Jawaharlal Nehru Technological University

KAKINADA

School of Pharmaceutical Sciences & Technologies

SYLLABUS FOR M.PHARMACY

Branch: Pharmaceutics

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY

Master of Pharmacy
Regulations and Syllabus
Four Semester Pattern
(With effect from 2003-2004)

1.1 The Degree of Master of Pharmacy of the J.N.T.University will be conferred on a candidate who has satisfied the following conditions.
The candidate must have passed the B.Pharm Degree examination of this University or of any other University recognized by the Academic Council as equivalent thereto in First or Second class and must have qualified in any entrance examination, if prescribed.

1.2 The candidate should have undergone a regular course of study as prescribed hereunder extending over a period of four semesters, ordinarily consecutive and satisfied the academic requirements as prescribed hereinafter. The course of instruction and periods of study shall be as given "in the scheme of instruction" and in the syllabus mentioned in the Annexure.

1 .3 The subject of specialization for Master of Pharmacy course shall be as follows:
i) Pharmaceutics.

1.4 Every candidate shall put in attendance for not less than 75% of the total number of days in each semester to be eligible to sit for the semester end examinations.
If a student represents the University officially at games, sports or other officially organized extra-curricular activities it will be deemed that he has attended the college on the days he is absent for this purpose.

2.1 Evaluation of performance of all candidates who pursue the above course shall be as per the 'scheme of examination' enclosed as the Annexure. In theory, the evaluation shall be on the basis of the semester end examinations. In practical 25% of the marks are earmarked for continuous evaluation and 75% are earmarked for the semester end examination. The marks certificate issued to the candidate by the University shall show separately that Sessional marks in practicals and the semester end examination marks.

2.2 Regulations concerning semester-end examinations of the first two semesters:
a) There shall be one semester end examination in each theory course based on the question paper set by the external paper setter and there shall be double valuation. There shall be one semester end examination in each practical course as per 'the scheme of examination" and the setting and valuation shall be done jointly by two examiners, one external examiner and the internal examiner.

b) In order to be eligible to be appointed as an internal examiner for the semester- end examination, a teacher shall have to put in at least three years of service as a teacher for the course concerned.

c) If the disparity between the marks awarded by both the examiners is 20% or less, the average marks shall be taken as the mark awarded in the paper. If the disparity happens to be more, reference to a third examiner will be made whose valuation shall be final.

3.1 A candidate shall be declared to have passed the examination held at the end of each semester if he obtains not less than 40% in each theory and each practical examination and 50% in the aggregate of all examinations including internal assessment marks in practicals.

3.2 If a candidate obtains 50% on aggregate but fails to secure the minimum of 40% in any course, he shall appear at the next examination for the semester end examination in that course to enable him to pass as per 3.1.

3.3 A candidate who has successfully completed the examination in a course by securing not less than 50% of marks shall not be permitted to retake the examination in that course.

3.4 A candidate who fails to secure 50% of marks on the aggregate but secures 50% or more in some courses and between 40-49% in the other courses, he shall be required to retake the next semester end examination in one or more of the courses in which he secures less than 50% of marks as per his choice to satisfy the requirement of 50% aggregate.

3.5 Candidates who secure not less than 75% of the total marks including the Sessional marks including practical in all the examinations of the four semesters taken together shall be declare to have passed in First Division with Distinction. Candidates who secure not less than 60% shall be declare to have passed in First Division. All the remaining successful candidates shall be declared to have passed in Second Division. However, any candidate who has not passed all the papers relating to an examination of any semester at first appearance shall not be declared to have passed in First Division with Distinction nor be eligible for the award of any medals or prized and is not eligible to receive a rank certificate.

4.1 a) The candidate should deliver two seminars in the First semester and One in the Second semester on the topics allotted. Each seminar shall be evaluated by three teachers of the concerned subject.

b) The candidates should do two assignments in First semester and one assignment in Second semester on the topics allotted. Each of the assignment shall be evaluated by two teachers of the concerned subject and average of two shall be the marks secured by the candidates.

4.2 a) The candidate should deliver one seminar in third semester on the proposed project and another in the fourth semester on completion of the project work. Each seminar shall be evaluated by teachers of the concerned subject.

b) A candidate shall submit five copies of his/her thesis either printed or typed, embodying the results of research done by him under the direction of an approved research director. All candidates must submit their thesis within 6 days after the end of the fourth semester. Any remaining candidates may submit their thesis after the prescribed date but the examination of their thesis will be arranged only after the next six months period is over.

4.3 Every candidate intending to apply for the Degree of Master of Pharmacy shall communicate is intension to do so to the Registrar Director and the Head of the Department along with five copies of synopsis of the thesis at least one month before submitting the thesis.

4.4 The thesis submitted by the candidate shall be evaluated by an External Examiner where as the viva-voce examination shall be conducted jointly by the Supervisor or the Director who guided the work and the External Examiner.

4.5 At the end of final course each candidate should face the comprehensive viva voce examination evaluation by an external examiner along with all faculty members.

M.PHARM

PHARMACEUTICS

I SEMESTER

Paper CEU 101	**-**	**B10-PHARMACEUTICS & PHARMACOKINETICS**
Paper CEU 102	**-**	**PHYSICAL PHARMACEUTICS**
Paper CEU 103	**-**	**DRUG REGULATORY AFFAIRS**
Paper CEU 104	**-**	**BlO PHARMACEUTICS & PHARMACOKINETICS PRACTICAL EXPERIMENTS BASED ON THEORY.**
Paper CEU 105	**-**	**PHYSICAL PHARMACEUTICS PRACTICALS: PRACTICALS BASED UPON THEORY**.

I SEMESTER

Paper CEU 201	**-**	**ADVANCES IN DRUG DELIVERY SYSTEMS**
Paper CEU 202	**-**	**ADVANCED PHARMACEUTICAL TECHNOLOGY**
Paper CEU 203	**-**	**INDUSTRIAL PHARMACY**
Paper CEU 204	**-**	**ADVANCES IN DRUG DELIVERY SYSTEMS PRACTICALS EXPERIMENTS BASED ON THEORY**
Paper CEU 205	**-**	**ADVANCED PHARMACEUTICAL TECHNOLOGY PRACTICALS EXPERIMENTS BASED UPON THEORY**

III SEMESTER & IV SEMESTER

Paper CEU 301	**-**	**Seminar-I (On the proposed project work with aims and objectives)**
Paper CEU 401	**-**	**Seminar-II (On the experimentation and results obtained in the project work)**
Paper CEU 402	**-**	**Thesis evaluation**
Paper CEU 403	**-**	**Defence (Viva-Voice)**
Paper CEU 404	**-**	**Comprehensive Viva voice**

SCHEME OF INSTRUCTIONS AND EVALUATION

PHARMACEUTICS SPECIALIZATION

I SEMESTER

Paper no.	Title of the paper	No. of periods of instructions per week		Evaluation / Marks			Total
		Theory	practical	Theory (university)	Practical		
					Internal	University	
CEU 101	Bio-Pharmaceutics and Pharmacokinetics	4		100			100
CEU 102	Physical Pharmaceutics	4		100			100
CEU 103	Drug Regulatory Affairs	4		100			100
CEU 104	Bio-Pharmaceutics and Pharmacokinetics		9		40	60	100
CEU 105	Physical Pharmaceutics		9		40	60	100
CEU 106	Seminar	1			50		50
CEU 107	Assignments	1			50		50
	Total Marks						600

SCHEME OF INSTRUCTIONS AND EVALUATION

PHARMACEUTICS SPECIALIZATION

II SEMESTER

Paper no.	Title of the paper	No. of periods of instructions per week		Evaluation / Marks			Total
		Theory	practical	Theory (university)	Practical		
					Internal	University	
CEU 201	Advances in Drug Delivery Systems	4		100			100
CEU 202	Advanced Pharmaceutical Technology	4		100			100
CEU 203	Industrial Pharmacy	4		100			100
CEU 204	Advances in Drug Delivery Systems		9		40	60	100
CEU 205	Advanced Pharmaceutical Technology		9		40	60	100
CEU 206	Seminar	1			50		50
CEU 207	Assignments	1			50		50
	Total Marks						600

SCHEME OF INSTRUCTIONS AND EVALUATION

PHARMACEUTICS SPECIALIZATION

III SEMESTER AND IV SEMESTER

Paper no.		Total
CEU 301	Seminar-I (On the proposed project work with aims and objectives)	50
CEU 302	Seminar-II (On the experimentation and results obtained in the project work	50
CEU 303	Thesis evaluation	200
CEU 304	Defence Viva voice	50
	Comprehensive viva voice	50
	Total marks	400
GRAND TOTAL FOR THE COURSE		1600

M.PHARM (PHARMACEUTICS)

I Semester

CEU 101 B10-PHARMACEUTICS & PHARMACOKINETICS

1. Bio-availability Bioequivalence and Therapeutic equivalence: Designing of bioavailability studies and interpretation of results.
2 Physicochemical properties affecting bioavailability, pH-partition theory, dissolution, surface area adsorption, complexion, polymorphism and techniques of enhancing dissolution rate.
3 Formulation factors affecting bioavailability of drugs in dosage forms of Tablets, capsules, parenterals, liquid orals and topical dosage forms.
4 Basic concepts of Pharmacokinetics: Compartmental 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) Absorption: (wherever applicable) absorption rate constant, Absorption half time, lag time and extent of absorption, AUC.
   b) Distribution: Apparent volume of distribution and its determination.
   c) Metabolism: Metabolic rate constant
   d) Elimination: Over all apparent elimination rate constant and half life under the following conditions:
      i. Intravenous bolus injection.
      ii. Intravenous infusion.
      iii. Single dose oral administration.
      iv. Multiple dose injections.
      v. Multiple dosage oral administration
   e) Non invasive methods of estimating Pharmacokinetic parameters with emphasis on salivary and urinary compartments.
   f) Concept of clearance: Organ clearance, total clearance, hepatic clearance, lung clearance and renal clearance.
5 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, non linearity of pharmacological responses.
6 Time dependent pharmacokinetics: Introduction, classification, physiologically induced time dependency: Chronopharmacokinetics, chemically induced dependency.
7 Drug Metabolism - sites of metabolism, factors affecting drug metabolism (genetic, species and environmental).
8 Clinical pharmacokinetics: Altered kinetics in pregnancy, child birth, infants and geriatrics. Kinetics in GI disease, malabsorption syndrome, Liver, cardiac, renal and pulmonary disease states.
9 Drug interactions: Kinetics of drug interaction, study of drug-drug interactions mediated through absorption, distribution, metabolism and elimination, mechanisms of interaction and consequence. Influence of alcohol, smoking, food and beverages on drug action.

References:

1. Biopharmaceutics and clinical Pharmacokinetics by Milo Gibaldi.
2. Remington's Pharmaceutical Sciences by Mack publishing company, Pennsylvania.
3. Pharmacokinetics by Milo Gibaldi, Donald Perrier; Marcel Dekker, Inc.
4. Handbook of clinical Pharmacokinetics by Milo Gibaldi and Laurie Prescott by ADIS Health Science Press.
5. Biopharmaceutics and Pharmacokinetics by Robert E. Notari.
6. Biopharmaceutics by Swarbrick.
7. Biopharmaceuties and Pharmacokinetics- A Treatise by D.M.Brahmankar and Sunil B.Jaiswal., Vallabh Prakashan Pitampura, Delhi.
8. Clinical Pharmacokinetics, Concepts and Applications by Malcolm Rowland and Thomas N.Tozer. Lea and Febiger, Philadelphia, 1995.
9. Dissolution, Bioavailability and Bioequivalence by Abdou. H.M., Mack Publishing Company, Pennsylvania, 1989.
10. Biopharmaceutics and Clinical Pharmacokinetics- An introduction; 4th edition, Revised and expanded By Robert. E. Notari, Marcel Dekker Inc, New York and Basel, 1987.
11. Encyclopedia of Pharmaceutical Technology, Vol 13, James Swarbrick, James. C.Boylan. Marcel Dekker Inc, New York, 1996.

CEU-102 PHYSICAL PHARMACEUTICS:

1. Particle science and powder technology: Crystal structure, Amorphous state, Polymorphism, particle size distribution, particle size analysis methods. Solid dispersions/solid solutions.
2. Physics of tablet compression: Compression, consolidation strength of granules, 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, strength of tablet, crushing strength, friability, lamination, instrumentation of tablet machines.
3. Dissolution and solubility: Solubility and solubilisation of non electrolytes, solubilisation by the use of surfactants, cosolvents, complexation, drug derivatisation and solid state manipulation, dissolution rates of solids in liquids, measurement of dissolution rates
4. Theories on stability of disperse systems: Adsorption, wetting, crystal growth mechanisms, physical stability of suspensions and emulsions, stability testing of emulsions and suspension and release of drugs from suspensions and emulsion formulations. Biopharmaceutical aspects of disperse systems.
5. Rheology: Theoretical consideration, instrumentation, rheological properties of disperse systems and semi solids.
6. Polymer science: Properties of polymers, thermodynamics of polymer solution, phase separation, polymers in solid state, applications of polymers in pharmaceutical formulations
7. Kinetics and drug stability: stability calculations, rate equation, Complex order Kinetics, kinetics of some decompositions, strategy of stability testing, methods of stabilization, methods of accelerated stability testing in dosage forms, Freeze-Thaw methods, centrifugal methods, temperature and humidity control, Physical stability testing of pharmaceutical products.
8. Physical properties, instrumental analysis of drug molecules, Differential Thermal Analysis, Differential Scanning Calorimetry, Diffusive Reflective Spectrophotometry, X-Ray Diffraction Analysis.

References:

1. Physical Pharmacy; By Alfred martin
2. Remington's Pharmaceutical Sciences.
3. Theory and Practice of Industrial Pharmacy By Lachmann and Libermann.
4. Pharmaceutical Preformulations; By J.J. Wells.
5. Modern Pharmaceutics; By Gillbert and S. Banker.
6. Instrumental Methods of Chemical Analysis – B. K. Sharma - 9th Edition.
7. Principles of Instrumental Analysis by Donglas A. Skoog, James, J. Leary, 4th Edition.

CEU 103 DRUG REGULATORY AFFAIRS:

1. Formulation development: Regulatory requirements involved in the preformulation studies, solid, liquid and semi-solid dosage forms, controlled release preparations, injections, ocular preparations as per the European community, United States and Indian regulatory authorities
2. Manufacturing: Regulatory requirements as per European community, United States and Indian regulatory authorities for manufacturing information, manufacturing formula, process, validation of manufacturing process, equipment, documentation, inspection requirement of regulatory guidelines for active ingredients, data requirement for new drug, International aspects of Excipients, approval as per guidelines of all the territories. Regulatory guidelines for packaging materials, test and evaluation of packaging materials, biological test, elastometer test, microbiological test and evaluation of closures.
3. Stability testing: Scientific and technical background to the design of stability testing regulatory requirements as per European community, United States and Indian regulatory authorities for testing of new active substances, bulk active drug substances, dosage form in their final packaging. Extension of shelf-life after authorization of drug international harmonization and current guidelines. Regulatory affairs in respect of residual solvents as per the ICH guidelines, analytical method validation, pharmacokinetic and toxicokinetic validation.
4. Biopharmaceutics: Different testing parameters and standards as per regulatory requirements of European community, United States and Indian regulatory authorities with respect to factors related to formulation, dosage form, manufacturing process, stability and storage.
5. Preclinical aspects of Biopharmaceutics: Current guidelines and developments as per regulatory requirements of European community, United States and Indian regulatory authorities in respect of clinical bioavailability , study design, presentation documentation and statistical analysis
6. Clinical pharmacology and Pharmacodynamics: Regulatory guidelines as per European community, United States and Indian regulatory authorities on clinical study design, documentation, presentation and interpretation. Clinical trials: Definition, phase I, phase II, phase III and phase IV studies, design documentation, presentation and interpretation, statistical analysis of clinical data and factorial design.
7. Intellectual property rights and patents: Introduction, purpose, international scenario and Indian scenario, guidelines as per European community, United States and Indian regulatory authorities, documentation, presentation and application, procedure for obtaining and writing a patent and patenting rules and regulations

Reference:

1. Quality Assurance Guide by Organization of Pharmaceutical producers of India.
2. Drug formulation manual by D.P.S. Kohli and D.H.Shah. Eastern publishers, New Delhi.
3. How to practice GMPs by P.P.Sharma. Vandhana Publications, Agra.
4. Pharmaceutical Process Validation by Fra. R. Berry and Robert A. Nash.
5. Pharmaceutical Preformulations by J.J. Wells.
6. Applied production and operations management by Evans, Anderson, Sweeney and Williams.

7. Basic Principles of Clinical Research and Methodology by Gupta.
8. Biopharmaceutics and Clinical Pharmacokinetics-An introduction; 4th edition, Revised and expanded by Robert. E. Notari, Marcel Dekker Inc, New York and Basel, 1987.

CEU 104 BlO PHARMACEUTICS & PHARMACOKINETICS PRACTICAL EXPERIMENTS BASED ON THEORY.

CEU -105 PHYSICAL PHARMACEUTICS PRACTICALS:
PRACTICALS BASED UPON THEORY.

2nd SEMESTER

CEU 201 ADVANCES IN DRUG DELIVERY SYSTEMS

1. Fundamentals of controlled drug delivery systems, use of polymers in controlled drug delivery, pharmacokinetic and pharmacodynamic basis of controlled drug delivery. Design, fabrication, evaluation and applications of the following controlled release systems.
   a) Controlled release oral drug delivery systems
   b) Parenteral controlled release drug delivery systems
   c) Implantable therapeutic systems
   d) Transdermal therapeutic systems and Iontophoresis
   e) Ocular and intrauterine delivery systems
   f) Bioadhesive drug delivery systems
   g) Proteins and peptide drug delivery
2 Biochemical and molecular biology approaches to controlled drug delivery
   a) Micro particulate drug carriers; Liposomes, Niosomes, Microspheres, Nanoparticles and Resealed erythrocytes.
   b) Monocional antibodies
3 Drug targeting to particular organs:
   a) Drug delivery to respiratory system
   b) Problems of drug delivery to the brain and targeting to brain
   c) Drug delivery to eye
   d) Drug targeting in Neoplastic diseases
4 Drug carrier systems targeted to widely dispersed cells
   a) Delivery to Macrophages
   b) Delivery to lymphoid cells of immune network
   c) Delivery to lysosomal storage diseases

References:

1. Encyclopedia of controlled delivery; by Edith Mathiowitz, Published by Wiley Interscience Publication, John Wiley and sons, Inc, New York / Chichester / Weinheim.
2. Controlled and Novel Drug Delivery by N.K.Jain, CBS Publishers and Distributors, New Delhi, First edition, 1997 (reprint in 2001).
3. Controlled Drug Delivery - Concepts and Advances by S.P.Vyas and R.K.Khar, Vallabh Prakashan, New Delhi, First edition, 2002.
4. Remington's Pharmaceutical Sciences.
5. Novel drug delivery system by Y.M.Chien, Marcel Dekker, Inc.
6. Controlled Drug Delivery - Fundamentals and Applications, 2nd edition by Joseph R.Robinson and Vincent H.L.Lee.
7. Pharmaceutical Dosage forms, disperse system: Volume 1, by Herbert A.Libermann et.al, Marcel Dekker, Inc.
8. Pharmaceutical Dosage forms: Tablets Volume II, Herbert A.Libermann et.al, Marcer Dekker, Inc.
9. Bentley's Textbook of Pharmaceutics by E.A.Rawline, ELBS Publications.
10. Microencapsulation and Related Drug Process by Patric B.Deasy.

CEU-202 ADVANCED PHARMACEUTICAL TECHNOLOGY:

1. Preformulation studies: Goal of preformulation, preformulation parameters, Methodology, Solid state properties, Solubility & partition coefficient, Drug-Excipient compatibility.
2. Formulation Development:
   a) Solid dosage forms:
      Improved production techniques for tablets: New materials, processess, equipments improvements, high shear mixers, compression machines, coating machines, Coating techniques in tablet technology for product development, Physics of tablet compression and computerization for in process quality control of tablets.
   b) Powder dosage forms:
      Formulation development and manufacture of powder dosage from for internal and external use including inhalation dosage forms.
   c) Liquid and Semi-solid dosage forms:
      Recent advances in formulation aspects and manufacturing of monophasic dosage forms, recent advances in formulation aspect and manufacturing of suspensions and semi-solid dosage forms.
   d) Parenteral dosage forms:
      Advances in materials & production techniques, filling machines, sterilizers & aseptic processing
   e) Aerosols:
      Advances in propellants, metered dose inhaler designs, dry powder inhalers, selection of containers & formulation aspects in aerosol formulation, Manufacture & quality control.
3. Aseptic processing operation:
   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.

References:

1. Theory and Practice of Industrial Pharmacy by Lachmann and Libermann.
2. Modern Pharmaceutics by Gillbert and S. Banker.
3. Remington's Pharmaceutical Sciences.
4. Pharmaceutical Preformulations by J.J. Wells.
5. Advances in Pharmaceutical Sciences Vol. 1-5 by H.S. Bean & A.H. Beckett.

CEU 203 INDUSTRIAL PHARMACY

1 A detailed study involving machinery and theory of pharmaceutical unit operations like Milling, Mixing, Filtration, Drying and Sterilization.
2 Materials of construction of pharmaceutical equipment and packaging materials.
Study of the principles, production techniques and scale up techniques in the large scale production of tablets, capsules, emulsions, suspensions, sterile products, Semisolids and liquid pharmaceuticals, ophthalmic products.
3 Production Management: Production organization, objectives and policies, good manufacturing practices, layout of buildings, services, equipment and their maintenance, materials management, handling and transportation, inventory management and control, production and planning control. Sales forecasting, budget and cost control, industrial and personal relationship.
4 Quality control, Process and Dosage form: Process control, control of manufacturing process, statistical quality control, control charts of automated process control, dosage form control, testing programme and method, product identification system, adulteration and misbranding , drug information profile.
5 Process Validation: Regulatory basis, Validation of solid dosage forms, sterile products, liquid dosage forms. Process validation of raw materials, Validation of analytical methods, Equipment and Process.

References:

1. Theory and Practice of Industrial Pharmacy by Lachmann and Libermann.
2. Pharmaceutical dosage forms: Tablets Vol. 1-3 by Leon Lachmann.
3. Pharmaceutical Dosage forms: Disperse systems, Vol, 1-2 by Leon Lachmann.
4. Pharmaceutical Dosage forms: Parenteral medications Vol. 1-2 by Leon Lachmann.
5. Modern Pharmaceutics by Gillbert and S. Banker.
6. Remington's Pharmaceutical Sciences.
7. Advances in Pharmaceutical Sciences Vol. 1-5 by H.S. Bean & A.H. Beckett.
8. Physical Pharmacy by Alfred martin
9. Bentley's Textbook of Pharmaceutics – Rawbins.
10. Good manufacturing practices for Pharmaceuticals: A plan for total quality control, Second edition by Sidney H. Willig.
11. Quality Assurance Guide by Organization of Pharmaceutical producers of India.
12. Drug formulation manual by D.P.S. Kohli and D.H.Shah. Eastern publishers, New Delhi.
13. How to practice GMPs; By P.P.Sharma. Vandhana Publications, Agra.
14. Pharmaceutical Process Validation by Fra. R. Berry and Robert A. Nash.
15. Pharmaceutical Preformulations by J.J. Wells.
16. Applied production and operations management by Evans, Anderson, Sweeney and Williams.

CEU 204 ADVANCES IN DRUG DELIVERY SYSTEMS PRACTICALS EXPERIMENTS BASED ON THEORY

CEU-205 ADVANCED PHARMACEUTICAL TECHNOLOGY PRACTICALS EXPERIMENTS BASED UPON THEORY