ACHARYA NAGARJUNA UNIVERSITY

MASTER OF PHARMACY

REGULATIONS AND SYLLABUS

Four Semester Pattern

(with effect from 2007-2008)

1.1 The Degree of Master of Pharmacy of the Nagarjuna 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 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 Annexures.

1.3 The subjects of specialization for **MASTER OF PHARMACY** course shall be as follows :

1) **PHARMACEUTICS**
2) **PHARMACEUTICAL ANALYSIS**
3) **PHARMACEUTICAL CHEMISTRY**
4) **INDUSTRIAL PHARMACY**
5) **PHARMACOLOGY**

1.4 Every candidate shall put in attendance for not less than 75% of the total number of working days in each semester to be eligible to sit for the semester end examination. 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 each of theory and practical courses the evaluation shall be on the basis of internal evaluation for 20 marks and the semester end examination for 80 marks as detailed in the scheme of examination. They shall be two sessional examinations in each theory course and best of the two shall be considered. In practical 20% of the marks are earmarked for continuous evaluation and 80% are earn marked for the semester end examination. The marks certificate issued to the candidate by the University shall show separately the Sessional marks (in theory, 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 evaluation. There shall be one semester end examination in each practical course as per "the scheme of examination" and the setting and evaluation 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 examination, a teacher shall have to put in atleast three years of service as a teacher of the course concerned.

c) If the disparity between the marks awarded by both the examiners is 20% or less than average mark shall be taken as the mark awarded in the paper. If the disparity happens be more, reference to a third examiner will be made whose evaluation 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 practicals in university examination (out of 80 marks the candidate needs to get a minimum of 32 marks to be declared as passed) 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 practicals in all the examinations of the four semesters taken together shall be declared to have passed in First Division with Distinction. Candidates who secure not less than 60% shall be declared 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 prizes 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) At the end of the Second semester each candidate should face the comprehensive viva-voce examination evaluated by an external examiner along with two internal examiners.

c) The candidate should submit two assignments in First semester and one assignment in Second semesters 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 candidate.

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 intention to do so to the Registrar through the Research 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 and the vive-voce examination shall be conducted jointly by the Supervisor or the Director who guided the work and the External Examiner.

A.N.U. M.PHARMACY SYLLABUS (WITH EFFECT FROM 2003 - 04 ACADEMIC YEAR)

I/II M.PHARMACY (1st Semester)
(INDUSTRIAL PHARMACY SPECIALIZATION)

Paper No.	Title of the Paper	No. of Periods of instruction per week		Evaluation / Marks				Total
				Theory (University)		Practical		
		Theory	Practical	Inter-nal	University	Inter-nal	University	
1.1 T & P	Advanced Instrumental Methods of Analysis	04	10	20	80	20	80	200
1.2 T & P	Advanced Pharmaceutical Technology	04	10	20	80	20	80	200
1.3 T	Drug Regulatory / Affairs	04	---	20	80	---	----	100
	Seminars	02	---	----	----	----	----	(2 x 25)50
	Assignments	02	---					(2 x 25)50
	Total Marks							**600**

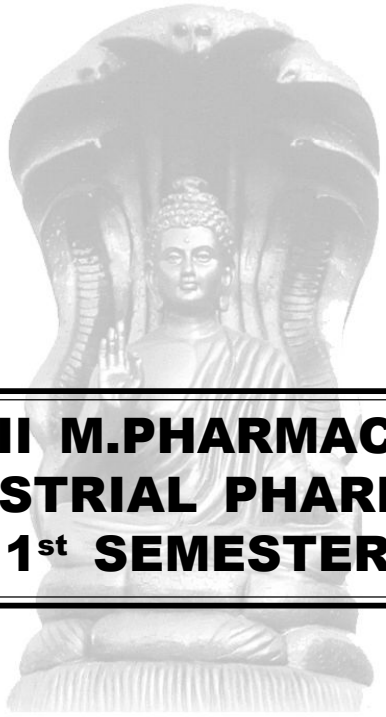
I/II M.PHARMACY (2nd Semester)
(INDUSTRIAL PHARMACY SPECIALIZATION)

Paper No.	Title of the Paper	No. of Periods of instruction per week		Evaluation / Marks				Total
				Theory (University)		Practical		
		Theory	Practical	Inter-nal	University	Inter-nal	University	
2.1 T & P	Advances in Drug Delivery Systems	04	10	20	80	20	80	200
2.2 T & P	Pharmaceutical Biotechnology	04	10	20	80	20	80	200
2.3 T	Advdanced Industrial Pharmacy	04	---	20	80	----	----	100
	Seminars	01	---	----	----	---	----	25
	Assignments	01	---					25
	Comprehensive Viva-voce	01	---					50
	Total Marks							**600**

II/II M.PHARMACY (3rd & 4th Semester)

Seminar-I (on the proposed project work with aims and objectives before commencement	50
Seminar-II (on the experimentation and results obtained in the project work after completion)	50
Thesis Evaluation	150
Defence Viva-voce	50
Total Marks	**300**
Grand Total for the Course	**1,500**

A.N.U. M.PHARMACY SYLLABUS (WITH EFFECT FROM 2003 - 04 ACADEMIC YEAR)



I/II M.PHARMACY
(INDUSTRIAL PHARMACY)
1st SEMESTER

ACHARYA NAGARJUNA UNIVERSITY

I/II M.PHARMACY (1st Semester)

1.1 T : ADVANCED INSTRUMENTAL METHODS OF ANALYSIS

1. **UV-VISUAL SPECTROSCOPY :** Brief review of electromagnetic spectrum, UV-Visual range, energy-wavelength-color relationship. Interaction of electromagnetic radiation (UV-Vis) and matter and its effects. Chromophores and their interaction with Electromagnetic Radiation. Absorption spectra of organic compounds and complexes illustrating the phenomenor and its utilization in qualitative and quantitative analysis of drugs. Shifts and their Interpretation (including solvent effects)

2. **INFRA-RED SPECTROSCOPY :** Nature of Infra-red radiation. Interaction of IR. Radiation with organic molecules and effects on bonds. Brief outline of classical I.R. instrumentation and the interpretation of spectra, including sample preparation for spectroscopy. Qualitative interpretation of I.R. spectra. Quantitative methods useful in drug analysis.

3. **NUCLEAR MAGNETIC RESONANCE SPECTROSCOPY :** Fundamental principles of NMR (Magnetic Properties of nuclei, applied field and precession; absorption and transition frequency). Chemical shifts concept; Isotopic nuclei, Reference standards; Proton Maganetic spectra, their characteristics, presentational terms used in describing spectra and their interpretation (Signal no. Position, intensity). Brief outline of instrumental arrangements and some practical details. Signal multiplicity phenomena in high resolution PMR Spin spin coupling. Application of Signal Sprit and coupling constant data to interpretation of spectra.

   Brief outline of principles of FT-NMR with reference to 13 CNMR; Spin-spin and spin-lattice relaxation phenomena. Free induction decay (FID) proton noise decoupling signal averaging time domain and frequency domain signals nuclear overhauser enhancement; CNMR spectra, their presentation, characteristics, interpretation examples and application in drug analysis.

4. **MASS SPECTROMETRY :** Basic principles and brief outline of instrumentation. Ion formation and types, molecular ion, meta stable ions, fragmentation processes, fragmentation patterns and fragment characteristics in relation to parent structure and functional groups. Relative abundances of isotopes and their contribution to characteristics peaks. Mass spectrum, its characteristics, presentation and interpretation. Chemical ionization mass spectrometry, GC-MS other recent advances in MS, FAST ATOM BOMBARDMENT MASS spectroscopy. Application of mass spectrometry in the analysis of drug.

5. **GAS CHROMATOGRAPHY :** Instrumentation packed and open tubular column, column efficiency parameters, the Van Deemeter equation, Resolution, liquid stationary phases, Derivatisation methods of GC including acylation, perfluoroacylation, alkylation and esterification. Detectors; FID, ECD, TCD, NPD. A critical comparison of sensitivity, selectivity and field of application of these detectors. Examples of GC applications in Pharmaceutical Analysis.

6. **LIQUID CHROMATOGRAPHY :** Comparison of GC and HPLC, instrumentation in HPLC, analytical, preparative and micropore columns, normal and reversed-phase packing materials, Reverse-phases HPLC, column selection, mobile phase selection, efficiency parameters, resolution, detectors in HPLC; refractive index, Photometric and electrochemical. Comparison of sensitivity, selectivity and field of applications of these detectors. HPTLC-instrumentation and applications.

7. **X-RAY DIFFRACTION AND DSC, DTA METHODS :** Introduction, Generation of X-Rays, Elementary crystallography; miller Indices, X-ray, diffraction Bragg's law, X-ray powder diffraction, X-ray powder diffractometer, obtaining and interpretation of X-ray powder diffraction data. Applications of XRD, DSC and DTA in the characterization of Pharmaceutical solids.

8. **RADIO IMMUNO ASSAY METHODS :**

I/II M.PHARMACY (1st Semester)

1.1 P : ADVANCED INSTRUMENTAL METHODS OF ANALYSIS-(PRACTICALS)

Practicals based on Theory will be conducted.

Recommended Books

1. Instrumental Methods of Analysis-**Willard, Merrit, Dean et.Al**
2. A Text Book of Pharmaceutical Analysis (Vol. 1 & 2)-**Roger E.Schirmer**
3. Methods of Drug Analysis -**Gaerian & Grabowski**
4. A Text Book of Pharmaceutical Analysis - **K.A.Connors**
5. Practical Pharmaceutical Chemistry (Vol. 1 & 2) - **Beckette & Stenlake**
6. Pharmaceutical Analysis - **P.Parimoo**
7. Spectroscopy - **Silverstein**
8. Organic Spectroscopy - **William Kemp**
9. Pharmaceutical Analysis-Modern Methods by **J.W.Munson, (Marcel Dekker)**

I/II M.PHARMACY (1st Semester)

1.2 T : ADVANCED PHARMACEUTICAL TECHNOLOGY

1. Preformulation Studies :

A) Goals of preformulation, Preformulation parameters, Methodology; Solid state properties, Solubility and Partition coefficient, Solubility, Modern concepts in rheology, Drug excipient compatability.

B) **Dissolution :** Theory, Mathematical models, types of dissolution equipments, sink condition and its importance. Automation in dissolution. "*In-vitro* / *In-vivo*" correlations, Recent advances in dissolution testing.

2. Excipients used in Pharmaceutical Dosage forms :

A) Polymers

B) Properties and selection criteria for various excipients like surfactant, viscosity promoters, diluents, coating materials, plasticizers, preservatives, flavors and colours.

3. Formulation Development :

A) **Solid dosage forms :**

Improved Production techniques for tablets : New materials, process, equipments improvements, high shear mixers, compression machines, coating machines, Coating techniques in tablet technology for product development, Physics of tablet compression computerization for in process quality control of tablets, types of tablets and their manufacture formulations production and evaluation of hard and soft gelatin capsules.

Powder Dosage Forms :

Formulation development and manufacture of power dosage form for internal and external use including inhalations dosage forms.

B) Compaction and compression :

Compaction of powders with special reference to distribution and measurement of forces in the powder mass undergoing compression. Effect of particle size, moisture content and lubrication on the strength of tablets.

C) Liquid and Semi-solid dosage forms :

Recent addvances in formulation aspects and manufacturing of monophasic dosage forms, Recent advances in formulation aspects and manufacturing of suspensions, dry syrup and semi-solid dosage forms.

D) Parentral dosage forms :

Advances in materials and production techniques, filling machines, sterilizers and aseptic processing. Manufacturing of small and large volume parenterals and quality control.

4. **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.
5. Pilot plant and scale-up techniques for the production of different pharmaceutical dosage forms.
6. **Packaging Technology :** Packaging materials, closures and containers, unit dose packaging, blister packing, strip packing. FDA regulations, packaging of tablets, capsules, ointments and aerosols.

I/II M.PHARMACY (1st Semester)

1.2 P : ADVANCED PHARMACEUTICAL TECHNOLOGY-(PRACTICALS)

Practicals based on Theory will be conducted.

Recommended Books :

1. Gennaro A ER, Remington : The science and practice of pharmacy, 20th Edition, Vol-1 & II, Lippincott Williams & Willkins, Philadellphia, PA 2000.
2. Lachman L & Liberman HA, The theory and practice of Industrial Pharmacy, 3rd Edn., Vergese Publishing House, Mumbai, 1991.
3. Banker GS and Rhodes CT, Modern Pharmaceutics, 3rd Edn., mercel Dekker, Inc., New York, 1995.
4. Turco'S and King RE, Sterile Dosage Forms, 3rd Edn., Lea & Febiger, Philadelphia, 1987.
5. Aulton ME, Pharmaceutics - The Science of Dosage Form Design, 1st (International Student) Edn., Churchill Livingstone, New York, 1996.
6. Wiseman A, Principles of Bio-Technology, 2nd Edn., Surrey Univ. Press, New York, 1985.
7. Ansel HC, Allen, Jr., LV et al, Pharmaceutical dosage Forms and Drug Delivery Systems, 6th Edn., Lippincott Williams & Wilkins, Philadelphia, PA-2000.
8. Wiseman, A, Handbook of Enzyme Biotechnology, Wnd Edn., Ellis Horwood Ltd, New York, 1985.
9. Theory and practice of Industrial Pharmacy by LIberman and Lachman.
10. Remington's Pharmaceutical Sciences.
11. GMP by Sidney H, Willing.
12. Quality Assurance Guide, Organization of Pharmaceutical Producers of India.
13. Drugs and Cosmetics Act. 1960 and Rules 1945.
14. S.H.Willing, M.M.T. Tuckerman, W.S.Hitchings IV, Good Manufacturing practices for pharmaceuticals, Marcel Dekker Inc, New York.
15. P.P.Sharma, How to practice GMP's Vandhana Publications, Agra.
16. Ira R.Berry and R.A.Nash (eds.) Pharmaceutical Process Validation, marcle Dekker Inc., New York.

I/II M.PHARMACY (1st Semester)

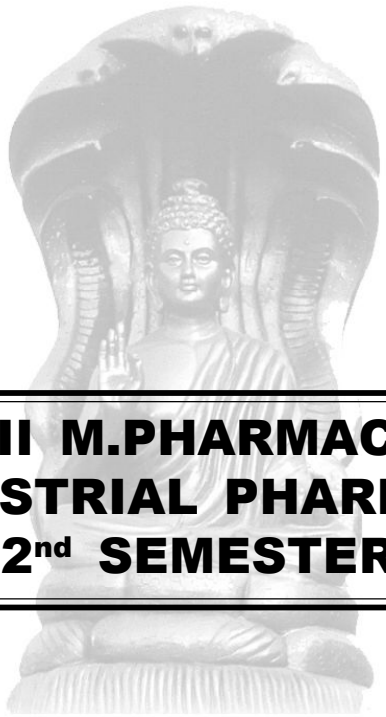
1.3. T : DRUG REGULATORY AFFAIRS

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 authorioties.
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, elastomer 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 self - 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 :** Introduction, purpose, international scenario and Indian scenario, guidelines as per European community, United states and Indian regulatory authorities, documentation, presentation and application.

A.N.U. M.PHARMACY SYLLABUS (WITH EFFECT FROM 2003 - 04 ACADEMIC YEAR)



I/II M.PHARMACY
(INDUSTRIAL PHARMACY)
2nd SEMESTER

ACHARYA NAGARJUNA UNIVERSITY

I/II M.PHARMACY (2nd SEMESTER)

2.1.T ADVANCES IN DRUG DELIVERY SYSTEMS

A. Fundamentals of controlled drug delivery system, Theory of mass transfer, use of polymers in controlled drug delivery, pharmaco-kinetic and Pharmacodynamic basis of controlled drug delivery, Design, fabrication, evaluation and applications of the following controlled release systems.
   1. Controlled release oral drug delivery systems.
   2. Parenteral controlled release drug delivery systems
   3. Implantable therapeutic systems.
   4. Transdermal therapeutic systems and iontophoresis.
   5. Ocular and intrauterine delivery systems.
   6. Bioadhesive drug delivery systems.
   7. Proteins and peptide drug delivery.

B. Biochemical and molecular biology approaches to controlled drug delivery
   1. Micro particulate drug carriers : Liposomes, Neosomes, Micropspheres, Nanoparticles and Resealed erythrocytes.
   2. Monoclonal antibodies for drug delivery.

C. Drug targeting to particular organs :
   1. Drug delivery to respiratory system.
   2. Problems of drugs delivery to the brain and targeting to brain.
   3. Drug delivery to eye.
   4. Drug targeting in neoplastic diseases.

D. Drug carrier systems targeted to widely dispersed cells.
   1. Delivery to Macrophages.
   2. Delivery to lymphoid cells of Immune network.
   3. Delivery to lysosomal storage diseases.

I/II M.PHARMACY (2nd SEMESTER)

2.1.P ADVANCES IN DRUG DELIVERY SYSTEMS PRACTICALS

Practicals based on Theory will be conducted.

Test Books :

1. Y.W.Chien, Novel Drug Delivery Systems, 2nd Edition, revised and expanded, Marcel Dekker, Inc., New York, 1992.
2. Robinson, J.R.Lee V.H.L,Controlled Drug Delivery Systems, Marcel Dekker, Inc., New York, 1992.

REFERENCE BOOKS & JOURNALS :

1. Encyclopedia of controlled delivery, Editor-Edith Mathiowitz, Published by Wiley Interscience Publication, John Wiley and Sons, Inc, New York / Chichester / Weinheim.
2. N.K.Jain, Controlled and Novel Drug Delivery, CBS Publishers and Distributors, New Delhi, First edition 1997 (reprint in 2001).
3. S.P.Vyas and R.K.Khar, Controlled Drug Delivery -concepts and advances, Vallabh Prakashan, New Delhi, First edition-2002.

JOURNALS :

1. Indian Journal of Pharmaceutical Sciences (IPA)
2. Indian Drugs (IDMA)
3. Journal of controlled release (Elsevier Sciences) {desirable}
4. Drug Development and Industrial Pharmacy (Marcel & Decker) {desirable}

I/II M.PHARMACY (2nd SEMESTER)

2.2.T PHARMACEUTICAL BIOTECHNOLOGY

1. **Enzyme Technology :** Sources of enzymes; production; isolation and purification of enzymes, applications of enzymes in pharmaceutical industry, in therapeutics and in clinical analysis. Production of amyloglucosidase, glucose isomerase, amylase, cellulase, takadiastase, trypsin, streptokinase and urokinase.
2. **Immobilized enzyme engineering :** Different techniques of immobilization of enzumes, kinetics of immobilized enzyme, design and operation of immobilized enzyme reactors, multi step immobilized enzyme systems, applications and future of enzyme engineering.
3. **Computer control of fermentation process :** Optimization of fermentation parameters.
4. **Biosynthesis of microbial metabolites :** General consideration of metabolic pathways, biosynthesis of alcohol, citric acid, antibiotics (Penicillin, Strepomycin, Tetracycline & Erythromycin), ergot alkaloids, riboflavin, vitamin B_{12} and Glutamic acid.
5. **Genetic engineering :** A broad study of the techniques of genetic engineering and application of techniques of genetic engineering in biotechnology. Recombinant DNA techniques (i) Hybrid DNA formation, (ii) Protoplast fusion, Interferon, Insulin, hepatitis-B vaccine, human growth hormone & interleukins production by micro organisms through genetic engineering techniques.
6. **Monoclonal antibodies** and other immunoreactive products of permanent immunoclones. Production & application of monoclonal antibodies.
7. **Current developments in immunotechnology-diagnostic kits for identifying infectious agents :** HIV, Malaria, Tuberculosis, VDRL and Pregnancy test. Current status of Development of Vaccines for HIV and Plasmodium.
8. **Bio-Informatics :** Information theory and biology, redundancy networking, network access, Internet & E-mail services, use of data base in biology, sequence data base for comparisons.
9. **Immunobiolotechnology :** Hybridoma, techniques, fusion method for myeloma cells and by-lymphocytes, selection and screening techniques, production and purification of monoclonal antibodies and their application in clinical diagnosis, immunotherapy, recombinant and submit vaccines.

2.2.P PHARMACEUTICAL BIOTECHNOLOGY PRACTICALS

Practicals based on Theory will be conducted.

LIST OF BOOKS :

01. Selected topics in enzyme Engineering by Wingard Jr., L.B.edited foi items 1 and 2.
02. Immobilized enzymes by Messing for item 2
03. Chapter 1, 2, 7 in Advances in Applied Microbiology Vol. 15, 1972 on enzymes. Immobilized enzymes and Animal and plant cell culture.
04. Principles of gene manipulation-An introduction to Genetic Engineering by R.W.Old and S.B.Primrose.
05. Molecular Biotechnology by Glick
06. Therapeutic Peptides and Proteins; Formulation, processing and delivery systems; Ajay K Banga
07. Industrial Biotechnology : vedpal S Malik and Padma Sridhar
08. Gene transfer and expression protocols-Methods in Moilecular Biology, Vol.-VII, Edit E T Murray.
09. Current protocols in Molecular Biology, Vol.-I and II; F M Asubel, John Wiley Publishers.
10. Current protocols in cellular biology, Vol.-I and II, John Wiley Publishers.
11. Cell Biology, Vol.-I, II and III edited by Julio E Celis
12. Biotechnology by B.D.Singh, Kalyani Publishers, New Delhi.

I/II M.PHARMACY (2nd SEMESTER)

2.3.T ADVANCED INDUSTRIAL PHARMACY

01. Pilot plant scale-up techniques : Significance, pilot study of some important dosage forms such as tablets, capsules and liquid orals, discussion on important parameters such as formula, equipments, product uniformity and stability, raw material process and physical layouts, personnel requirements and reporting responsibilities.

02. Production, Planning, Control and Documentation : Production scheduling, forecasting, vendor development capacity assessment (Plant, machines, human resources), production management, production organisation, objectives and policies. Productivity, good manufacturing practices, guide to pharmaceutical manufacturing practices, guide to pharmaceutical manufacturing facilities, tablets and liquid orals, materials management and cost controls.

03. Inventory management, Material Management and Maintenance Management : Costs in inventory, inventory categories special considerations, selective inventory control, reorder quantity methods and EOQ, inventory models, safety stock-stock out, lead time-reorder time methods, modern inventory management systems, inventory evaluation. Materials-quality and quantity, value analysis, purchasing-centralized and decentralized, vendor development, buying techniques, purchasing cycle and procedures, stores management, salvaging and disposal of scrap and surplus. Selection of material handling systems, maintenance of material handling equipment, unit-load, palletization and containerization, types of material handling systems. Classification of maintenance, corrective (breakdown) maintenance, scheduled maintenance, preventive maintenance, predictive maintenance.

04. Human Resource Development : Personal training, job specification, job enlargement and enrichment, blue and white-collar jobs. Labor welfare.

05. **Industrial hazards, pollution and effluent treatment :** Introduction, Factory act and rules, fundamentals of accident prevention, organizing for safety, electrical hazards, industrial chemicals and their health hazards, material handling, Fire prevention and control, Physicochemical measurements of effluents, BOD, COD, Determination of some contaminants. Effluent treatment procedure, treatment of some characteristic effluent.

06. **ISO 9000 and 1400 Validation :** Sailent features, total quality management and productivity, process products and equipment and instrument validation.

07. **Quality Control :** Process and Dosage form, Process control, Control of manufacturing process, statistical quality control, control charats of automated process control, Dosage form control, Testing programme and methods, product identification system, Adulteration and misbranding, Drug information profile.

08. **Optimisation techniques in Pharmaceutical and Processing :** Optimization parameters, statistical design and other applications, design development and optimization of in-vitro test systems to evaluate and monitor the performance of different types of dosage forms, the relevance and importance of in-vitro/in-vivo associations at every stage of product development and manufacture, the regulatory evaluation and current thinking on this aspect, application of statistical techniques in product development and evaluation including quality control.

09. **Industrial Safety :** Industry hazards due to fire accidents, mechanical and electrical equipment, chemicals and pharmaceuticals, Monitoring and prevention systems. Industrial efficiency testing.

10. **Unit Operations :** An advanced study of the following unit operations with special reference to formulation and production of pharmaceuticals milling, mixing, tablet compression, tablet coating, filtration, drying and sterilization.

REFERENCE BOOKS :

01. Evans, Anderson, Sweeney and Williams Applied production and operations management 3rd edition, West publishing company Ltd., St., Paul.
02. Peter F.Drucker, Management (tast, responsibility and practices) Allied publication, Bangalore.
03. H W Tomski A Text of Pharmacy management Kogan Page Ltd. London.
04. Harold Koonz, Cy ril O Donnell, Heinz, Weihrich Essentials of Management Maggraw Hill Book Company, New Delhi.
05. Lachman L Liberman Theory and practice of industrial pharmacy by 3rd edition.
06. Sidney H, Willing, Murray M, Tuckerman, Williams Hitchings IV, Good manufacturing of pharmaceuticals (A Plan for total quality control) 3rd Edition, Bhalani publishing house Mumbai.
07. ISO 9000 and 14000 Series.