# Course Structure and Syllabus

**Jawaharlal Nehru Technological University Hyderabad**<br>**M. Pharmacy (Pharmaceutics / Pharmaceutical Technology)**

## I Year – II Semester

<table>
<thead>
<tr>
<th>Category</th>
<th>Course Title</th>
<th>Intern. marks</th>
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<tr>
<td>Core Course IV</td>
<td>Advanced Drug Delivery Systems</td>
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<td>Core Course V</td>
<td>Industrial Pharmacy</td>
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<td>Core Course VI</td>
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<td>Core Elective II</td>
<td>1. Biostatistics And Research Methodology</td>
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<td>2. Screening Methods &amp; Clinical Research</td>
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<td>Open Elective II</td>
<td>1. Stability of Drugs and Dosage Forms</td>
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<td>2. Nano Based Drug Delivery Systems</td>
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<td>3. Nutraceuticals</td>
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<td>4. Pharmaceutical Management-II</td>
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<td>Laboratory III</td>
<td>Advanced Drug Delivery Systems Lab</td>
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<td>Laboratory IV</td>
<td>Advanced Pharmaceutical Technology Lab</td>
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<td>Seminar II</td>
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<td><strong>Total Credits</strong></td>
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Objective: 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.

UNIT 1
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 neoplasams

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

Text Books
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
INDUSTRIAL PHARMACY

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.

UNIT I
Pharmaceutical unit operations: A detailed study involving machinery and theory of Pharmaceutical unit operations like milling, mixing, filtration, and drying.

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 of analytical methods, and process, in solid dosage forms, sterile products, and liquid dosage forms.

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.

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.

Recommended Text 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.
4. CGMP, H.P.P. Sharma
ADVANCED PHARMACEUTICAL TECHNOLOGY-II

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.

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, sterilizers, 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
b. Nutraceuticals:
   1. Introduction, source, manufacture and analysis of glucosamine and cartinine.

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.

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.

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.
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

Recommended Books
1. Bentley’s Text Book of Pharmaceutics by EA Rawlins.
3. Dispensing for Pharmaceutical Students by SJ Carter.
6. Industrial Pharmacy - Selected Topics, CVS Subramanyam and J Thimmasetty, VallabhaPrakashan Delhi - 2013
Objective: The student shall know the introduction, scope of biostatistics and Research work, calculation and present of the data. It also informs the students, how the present research work writing and correlating.

UNIT I

UNIT II
Measures of central tendency: computation of means, median and mode from grouped and ungrouped data.
Measure of dispersion: computation of variance, standard deviation, standard error and their coefficients.

UNIT III
Measures of Correlation and Regression: Experimental designing, planning of an experiment, replication and randomization. Probit analysis.
Probability rules: Binomial, Poison and Normal distribution.
Hypothesis testing: Student’s test, Chi square test, Analysis of Variance (ANOVA): 1-way, 2-way, 3-ways

UNIT IV
Developing a research question, Resources for research question, Literature Review: Traditional Qualitative Review, Meta-Analysis—A Quantitative Review
Preparation of Research Proposal
Variables—Definition of Variable, Types of variables (Dependent and Independent variables, Confounded variables), Measurement of variables, Types of measurement scales and their comparison. Reliability and Validity of Measurements.

UNIT V
The research report paper writing/ thesis writing
Different parts of the research paper
1. Title-Title of project with authors’ name
2. Abstract – Statement of the problem, Background list in brief and purpose and scope
3. Key words
4. Methodology- subject, apparatus, instrumentation and procedure
5. Results – tables, graphs figure and statistical presentation
6. Discussion support or non-support of hypothesis, practical and theoretical implications
7. Conclusion
8. Acknowledgements
9. References
10. Errata
11. Importance of Spell check for entire projects
12. Uses of footnotes

Outcome: The student will be known the Biostatistics arrangement, presentation and formation of tables and charts. They also know the correlation and regression & application of different methods, analysis of data and also learn how to write dissertation, thesis and Research paper
Text Books
1. Deepak Chawla Neena Sondhi, Research Methodology Concepts and Cases, Vikas books publishers
2. Donald H. McBurney - Theresa L. White “Research Methods” (Cengage learning India Pvt. Ltd)

Reference Books
1. Remington’s Pharmaceutical Sciences
2. Theory & Practice of Industrial Pharmacy by Lachman
3. Statistics for business and economics 3rd edition by Vikas books publications
4. Biostatistics & Computer applications by GN Rao and NK Tiwari
10. Research Methodology by RK Khanna bis and Suvasis Saha
11. Research methods and Quantity methods by G.N. Rao
SCREENING METHODS AND CLINICAL RESEARCH
(Core Elective - II)

Objective: - The students is going to study about various techniques for screening of drugs for various pharmacological activities and guidelines for handling animals and human and animal ethics for screening of drugs

UNIT I
Care Handling and breeding techniques of laboratory animals, Regulations for laboratory animals, CPCSEA guidelines, alternatives to animal studies, Good laboratory Practices.

UNIT II
Bioassays: Basic principles of Biological standardization: Methods used in the bio-assay of Rabbis Vaccine, Oxytocin, Tetanus Antitoxin and Diphtheria Vaccine. Test for pyrogens.

UNIT III
Toxicity tests: OECD guidelines, determination of LD50, acute, sub-acute and chronic toxicity studies.

UNIT IV
Organization of screening for the Pharmacological activity of new substances with emphasis on the evaluation cardiac, psychopharmacological, anti-inflammatory, analgesic and anti-diabetic.

UNIT V
Clinical evaluation of new drugs, Phases of clinical trial, protocol design, Ethics in human research.

Outcome: - The expected outcomes are student will know how to handle animals and know about various techniques for screening drugs for different pharmacological activities and guidelines and regulations for screening new drug molecules on animals and human volunteers.

Text Books:
5. Principles of clinical research edited by Giovanna di ignazio, Di Giovanna and Haynes

Reference Books:
1. ICH of technical requirements for registration of pharmaceuticals for human use, ICH harmonized tripartite guidelines - Guidelines for good clinical practice, E6, May 1996.
Stability of Drugs and Dosage Forms

(Open Elective - II)

Objective: These topics are designed to 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.

UNIT-I
Drug decomposition mechanisms:
1. Hydrolysis and acyltransfers: Nature of reaction, structure and utility, stabilization of pharmaceutical examples.

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

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.

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.

REFERENCE BOOKS:
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.
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.

UNIT I – Introduction to Nanotechnology
a) Definition of nanotechnology
b) History of nanotechnology
c) Unique properties of nanomaterials
d) Role of size and size distribution of nanoparticles properties, classification.

UNIT II – Synthesis of Nanomaterials
a) Physical, chemical and biological Methods
b) Methods for synthesis of
   • Gold nanoparticles
   • Magnetic nanoparticles
   • Polymeric nanoparticles
   • Self – assembly structures such as liposomes, 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

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

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
9. Nanoparticles as Drug carriers, Vladimir P Torchiling, Imperial College Press, USA, 2006
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.

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, Allyl trisulfide.
c) Polyphenolics: Reservetrol
d) Flavonoids- Rutin , Naringin, Quercitin, Anthocyanidins, catechins, Flavones
e) Prebiotates / Probiotics.: Fructo oligosaccharides, Lacto bacillum
f) Phytoestrogens : Isoflavones, daidzein, Geebustin, 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
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 : Butylated hydroxy Toluene, Butylated hydroxy Anisole.

UNIT V
Food Laws and Regulations: FDA, FPO, MPO, AGMARK. HACCP and GMPs on Food Safety. Adultration of foods.
Regulations and Claims – Current Products: Label Claims, Nutrient Content Claims, Health Claims, Dietary Supplements Claims

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

REFERENCES:
1. Dietetics by Sri Lakshmi
2. Role of dietary fibres and nutraceuticals in preventing diseases by K.T Agusti and P.Faizal: BSPublication.
PHARMACEUTICAL MANAGEMENT-II
(Open Elective-II)

Objective: To know the pharmaceutical product management, planning, marketing accounts and finance. They also know the Inventory control, concept and techniques to improve production In packaging, marketing, sale and accounting

UNIT I
Production Management: Fundamentals of production, organization, economic policy, manufacturing economics, production capacities, production lines and job balancing, visible and invisible inputs, methodology of activities. Development of efficient work methods, quality control and management of R&D.
Production planning and control, production processes - mass, job and project; plant location and lay out; work study (preliminary idea only), materials management- purchase, inventory control and store keeping. Productivity management: Concepts, problems, tools and techniques for improvement. Operation research techniques by PERT and CPM.
Considerations for design of large scale manufacturing units including intricate design criteria for units to manufacture sterile and non-sterile products with special reference to tablets, capsules, and injections. Design and development of packaging units including recent advances in packaging techniques for various types of sterile and non-sterile dosage forms. Warehousing design, construction, maintenance and sanitation; good warehousing practice, materials management.

UNIT II
Pharmaceutical Marketing: Evolution of marketing concept; production oriented, sales oriented, promotion oriented and consumer oriented (modern concept); market segmentation; concept of marketing, mix Role of 7 P’s (Product, Price, Promotion, Place, Physical Evidence, Process, People) in Pharmaceutical Marketing Management, corporate planning & strategy, Pharmaceutical industrial marketing management. Pharmaceutical marketing environment.Product management. E-Pharma Marketing.

UNIT III
Product Planning: Selection of product, new product development and product differentiation, pricing, promotion – personal selling; salesmanship, qualities of salesman, management of sales force, advertising, publicity and window display, channels of distribution. Marketing Research: Definition and importance, Pharmaceutical Marketing Research techniques, marketing information system, pharmaceutical marketing research area. Market Demands and Sales Forecasting: Major concepts in the demand measurement, estimating current demands, geo-demographic analysis, estimating industry sales, market share and future demand, sales forecasting.

UNIT IV
Introduction to financial management, financial planning and control, working capital management, management of fixed assets. Concepts and techniques of financial management decision, concepts in evaluation – time value of money, valuation of a firm’s stock, capital assets pricing model, investment in assets and required returns, risk analysis, financing and dividend policies, capital structure decision, working capital management, management of cash, management of accounts receivable, inventory management. Banking and finance: Service and functions of bank, finance planning and sources of finance, short, intermediate and long term financing, tools of financial analysis, financial ratio analysis, funds analysis and financial forecasting, operating and financial leverages. General principles of insurance. Introduction to financial management, financial planning and control, working capital management, management of fixed assets.
Evaluation of investment decisions by payback period, accounting rate of return, net present value methods, break even analysis.

**UNIT V**

Accounting & Finance: Financial accounting, GAAP, cost accounting, budgetary control, valuation of inventory and assets, modern trends, role of internal auditing, internal versus external auditing, accounting control and information systems.


Institutional Finance and Project Appraisal: Framework for domestic/ international finance evaluation, project identification, feasibility, appraisal, financial and capital structures, capital market instruments, managing new issues, negotiations with FIs, FIIs, and other market players, issue pricing, SEBI guidelines, syndication of loans including term loans, lease financing.

**Outcome:** Student will get knowledge about production management, production planning and control, design and development of packaging, marketing of pharmaceuticals.

**Text and reference books**

3. Stock Exchange and Investment Analysis by Briston, R. J.
7. Project Management: A System Approach to Planning Scheduling and Controlling by Harold Kerzner; CRS Publishers and Distributors, Delhi.
17. Principle and Practice of Marketing in India by Memoria C. B.
20. Production and Operations Management by S.N.Chary
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)
ADVANCED PHARMACEUTICAL TECHNOLOGY LAB

List of Experiments

1. Preparation of four different types of semisolid forms and evaluation of their performance using in vitro diffusion method
2. Evaluation of test sterility for commercial preparations including sterile water for injection and antibiotic injection.
3. Collecting samples of environment of aseptic room and counting the colonies
4. Validation of one unit operation (e.g., Mixing) and development of protocol.
5. Comparative evaluation of different marketed products (tablets) of the same API
6. Dissolution studies of drug in three different bio relevant dissolution media
7. Stability study testing of tablet dosage forms (Any two products)