

**JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD**  
**M.PHARMACY (PHARMACEUTICS / PHARMACEUTICAL TECHNOLOGY)**  
**R22 COURSE STRUCTURE AND SYLLABUS**  
**Effective from Academic Year 2022-23 Admitted Batch**

**I YEAR I Semester**

Course Code	Course Title	L	T	P	Credits
Professional Core-I	Modern Pharmaceutics-I	3	1	0	4
Professional Core-II	Applied Biopharmaceutics and Pharmacokinetics	3	1	0	4
Professional Elective-I	1. Advanced Physical Pharmaceutics 2. Drug Regulatory affairs 3. Total Quality Management	3	1	0	4
Professional Elective-II	1. Cosmetics and Cosmeceuticals 2. Pharmaceutical Validation 3. Stability of Drugs and Dosage Forms	3	1	0	4
	Research methodology and IPR	2	0	0	2
Laboratory- I	Modern Pharmaceutics – I Lab	0	0	6	3
Laboratory- II	Applied Biopharmaceutics and Pharmacokinetics Lab	0	0	6	3
Audit - I	Audit Course- I	2	0	0	0
	Seminar & Assignment	0	0	4	2
	<b>TOTAL</b>	<b>16</b>	<b>4</b>	<b>16</b>	<b>26</b>

**I YEAR II Semester**

Course Code	Course Title	L	T	P	Credits
Professional Core-III	Modern Pharmaceutics - II	3	1	0	4
Professional Core-IV	Advanced Drug Delivery Systems	3	1	0	4
Professional Elective-III	1. Industrial Pharmacy 2. Herbal Cosmetics 3. Pharmaceutical Management	3	1	0	4
Professional Elective-IV	1. Nano based Drug Delivery Systems 2. Nutraceuticals 3. Clinical Research and Pharmacovigilance	3	1	0	4
Laboratory- III	Modern Pharmaceutics – II Lab	0	0	6	3
Laboratory- IV	Advanced Drug Delivery System Lab	0	0	6	3
	Mini Project	2	0	0	2
Audit - II	Audit Course- II	2	0	0	0
	Seminar & Assignment	0	0	4	2
	<b>TOTAL</b>	<b>16</b>	<b>4</b>	<b>16</b>	<b>26</b>

**II YEAR I Semester**

Course Code	Course Title	L	T	P	Credits
Professional Elective-V	1. Biostatistics 2. Scale up and Technology Transfer 3. Production area, Design and Packaging Development	3	1	0	4
Open Elective	Open Elective	3	1	0	4
	Comprehensive Viva voce	0	0	8	4
	Dissertation Work Review – II	0	0	24	12
	<b>TOTAL</b>	<b>6</b>	<b>2</b>	<b>32</b>	<b>24</b>



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**II YEAR II Semester**

Course Code	Course Title	L	T	P	Credits
Dissertation	Dissertation Work Review - III	0	0	24	12
Dissertation	Dissertation Viva-Voce	0	0	20	10
	<b>TOTAL</b>	<b>0</b>	<b>0</b>	<b>44</b>	<b>22</b>

**\*For Dissertation Work Review - I, Please refer R22 Academic Regulations.**

**Audit Courses I & II:**

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



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**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 as per ICH.

**UNIT II**

**Formulation development of solid dosage forms – I:** New materials, excipient science - diluents, disintegrants, superdisintegrants, etc, evaluation of functional properties of excipient, 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.




  
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6. Pharmaceutical statistics by Bolton

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



  
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**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, *In vitro- In vivo* 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.



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**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 NiaziSarfaraz, Pharmed Press

#### 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



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**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.



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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. Text Book of Forensic Pharmacy by C K Kokate, Pharmamed Press
6. Pharmaceutical Regulatory Affairs - Selected Topics, CVS Subramanyam and J Thimmasetty, Vallabh Prakashan Delhi - 2013



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**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.



  
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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



  
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**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.



**REFERENCE BOOKS:**

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. Cosmeceuticals by Y Madhusudan Rao, Pharmamed Press
6. Cosmetics for the Skin: Physiological and Pharmaceutical Approach by A. K. Mohiuddin, Pharmamed Press.
7. Cosmetic and Toiletries recent suppliers' catalogue.
8. CTFA directory.



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**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

**REFERENCE BOOKS:**

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).



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5. Michael Levin, Pharmaceutical Process Scale-UpII, 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. Pharmaceutical Facilities: Design, Layouts and Validation, 2nd Ed, Potdar, Pharmamed Press.
9. Validation of Pharmaceutical Processes: Sterile Products, Frederick J. Carlton (Ed.) and James Agalloco (Ed.), Marcel Dekker, 2nd Ed.
10. Analytical Method validation and Instrument Performance Verification by Churg Chan, Heiman Lam



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**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.



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**REFERENCE BOOKS:**

1. Comprehensive Pharmacy Review 5th Edition by Leon Shargel, Alan H. Mutnick, Paul F. Souney, Larry N. Sawson – 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.,BSP Books



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**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 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.



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**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"
3. Pharmaceutical Research Methodology and BioStatistics, B Subba Rao, Pharmamed Press
4. Intellectual Property Rights in Pharmaceutical Industry, B Subba Rao, Pharmamed Press

**REFERENCE BOOKS:**

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



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**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 capsules.
5. To study the effect of binders on dissolution of tablets
6. To study enteric coated tablets dissolution in relevant pH.
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
11. Design of experiments (DOE) in the optimization of an immediate release tablets.
12. Calculation of shelf life using accelerated stability data,



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**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 MIVC 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 Agargel method or Franz diffusion cell.



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

**MODERN PHARMACEUTICS - II (Professional Core - III)**

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

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

**UNIT I**

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

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

**UNIT II**

**Formulation development of parenteral dosage forms:** Advances in materials and production techniques, filling machines, sterilization methods (Moist heat, dry heat, filtration, radiation, gaseous sterilization), product layout.

**UNIT III**

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

**UNIT IV**

**a. Cosmetics:** Formulation approaches, preparation & method of manufacturing labelling & Q.C. of anti-ageing products, sun screen lotion and fairness creams.

**b. Nutraceuticals:**

1. Introduction, source, manufacture and analysis of glucosamine & cartinine.
2. Monographs: General and specific properties of glucosamine & cartinine.
3. A brief overview of role of nutraceuticals in cancer prevention & cardio vascular disorders.

**UNIT V**

**Aseptic processing operation**

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

**TEXT BOOKS:**

1. Pharmaceutics - The Science of Dosage form design by ME Aulton.
2. The Theory and Practice of industrial Pharmacy by Leon Lachman, Herbert A. Lieberman.
3. Remington's Science and Practice of Pharmacy by A. Gennaro.



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4. Ansel's Pharmaceutical Dosage form and Drug delivery system by Loyd V. Allen, Jr.
5. Nicholas G. Popovich, Howard C. Ansel.
6. Pharmaceutical Dosage forms - Parenterals (Vol I, II and III) by Avis, Lieberman and Lachman.
7. Scale up techniques – Pharmaceutical process by Michael Levin, Marcel Dekker

**REFERENCE BOOKS:**

1. Bentley's Text Book of Pharmaceutics by EA Rawlins.
2. Generic Drug Product Development by Leon Shargel.
3. Dispensing for Pharmaceutical Students by SJ Carter.
4. Modern Pharmaceutics by Gilbert S. Banker and Christopher T. Rhodes.
5. Nutraceuticals, 2nd edition by Brian lock wood.
6. Industrial Pharmacy - Selected Topics, CVS Subramanyam and J Thimmasetty, Vallabha Prakashan Delhi - 2013



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

**ADVANCED DRUG DELIVERY SYSTEMS (Professional Core - IV)**

**Course Objectives:** The students shall apply the pharmacokinetic and pharmacodynamic principles in the design of CDDS. They also apply the design, evaluation and applications related to oral, parenteral, transdermal, implants, bioadhesives and targeted drug delivery systems.

**Course Outcomes:** Students will select the drugs for CDDS design of the formulation fabrication of systems of above drug delivery systems with relevant applications.

**UNIT I**

Fundamentals of controlled drug delivery systems, pharmacokinetic and pharmacodynamic basis of controlled drug delivery. Design, fabrication, evaluation and applications of the following controlled releasing systems

- a. Controlled release oral drug delivery systems
- b. Parenteral controlled release drug delivery systems

**UNIT II**

Design, fabrication, evaluation and applications of the following

- a. Implantable Therapeutic systems
- b. Transdermal delivery systems
- c. Ocular and Intrauterine delivery systems
- d. Vaccine delivery: Delivery systems used to promote uptake, absorption enhancers, oral immunization, controlled release microparticles for vaccine development

**UNIT III**

Biochemical and molecular biology approaches for drug delivery using following technologies

- a. Bioadhesive drug delivery systems
- b. Nasal drug delivery systems
- c. Drug delivery to Colon

**UNIT IV**

Biochemical and molecular biology approaches to control drug delivery of

- a. Liposomes
- b. Niosomes
- c. Microspheres
- d. Nanoparticles
- e. Resealed erythrocytes

**UNIT - V**

Drug targeting to particular organs

- a. Delivery to lungs
- b. Delivery to the brain and problems involved
- c. Drug targeting in neoplasms

**TEXT BOOKS:**

1. Novel Drug Delivery System by Yie W. Chien.
2. Controlled Drug Delivery by Joseph R. Robinson and Vincent H. L. Lee.
3. Controlled and Novel Drug Delivery Systems by N. K. Jain.
4. Targeted and Controlled Drug Delivery (Novel carrier systems) by S. P. Vyas and Khar.



5. *Advances in Drug Delivery*, 4 Vol. set, Rao Madhusudan Y, Pharmamed Press
6. *Modern Pharmaceutics* by Gilbert S. Banker and Christopher T. Rhodes.
7. *Oral Drug Delivery Technology*, 2<sup>nd</sup>ed, by Aukunuru Jithan



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

**INDUSTRIAL PHARMACY (Professional Elective - III)**

**Course Objectives:** The students shall learn the theory of unit operations, machinery, materials of constructions, qualification of equipments and its utility. The students shall also understand about the objectives and principles of GMP, TQM and effluent analysis and specifications. They also understand the regulatory basis for the validation of analytical methods related to solids, sterile and liquid dosage forms

**Course Outcome:** The students will explain the machinery involved in milling, mixing, filtration, drying and packing material constructions used in the production of pharmaceutical materials. They also learn salient features of GMP, TQM applicable in industry. They also understand the effluent treatments and prevent the pollution. They also should evaluate the validation of analytical methods and processes

**UNIT I**

**Pharmaceutical unit operations:** A detailed study involving machinery and theory of Pharmaceutical unit operations like milling, mixing, filtration, granulation, drying and blending.

**UNIT II**

- a. Materials of construction of pharmaceutical equipment and packaging materials: Study of the principles, production techniques in the large scale production of tablets, capsules, suspensions, liquid pharmaceuticals, ophthalmic products and sterile products.
- b. Qualification of equipment (IQ, OQ, PQ)

**UNIT III**

**Production management:** Production organization, objectives and policies of good manufacturing practices, layout of buildings, services, equipments and their maintenance, material management, handling and transportation, inventory management and control, production and planning control, Sales forecasting, budget and cost control, industrial and personal relationship. Total Quality Management (TQM)

**UNIT IV**

**Effluent Testing and Treatment:** Effluent analysis, specifications and preventive measures water of pollution, solid pollution, air pollution and sound pollution.

**UNIT V**

**Validation:** Regulatory basis, validation process for solid dosage forms, sterile products, and liquid dosage forms.

**TEXT BOOKS:**

1. The Theory and Practice of industrial Pharmacy by Leon Lachman, Herbert A. Lieberman.
2. Good Manufacturing Practice for Pharmaceuticals by Sidney H. Willig.
3. Pharmaceutical Process validation by Robert A. Nash, Alfred H. Wachter.
4. Modern Pharmaceutics by Gilbert S. Banker and Christopher T. Rhodes.
5. Pharmaceutical production management, C.V.S. Subrahmanyam, Vallabh Prakash.
6. Industrial Pharmacy: A Comprehensive Approach, D K Tripathi, Pharmamed Press.



**REFERENCE BOOKS:**

1. Unit operations of Chemical Engineering by Warren L. McCabe, Julian C. Smith, Peter Harriott.
2. Remington's Science and Practice of Pharmacy by A. Gennaro.
3. Bentley's Text book of Pharmaceutics by EA Rawlins.
4. CGMP, H.P.P. Sharma



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

**HERBAL COSMETICS (Professional Elective - III)**

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

**Course Outcome:** 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 - V**

**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.

**REFERENCE BOOKS:**

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



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

**PHARMACEUTICAL MANAGEMENT (Professional Elective - III)**

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

**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 labsetc.

**UNIT IV**

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

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

**UNIT V**

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

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

**TEXT AND REFERENCE BOOKS:**

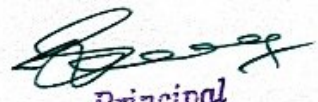
1. Marketing Management by Philip Kotlar; Prentice-Hall of India Ltd., New Delhi.
2. Management and Organization by Louis A. Allen; McGraw Hill, Tokyo.
3. Corporate Strategy by Ansoff, H.T.; McGraw Hill, New York.



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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 3<sup>rd</sup> Edition Harry A. Smith.
10. Management "Global Perspective Heinz Wehrich, Harold Koontz by Tata Mcgraw Hill".
11. Personnel Management and Industrial Relations by P. C.Tripathi.
12. Pharmaceutical Industrial Management by G. Vidya Sagar, Pharmamed Press.



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

**NANO BASED DRUG DELIVERY SYSTEMS (Professional Elective - IV)**

**Course Objective** - To develop expertise regarding suitability and evaluation of nanomaterials, able to apply the properties to the fabrication of nanopharmaceutical, evaluate the intensity of dosage forms and availability for targeting and controlled delivery.

**Course Outcomes** – The students should be able to select the right kind of materials, able to develop nano formulations with appropriate technologies, evaluate the product related test and for identified diseases

**UNIT - I – Introduction to Nanotechnology**

- a. Definition of nanotechnology
- b. History of nanotechnology
- c. Unique properties and classification of nanomaterials
- d. Role of size and size distribution of nanoparticles properties.
- e. Marketed formulations based on nanotechnology and science behind them

**UNIT - II – Synthesis of Nanomaterials**

Physical, chemical and biological Methods

Methods for synthesis of

- Gold nanoparticles
- Magnetic nanoparticles
- Polymeric nanoparticles
- Self – assembly structures such as liposomes, Niosomes, transferosomes, micelles, aquasomes and nanoemulsions

**UNIT - III - Biomedical applications of Nanotechnology**

- a. Nanotechnology products used for in vitro diagnostics
- b. Improvements to medical or molecular imaging using nanotechnology
- c. Targeted nanomaterials for diagnostic and therapeutic purpose

**UNIT - IV**

Design of nanomaterials for drug delivery, pulmonary and nasal drug delivery, nanomaterials for cancer therapy and cardiovascular diseases. Localized drug delivery systems.

**UNIT - V**

Characterization including the principles, size reduction, analysis of nanoparticles, size, PDI, size separation, stability, methods of analysis regarding integrity and release of drugs

**TEXT AND REFERENCE BOOKS:**

1. Nanomedicine and Nanoproducts: Applications, Disposition and Toxicology in the Human body, Eiki Igarashi, CRC press. 2015
2. Nanotechnology and Drug Delivery Volume one and two: Nanoplatfoms in Drug Delivery, Jose L. Arias, CRC press
3. Nano: The Essentials: Understanding Nanoscience and Nanotechnology, T. Pradeep, Tata McGraw-Hill Publishing Company Limited, New Delhi, 2008.
4. Nanocrystals: Synthesis, Properties and Applications, C. N. R. Rao, P. J. Thomas and G.U. Kulkarni, Springer (2007)




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5. Nanostructures and Nanomaterials: Synthesis, Properties and Application, Guozhong Gao, Imperial College Press (2004)
6. Nano-Carrier Systems Theories, Methods & Applications, Amit K. Goyal, Goutam Rath, Pharmamed Press.
7. Nano chemistry: A Classical Approach to Nanomaterials – Royal Society for Chemistry, Cambridge, UK (2005)
8. Nanocomposite science and technology, pulickel M. Ajayan, Linda S. Schadler, paul V. Braun, Wiley - VCH Verlag, Weiheim (2003)
9. Nanoscale materials in chemistry, Edited by Kenneth J. Klabunde, John Wiley & Sons, 2009
10. Nanoparticles as Drug carriers, Vladimir P Torchiling, Imperial College Press, USA, 2006
11. Introduction to Nano Science and Technologies, Ankaneyulu Yerramilli, BS Publications. 2016



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

**NUTRACEUTICALS (Professional Elective - IV)**

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

**Course Outcomes:** Helps the student to understand the importance of Nutraceuticals in various common problems with the concept of free radicals

**UNIT I**

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

b. Source, Name of marker compounds and their chemical nature, Medicinal uses and health benefits of following used as nutraceuticals/functional foods:

Spirulina, Soya bean, Ginseng, Garlic, Broccoli, Gingko, Flaxseeds

**UNIT II**

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

- a) Carotenoids-  $\alpha$  and  $\beta$ -Carotene, Lycopene, Xanthophylls, lutein
- b) Sulfides: Diallylsulfides, Allyltrisulfide.
- c) Polyphenolics: Resveratrol
- d) Flavonoids- Rutin, Naringin, Quercetin, Anthocyanidins, catechins, Flavones
- e) Prebiotics / Probiotics.: Fructo oligosaccharides, Lactobacillum
- f) Phytoestrogens: Isoflavones, daidzein, Geobustin, lignans
- g) Tocopherols

**UNIT III**

a. Introduction to free radicals: Free radicals, reactive oxygen species, production of free radicals in cells, damaging reactions of free radicals on lipids, proteins, Carbohydrates, nucleic acids.

b. Measurement of free radicals: Lipid peroxidation products, lipid hydroperoxide, malondialdehyde.

**UNIT IV**

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

b. Antioxidants: Endogenous antioxidants – enzymatic and nonenzymatic antioxidant defence, Superoxide dismutase, catalase, Glutathione peroxidase, Glutathione Vitamin C, Vitamin E,  $\alpha$ -Lipoic acid, melatonin

Synthetic antioxidants: Butylatedhydroxy Toluene, Butylatedhydroxy Anisole.

**UNIT V**

**Food Laws and Regulations;** FDA, FPO, MPO, AGMARK. HACCP and GMPs on Food Safety. Adulteration of foods.

**Regulations and Claims – Current Products:** Label Claims, Nutrient Content Claims, Health Claims, Dietary Supplements Claims



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**REFERENCE BOOKS:**

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



A handwritten signature in blue ink, appearing to read "S. Rao", is written over the printed name of the Principal.

**Principal**  
**Vaagdevi Pharmacy College**  
Bommanata, Warangal-506005 (T.S)

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

**CLINICAL RESEARCH AND PHARMACOVIGILANCE (Professional Elective - IV)**

**Course Objectives:** 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**

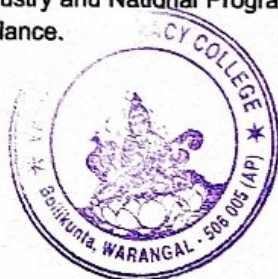
**Clinical Trial Documentation:**

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 Program, WHO and Regulatory terminologies of ADR, evaluation of medication safety, establishing pharmacovigilance centres in Hospitals, Industry and National Programs related to pharmacovigilance. Roles and responsibilities in Pharmacovigilance.



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

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

**REFERENCE BOOKS:**

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. A Textbook of Clinical Research and Pharmacovigilance by KPR Chowdary, Pharmamed Press.
7. Handbook of clinical Research. Julia Lloyd and Ann Raven Ed. Churchill Livingstone.
8. Principles of Clinical Research edited by Giovanna di Ignazio, Di Giovanna and Haynes.
9. Textbook of Pharmacovigilance: Concept and Practice. G.P. Mohanta and P. K. Manna. 2016, Pharma Med Press.
10. A textbook of Clinical Pharmacy Practice: Essential Concepts and Skills. Second Edition, 2012, University Press



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

**MODERN PHARMACEUTICS – II LAB (Laboratory- III)**

**List of Experiments:**

1. Scale up calculations from R&D to pilot plant for the following unit operations
  - a) Wet granulations using RMG/PLM
  - b) Blending & Lubrications
  - c) Film coating
2. Preparation of Injectables, Ampoules & Vials
3. Preparation of Ophthalmic products, Eye drops and Eye ointments
4. Preparation of Dry powder Inhalations
5. Formulation Development and Demonstration of function of DPI of marketed products
6. Formulation of Aerosol Demonstration of marketed products



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

**ADVANCED DRUG DELIVERY SYSTEMS LAB (Laboratory- IV)**

**List of Experiments:**

1. Study on diffusion of drugs through various polymeric membranes (2 experiments)
2. Formulation and Evaluation of sustained release Oral Matrix Tablet (2 experiments)
3. Formulation and Evaluation of sustained release Oral Reservoir System (2 experiments)
4. Formulation and Evaluation of Microspheres / Microencapsules (2 experiments)
5. Study of in-vitro Dissolution of various SR products in market (2 experiments)
6. Formulation and Evaluation of Transdermal Films (2 experiments)
7. Formulation and Evaluation of Mucoadhesive System (2 experiments)
8. Preparation and Evaluation of Enteric Coated Pellets / Tablets (2 experiments)
9. Preparation and Evaluation of Liposomes, Niosomes and Nanoparticles



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

**BIOSTATISTICS (Professional Elective - V)**

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

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

**UNIT I**

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

**UNIT II**

**Measures of central tendency:** computation of means, median and mode from grouped and ungrouped data.

**Measure of dispersion:** computation of variance, standard deviation, standard error and their coefficients.

**UNIT III**

Measures of Correlation and Regression

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

**UNIT IV**

Experimental designing, planning of an experiment, replication and randomization.

**Analysis of Variance (ANOVA):** 1-way, 2- Way

**UNIT V**

**Hypothesis testing:** Student 't' test, Chi square test,

**Non- Parametric Tests:** Sign Test, Sign Rank Test, Wilcoxon Sign Rank Test

**REFERENCE BOOKS:**

1. Statistics for business and economics 3<sup>rd</sup> edition by Vikas books publications
2. Biostatistics & Computer applications by GN Rao and NK Tiwari
3. Sokal, R.R. and Rohlf, F.J. 1987. An Introduction to Biostatistics. W.H. Freeman and Company.
4. Bailey, N.T.J. 1981. Statistical Methods in Biology. English University Press.
5. Mitchell, K. and Glover, T. 2001. Introduction to Biostatistics. McGraw Hill, Publishing Co.
6. A Textbook of Research Methodologies and Biostatistics for Pharmacy Students, KPR Chowdary, Pharmamed Press.



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**JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD**  
**M.Pharm II Year I Sem (Pharmaceutics/Pharmaceutical Technology)**  
**SCALE UP AND TECHNOLOGY TRANSFER (Professional Elective - V)**

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

**Course Outcomes:** On completion of this course it is expected that students will be able to;

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

**UNIT I**

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

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

**UNIT II**

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

**UNIT III**

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

**UNIT IV**

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

**UNIT V**

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

**REFERENCE BOOKS:**

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



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**JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD**  
**M.Pharm II Year I Sem (Pharmaceutics/Pharmaceutical Technology)**  
**PRODUCTION AREA DESIGN & PACKAGING DEVELOPMENT**  
**(Professional Elective - V)**

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

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

**UNIT I**

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

**UNIT II**

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

**UNIT III**

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

**UNIT IV**

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

**UNIT V**

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

**REFERENCE BOOKS:**

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



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**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



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**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.




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**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.



  
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**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.



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**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



  
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**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.



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**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.



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**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. 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 of 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).



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**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.

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

**UNIT-IV:**

Asan and Pranayam

**UNIT-V:**

- Various yog poses and their benefits for mind & body
- 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



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**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.



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**JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD**  
**M.PHARMACY (PHARMACEUTICAL ANALYSIS)**  
**R22 COURSE STRUCTURE AND SYLLABUS**  
**Effective from Academic Year 2022-23 Admitted Batch**

**I YEAR I Semester**

Course Code	Course Title	L	T	P	Credits
Professional Core-I	Modern Pharmaceutical Analytical Techniques	3	1	0	4
Professional Core-II	Pharmaceutical Food Analysis	3	1	0	4
Professional Elective-I	1. Advanced Pharmaceutical Analysis	3	1	0	4
	2. Drug Regulatory Affairs				
	3. Phytochemistry				
Professional Elective-II	1. Pharmaceutical Validation	3	1	0	4
	2. Cosmetics and Cosmeceuticals				
	3. Stability of Drugs and Dosage forms				
	Research Methodology & IPR	2	0	0	2
Laboratory-I	Modern Pharmaceutical Analytical Techniques lab	0	0	6	3
Laboratory-II	Pharmaceutical food Analysis Lab	0	0	6	3
Audit - II	Audit course- I	2	0	0	0
	Seminar & Assignment	0	0	4	2
	<b>TOTAL</b>	<b>16</b>	<b>4</b>	<b>16</b>	<b>26</b>

**I YEAR II Semester**

Course Code	Course Title	L	T	P	Credits
Professional Core-III	Advanced Instrumental Analysis - I	3	1	0	4
Professional Core-IV	Pharmaceutical Quality Control & Quality Assurance	3	1	0	4
Professional Elective-III	1. Modern Bio-analytical Techniques	3	1	0	4
	2. Herbal Cosmetics				
	3. Pharmacoepidemiology & Pharmacoeconomics				
Professional Elective-IV	1. Advanced Instrumental Analysis - II	3	1	0	4
	2. Nutraceuticals				
	3. Clinical Research and Pharmacovigilance				
Laboratory- III	Advanced Instrumental Analysis I Lab	0	0	6	3
Laboratory- IV	Pharmaceutical Quality Control & Quality Assurance Lab	0	0	6	3
	Mini project	2	0	0	2
Audit - II	Audit Course - II	2	0	0	0
	Seminar & Assignment	0	0	4	2
	<b>Total</b>	<b>16</b>	<b>4</b>	<b>16</b>	<b>26</b>

**II YEAR I Semester**

Course Code	Course Title	L	T	P	Credits
Professional Elective-V	1. Biostatistics	3	1	0	4
	2. Scale up and Technology Transfer				
	3. Production Area Design and Packaging Development				
Open Elective	Open Elective	3	1	0	4
Dissertation	Comprehensive Viva Voce	0	0	8	4
	Dissertation Work Review - II	0	0	24	12
	<b>Total</b>	<b>6</b>	<b>2</b>	<b>32</b>	<b>24</b>



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## II YEAR II SEMESTER

Course Code	Course Title	L	T	P	Credits
Dissertation	Dissertation Work Review - III	0	0	24	12
Dissertation	Dissertation Viva-Voce	0	0	20	10
	<b>Total</b>	<b>0</b>	<b>0</b>	<b>44</b>	<b>22</b>

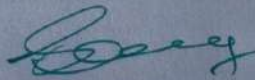
\*For Dissertation Work Review - I, Please refer R22 Academic Regulations.

**Audit Courses I&II:**

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



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**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

**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.



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**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



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

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

**UNIT III**

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

**UNIT IV**

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

**UNIT V**

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

**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

**REFERENCES:**

1. Remington's Pharmaceutical Sciences by Alfonso and Gennaro
2. Food Chemistry and Nutrition: A Comprehensive Treatise, Sumathi S, Pharmamed Press.
3. David Pearson, The Chemical Analysis of Foods, 7<sup>th</sup> edn, Churchill Livingstone, Edinburgh.
4. Nielsen S. Introduction to chemical analysis of foods. Jones & Bartlett Publishers, Boston, 1974
5. Indian Pharmacopoeia 2012



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**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.



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**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.
7. Fundamentals of Analytical Chemistry, DK Sarkar, Pharmamed Press

**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. Jomals (Indian Drugs, IJPS etc.)



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**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



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- 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



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**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 phytoconstituents 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.

**REFERENCES:**

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



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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. Pharmacognosy and Phytochemistry: A Comprehensive Approach, S L Deore, Pharmamed Press
14. Medicinal chemistry and drug discovery by Burger's
15. Foye's Principles of medicinal chemistry.
16. Pharmacognosy and phytochemistry by Biren seth
17. Herbal Perfumes and cosmetics by Panda
18. Herbal Drug Technology by SS Agarwal
19. Pharmacognosy and Phytochemistry by VD Rangari.
20. Textbook of Pharmacognosy by G. E. Trease, W. C. Evans, ELBS





**JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD**  
**M.Pharm I Year I Sem (Pharmaceutical Analysis)**  
**PHARMACEUTICAL VALIDATION (Professional Elective - III)**

**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. Pharmaceutical Facilities: Design, Layouts and Validation, Potdar, Pharmamed Press

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



  
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**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 syndet bars. **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.



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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. Cosmeceuticals by Y Madhusudan Rao, Pharmamed Press
6. Cosmetic and Toiletries recent suppliers' catalogue.
7. CTFA directory.



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**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**

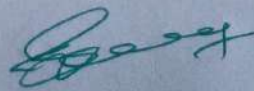
Methods of analysis to determine the quality of cosmetics in the finished forms such as Hair care products, Skin care products, Baby care products, Dental products, Personal hygiene products, Colour cosmetics, Ethnic products, Colour makeup preparation, Lipsticks, Hair setting lotions and Eye shadows.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



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**REFERENCES:**

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



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**JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD**  
**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 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"



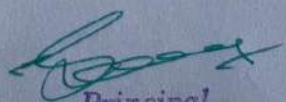
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2. Wayne Goddard and Stuart Melville, "Research Methodology: An Introduction".
3. Pharmaceutical Research Methodology and Biostatistics, B Subba Rao, Pharmamed Press.
4. Intellectual Property Rights in Pharmaceutical Industry, B Subba Rao, Pharmamed Press.

**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



  
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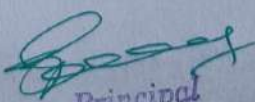
**JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD**  
**M.Pharm I Year I Sem (Pharmaceutical Analysis)**  
**MODERN PHARMACEUTICAL ANALYTICAL TECHNIQUES LAB (Laboratory – I)**

**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



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**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



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**JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD**  
**M.Pharm I Year II Sem (Pharmaceutical Analysis)**  
**ADVANCED INSTRUMENTAL ANALYSIS – I (Professional Core - III)**

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

**Course Outcome:** By the completion of topics the students will come out with the thorough knowledge of various spectral aspects of X-Ray, IR, SEM, ORD etc which help them in further projects works and also industrial opportunities.

**UNIT I**

**X-Ray diffraction methods:** Origin of X-rays, basic aspects of crystals, X-ray crystallography, miller indices, rotating crystal techniques, single crystal diffraction, powder diffraction, structural elucidation and applications.

**UNIT II**

- a. **Biochromatography:** Size exclusion chromatography, ion exchange chromatography, ion pair chromatography, affinity chromatography general principles, stationary phases and mobile phases.
- b. **Super critical fluid chromatography:** Principles, instrumentation, pharmaceutical applications.

**UNIT III**

**Capillary Electrophoresis:** Overview of CE in pharmaceutical analysis, basic configuration, CE characteristics, principles of CE, methods and modes of CE. General considerations and method development in CE,

**UNIT IV**

- a. **DSC:** Principle, thermal transitions, instrumentation (Heat flux and power- compensation designs), Modulated DSC, Hyper DSC, experimental parameters (sample preparation, experimental conditions, calibration, heating and cooling rates, resolution, Sources of errors) and their influence, advantages and disadvantages, pharmaceutical applications.
- b. **DTA:** Principle, instrumentation, advantage and disadvantage, pharmaceutical application, derivative differential thermal analysis (DDTA).
- c. **TGA:** Principle, instrumentation, factors affecting results, advantages and disadvantages, pharmaceutical application.

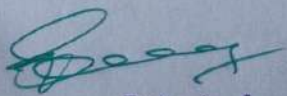
**UNIT V**

**Scanning electron microscope (SEM):** Principles, Instrumentation and applications.  
Optical Rotatory Dispersion (ORD), Circular Dichroism, Cotton effect, Octane rule and applications.

**REFERENCES:**

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



  
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**JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD**  
**M.Pharm I Year II Sem (Pharmaceutical Analysis)**  
**PHARMACEUTICAL QUALITY CONTROL AND QUALITY ASSURANCE**  
**(Professional Core – IV)**

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

**UNIT I**

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

**UNIT II**

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

**UNIT III**

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

**UNIT IV**

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

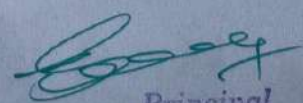
**UNIT V****Manufacture and controls on dosage forms**

- a. Manufacturing documents, Master Formula, Batch Formula, Records, Standard Operating Procedures,
- b. In process quality control on various dosage forms sterile and biological products, standard operating procedures for various operations like cleaning, filling, drying, compression, coating, disinfection, sterilization, membrane filtration etc.

**TEXT BOOKS:**

1. The International Pharmacopoeia Vol 1,2,3,4, 3<sup>rd</sup> edition General Methods of Analysis Quality Specifications for Pharmaceutical Substances, Excipients, Dosage Forms.
2. Quality Assurance of Pharmaceuticals. A Compendium of Guidelines and Related Material Vol. 1 and Vol. 2, WHO 2007)
3. GMP by Mehra



  
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4. Pharmaceutical Process Validation by Berry and Nash
5. How to Practice GMP's – P.P. Sharma

**REFERENCES:**

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



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**JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD**  
**M.Pharm I Year II Sem (Pharmaceutical Analysis)**  
**MODERN BIO-ANALYTICAL TECHNIQUES (Professional Core - IV)**

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

**Course Outcomes:** Upon completion of the course, the student shall be able to understand

- Extraction of drugs from biological samples
- Separation of drugs from biological samples using different techniques
- Guidelines for BA/BE studies

#### UNIT I

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

#### UNIT II

**Biopharmaceutical Consideration:** Introduction, Biopharmaceutical Factors Affecting Drug Bioavailability, In Vitro: Dissolution and Drug Release Testing, Alternative Methods of Dissolution Testing Transport models, Biopharmaceutics Classification System. Solubility: Experimental methods. Permeability: In-vitro, in-situ and In-vivo methods.

#### UNIT III

**Bioanalysis and bioanalytical method validation:**

- a. Types of body fluids, requirement of analysis, matrix effects, non-biological analytical samples.
- b. Bioanalytical method validation: USFDA and EMEA guidelines. Acceptance criteria in comparison to non-biological samples.

#### UNIT IV

**Pre-Formulation:** A consideration of following characteristics of medicinal agents in their dosage form:

**Physical characteristics-**Particle size, polymorphism, crystal form, solubility, Interfacial tension, Salt formation, wetting of solids, flow characteristics, compressibility and Partition coefficient.

**Chemical Characteristics-Degradation:** Hydrolytic, oxidative, reductive and photolytic, Drug – Excipient compatibility studies.

#### UNIT V

- a. **Automation and computer-aided analysis, LIMS:** The concept of auto samplers and high throughput analysis, computer-controlled instrumentation and networked laboratory. Peculiarities of laboratory information management systems (LIMS).
- b. **Drug Product Performance, In Vivo:** Purpose of Bioavailability Studies, Bioavailability and Bioequivalence Studies.

#### REFERENCES:

1. Analysis of drugs in Biological fluids - Joseph Chamberlain, 2nd Edition.CRC Press, New York. 1995.
2. Principles of Instrumental Analysis - Douglas A Skoog, F. James Holler, Timothy A. Nieman, 5th edition, Eastern press, Bangalore, 1998.
3. Pharmaceutical Analysis - Higuchi, Brochman and Hassen, 2nd Edition, Wiley – Interscience Publications, 1961.



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4. Pharmaceutical Analysis- Modern methods – Part B - J W Munson, Volume 11, Marcel Dekker Series
5. Practical HPLC method Development – Snyder, Kirkland, Glaich, 2<sup>nd</sup> Edition, John Wiley & Sons, New Jerco. USA.
6. Chromatographic Analysis of Pharmaceuticals – John A Adamovics, 2<sup>nd</sup> Edition, Marcel Dekker, New York, USA, 1997.
7. Chromatographic methods in clinical chemistry & Toxicology – Roger L Bertholf, Ruth E Winecker, John Wiley & Sons, New Jersey, USA, 2007.
8. Good Laboratory Practice Regulations, 2nd Edition, Sandy Weinberg Vol.69, Marcel Dekker Series, 1995.
9. Good laboratory Practice Regulations – Allen F. Hirsch, Volume 38, Marcel Dekker Series, 1989.
10. ICH, USFDA & CDSCO Guidelines
11. Palmer



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**JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD**  
**M.Pharm I Year II Sem (Pharmaceutical Analysis)**  
**HERBAL COSMETICS (Professional Elective - III)**

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

**Course Outcome:** Students will learn about the raw materials used in herbal cosmetics and get exposed tovarious 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 V**

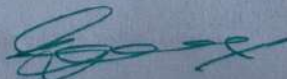
**Herbs in cosmetics:**

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



  
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**JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD**  
**M.Pharm. I Year II Sem (Pharmaceutical Analysis)**  
**PHARMACOEPIDEMOLOGY & PHARMACOECONOMICS (Professional Elective - III)**

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

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

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

#### UNIT I

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

#### UNIT II

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

#### UNIT III

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

#### UNIT IV

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

#### UNIT V

**Definition, Steps involved, Applications, Advantages and disadvantages of the following:**



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

**REFERENCES:**

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



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**JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD**  
**M.Pharm Sem – II (PHARMACEUTICAL ANALYSIS)**  
**ADVANCED INSTRUMENTAL ANALYSIS – II (Professional Elective - IV)**

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

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

**UNIT I**

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

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

**UNIT II**

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

b. **Conductometry**– Introduction, Conductivity cell, Conductometric titrations, applications

**UNIT III**

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

**UNIT IV**

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

**UNIT V**

a. **Radio chemical methods including RIA:** Radio Active Isotopes, tagging of compounds, Labeled Reagents, Isotope dilution Analysis, Scintillation counter, RIA.

b. **ELISA:** Principle, types and application of ELISA

**REFERENCES:**

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



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**JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD**  
**M.Pharm I Year II Sem (Pharmaceutical Analysis)**  
**NUTRACEUTICALS (Professional Elective - IV)**

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

**Course Outcome:** Helps the student to understand the importance of Nutraceuticals in various common problems with the concept of free radicals

**UNIT I**

- a. Definitions of Functional foods, Nutraceuticals and Dietary supplements. Classification of Nutraceuticals, Health problems and diseases that can be prevented or cured by Nutraceuticals i.e. weight control, diabetes, cancer etc.
- b. Source, Name of marker compounds and their chemical nature, Medicinal uses and health benefits of following used as nutraceuticals/functional foods:  
Spirulina, Soya bean, Ginseng, Garlic, Broccoli, Gingko, Flaxseeds

**UNIT II**

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

- a. Carotenoids-  $\alpha$  and  $\beta$ -Carotene, Lycopene, Xanthophylls, lutein
- b. Sulfides: Diallylsulfides, Allyltrisulfide.
- c. Polyphenolics: Resveratrol
- d. Flavonoids- Rutin, Naringin, Quercetin, Anthocyanidins, catechins, Flavones
- e. Prebiotics / Probiotics.: Fructo oligosaccharides, Lacto bacillum
- f. Phytoestrogens, Isoflavones, daidzein, Geobustin, lignans
- g. Tocopherols

**UNIT III**

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

**UNIT IV**

- a. Free radicals in Diabetes mellitus, Inflammation, Ischemic reperfusion injury, Cancer, Atherosclerosis, Free radicals in brain metabolism and pathology, kidney damage, muscle damage. Free radicals involvement in other disorders. Free radicals theory of ageing.
- b. Antioxidants: Endogenous antioxidants – enzymatic and nonenzymatic antioxidant defence, Superoxide dismutase, catalase, Glutathione peroxidase, Glutathione Vitamin C, Vitamin E,  $\alpha$ -Lipoic acid, melatonin
- c. Synthetic antioxidants: Butylatedhydroxy Toluene, Butylatedhydroxy Anisole.

**UNIT V**

**Food Laws and Regulations;** FDA, FPO, MPO, AGMARK. HACCP and GMPs on Food Safety. Adulteration of foods.

**Regulations and Claims – Current Products:** Label Claims, Nutrient Content Claims, Health Claims, Dietary Supplements Claims

**REFERENCES:**

1. Dietetics by Sri Lakshmi

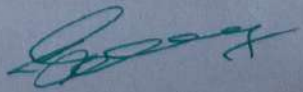


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2. Role of dietary fibres and nutraceuticals in preventing diseases by K. T Agusti and P. Faizal: BS Publication.
3. Advanced Nutritional Therapies by Cooper, K.A., (1996).
4. The Food Pharmacy by Jean Carper, Simon & Schuster, UK Ltd., (1988).
5.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



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**JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD**  
**M.Pharm I Year II Sem (Pharmaceutical Analysis)**  
**CLINICAL RESEARCH AND PHARMACOVIGILANCE (Professional Elective - IV)**

**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.




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Spontaneous reporting system and Reporting to regulatory authorities, Guidelines for ADRs reporting. Argus, ArisG Pharmacovigilance, VigiFlow, 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; May1996.230
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. A Textbook of Clinical Research and Pharmacovigilance by KPR Chowdary, Pharmamed Press
7. Handbook of clinical Research. Julia Lloyd and Ann Raven Ed. Churchill Livingstone.
8. Principles of Clinical Research edited by Giovanna di Ignazio, Di Giovanna and Haynes.
9. Textbook of Pharmacovigilance: Concept and Practice. G. P. Mohanta and P. K. Manna. 2016, Pharma Med Press.
10. A textbook of Clinical Pharmacy Practice: Essential Concepts and Skills. Second Edition, 2012, University Press



  
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JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD  
M.Pharm I Year II Sem (Pharmaceutical Analysis)  
ADVANCED INSTRUMENTAL ANALYSIS-I LAB (Laboratory -III)


**LIST OF EXPERIMENTS:**

1. Determination of chlorides and sulphates by Nephelo -Turbidimetry
2. Determination of compounds of sodium, potassium and calcium by Flame photometry.
3. Estimation of riboflavin/quinine sulphate by fluorimetry
4. Assay of official compounds by potentiometric titrations **(Any 2)**
5. Assay of official compounds by conductimetric titrations **(Any 2)**
6. Demonstration on ELISA
7. Quenching of fluorescence
8. Perform phosphate interference on absorption of calcium

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



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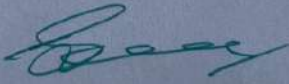


**JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD**  
**M.Pharm I Year II Sem (Pharmaceutical Analysis)**  
**PHARMACEUTICAL QUALITY CONTROL AND QUALITY ASSURANCE LAB**

**LIST OF EXPERIMENTS:**

1. QC tests for tablets (minimum 2 experiments)
2. QC tests for capsules (minimum 2 experiments)
3. QC tests for oral liquids monophasic (minimum 2 experiments)
4. QC tests for oral liquids biphasic (minimum 2 experiments)
5. Forced degradation studies of some drugs.
6. Interpretation of spectras by IR, NMR and MASS
7. Assay of drug formulations using UV-Spectrophotometer (Any four)
8. Demonstration of functional groups of the given samples by IR Spectrophotometer.
9. Physicochemical tests for water
10. Solubility studies of weakly acidic and weakly basic drugs.



  
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**JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD**  
**M.Pharm II Year I Sem (Pharmaceutical Analysis)**  
**BIostatISTICS (Professional Elective - V)**

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

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

**UNIT I**

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

**UNIT II**

**Measures of central tendency:** computation of means, median and mode from grouped and ungrouped data.

**Measure of dispersion:** computation of variance, standard deviation, standard error and their coefficients.

**UNIT III**

Measures of Correlation and Regression

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

**UNIT IV**

Experimental designing, planning of an experiment, replication and randomization.

**Analysis of Variance (ANOVA):** 1-way, 2- Way

**UNIT V**

**Hypothesis testing:** Student 't' test, Chi square test,

**Non- Parametric Tests:** Sign Test, Sign Rank Test, Wilcoxon Sign Rank Test

**REFERENCES:**

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



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**JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD**  
**M.Pharm II Year I Sem (Pharmaceutical Analysis)**  
**SCALE UP AND TECHNOLOGY TRANSFER (Professional Elective - V)**

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

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

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

**UNIT I**

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

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

**UNIT II**

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

**UNIT III**

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

**UNIT IV**

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

**UNIT V**

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

**REFERENCES:**

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



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**JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD**  
**M.Pharm II Year I Sem (Pharmaceutical Analysis)**  
**PRODUCTION AREA DESIGN & PACKAGING DEVELOPMENT (Professional Elective - V)**

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

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

**UNIT I**

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

**UNIT II**

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

**UNIT III**

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

**UNIT IV**

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

**UNIT V**

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

**REFERENCES:**

1. Lachman; Lieberman Herbert A.; Kanig, The theory and Practice of Industrial Pharmacy.
2. Gilbert Banker and Christopher Rhodes. Modern Pharmaceutics.
3. Aulton's Pharmaceutics: The design and Manufacture of Medicine
4. D. A. Dean, Roy Evans, Ian Hall. Pharmaceutical packaging technology. Tylor and Francis.
5. Edward J. Bauer, Pharmaceutical Packaging Handbook. Bausch and Lomb, Rochester
6. Pharmaceutical Facilities: Design, Layouts and Validation, Potdar, Pharmamed Press
7. Wilmer A. Jenkins, Kenton R. Osborn. Packaging drugs and pharmaceuticals.
8. Remington: The Science and Practice of Pharmacy. 8. Michael E. Aulton, Kevin Tylor
9. Pharmaceutical Packaging Technology, UK jain, Pharmamed Press



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**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,

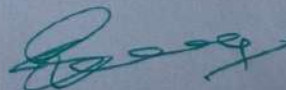
**UNIT-V:**

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



  
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**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 Spills 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.



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**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.



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**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.



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**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



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**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. Pachayat 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.



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**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.



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**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 in depth stage: quality assessment of included studies. How can teacher education (curriculum and practicum) and the school 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.



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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).



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**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



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**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 (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:

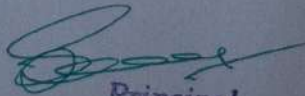
**UNIT-V:**

- 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 SwarupanandaAdvaita Ashram (Publication Department), Kolkata.
2. Bhartrihari's Three Satakam (Niti-sringar-vairagya) by P.Gopinath, Rashtriya Sanskrit Sansthanam, New Delhi.



  
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**JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD**  
**M.PHARMACY (PHARMACEUTICAL REGULATORY AFFAIRS)**  
**R22 COURSE STRUCTURE AND SYLLABUS**  
**Effective from Academic Year 2022-23 Admitted Batch**

**I YEAR I Semester**

Course Code	Course Title	L	T	P	Credits
Professional Core-I	Good Regulatory Practices	3	1	0	4
Professional Core-II	Drug Regulatory Affairs	3	1	0	4
Professional Elective-I	1. Intellectual Property Rights 2. Total Quality management 3. Pharmaceutical Validation	3	1	0	4
Professional Elective-II	1. Stability of Drugs and Dosage Forms 2. Pharmaceutical Formulation Technology 3. Documentation and Regulatory Writing	3	1	0	4
	Research methodology and IPR	2	0	0	2
Laboratory- I	Regulatory Practice and Documentation Lab	0	0	6	3
Laboratory- II	Drug Regulation and Registration Lab	0	0	6	3
Audit - I	Audit Course - I	2	0	0	0
	Seminar & Assignment	0	0	4	2
	<b>Total</b>	<b>16</b>	<b>4</b>	<b>16</b>	<b>26</b>

**I YEAR II Semester**

Course Code	Course Title	L	T	P	Credits
Professional Core-III	Regulatory aspects of herbals and biologicals	3	1	0	4
Professional Core-IV	Regulatory aspects of medical devices	3	1	0	4
Professional Elective-III	1. Regulatory aspects of Foods and Nutraceuticals 2. Pharmaceutical Quality Control and Quality Assurance 3. Nano Based Drug Delivery Systems	3	1	0	4
Professional Elective-IV	1. Clinical Research and Pharmacovigilance 2. Nutraceuticals 3. Advanced Drug Delivery Systems	3	1	0	4
Laboratory- III	Regulatory aspects of herbals and biologicals lab	0	0	6	3
Laboratory- IV	Regulatory aspects of medical devices lab	0	0	6	3
	Mini project	2	0	0	2
Audit - II	Audit Course - II	2	0	0	0
	Seminar & Assignment	0	0	4	2
	<b>Total</b>	<b>16</b>	<b>4</b>	<b>16</b>	<b>26</b>

**II YEAR I Semester**

Course Code	Course Title	L	T	P	Credits
Professional Elective-V	1. Biostatistics 2. Scale up and Technology Transfer 3. Production area, Design and Packaging Development	3	1	0	4
Open Elective	Open Elective	3	1	0	4
	Comprehensive Viva Voce	0	0	8	4
	Dissertation Work Review - II	0	0	24	12
	<b>Total</b>	<b>6</b>	<b>2</b>	<b>32</b>	<b>24</b>



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**II YEAR II Semester**

Course Code	Course Title	L	T	P	Credits
Dissertation	Dissertation Work Review - III	0	0	24	12
Dissertation	Dissertation Viva-Voce	0	0	20	10
	<b>Total</b>	<b>0</b>	<b>0</b>	<b>44</b>	<b>22</b>

\*For Dissertation Work Review - I, Please refer R22 Academic Regulations.

**Audit Courses I & II:**

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



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

**GOOD REGULATORY PRACTICE (Professional Core - I)**

**Course Objective:** This course is designed to impart fundamental knowledge on various Good Regulatory Practices viz., cGMP, GLP, GALP and GDP for Pharmaceuticals, Cosmetics, Food & Nutraceuticals, Medical devices, In-vitro Diagnostic Medical Devices (IVDs) and biological products and understand the rationale behind these requirements and will propose ways and means of complying with them.

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

- The key regulatory and compliance elements with respect to Good Manufacturing Practices, Good Laboratory Practices, Good Automated Laboratory Practices and Good Documentation Practices.
- Prepare and implement the check lists and SOPs for various Good Regulatory Practices.
- Implement Good Regulatory Practices in the Healthcare and related Industries.
- Prepare for the readiness and conduct of audits and inspections.

**UNIT I**

Current Good Manufacturing Practices: Introduction, US Cgmp Part 210 and Part 211.EC Principles of GMP (Directive 91/356/EEC) Article 6 to Article 14 and WHO cGMP guidelines GAMP-5; Medical device and IVDs Global Harmonization Task Force (GHTF) Guidance docs.

**UNIT II**

Good Laboratory Practices: Introduction, USFDA GLP Regulations (Subpart A to Subpart K), Controlling the GLP inspection process, Documentation, Audit, goals of Laboratory Quality Audit, Audit tools, Future of GLP regulations, relevant ISO and Quality Council of India (QCI) Standards

**UNIT III**

Good Automated Laboratory Practices: Introduction to GALP, Principles of GALP, GALP Requirements, SOPs of GALP, Training Documentation, 21 CFR Part 11, General check list of 21CFR Part 11, Software Evaluation checklist, relevant ISO and QCI Standards.

**UNIT IV**

Good Distribution Practices: Introduction to GDP, Legal GDP requirements put worldwide, Principles, Personnel, Documentation, Premises and Equipment, Deliveries to Customers, Returns, Self-Inspection, Provision of information, Stability testing principles, WHO GDP, USP GDP (Supply chain integrity), relevant CDSCO guidance and ISO standards

**UNIT V**

Quality management systems: Concept of Quality, Total Quality Management, Quality by design, Six Sigma concept, Out of Specifications (OOS), Change control. Validation: Types of Validation, Types of Qualification, Validation master plan (VMP), Analytical Method Validation. Validation of utilities, [Compressed air, steam, water systems, Heat Ventilation and Air conditioning (HVAC)]and Cleaning Validation. The International Conference on Harmonization (ICH) process, ICH guidelines to establish quality, safety and efficacy of drug substances and products, ISO 13485, Sch MIII and other relevant CDSCO regulatory guidance documents.



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**TEXT AND REFERENCE BOOKS:**

1. Good Laboratory Practice Regulations, by Sandy Weinberg, Fourth Edition Drugs and the Pharmaceutical Sciences, Vol.168
2. Good Pharmaceutical Manufacturing practice, Rational and compliance by John Sharp, CRC Press
3. Establishing a cGMP Laboratory Audit System, A practical Guide by David M. Bleisner, Wiley Publication.
4. How to practice GLP by PP Sharma, Vandana Publications.
5. Laboratory Auditing for Quality and Regulatory compliance bu Donald C. Singer, Drugs and the Pharmaceutical Sciences, Vol.150.
6. Drugs & Cosmetics Act, Rules & Amendments



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**JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD**  
**M.Pharm I Year I Sem (Pharmaceutical Regulatory Affairs)**  
**DRUG REGULATORY AFFAIRS (Professional Core - II)**

**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 Licenses – Test Lic., Import lic., for testing of drugs and API's, Manufacturing Contract and Loan license 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



  
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- b. Product Filing
- c. Responding Regulatory Deficiencies
- d. 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 JThimmasetty, Vallabh Prakashan Delhi – 2013



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

**INTELLECTUAL PROPERTY RIGHTS (Professional Elective - I)**

**Course Objective:** Various types of Intellectual Property Rights Patentable Subject History of Indian Patent Protection, Patent filing procedure in India, Opposition- pre-grant opposition and post-grant opposition, Patent filing procedure under PCT, advantages, patent search and literature and Salient features of Indian Patents are discussed in detail.

**Course Outcome:** The clear information about the patent laws, intellectual property rights and drug regulation in India and abroad is gained by the students.

**UNIT - I**

Introduction, Types of Intellectual Property Rights (Patents, Trademarks, Copyrights, Geographical Indications Industrial Designs and Trade secrets), Patentable Subject Matter (Novelty, Non-Obviousness, Utility, enablement and Best mode),

**UNIT - II**

- a. History of Indian Patent Protection, Rationale behind Patent System, Objectives and Advantages of Patent System, and future challenges. Indian Patents Act 1970, Definitions and Key Terminology, Types of Patent applications, Inventions not patentable (section 3 and 4).
- b. Patent filing procedure in India (Patent Prosecution), Specifications (Provisional and Complete), Claims- types of claims and legal importance of claims, Grant of patent, Rights of Patentee and co-owners
- c. Opposition - pre-grant opposition and post-grant opposition, Anticipation, Infringement, Compulsory Licensing, revocation of patents, and power of Controller.
- d. Patent filing procedure under PCT, advantages, patent search and literature

**UNIT - III**

- a. Salient features of Indian Patents (Amendments) Act 1999, 2002 and 2005. US and European Patent System,
- b. Background, Salient Features and Impact of International Treaties / Conventions like
  1. Paris Convention, Berne convention
  2. World Trade Organization (WTO)
  3. World Intellectual Property Organization (WIPO)
  4. Trade Related Aspects of Intellectual Property Rights (TRIPS)
  5. Patent Co-operation Treaty (PCT), Madrid Protocol

**UNIT - IV**

- a. PCT Application procedure and review procedure
- b. National phase application procedure for US & EU
- c. Patent prosecution procedure in US and EU
- d. WIPO and its role in IPR
- e. Hatch-Waxman provision for IPR

**UNIT - V**

- a. Patent in validation process in India, US and Europe
- b. IPR related to copyright, trade mark, trade secret and geographical indication.
- c. Patent application writing
- d. Claim construction and claims.



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**RECOMMENDED BOOKS:**

1. Research Methodology concepts and cases by Depak Chawla, Neena Sondhi
2. Draft manual of Patent Practice and Procedure -2008, The Patent Office, India
3. Intellectual Property Rights in Pharmaceutical Industry, B Subba Rao, Pharmamed Press
4. Fundamentals of Patents and Patenting, Vivekananda Mandal, Pharmamed Press
5. Manual of Patent Office Practice and Procedure -2010
6. Original Laws Published by Govt. of India
7. Protection of Industrial Property rights by P. Das and Gokul Das
8. Law and Drugs, Law Publications by S.N. Katju
9. Laws of drugs in India, Hussain
10. New drug approval process, 5<sup>th</sup> edition, by Guarino
11. Commercial Manual on Drugs and Cosmetics 2004, 2<sup>nd</sup> edition
12. Drugs and Cosmetics act by Vijay Malik
13. Good Manufacturing Practices for Pharmaceuticals, S.H. Wiling, Vol. 78, Marcel Decker.
14. fda.org, wipo.int, patentlawlinks.com, hc-sc.gc.ca, ich.org, cder.org
15. Current good manufacturing practices for pharmaceuticals by Manohar A. Potdar
16. Pharmaceutical Regulatory affairs –selected topics. CVS subhramanyam and J Thimma settee. Delhi, Vallabh Prakashan, 2012



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



  
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3. A Guide to Total Quality Management by Kaushik Maltra 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



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**JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD**  
**M.Pharm I Year I Sem (Pharmaceutical Regulatory Affairs)**  
**PHARMACEUTICAL VALIDATION (Professional Elective - I)**

**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

#### REFERENCE BOOKS:

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, 2<sup>nd</sup>

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- 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, Interpham 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



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

**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.



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**REFERENCE BOOKS:**

1. Comprehensive Pharmacy Review 5th Edition by Leon Shargel, Alan H. Mutnick, Paul F. Souney, Larry N. Sawson – 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.



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

**PHARMACEUTICAL FORMULATION TECHNOLOGY (Professional Elective - II)**

**Course Objective:** Students will know the pre-formulation 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 pre-formulation 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**

**Pre-formulation:** Goals of pre-formulation, solid state manipulation and characterization. pH dependent solubility of drug, equilibrium solubility, intrinsic dissolution of drug, particle size distribution.

**Flow of Powders:** Physical properties and importance. Angle of repose, Carr's index, compressibility, bulk density, tapped density.

**UNIT II**

Excipients used in various dosage forms like tablets, capsules, emulsions, suspensions, semisolids and sterile products. Knowledge of packing materials. Drug- excipient compatibility- Drug stability, factors affecting stability, stabilization methods.

**UNIT III**

**Tablets:** Types of tablets, granulation methods, highlighting operations such as mixing, drying, milling, blending, lubrication and compression.

**Tablet coating:** Types of coating, steps involved in coating process- pan coating and fluid bed coating and problems associated with coating.

**Hard Gelatin Capsules:** General principles and steps involved in the production of drug loaded hard gelatin capsules, filling operation, filling of powders, granules and pellets.

**UNIT IV**

**Dissolution:** Principles of dissolution, factors influencing dissolution, official methods and apparatus. Dissolution of immediate release, controlled release and delayed release products.

**UNIT V**

**Stability testing:** Chemical degradation and preventive measures. Various stability testing conditions and use of stabilizers in packing

**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. Pharmaceutical Dosage Form: Basics and Beyond, Kamlesh J. Wadher, Pharmamed Press
6. Modern Pharmaceutics by Gilbert S. Banker and Christopher T. Rhodes.
7. Pharmaceutical statistics by Bolton Industrial Pharmacy - Selected Topics, CVS




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Subramanyam and J Thimmasetty, Vallabha Prakashan Delhi - 2013

**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.



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

**DOCUMENTATION AND REGULATORY WRITING (Professional Elective - II)**

**Course Objective:** This course is designed to impart fundamental knowledge on documentation and general principles involved in regulatory writing and submission to agencies.

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

- Know the various documents pertaining to drugs in pharmaceutical industry
- Understand the basics of regulatory compilation
- Create and assemble the regulation submission as per the requirements of agencies
- Follow up the submissions and post approval document requirements

**UNIT I**

**Documentation in pharmaceutical industry:** Exploratory Product Development Brief (EPDB) for Drug substance and Drug product, Product Development Plan (PDP), Product Development Report (PDR), Master Formula Record, Batch Manufacturing Record and its calculations, Batch Reconciliation, Batch Packaging Records, Print pack specifications, Distribution records, Certificate of Analysis (CoA), Site Master File and Drug Master Files (DMF).

**UNIT II**

**Dossier preparation and submission:** Introduction and overview of dossiers, contents and organization of dossier, binders and sections, compilation and review of dossier. Paper submissions, overview and modules of CTD, electronic CTD submissions; Electronic submission: Planning electronic submission, requirements for submission, regulatory bindings and requirements, Tool and Technologies, electronic dossier submission process and validating the submission, Electronic Submission Gateway (ESG). None CTD electronic submissions (NeeS), Asian CTD formats (ACTD) submission. Organizing, process and validation of submission. Submission in Sugam system of CDSCO.

**UNIT III**

**Audits:** Introduction, Definition, Summary, Types of audits, GMP compliance audit, Audit policy, Internal and External Audits, Second Party Audits, External third-party audits, Auditing strategies, Preparation and conducting audit, Auditing strategies, audit analysis, audit report, audit follow up. Auditing/inspection of manufacturing facilities by regulatory agencies. Timelines for audits/inspection. GHTF study group 4 guidance document. ISO 13485.

**UNIT IV**

**Inspections:** Pre-approval inspections, Inspection of pharmaceutical manufacturers, Inspection of drug distribution channels, Quality systems requirements for national good manufacturing practice inspectorates, inspection report, model certificate of good manufacturing practices, Root cause analysis, Corrective and Preventive action (CAPA).

**UNIT - V**

**Product life cycle management:** Prior Approval Supplement (PAS), Post Approval Changes [SUPAC], Changes Being Affected in 30 Days (CBE-30), Annual Report, Post marketing Reporting Requirements, Post approval Labeling Changes, Lifecycle Management, FDA Inspection and Enforcement, Establishment Inspection Report (EIR), Warning Letters, Recalls, Seizure and Injunctions. ISO Risk Management Standard

**TEXT AND REFERENCE BOOKS:**

1. Compliance auditing for Pharmaceutical Manufacturers. Karen Ginsbury and Gil Bismuth,





- Interpharm/CRC, Boca Raton, London New York, Washington D.C.
2. Pharmaceutical Manufacturing Handbook, Regulations and Quality by Shayne Cox Gad. Wiley- Interscience, A John Wiley and sons, Inc., Publications.
  3. Handbook of microbiological Quality control. Rosamund M. Baird, Norman A. Hodges, Stephen P. Denyar. CRC Press. 2000.
  4. Academic Writing, Ajay Semalty, Pharmamed Press
  5. Laboratory auditing for quality and regulatory compliance. Donald C. Singer, Raluca-Ioana Stefan, Jacobus F. Van Staden. Taylor and Francis (2005).
  6. Implementing Juran's Road Map for Quality Leadership: Benchmarks and Results, By Al Endres, Wiley, 2000
  7. Understanding, Managing and Implementing Quality: Frameworks, Techniques and Cases, By Jiju Antony; David Preece, Routledge, 2002
  8. Organizing for High Performance: Employee Involvement, TQM, Reengineering, and Knowledge Management in the Fortune 1000: The CEO Report By Edward E. Lawler; Susan Albers Mohrman; George Benson, Jossey-Bass, 2001
  9. Corporate Culture and the Quality Organization By James W. Fairfield- Sonn, Quorum Books, 2001
  10. The Quality Management Sourcebook: An International Guide to Materials and Resources By Christine Avery; Diane Zabel, Routledge, 1997
  11. The Quality Toolbox, Second Edition, Nancy R. Tague, ASQ Publications
  12. Juran's Quality Handbook, Sixth Edition, Joseph M. Juran and Joseph A. De Feo, ASQ Publications
  13. Root Cause Analysis, The Core of Problem Solving and Corrective Action, Duke Okes, 2009, ASQ Publications
  14. International Medical Device Regulators Forum (IMDRF) Medical Device Single Audit Program (MDSAP)



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

**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"
3. Pharmaceutical Research Methodology and BioStatistics, B Subba Rao, Pharmamed Press
4. Intellectual Property Rights in Pharmaceutical Industry, B Subba Rao, Pharmamed Press

**REFERENCE BOOKS:**

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



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

**REGULATORY PRACTICE AND DOCUMENTATION LAB (Laboratory - I)**

**List of Experiments:**

1. Case studies (4 Nos.) of each of Good Pharmaceutical Practices.
2. Documentation for in process and finished products Quality control tests for Solid, liquid, Semisolid and Sterile preparations.
3. Preparation of SOPs, Analytical reports (Stability and validation)
4. Protocol preparation for documentation of various types of records (BMR, MFR, DR) Labeling comparison between brand & generics.
5. Preparation of regulatory dossier as per Indian CTD format and submission in SUGAM
6. Case studies on response with scientific rationale to USFDA Warning Letter
7. Preparation of submission checklist of IMPD for EU submission.
8. Comparison study of marketing authorization procedures in EU.



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

**DRUG REGULATION & REGISTRATION LAB (Laboratory - II)**

**List of Experiments:**

1. Case studies on Change Management/ Change control. Deviations and Corrective & Preventive Actions (CAPA)
2. Import of drugs for research and developmental activities
3. GMP Audit Requirements as per CDSCO
4. Preparation of checklist for registration of IND as per ICH CTD format.
5. Preparation of checklist for registration of NDA as per ICH CTD format.
6. Preparation of checklist for registration of ANDA as per ICH CTD format.
7. Comparative study of DMF system in US, EU and Japan
8. Preparation of regulatory submission using eCTD software
9. Documentation of raw materials analysis as per official monographs
10. Preparation of audit checklist for various agencies
11. Preparation of submission to FDA using eCTD software
12. Preparation of submission to EMA using eCTD software
13. Preparation of submission to MHRA using eCTD software



  
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**JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD**  
**M.Pharm I Year II Sem (Pharmaceutical Regulatory Affairs)**

**REGULATORY ASPECTS OF HERBALS AND BIOLOGICALS (Professional Core - III)**

**Course Objective:** This course is designed to impart fundamental knowledge on Regulatory Requirements, Licensing and Registration, Regulation on Labelling of Biologics in India, USA and Europe It prepares the students to learn in detail on Regulatory Requirements for biologics, Vaccines and Blood Products

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

- Know the regulatory Requirements for Biologics and Vaccines
- Understand the regulation for newly developed biologics and biosimilars
- Know the pre-clinical and clinical development considerations of biologics
- Understand the Regulatory Requirements of Blood and/or Its Components Including Blood Products and label requirements

**UNIT - I**

India: Introduction, Applicable Regulations and Guidelines, Principles for Development of Similar Biologics, Data Requirements for Preclinical Studies, Data Requirements for Clinical Trial Application, Data Requirements for Market Authorization Application, Post-Market Data for Similar Biologics, Pharmacovigilance. GMP and GDP.

**UNIT - II**

USA: Introduction to Biologics; biologics, biological and biosimilars, different biological products, difference between generic drug and biosimilars, laws, regulations and guidance on biologics/ biosimilars, development and approval of biologics and biosimilars (IND, PMA, BLA, NDA, 510(k), pre-clinical and clinical development considerations, advertising, labelling and packing of biologics.

**UNIT - III**

European Union: Introduction to Biologics; directives, scientific guidelines and guidance related to biologics in EU, comparability/ bio similarity assessment, Plasma master file, TSE/ BSE evaluation, development and regulatory approval of biologics (Investigational medicinal products and biosimilars), pre-clinical and clinical development considerations; stability, safety, advertising, labelling and packing of biologics in EU.

**UNIT - IV**

Vaccine regulations in India, US and European Union: Clinical evaluation, Marketing authorization, Registration or licensing, Quality assessment, Pharmacovigilance, Additional requirements Blood and Blood Products Regulations in India, US and European Union: Regulatory Requirements of Blood and/or Its Components Including Blood Products, Label Requirements, ISBT (International Society of Blood Transfusion) and IHN (International Haemovigilance Network)

**UNIT - V**

Herbal Products: Quality, safety and legislation for herbal products in India, USA and European Union.

**TEXT AND REFERENCE BOOKS:**

1. FDA Regulatory Affairs: A Guide for Prescription Drugs, Medical Devices, and Biologics, Douglas J. Pisano, David S. Mantus; Informa, 2008
2. Biological Drug Products: Development and Strategies; Wei Wang, Manmohan Singh; wiley, 2013



3. Development of Vaccines: From Discovery to Clinical Testing; Manmohan Singh, Indresh K. Srivastava; Wiley, 2011
4. [www.who.int/biologicals/en](http://www.who.int/biologicals/en)
5. [www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/](http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/)
6. [www.ihn-org.com](http://www.ihn-org.com)
7. [www.isbtweb.org](http://www.isbtweb.org)
8. Guidelines on Similar Biologics: Regulatory Requirements for Marketing Authorization in India
9. [www.cdsc.nic.in](http://www.cdsc.nic.in)
10. [www.ema.europa.eu](http://www.ema.europa.eu) › scientific guidelines › Biologicals
11. [www.fda.gov/biologicsbloodVaccines/GuidanceComplianceRegulatoryInformation](http://www.fda.gov/biologicsbloodVaccines/GuidanceComplianceRegulatoryInformation) (Biologics)



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**JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD**  
**M.Pharm I Year II Sem (Pharmaceutical Regulatory Affairs)**

**REGULATORY ASPECTS OF MEDICAL DEVICES (Professional Core - IV)**

**Course Objective:** This course is designed to impart the fundamental knowledge on the medical devices and in vitro diagnostics, basis of classification and product life cycle of medical devices, regulatory requirements for approval of medical devices in regulated countries like US, EU and Asian countries along with WHO regulations. It prepares the students to learn in detail on the harmonization initiatives, quality and ethical considerations, regulatory and documentation requirements for marketing medical devices and IVDs in regulated countries.

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

- Basics of medical devices and IVDs, process of development, ethical and quality considerations.
- Harmonization initiatives for approval and marketing of medical devices and IVDs.
- Regulatory approval process for medical devices and IVDs in India, US, Canada, EU, Japan and ASEAN.
- Clinical evaluation and investigation of medical devices and IVDs.

**UNIT - I**

**Medical Devices:** Introduction, Definition, Risk based classification and Essential Principles of Medical Devices and IVDs. Differentiating medical devices IVDs and Combination Products from that of pharmaceuticals, History of Medical Device Regulation, Product Lifecycle of Medical Devices and Classification of Medical Devices.

**IMDRF/GHTF:** Introduction, Organizational Structure, Purpose and Functions, Regulatory Guidelines, Working Groups, Summary Technical Document (STED), Global Medical Device Nomenclature (GMDN).

**UNIT - II**

**Ethics:** Clinical Investigation of Medical Devices, Clinical Investigation Plan for Medical Devices, Good Clinical Practice for Clinical Investigation of medical devices (ISO 14155:2011) Quality: Quality System Regulations of Medical Devices: ISO 13485, Quality Risk Management of Medical Devices: ISO 14971, Validation and Verification of Medical device, Adverse Event Reporting of Medical device

**UNIT - III**

**USA:** Introduction, Classification, Regulatory approval process for Medical Devices (510k) Premarket Notification, Pre-Market Approval (PMA), Investigational Device Exemption (IDE) and In vitro Diagnostics, Quality System Requirements 21 CFR Part 820, Labeling requirements 21 CFR Part 801, Post marketing surveillance of MD and Unique Device Identification (UDI). Basics of In vitro diagnostics, classification and approval process.


**UNIT - IV**

**European Union:** Introduction, Classification, Regulatory approval process for Medical Devices (Medical Device Directive, Active Implantable Medical Device Directive) and In vitro Diagnostics (In Vitro Diagnostics Directive), CE certification process. Basics of In vitro diagnostics, classification and approval process.

**UNIT - V**

**ASIAN, China & Japan:** Medical Devices and IVDs, Regulatory registration procedures, Quality System requirements and clinical evaluation and investigation. IMDRF study groups and guidance documents.



  
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**REFERENCE BOOKS:**

1. FDA regulatory affairs: a guide for prescription drugs, medical devices, and biologics by Douglas J. Pisano, David Mantis.
2. Medical Device Development: A Regulatory Overview by Jonathan S. Kahan
3. Medical Product Regulatory Affairs: Pharmaceuticals, Diagnostics, Medical Devices by John J. Tobin and Gary Walsh
4. Compliance Handbook for Pharmaceuticals, Medical Devices and Biologics by Carmen Medina



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**JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD**  
**M.Pharm I Year II Sem (Pharmaceutical Regulatory Affairs)**

**REGULATORY ASPECTS OF FOOD AND NUTRACEUTICALS (Professional Elective – III)**

**Course Objective:** This course is designed to impart the fundamental knowledge on Regulatory Requirements, Registration and Labeling Regulations of Nutraceuticals in India, USA and Europe. It prepares the students to learn in detail on Regulatory Aspects for nutraceuticals and food supplements.

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

- a. Know the regulatory Requirements for nutraceuticals
- b. Understand the regulation for registration and labeling of nutraceuticals and food supplements in India, USA and Europe.

**UNIT - I**

**Nutraceuticals:** Introduction, History of Food and Nutraceutical Regulations, Meaning of Nutraceuticals, Dietary Supplements, Functional Foods, Medical Foods, Scope and Opportunities in Nutraceutical Market.

**UNIT - II**

**Global Aspects:** WHO guidelines on nutrition. NSF International: Its Role in the Dietary Supplements and Nutraceuticals Industries, NSF Certification, NSF Standards for Food And Dietary Supplements. Good Manufacturing Practices for Nutraceuticals.

**UNIT - III**

**India:** Food Safety and Standards Act, Food Safety and Standards Authority of India: Organization and Functions, Regulations for import, manufacture and sale of nutraceutical products in India, Recommended Dietary Allowances (RDA) in India.

**UNIT - IV**

**USA:** US FDA Food Safety Modernization Act, Dietary Supplement Health and Education Act. U.S. regulations for manufacture and sale of nutraceuticals and dietary supplements, Labelling Requirements and Label Claims for Dietary Supplements, Recommended Dietary Allowances (RDA) in the U.S

**UNIT - V**

**European Union:** European Food Safety Authority (EFSA): Organization and Functions. EU Directives and regulations for manufacture and sale of nutraceuticals and dietary supplements. Nutrition labelling. European Regulation on Novel Foods and Novel Food Ingredients. Recommended Dietary Allowances (RDA) in Europe.

**TEXT AND REFERENCE BOOKS:**

1. Regulation of Functional Foods and Nutraceuticals: A Global Perspective by Clare M. Hasler (Wiley Online Library)
2. Nutraceutical and Functional Food Regulations in the United States and Around the World by Debasis Bagchi (Academic Press, Elsevier)
3. <http://www.who.int/publications/guidelines/nutrition/en/>
4. [http://www.europarl.europa.eu/RegData/etudes/STUD/2015/536324/IPOL\\_STU\(2015\)536324\\_EN.pdf](http://www.europarl.europa.eu/RegData/etudes/STUD/2015/536324/IPOL_STU(2015)536324_EN.pdf)
5. Handbook of Nutraceuticals by Yashwant Pathak (CRC Press)
6. Food Regulation: Law, Science, Policy and Practice by Neal D. Fortin (Wiley)
7. Country Specific Guidelines from official websites.

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**JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD**  
**M.Pharm I Year II Sem (Pharmaceutical Regulatory Affairs)**

**PHARMACEUTICAL QUALITY CONTROL AND QUALITY ASSURANCE**  
**(Professional Elective – III)**

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

**UNIT I**

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

**UNIT II**

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

**UNIT III**

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

**UNIT IV**

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

**UNIT V**

**Manufacture and controls on dosage forms**

- a. Manufacturing documents, Master Formula, Batch Formula, Records, Standard Operating Procedures,
- b. In process quality control on various dosage forms sterile and biological products, standard operating procedures for various operations like cleaning, filling, drying, compression, coating, disinfection, sterilization, membrane filtration etc.

**TEXT BOOKS:**

1. The International Pharmacopoeia Vol 1,2,3,4, 3<sup>rd</sup> edition General Methods of Analysis Quality Specifications for Pharmaceutical Substances, Excipients, Dosage Forms.
2. Quality Assurance of Pharmaceuticals. A Compendium of Guidelines and Related Material Vol. 1 and Vol. 2, WHO 2007)



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3. GMP by Mehra
4. Pharmaceutical Process Validation by Berry and Nash
5. How to Practice GMP's – P.P. Sharma

**REFERENCES BOOKS:**

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



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**JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD**  
**M.Pharm I Year II Sem (Pharmaceutical Regulatory Affairs)**

**NANO BASED DRUG DELIVERY SYSTEMS (Professional Elective – III)**

**Course Objective** - To develop expertise regarding suitability and evaluation of nanomaterials, able to apply the properties to the fabrication of nanopharmaceutical, evaluate the intensity of dosage forms and availability for targeting and controlled delivery.

**Course Outcomes** – The students should be able to select the right kind of materials, able to develop nano formulations with appropriate technologies, evaluate the product related test and for identified diseases

**UNIT I**

**Introduction to Nanotechnology**

- a. Definition of nanotechnology
- b. History of nanotechnology
- c. Unique properties and classification of nanomaterials
- d. Role of size and size distribution of nanoparticles properties.
- e. Marketed formulations based on nanotechnology and science behind them

**UNIT II**

**Synthesis of Nanomaterials** Physical, chemical and biological Methods Methods for synthesis of

- Gold nanoparticles
- Magnetic nanoparticles
- Polymeric nanoparticles
- Self – assembly structures such as liposomes, Niosomes, transferosomes, micelles, aquasomes and nanoemulsions

**UNIT III**

**Biomedical applications of Nanotechnology**

- a. Nanotechnology products used for in vitro diagnostics
- b. Improvements to medical or molecular imaging using nanotechnology
- c. Targeted nanomaterials for diagnostic and therapeutic purpose

**UNIT IV**

Design of nanomaterials for drug delivery, pulmonary and nasal drug delivery, nanomaterials for cancer therapy and cardiovascular diseases. Localized drug delivery systems.

**UNIT V**

Characterization including the principles, size reduction, analysis of nanoparticles, size, PDI, size separation, stability, methods of analysis regarding integrity and release of drugs

**REFERENCE BOOKS:**

1. Nanomedicine and Nanoproducts: Applications, Disposition and Toxicology in the Human body, Eiki Igarashi, CRC press. 2015
2. Nanotechnology and Drug Delivery Volume one and two: Nanoplatfroms in Drug Delivery, Jose L. Arias, CRC press
3. Nano: The Essentials: Understanding Nanoscience and Nanotechnology, T. Pradeep, Tata McGraw-Hill Publishing Company Limited, New Delhi, 2008.
4. Nanocrystals: Synthesis, Properties and Applications, C. N. R. Rao, P. J. Thomas and G.U. Kulkarni, Springer (2007)



5. Nanostructures and Nanomaterials: Synthesis, Properties and Application, Guozhong Gao, Imperial College Press (2004)
6. Nano-Carrier Systems Theories, Methods & Applications, Amit K. Goyal, Goutam Rath, Pharmamed Press.
7. Nano chemistry: A Classical Approach to Nanomaterials – Royal Society for Chemistry, Cambridge, UK (2005)
8. Nanocomposite science and technology, pulickel M. Ajayan, Linda S. Schadler, paul V. Braun, Wiley - VCH Verlag, Weiheim (2003)
9. Nanoscale materials in chemistry, Edited by Kenneth J. Klabunde, John Wiley & Sons, 2009
10. Nanoparticles as Drug carriers, Vladimir P Torchiling, Imperial College Press, USA, 2006
11. Introduction to Nano Science and Technologies, Ankaneyulu Yerramilli, BS Publications. 2016
12. Nanoparticles as Drug carriers, Vladimir P Torchiling, Imperial College Press, USA, 2006



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**JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD**  
**M.Pharm I Year II Sem (Pharmaceutical Regulatory Affairs)**

**CLINICAL RESEARCH AND PHARMACOVIGILANCE (Professional Elective - IV)**

**Course Objectives:** 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 Program, WHO and Regulatory terminologies of ADR, evaluation of medication safety, establishing pharmacovigilance centres in Hospitals, Industry and National Programs 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,



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Comparative observational studies, Targeted clinical investigations and Vaccine safety surveillance. Spontaneous reporting system and Reporting to regulatory authorities, Guidelines for ADRs reporting. Argus, Aris G Pharmacovigilance, VigiFlow, Statistical methods for evaluating medication safety data.

**REFERENCE BOOKS:**

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. A Textbook of Clinical Research and Pharmacovigilance by KPR Chowdary, Pharmamed Press
7. Handbook of clinical Research. Julia Lloyd and Ann Raven Ed. Churchill Livingstone.
8. Principles of Clinical Research edited by Giovanna di Ignazio, Di Giovanna and Haynes.
9. Textbook of Pharmacovigilance: Concept and Practice. G.P. Mohanta and P. K. Manna. 2016, Pharma Med Press.
10. A textbook of Clinical Pharmacy Practice: Essential Concepts and Skills. Second Edition, 2012, University Press





**JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD**  
**M.Pharm I Year II Sem (Pharmaceutical Regulatory Affairs)**

**NUTRACEUTICALS (Professional Elective - IV)**

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

**Course Outcomes:** Helps the student to understand the importance of Nutraceuticals in various common problems with the concept of free radicals

**UNIT I**

- a. Definitions of Functional foods, Nutraceuticals and Dietary supplements. Classification of Nutraceuticals, Health problems and diseases that can be prevented or cured by Nutraceuticals i.e. weight control, diabetes, cancer etc.
- b. Source, Name of marker compounds and their chemical nature, Medicinal uses and health benefits of following used as nutraceuticals/functional foods: Spirulina, Soyabean, Ginseng, Garlic, Broccoli, Gingko, Flaxseeds

**UNIT II**

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

- a) Carotenoids-  $\alpha$  and  $\beta$ -Carotene, Lycopene, Xanthophylls, lutein
- b) Sulfides: Diallylsulfides, Allyltrisulfide.
- c) Polyphenolics: Resveratrol
- d) Flavonoids- Rutin, Naringin, Quercetin, Anthocyanidins, catechins, Flavones
- e) Prebiotics / Probiotics.: Fructo oligosaccharides, Lactobacillum
- f) Phytoestrogens: Isoflavones, daidzein, Geobustin, lignans
- g) Tocopherols

**UNIT III**

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

**UNIT IV**

- a. Free radicals in Diabetes mellitus, Inflammation, Ischemic reperfusion injury, Cancer, Atherosclerosis, Free radicals in brain metabolism and pathology, kidney damage, muscle damage. Free radicals involvement in other disorders. Free radicals theory of ageing.
- b. Antioxidants: Endogenous antioxidants – enzymatic and nonenzymatic antioxidant defence, Superoxide dismutase, catalase, Glutathione peroxidase, Glutathione Vitamin C, Vitamin E,  $\alpha$ -Lipoic acid, melatonin. Synthetic antioxidants: Butylatedhydroxy Toluene, Butylatedhydroxy Anisole.

**UNIT V**

**Food Laws and Regulations;** FDA, FPO, MPO, AGMARK, HACCP and GMPs on Food Safety, Adulteration of foods.

**Regulations and Claims – Current Products:** Label Claims, Nutrient Content Claims, Health Claims, Dietary Supplements Claims



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**REFERENCE BOOKS:**

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



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**JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD**  
**M.Pharm I Year II Sem (Pharmaceutical Regulatory Affairs)**

**ADVANCED DRUG DELIVERY SYSTEMS (Professional Elective - IV)**

**Course Objectives:** The students shall apply the pharmacokinetic and pharmacodynamic principles in the design of CDDS. They also apply the design, evaluation and applications related to oral, parenteral, transdermal, implants, bio adhesives and targeted drug delivery systems.

**Course Outcomes:** Students will select the drugs for CDDS design of the formulation fabrication of systems of above drug delivery systems with relevant applications.

**UNIT I**

Fundamentals of controlled drug delivery systems, pharmacokinetic and pharmacodynamic basis of controlled drug delivery. Design, fabrication, evaluation and applications of the following controlled releasing systems

- a. Controlled release oral drug delivery systems
- b. Parenteral controlled release drug delivery systems

**UNIT II**

Design, fabrication, evaluation and applications of the following

- a. Implantable Therapeutic systems
- b. Transdermal delivery systems
- c. Ocular and Intrauterine delivery systems
- d. Vaccine delivery: Delivery systems used to promote uptake, absorption enhancers, oral immunization, controlled release microparticles form vaccine development

**UNIT III**

Biochemical and molecular biology approaches to controlled drug delivery of

- a. Bioadhesive drug delivery systems
- b. Nasal drug delivery systems
- c. Drug delivery to Colon

**UNIT IV**

Biochemical and molecular biology approaches to control drug delivery of

- a. Liposomes
- b. Niosomes
- c. Microspheres
- d. Nanoparticles
- e. Resealed erythrocytes

**UNIT V**

Drug targeting to particular organs

- a. Delivery to lungs
- b. Delivery to the brain and problems involved
- c. Drug targeting in neoplasms

**TEXT BOOKS:**

1. Novel Drug Delivery System by Yie W. Chien.
2. Controlled Drug Delivery by Joseph R. Robinson and Vincent H. L. Lee.
3. Controlled and Novel Drug Delivery Systems by N. K. Jain.
4. Targeted and Controlled Drug Delivery (Novel carrier systems) by S. P. Vyas and Khar.
5. Modern Pharmaceutics by Gilbert S. Banker and Christopher T. Rhodes.
6. Advances in Drug Delivery, Vol 1, 2, 3,4 by Y. Madhusudan Rao, A.V. Jithan
7. Oral Drug Delivery Technology, 2<sup>nd</sup> ed, by Aukunuru Jithan



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**M.Pharm I Year II Sem (Pharmaceutical Regulatory Affairs)**

**REGULATORY ASPECTS OF HERBALS AND BIOLOGICAL LAB (Laboratory - III)**

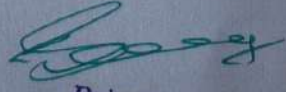
**List of Experiments:**

1. Preparation of Biologics License Applications (BLA)
2. Preparation of documents required for Vaccine Product Approval
3. Comparison of clinical trial application requirements of US, EU and India of Biologics
4. Preparation of Checklist for Registration of Blood and Blood Products
5. Registration requirement comparison study in 5 emerging markets (WHO) and preparing check list for market authorization
6. Registration requirement comparison study in emerging markets (BRICS) and preparing check list for market authorization
7. Registration requirement comparison study in emerging markets (China and South Korea) and preparing check list for market authorization
8. Registration requirement comparison study in emerging markets (ASEAN) and preparing check list for market authorization
9. Registration requirement comparison study in emerging markets (GCC) and preparing check list for market authorization
10. Preparation of document required for the approval of herbal products of diverse dosage forms(3products) as per regulations requirements

**Practical work shall be carried out based on the theory syllabus.**



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**JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD  
M.Pharm I Year II Sem (Pharmaceutical Regulatory Affairs)**

**REGULATORY ASPECTS OF MEDICAL DEVICES LAB (Laboratory - IV)**

**List of Experiments:**

1. Checklists for 510k and PMA for US market
2. Checklist for CE marking for various classes of devices for EU
3. STED Application for Class III Devices
4. Audit Checklist for Medical Device Facility
5. Clinical Investigation Plan for Medical Devices
6. Preparation and submission of medical devices for approval (3 products)
7. GMP of manufacturing of medical devices of diverse nature (3 products)
8. preparation and submission of nutraceuticals devices for approval (3 products)

**Practical work shall be carried out based on the theory syllabus**



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**JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD**  
**M.Pharm I Year III Sem (Pharmaceutical Regulatory Affairs)**

**BIostatISTICS (Professional Elective - V)**

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

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

**UNIT I**

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

**UNIT II**

**Measures of central tendency:** computation of means, median and mode from grouped and ungrouped data.

**Measure of dispersion:** computation of variance, standard deviation, standard error and their coefficients.

**UNIT III**

Measures of Correlation and Regression

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

**UNIT IV**

Experimental designing, planning of an experiment, replication and randomization.

**Analysis of Variance (ANOVA):** 1-way, 2- Way

**UNIT V**

**Hypothesis testing:** Student 't' test, Chi square test,

**Non- Parametric Tests:** Sign Test, Sign Rank Test, Wilcoxon Sign Rank Test

**REFERENCE BOOKS:**

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



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**M.Pharm II Year I Sem (Pharmaceutical Regulatory Affairs)**

**SCALE UP AND TECHNOLOGY TRANSFER (Professional Elective - V)**

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

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

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

**UNIT I**

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

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

**UNIT II**

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

**UNIT III**

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

**UNIT IV**

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

**UNIT V**

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

**REFERENCE BOOKS:**

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



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**JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD**  
**M.Pharm II Year I Sem (Pharmaceutical Regulatory Affairs)**

**PRODUCTION AREA DESIGN & PACKAGING DEVELOPMENT (Professional Elective - V)**

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

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

**UNIT I**

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

**UNIT II**

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

**UNIT III**

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

**UNIT IV**

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

**UNIT V**

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

**REFERENCE BOOKS:**

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



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

**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



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**M.Pharm (Pharmaceutical Regulatory Affairs)**

**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:**

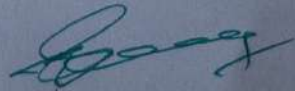
Meaning, Concept and Strategies of Disaster Mitigation, Emerging Trends In Mitigation. Structural Mitigation and Non-Structural Mitigation, Programs of Disaster Mitigation in India.



**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.



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

**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.



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

**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**  
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**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.



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**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.



A handwritten signature in green ink, appearing to be "S. S. S.", written in a cursive style.

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**M.Pharm (Pharmaceutical Regulatory Affairs)**

**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. Akyeamong 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).



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

**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



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

**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.



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**JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD**  
**B. PHARMACY COURSE STRUCTURE AND I & II YEARS SYLLABUS**

Effective from Academic Year 2022-23 Admitted Batch

**I Year I semester**

S. No	Course Code	Subject	L	T	P	Credits
1	PS101	Human Anatomy and Physiology I	3	1	-	4
2	PS102	Pharmaceutical Analysis I	3	1	-	4
3	PS103	Pharmaceutics	3	1	-	4
4	PS104	Pharmaceutical Inorganic Chemistry	3	1	-	4
5	HS105	Communication skills	2	-	-	2
6	BS106/BS107	Remedial Biology <sup>#</sup> / Remedial Mathematics <sup>§</sup>	2 <sup>#</sup> /3 <sup>§</sup>	-	-	2 <sup>#</sup> /3 <sup>§</sup>
7	PS108	Human Anatomy and Physiology-I lab	-	-	4	2
8	PS109	Pharmaceutical Analysis I lab	-	-	4	2
9	PS110	Pharmaceutics lab	-	-	4	2
10	PS111	Pharmaceutical Inorganic Chemistry lab	-	-	4	2
11	HS112	Communication skills lab	-	-	2	1
12	BS113	Remedial Biology lab	-	-	2	1
<b>Total</b>			<b>16/17</b>	<b>4</b>	<b>20</b>	<b>30<sup>#</sup>/30</b>

<sup>#</sup>Applicable ONLY for the students who have studied Mathematics / Physics / Chemistry at HSC and appearing for Remedial Biology (RB) course.

<sup>§</sup>Applicable ONLY for the students who have studied Physics / Chemistry / Botany / Zoology at HSC and appearing for Remedial Mathematics (RM) course.

**I Year II semester**

S. No	Course Code	Subject	L	T	P	Credits
1	PS201	Human Anatomy and Physiology II	3	1	-	4
2	PS202	Pharmaceutical Organic Chemistry-I	3	1	-	4
3	BS203	Biochemistry	3	1	-	4
4	BS204	Pathophysiology	3	1	-	4
5	CS205	Computer Applications in Pharmacy	3	-	-	3
6	PS206	Human Anatomy and Physiology II lab	-	-	4	2
7	PS207	Pharmaceutical Organic Chemistry-I Lab	-	-	4	2
8	BS208	Biochemistry lab	-	-	4	2
9	CS209	Computer Applications in Pharmacy lab	-	-	2	1
10	*MC200	NSS	-	-	-	-
<b>Total</b>			<b>15</b>	<b>4</b>	<b>14</b>	<b>26</b>

**II YEAR I SEMESTER**

S. No	Course Code	Course Title	L	T	P	Credits
1	PS301	Pharmaceutical Organic Chemistry-II	3	1	0	4
2	PS302	Physical Pharmaceutics-I	3	1	0	4
3	BS303	Pharmaceutical Microbiology	3	1	0	4
4	PC304	Pharmaceutical Engineering	3	1	0	4
5	PS305	Pharmaceutical Organic Chemistry-II Lab	0	0	4	2
6	PS306	Physical Pharmaceutics-I Lab	0	0	4	2
7	BS307	Pharmaceutical Microbiology Lab	0	0	4	2
8	PC308	Pharmaceutical Engineering Lab	0	0	4	2
10	*MC300	NSS	0	0	0	0
<b>Total Credits</b>			<b>12</b>	<b>04</b>	<b>16</b>	<b>24</b>



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**II YEAR II SEMESTER**

S. No	Course Code	Course Title	L	T	P	Credits
1	PS401	Pharmaceutical Organic Chemistry-III	3	1	0	4
2	PC402	Physical Pharmaceutics-II	3	1	0	4
3	PS403	Pharmacology-I	3	1	0	4
4	PC404	Pharmacognosy and Phytochemistry-I	3	1	0	4
5	PS405	Pharmaceutical Jurisprudence	3	1	0	4
6	PC406	Physical Pharmaceutics-II Lab	0	0	4	2
7	PS407	Pharmacology-I Lab	0	0	4	2
8	PC408	Pharmacognosy and Phytochemistry-I Lab	0	0	4	2
9	*MC400	Gender Sensitization Lab	1	0	0	0
<b>Total Credits</b>			<b>16</b>	<b>05</b>	<b>12</b>	<b>26</b>

**III Year I Semester**

S. No.	Course Code	Course Title	L	T	P	Credits
1	PS501	Medicinal Chemistry I	3	1	0	4
2	PS502	Industrial Pharmacy - I	3	1	0	4
3	PS503	Pharmacology II	3	1	0	4
4	PS504	Pharmacognosy and Phytochemistry - II	3	1	0	4
5		<b>Open Elective - I</b>	3	1	0	4
	PS505	I. Generic Product Development				
	PS506	II. Green Chemistry				
	PS507	III. Cell and Molecular Biology				
	PS508	IV. Cosmetic science				
6	PC509	Medicinal Chemistry I Lab	0	0	4	2
7	PS510	Industrial Pharmacy - I lab	0	0	4	2
8	PS511	Pharmacology - II lab	0	0	4	2
9	PS512	Pharmacognosy and Phytochemistry - II lab	0	0	4	2
10	*MC500	Environmental sciences	1	0	0	0
<b>Total</b>			<b>16</b>	<b>05</b>	<b>16</b>	<b>28</b>

**III Year II Semester**

S. No.	Course Code	Course Title	L	T	P	Credits
1	PS601	Medicinal Chemistry - II	3	1	0	4
2	PS602	Pharmacology - III	3	1	0	4
3	PS603	Herbal Drug Technology	3	1	0	4
4	PS604	Biopharmaceutics and Pharmacokinetics	3	1	0	4
5		<b>Open Elective - II</b>	3	1	0	4
	PS605	I. Pharmaceutical Quality Assurance				
	PS606	II. Pharmaceutical Biotechnology				
	PS607	III. Bioinformatics				
	PS608	IV. Screening Methods in Pharmacology				
6	PS609	Medicinal chemistry - II lab	0	0	4	2
7	PS610	Pharmacology - III lab	0	0	4	2
8	PS611	Herbal Drug Technology lab	0	0	4	2
9	PS612	Biopharmaceutics and Pharmacokinetics Lab	0	0	4	2
10	*MC600	Human Values and Professional Ethics	1	0	0	0
<b>Total</b>			<b>16</b>	<b>05</b>	<b>16</b>	<b>28</b>

**IV Year I Semester**

S.No	Course Code	Course Title	L	T	P	Credits
1	PS701	Instrumental Methods of Analysis	3	1	0	4
2	PS702	Industrial Pharmacy-II	3	1	0	4
3	PS703	Pharmacy Practice	3	1	0	4
4	PS704	Medicinal Chemistry - III	3	1	0	4
5		<b>Open Elective - III</b>	3	1	0	4
	PS705	i. Pharmaceutical Marketing	3	1	0	4



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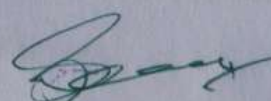
	PS706 PS707 PS708	ii. Pharmaceutical Regulatory Science iii. Pharmacovigilance iv. Quality Control and Standardization of Herbals				
6	PS709	Instrumental Methods of Analysis Lab	0	0	4	2
7	PS710	Practice School	0	0	4	2
8	PS711	Industrial Training	0	0	4	2
<b>Total</b>			<b>15</b>	<b>5</b>	<b>12</b>	<b>26</b>

**IV Year II Semester**

S.No	Course Code	Course Title	L	T	P	Credits
1	PS801	Biostatistics and Research Methodology	3	1	0	4
2	PS802	Social and Preventive Pharmacy	3	1	0	4
3	PS803	Novel Drug Delivery System	3	1	0	4
4		<b>Open Elective - IV</b>	3	1	0	4
	PS804	i. Computer Aided Drug Design				
	PS805	ii. Nano Technology				
	PS806	iii. Experimental Pharmacology				
	PS807	iv. Advanced Instrumentation Techniques				
5	PS808	Novel Drug Delivery System Lab	0	0	4	2
6		Project Work	0	0	6	3
<b>Total</b>			<b>12</b>	<b>4</b>	<b>10</b>	<b>21</b>

\*MC - Mandatory Course - Satisfactory/ Unsatisfactory.



  
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**PS101: HUMAN ANATOMY AND PHYSIOLOGY - I****B. Pharm. I Year I Sem**

L	T	P	C
3	1	0	4

**Scope:** This subject is designed to impart fundamental knowledge on the structure and functions of the various systems of the human body. It also helps in understanding both homeostatic mechanisms. The subject provides the basic knowledge required to understand the various disciplines of pharmacy.

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

- Explain the gross morphology, structure, and functions of various organs of the human body.
- Describe the various homeostatic mechanisms and their imbalances.
- Identify the various tissues and organs of different systems of human body.
- Perform the various experiments related to special senses and nervous system.
- Appreciate coordinated working pattern of different organs of each system

**UNIT – I****10 hours****Introduction to human body**

Definition and scope of anatomy and physiology, levels of structural organization and body systems, basic life processes, homeostasis, basic anatomical terminology.

**Cellular level of organization**

Structure and functions of cell, transport across cell membrane, cell division, cell junctions. General principles of cell communication, intracellular signaling pathway activation by extracellular signal molecule, Forms of intracellular signaling: a) Contact-dependent b) Paracrine c) Synaptic d) Endocrine

**Tissue level of organization**

Classification of tissues, structure, location and functions of epithelial, muscular and nervous and connective tissues.

**UNIT – II****10 hours****Integumentary system** Structure and functions of skin**Skeletal system**

Divisions of skeletal system, types of bone, salient features, and functions of bones of axial and appendicular skeletal system

Organization of skeletal muscle, physiology of muscle contraction, neuromuscular junction

**Joints**

Structural and functional classification, types of joints movements and its articulation

**UNIT – III****10 hours****Nervous system**

Organization of nervous system, neuron, neuroglia, classification and properties of nerve fibre, electrophysiology, action potential, nerve impulse, receptors, synapse, neurotransmitters.

Central nervous system: Meninges, ventricles of brain and cerebrospinal fluid. Structure and functions of brain (cerebrum, brain stem, cerebellum), spinal cord (gross structure, functions of afferent and efferent nerve tracts, reflex activity)

**UNIT – IV****08 hours****Peripheral nervous system:**

Classification of peripheral nervous system: Structure and functions of sympathetic and parasympathetic nervous system. Origin and functions of spinal and cranial nerves.

**Special senses:** Structure and functions of eye, ear, nose and tongue and their disorders.

**UNIT – V****07 hours****Endocrine system**

Classification of hormones, mechanism of hormone action, structure and functions of pituitary gland, thyroid gland, parathyroid gland, adrenal gland, pancreas, pineal gland, thymus and their disorders.



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**TEXT BOOKS: (Latest Editions)**

1. Essentials of Medical Physiology by K. Sembulingam and P. Sembulingam. Jaypee brothers medical publishers, New Delhi.
2. Anatomy and Physiology in Health and Illness by Kathleen J.W. Wilson, Churchill Livingstone, New York
3. Physiological basis of Medical Practice-Best and Taylor. Williams & Wilkins Co, Riverview, MI USA
4. Text book of Medical Physiology- Arthur C, Guyton and John.E. Hall. Miamisburg, OH, U.S.A.
5. Principles of Anatomy and Physiology by Tortora Grabowski. Palmetto, GA, U.S.A.
6. Textbook of Human Histology by Inderbir Singh, Jaypee brother's medical publishers, New Delhi.
7. Textbook of Practical Physiology by C.L. Ghai, Jaypee brother's medical publishers, New Delhi.
8. Practical workbook of Human Physiology by K. Srinageswari and Rajeev Sharma, Jaypee brother's medical publishers, New Delhi.

**REFERENCE BOOKS: (Latest Editions)**

1. Physiological basis of Medical Practice-Best and Taylor. Williams & Wilkins Co, Riverview, MI USA
2. Text book of Medical Physiology- Arthur C, Guyton and John. E. Hall. Miamisburg, OH, U.S.A.
3. Human Physiology (vol 1 and 2) by Dr. C.C. Chatterje, Academic Publishers Kolkata



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## PS102: PHARMACEUTICAL ANALYSIS - I

B. Pharm. I Year I Sem

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**Scope:** This course deals with the fundamentals of analytical chemistry and principles of electrochemical analysis of drugs

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

- understand the principles of volumetric and electro chemical analysis
- carryout various volumetric and electrochemical titrations
- develop analytical skills

## UNIT - I

10 Hours

(a) **Pharmaceutical analysis-** Definition and scope

- Different techniques of analysis
- Methods of expressing concentration
- Primary and secondary standards.
- Preparation and standardization of various molar and normal solutions-Oxalic acid, sodium hydroxide, hydrochloric acid, sodium thiosulphate, sulphuric acid, potassium permanganate and ceric ammonium sulphate

(b) **Errors:** Sources of errors, types of errors, methods of minimizing errors, accuracy, precision and significant figures

## UNIT - II

10 Hours

**Acid base titration:** Theories of acid base indicators, classification of acid base titrations and theory involved in titrations of strong, weak, and very weak acids and bases, neutralization curves

**Non-aqueous titration:** Solvents, acidimetry and alkalimetry titration and estimation of Sodium benzoate and Ephedrine HCl

## UNIT - III

10 Hours

**Precipitation titrations:** Mohr's method, Volhard's, Modified Volhard's, Fajans method, estimation of sodium chloride.

**Complexometric titration:** Classification, metal ion indicators, masking and demasking reagents, estimation of Magnesium sulphate, and calcium gluconate.

**Gravimetry:** Principle and steps involved in gravimetric analysis. Purity of the precipitate: co-precipitation and post precipitation, Estimation of barium sulphate.

## UNIT - IV

08 Hours

**Redox titrations:**

- Concepts of oxidation and reduction
  - Types of redox titrations (Principles and applications)
- Cerimetry, Iodimetry, Iodometry, Bromatometry, Dichrometry, Titration with potassium iodate

## UNIT - V

07 Hours

**Electrochemical methods of analysis:**

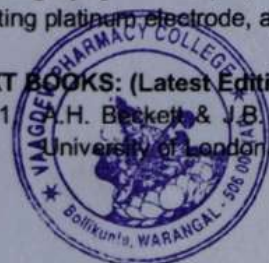
**Conductometry-** Introduction, Conductivity cell, Conductometric titrations, applications.

**Potentiometry -** Electrochemical cell, construction and working of reference (Standard hydrogen, silver chloride electrode and calomel electrode) and indicator electrodes (metal electrodes and glass electrode), methods to determine end point of potentiometric titration and applications.

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

## TEXT BOOKS: (Latest Editions)

- H. Beckett & J.B. Stenlake's, Practical Pharmaceutical Chemistry Vol I & II, Stahlone Press of University of London



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2. Introduction to Pharmaceutical Analysis by Badwaik Hemant R. published by Pharma Med Press
3. A.I. Vogel, Text Book of Quantitative Inorganic analysis
4. P. GunduRao, Inorganic Pharmaceutical Chemistry
5. Bentley and Driver's Textbook of Pharmaceutical Chemistry
6. John H. Kennedy, Analytical chemistry principles
7. Indian Pharmacopoeia.
8. Badwaik Hemant R., Introduction to Pharmaceutical Analysis, Pharma Med Press



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## PS103: PHARMACEUTICS

## B. Pharm. I Year I Sem

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**Scope:** This course is designed to impart a fundamental knowledge on the preparatory pharmacy with arts and science of preparing the different conventional dosage forms.

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

- Know the history of profession of pharmacy
- Understand the basics of different dosage forms, pharmaceutical incompatibilities and pharmaceutical calculations
- Understand the professional way of handling the prescription
- Preparation of various conventional dosage forms

## UNIT – I

10 Hours

**Historical background and development of profession of pharmacy:** History of profession of Pharmacy in India in relation to pharmacy education, industry, and organization, Pharmacy as a career, Pharmacopoeias: Introduction to IP, BP, USP and Extra Pharmacopoeia.

**Dosage forms:** Introduction to dosage forms, classification and definitions

**Prescription:** Definition, Parts of prescription, handling of Prescription and Errors in prescription.

**Posology:** Definition, Factors affecting posology. Pediatric dose calculations based on age, body weight and body surface area.

## UNIT – II

10 Hours

**Pharmaceutical calculations:** Weights and measures—Imperial & Metric system, Calculations involving percentage solutions, alligation, proof spirit and isotonic solutions based on freezing point and molecular weight.

**Powders:** Definition, classification, advantages and disadvantages, Simple & compound powders – official preparations, dusting powders, effervescent, efflorescent and hygroscopic powders, eutectic mixtures. Geometric dilutions.

**Liquid dosage forms:** Advantages and disadvantages of liquid dosage forms. Excipients used in formulation of liquid dosage forms. Solubility enhancement techniques

## UNIT – III

08 Hours

**Monophasic liquids:** Definitions and preparations of Gargles, Mouthwashes, Throat Paint, Eardrops, Nasal drops, Enemas, Syrups, Elixirs, Liniments and Lotions.

**Biphasic liquids:**

**Suspensions:** Definition, advantages and disadvantages, classifications, Preparation of suspensions; Flocculated and Deflocculated suspension & stability problems and methods to overcome.

**Emulsions:** Definition, classification, emulsifying agent, test for the identification of type of Emulsion, Methods of preparation & stability problems and methods to overcome.

## UNIT – IV

08 Hours

**Suppositories:** Definition, types, advantages and disadvantages, types of bases, methods of preparations. Displacement value & its calculations, evaluation of suppositories.

**Pharmaceutical incompatibilities:** Definition, classification, physical, chemical and therapeutic incompatibilities with examples.

## UNIV – V

07 Hours

**Semisolid dosage forms:** Definitions, classification, mechanisms and factors influencing dermal penetration of drugs. Preparation of ointments, pastes, creams and gels. Excipients used in semi solid dosage forms. Evaluation of semi solid dosage forms



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**TEXT BOOKS: (Latest Editions)**

1. H.C. Ansel et al., Pharmaceutical Dosage Form and Drug Delivery System, Lippincott Williams and Walkins, New Delhi.
2. Carter S.J., Cooper and Gunn's-Dispensing for Pharmaceutical Students, CBS publishers, New Delhi.
3. M.E. Aulton, Pharmaceutics, The Science & Dosage Form Design, Churchill Livingstone, Edinburgh.
4. Indian pharmacopoeia.
5. British pharmacopoeia.
6. Lachmann. Theory and Practice of Industrial Pharmacy, Lea & Febiger Publisher, The University of Michigan.
7. Alfonso R. Gennaro Remington. The Science and Practice of Pharmacy, Lippincott Williams, New Delhi.
8. Carter S.J., Cooper and Gunn's. Tutorial Pharmacy, CBS Publications, New Delhi.
9. E.A. Rawlins, Bentley's Text Book of Pharmaceutics, English Language Book Society, Elsevier Health Sciences, USA.
10. Isaac GhebreSellassie: Pharmaceutical Pelletization Technology, Marcel Dekker, INC, New York.
11. Dilip M. Parikh: Handbook of Pharmaceutical Granulation Technology, Marcel Dekker, INC, New York.
12. Francoise Nieloud and Gilberte Marti-Mestres: Pharmaceutical Emulsions and Suspensions, Marcel Dekker, INC, New York.
13. Tripathi Dulal Krishna, Pharmaceutics: Basic Principles and Formulations, Pharma Med Press



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## PS104: PHARMACEUTICAL INORGANIC CHEMISTRY

B. Pharm. I Year I Sem

L T P C  
3 1 0 4**Scope:** This subject deals with the monographs of inorganic drugs and pharmaceuticals.**Course Objectives:** Upon completion of course, student shall be able to

- know the sources of impurities and methods to determine the impurities in inorganic drugs and pharmaceuticals
- understand the medicinal and pharmaceutical importance of inorganic compounds

**UNIT – I****10 Hours****Impurities in pharmaceutical substances:** History of Pharmacopoeia, Sources and types of impurities, principle involved in the limit test for Chloride, Sulphate, Iron, Arsenic, Lead and Heavy metals, modified limit test for Chloride and Sulphate**General methods of preparation,** assay for the compounds superscripted with **asterisk (\*)**, properties and medicinal uses of inorganic compounds belonging to the following classes**UNIT – II****10 Hours****Acids, Bases and Buffers:** Buffer equations and buffer capacity in general, buffers in pharmaceutical systems, preparation, stability, buffered isotonic solutions, measurements of tonicity, calculations and methods of adjusting isotonicity.**Major extra and intracellular electrolytes:** Functions of major Physiological ions, Electrolytes used in the replacement therapy: Sodium chloride\*, Potassium chloride, Calcium gluconate\* and Oral Rehydration Salt (ORS), Physiological acid base balance.**Dental products:** Dentifrices, role of fluoride in the treatment of dental caries, Desensitizing agents, Calcium carbonate, Sodium fluoride, and Zinc eugenol cement.**UNIT – III****10 Hours****Gastrointestinal agents****Acidifiers:** Ammonium chloride\* and Dil. HCl**Antacid:** Ideal properties of antacids, combinations of antacids, Sodium Bicarbonate\*, Aluminum hydroxide gel, Magnesium hydroxide mixture**Cathartics:** Magnesium sulphate, Sodium orthophosphate, Kaolin and Bentonite**Antimicrobials:** Mechanism, classification, Potassium permanganate, Boric acid, Hydrogen peroxide\*, Chlorinated lime\*, Iodine and its preparations**UNIT – IV****08 Hours****Miscellaneous compounds****Expectorants:** Potassium iodide, Ammonium chloride\***Emetics:** Copper sulphate\*, Sodium potassium tartarate**Haematinics:** Ferrous sulphate\*, Ferrous gluconate**Poison and Antidote:** Sodium thiosulphate\*, Activated charcoal, Sodium nitrite<sup>333</sup>**Astringents:** Zinc Sulphate, Potash Alum**UNIT – V****07 Hours****Radiopharmaceuticals:** Radio activity, Measurement of radioactivity, Properties of  $\alpha$ ,  $\beta$ ,  $\gamma$  radiations, Half life, radio isotopes and study of radio isotopes - Sodium iodide  $I^{131}$ , Storage conditions, precautions & pharmaceutical application of radioactive substances.**TEXT BOOKS: (Latest Editions)**

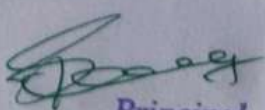
1. A.H. Beckett & J.B. Stenlake's, Practical Pharmaceutical Chemistry Vol I & II, Stahlone Press of University of London, 4<sup>th</sup> edition.
2. Vogel, Text Book of Quantitative Inorganic analysis
3. P. Gundu Rao, Inorganic Pharmaceutical Chemistry, 3<sup>rd</sup> Edition



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4. M.L Schroff, Inorganic Pharmaceutical Chemistry
5. Bentley and Driver's Textbook of Pharmaceutical Chemistry
6. Anand&Chatwal, Inorganic Pharmaceutical Chemistry
7. Indian Pharmacopoeia
8. Algarsamy V. Pharmaceutical Inorganic Chemistry, 2nd Ed. Pharma Med Press
9. Rao Somasekhar, Pharmaceutical Inorganic Chemistry, Pharma Med Press



  
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## HS105: COMMUNICATION SKILLS

## B. Pharm. I Year I Sem

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**Scope:** This course will prepare the young pharmacy student to interact effectively with doctors, nurses, dentists, physiotherapists and other health workers. At the end of this course the student will get the soft skills set to work cohesively with the team as a team player and will add value to the pharmaceutical business.

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

- Understand the behavioral needs for a Pharmacist to function effectively in the areas of pharmaceutical operation
- Communicate effectively (Verbal and Non-Verbal)
- Effectively manage the team as a team player
- Develop interview skills
- Develop Leadership qualities and essentials

**UNIT – I****07 Hours**

**Communication Skills:** Introduction, Definition, The Importance of Communication, The Communication Process – Source, Message, Encoding, Channel, Decoding, Receiver, Feedback, Context

**Barriers to communication:** Physiological Barriers, Physical Barriers, Cultural Barriers, Language Barriers, Gender Barriers, Interpersonal Barriers, Psychological Barriers, Emotional barriers

**Perspectives in Communication:** Introduction, Visual Perception, Language, Other factors affecting our perspective - Past Experiences, Prejudices, Feelings, Environment

**UNIT – II****07 Hours**

**Elements of Communication:** Introduction, Face to Face Communication - Tone of Voice, Body Language (Non-verbal communication), Verbal Communication, Physical Communication

**Communication Styles:** Introduction, The Communication Styles Matrix with example for each - Direct Communication Style, Spirited Communication Style, Systematic Communication Style, Considerate Communication Style

**UNIT – III****07 Hours**

**Basic Listening Skills:** Introduction, Self-Awareness, Active Listening, Becoming an Active Listener, Listening in Difficult Situations

**Effective Written Communication:** Introduction, When and When Not to Use Written Communication - Complexity of the Topic, Amount of Discussion Required, Shades of Meaning, Formal Communication

**Writing Effectively:** Subject Lines, Put the Main Point First, Know Your Audience, Organization of the Message

**UNIT – IV****05 Hours**

**Interview Skills:** Purpose of an interview, Do's and Don't's of an interview

**Giving Presentations:** Dealing with Fears, Planning your Presentation, Structuring Your Presentation, Delivering Your Presentation, Techniques of Delivery

**UNIT – V****04 Hours**

**Group Discussion:** Introduction, Communication skills in group discussion, Do's and Don't's of group discussion

**TEXT BOOKS: (Latest Editions)**

1. Basic communication skills for Technology, Andreja. J. Ruther Ford, 2<sup>nd</sup> Edition, Pearson Education, 2011
2. Communication skills, Sanjay Kumar, Pushpalata, 1<sup>st</sup> Edition, Oxford Press, 2011
3. Organizational Behaviour, Stephen.P. Robbins, 1<sup>st</sup> Edition, Pearson, 2013
4. Brilliant- Communication skills, Gill Hasson, 1<sup>st</sup> Edition, Pearson Life, 2011



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5. The Ace of Soft Skills: Attitude, Communication and Etiquette for success, GopalaSwamy Ramesh, 5<sup>th</sup>Edition, Pearson, 2013
6. Developing your influencing skills, Deborah Dalley, Lois Burton, Margaret, Green hall, 1st Edition Universe of Learning LTD, 2010
7. Communication skills for professionals, Konarnira, 2<sup>nd</sup>Edition, New arrivals – PHI, 2011
8. Personality development and soft skills, Barun K Mitra, 1<sup>st</sup>Edition, Oxford Press, 2011
9. Soft skill for everyone, Butter Field, 1st Edition, Cengage Learning India pvt.ltd, 2011
10. Soft skills and professional communication, Francis Peters SJ, 1<sup>st</sup>Edition, McGraw Hill Education, 2011
11. Effective communication, John Adair, 4<sup>th</sup>Edition, Pan Mac Millan, 2009
12. Bringing out the best in people, Aubrey Daniels, 2<sup>nd</sup>Edition, McGraw Hill, 1999
13. Rao Bhaskara, Communication Skills, BS Publications



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**BS106: REMEDIAL BIOLOGY****B. Pharm. I Year I Sem**

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2	0	0	2

**Scope:** To learn and understand the components of living world, structure and functional system of plant and animal kingdom.

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

- know the classification and salient features of five kingdoms of life
- understand the basic components of anatomy & physiology of plant
- know understand the basic components of anatomy & physiology animal with special reference to human

**UNIT - I****07 Hours****Living world:**

- Definition and characters of living organisms
- Diversity in the living world
- Binomial nomenclature
- Five kingdoms of life and basis of classification. Salient features of Monera, Protista, Fungi, Animalia and Plantae, Virus,

**Morphology of Flowering plants**

Morphology of different parts of flowering plants – Root, stem, inflorescence, flower, leaf, fruit, seed.  
General Anatomy of Root, stem, leaf of monocotyledons & Dicotyledones.

**UNIT – II****07 Hours****Body fluids and circulation**

Composition of blood, blood groups, coagulation of blood, Composition and functions of lymph  
Human circulatory system, Structure of human heart and blood vessels, Cardiac cycle, cardiac output and ECG

**Digestion and Absorption**

Human alimentary canal and digestive glands, Role of digestive enzymes, Digestion, absorption and assimilation of digested food

**Breathing and respiration**

Human respiratory system, Mechanism of breathing and its regulation, Exchange of gases, transport of gases and regulation of respiration, Respiratory volumes

**UNIT – III****07 Hours****Excretory products and their elimination**

Modes of excretion, Human excretory system- structure and function, Urine formation, Renin angiotensin system

**Neural control and coordination**

Definition and classification of nervous system, Structure of a neuron, Generation, and conduction of nerve impulse, Structure of brain and spinal cord, Functions of cerebrum, cerebellum, hypothalamus, and medulla oblongata

**Chemical coordination and regulation**

Endocrine glands and their secretions, Functions of hormones secreted by endocrine glands

**Human reproduction**

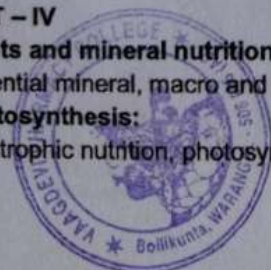
Parts of female reproductive system, Parts of male reproductive system, Spermatogenesis and Oogenesis, Menstrual cycle

**UNIT – IV****05 Hours****Plants and mineral nutrition:**

Essential mineral, macro and micronutrients, Nitrogen metabolism, Nitrogen cycle, biological nitrogen fixation

**Photosynthesis:**

Autotrophic nutrition, photosynthesis, Photosynthetic pigments, Factors affecting photosynthesis.



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**UNIT – V**

**Plant respiration:** Respiration, glycolysis, fermentation (anaerobic).

**Plant growth and development**

Phases and rate of plant growth, Condition of growth, Introduction to plant growth regulators

**Cell - The unit of life**

Structure and functions of cell and cell organelles. Cell division

**Tissues**

Definition, types of tissues, location and functions.

**TEXT BOOKS:**

1. Text book of Biology by S. B. Gokhale
2. A Text book of Biology by Dr. Thulajappa and Dr. Seetaram.

**REFERENCE BOOKS:**

1. Text book of Biology by B.V. Sreenivasa Naidu
2. A Text book of Biology by Naidu and Murthy
3. Botany for Degree students By A.C. Dutta.
4. Outlines of Zoology by M. Ekambaranathaayyer and T. N. Ananthkrishnan.
5. A manual for pharmaceutical biology practical by S.B. Gokhale and C. K. Kokate



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**BS107: REMEDIAL MATHEMATICS****B. Pharm. I Year I Sem**

L	T	P	C
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**Scope:** This is an introductory course in mathematics. This subject deals with the introduction to Partial fraction, Logarithm, matrices and Determinant, Analytical geometry, Calculus, differential equation and Laplace transform.

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

- Know the theory and their application in Pharmacy
- Solve the different types of problems by applying theory
- Appreciate the important application of mathematics in Pharmacy

**UNIT – I****06 Hours****Matrices and Determinant:**

Introduction matrices, Types of matrices, Operation on matrices, Transpose of a matrix, Matrix Multiplication, Determinants, Properties of determinants, Product of determinants, Singular and non-singular matrices, Inverse of a matrix, Solution of system of linear of equations using Gauss Elimination method.

**UNIT- II****06 Hours****Logarithms:**

Introduction, Definition, Theorems/Properties of logarithms, Common logarithms, Characteristic and Mantissa, worked examples, application of logarithm to solve pharmaceutical problems.

**Function:**

Real Valued function, Classification of real valued functions

**UNIT – III****06 Hours****Calculus****Limits and continuity:**

Introduction, Limit of a function, Definition of limit of a function

**Differentiation:**

Introductions, properties of derivatives, Finding derivative of a function using Standard Derivatives, Derivative of the sum or difference of two functions, Derivative of the product of two functions (product formula), Derivative of the quotient of two functions (Quotient formula) – **Without Proof**. Related problem.

**UNIT – IV****06 Hours****Integration:**

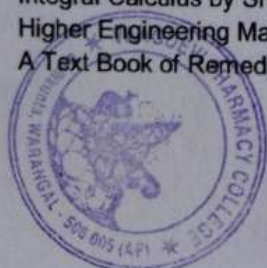
Introduction, Definition, Standard formulae, Rules of integration, Method of substitution, Method of Partial fractions, Integration by parts, definite integrals, application

**UNIT – V****06 Hours****Differential Equations:**

Some basic definitions, Order and degree, Equations in separable form, Homogeneous equations, Linear Differential equations, Exact equations, Application in solving Pharmacokinetic equations

**TEXT BOOKS: (Latest Edition)**

1. Differential Calculus by Shanthinarayan
2. Intermediate telugu academy mathematics text book
3. Integral Calculus by Shanthinarayan
4. Higher Engineering Mathematics by Dr.B.S. Grewal
5. A Text Book of Remedial Mathematics by P seshagiri Rao, Pharmamed Press.



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**PS108: HUMAN ANATOMY AND PHYSIOLOGY- I Lab****B. Pharm. I Year I Sem****L T P C**  
**0 0 4 2**

Practical physiology is complimentary to the theoretical discussions in physiology. Practicals allow the verification of physiological processes discussed in theory classes through experiments on living tissue, intact animals, or normal human beings. This is helpful for developing an insight on the subject.

**List of Experiments:**

1. Study of compound microscope.
2. Microscopic study of epithelial and connective tissue
3. Microscopic study of muscular and nervous tissue
4. Identification of axial bones
5. Identification of appendicular bones
6. To study the integumentary and special senses using specimen, models, etc.,
7. To study the nervous system using specimen, models, etc.,
8. To study the endocrine system using specimen, models, etc
9. To demonstrate the general neurological examination
10. To demonstrate the function of olfactory nerve
11. To examine the different types of taste.
12. To demonstrate the visual acuity
13. To demonstrate the reflex activity
14. Recording of body temperature
15. To demonstrate positive and negative feedback mechanism.



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## PS109: PHARMACEUTICAL ANALYSIS - I Lab

B. Pharm. I Year I Sem

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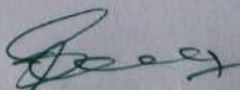
## List of Experiments:

1. **Preparation and standardization of**
  - 1) Sodium hydroxide
  - 2) Sulphuric acid
  - 3) Sodium thiosulfate
  - 4) Potassium permanganate
  - 5) Ceric ammonium sulphate
  
2. **Assay of the following compounds along with Standardization of Titrant**
  - 1) Ammonium chloride by acid base titration
  - 2) Ferrous sulphate by Cerimetry
  - 3) Copper sulphate by Iodometry
  - 4) Calcium gluconate by complexometry
  - 5) Hydrogen peroxide by Permanganometry
  - 6) Sodium benzoate by non-aqueous titration
  - 7) Sodium Chloride by precipitation titration
  
3. **Determination of Normality by electro-analytical methods**
  - 1) Conductometric titration of strong acid against strong base
  - 2) Conductometric titration of strong acid and weak acid against strong base
  - 3) Potentiometric titration of strong acid against strong base

## REFERENCE:

1. Pharmaceutical Analysis: A Practical Manual by Randhir Singh Dahiya, Navpreet Kaur, Lalit Kishore, Pharmamed.



  
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## PS110: PHARMACEUTICS LAB

B. Pharm. I Year I Sem

L T P C  
0 0 4 2

## List of Experiments:

1. **Syrups**
  - a) Syrup IP
  - b) Paracetamol pediatric syrup
2. **Elixirs**
  - a) Piperazine citrate elixir
  - b) Paracetamol pediatric elixir
3. **Linctus** a) Simple Linctus BPC
4. **Solutions**
  - a) Strong solution of ammonium acetate
  - b) Cresol with soap solution
5. **Suspensions**
  - a) Calamine lotion
  - b) Magnesium Hydroxide mixture
5. **Emulsions**
  - a) Turpentine Liniment
  - b) Liquid paraffin emulsion
6. **Powders and Granules**
  - a) ORS powder (WHO)
  - b) Effervescent granules c) Dusting powder
7. **Suppositories**
  - a) Glycero gelatin suppository
  - b) Soap glycerin suppository
8. **Semisolids**
  - a) Sulphur ointment
  - b) Non-staining iodine ointment with methyl salicylate
  - c) Bentonite gel
9. **Gargles and Mouthwashes**
  - a) Potassium chlorate gargle
  - b) Chlorhexidine mouthwash

## REFERENCES BOOKS:

1. Pharmaceutics-I (General Pharmacy) A Practical Manual by Mishra Vijay, Pharmamed Press
2. Pharmaceutics: A Practical Manual for B PHARM & PHARM D Courses, Abraham Sindhu by Pharmamed Press.



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**PS111: PHARMACEUTICAL INORGANIC CHEMISTRY - LAB**

**B. Pharm. I Year I Sem**

**L T P C**  
**0 0 4 2**

**Limit tests for following ions**

- a) Limit test for Chlorides and Sulphates Modified limit test for Chlorides and Sulphates Limit test for Iron
- b) Limit test for Heavy metals Limit test for Lead
- c) Limit test for Arsenic

**Identification test** Magnesium hydroxide Ferrous sulphate Sodium bicarbonate Calcium gluconate Copper sulphate

**Test for purity**

- a) Swelling power of Bentonite
- b) Neutralizing capacity of aluminum hydroxide gel
- c) Determination of potassium iodate and iodine in potassium iodide

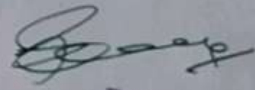
**Preparation of inorganic pharmaceuticals**

- a) Boric acid
- b) Potash alum
- c) Ferrous sulphate

**REFERENCE BOOK:**

1. Practical Pharmaceutical In-Organic Chemistry, by Bayya Subba Rao, Pharmamed Press.



  
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## PS111: PHARMACEUTICAL INORGANIC CHEMISTRY - LAB

B. Pharm. I Year I Sem

L T P C  
0 0 4 2

## Limit tests for following ions

- Limit test for Chlorides and Sulphates Modified limit test for Chlorides and Sulphates Limit test for Iron
- Limit test for Heavy metals Limit test for Lead
- Limit test for Arsenic

**Identification test** Magnesium hydroxide Ferrous sulphate Sodium bicarbonate Calcium gluconate Copper sulphate

## Test for purity

- Swelling power of Bentonite
- Neutralizing capacity of aluminum hydroxide gel
- Determination of potassium iodate and iodine in potassium iodide


## Preparation of inorganic pharmaceuticals

- Boric acid
- Potash alum
- Ferrous sulphate

## REFERENCE BOOK:

- Practical Pharmaceutical In-Organic Chemistry, by Bayya Subba Rao, Pharmamed Press.



  
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**HS112: COMMUNICATION SKILLS - LAB**

**B. Pharm. I Year I Sem**

**L T P C**  
**0 0 2 1**

The following learning modules are to be conducted using wordsworth® English language lab software

**Basic communication covering the following topics**

Meeting People  
Asking Questions  
Making Friends  
What did you do?  
Do's and Dont's

**Pronunciations covering the following topics**

Pronunciation (Consonant Sounds)  
Pronunciation and Nouns  
Pronunciation (Vowel Sounds)

**Advanced Learning**

Listening Comprehension / Direct and Indirect Speech  
Figures of Speech  
Effective Communication  
Writing Skills  
Effective Writing  
Interview Handling Skills  
E-Mail etiquette  
Presentation Skills

**REFERENCE BOOK:**

1. Successful Career Soft Skills and Business English Personality Development and Career Path  
by Varanasi Bhaskara Rao, Y. Kameswari



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## BS113: REMEDIAL BIOLOGY LAB

B. Pharm. I Year I Sem

L T P C  
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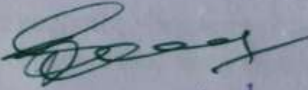
## List of Experiments:

1. Introduction to experiments in biology
  - a) Study of Microscope
  - b) Section cutting techniques
  - c) Mounting and staining
  - d) Permanent slide preparation
2. Study of cell and its inclusions
3. Study of Stem, Root, Leaf and its modifications
4. Detailed study of frog by using computer models
5. Microscopic study and identification of tissues
6. Identification of bones
7. Determination of blood group
8. Determination of blood pressure
9. Determination of tidal volume

## REFERENCE BOOKS:

1. Practical human anatomy and physiology. By S.R. Kale and R.R. Kale.
2. A Manual of pharmaceutical biology practical by S.B. Gokhale, C.K. Kokate and S.P. Shrivastava.
3. Biology practical manual according to National core curriculum. Biology forum of Karnataka. Prof.M.J.H. Shafi



  
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**PS201: HUMAN ANATOMY AND PHYSIOLOGY-II****B. Pharm. I Year II Sem****L T P C**  
**3 1 0 4**

**Scope:** This subject is designed to impart fundamental knowledge on the structure and functions of the various systems of the human body. It also helps in understanding both homeostatic mechanisms. The subject provides the basic knowledge required to understand the various disciplines of pharmacy.

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

- Explain the gross morphology, structure, and functions of various organs of the human body.
- Describe the various homeostatic mechanisms and their imbalances.
- Identify the various tissues and organs of different systems of human body.
- Perform the hematological tests like blood cell counts, hemoglobin estimation, bleeding/clotting time etc and also record blood pressure, heart rate, pulse and respiratory volume.
- Appreciate coordinated working pattern of different organs of each system
- Appreciate the interlinked mechanisms in the maintenance of normal functioning (homeostasis) of human body.

**Unit – I****10 hours****Body fluids and blood**

Body fluids, composition and functions of blood, hemopoiesis, formation of hemoglobin, anemia, mechanisms of coagulation, blood grouping, Rh factors, transfusion, its significance and disorders of blood, Reticulo endothelial system.

**Lymphatic system**

Lymphatic organs and tissues, lymphatic vessels, lymph circulation and functions of lymphatic system

**UNIT – II****10 hours****Cardiovascular system**

Heart – anatomy of heart, blood circulation, blood vessels, structure and functions of artery, vein and capillaries, elements of conduction system of heart and heart beat, its regulation by autonomic nervous system, cardiac output, cardiac cycle. Regulation of blood pressure, pulse, electrocardiogram and disorders of heart.

**UNIT – III****06 hours****Digestive system**

Anatomy of GI Tract with special reference to anatomy and functions of stomach, (Acid production in the stomach, regulation of acid production through parasympathetic nervous system, pepsin role in protein digestion) small intestine and large intestine, anatomy and functions of salivary glands, pancreas and liver, movements of GIT, digestion and absorption of nutrients and disorders of GIT.

**Respiratory system**

Anatomy of respiratory system with special reference to anatomy of lungs, mechanism of respiration, regulation of respiration

**UNIT – IV****10 hours****Respiratory system**

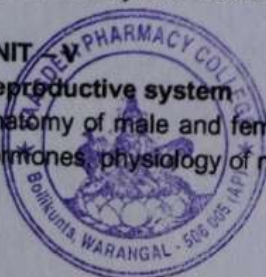
Lung Volumes and capacities transport of respiratory gases, artificial respiration, and resuscitation methods.

**Urinary system**

Anatomy of urinary tract with special reference to anatomy of kidney and nephrons, functions of kidney and urinary tract, physiology of urine formation, micturition reflex and role of kidneys in acid base balance, role of RAS in kidney and disorders of kidney.

**UNIT – V****09 hours****Reproductive system**

Anatomy of male and female reproductive system, Functions of male and female reproductive system, sex hormones, physiology of menstruation, fertilization, spermatogenesis, oogenesis, pregnancy and parturition



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**Introduction to genetics**

Chromosomes, genes and DNA, protein synthesis, genetic pattern of inheritance

**TEXT BOOKS: (Latest Editions)**

1. Essentials of Medical Physiology by K. Sembulingam and P. Sembulingam. Jaypeebrothers medical publishers, New Delhi.
2. Anatomy and Physiology in Health and Illness by Kathleen J.W. Wilson, Churchill Livingstone, New York
3. Physiological basis of Medical Practice-Best and Taylor. Williams & Wilkins Co, Riverview, MI USA
4. Text book of Medical Physiology- Arthur C. Guyton and John.E. Hall. Miamisburg, OH, U.S.A.
5. Principles of Anatomy and Physiology by Tortora Grabowski. Palmetto, GA, U.S.A.
6. Textbook of Human Histology by Inderbir Singh, Jaypeebrothers medical publishers, New Delhi.
7. Human Anatomy and Physiology-II by Singh Amteshwar Jaggi, Pharmamed Press

**REFERENCE BOOKS:**

1. Physiological basis of Medical Practice-Best and Taylor. Williams & Wilkins Co, Riverview, MI USA
2. Text book of Medical Physiology- Arthur C. Guyton and John. E. Hall. Miamisburg, OH, U.S.A.
3. Human Physiology (vol 1 and 2) by Dr. C.C. Chatterje, Academic Publishers Kolkata



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**PS202: PHARMACEUTICAL ORGANIC CHEMISTRY –I****B. Pharm. I Year II Sem**

L	T	P	C
4	1	0	4

**Scope:** This subject deals with classification and nomenclature of simple organic compounds, structural isomerism, intermediates forming in reactions, important physical properties, reactions and methods of preparation of these compounds. The syllabus also emphasizes on mechanisms and orientation of reactions.

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

- write the structure, name and the type of isomerism of the organic compound
- write the reaction, name the reaction and orientation of reactions
- account for reactivity/stability of compounds,
- identify/confirm the identification of organic compound

General methods of preparation and reactions of compounds superscripted with asterisk (\*) to be explained

To emphasize on definition, types, classification, principles/mechanisms, applications, examples and differences

**UNIT - I****07 Hours****Classification, nomenclature and isomerism**

Brief review of structural theory of organic chemistry, hybridization, bond length, bond angle, bond energy; inductive effect, electromeric effect, resonance, hyperconjugation and their application in the analysis of strength of organic acids, bases and stability of organic compounds; structure, shape and reactivity of nucleophiles, electrophiles and free radicals; cleavage of bonds-homolysis and heterolysis

**Classification of Organic Compounds:** Common and IUPAC systems of nomenclature of organic compounds (up to 10 Carbons open chain and carbocyclic compounds)

Structural isomerisms in organic compounds

**Types of organic reactions:** Addition reactions-electrophilic, nucleophilic and free radical; Substitution reactions-electrophilic, nucleophilic and free radical; elimination and rearrangement reactions

**UNIT – II****10 Hours****Alkanes\*, Alkenes\* and Conjugated dienes\***

Functional group approach for the following reactions (preparations & reactions) to be studied in context to their structure

**Alkanes:** Preparation: Catalytic hydrogenation, Wurtz reaction, Kolbe's synthesis, from Grignard reagent. Reactions: Free radical Substitution: Halogenation, Synthesis of cycloalkanes and different kinds of strains in cycloalkanes

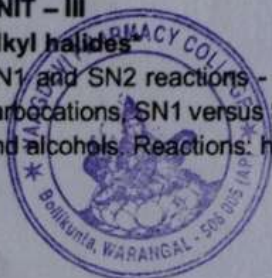
**Alkenes:** Preparation: Elimination reactions: Dehydration of alkenes and dehydrohalogenation of alkyl halides (Saytzeff's rule); cis alkenes (Partial catalytic hydrogenation) and trans alkenes (Birch reduction). Reactions: cis-addition (alk.  $\text{KMnO}_4$ ) and trans-addition (bromine), Addition of HX (Markownikoff's and anti-Markownikoff's addition), Hydration, Ozonolysis, oxymecuration-demercuration, Hydroboration-oxidation, stability of alkenes

**Conjugated dienes:** Stability, Diel-Alder, electrophilic addition, free radical addition reactions of conjugated dienes, allylic rearrangement

**Alkynes:** Preparation: Acetylene from  $\text{CaC}_2$  and conversion into higher alkynes; by dehalogenation of tetra halides and dehydrohalogenation of vicinal-dihalides. Reactions: formation of metal acetylides, addition of bromine and alkaline  $\text{KMnO}_4$ , ozonolysis and oxidation with hot alk.  $\text{KMnO}_4$

**UNIT – III****10 Hours****Alkyl halides**

**SN1 and SN2 reactions** – kinetics, order of reactivity of alkyl halides, stereochemistry and rearrangement of carbocations, SN1 versus SN2 reactions, Factors affecting SN1 and SN2 reactions, Preparation: from alkenes and alcohols. Reactions: hydrolysis, nitrite & nitro formation, nitrile & isonitrile formation.



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**Alcohols:** Preparation of alcohols: using Grignard reagent, Ester hydrolysis, Reduction of aldehydes, ketones, carboxylic acid and esters. Reactions: With sodium, HX (Lucas test), esterification, oxidation reactions.

**UNIT – IV****10 Hours****Carbonyl compounds\* (Aldehydes and ketones)**

Preparation: from acid chlorides and from nitriles. Reactions: Reaction with HCN, ROH, NaHSO<sub>3</sub>, NH<sub>2</sub>-G derivatives. Aldol Condensation, Cannizzaro's reaction, Wittig reaction, Benzoin condensation, Clemensen reduction and Wolff Kishner reduction, Meerwein-Ponndorf Verley reduction, Analysis of aldehydes and ketones: haloform test, 2,4-DNP test, Tollens and Fehling test.

**UNIT - V****08 Hours****Carboxylic acids\* (aliphatic and aromatic)**

Preparation and reactions of carboxylic acids.

Carboxylic acid derivatives (aliphatic): Preparation: Acid chlorides, Anhydrides, Esters and Amides from acids and their interconversion.

Acidity of carboxylic acids, effect of substituents on acidity, inductive effect and qualitative tests for carboxylic acids, amide and ester

**Aliphatic amines\* -**

Preparation: from alkyl halides, Gabriel's Phthalimide synthesis, Hofmann Bromamide reaction.

Reactions: Hofmann vs. Saytzeff elimination, Quaternary ammonium salts, Carbylamine test.

Basicity, effect of substituent on Basicity. Qualitative tests.

**TEXT BOOKS: (Latest Editions)**

1. Organic Chemistry by Morrison and Boyd
2. Organic Chemistry by I.L. Finar, Volume-I
3. Algarsamy V., Pharmaceutical organic Chemistry, Pharma Med Press
4. Textbook of Organic Chemistry by B.S. Bahl & Arun Bahl.
5. Organic Chemistry by P.L. Soni
6. Practical Organic Chemistry by Mann and Saunders.
7. Vogel's text book of Practical Organic Chemistry
8. Advanced Practical organic chemistry by N.K. Vishnoi.
9. Introduction to Organic Laboratory techniques by Pavia, Lampman and Kriz.
10. Pharmaceutical organic Chemistry-1, Pooja Chawla.
11. McMurry E. John, Organic Chemistry, Cengage



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**BS203: BIOCHEMISTRY****B. Pharm. I Year II Sem**

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**3 1 0 4**

**Scope:** Biochemistry deals with complete understanding of the molecular levels of the chemical process associated with living cells. The scope of the subject is providing biochemical facts and the principles to understand metabolism of nutrient molecules in physiological and pathological conditions. It is also emphasizing on genetic organization of mammalian genome and hetero & autocatalytic functions of DNA.

**Course Objectives:** Upon completion of course, student shall be able to

- Understand the catalytic role of enzymes, importance of enzyme inhibitors in design of new drugs, therapeutic and diagnostic applications of enzymes.
- Understand the metabolism of nutrient molecules in physiological and pathological conditions.
- Understand the genetic organization of mammalian genome and functions of DNA in the synthesis of RNAs and proteins.

**UNIT – I****10 Hours****Carbohydrate metabolism**

Glycolysis – Pathway, energetics and significance Citric acid cycle- Pathway, energetics and significance HMP shunt and its significance; Glucose-6-Phosphate dehydrogenase (G6PD) deficiency

Glycogen metabolism Pathways and glycogen storage diseases (GSD) Gluconeogenesis- Pathway and its significance

Hormonal regulation of blood glucose level and Diabetes mellitus

**Biological oxidation**

Electron transport chain (ETC) and its mechanism. Oxidative phosphorylation & its mechanism and substrate level phosphorylation, Inhibitors ETC and oxidative phosphorylation/Uncouplers

**UNIT – II****10 Hours****Lipid metabolism**

$\beta$ -Oxidation of saturated fatty acid (Palmitic acid)

Formation and utilization of ketone bodies; ketoacidosis De novo synthesis of fatty acids (Palmitic acid)

Biological significance of cholesterol and conversion of cholesterol into bile acids, steroid hormone and vitamin D

Disorders of lipid metabolism: Hypercholesterolemia, atherosclerosis, fatty liver and obesity.

**UNIT – III****10 Hours****Amino acid metabolism**

General reactions of amino acid metabolism: Transamination, deamination & decarboxylation, urea cycle and its disorders

Catabolism of phenylalanine and tyrosine and their metabolic disorders (Phenylketonuria, Albinism, alcaptonuria, tyrosinemia)

Synthesis and significance of biological substances; 5-HT, melatonin, dopamine, noradrenaline, adrenaline

Catabolism of heme; hyperbilirubinemia and jaundice

**UNIT – IV****08 Hours**

**Nucleic acid metabolism and genetic information transfer** Biosynthesis of purine and pyrimidine nucleotides

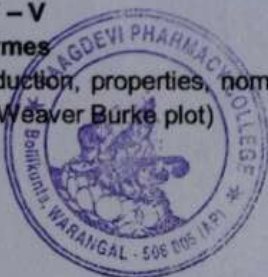
Catabolism of purine nucleotides and Hyperuricemia and Gout disease Organization of mammalian genome

Structure of DNA and RNA and their functions DNA replication (semi conservative model) Transcription or RNA synthesis

Genetic code, Translation or Protein synthesis and inhibitors

**UNIT – V****07 Hours****Enzymes**

Introduction, properties, nomenclature, and IUB classification of enzymes Enzyme kinetics (Michaelis plot, Line Weaver Burke plot)



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Enzyme inhibitors with examples

Regulation of enzymes: enzyme induction and repression, allosteric enzymes regulation

Therapeutic and diagnostic applications of enzymes and isoenzymes Coenzymes –Structure and biochemical functions

**TEXT BOOKS: (Latest Editions)**

1. Principles of Biochemistry by Lehninger
2. Algarsamy V. Pharmaceutical Biochemistry, Pharma Med Press.
3. Harper's Biochemistry by Robert K. Murry, Daryl K. Granner and Victor W. Rodwell.
4. Biochemistry by Stryer.
5. Biochemistry by D. Satyanarayan and U. Chakrapani
6. Textbook of Biochemistry by Rama Rao.
7. Textbook of Biochemistry by Deb.
8. Outlines of Biochemistry by Conn and Stumpf
9. Introduction of Practical Biochemistry by David T. Plummer. (3rd Edition)



  
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**BS204: PATHOPHYSIOLOGY****B. Pharm. I Year II Sem**

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<b>3</b>	<b>1</b>	<b>0</b>	<b>4</b>

**Scope:** Pathophysiology is the study of causes of diseases and reactions of the body to such disease producing causes. This course is designed to impart a thorough knowledge of the relevant aspects of pathology of various conditions with reference to its pharmacological applications, and understanding of basic pathophysiological mechanisms. Hence it will not only help to study the syllabus of pathology, but also to get baseline knowledge required to practice medicine safely, confidently, rationally and effectively.

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

- Describe the etiology and pathogenesis of the selected disease states;
- Name the signs and symptoms of the diseases; and
- Mention the complications of the diseases.

**UNIT – I****10 Hours****Basic principles of Cell injury and Adaptation:**

Introduction, definitions, Homeostasis, Components and Types of Feedback systems, causes of cellular injury, Pathogenesis (Cell membrane damage, Mitochondrial damage, Ribosome damage, Nuclear damage), Morphology of cell injury – Adaptive changes (Atrophy, Hypertrophy, hyperplasia, Metaplasia, Dysplasia), Cell swelling, Intra cellular accumulation, Calcification, Enzyme leakage and Cell Death Acidosis & Alkalosis, Electrolyte imbalance

**Basic mechanism involved in the process of inflammation and repair:**

Introduction, Clinical signs of inflammation, Different types of Inflammation, Mechanism of Inflammation – Alteration in vascular permeability and blood flow, migration of WBC's, Mediators of inflammation, Basic principles of wound healing in the skin, Pathophysiology of Atherosclerosis

**UNIT – II****10 Hours****Cardiovascular System:**

Hypertension, congestive heart failure, ischemic heart disease (angina, myocardial infarction, atherosclerosis, and arteriosclerosis)

**Respiratory system:** Asthma, Chronic obstructive airways diseases.

**Renal system:** Acute and chronic renal failure

**UNIT - III****10 Hours****Haematological Diseases:**

Iron deficiency, megaloblastic anemia (Vit B12 and folic acid), sickle cell anemia, thalasemia, hereditary acquired anemia, hemophilia

**Endocrine system:** Diabetes, thyroid diseases, disorders of sex hormones

**Nervous system:** Epilepsy, Parkinson's disease, stroke, psychiatric disorders: depression, schizophrenia and Alzheimer's disease.

**Gastrointestinal system:** Peptic Ulcer

**UNIT – IV****8 Hours**

Inflammatory bowel diseases, jaundice, hepatitis (A,B,C,D,E,F) alcoholic liver disease.

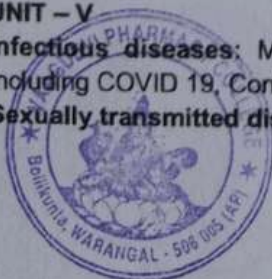
**Disease of bones and joints:** Rheumatoid arthritis, osteoporosis, and gout

**Principles of cancer:** classification, etiology and pathogenesis of cancer

**UNIT – V****7 Hours**

**Infectious diseases:** Meningitis, Typhoid, Leprosy, Tuberculosis, Urinary tract infections, SARS virus including COVID 19, Conjunctivitis, Measles

**Sexually transmitted diseases:** AIDS, Syphilis, Gonorrhoea



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**TEXT BOOKS: (Latest Editions)**

1. Vinay Kumar, Abul K. Abas, Jon C. Aster; Robbins & Cotran Pathologic Basis of Disease; South Asia edition; India; Elsevier, 2014.
2. Harsh Mohan; Text book of Pathology; 6<sup>th</sup> edition; India; Jaypee Publications; 2010.
3. Laurence B, Bruce C, Bjorn K.; Goodman Gilman's The Pharmacological Basis of Therapeutics; 12<sup>th</sup> edition; New York; McGraw-Hill; 2011.
4. Sujesh M., Pathophysiology for Pharmacy - A Concise Review, Pharma Med Press
5. Best, Charles Herbert 1899-1978; Taylor, Norman Burke 1885-1972; West, John B (John Burnard); Best and Taylor's Physiological basis of medical practice; 12th ed; united states;
6. William and Wilkins, Baltimore; 1991 [1990 printing].
7. Nicki R. Colledge, Brian R. Walker, Stuart H. Ralston; Davidson's Principles and Practice of Medicine; 21<sup>st</sup> edition; London; ELBS/Churchill Livingstone; 2010.
8. Guyton A, John. E Hall; Textbook of Medical Physiology; 12<sup>th</sup> edition; WB Saunders Company; 2010.
9. Joseph DiPiro, Robert L. Talbert, Gary Yee, Barbara Wells, L. Michael Posey; Pharmacotherapy: A Pathophysiological Approach; 9<sup>th</sup> edition; London; McGraw-Hill Medical; 2014.
10. V. Kumar, R. S. Cotran and S. L. Robbins; Basic Pathology; 6<sup>th</sup> edition; Philadelphia; WB Saunders Company; 1997.
11. Roger Walker, Clive Edwards; Clinical Pharmacy and Therapeutics; 3<sup>rd</sup> edition; London; Churchill Livingstone publication; 2003.



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**CS205: COMPUTER APPLICATIONS IN PHARMACY****B. Pharm. I Year II Sem**

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**Scope:** This subject deals with the introduction Database, Database Management system, computer application in clinical studies and use of databases.

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

- know the various types of application of computers in pharmacy
- know the various types of databases
- know the various applications of databases in pharmacy

**UNIT – I****06 hours**

**Number system:** Binary number system, Decimal number system, Octal number system, Hexadecimal number systems, conversion decimal to binary, binary to decimal, octal to binary etc, binary addition, binary subtraction – One's complement, Two's complement method, binary multiplication, binary division

**Concept of Information Systems and Software:** Information gathering, requirement and feasibility analysis, data flow diagrams, process specifications, input/output design, process life cycle, planning and managing the project

**UNIT –II****06 Hours**

**Web technologies:** Introduction to HTML, XML, CSS and Programming languages, introduction to web servers and Server Products

Introduction to databases, MYSQL, MS ACCESS, Pharmacy Drug database

**UNIT – III****06 Hours**

**Application of computers in Pharmacy** –Drug information storage and retrieval, Pharmacokinetics, Mathematical model in Drug design, Hospital and Clinical Pharmacy, Electronic Prescribing and discharge (EP) systems, barcode medicine identification and automated dispensing of drugs, mobile technology, and adherence monitoring

Diagnostic System, Lab-diagnostic System, Patient Monitoring System, Pharma Information System

**UNIT – IV****06 hours**

**Bioinformatics:** Introduction, Objective of Bioinformatics, Bioinformatics Databases, Concept of Bioinformatics, Impact of Bioinformatics in Vaccine Discovery

**UNIT-V****06 hours**

**Computers as data analysis in Preclinical development:** Chromatographic data analysis (CDS), Laboratory Information management System (LIMS) and Text Information Management System (TIMS)

**TEXT BOOKS: (Latest edition):**

1. Computer Application in Pharmacy – William E. Fassett –Lea and Febiger, 600 South Washington Square, USA, (215) 922-1330.
2. Computer Application in Pharmaceutical Research and Development –Sean Ekins – Wiley-Interscience, A John Willey and Sons, INC., Publication, USA
3. Bioinformatics (Concept, Skills and Applications) – S.C. Rastogi-CBS Publishers and Distributors, 4596/1- A, 11 Darya Gani, New Delhi – 110 002(INDIA)
4. Microsoft office Access - 2003, Application Development Using VBA, SQL Server, DAP and Infopath – Cary N. Prague – Wiley Dreamtech India (P) Ltd., 4435/7, Ansari Road, Daryagani, New Delhi – 110002
5. Monidhin S, D. Computer Applications in Pharmaceutical Sciences, Pharma Med Press.



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**PS206: HUMAN ANATOMY AND PHYSIOLOGY –II LAB****B. Pharm. I Year II Sem****L T P C**  
**0 0 4 2**

Practical physiology is complimentary to the theoretical discussions in physiology. Practicals allow the verification of physiological processes discussed in theory classes through experiments on living tissue, intact animals or normal human beings. This is helpful for developing an insight on the subject.

**List of Experiments:**

1. Introduction to hemocytometry.
2. Enumeration of white blood cell (WBC) count
3. Enumeration of total red blood corpuscles (RBC) count
4. Determination of bleeding time
5. Determination of clotting time
6. Estimation of hemoglobin content
7. Determination of blood group.
8. Determination of erythrocyte sedimentation rate (ESR).
9. Determination of heart rate and pulse rate.
10. Recording of blood pressure.
11. Determination of tidal volume and vital capacity.
12. Study of digestive, respiratory, cardiovascular systems, urinary and reproductive systems with the help of models, charts and specimens.
13. Recording of basal mass index .
14. Study of family planning devices and pregnancy diagnosis test.
15. Demonstration of total blood count by cell analyser
16. Permanent slides of vital organs and gonads.

**REFERENCE BOOKS:**

1. Textbook of Practical Physiology by C.L. Ghai, Jaypee brothers medical publishers, New Delhi.
2. Practical workbook of Human Physiology by K. Srinageswari and Rajeev Sharma, Jaypee brother's medical publishers, New Delhi.



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## PS207: PHARMACEUTICAL ORGANIC CHEMISTRY -I LAB

B. Pharm. I Year II Sem

L T P C  
0 0 4 2**List of Experiments:**

- a) Systematic qualitative analysis of unknown organic compounds like
1. Preliminary test: Color, odour, aliphatic/aromatic compounds, saturation and unsaturation, etc.
  2. Detection of elements like Nitrogen, Sulphur and Halogen by Lassaigne's test
  3. Solubility test
  4. Functional group test like Phenols, Amides/ Urea, Carbohydrates, Amines, Carboxylic acids, Aldehydes and Ketones, Alcohols, Esters, Aromatic and Halogenated Hydrocarbons, Nitro compounds and Anilides.
  5. Melting point/Boiling point of organic compounds
  6. Identification of the unknown compound from the literature using melting point/ boiling point.
  7. Preparation of the derivatives and confirmation of the unknown compound by melting point/ boiling point.
  8. Minimum 5 unknown organic compounds to be analysed systematically.
- b) Preparation of suitable solid derivatives from organic compounds
- c) Construction of molecular models

**RECOMMENDED BOOKS (Latest Editions)**

1. Practical Organic Chemistry by Mann and Saunders.
2. Advanced Practical organic chemistry by N.K. Vishnoi.



  
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**BS208: BIOCHEMISTRY LAB****B. Pharm. I Year II Sem****L T P C**  
**0 0 4 2****List of Experiments:**

1. Qualitative analysis of carbohydrates (Glucose, Fructose, Lactose, Maltose, Sucrose and starch)
2. Identification tests for Proteins (albumin and Casein)
3. Quantitative analysis of reducing sugars (DNSA method) and Proteins (Biuret method)
4. Qualitative analysis of urine for abnormal constituents
5. Determination of blood creatinine
6. Determination of blood sugar
7. Determination of serum total cholesterol
8. Preparation of buffer solution and measurement of pH
9. Study of enzymatic hydrolysis of starch
10. Determination of Salivary amylase activity
11. Study the effect of Temperature on Salivary amylase activity.
12. Study the effect of substrate concentration on salivary amylase activity.

**RECOMMENDED BOOKS (Latest Editions)**

- 1) Biochemistry: A Practical Manual, Bose Sharad Chandra
- 2) Practical Biochemistry by R.C. Gupta and S. Bhargavan.
- 3) Practical Biochemistry for Medical students by Rajagopal and Ramakrishna.
- 4) Practical Biochemistry by Harold Varley.



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**CS209: COMPUTER APPLICATIONS IN PHARMACY LAB****B. Pharm. I Year II Sem****L T P C**  
**0 0 2 1****List of Experiments:**

1. Design a questionnaire using a word processing package to gather information about a particular disease.
2. Create a HTML web page to show personal information.
3. Retrieve the information of a drug and its adverse effects using online tools
4. Creating mailing labels Using Label Wizard, generating label in MS WORD
5. Create a database in MS Access to store the patient information with the required fields Using access
6. Design a form in MS Access to view, add, delete and modify the patient record in the database
7. Generating report and printing the report from patient database
8. Creating invoice table using – MS Access
9. Drug information storage and retrieval using MS Access
10. Creating and working with queries in MS Access
11. Exporting Tables, Queries, Forms and Reports to web pages
12. Exporting Tables, Queries, Forms and Reports to XML pages



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