versatile personality of students

**UNIT-I:**

Neetisatakam-Holistic development of personality

- Verses- 19,20,21,22 (wisdom)
- Verses- 29,31,32 (pride & heroism)
- Verses- 26,28,63,65 (virtue)

**UNIT-II:**

Neetisatakam-Holistic development of personality

- Verses- 52,53,59 (don't's)
- Verses- 71,73,75,78 (do's)

**UNIT-III:**

Approach to day to day work and duties.

- Shrimad Bhagwad Geeta: Chapter 2-Verses 41, 47,48,
- Chapter 3-Verses 13, 21, 27, 35, Chapter 6-Verses 5,13,17, 23, 35,
- Chapter 18-Verses 45, 46, 48.

**UNIT-IV:**

Statements of basic knowledge.

- Shrimad Bhagwad Geeta: Chapter2-Verses 56, 62, 68
- Chapter 12 -Verses 13, 14, 15, 16,17, 18
- Personality of Role model. Shrimad Bhagwad Geeta:

**UNIT-V:**

- Chapter2-Verses 17, Chapter 3-Verses 36,37,42,
- Chapter 4-Verses 18, 38,39
- Chapter18 – Verses 37,38,63

**TEXT BOOKS/ REFERENCES:**

1. "Srimad Bhagavad Gita" by Swami Swarupananda Advaita Ashram (Publication Department), Kolkata.
2. Bhartrihari's Three Satakam (Niti-sringar-vairagya) by P.Gopinath, Rashtriya Sanskrit Sansthanam, New Delhi.

## JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD

## M.PHARMACY (PHARMACOLOGY)

## COURSE STRUCTURE AND SYLLABUS

Effective from Academic Year 2019-20 Admitted Batch

## I YEAR I Semester

Course Code	Course Title	L	T	P	Credits
Professional Core-I	Advanced Pharmacology – I	3	0	0	3
Professional Core-II	Clinical Pharmacology and Pharmacotherapeutics	3	0	0	3
Professional Elective-I	1. Pharmacokinetics and Drug Metabolism 2. Clinical Research and Pharmacovigilance 3. Principles of Drug Discovery	3	0	0	3
Professional Elective-II	1. Animal cell cultures and applications 2. Molecular Biology 3. Principles of Toxicology	3	0	0	3
MC	Research Methodology and IPR	2	0	0	2
Laboratory-I	Advanced Pharmacology - I Lab	0	0	4	2
Laboratory-II	Clinical Pharmacology and Pharmacotherapeutics Lab	0	0	4	2
Audit	Audit Course - I	2	0	0	0
<b>TOTAL</b>		<b>16</b>	<b>0</b>	<b>8</b>	<b>18</b>

## I YEAR II Semester

Course Code	Course Title	L	T	P	Credits
Professional Core-III	Advanced Pharmacology- II	3	0	0	3
Professional Core-IV	Pharmacological Screening Methods and Toxicology	3	0	0	3
Professional Elective-III	1. Quality Use of Medicines 2. Pharmacoepidemiology and Pharmacoconomics 3. Advanced Drug Delivery Systems	3	0	0	3
Professional Elective-IV	1. Pharmaceutical Management 2. Nutraceuticals 3. Pharmacokinetic and therapeutic drug monitoring	3	0	0	3
Laboratory-III	Advanced Pharmacology – II Lab	0	0	4	2
Laboratory-IV	Pharmacological Screening Methods and Toxicology lab	0	0	4	2
--	Mini project with seminar	2	0	0	2
Audit	Audit Course – II	2	0	0	0
<b>TOTAL</b>		<b>16</b>	<b>0</b>	<b>8</b>	<b>18</b>

**Audit Courses 1 & 2**

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

**JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD  
M.Pharm I Year I Sem (Pharmacology)**

**ADVANCED PHARMACOLOGY- I (Professional Core-I)**

**Course Objective:** The subject is designed to strengthen the basic knowledge in the field of pharmacology and to impart recent advances in the drugs used for the treatment of various diseases. In addition, this subject helps the students to understand the concepts of drug action and mechanisms involved.

**Course Outcome:** Upon completion of the course the student shall be able to:

- Discuss the pathophysiology and pharmacotherapy of certain diseases
- Explain the mechanism of drug actions at cellular and molecular level
- Understand the adverse effects, contraindications and clinical uses of drugs used in treatment of diseases

**UNIT - I**

**General Pharmacology:**

- a. Pharmacokinetics: The dynamics of drug absorption, distribution, biotransformation and elimination. Concepts of linear and non-linear compartment models. Significance of Protein binding.
- b. Pharmacodynamics: Mechanism of drug action and the relationship between drug concentration and effect. Receptors, structural and functional families of receptors quantitation of drug receptors interaction and elicited effects.

**UNIT-II**

**Neurotransmission**

- a. General aspects and steps involved in neurotransmission.
  - b. Neurohumoral transmission in autonomic nervous system (Detailed study about neurotransmitters- Adrenaline and Acetylcholine).
  - c. Neurohumoral transmission in central nervous system (Detailed study about neurotransmitters- histamine, serotonin, dopamine, GABA, glutamate and glycine].
  - d. Non-adrenergic non-cholinergic transmission (NANC). Cotransmission
- Systemic Pharmacology A detailed study on pathophysiology of diseases, mechanism of action, pharmacology and toxicology of existing as well as novel drugs used in the following systems  
Autonomic Pharmacology Parasympathomimetics and lytics, sympathomimetics and lytics, agents affecting neuromuscular junction

**UNIT-III**

**Central nervous system Pharmacology**

General and local anesthetics Sedatives and hypnotics, drugs used to treat anxiety. Depression, psychosis, mania, epilepsy, neurodegenerative diseases. Narcotic and non-narcotic analgesics.

**UNIT-IV**

**Cardiovascular Pharmacology**

Diuretics, antihypertensives, antiischemics, anti-arrhythmics, drugs for heart failure and hyperlipidemia. Hematinics, coagulants, anticoagulants, fibrinolytics and antiplatelet drugs.

**UNIT-V**

**Autacoid Pharmacology**

The physiological and pathological role of Histamine, Serotonin, Kinins Prostaglandins Opioid autacoids. Pharmacology of antihistamines, 5HT antagonists.

**REFERENCES:**

1. The Pharmacological Basis of Therapeutics, Goodman and Gillman's
2. Principles of Pharmacology. The Pathophysiologic basis of drug Therapy by David E Golan, Armen H, Tashjian Jr, EhrinJ, Armstrong, April W, Armstrong, Wolters, Kluwer-Lippincott Williams & Wilkins Publishers.
3. Basic and Clinical Pharmacology by B. G Katzung
4. Hand book of Clinical Pharmacokinetics by Gibaldi and Prescott.
5. Applied biopharmaceutics and Pharmacokinetics by Leon Shargel and Andrew B. C. Yu.
6. Graham Smith. Oxford textbook of Clinical Pharmacology.
7. Avery Drug Treatment
8. Dipiro Pharmacology, Pathophysiological approach.
9. Green Pathophysiology for Pharmacists.

**JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD**  
**M.Pharm I Year I Sem (Pharmacology)**

**CLINICAL PHARMACOLOGY AND PHARMACOTHERAPEUTICS (Professional Core - II)**

**Course Objective**

This course is designed to impart knowledge and skills necessary for contribution to quality use of medicines. Chapters dealt cover briefly pathophysiology and mostly therapeutics of various diseases. This will enable the student to understand the pathophysiology of common diseases and their management.

**Course Outcome:** At completion of this subject it is expected that students will be able to understand –

- the pathophysiology of selected disease states and the rationale for drug therapy;
- the controversies in drug therapy;
- the importance of preparation of individualised therapeutic plans based on diagnosis;
- needs to identify the patient-specific parameters relevant in initiating drug therapy, and monitoring therapy (including alternatives, time-course of clinical and laboratory indices of therapeutic response and adverse effects);
- summarize the therapeutic approach to management of these diseases including reference to the latest available evidence;
- Therapy (including alternatives, time-course of clinical and laboratory indices of therapeutic response and adverse effects).
- Pathophysiology and applied Pharmacotherapeutics of diseases associated with following system/diseases with of special reference to the drug of choice.

**UNIT - I**

Principles of Pharmacokinetics

1. Revision of basic concepts.
2. Clinical Pharmacokinetics.
  - a. Dose – response in man
  - b. Influence of renal and hepatic disease on Pharmacokinetics
  - c. Therapeutics drug monitoring & individualization of drug therapy
  - d. Population Pharmacokinetics.

**UNIT - II**

Adverse Drug Reactions, Drug Interactions, ADR monitoring & Pharmacovigilance.

**UNIT - III**

Pathophysiology and drug therapy of the following disorders.

Schizophrenia, anxiety, depression, epilepsy, Parkinson's, alzheimer's diseases, migraine, hypertension, angina pectoris, arrhythmias, atherosclerosis, myocardial infarction.

**UNIT - IV**

Pathophysiology and drug therapy of the following disorders.

TB, leprosy, leukemia, solid tumors, lymphomas, psoriasis, respiratory, urinary, g.i. tract infections, endocarditis, fungal and HIV infection, rheumatoid arthritis, glaucoma, menstrual disorders, menopause.



**UNIT - V**

Drug therapy in

- a) Geriatrics
- b) Pediatrics
- c) Pregnancy & Lactation.
- d) Renal & hepatic insufficiency

**REFERENCES:**

1. Clinical Pharmacy and Therapeutics - Roger and Walker, Churchill Livingstone publication.
2. Pharmacotherapy: A Pathophysiologic approach - Joseph T. Dipiro et al. Appleton & Lange.
3. Pathologic basis of disease - Robins SL, W.B. Saunders publication.
4. Pathology and therapeutics for Pharmacists: A Basis for Clinical Pharmacy Practice - Green and Harris, Chapman and Hall publication.
5. Clinical Pharmacy and Therapeutics - Eric T. Herfindal, Williams and Wilkins Publication.
6. Applied Therapeutics: The clinical Use of Drugs. Lloyd Young and Koda-Kimble MA
7. Avery's Drug Treatment, 4th Edn, 1997, Adis International Limited.
8. Relevant review articles from recent medical and pharmaceutical literature.
9. Pharmacotherapy: A Pathophysiologic approach - Joseph T. Dipiro et al. Appleton & Lange
10. Clinical Pharmacy and Therapeutics - Eric T. Herfindal, Williams and Wilkins Publication
11. Applied Therapeutics: The clinical Use of Drugs. Lloyd Young and Koda-Kimble MA

**JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD**  
**M.Pharm I Year I Sem (Pharmacology)**

**PHARMACOKINETICS AND DRUG METABOLISM (Professional Elective - I)**

**Course Objective:** In current methods of treatment which involves individualization of drug therapy, the student should have sound knowledge in pharmacokinetics and the effects of changes in pharmacokinetic parameters on therapeutic efficacy of the drugs.

**Course Outcomes:** Upon completion of the subject student shall be able to (Know, do, appreciate);

- Understand various pharmacokinetic parameters
- Influence of these parameters on efficacy of drugs
- Identify and resolve drug related problems;
- Pharmacogenetics

**UNIT - I**

Drug Absorption: Gastrointestinal, percutaneous, and rectal kinetics and factors affecting drug absorption. Absorption kinetics

**UNIT - II**

Drug Distribution: Plasma protein binding – factors affecting plasma protein binding – Tissue binding – transfer of drugs through biological barriers their therapeutic implication in drug action. Volume of distribution. Reaction of the body to foreign substances: Biotransformation of drugs, phase I and phase II metabolic reactions.

**UNIT - III**

Elimination of drugs: Concept of renal clearance and excretion of drugs –biological half – life, area under curve.

**UNIT - IV**

Bioavailability of drug products: Bioavailability tests. Bioequivalence. Compartment models and relevant pharmacokinetic parameters.

**UNIT - V**

Pharmacogenetics: Inter racial and individual variability in drug metabolism.

**REFERENCES:**

1. Shargel and Leon. Applied Biopharmaceutics and pharmacokinetics. Latest edition. Publisher: Prentice Hall, London.
2. Biopharmaceutics and Clinical Pharmacokinetics by, Milo Gibaldi b. Remington's Pharmaceutical Sciences, By Mack Publishing Company, Pennsylvania.
3. Pharmacokinetics: By Milo Gibaldi Donald, R. Merceel Dekker Inc.
4. Hand Book of Clinical Pharmacokinetics, By Milo Gibaldi and Laurie Prescott by ADIS Health Science Press.
5. Biopharmaceutics and Pharmacokinetics; By Robert F Notari f. Biopharmaceutics; By Swarbrick
6. Biopharmaceutics and Pharmacokinetics-A Treatise, By D. M. Brahmanekar and Sunil B. Jaiswal, Vallabh Prakashan Pitampura, Delhi
7. Clinical Pharmacokinetics, Concepts and Applications: By Malcolm Rowland and Thomas, N. Tozer, Lea and Febiger, Philadelphia, 1995.

8. Dissolution, Bioavailability and Bioequivalence, By Abdou H.M, Mack, Publishing Company, Pennsylvania 1989.
9. Biopharmaceutics and Clinical Pharmacokinetics-An introduction 4th edition Revised and expanded by Robert F Notari Marcel Dekker Inn, New York and Basel, 1987.
10. Encyclopedia of Pharmaceutical Technology, Vol 13, James Swarbrick, James, Roylan, Marcel Dekker Inc, New York 1996.

**JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD**  
**M.Pharm I Year I Sem (Pharmacology)**

**CLINICAL RESEARCH AND PHARMACOVIGILANCE (Professional Elective - I)**

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

**Course Outcomes:** Upon completion of the course, the student shall be able to,

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

**UNIT- I**

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

**UNIT - II**

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

**UNIT- III**

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

**UNIT- IV**

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

**UNIT- V**

**Methods, ADR reporting and tools used in pharmacovigilance:** International classification of

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

**REFERENCES:**

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

**JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD**  
**M.Pharm I Year I Sem (Pharmacology)**

**PRINCIPLES OF DRUG DISCOVERY (Professional Elective - I)**

**Course Objective:** The subject imparts basic knowledge of drug discovery process. This information will make the student Competent in drug discovery process.

**Course Outcome:** Upon completion of the course, the student shall be able to,

- Explain the various stages of drug discovery.
- Appreciate the importance of the role of genomics, proteomics and bioinformatics in drug discovery
- Explain various targets for drug discovery.
- Explain various lead seeking method and lead optimization
- Appreciate the importance of the role of computer aided drug design in drug discovery

**UNIT- I**

**An overview of modern drug discovery process:** Target identification, target validation, lead identification, and lead Optimization. Economics of drug discovery. Target Discovery and validation- Role of Genomics, Proteomics and Bioinformatics. Role of Nucleic acid microarrays, Protein microarrays, Antisense technologies, siRNAs, antisense oligonucleotides, Zinc finger proteins. Role of transgenic animals in target validation.

**UNIT- II**

**Lead Identification:** combinatorial chemistry & high throughput screening, in silico lead discovery techniques; Assay development for hit identification. Protein structure Levels of protein structure, Domains, motifs, and folds in protein structure. Computational prediction of protein structure: Threading and homology modeling methods. Application of NMR and X-ray crystallography in protein structure prediction.

**UNIT-III**

**Rational Drug Design:** Traditional vs rational drug design, Methods followed in traditional drug design, High throughput screening, Concepts of Rational Drug Design, Rational Drug Design Methods: Structure and Pharmacophore based approaches. Virtual Screening techniques: Drug likeness screening, Concept of pharmacophore mapping and pharmacophore based Screening,

**UNIT-IV**

**Molecular docking:** Rigid docking, flexible docking, manual docking; Docking based screening. De novo drug design. Quantitative analysis of Structure Activity Relationship History and development of QSAR, SAR versus QSAR, Physicochemical parameters, Hansch analysis, Fee Wilson analysis, and relationship between them.

**UNIT-V**

**QSAR Statistical methods:** regression analysis, partial least square analysis (PLS) and other multivariate statistical methods. 3D-QSAR approaches like COMFA and COMSIA Prodrug design- Basic concept, Prodrugs to improve patient acceptability, Drug solubility, Drug absorption, and distribution, site specific drug delivery and sustained drug action. Rationale of prodrug design and practical consideration of prodrug design.

## REFERENCES

1. Mouldy Sioud. Target Discovery and Validation Reviews and Protocols: Volume 2 Emerging Molecular Targets and Treatment Options. 2007 Humana Press Inc.
2. Darryl León. Scott Markelln. Silico Technologies in Drug Target Identification and Validation 2006 by Taylor and Francis Group, LLC.
3. Johanna K. DiStefano. Disease Gene Identification. Methods and Protocols. Springer New York Dordrecht Heidelberg London.
4. Hugo Kubiny. QSAR: Hansch Analysis and Related Approaches. Methods and Principles in Medicinal Chemistry. Publisher Wiley-VCH
5. Klaus Gubernator, Hans-Joachim Böhm. Structure-Based Ligand Design.
6. Methods and Principles in Medicinal Chemistry. Publisher Wiley-VCH
7. Abby L .Parrill. M. Rami Reddy. Rational Drug Design. Novel Methodology and Practical Applications. ACS Symposium Series; American Chemical Society: Washington, DC, 1999.
8. J. Rick Turner. New drug development design, methodology and, analysis. John Wiley & Sons, Inc., New Jersey.

**JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD  
M.Pharm I Year I Sem (Pharmacology)**

**ANIMAL CELL CULTURE (Professional Elective - II)**

**Course Objective:** The subject imparts basic knowledge of animal cell culture. This information will make the student Competent in various cell culture techniques and their applications.

**Course Outcome:** Upon completion of the course, the student shall be able to,

- Explain the various types of cell cultures, their requirements and advantages
- Appreciate the importance of the bioreactor, cell lines and their applications
- Explain various culture, preservation and maintenance techniques
- Explain various IVF techniques, embryo cultures and gene transfer
- Appreciate the importance of the role embryo culture in and its applications

**UNIT - I**

Introduction to Animal Biotechnology and its applications: History and scope of animal cell and tissue culture, Advantages and disadvantages of tissue culture, Laboratory facilities for tissue culture. Primary and secondary cell lines cell culture environment, Safety measures laminar hood,

**UNIT - II**

Basic tissue culture techniques, various types of cultures, Bioreactors, Common cell lines and aseptic methods, Culture media, maintenance and preservation of cell cultures, freezing media, treatment of substrate surfaces.

**UNIT - III**

Feeder layers on substrate, gas phase for tissue culture, Culture media for cells and tissues, Culture procedures, Disaggregation (enzymatic and mechanical) of tissue and primary culture

**UNIT - IV**

Cultured cells and evolution of cell lines, Maintenance of culture-cell lines, Tissue culture (slide, flask and test tube cultures), Organ culture, Whole embryo culture, Tissue engineering (artificial skin and artificial cartilage). Cell cultures as a source of valuable products

**UNIT - V**

In Vitro Fertilization & Transgenic Animals In vitro fertilization (IVF) in humans; embryo transfer (ET) in humans; superovulation, IVF and embryo culture in farm animals (e.g. cow); embryo transfer in cattle, Gene transfer or transfection (using eggs and cultured stem cells); targeted gene transfer; transgenic animals. (mice, sheep, pigs, rabbits, goats, cows, fish).

**REFERENCE BOOKS:**

1. Introduction to Biotechnology, P.K.Gupta, Kalyani Publishers,second edition.
2. Introduction to plant Biotechnology, H.S.Chawala, second ed., PHI
3. Plant Biotechnology – P. C. Trivedi
4. Applied Plant Biotechnology – Ignacimuthu
5. Animal Biotechnology – Babinnk and Philips.
6. Biotechnology – B. D. Singh.
7. Plant Tissue Culture – S.S. Bhojwani, M.K. Razdan.
8. Biotechnology Fundamentals and Applications – Purohis S S
9. Biotechnology in the Welfare of Mankind – Ali Khan



**JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD**  
**M.Pharm I Year I Sem (Pharmacology)**

**MOLECULAR BIOLOGY (Professional Elective - II)**

**Course Objective:** The subject imparts basic knowledge of molecular biology. This information will make the student Competent in molecular biology DNA topology, mutations and Transcriptions and Translations and Gene expressions.

**Course Outcome:** Upon completion of the course, the student shall be able to,

- Explain the various structure and chemistry of DNA, RNA etc.
- Explain topology of DNA, organization of DNA in chromosomes
- Appreciate the importance and mechanism of mutations and their repar.
- Explain various mechanism of DNA replications and Transcription
- Appreciate the importance of gene expression.

**UNIT - I**

**Introduction to Molecular biology**

**Nucleic acids** - DNA and RNA structure and functions, DNA as genetic material. Griffith, Avery-McCarty-McLeod, Hershey-Chase, Franklin Conrat Experiments

**DNA Structure:** Chemistry of DNA, Forces stabilizing DNA structure, Helix parameters, Forms of DNA (A,B,C,D,T and Z), Watson – Crick and Hoogsteen base pairing, Physical Properties of ds DNA (UV absorption spectra Denaturation and renaturation), Chemical that react with DNA.

**UNIT - II**

**DNA topology:** DNA supercoiling, Supercoiled form of DNA, Superhelical density, Energetic of supercoiled DNA, Biology of supercoiled DNA (Topological domain of DNA, DNA topoisomerases, Mechanisms of supercoiling in cells, mechanisms of action of topoisomerase I and II, effect of supercoiling on structure of DNA and role of supercoiling in gene expression and DNA replication).

**Organization of DNA into chromosomes:** Packaging of DNA and organization of chromosome in bacteria and eukaryotic cells; packaging of DNA in eukaryotic nucleosome and chromatin condensation assembly of nucleosomes upon replication. Chromatin modification and genome expression.

**UNIT - III**

**Mutations-** molecular mechanism - types of DNA mutations and its significance. DNA repair - repair mechanisms - need of DNA repairs, DNA recombination – molecular mechanism of recombination-relationship between repair and recombination, SOS mechanism. Proteins and enzymes involved DNA repair and recombination.

**DNA – Protein Interactions:** General features interaction of Helix- turn Helix motif, B sheet, Zn-DNA binding domain etc with DNA.

**UNIT - IV**

**DNA Replication:** Mechanism of DNA polymerase catalyzed synthesis of DNA, types of DNA polymerases in bacteria and their role. Initiation of chromosomal DNA replication and its regulation in prokaryotes assembly of replisome and progress of replication fork, termination of replication. Types and function of eukaryotic DNA polymerases initiation of replication in eukaryotes, role of telomerases in replication of eukaryotic chromosomes. Inhibitor of DNA replication (Blocking precursor synthesis nucleotide polymerization, altering DNA structure).

**Transcription:** RNA polymerases, features of prokaryotic and eukaryotic promoters. Strong and weak promoters. Assembly of transcription initiation complex in prokaryotes and eukaryotes and its

regulation; synthesis and processing of prokaryotic and eukaryotic transcripts. Transport of RNA within eukaryotic cell. Regulatory elements of genes-promoters. Fate of mRNA.

#### **UNIT 5**

**Translation- Synthesis and Processing of Proteome:** Structure and role of tRNA in protein synthesis, ribosome structure, basic feature of genetic code and its deciphering, translation (initiation, elongation and termination in detail in prokaryotes as well as eukaryotes), Post translational processing of protein (protein folding, processing by proteolytic cleavage, processing by chemical modification, inteins). Protein degradation.

**Regulation of Gene expression in prokaryotes and eukaryotes:** Positive and negative regulation. lac-, ara-, his- and trp- operon regulation; antitermination, global regulatory responses; Regulation of gene expression in eukaryotes: Transcriptional, translational and processing level control mechanisms.

**DNA- transposable elements-** types of transposable elements, its importance in variation and evolution. Possible origin of virus, Oncogenes.

#### **REFERENCES:**

1. Cell & Molecular Biology: Cell and Molecular Biology: Concepts and Experiments, Gerald Karp, John Wiley, NY
2. Molecular Cell Biology, H.S. Bramrah, Anmol Publications Pvt. Ltd., New Delhi
3. Advanced Molecular Biology, H.S. Bhamrah Viva Books, Pvt. Ltd., New Delhi
4. Plant Biochemistry and Molecular Biology, Hans Walter Held, Oxford, NY
5. Molecular Biology of the Gene, Watson, Baker, Bell, Gann Levine, Losick, Pearson Education Pvt. Ltd., New Delhi
6. Essential Molecular Biology: A Practical Approach, TA Brown, Oxford

**JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD  
M.Pharm I Year I Sem (Pharmacology)**

**PRINCIPLES OF TOXICOLOGY (Professional Elective - II)**

**Course Objective:** The subject imparts basic knowledge of toxicology. This information will make the student Competent in various toxicologies of liver, neuro, kidney etc

**Course Outcome:** Upon completion of the course, the student shall be able to,

- Explain the various toxicologies
- Explain various toxicologies of lungs, liver, gentic etc
- Appreciate the importance and mechanism of skin and reproductive toxicology
- Explain various mechanisms and affects of pesticides

**UNIT - I - Introduction to General Toxicology:**

History of toxicology, classification of toxicology, toxicants exposure, routes exposure and exposure characterization. animal and plant toxins, mechanisms of toxicity, toxicokinetics, biotransformation of xenobiotics.

**UNIT - II**

Toxicology of the liver, Toxicology of the Lung, Chemical Carcinogenesis & Genetic Toxicology

**UNIT - III**

Neurotoxicology, Cardiovascular Toxicology, Molecular Toxicology & Toxicogenomics, Immuno-toxicology, Toxicology of the Kidney

**UNIT - IV**

Toxicology of the Intestine, Toxicology of the Skin, Reproductive Toxicology & Teratology, Risk Assessment

**UNIT - V**

Nanotoxicology, Ecotoxicology, Toxicology of Metals, Analytical/Forensic Toxicology, Toxic Effects of Pesticides, Pesticide Regulation at EPA

**REFERENCE BOOKS:**

1. Casarett & Doull's Essentials of Toxicology by Curtis D. Klaassen, John B. Watkins
2. Principles of Toxicology by Karen Stine, Thomas M. Brown
3. Text Book of Pathology by Harsh Mohan

**JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD**  
**M.Pharm I Year I Sem (Pharmacology)**

**RESEARCH METHODOLOGY AND IPR**

**Course Objectives:**

- To understand the research problem
- To know the literature studies, plagiarism and ethics
- To get the knowledge about technical writing
- To analyze the nature of intellectual property rights and new developments
- To know the patent rights

**Course Outcomes:** At the end of this course, students will be able to

- Understand research problem formulation.
- Analyze research related information
- Follow research ethics
- Understand that today's world is controlled by Computer, Information Technology, but tomorrow world will be ruled by ideas, concept, and creativity.
- Understanding that when IPR would take such important place in growth of individuals & nation, it is needless to emphasize the need of information about Intellectual Property Right to be promoted among students in general & engineering in particular.
- Understand that IPR protection provides an incentive to inventors for further research work and investment in R & D, which leads to creation of new and better products, and in turn brings about, economic growth and social benefits.

**UNIT - I**

Meaning of research problem, Sources of research problem, Criteria Characteristics of a good research problem, Errors in selecting a research problem, Scope and objectives of research problem.

Approaches of investigation of solutions for research problem, data collection, analysis, interpretation, Necessary instrumentations

**UNIT - II**

Effective literature studies approaches, analysis, Plagiarism, Research ethics

**UNIT - III**

Effective technical writing, how to write report, Paper Developing a Research Proposal, Format of research proposal, a presentation and assessment by a review committee

**UNIT - IV**

Nature of Intellectual Property: Patents, Designs, Trade and Copyright. Process of Patenting and Development: technological research, innovation, patenting, development. International Scenario: International cooperation on Intellectual Property. Procedure for grants of patents, Patenting under PCT.

**UNIT-V:**

Patent Rights: Scope of Patent Rights. Licensing and transfer of technology. Patent information and databases. Geographical Indications. New Developments in IPR: Administration of Patent System. New developments in IPR; IPR of Biological Systems, Computer Software etc. Traditional knowledge Case Studies, IPR and IITs.

**TEXT BOOKS:**

1. Stuart Melville and Wayne Goddard, "Research methodology: an introduction for science & engineering students"
2. Wayne Goddard and Stuart Melville, "Research Methodology: An Introduction"

**REFERENCES:**

1. Ranjit Kumar, 2nd Edition, "Research Methodology: A Step by Step Guide for beginners"
2. Halbert, "Resisting Intellectual Property", Taylor & Francis Ltd ,2007.
3. Mayall, "Industrial Design", McGraw Hill, 1992.
4. Niebel, "Product Design", McGraw Hill, 1974.
5. Asimov, "Introduction to Design", Prentice Hall, 1962.
6. Robert P. Merges, Peter S. Menell, Mark A. Lemley, "Intellectual Property in New Technological Age", 2016.
7. T. Ramappa, "Intellectual Property Rights Under WTO", S. Chand, 2008

**JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD  
M.Pharm I Year I Sem (Pharmacology)**

**ADVANCED PHARMACOLOGY – I LAB (Lab – I)**

**List of experiments**

**Handling of laboratory animals.**

1. Various routes of drug administration.
2. Study of techniques of blood sampling, anesthesia and euthanasia of experimental animals.
3. To record the dose response curve of Ach using isolated ileum/rectus abdominis muscle preparation.
4. To carry out bioassay of Ach using isolated ileum/rectus abdominis muscle preparation by interpolation method.
5. To carry out bioassay of Ach using isolated ileum/rectus abdominis muscle preparation by three point method.
6. To carry out bioassay of Ach using isolated ileum/rectus abdominis muscle preparation by four point method.
7. Estimation of pA<sub>2</sub> value on isolated tissues
8. Bioassay of 5-HT using rat fundus strip
9. Bioassay of oxytocin using rat uterus

**REFERENCES:**

1. CPCSEA, OECD, ICH, USFDA, Schedule Y, EPA guidelines,
2. Fundamentals of experimental Pharmacology by M. N. Ghosh
3. Handbook of Experimental Pharmacology by S.K. Kulkarni.
4. Drug discovery and Evaluation by Vogel H.G.
5. Practical Manual of Experimental and Clinical Pharmacology by Bikash Medhi (Author), Ajay Prakash (Author) Jaypee brothers' medical publishers Pvt. Ltd

**JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD**  
**M.Pharm I Year I Sem (Pharmacology)**

**CLINICAL PHARMACOLOGY AND PHARMACOTHERAPEUTICS LAB (Lab – II)**

The students are required to be collect Prescriptions and of clinical details of different patients for their exposure with therapeutic management and other clinical aspects. They are expected to have experience and do a case presentation in the following clinical conditions. The students have to make at least 5 case presentations covering most common diseases. The student should also submit a record of the cases presented. The list of clinical cases presented should include follow-up of the clinical cases mentioned below from the day of admission till discharge and presented in the SOAP (Subjective, Objective, Assessment and Plan) format.

I. The cases may be selected from the following diseases:

1. Neurology & Psychiatry
2. Oncology
3. Infectious Diseases & Immunology
4. Gynecologic & Obstetric Disorders/ Ophthalmology
5. Cardiology
6. Dermatology
7. Endocrinology

II. Rational use of medicines in special population (three)

III. Calculation of Bioavailability and Bioequivalence from the given data (two)

IV. Interpretation of Therapeutic Drug Monitoring reports of a given patient (three)

V. Calculation of various Pharmacoeconomic outcome analysis for the given data (two)

**Assignments**

The students are required to submit a minimum of three written assignments (1500 to 2000 words) selected from the topics on different disease conditions given to them. The students are required to discuss both the clinical and therapeutic aspects in the same.

**JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD  
M.Pharm (Pharmacology)**

**ENGLISH FOR RESEARCH PAPER WRITING (Audit Course - I & II)**

**Prerequisite:** None

**Course objectives:** Students will be able to:

- Understand that how to improve your writing skills and level of readability
- Learn about what to write in each section
- Understand the skills needed when writing a Title Ensure the good quality of paper at very first-time submission

**UNIT-I:**

Planning and Preparation, Word Order, Breaking up long sentences, Structuring Paragraphs and Sentences, Being Concise and Removing Redundancy, Avoiding Ambiguity and Vagueness

**UNIT-II:**

Clarifying Who Did What, Highlighting Your Findings, Hedging and Criticizing, Paraphrasing and Plagiarism, Sections of a Paper, Abstracts. Introduction

**UNIT-III:**

Review of the Literature, Methods, Results, Discussion, Conclusions, The Final Check.

**UNIT-IV:**

key skills are needed when writing a Title, key skills are needed when writing an Abstract, key skills are needed when writing an Introduction, skills needed when writing a Review of the Literature,

**UNIT-V:**

skills are needed when writing the Methods, skills needed when writing the Results, skills are needed when writing the Discussion, skills are needed when writing the Conclusions. useful phrases, how to ensure paper is as good as it could possibly be the first- time submission

**TEXT BOOKS/ REFERENCES:**

1. Goldbort R (2006) Writing for Science, Yale University Press (available on Google Books)
2. Day R (2006) How to Write and Publish a Scientific Paper, Cambridge University Press
3. Highman N (1998), Handbook of Writing for the Mathematical Sciences, SIAM. Highman's book.
4. Adrian Wallwork, English for Writing Research Papers, Springer New York Dordrecht Heidelberg London, 2011



**JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD  
M.Pharm (Pharmacology)**

**DISASTER MANAGEMENT (Audit Course - I & II)**

**Prerequisite:** None

**Course Objectives:** Students will be able to

- learn to demonstrate a critical understanding of key concepts in disaster risk reduction and humanitarian response.
- critically evaluate disaster risk reduction and humanitarian response policy and practice from multiple perspectives.
- develop an understanding of standards of humanitarian response and practical relevance in specific types of disasters and conflict situations.
- critically understand the strengths and weaknesses of disaster management approaches,
- planning and programming in different countries, particularly their home country or the countries they work in

**UNIT-I:**

**Introduction:**

Disaster: Definition, Factors and Significance; Difference Between Hazard and Disaster; Natural and Manmade Disasters: Difference, Nature, Types and Magnitude.

**Disaster Prone Areas in India:**

Study of Seismic Zones; Areas Prone to Floods and Droughts, Landslides and Avalanches; Areas Prone to Cyclonic and Coastal Hazards with Special Reference to Tsunami; Post-Disaster Diseases and Epidemics

**UNIT-II:**

**Repercussions of Disasters and Hazards:**

Economic Damage, Loss of Human and Animal Life, Destruction of Ecosystem. Natural Disasters: Earthquakes, Volcanisms, Cyclones, Tsunamis, Floods, Droughts and Famines, Landslides and Avalanches, Man-made disaster: Nuclear Reactor Meltdown, Industrial Accidents, Oil Slicks and Spills, Outbreaks of Disease and Epidemics, War and Conflicts.

**UNIT-III:**

**Disaster Preparedness and Management:**

Preparedness: Monitoring of Phenomena Triggering A Disaster or Hazard; Evaluation of Risk: Application of Remote Sensing, Data from Meteorological and Other Agencies, Media Reports: Governmental and Community Preparedness.

**UNIT-IV:**

**Risk Assessment Disaster Risk:**

Concept and Elements, Disaster Risk Reduction, Global and National Disaster Risk Situation. Techniques of Risk Assessment, Global Co-Operation in Risk Assessment and Warning, People's Participation in Risk Assessment. Strategies for Survival.

**UNIT-V:**

**Disaster Mitigation:**

Meaning, Concept and Strategies of Disaster Mitigation, Emerging Trends In Mitigation. Structural Mitigation and Non-Structural Mitigation, Programs of Disaster Mitigation in India.

**TEXT BOOKS/ REFERENCES:**

1. R. Nishith, Singh AK, "Disaster Management in India: Perspectives, issues and strategies "New Royal book Company.
2. Sahni, Pardeep Et. Al. (Eds.)," Disaster Mitigation Experiences and Reflections", Prentice Hall of India, New Delhi.
3. Goel S. L., Disaster Administration and Management Text and Case Studies", Deep &Deep Publication Pvt. Ltd., New Delhi.

**JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD**  
**M.Pharm (Pharmacology)**

**SANSKRIT FOR TECHNICAL KNOWLEDGE (Audit Course - I & II)**

**Prerequisite:** None

**Course Objectives:**

- To get a working knowledge in illustrious Sanskrit, the scientific language in the world
- Learning of Sanskrit to improve brain functioning
- Learning of Sanskrit to develop the logic in mathematics, science & other subjects enhancing the memory power
- The engineering scholars equipped with Sanskrit will be able to explore the huge knowledge from ancient literature

**Course Outcomes:** Students will be able to

- Understanding basic Sanskrit language
- Ancient Sanskrit literature about science & technology can be understood
- Being a logical language will help to develop logic in students

**UNIT-I:**

Alphabets in Sanskrit,

**UNIT-II:**

Past/Present/Future Tense, Simple Sentences

**UNIT-III:**

Order, Introduction of roots,

**UNIT-IV:**

Technical information about Sanskrit Literature

**UNIT-V:**

Technical concepts of Engineering-Electrical, Mechanical, Architecture, Mathematics

**TEXT BOOKS/ REFERENCES:**

1. "Abhyasustakam" – Dr. Vishwas, Samskrita-Bharti Publication, New Delhi
2. "Teach Yourself Sanskrit" Prathama Deeksha-Vempati Kutumbshastri, Rashtriya Sanskrit Sansthanam, New Delhi Publication
3. "India's Glorious Scientific Tradition" Suresh Soni, Ocean books (P) Ltd., New Delhi.

**JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD  
M.Pharm (Pharmacology)**

**VALUE EDUCATION (Audit Course - I & II)**

**Prerequisite:** None

**Course Objectives:** Students will be able to

- Understand value of education and self- development
- Imbibe good values in students
- Let the should know about the importance of character

**Course outcomes:** Students will be able to

- Knowledge of self-development
- Learn the importance of Human values
- Developing the overall personality

**UNIT-I:**

Values and self-development –Social values and individual attitudes. Work ethics, Indian vision of humanism. Moral and non- moral valuation. Standards and principles. Value judgements

**UNIT-II:**

Importance of cultivation of values. Sense of duty. Devotion, Self-reliance. Confidence, Concentration. Truthfulness, Cleanliness. Honesty, Humanity. Power of faith, National Unity. Patriotism. Love for nature, Discipline

**UNIT-III:**

Personality and Behavior Development - Soul and Scientific attitude. Positive Thinking. Integrity and discipline, Punctuality, Love and Kindness.

**UNIT-IV:**

Avoid fault Thinking. Free from anger, Dignity of labour. Universal brotherhood and religious tolerance. True friendship. Happiness Vs suffering, love for truth. Aware of self-destructive habits. Association and Cooperation. Doing best for saving nature

**UNIT-V:**

Character and Competence –Holy books vs Blind faith. Self-management and Good health. Science of reincarnation, Equality, Nonviolence, Humility, Role of Women. All religions and same message. Mind your Mind, Self-control. Honesty, Studying effectively

**TEXT BOOKS/ REFERENCES:**

1. Chakroborty, S.K. "Values and Ethics for organizations Theory and practice", Oxford University Press, New Delhi

**JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD  
M.Pharm (Pharmacology)**

**CONSTITUTION OF INDIA (Audit Course - I & II)**

**Prerequisite:** None

**Course Objectives:** Students will be able to:

- Understand the premises informing the twin themes of liberty and freedom from a civil rights perspective.
- To address the growth of Indian opinion regarding modern Indian intellectuals' constitutional role and entitlement to civil and economic rights as well as the emergence of nationhood in the early years of Indian nationalism.
- To address the role of socialism in India after the commencement of the Bolshevik Revolution in 1917 and its impact on the initial drafting of the Indian Constitution.

**Course Outcomes:** Students will be able to:

- Discuss the growth of the demand for civil rights in India for the bulk of Indians before the arrival of Gandhi in Indian politics.
- Discuss the intellectual origins of the framework of argument that informed the conceptualization of social reforms leading to revolution in India.
- Discuss the circumstances surrounding the foundation of the Congress Socialist Party [CSP] under the leadership of Jawaharlal Nehru and the eventual failure of the proposal of direct elections through adult suffrage in the Indian Constitution.
- Discuss the passage of the Hindu Code Bill of 1956.

**UNIT-I:**

**History of Making of the Indian Constitution:** History Drafting Committee, (Composition & Working), **Philosophy of the Indian Constitution:** Preamble, Salient Features.

**UNIT-II:**

**Contours of Constitutional Rights & Duties:** Fundamental Rights Right to Equality, Right to Freedom, Right against Exploitation, Right to Freedom of Religion, Cultural and Educational Rights, Right to Constitutional Remedies, Directive Principles of State Policy, Fundamental Duties.

**UNIT-III:**

**Organs of Governance:** Parliament, Composition, Qualifications and Disqualifications, Powers and Functions, Executive, President, Governor, Council of Ministers, Judiciary, Appointment and Transfer of Judges, Qualification, Powers and Functions.

**UNIT-IV:**

**Local Administration:** District's Administration head: Role and Importance, Municipalities: Introduction, Mayor and role of Elected Representative, CEO of Municipal Corporation. Pachayati raj: Introduction, PRI: Zila Pachayat. Elected officials and their roles, CEO Zila Pachayat: Position and role. Block level: Organizational Hierarchy (Different departments), Village level: Role of Elected and Appointed officials, Importance of grass root democracy.

**UNIT-V:**

**Election Commission:** Election Commission: Role and Functioning. Chief Election Commissioner and Election Commissioners. State Election Commission: Role and Functioning. Institute and Bodies for the welfare of SC/ST/OBC and women.

**TEXT BOOKS/ REFERENCES:**

1. The Constitution of India, 1950 (Bare Act), Government Publication.
2. Dr. S. N. Busi, Dr. B. R. Ambedkar framing of Indian Constitution, 1st Edition, 2015.
3. M. P. Jain, Indian Constitution Law, 7th Edn., Lexis Nexis, 2014.
4. D.D. Basu, Introduction to the Constitution of India, Lexis Nexis, 2015.

**JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD**

**M.Pharm (Pharmacology)**

**PEDAGOGY STUDIES (Audit Course - I & II)**

**Prerequisite:** None

**Course Objectives:** Students will be able to:

- Review existing evidence on the review topic to inform programme design and policy making undertaken by the DfID, other agencies and researchers.
- Identify critical evidence gaps to guide the development.

**Course Outcomes:** Students will be able to understand:

- What pedagogical practices are being used by teachers in formal and informal classrooms in developing countries?
- What is the evidence on the effectiveness of these pedagogical practices, in what conditions, and with what population of learners?
- How can teacher education (curriculum and practicum) and the school curriculum and guidance materials best support effective pedagogy?

**UNIT-I:**

**Introduction and Methodology:** Aims and rationale, Policy background, Conceptual framework and terminology Theories of learning, Curriculum, Teacher education. Conceptual framework, Research questions. Overview of methodology and Searching.

**UNIT-II:**

**Thematic overview:** Pedagogical practices are being used by teachers in formal and informal classrooms in developing countries. Curriculum, Teacher education.

**UNIT-III:**

Evidence on the effectiveness of pedagogical practices, Methodology for the indepth stage: quality assessment of included studies. How can teacher education (curriculum and practicum) and the scho curriculum and guidance materials best support effective pedagogy? Theory of change. Strength and nature of the body of evidence for effective pedagogical practices. Pedagogic theory and pedagogical approaches. Teachers' attitudes and beliefs and Pedagogic strategies.

**UNIT-IV:**

**Professional development:** alignment with classroom practices and follow-up support, Peer support, Support from the head teacher and the community. Curriculum and assessment, Barriers to learning: limited resources and large class sizes

**UNIT-V:**

**Research gaps and future directions:** Research design, Contexts, Pedagogy, Teacher education, Curriculum and assessment, Dissemination and research impact.

**TEXT BOOKS/ REFERENCES:**

1. Ackers J, Hardman F (2001) Classroom interaction in Kenyan primary schools, Compare, 31 (2): 245-261.
2. Agrawal M (2004) Curricular reform in schools: The importance of evaluation, Journal of Curriculum Studies, 36 (3): 361-379.

3. Akyeampong K (2003) Teacher training in Ghana - does it count? Multi-site teacher education research project (MUSTER) country report 1. London: DFID.
4. Akyeampong K, Lussier K, Pryor J, Westbrook J (2013) Improving teaching and learning of basic maths and reading in Africa: Does teacher preparation count? *International Journal Educational Development*, 33 (3): 272–282.
5. Alexander RJ (2001) *Culture and pedagogy: International comparisons in primary education*. Oxford and Boston: Blackwell.
6. Chavan M (2003) Read India: A mass scale, rapid, 'learning to read' campaign.
7. [www.pratham.org/images/resource%20working%20paper%202.pdf](http://www.pratham.org/images/resource%20working%20paper%202.pdf).



**JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD**  
**M.Pharm (Pharmacology)**

**STRESS MANAGEMENT BY YOGA (Audit Course - I & II)**

**Prerequisite:** None

**Course Objectives:**

- To achieve overall health of body and mind
- To overcome stress

**Course Outcomes:** Students will be able to:

- Develop healthy mind in a healthy body thus improving social health also
- Improve efficiency

**UNIT-I:**

Definitions of Eight parts of yog. (Ashtanga)

**UNIT-II:**

Yam and Niyam.

**UNIT-III:**

Do`s and Don`ts in life.

- i) Ahinsa, satya, astheya, bramhacharya and aparigraha
- ii) Shaucha, santosh, tapa, swadhyay, ishwarpranidhan

**UNIT-IV:**

Asan and Pranayam

**UNIT-V:**

- i) Various yog poses and their benefits for mind & body
- ii) Regularization of breathing techniques and its effects-Types of pranayam

**TEXT BOOKS/ REFERENCES:**

1. 'Yogic Asanas for Group Training-Part-I': Janardan Swami Yogabhyasi Mandal, Nagpur
2. "Rajayoga or conquering the Internal Nature" by Swami Vivekananda, Advaita Ashrama (Publication Department), Kolkata

**JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD**  
**M.Pharm (Pharmacology)**

**PERSONALITY DEVELOPMENT THROUGH LIFE ENLIGHTENMENT SKILLS**  
**(Audit Course - I & II)**

**Prerequisite:** None

**Course Objectives:**

- To learn to achieve the highest goal happily
- To become a person with stable mind, pleasing personality and determination
- To awaken wisdom in students

**Course Outcomes:** Students will be able to

- Study of Shrimad-Bhagwad-Geeta will help the student in developing his personality and achieve the highest goal in life
- The person who has studied Geeta will lead the nation and mankind to peace and prosperity
- Study of Neetishatakam will help in developing versatile personality of students

**UNIT-I:**

Neetisatakam-Holistic development of personality

- Verses- 19,20,21,22 (wisdom)
- Verses- 29,31,32 (pride & heroism)
- Verses- 26,28,63,65 (virtue)

**UNIT-II:**

Neetisatakam-Holistic development of personality

- Verses- 52,53,59 (don't's)
- Verses- 71,73,75,78 (do's)

**UNIT-III:**

Approach to day to day work and duties.

- Shrimad Bhagwad Geeta: Chapter 2-Verses 41, 47,48,
- Chapter 3-Verses 13, 21, 27, 35, Chapter 6-Verses 5,13,17, 23, 35,
- Chapter 18-Verses 45, 46, 48.

**UNIT-IV:**

Statements of basic knowledge.

- Shrimad Bhagwad Geeta: Chapter2-Verses 56, 62, 68
- Chapter 12 -Verses 13, 14, 15, 16,17, 18
- Personality of Role model. Shrimad Bhagwad Geeta:

**UNIT-V:**

- Chapter2-Verses 17, Chapter 3-Verses 36,37,42,
- Chapter 4-Verses 18, 38,39
- Chapter18 – Verses 37,38,63

**TEXT BOOKS/ REFERENCES:**

1. "Srimad Bhagavad Gita" by Swami Swarupananda Advaita Ashram (Publication Department), Kolkata.
2. Bhartrihari's Three Satakam (Niti-sringar-vairagya) by P.Gopinath, Rashtriya Sanskrit Sansthanam, New Delhi.