

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD
M.PHARMACY (INDUSTRIAL PHARMACY)
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	Advanced Physical Pharmaceutics	3	1	0	4
Professional Core-II	Pharmaceutical Formulation Development	3	1	0	4
Professional Elective-I	1. Applied Biopharmaceutics and Pharmacokinetics 2. Drug Regulatory Affairs 3. Pharmaceutical Management	3	1	0	4
Professional Elective-II	1. Pharmaceutical Validation 2. Herbal Cosmetics Technology 3. Stability of Drugs and Dosage Forms	3	1	0	4
	Research methodology and IPR	2	0	0	2
Laboratory- I	Advanced Physical Pharmaceutics Lab	0	0	6	3
Laboratory- II	Pharmaceutical Formulation Development Lab	0	0	6	3
Audit - I	Audit Course - I	2	0	0	0
	Seminar & Assignment	0	0	4	2
	Total	16	4	16	26

I YEAR II Semester

Course Code	Course Title	L	T	P	Credits
Professional Core-III	Advanced Drug Delivery Systems	3	1	0	4
Professional Core-IV	Pharmaceutical Production Technology	3	1	0	4
Professional Elective-III	1. Nano Based Drug Delivery Systems 2. Nutraceuticals 3. Pharmaceutical Industrial Management	3	1	0	4
Professional Elective-IV	1. Quality by Design of Dosage Forms 2. Total Quality Management 3. Clinical Research and Pharmacovigilance	3	1	0	4
Laboratory- III	Advanced Drug Delivery System Lab	0	0	6	3
Laboratory- IV	Pharmaceutical Production Technology 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
	Total	16	4	16	26

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
	Total	6	2	32	24

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
	Total	0	0	44	22

***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

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

ADVANCED PHYSICAL PHARMACEUTICS (Professional Core– I)

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

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

UNIT I

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

UNIT II

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

UNIT III

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

UNIT IV

Visco elasticity: 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, co solvents, Complexation, drug derivatization 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, 4th Edition by Alfred Martin.
2. Theory and Practice of Tablets – Lachman, Vol.4

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

REFERENCE BOOKS

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

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

PHARMACEUTICAL FORMULATION DEVELOPMENT (Professional Core – II)

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

Course Outcomes:

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

UNIT I

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

UNIT II

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

UNIT III

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

UNIT IV

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

UNIT V

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

TEXT BOOKS

1. Pharmaceutics - The Science of Dosage form design by ME Aulton.
2. Pharmaceutical Dosage forms - Tablets (Vol I, II and III) by Lieberman, Lachman and Schwartz.

3. Pharmaceutical Dosage forms - Capsules (Vol I, II and III) by Avis, Lieberman and Lachman.
4. Pharmaceutical Dosage forms – Disperse systems (Vol I, II and III) by Avis, Lieberman and Lachman.
5. Modern Pharmaceutics by Gilbert S. Banker and Christopher T. Rhodes.
6. Hand book of Pharmaceutical excipients
7. CVS Subhramanyam& J Thimmasethy, Industrial Pharmacy, Vallabh Prakasham, Delhi, 2014

REFERENCE BOOKS:

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

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

APPLIED BIOPHARMACEUTICS AND PHARMACOKINETICS (Professional Elective – I)

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

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

UNIT I

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

UNIT II

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

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

UNIT III

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

UNIT IV

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

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

UNIT V

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

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

❖ Numerical problems associated with all units, if any.

TEXT BOOKS

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

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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M.Pharm I Year I Sem (Industrial Pharmacy)

DRUG REGULATORY AFFAIRS (Professional Elective-I)

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

Course Outcomes:

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

UNIT I

Drug Regulatory Aspects (India)

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

UNIT II

Good Manufacturing Practices (GMP)

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

UNIT III

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

UNIT IV

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

UNIT V

Governing Regulatory Bodies across the globe.

Country Authority Submission

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

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

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

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

TEXT AND REFERENCE BOOKS

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

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PHARMACEUTICAL MANAGEMENT (Professional Elective – I)

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

Course Outcomes:

- These topics are useful for the students to know how to manage a pharma industry and its various departments viz QA, QC, RA, Production etc.
- Along with this it aids the students to develop leadership qualities, communication & interpersonal skills, decisions making, motivation, organization & various managerial functions & professional skills required for a dynamic professional.
- Management helps to understand the concept of managerial control, its levels & role, importance in pharma industry.

UNIT I

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

UNIT II

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

UNIT III

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

UNIT IV

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

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

UNIT V

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

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

TEXT AND REFERENCE BOOKS

1. Marketing Management by Philip Kotlar; Prentice-Hall of India Ltd., New Delhi.0
2. Management and Organization by Louis A. Allen; McGraw Hill, Tokyo.

3. Corporate Strategy by Ansoff, H.T.; McGraw Hill, New York.
4. Modern Management by Hempran David R.; McGraw Hill, New York.
5. Management by Stoner and Freeman; Prentice Hall, New Delhi.
6. Motivation and Personality by Maslow, Abraham, Harper & Row, New York.
7. Management of Organizational Behavior, Utilizing the Human Resources by Harcey, Paul and Blanchard Kenneth; Prentice Hall of India, New Delhi
8. Organization Structure, Process and out comes Vth Edition Richard. H. Hall
9. Principles and Methods of Pharmacy Management III rd Edition Harry A. Smith.
10. Management "Global Perspective Heinz Weihrich, Harold Koontz by Tata Mcgraw Hill".
11. Personnel Management and Industrial Relations by P. C. Tripathi.

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PHARMACEUTICAL VALIDATION (Professional Elective – II)

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

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

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

UNIT I

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

Qualification: User Requirement Specification, Design Qualification, Factory Acceptance Test (FAT)/ Site Acceptance Test (SAT), Installation Qualification, Operational Qualification, Performance Qualification, Re- Qualification (Maintaining status-Calibration Preventive Maintenance, Change management), Qualification of Manufacturing 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 and Validation, validation of analytical method used in cleaning. Cleaning of Equipment. Cleaning of Facilities. Cleaning in place (CIP).

UNIT V

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

REFERENCES:

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

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

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M.Pharm I Year I Sem (Industrial Pharmacy)

HERBAL COSMETIC TECHNOLOGY (Professional Elective - II)

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

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

UNIT I

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

UNIT II

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

UNIT III

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

UNIT IV

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

UNIT IV

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

REFERENCES:

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

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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.

REFERENCE BOOKS:

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

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

RESEARCH METHODOLOGY AND IPR

Course Objectives:

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

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

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

UNIT-I:

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

UNIT-II:

Effective literature studies approaches, analysis, Plagiarism, Research ethics

UNIT-III:

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

UNIT-IV:

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

UNIT-V:

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

TEXT BOOKS:

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

REFERENCES:

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

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

ADVANCED PHYSICAL PHARMACEUTICS LAB (Laboratory- I)

List of experiments

1. Study of Effect of process parameters on Disintegration time & Dissolution during compression of tablets.
2. Determinates of molecular weight of some selected polymers.
3. Preparation and evaluation of solid dispersions (Immediate release and sustained release)
4. Accelerated stability testing of Aspirin Tablets
5. Stability evaluation of Aspirin at various pH and temperature conditions
6. Determination of 1st order and 2nd order rate constant. Half life by Acid / Alkali hydrolysis
7. Generation of dissolution profiles of few dosage forms and application of the data into various kinetic equations. Calculation of Hixon-crowell dissolution rate constant
8. Preparation and dissolution study of paracetamol tablets and comparison with the marketed product.
9. Study of solubility and dissolution for few drugs and their respective salts.
10. Study of solubility enhancement of Poorly soluble drugs using following techniques
a. Surfactants b. Co solvents c. Complexing Agents
11. Study of Rheological properties of Pharmaceutical Liquids and semi solids using Brookfield Viscometer
12. Study of drug excipient compatibility using DSC Thermo Grams using Published data

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

PHARMACEUTICAL FORMULATION DEVELOPMENT LAB (Laboratory- II)

List of Experiments

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

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

ADVANCED DRUG DELIVERY SYSTEMS (Professional Core- III)

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 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 by Y. Madhusudan Rao, A.V. Jithan
7. Oral Drug Delivery Technology, 2nd ed, by AukunuruJithan

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

PHARMACEUTICAL PRODUCTION TECHNOLOGY (Professional Core - IV)

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

Course Outcomes: Students will know about the scale up and pilot plant techniques used for all pharmaceutical dosage forms like 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 labeling & Q.C. of anti ageing products, sun screen lotion and fairness creams.
- b. **Nutraceuticals:**
 1. Introduction, source, manufacture and analysis of glucosamine and cartinine.
 2. Monographs: General and specific properties of glucosamine & cartinine.
 3. A brief overview of role of nutraceuticals in cancer prevention & cardio vascular disorders.

UNIT - V

Aseptic processing operation

- 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.

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

REFERENCEBOOKS:

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

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

NANO BASED DRUG DELIVERY SYSTEMS (Professional Elective - III)

Course Objectives - 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

- a) 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

RECOMMENDED 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: Nanoplatforms 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 chemistry:A Classical Approach to Nanomaterials – Royal Society for Chemistry, Cambridge, UK (2005)
7. Nanocomposite science and technology, pulickel M.Ajayan, Linda S. Schadler, paul V. Braun, Wiley-VCH Verlag, Weiheim (2003)
8. Nanoscale materials in chemistry, Edited by Kenneth J.Klabunde, John Wiley & Sons,2009
9. Nanoparticles as Drug carriers, Vladimir P Torchiling, Imperial College Press, USA, 2006
10. Introduction to Nano Science and Technologies, Ankaneyulu Yerramilli, BS Publications. 2016

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

NUTRACEUTICALS (Professional Elective - III)

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- α and β -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, Geobustan, 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, α - 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

REFERENCES:

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 2nd 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

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

PHARMACEUTICAL INDUSTRIAL MANAGEMENT (Professional Elective - III)

Course Objective: This particular study of the course aimed at achieving, enabling the student effectively manage a given organization in planning, hiring, personnel, selection training and other infrastructures maintenance apart from design, lay-out and handling of the equipment.

Course Outcomes: This subject aims at validation of different process, equipment methods and effective management of waste materials.

UNIT - I

Human Resource management: Human resource planning, job analysis and design, recruitment, Personnel selection, orientation and placement, training and development, supervision, performance appraisal key result area and key performance area remuneration and salaries, Compensation and incentives, industrial relations, motivation.

UNIT - II

Entrepreneurship and Project Management - Quality Assurance Management: Total quality management, Organization and personnel, responsibilities, training, hygiene Premises: Location, design, layout, construction, maintenance, and sanitations, environmental control, sterile areas, control contamination, Equipments procedure and documentation for selection, purchase, specification, installation and maintenance, clean in place, sterilization in place.,

UNIT - III

Production management: Production organization, objectives and policies of good manufacturing practices, layout of buildings, services, equipments and their maintenance, materials management, handling and transportation, inventory management and control, production planning and control, selection of vendors, purchase cycle, sales forecasting, budget and cost control.

UNIT - IV

Process validation: General Principles of Validation, Regulatory basis, validation of pharmaceutical equipment and processes, validation of analytical methods.

UNIT - V

Industrial Hazards and Pollution Management: Chemical hazards, gas hazards, fire and explosion hazards, safety management. Water pollution, water Pollution abatement and effluent treatment, Air Pollution, air Pollution Control Devices. Solid waste, Solid Waste Management, Noise Pollution, Noise Abatement, Effluent Analysis and Treatment-Methods, Effluent Treatment in Formulation Plants, Effluent Treatment in Synthetic Drugs Industry, Effluent Treatment in Fermentation Industry, Introduction of Echo Pharmacovigilance.

TEXT BOOKS:

1. Unit operations of Chemical Engineering by Warren L. McCabe, Julian C. Smith, Peter Harriott.
2. The Theory and Practice of industrial Pharmacy by Leon Lachman, Herbert A. Lieberman.
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.

REFERENCEBOOKS:

1. Remington's Science and Practice of Pharmacy by A. Gennaro.
2. Bentley's Text book of Pharmaceutics by EA Rawlins.

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

QUALITY BY DESIGN OF DOSAGE FORMS (Professional Elective-IV)

Course Objectives: The objective of Quality by Design is a modern, approach that formalizes product design, automates manual testing and streamlines trouble shooting. It uses a systemic approach to ensure quality by developing a thorough understanding of the compatibility of a finished product to all the components and processes involved in manufacturing that product.

Course Outcome: This subject aims at

- More efficient use of development time and costs
- Ability to meet FDA Submission Guidelines and expectations
- Reduced approval times and fewer queries

UNIT-I

Overview of QbD

Introduction, history of QbD, Regulatory aspects of QbD, Pharmaceutical quality by testing, Elements of QbD, benefits of QbD and current state of QbD.

UNIT-II

Aspects of QbD to product development:

Introduction, Quality Target Product Profile (QTPP), Critical Quality Attributes (CQAs), Critical process parameters, risk assessment, design space, control strategy, product lifecycle management and continual improvement.

UNIT-III

DOE, PAT and RTRT:

Design of Experiment (DOE), Process Analytical Techniques (PAT), Real Time Release Testing (RTRT).

UNIT-IV

Implementation of QbD in product development (case studies):

Introduction, Implementation of QbD in tablet formulation, implementation of QbD in pellet formulation.

UNIT-V

Implementation of QbD in product development (case studies):

Implementation of QbD in emulsion formulation, Implementation of QbD in powder formulation and Implementation of QbD in Liposomes formulation.

REFERENCES:

1. Introduction to Quality by Design for Pharmaceuticals by Nilesh Desai and Manohar A. Potdar
2. Quality by Design (QbD): A new concept for Development of quality Pharmaceuticals by Patil.A.S. and Pethe

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TOTAL QUALITY MANAGEMENT (Professional Elective-IV)

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

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

UNIT - I

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

UNIT – II

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

UNIT - III

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

UNIT - IV

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

UNIT - V

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

TEXT AND REFERENCE BOOKS:

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

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

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

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, 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.

REFERENCES:

1. Central Drugs Standard Control Organization- Good Clinical Practices, Guidelines for Clinical Trials on Pharmaceutical Products in India. New Delhi: Ministry of Health;2001.
2. International Conference on Harmonization of Technical requirements for registration of Pharmaceuticals for human use. ICH Harmonized Tripartite Guideline. Guideline for Good Clinical Practice.E6; May 1996.230
3. Ethical Guidelines for Biomedical Research on Human Subjects 2000.Indian Council of Medical Research, New Delhi.
4. Textbook of Clinical Trials edited by David Machin, Simon Day and Sylvan Green, March 2005, John Wiley and Sons.
5. Clinical Data Management edited by R K Rondels, S A Varley, C F Webbs. Second Edition, Jan 2000, Wiley Publications.
6. Handbook of clinical Research. Julia Lloyd and Ann Raven Ed. Churchill Livingstone.
7. Principles of Clinical Research edited by Giovanna di Ignazio, Di Giovanna and Haynes.
8. Textbook of Pharmacovigilance: Concept and Practice. G.P. Mohanta and P. K. Manna. 2016, PharmaMed Press.
9. A textbook of Clinical Pharmacy Practice: Essential Concepts and Skills. Second Edition, 2012, University Press

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ADVANCED DRUG DELIVERY SYSTEMS LAB (Laboratory – III)

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 mucoadhesive system (2 experiments)
8. Preparation and evaluation enteric coated pellets / tablets. (2 experiments)

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PHARMACEUTICAL PRODUCTION TECHNOLOGY LAB (Laboratory – IV)

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

7. Evaluation of test sterility for commercial preparations including sterile water for injection and antibiotic injection.
8. Collecting samples of environment of aseptic room and counting the colonies
9. Comparative evaluation of different marketed products (tablets) of the same API
10. Dissolution studies of drug in three different bio relevant dissolution media
11. Stability study testing of tablet dosage forms (Any two products)

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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, Poison 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.

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

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.

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 Wiloy.
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.

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

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.

References:

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 York, USA.
6. Wilmer A. Jenkins, Kenton R. Osborn. Packaging drugs and pharmaceuticals.
7. Remington: The Science and Practice of Pharmacy. 8. Michael E. Aulton, Kevin Tylor

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

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

Prerequisite: None

Course objectives: Students will be able to:

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

UNIT-I:

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

UNIT-II:

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

UNIT-III:

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

UNIT-IV:

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

UNIT-V:

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

TEXT BOOKS/ REFERENCES:

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

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

DISASTER MANAGEMENT (Audit Course - I & II)

Prerequisite: None

Course Objectives: Students will be able to

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

UNIT-I:

Introduction:

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

Disaster Prone Areas in India:

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

UNIT-II:

Repercussions of Disasters and Hazards:

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

UNIT-III:

Disaster Preparedness and Management:

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

UNIT-IV:

Risk Assessment Disaster Risk:

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

UNIT-V:

Disaster Mitigation:

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

TEXT BOOKS/ REFERENCES:

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

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

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

Prerequisite: None

Course Objectives:

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

Course Outcomes: Students will be able to

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

UNIT-I:

Alphabets in Sanskrit,

UNIT-II:

Past/Present/Future Tense, Simple Sentences

UNIT-III:

Order, Introduction of roots,

UNIT-IV:

Technical information about Sanskrit Literature

UNIT-V:

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

TEXT BOOKS/ REFERENCES:

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

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

VALUE EDUCATION (Audit Course - I & II)

Prerequisite: None

Course Objectives: Students will be able to

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

Course outcomes: Students will be able to

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

UNIT-I:

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

UNIT-II:

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

UNIT-III:

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

UNIT-IV:

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

UNIT-V:

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

TEXT BOOKS/ REFERENCES:

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

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

CONSTITUTION OF INDIA (Audit Course - I & II)

Prerequisite: None

Course Objectives: Students will be able to:

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

Course Outcomes: Students will be able to:

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

UNIT-I:

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

UNIT-II:

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

UNIT-III:

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

UNIT-IV:

Local Administration: District's Administration head: Role and Importance, Municipalities: Introduction, Mayor and role of Elected Representative, CEO of Municipal Corporation. 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.

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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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 Pedagogical strategies.

UNIT-IV:

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

UNIT-V:

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

TEXT BOOKS/ REFERENCES:

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

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

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

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

Prerequisite: None

Course Objectives:

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

Course Outcomes: Students will be able to:

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

UNIT-I:

Definitions of Eight parts of yog. (Ashtanga)

UNIT-II:

Yam and Niyam.

UNIT-III:

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

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

UNIT-IV:

Asan and Pranayam

UNIT-V:

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

TEXT BOOKS/ REFERENCES:

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

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

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

Prerequisite: None

Course Objectives:

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

Course Outcomes: Students will be able to

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

UNIT-I:

Neetisatakam-Holistic development of personality

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

UNIT-II:

Neetisatakam-Holistic development of personality

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

UNIT-III:

Approach to day to day work and duties.

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

UNIT-IV:

Statements of basic knowledge.

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

UNIT-V:

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

TEXT BOOKS/ REFERENCES:

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