JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY ANANTAPUR
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ANANTHAPURAMU – 515 002 (A.P) INDIA

M.PHARM. IN INDUSTRIAL PHARMACY

COURSE STRUCTURE & SYLLABI

SEMESTER – I

S. No.	Course codes	Course Name	Hours per week			Credits
			L	T	P	
1.	21S01101	Modern Pharmaceutical Analytical Techniques	4	-	-	4
2.	21S03101	Advanced Physical Pharmaceutics	4	-	-	4
3.	21S08101	Pharmaceutical formulation Development	4	-	-	4
4.	21S03103	Advanced Biopharmaceutics & Pharmacokinetics	4	-	-	4
5.	21S01105	Modern Pharmaceutical Analytical Techniques Lab	-	-	6	3
6.	21S08102	Advanced Physical Pharmaceutics Lab	-	-	6	3
7.	21DAC101a 21DAC101b 21DAC101c	**Audit Course – I** English for Research paper writing Disaster Management Sanskrit for Technical Knowledge	2	-	-	0
8.	21S08103	Seminar/Assignment	-	1	6	4
		Total	18	1	18	26

SEMESTER – II

S.No.	Course codes	Course Name	Hours per week			Credits
			L	T	P	
1.	21S08201	Pharmaceutical Production Technology	4	-	-	4
2.	21S08202	Advanced Drug Delivery systems	4	-	-	4
3.	21S08203	Pharmaceutical Industrial Management	4	-	-	4
4.	21S03204	Nano Drug Delivery systems	4	-	-	4
5.	21S08204	Pharmaceutical Production Technology Lab	-	-	6	3
6.	21S03206	Advanced Drug Delivery systems Lab	-	-	6	3
7.	21DAC201a 21DAC201b 21DAC201c	**Audit Course – II** Pedagogy Studies Stress Management for Yoga Personality Development through Life Enlightenment Skills	2	-	-	0
8.	21S08205	Seminar/Assignment	-	1	6	4
		Total	18	1	18	26

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SEMSTER - III

S.No.	Course codes	Course Name	Hours per week			Credits
			L	T	P	
1.	21DRM101	Research Methodology and Intellectual Property Right	4	-	-	4
2.	 21SOE301d 21SOE301a 21SOE301c	**Electives** Biological Screening methods Pharmaceutical Validation Entrepreneurship Management	3	-	-	3
3.	21S08301	Teaching Practice/Assignment	-	-	4	2
4.	21S08302	Comprehensive viva voce	-	-	4	2
5.	21S08303	Research Work - I	-		24	12
		Total	7	-	32	23

SEMESTER - IV

S.No.	Course codes	Course Name	Hours per week			Credits
			L	T	P	
1.	21S08401	Co-Curricular Activities	2			2
2.	21S08402	Research Work - II	3		30	18
		Total	5		30	20

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Course Code	MODERN PHARMACEUTICAL ANALYTICAL TECHNIQUES		L	T	P	C
21S01101			4	0	0	4
Pre-requisite		Semester	I			

Course Objectives:

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

Course Outcomes (CO): Student will be able to

- Modern Analytical Techniques and can apply the theories in analysis of various drugs in single and combination dosage forms
- Theoretical and practical skills of the instruments
- Apply their knowledge in developing the new methods for the determination and validate the procedures.

UNIT - I

UV-Visible spectroscopy

Introduction, Theory, Laws, and Instrumentation associated with UV-Visible spectroscopy, Choice of solvents and solvent effect and Applications of UV-Visible spectroscopy, Difference/ Derivative spectroscopy.

UNIT - II

IR spectroscopy

Theory, Modes of Molecular vibrations, Sample handling, Instrumentation of Dispersive and Fourier -Transform IR Spectrometer, Factors affecting vibrational frequencies and Applications of IR spectroscopy, Data Interpretation.

UNIT - III

NMR spectroscopy

Quantum numbers and their role in NMR ,Principle, Instrumentation, Solvent requirement in NMR, Relaxation process, NMR signals in various compounds, Chemical shift, Factors influencing chemical shift, Spin-Spin coupling, Coupling constant, Nuclear magnetic double resonance, Brief outline of principles of FT-NMR and ^{13}C NMR. Applications of NMR spectroscopy

UNIT – IV

Mass Spectroscopy

Principle, Theory, Instrumentation of Mass Spectroscopy, Different types of ionization like electron impact, chemical, field, FAB and MALDI, APCI, ESI, APPI Analyzers of Quadrupole and Time of Flight, Mass fragmentation and its rules, Meta stable ions, Isotopic peaks and Applications of Mass spectroscopy.

UNIT – V

Chromatography

Introduction to chromatography and classification of chromatographic methods based on the mechanism of separation, Principle, instrumentation, selection of solvents; chromatographic parameters, factors affecting resolution, applications of the following:

a) Thin Layer chromatography; b) High Performance Thin Layer Chromatography
c) Paper Chromatography; d) Column chromatography
e) Gas chromatography; f) High Performance Liquid chromatography

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g) Affinity chromatography; h) Gel Chromatography
i)Hyphenated techniques :

- Ultra High Performance Liquid chromatography- Mass spectroscopy
- Gas Chromatography-Mass Spectroscopy

Textbooks:

1. Instrumental Methods of Chemical Analysis by B.K Sharma
2. Vogel's Text book of Quantitative Chemical Analysis by A.I. Vogel
3. Textbook of Pharmaceutical Analysis, KA.Connors, 3rd Edition, John Wiley& Sons, 1982.

Reference Books:

1. Spectrometric Identification of Organic compounds - Robert M Silverstein, Sixth edition, John Wiley & Sons, 2004.
2. Principles of Instrumental Analysis - Doglas A Skoog, F. James Holler, Timothy A. Nieman, 5th edition, Eastern press, Bangalore, 1998.
3. Instrumental methods of analysis – Willards, 7th edition, CBS publishers.
4. Practical Pharmaceutical Chemistry – Beckett and Stenlake, Vol II, 4thedition, CBS Publishers, New Delhi, 1997.
5. Organic Spectroscopy - William Kemp, 3rd edition, ELBS, 1991.
6. Quantitative Analysis of Drugs in Pharmaceutical formulation - P D Sethi,3rd Edition, CBS Publishers, New Delhi, 1997.
7. Pharmaceutical Analysis - Modern Methods – Part B - J W Munson, Vol11, Marcel. Dekker Series
8. Spectroscopy of Organic Compounds, 2nd edn., P.S/Kalsi, Wiley esternLtd., Delhi.
9. Organic Chemistry by I. L. Finar
10. Quantitative Analysis of Drugs by D. C. Garrett
11. HPTLC by P.D. Seth
12. Indian Pharmacopoeia 2007
13. High Performance thin layer chromatography for the analysis of medicinal plants by Eike
14. Reich, Anne Schibli
15. Introduction to instrumental analysis by Robert. D. Braun

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Course Code	ADVANCED PHYSICAL PHARMACEUTICS	L	T	P	C
21S03101		4	0	0	4
	Semester	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 (CO): Student will be able to

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

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

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

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

UNIT - V

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

Textbooks:

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.

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5. Industrial Pharmacy - Selected Topics, CVS Subramanyam and J Thimmasetty, Vallabh Prakashan Delhi – 2013
Reference Books:
1. Dispersive systems I, II, and III 2. Robinson. Controlled Drug Delivery Systems

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COURSE STRUCTURE & SYLLABI

Course Code	PHARMACEUTICAL FORMULATION DEVELOPMENT		L	T	P	C
21S08101			4	0	0	4
Pre-requisite		Semester	I			

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 (CO): Student will be able to

- 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.

Textbooks:

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

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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.

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COURSE STRUCTURE & SYLLABI

Course Code	ADVANCED BIOPHARMACEUTICS AND PHARMACOKINETICS		L	T	P	C
21S03103			4	0	0	4
Pre-requisite		Semester	I			

Course Objectives:

The student shall know about bioavailability, bioequivalence and factor affecting bioavailability. They also know the pharmacokinetic parameters like drug disposition, absorption, nonlinear and time dependant pharmacokinetics. They also know about the drug interactions & problems associated in pharmacokinetic parameters and calculations.

Course Outcomes (CO): Student will be able to

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 nonlinear 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 volume of distribution
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 clearance, 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, nonlinear

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binding, and non-linearity of pharmacological responses. **Clinical Pharmacokinetics**: Altered kinetics in pregnancy, child birth, infants and geriatrics. Kinetics in GI disease, malabsorption syndrome, liver, cardiac, renal and pulmonary disease states.
UNIT - V
Time dependent pharmacokinetics: Introduction, classification, physiologically induced time dependency: Chronopharmacokinetics - principles, drugs– (amino glycosides, NSAIDS, antihypertensive drug) chemically induced dependency. **Drug Interactions:** Kinetics of drug interaction, study of drug-drug interaction mediated through absorption, distribution, metabolism and elimination, mechanisms of interaction and consequence. **Numerical problems associated with all units, if any.**
Textbooks:
1. Biopharmaceutics and Clinical Pharmacokinetics by Milo Gibaldi. 2. Learn Shargel and ABC yu, Applied Biopharmacokinetics and Pharmacokinetics 3.Biopharmaceutics and Pharmacokinetics by C.V.S. Subrahmanyam, Vallabh Prakashan.2010. 4. Basic biopharmaceutics, Sunil S. Jambhekar and Philip J Brean. 5. Text book of Biopharmaceutics and Clinical Pharmacokinetics by NiaziSarfaraz
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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Course Code	MODERN PHARMACEUTICAL ANALYTICAL TECHNIQUES LAB	L	T	P	C
21S01105		0	0	6	3
	Semester	I			

List of Experiments

1. Analysis of Pharmacopoeial compounds and their formulations by UV Vis Spectrophotometer.
2. Simultaneous estimation of multi component containing formulations by UV Spectrophotometry
3. Effect of pH and solvent on UV –Spectrum
4. Determination of Molar absorption coefficient
5. Estimation of riboflavin/ quinine sulphate by fluorimetry
6. Study of quenching effect by fluorimetry
7. Estimation of sodium or potassium by flame photometry
8. Colorimetric determination of drugs by using different reagents
9. Quantitative determination of functional groups
10. Experiments based on Column chromatography
11. Experiments based on HPLC
12. Experiments based on Gas Chromatography

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Course Code	ADVANCED PHYSICAL PHARMACEUTICS LAB		L	T	P	C
21S08102			0	0	6	3
Pre-requisite		Semester	I			

List of Experiments

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

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COURSE STRUCTURE & SYLLABI

Course Code	PHARMACEUTICAL PRODUCTION TECHNOLOGY	L	T	P	C
21S08201		4	0	0	4
	Semester	II			

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 (CO): Student will be able to

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, 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

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.

Textbooks:

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.

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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
Reference Books:
1. Bentley`s Text Book of Pharmaceutics by EA Rawlins. 2. Generic Drug Product Development by Leon Shargel. 3. Dispensing for Pharmaceutical Students by SJ Carter. 4. Modern Pharmaceutics by Gilbert S. Banker and Christopher T. Rhodes. 5. Nutraceuticals, 2nd edition by Brian lock wood

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COURSE STRUCTURE & SYLLABI

Course Code	ADVANCED DRUG DELIVERY SYSTEMS	L	T	P	C
21S08202		4	0	0	4
	Semester	**II**			

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 (CO): Student will be able to

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

Textbooks:

1. Novel Drug Delivery System by Yie W. Chien.
2. Controlled Drug Delivery by Joseph R. Robinson and Vincent H. L. Lee.

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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 Aukunuru Jithan

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COURSE STRUCTURE & SYLLABI

Course Code	PHARMACEUTICAL INDUSTRIAL MANAGEMENT	L	T	P	C
21S08203		4	0	0	4
	Semester	**II**			

Course Objectives:

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 (CO): Student will be able to

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, speciation, 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 Parmacovigilance.

Textbooks:

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.

Online Learning Resources:

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COURSE STRUCTURE & SYLLABI

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

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COURSE STRUCTURE & SYLLABI

Course Code	NANO DRUG DELIVERY SYSTEMS	L	T	P	C
21S03204		4	0	0	4
	Semester	II			

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 (CO): Student will be able to

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

UNIT - I

Introduction to Nanotechnology

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

UNIT - II

Synthesis of Nanomaterials

Physical, chemical and biological Methods
Methods for synthesis of

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

UNIT - III

Biomedical applications of Nanotechnology

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

UNIT - IV

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

UNIT - V

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

Reference Books:

1. Nanomedicine and Nanoproducts: Applications, Disposition and Toxicology in the Humanbody, 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

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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

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COURSE STRUCTURE & SYLLABI

Course Code	PHARMACEUTICAL PRODUCTION TECHNOLOGY LAB	L	T	P	C
21S08204		0	0	6	3
	Semester	II			

List of Experiments

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

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COURSE STRUCTURE & SYLLABI

Course Code	ADVANCED DRUG DELIVERY SYSTEMS LAB	L	T	P	C
21S03206		0	0	6	3
	Semester	II			

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 / microen capsules (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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COURSE STRUCTURE & SYLLABI

Course Code	RESEARCH METHODOLOGY AND	L	T	P	C
21DRM101	INTELLECTUAL PROPERTY RIGHTS	4	0	0	4
	Semester	**III**			

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 (CO): Student will be able to

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, 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.

Reference Books:

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COURSE STRUCTURE & SYLLABI

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

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COURSE STRUCTURE & SYLLABI

AUDIT COURSE-I

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COURSE STRUCTURE & SYLLABI

Course Code	ENGLISH FOR RESEARCH PAPER WRITING	L	T	P	C
21DAC101a		2	0	0	0
	Semester	I			

Course Objectives: This course will enable students:

- Understand the essentials of writing skills and their level of readability
- Learn about what to write in each section
- Ensure qualitative presentation with linguistic accuracy

Course Outcomes (CO): Student will be able to

- Understand the significance of writing skills and the level of readability
- Analyze and write title, abstract, different sections in research paper
- Develop the skills needed while writing a research paper

UNIT - I	Lecture Hrs:10

1Overview of a Research Paper- Planning and Preparation- Word Order- Useful Phrases - Breaking up Long Sentences-Structuring Paragraphs and Sentences-Being Concise and Removing Redundancy -Avoiding Ambiguity

UNIT - II	Lecture Hrs:10

Essential Components of a Research Paper- Abstracts- Building Hypothesis-Research Problem - Highlight Findings- Hedging and Criticizing, Paraphrasing and Plagiarism, Cauterization

UNIT - III	Lecture Hrs:10

Introducing Review of the Literature – Methodology - Analysis of the Data-Findings - Discussion-Conclusions-Recommendations.

UNIT - IV	Lecture Hrs:9

Key skills needed for writing a Title, Abstract, and Introduction

UNIT - V	Lecture Hrs:9

Appropriate language to formulate Methodology, incorporate Results, put forth Arguments and draw Conclusions

Suggested Reading

1. Goldbort R (2006) Writing for Science, Yale University Press (available on Google Books) Model Curriculum of Engineering & Technology PG Courses [Volume-I]
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'sbook
4. Adrian Wallwork , English for Writing Research Papers, Springer New York Dordrecht Heidelberg London, 2011

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COURSE STRUCTURE & SYLLABI

Course Code	DISASTER MANAGEMENT	L	T	P	C
21DAC101b		2	0	0	0
	Semester	I			

Course Objectives: This course will enable students:

- Learn to demonstrate critical understanding of key concepts in disaster risk reduction and humanitarian response.
- Critically evaluatedisasterriskreduction and humanitarian response policy and practice from Multiple perspectives.
- Developanunderstandingofstandardsofhumanitarianresponseandpracticalrelevanceinspecific types of disasters and conflict situations
- Criticallyunderstandthestrengthsandweaknessesofdisastermanagementapproaches,planningand programming in different countries, particularly their home country or the countries they work in

UNIT - I

Introduction:
Disaster:Definition,FactorsandSignificance;DifferenceBetweenHazardandDisaster;Naturaland 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,DroughtsandFamines,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 ADisasteror 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. TechniquesofRiskAssessment,GlobalCo-OperationinRiskAssessmentand Warning, People's Participation in Risk Assessment. Strategies for Survival.

UNIT - V

Disaster Mitigation:
Meaning,ConceptandStrategiesofDisasterMitigation,EmergingTrendsInMitigation.Structural Mitigationand Non-Structural Mitigation, Programs of Disaster Mitigation in India.

Suggested Reading

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COURSE STRUCTURE & SYLLABI

1. R.Nishith,SinghAK,"DisasterManagementinIndia:Perspectives,issuesandstrategies
2. "'New Royal book Company..Sahni,PardeepEt.Al.(Eds.),"DisasterMitigationExperiencesAndReflections",PrenticeHall OfIndia, New Delhi.
3. GoelS.L.,DisasterAdministrationAndManagementTextAndCaseStudies",Deep&Deep Publication Pvt. Ltd., New Delhi

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COURSE STRUCTURE & SYLLABI

Course Code	SANSKRITFOR TECHNICAL KNOWLEDGE	L	T	P	C
21DAC101c		2	0	0	0
	Semester	**I**			

Course Objectives: This course will enable students:

- To get a working knowledge in illustrious Sanskrit, the scientific language in the world
- Learning of Sanskrit to improve brain functioning
- LearningofSanskrittodevelopthelogicinmathematics,science&othersubjects enhancing the memory power
- The engineering scholars equipped with Sanskrit will be able to explore the huge
- Knowledge from ancientliterature

Course Outcomes (CO): Student 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

Suggested Reading

1.“Abhyaspustakam” –Dr.Vishwas, Sanskrit-Bharti Publication, New Delhi
2.“Teach Yourself Sanskrit” Prathama Deeksha- VempatiKutumbshastri, RashtriyaSanskrit Sansthanam, New Delhi Publication
3.“India’s Glorious ScientificTradition” Suresh Soni, Ocean books (P) Ltd.,New Delhi

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COURSE STRUCTURE & SYLLABI

AUDIT COURSE-II

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COURSE STRUCTURE & SYLLABI

Course Code	PEDAGOGY STUDIES	L	T	P	C
21DAC201a		2	0	0	0
	Semester	**II**			

Course Objectives: This course will enable students:

- Reviewexistingevidenceonthereviewtopictoinformprogrammedesignandpolicy making undertaken by the DfID, other agencies and researchers.
- Identify critical evidence gaps to guide the development.

Course Outcomes (CO): Student will be able to

Students will be able to understand:

- Whatpedagogicalpracticesarebeingusedbyteachersinformalandinformalclassrooms in developing countries?
- What is the evidence on the effectiveness of these pedagogical practices, in what conditions, and with what population of learners?
- Howcanteachereducation(curriculumandpracticum)andtheschoolcurriculumand guidance materials best support effective pedagogy?

UNIT - I

Introduction and Methodology: Aims and rationale, Policy back ground, Conceptual frame work and terminology Theories oflearning,Curriculum,Teachereducation.Conceptualframework,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 theeffectivenessofpedagogicalpractices,Methodologyfortheindepthstage:quality assessmen t of included studies. How can teacher education (curriculumandpracticum) andthescho curriculum and guidance materials best support effective pedagogy? Theory of change. Strength and nature of th body of evidence for effective pedagogical practices. Pedagogic theory and pedagogical approaches. Teachers' attitudes and beliefs and Pedagogic strategies.

UNIT - IV

Professional development: alignment with classroom practices and follow-up support, Peer support, Support from the head teacherandthecommunity.Curriculumandassessment,Barrierstolearning:limitedresourcesand large class sizes

UNIT - V

Researchgapsandfuturedirections: Researchdesign**,**Contexts**,**Pedagogy**,**Teachereducation**,** Curriculum and assessment**,** Dissemination and research impact.

Suggested Reading

1. AckersJ,HardmanF(2001)ClassroominteractioninKenyanprimaryschools,Compare, 31 (2): 245-261.
2. AgrawalM(2004)Curricularreforminschools:Theimportanceofevaluation,Journalof

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3. Curriculum Studies, 36 (3): 361-379.
4. AkyeampongK(2003) Teacher training in Ghana - does it count? Multi-site teachereducation research project (MUSTER) country report 1. London: DFID.
5. Akyeampong K, LussierK, PryorJ, Westbrook J (2013)Improving teaching and learning of basic maths and reading in Africa: Does teacherpreparation count?International Journal Educational Development, 33 (3): 272–282.
6. Alexander RJ(2001) Culture and pedagogy: International comparisons in primary education. Oxford and Boston: Blackwell.
   Chavan M (2003)ReadIndia: A mass scale, rapid, 'learning to read'campaign.
7. www.pratham.org/images/resource%20working%20paper%202.pdf.

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COURSE STRUCTURE & SYLLABI

Course Code	STRESSMANAGEMENT BY YOGA	L	T	P	C
21DAC201b		2	0	0	0
	Semester	**II**			

Course Objectives: This course will enable students:

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

Course Outcomes (CO): Student 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`sand Don't'sin life. i) Ahinsa,satya,astheya,bramhacharyaand aparigrahaii) Shaucha,santosh,tapa,swadhyay,ishwarpranidhan		
UNIT - IV		
Asan and Pranayam		
UNIT - V		
i)Variousyogposesand theirbenefitsformind &body ii)Regularizationofbreathingtechniques and its effects-Types ofpranayam		

Suggested Reading

1.'Yogic Asanas forGroupTarining-Part-I": Janardan SwamiYogabhyasiMandal, Nagpur
2."Rajayogaor conquering the Internal Nature" by Swami Vivekananda, Advaita Ashrama (Publication Department), Kolkata

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COURSE STRUCTURE & SYLLABI

Course Code	PERSONALITY DEVELOPMENT THROUGHLIFE ENLIGHTENMENTSKILLS	L	T	P	C
21DAC201c		2	0	0	0
	Semester	**II**			

Course Objectives: This course will enable students:

- 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 (CO): Student will be able to

- StudyofShrimad-Bhagwad-Geetawillhelpthestudentindevelopinghispersonalityand achieve the highest goal in life
- The person who has studied Geetawilllead 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.
ShrimadBhagwadGeeta:Chapter2-Verses41,47,48,
Chapter3-Verses13,21,27,35,Chapter6-Verses5,13,17,23,35,
Chapter18-Verses45,46,48.

UNIT - IV

Statements of basic knowledge.
ShrimadBhagwadGeeta:Chapter2-Verses 56,62,68
Chapter12 -Verses13,14,15,16,17,18
Personality of Rolemodel. Shrimad Bhagwad Geeta:

UNIT - V

Chapter2-Verses 17,Chapter3-Verses36,37,42,
Chapter4-Verses18,38,39
Chapter18– Verses37,38,63

Suggested Reading

1."SrimadBhagavadGita"bySwamiSwarupanandaAdvaitaAshram(PublicationDepartment), Kolkata
2.Bhartrihari'sThree Satakam (Niti-sringar-vairagya) by P.Gopinath, RashtriyaSanskrit Sansthanam, New Delhi.

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COURSE STRUCTURE & SYLLABI

OPEN ELECTIVE

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COURSE STRUCTURE & SYLLABI

Course Code	BIOLOGICAL SCREENING METHODS	L	T	P	C
21SOE301d	(Elective)	3	0	0	3
	Semester	**III**			

Course Objectives:

The students are going to study about various techniques for screening of drugs for various pharmacological activities and guide lines for handling animals and human and animal ethics for screening of drugs.

Course Outcomes (CO): Student will be able to

The expected outcomes are students will know how to handle animals and know about various techniques for screening of drugs for different pharmacological activities, guidelines and regulations for screening new drug molecules on animals.

UNIT - I

Drug discovery process: Principles, techniques and strategies used in new drug discovery. High throughput screening, human genomics, robotics and economics of drug discovery, Regulations. Alternatives to animal screening procedures, cell-line, patch –clamp technique, In-vitro models, molecular biology techniques

UNIT - II

Bioassays: Basic principles of bioassays, official bioassays, experimental models and statistical designs employed in biological standardization.

UNIT - III

Principles of toxicity evaluations, ED50, LD50 and TD values, International guidelines (ICH recommendations).

Preclinical studies: General principles and procedures involved in acute, sub-acute, chronic, teratogenicity, mutagenicity and carcinogenicity

UNIT - IV

Screening of different classes of drugs using micro-organisms. Vitamin and antibiotic assays. Screening methods involved in toxins and pathogens.

UNIT - V

Enzymatic screening methods: α-glucosidase, α- amylase, DNA polymerase, nucleases, L-asparginase, lipases and peptidases.

Reference Books:

1. Basic and clinical pharmacology by Bertram G. Katzung (International edition) lange medical book / Mc Graw Hill, USA 2001 8th edition
2. Pharmacology by Rang H.P, Dale MM and Ritter JM., Churchill Livingston, London, 4/e
3. Goodman and Gilman's The pharmacological basis of therapeutics (International edition) Mc Graw Hill, USA 2001 10th edition.
4. General and applid toxicology by B.Ballantyne, T.Marrs, P.Turner (Eds) The Mc Millan press Ltd, London.
5. Drug Discovery by Vogel's
6. Drug Discovery and evaluation – Pharmacological assays by H.Gerhard.Vogel, 2nd edition, Springer verlag, Berlin, Heidelberg.
7. Tutorial Pharmacy (Vol I and II) by Cooper and Gunns.

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COURSE STRUCTURE & SYLLABI

Course Code	PHARMACEUTICAL VALIDATION	L	T	P	C
21SOE301a	(Elective)	3	0	0	3
	Semester	III			

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 (CO): Student will be able to

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

- Explain the aspect of validation
- Carryout validation of manufacturing processes
- Apply the knowledge of validation to instruments and equipments
- 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, Validation and validation of analytical method used in cleaning. Cleaning of Equipment. Cleaning of Facilities. Cleaning in place (CIP).

UNIT - V

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

Reference Books:

1. T. Loftus & R. A. Nash, "Pharmaceutical Process Validation", Drugs and Pharm Sci. Series, Vol.129, 3rd Ed., Marcel Dekker Inc., N.Y.
2. The Theory & Practice of Industrial Pharmacy, 3rd edition, Leon Lachman, Herbert A. Lieberman,Joseph. L. Karig, Varghese Publishing House, Bombay.
3. Validation Master plan by Terveeks or Deeks, Davis Harwood International publishing.
4. Validation of Aseptic Pharmaceutical Processes, 2nd Edition, by Carleton & Agalloco, (Marcel Dekker).
5. Michael Levin, Pharmaceutical Process Scale-Up‖, Drugs and Pharm. Sci. Series, Vol. 157, 2nd Ed., Marcel Dekker Inc., N.Y.

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY ANANTAPUR
(Established by Govt. of A.P., ACT No.30 of 2008)
ANANTHAPURAMU – 515 002 (A.P) INDIA

M.PHARM. IN INDUSTRIAL PHARMACY

COURSE STRUCTURE & SYLLABI

Course Code	ENTREPRENEURSHIP MANAGEMENT	L	T	P	C
21SOE301c	(Elective)	3	0	0	3
	Semester	III			

Course Objectives:

This course is designed to impart knowledge and skills necessary to train the students on entrepreneurship management.

Course Outcomes (CO): Student will be able to

On completion of this course it is expected that students will be able to:

- The Role of enterprise in national and global economy
- Dynamics of motivation and concepts of entrepreneurship
- Demands and challenges of Growth Strategies and Networking

UNIT - I

Conceptual Frame Work: Concept need and process in entrepreneurship development. Role of enterprise in national and global economy. Types of enterprise – Merits and Demerits. Government policies and schemes for enterprise development. Institutional support in enterprise development and management.

UNIT - II

Entrepreneur: Entrepreneurial motivation – dynamics of motivation. Entrepreneurial competency – Concepts. Developing Entrepreneurial competencies - requirements and understanding the process of entrepreneurship development, self-awareness, interpersonal skills, creativity, assertiveness, achievement, factors affecting entrepreneur role.

UNIT - III

Launching and Organizing an Enterprise: Environment scanning – Information, sources, schemes of assistance, problems. Enterprise selection, market assessment, enterprise feasibility study, SWOT Analysis. Resource mobilization -finance, technology, raw material, site and manpower. Costing and marketing management and quality control. Feedback, monitoring and evaluation.

UNIT - IV

Growth Strategies and Networking: Performance appraisal and assessment. Profitability and control measures, demands and challenges. Need for diversification. Future Growth – Techniques of expansion and diversification, vision strategies. Concept and dynamics. Methods, Joint venture, coordination and feasibility study.

UNIT - V

Preparing Project Proposal to Start on New Enterprise Project work – Feasibility report; Planning, resource mobilization and implementation.

Reference Books:

1. Akhauri, M. M. P.(1990): Entrepreneurship for Women in India, NIESBUD, New Delhi.
2. Hisrich, R. D & Brush, C.G. (1996) The Women Entrepreneurs, D.C. Health& Co., Toranto.
3. Hisrich, R.D. and Peters, M.P. (1995): Entrepreneurship – Starting Developing and Managing a New Enterprise, Richard D., Inwin, INC, USA.
4. Meredith, G.G. etal (1982): Practice of Entrepreneurship, ILO, Geneva.
5. Patel, V.C. (1987): Women Entrepreneurship – Developing New Entrepreneurs, Ahmedabad EDII
6. Arya kumar.(2012): Entrepreneurship- Creating and Leading an Entrepreneurial Organization, Pearson