JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY ANANTAPUR
ANANTAPUR-515002 (A.P) INDIA

ACADEMIC REGULATIONS COURSE STRUCTURE AND DETAILED SYLLABI

MASTER OF PHARMACY

INDUSTRIAL PHARMACY

M.Pharm Regular Two Years P.G. Degree Course
(Applicable for the batches admitted from 2011-12)

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY ANANTAPUR
ACADEMIC REGULATIONS FOR THE AWARD OF FULL TIME
M. Pharm. DEGREE
(WITH EFFECT FROM THE ACADEMIC YEAR 2010-11)

The Jawaharlal Nehru Technological University Anantapur shall confer M.Pharm. Post Graduate degree to candidates who are admitted to the Master of Pharmacy Programs and fulfill all the requirements for the award of the degree.

1.0 ELIGIBILITY FOR ADMISSIONS:

Admission to the above programme shall be made subject to the eligibility, qualifications and specialization prescribed by the University for each programme, from time to time.

1.1. Admissions shall be made either on the basis of merit rank obtained by the qualified candidates at an Entrance Test conducted by the University or on the basis of GATE / PGECET score, subject to reservations prescribed by the University or Government policies from time to time.

2.0 COURSE WORK:

2.1 A Candidate after securing admission must pursue the M.Pharm.course of study for Four Semesters duration.

2.2 Each semester shall be of 20 weeks duration including all examinations.

2.3 A candidate admitted to a programme should complete it within a period equal to twice the prescribed duration of the programme from the date of admission.

3.0 ATTENDANCE

3.1 A candidate shall be deemed to have eligibility to write end semester examinations if he has put in at least 75% of attendance on cumulative basis of all subjects/courses in the semester.

3.2 Condonation of shortage of attendance up to 10% i.e., from 65% and above and less than 75% may be given by the college on the recommendation of the Principal.

3.3 Condonation of shortage of attendance shall be granted only on genuine and valid reasons on representation by the candidate with supporting evidence.

3.4 If the candidate does not satisfy the attendance requirement he is detained for want of attendance and shall reregister for that semester. He / she shall not be promoted to the next semester.

4.0. EVALUATION:

The performance of the candidate in each semester shall be evaluated subject wise, with a maximum of 100 marks for Theory and 100 marks for practicals, on the basis of Internal Evaluation and End Semester Examination.

4.1 For the theory subjects 60% of the marks will be for the External End Examination. While 40% of the marks will be for Internal Evaluation, based on the better of the marks secured in the two Mid Term-Examinations held, one in the middle of the Semester (I-IV units) and another immediately after the completion of instruction (V-VIII) units with Three questions to be answered out of four in 2 hours, evaluated for 40 marks.

*****Note: All the Questions shall have equal weightage of 10 marks and the marks obtained for 3 questions shall be extrapolated to 40 marks, any fraction rounded off to the next higher mark

4.2 For practical subjects, 60 marks shall be for the End Semester Examinations and 40 marks will be for internal evaluation based on the day to day performance.

4.3 For mini project there will be an internal evaluation of 50 marks. The candidate has to secure a minimum of 50% to be declared successful. The assessment will be made by a board consisting H.O.D. and two internal staff members/experts.

4.4 For Seminar there will be an internal evaluation of 50 marks. A candidate has to secure a minimum of 50% to be declared successful. The assessment will be made by a board consisting of HOD and two internal experts at the end of IV semester instruction.

4.5 A candidate shall be deemed to have secured the minimum academic requirement in a subject if he secures a minimum of 40% of marks in the End Examination and a minimum aggregate of 50% of the total marks in the End Semester Examination and Internal Evaluation taken together.

4.6 In case the candidate does not secure the minimum academic requirement in any subject (as specified in 4.5.) he has to reappear for the Semester Examination either supplementary or regular in that subject, or repeat the course when next offered or do any other specified subject as may be required.

5.0 RE-REGISTRATION FOR IMPROVEMENT OF INTERNAL EVALUATION MARKS:

Following are the conditions to avail the benefit of improvement of internal evaluation marks.

5.1 The candidate should have completed the course work and obtained examinations results for I & II semesters.

5.2 He should have passed all the subjects for which the Internal evaluation marks secured are more than 50%.

5.3 Out of the subjects the candidate has failed in the examination due to Internal evaluation marks secured being less than 50%, the candidate shall be given one chance for each Theory subject and for a maximum of two Theory subjects for Improvement of Internal evaluation marks.

5.4 The candidate has to re-register for the chosen subjects and fulfill the academic requirements.

5.5 For each subject, the candidate has to pay a fee equivalent to one third of the semester tuition fee and the amount is to be remitted in the form of D.D. in favour of the Registrar,

JNTUA payable at Anantapur along with the requisition through the Principal of the respective college.

5.6 In the event of availing the Improvement of Internal evaluation marks, the internal marks as well as the End Examinations marks secured in the previous attempt(s) for the reregistered subjects stand cancelled.

6.0 EVALUATION OF PROJECT WORK:

Every candidate shall be required to submit thesis or dissertation after taking up a topic approved by the college/ institute.

6.1 Registration of Project work: A candidate is permitted to register for the project work after satisfying the attendance requirement of all the courses (theory and practical courses of I & II Sem)

6.2 An Internal Departmental Committee (I.D.C) consisting of HOD, Supervisor and one internal senior expert shall monitor the progress of the project work.

6.3 The work on the project shall be initiated in the penultimate semester and continued in the final semester. The duration of the project is for two semesters. The candidate can submit Project thesis with the approval of I.D.C. after 36 weeks from the date of registration at the earliest and one calendar year from the date of registration for the project work. Extension of time within the total permissible limit for completing the programme is to be obtained form the Head of the Institution.

6.4 The student must submit status report at least in three different phases during the project work period. These reports must be approved by the I.D.C. before submission of the Project Report.

6.5 A candidate shall be allowed to submit the thesis / dissertation only after passing in all the prescribed subjects (both theory and practical) and then take viva voce examination of the project. The viva-voce examination may be conducted once in two months for all the candidates submitted during that period.

6.6 Three copies of the Thesis / Dissertation certified in the prescribed form by the supervisor & HOD shall be presented to the University.

6.7 The college shall submit a panel of three experts for a maximum of 5 students at a time. However, the thesis / dissertation will be adjudicated by one examiner nominated by the University.

6.8 If the report of the examiner is favorable viva-voce examination shall be conducted by a board consisting of the Supervisor, Head of the Department and the examiner who adjudicated the thesis / dissertation. The board shall jointly report candidates work as:

1.	Very Good	Grade A
2.	Good	Grade B
3.	Satisfactory	Grade C
4.	Not satisfactory	Grade D

If the report of the viva-voce is not satisfactory (Grade D) the candidate will retake the viva-voce examination after three months. If he fails to get a satisfactory report at the second viva-voce examination he will not be eligible for the award of the degree unless the candidate is permitted to revise and resubmit thesis.

7.0 AWARD OF DEGREE AND CLASS:

A candidate shall be eligible for the award of respective degree if he satisfies the minimum academic requirements in every subject and secures 'satisfactory' or higher grade report on his thesis/dissertation and viva-voce. Based on overall percentage of marks obtained, the following class is awarded.

First class with Distinction:	70% or more
First class	below 70% but not less than 60%
Second class	below 60% but not less than 50%

8.0 WITH – HOLDING OF RESULTS:

If the candidate has dues not paid to the university or if any case of in- discipline or malpractice is pending against him, the result of the candidate shall be withheld and he will not be allowed/ promoted into the next higher semester. The issue of degree is liable to be withheld in such cases.

9.0 TRANSITORY REGULATIONS:

Candidates who have discontinued or have been detained for want of attendance or who have failed after having undergone the course in earlier regulations and wish to continue the course are eligible for admission into the unfinished semester from the date of commencement of class work with the same or equivalent subjects as and when subjects are offered, subject to 4.6 and 2.3 sections. Whereas they continue to be in the academic regulations they were first admitted.

10.0 GENERAL:

i. **The academic regulations should be read as a whole for purpose of any interpretation**.
ii. **Disciplinary action for Malpractice/improper conduct in examinations is appended.**
iii. **There shall be no place transfer within the constituent colleges and affiliated colleges of Jawaharlal Nehru Technological University Anantapur.**
iv. **Where the words "he", "him", "his", occur in the regulations, they include "she", "her", "hers".**
v. **In the case of any doubt or ambiguity in the interpretation of the above rules, the decision of the Vice-Chancellor is final.**
vi. **The University may change or amend the academic regulations or syllabi at any time and the changes or amendments shall be made applicable to all the students on roles with effect from the dates notified by the University.**

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RULES FOR DISCIPLINARY ACTION FOR MALPRACTICE / IMPROPER CONDUCT IN EXAMINATIONS

	Nature of Malpractices/Improper conduct	Punishment
	If the candidate:	
1. (a)	Possesses or keeps accessible in examination hall, any paper, note book, programmable calculators, Cell phones, pager, palm computers or any other form of material concerned with or related to the subject of the examination (theory or practical) in which he is appearing but has not made use of (material shall include any marks on the body of the candidate which can be used as an aid in the subject of the examination)	Expulsion from the examination hall and cancellation of the performance in that subject only.
(b)	Gives assistance or guidance or receives it from any other candidate orally or by any other body language methods or communicates through cell phones with any candidate or persons in or outside the exam hall in respect of any matter.	Expulsion from the examination hall and cancellation of the performance in that subject only of all the candidates involved. In case of an outsider, he will be handed over to the police and a case is registered against him.
2.	Has copied in the examination hall from any paper, book, programmable calculators, palm computers or any other form of material relevant to the subject of the examination (theory or practical) in which the candidate is appearing.	Expulsion from the examination hall and cancellation of the performance in that subject and all other subjects the candidate has already appeared including practical examinations and project work and shall not be permitted to appear for the remaining examinations of the subjects of that Semester/year. The Hall Ticket of the candidate is to be cancelled and sent to the University.
3.	Comes in a drunken condition to the examination hall.	Expulsion from the examination hall and cancellation of the performance in that subject and all other subjects the candidate has already appeared including practical examinations and project work and shall not be permitted for the remaining examinations of the subjects of that semester/year.

4.	Smuggles in the Answer book or additional sheet or takes out or arranges to send out the question paper during the examination or answer book or additional sheet, during or after the examination.	Expulsion from the examination hall and cancellation of performance in that subject and all the other subjects the candidate has already appeared including practical examinations and project work and shall not be permitted for the remaining examinations of the subjects of that semester/year. The candidate is also debarred for two consecutive semesters from class work and all University examinations. The continuation of the course by the candidate is subject to the academic regulations in connection with forfeiture of seat.
5.	Leaves the exam hall taking away answer script or intentionally tears of the script or any part thereof inside or outside the examination hall.	Expulsion from the examination hall and cancellation of performance in that subject and all the other subjects the candidate has already appeared including practical examinations and project work and shall not be permitted for the remaining examinations of the subjects of that semester/year. The candidate is also debarred for two consecutive semesters from class work and all University examinations. The continuation of the course by the candidate is subject to the academic regulations in connection with forfeiture of seat.
6.	Possess any lethal weapon or firearm in the examination hall.	Expulsion from the examination hall and cancellation of the performance in that subject and all other subjects the candidate has already appeared including practical examinations and project work and shall not be permitted for the remaining examinations of the subjects of that semester/year. The candidate is also debarred and forfeits the seat.

7.	Impersonates any other candidate in connection with the examination.	The candidate who has impersonated shall be expelled from examination hall. The candidate is also debarred and forfeits the seat. The performance of the original candidate who has been impersonated, shall be cancelled in all the subjects of the examination (including practicals and project work) already appeared and shall not be allowed to appear for examinations of the remaining subjects of that semester/year. The candidate is also debarred for two consecutive semesters from class work and all University examinations. The continuation of the course by the candidate is subject to the academic regulations in connection with forfeiture of seat. If the impostor is an outsider, he will be handed over to the police and a case is registered against him.
8.	Refuses to obey the orders of the Chief Superintendent/Assistant – Superintendent / any officer on duty or misbehaves or creates disturbance of any kind in and around the examination hall or organizes a walk out or instigates others to walk out, or threatens the officer-in charge or any person on duty in or outside the examination hall of any injury to his person or to any of his relations whether by words, either spoken or written or by signs or by visible representation, assaults the officer-in-charge, or any person on duty in or outside the examination hall or any of his relations, or indulges in any other act of misconduct or mischief which result in damage to or destruction of property in the examination hall or any part of the College campus or engages in any other act which in the opinion of the officer on duty amounts to use of unfair means or misconduct or has the tendency to disrupt the orderly conduct of the examination.	In case of students of the college, they shall be expelled from examination halls and cancellation of their performance in that subject and all other subjects the candidate(s) has (have) already appeared and shall not be permitted to appear for the remaining examinations of the subjects of that semester/year. The candidates also are debarred and forfeit their seats. In case of outsiders, they will be handed over to the police and a police case is registered against them.

9.	If student of the college, who is not a candidate for the particular examination or any person not connected with the college indulges in any malpractice or improper conduct mentioned in clause 6 to 8.	Student of the colleges expulsion from the examination hall and cancellation of the performance in that subject and all other subjects the candidate has already appeared including practical examinations and project work and shall not be permitted for the remaining examinations of the subjects of that semester/year. The candidate is also debarred and forfeits the seat. Person(s) who do not belong to the College will be handed over to police and, a police case will be registered against them.
10.	Uses objectionable, abusive or offensive language in the answer paper or in letters to the examiners or writes to the examiner requesting him to award pass marks.	Cancellation of the performance in that subject.
11.	Copying detected on the basis of internal evidence, such as, during valuation or during special scrutiny.	Cancellation of the performance in that subject and all other subjects the candidate has appeared including practical examinations and project work of that semester/year examinations.
12.	If any malpractice is detected which is not covered in the above clauses 1 to 11 shall be reported to the University for further action to award suitable punishment.	

Malpractices identified by squad or special invigilators

1. Punishments to the candidates as per the above guidelines.
2. Punishment for institutions : (if the squad reports that the college is also involved in encouraging malpractices)
   (i) A show cause notice shall be issued to the college.
   (ii) Impose a suitable fine on the college.
   (iii) Shifting the examination centre from the college to another college for a specific period of not less than one year.

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY ANANTAPUR
Course Structure and Syllabi for
M. Pharm-Industrial Pharmacy
for affiliated Pharmacy Colleges 2010-11

I YEAR I SEMESTER

S. No	Course code	Subject	Theory	Lab.	Credits
1.	9S01101	Modern Pharmaceutical Analysis	4		4
2.	9S01102	Biostatistics, Intellectual Property Rights and Regulatory affairs	4		4
3.	9S08101	Advanced Industrial Pharmacy	4		4
4.	9S08102	Advanced Physical Pharmacy	4		4
5.	9S01105	Modern Pharmaceutical Analysis- Lab		6	4
6.	9S08103	Advanced Industrial Pharmacy - Lab		6	4
7.	9S08104	Mini-project- I		3	2
		contact periods/week	16	15	26
			Total 31		

I YEAR II SEMESTER

S. No	Course code	Subject	Theory	Lab.	Credits
1.	9S01201	Biopharmaceutics and Pharmacokinetics	4		4
2.	9S08201	Advanced Drug Delivery Systems	4		4
3.	9S08202	Packing Technology	4		4
4.	9S08203	Drug Regulatory Affairs	4		4
5.	9S08204	Biopharmaceutics and Pharmacokinetics-Lab		6	4
6.	9S08205	Advanced Drug Delivery System - Lab		6	4
7.	9S08206	Mini-project- II		3	2
		contact periods/week	16	15	26
			Total 31		

II YEAR (III & IV Semesters)

S. No	Course code	Subject		credits
1	9S08401	Seminar		2
2	9S08402	Project work		16

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M.Pharm I year I semester (Industrial Pharmacy) **Th 4** **C 4**

(9S01101) MODERN PHARMACEUTICAL ANALYSIS

1. **UV-Visible Spectroscopy**: Brief review of electromagnetic spectrum, UV-Visible range, energy, wavelength and color relationships. Interaction of electromagnetic radiation (UV-visible) with matter and its effects. Chromophores and their interactions with E.M.R. Absorption spectra of organic compounds and complexes illustrating the phenomenon and its utilization in qualitative and quantitative studies of drugs. Shifts and their interpretation (including solvent effects). Empirical correlation of structure with absorption phenomena (Woodward's rules etc) Quantitative estimations, Modern instrumentation.

2. **Infrared Spectroscopy**: Nature of Infra-red radiation. Interaction of I.R radiation with I.R molecules and effects on bonds. Molecular Infrared Spectra. Brief outline of classical I.R instrumentation and practical details of obtaining spectra, including sample preparation for spectroscopy, quantitative interpretation of I.R spectroscopy including FT-IR, ATR.
   Optical Rotatory Dispersion: Fundamental principles of ORD, cotton effect curves, their characteristics and interpretation. Octant rule and its application with examples. Circular dichroism and its relation to ORD.

3. **NMR 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 magnetic spectra, their characteristics, presentation terms used in describing spectra and their interpretation (Signal No., Position, Intensity). Brief outline of instrumental arrangements and some practical details. Signal multiplicity phenomenon in high resolution PMR. Spin-spin coupling. Application of Signal split and coupling constant data to interpretation of spectra. De-coupling and shift reagent methods. Brief outline of principles of FT-NMR with reference to 13CNMR. Spin-spin and spin-lattice relaxation phenomenon. Free induction decay (FID) proton noise de-coupling signal, average time domain and frequency domain signals nuclear overhauser enhancement 13CNMR spectra, their presentation; characteristics, interpretation, examples and applications. Brief indication of application of magnetic resonance spectral data of other nuclei by modern NMR instruments. Introduction to 2-D NMR techniques.

4. **Mass Spectroscopy**: Basic principles and brief outline of instrumentation. Ion formation and types; molecular ion, Meta stable ions, fragmentation processes. Fragmentation patterns and fragmentation characteristics in relation to parent structure and functional groups. Relative abundances of isotopes and their contribution to characteristic peaks. Mass spectrum, its characteristics, presentation and interpretation. Chemical ionization Mass Spectroscopy. GC-MS, other recent advances in MS. Fast atom bombardment mass spectrometry. LC-MS, LC-MS-MS.

5. **Chromatographic Techniques**: Classification of chromatographic methods based on mechanism of separation. Paper chromatography; techniques and applications. Thin Layer Chromatography, comparison to paper chromatography and HPLC, adsorbents for TLC. Preparation techniques, mobile phase selection, reversed phase TLC, High performance TLC detection methods, quantitative methods in TLC. Programmed multiple development techniques.

6. **Gas Chromatography**: Instrumentation packed and open tubular column, Column efficiency parameters, the Vandeemer equation, Resolution, liquid stationary phase, derivitazation methods of GC including acylation, perfloro acylation, alkylation and esterification. Detectors: FID, ECD, TCD, NPDA. Critical comparison of sensitivity, selectivity and field of applications of these detectors. Examples of GC applications in pharmaceutical analysis.

7. **Liquid Chromatography**: Comparison of GC and HPLC, instrumentation in HPLC, analytical, preparative and microbore columns, normal and reversed phase packing materials, reverse phase 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.

8. **Electrophoresis:** Moving boundary electrophoresis, Zone electrophoresis, Isotacophoresis and applications in pharmacy. X-ray Diffraction methods: introduction, generation of X-rays, elementary crystallography, Miller Indices, X-rays diffraction, Bragg's law, X-ray powder diffraction, X-ray powder diffractometer, obtaining and interpretation of X-ray powder diffraction data. Principle, instrumentation and application of the following: Differential Scanning Colorimetry (DSC), DTA &TGA in analysis of pharmaceuticals.

Recommended Books

1. Instrumental methods of chemical analysis by **chatwal. K, anand,** 5th edition, 2008 Himalaya Publication India.
2. Vogel's text book of quantitative chemical analysis by **G.H.Jeffery, J.Bassett, J.Mendhan, R.C.Denny.** Pearson Education 2007.
3. Instrumental methods of analysis by **Willard, Merit**, Dean, Settle. 7th edition CBS Publisher 2007.
4. Organic spectroscopy by **Y.R.Sharma.** S.Chand & Co New Delhi. 2008
5. Spectrometric identification of organic compounds by **silverstein,** Webster publish John Wiley & Sons 2005.
6. Spectroscopy by **B.K.Sharma** Pub by Krishna "2007" Prakashan
7. Fundamentals of analytical chemistry by **Skoog,** 6th edition Thomson Brooks, 2007
8. Instrumental methods of analysis by **Skoog.** 6th edition, Thomson Brooks, 2007
9. Text book of pharmaceutical analysis by **S.Ravishankar.**
10. Organic spectroscopy by **William and Kemp** 3rd edition, Palgrave, N.Y.2006
11. Spectroscopic methods in Organic chemistry by **Dudley William and Ian Flemming,** Tata Mc Graw Hill 6th edition 2008.

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M.Pharm I year I semester (Industrial Pharmacy) **Th 4** **C 4**

(9S01102) BIO-STATISTICS, INTELLECTUAL PROPERTY RIGHTS & REGULATORY AFFAIRS

Bio-Statistics

1. An introduction to statistics and biostatistics-collection and organization of data, graphical, pictorial presentation of data, measures of central tendency and dispersion, sampling techniques, sample size, Coefficient of variation, mean error, relative error, precision and accuracy

2. Tests of significance: Testing hypothesis – Principles and applications of Z, t, F– ratio and chi-square tests in pharmaceutical and medical research. Non-parametric tests: sign test, Wilcoxon signed rank test, Wilcoxon rank sum test, Kruskal Wallis test, run test and median tests.

3. Design of Experiments: Principles of randomization, replication and local control; CRD, RBD, LSD – their applications and analysis of data; Factorial Experiments – Principles and applications; Probit analysis: Dose – effect relationships, calculation of LD_{50}, ED_{50}.

4. Statistical quality control: Meaning and uses, Construction of $\bar{X}$, R, P, ηp and C charts.

Intellectual Property Rights & Regulatory Affairs

1. Patents and Intellectual Property Rights (IPR): Definition, scope, objectives, sources of patent information, patent processing and application. Patents, Copyrights, Trademarks, Salient features, international and regional agreements.

2. GATT & WTO: GATT – Historical perspective, objectives, fundamental principles, impact on developing countries. WTO – objectives, scope, functions, structure, status, membership and withdrawal, dispute settlement, impact on globalization, India – task and challenges, trade related aspects (TRIPS).

3. Regulatory Affairs : Indian context – requirements and guidelines of GMP, understanding of Drugs and Cosmetics Act 1940 and Rules 1945 with reference to Schedule N ,U & Y.

4. a) Related Quality Systems: Objectives and guidelines of USFDA, WHO and ICH. Introduction to ISO series.
   b) Documentation: Types related to pharmaceutical industry, protocols, harmonizing formulations, development for global filings, ANDA, NDA, CTD, dealing with post – approval changes – SUPAC, handling and Maintenance including electronic documentation.

Recommended Books:

1. Bio-statistics by **Dr. K Balaji and AVS Raghavaiah**. IK International Publishing House Bangalore. 2010.
2. 'Biostatistics' **KS Negi** AITB Publishers, Delhi, 2002
3. 'Fundamentals of Biostatistics' **Irfan Alikhan** Ukaaz Publications 2nd edition, 1994
4. 'Biostatistics for Pharmacy' **Khan and Khanum** Ukaaz Publications vol:16, 2nd edition, chapman & Hall / CRC 2006
5. 'Basic statistics and Pharmaceutical applications' **J.E, Demuth** Mercel & Dekker.
6. Applied statistics by **S.C.Gupta & V.K.Kapoor** S.Chand & Co Pub. 6th edition, 1996
7. Funadamentals of mathematical statistics by **S.C.Gupta & V.K.Kapoor,** S.Chand & Co Pub. 10th edition, 2000
8. Good Manufacturing Practices for Pharmaceuticals, **S.H. Wiling,** Vol. 78, Marcel Decker. NY.
9. Protection of Industrial Property rights, **P. Das & Gokul Das**
10. Law and Drugs, Law Publications. **S.N. Katju** Delhi law House, 2002 4th edition
11. Original Laws Published By **Govt. of India**
12. Laws of drugs in India, **Hussain** Universal Law publesors.
13. New Drug Approval Process, **R.A.Guarino**,Vol 100, Marcel Decker, NY 1992
14. fda.org,wipo.int,patentlawlinks.com, hc-sc.gc.ca,ich.org,cder.org

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY ANANTAPUR

M.Pharm I year I semester (Industrial Pharmacy) **Th** **C**
4 **4**

(9S08101) Advanced Industrial Pharmacy

1. **Preformulation studies:** Introduction, organoleptic properties, purity, particle size, shape and surface area. Solubility, Methods to improve solubility of Drugs: Surfactants & its importance, co-solvency. Techniques for the study of Crystal properties and polymorphism. Preformulation stability studies.

2. **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.

3. **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. Production, Planning, Control and Documentation: production scheduling, forecasting, vendor development, capacity assessment (plant, machines, human resources), production management, production organization, objectives and policies. Productivity, management and cost controls.

4. **Excipients in pharmaceutical formulations:** Introduction to excipients and their importance in pharmaceutical industry; requirement of excipients, classification and properties of excipients, specialized type of excipients used in tablets such as directly compressible excipients and super-disintegrants; surfactants and hydrocolloids in disperse systems, taste masking excipients, colors, flavours, sweetening agents, gel and film forming agents, solubilizers etc. and their quality control, pharmaceutical-excipient interaction.

5. **Industrial hazards, safety, pollution control and effluent treatment:** Introduction, Factory act and rules, fundamentals of accident prevention, elements of safety programme and safety management, electrical hazards, chemicals hazards and management of over exposure to chemicals, Gas hazards and handling of gases, dust explosion and its control, Fire prevention and control, Physicochemical measurements of effluents, BOD, COD, Determination of some contaminants, Effluent treatment procedure, treatment of some characteristic effluent. Drinking water standards as per (EPA, USA, WHO and BIS).

6. **Production planning & control and documentation:** Production scheduling, forecasting, vendor development, capacity assessment (plant, machines, human resources), production management, production organization, objectives and policies. Productivity, management and cost controls. **Entrepreneurship and project management:** Creativity, innovation entrepreneurship & project management

7. **Optimization techniques in pharmaceutical formulation and processing:** Concept of optimization, optimization parameters, classical optimization, statistical design, and optimization methods.
   Pharmaceutical process validation: Prospective validation, reterospective validation, concurrent validation, significance of validation, validation phases, design qualification, operational qualification, installation qualification, process performance qualification, validation report, statistical methods and tools for process validation, validation of tablet manufacturing process and manufacturing process for sterile products.

8. **Current Good manufacturing practices**: Manufacturing facilities for tablets, capsule, liquid orals, semisolids and parenterals as per schedule M. Certification for pharmaceutical industries, US federal standard 209 E: Class designation, testing and monitoring reports, calibrations, URS,FAT,DQ, SAT, IQ, OQ, PQ of machines and equipment, WHO GMP minimum document check list, Schedule U and U1. Master formula record as per WHO GMP and US FDA. Drug Master files US FDA, Preparation for WHO GMP audit, preparation of Site Master File, environment management system clauses. Technology transfer guidance.

Recommended Books:

1. Applied production and operations management **Evans, Anderson, Sweeney and Williams** 3rd edition, West publishing company Ltd. St.paul. 1st reprint USA (1985)
2. Management (task, responsibility and practices) **Peter F. Drucker.** Allied publication. Bangalore (2009) Harper Paperbacks
3. A Text of Pharmacy management **HWTomski** Kogan Page ltd. London
4. Essentials of Management **Harold Koonz, Cyril a Donnell, Heinz, Weihrich** McGraw Hill Book Company. New Delhi. 4th edition.
5. Good manufacturing Practices for pharmaceuticals : A Plan for total Quality control for Manufacturar (Drugs and Pharmaceutical Sciences) 2000 **Sidney H Willing, Murray M, Tuckerman. Williams Hitchings IV,**3rd Edition. Bhalani publishing house Mumbai.
6. ISO 9000 and 14000 Series. Brian Rothery. Gower pub company 3rd edition, 1995.
7. The Pharmaceuticl Sciences; the Pharma Path way 'Pure and applied Pharmacy' by **D. A Sawant**, Pragathi Books Pvt Ltd.
8. Pharmaceutical Production and management by **C.V.S. Subrahmanyam**, Vallabh Prakashan. Publication, 1st edition 2005.
9. Current Good Manufacturing Practices. **Pothdar M.A** BS Publications
10. Validation of Aseptic Pharmaceutical Processes**12. Careleton F.J., Agallow, J.P.**. Marcel Dekker, Inc. 3rd edition. 2007
11. Pharmaceutical Powder Compaction Technology. **Alderborn** Marcel Dekker, Inc. 2nd edition. 1995
12. Stability of Drugs and Dosage Forms **Yoshoika S., Stella V.J.**. Kluwer Academic/Plenum Publishers. 1st edition 2005, springer.
13. Drug Formulation. **Racz Istvan. John** Wiley & sons 1989
14. Industrial Waste Treatment Handbook. **Woodard F.** Butterworth-Hienneman 2nd edition, 2006.
15. . Pharmaceutical Process Scale Up **Levin M**. Marcel Dekker Inc 2001.
16. The Theory and Practice of Industria Pharmacy. **Lachman L., Lieberman H.A., Kanig J.L.** Lea & Febiger. 2008, 3rd edition.
17. Pharmaceutical Manufacturing Handbook: Production and Processes **Gad S.C.**. John Wiley & Sons. 1st edition 2008
18. Total Quality Management-Principles, Implementation and Cases. **Sharma B.S.**Anmol-Publications Pvt Ltd 2007, 2nd edition.
19. The Managers Guide to ISO 9000. **Kenneth L. A.** Free Press. 1994.

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY ANANTAPUR

M.Pharm I year I semester (Industrial Pharmacy) **Th 4** **C 4**

(9S08102) Advanced Physical Pharmacy

1. **Theory of solubilization and solubilization techniques:** solubility and solubilization of non electrolytes, solubilization by the use of surfactants, cosolvents, complexation, drug derivatisation and solid state manipulation.

2. **Theories of Dispersion:** Solid liquid dispersion: adsorption, wetting, crystal growth mechanisms and prevention of crystal growth. **Emulsion:** Formation and stability of emulsion with special emphasis on electrical theory, H.L.B, theory and di-electric properties. Preparation, evaluation, and applications of multiple and micro emulsions.

3. **Solid state properties:** Crystal properties and polymorphism techniques for study of Crystal properties; solid state stability, flow properties of powders, segregation and its importance.

4. **Theories of compaction and compression:** Compression, consolidation strength of granules, compression and consolidation under high loads, effects 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.

5. **Polymers:** Properties of polymers, thermodynamics of polymer solution, phase separation, polymers in solid state. Applications of polymers in pharmaceutical formulations.

6. **Diffusion and Dissolution:** Diffusion, steady state diffusion procedures and apparatus. Diffusion principles in biological systems, Thermodynamics of diffusion. Dissolution : Basic theories of dissolution, models. Sink conditions in dissolution and its importance. In-vitro-in-vivo correlations.

7. **Kinetics and Drugs stability:** Stability calculations, rate equation, kinetics of some decomposition, strategy of stability testing, methods of stabilization, methods of accelerated stability testing in dosage forms. Freeze thaw methods, centrifugal methods, temperature and humidity control.

8. **Surfactant System** Introduction, micellization, thermodynamics and kinetics of micelle formation, classification. Pharmaceutical aspects of Solubilization, Solubilization in nonaqueous system, interactions with polymers and oppositely charged species. Surfactants in emulsions and suspensions. drug absorption, antibacterial activity.

Recommended Books:

1. Theory and Practice of Industrial Pharmacy By **Lachmann and Libermann**. Pub: Lea & Febiger 2008
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; Leon Lachmann.
5. Modern Pharmaceutics; By **Gillbert and S. Banker.** Informa health care 4th edition, vol-121 Marcel Dekker publication. 2002
6. Pharmaceutical Sciences **Remington's** 21st edition, Lippincott Williams & Wilkins Publications
7. Advances in Pharmaceutical Sciences Vol. 1-5; By **H.S. Bean & A.H. Beckett**.
8. Physical Pharmacy; By **Alfred martin** 5th edition Lippin cott & Williams & Wilkins 2005.
9. Bentley's Textbook of Pharmaceutics –Rawlins, pub by **Bailliere Tindall** 8th edition. 1977.
10. Good manufacturing practices for Pharmaceuticals: A plan for total quality control, Second edition; By **Sidney H. Willig,** 5th edition, vol.109
11. Drug formulation manual; By **D.P.S. Kohli and D.H.Shah.** Eastern publishers, New Delhi. 4th edition.
12. Pharmaceutical Preformulations; By **James.I.Wells, Ellis** horwood Ltd, 1988.

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY ANANTAPUR

M.Pharm I year I semester (Industrial Pharmacy) **L** **C**
6 **4**

(9S01105) Modern Pharmaceutical Analysis (Practicals)

1. Simultaneous estimation of Paracetamol Ibuprofen, Rifampicin and INH, aspirin and caffeine.
2. UV-Visible spectrum scanning of certain organic compounds- absorption and co-relation of structures, comparisions.
   a. Choramphenicol
   b. Sulphadiazine
   c. Analgin
3. Effect of pH and solvent and UV spectrum of certain drugs.
4. Two dimensional paper chromatography and TLC.
5. Gradient elution and other techniques in column chromatography.
6. Separation by electrophoresis.
7. Experiments based on HPLC and GC.
8. IR, NMR and Mass spectroscopy on compound each.
9. DSC/XRD curves of a sample and mixture to understand polymorphism.
10. Determination of insulin / any other hormones by ELISA method.

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M.Pharm I year I semester (Industrial Pharmacy) **L** **C**
6 **4**

(9S08103) Advanced Industrial Pharmacy (Lab)

Suggested practical experiments (at least 15 experiments to be conducted)

1. To study the effect of pH on the solubility of drugs.
2. Accelerated stability of drugs in solution dosage forms.
3. Effect of pH on the stability of drugs in solution at elevated temperature.
4. Improved solubility of drugs using surfactant systems.
5. Improved solubility of drugs using co-solvency method.
6. GMP in three different formulations (Tablets, liquid orals and semi solids).
7. Effluent treatment from bulk drug and formulation industry.
8. Equipment validation (4 Equipments).

Case studies & Assignments

1. Production planning (Weekly and monthly)
2. Human resource development (Industrial case to be discussed)
3. Production scheduling (pertaining to particular industry)
4. Layout plan for different dosage form.
5. Production protocol for tablets liquids and semisolid dosage forms.

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M.Pharm I year I semester (Industrial Pharmacy)

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(9S08104) Mini Project-I:

The mini projects can be taken up as industrial visit/ training and report submission.

OR

A suitable project shall be carried out in the college

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M.Pharm I year II semester (Industrial Pharmacy) **Th** **C**
4 **4**

(9S01201) Bio-Pharmaceutics and Pharmacokinetics (Theory)

1. **Bioavailability:** Designing of bioavailability and bioequivalence studies and interpretation of results. Tests of significance - ANOVA.

2. Physicochemical properties affecting bioavailability, pH-partition theory, dissolution, surface area adsorption, Complexation, polymorphism and techniques of enhancing dissolution rate.

3. Formulation factors affecting bioavailability of drugs in dosage forms like tablets, capsules, parenterals, liquid orals and topical dosage forms. Methods of assessing bioavailability, *In- vivo* methods

4. **Basic concepts of pharmacokinetics:** 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. Absorption: (wherever applicable) absorption rate constant, absorption half-life, lag time and extent of absorption, AUC, AUMC.
    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.

        All the above under the following conditions:
        1. Intravenous bolus injection
        2. Intravenous infusion
        3. Single dose oral administration
        4. Multiple dose injections
        5. Multiple dosage oral administration

    e. Noninvasive methods of estimating pharmacokinetics parameters with emphasis on salivary and urinary compartments
    f. Concept of clearance: organ, total clearance, hepatic clearance, lung clearance and renal clearance.

g. Concept of loading dose, maintenance dose, accumulation index, dosage adjustment in renal and hepatic impairment, individualization of therapeutic drug monitoring.

5. **Non-linear Pharmacokinetics:** Concepts of linear and non-liner pharmacokinetics, Michaelis-Menten Kinetics characteristics. Basic Kinetic parameters, possible causes of non-induction, non-linear binding, and non-linearity of pharmacological responses.
6. **Time dependent pharmacokinetics**: Introduction, classification, physiologically induced time dependency, Chronopharmacokinetics.

7. **Clinical pharmacokinetics**: Altered kinetics in pregnancy, child birth, infants and geriatrics, liver and renal disease states.

8. **Bioequivalence**: Regulations, Criteria for establishing a bioequivalence requirements, Types of bioequivalence requirements, bioequivalence testing, study design, assessment of bioequivalence, *In-vitro* dissolution studies, Qualification and Validation, *In - vitro – In -vivo* comparison, Dissolution limits, Controversies and concerns in bioequivalence.

Recommended Books

1. Pharmacokinetics, by **Gibaldi M.,** Marcel Decker Inc, New York. 4th edition Vol 15, 1982.
2. Dissolution, Bioavailability and bioequivalence, by **Abtou, H.M.,** Mack publishing Co, Easton, PA. 1st edition Nov 1989.
3. Text book of Biopharmaceutical Analysis, by **Smith, RV & Stewart JT,**Lea and Febiger, Philadelphia. 2nd edition. (1981)
4. Fundamentals of Clinical Pharmacokinetics, **Wagner JG,**Drug intelligence Pub. Hamilton. 1975
5. Pharmaceutical Bioequivalence, **Welling, P.G., Tse, FIS & Dighe, S.V. (eds),** Marcel & Decker Inc, New York. (Vol.48) Reprint 2006.
6. Clinical Pharmacokinetics- Concept and Applications, by **Rowland, M & Tozer, T.N.** Lea & febiger, USA. 3rd edition. Lippincott Williams & Wilkins 2011.
7. Applied Biopharmaceutics & Pharmacokinetics, by **Shargel, L & Yu, ABC,** Appleton and Lange, Connecticut, USA. 5th edition. 2004 (McGraw-Hill)
8. Biopharmaceutics and Clinical Pharmacokinetics, Hotari, NOTARI. RE, Marcel Dekker Inc, New York and Basel. 1988, 4th edition.
9. Computer applications in Pharmaceutical research and development Seaqn Ekins Wily Interscience 2006.

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY ANANTAPUR

M.Pharm I year II semester (Industrial Pharmacy) **Th 4** **C 4**

(9S08201) Advanced Drug Delivery Systems

1) Fundamentals of controlled drug delivery system, Theory of mass transfer, 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.

2) **Targeted Drug Delivery Systems:** Concept. Advantages and disadvantages, biological processes and event involved in drug targeting, nanoparticles, liposomes, resealed erythrocytes, microspheres, magnetic microspheres, and monoclonal antibodies.

3) 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.

4) **Mucoadhesive Drug Delivery Systems:** Buccal drug delivery systems, concepts, advantages and disadvantages, structure of oral mucosa, transmucosal permeability, mucosal membrane models, permeability enhancers, in vitro and in vivo methods for buccal absorption. Nasal and pulmonary drug delivery systems and its applications.

5) **Intrauterine Drug Delivery Systems:** Development of intra uterine devices (IUDs), copper IUDs, hormone-releasing IUDs.

6) **Polymer Science:** Introduction, polymer classification, application of polymers in formulation of controlled drug delivery systems, biodegradable and natural polymers.

7) Drug targeting to particular organs:

   a) Drug delivery to respiratory system.
   b) Problems of drugs delivery to the brain and targeting to brain.
   c) Drug targeting in neoplastic diseases.

8) **Protein and Peptide Drug Delivery:** Introduction, classification and structure of protein, drug delivery systems for proteins and peptides, manifestation of protein instability and stability.

Recommended Books:

1. Novel Drug Delivery Systems, by **Y W. Chien,** 2nd edition, revised and expanded, Marcel Dekker, Inc., New York, 1992. Vol 50, 2nd edition.
2. Controlled Drug Delivery Systems, by **Robinson, J. R., Lee V. H. L,**Marcel Dekker, Inc., New York, 1992. (2nd edition, vol.29)
3. Encyclopedia of controlled delivery, Editor- Edith Mathiowitz, Published by **Wiley** Interscience Publication, John Wiley and Sons, Inc, New York! Chichester/Weinheim
4. Controlled and Novel Drug Delivery, by **N.K. Jain,** CBS Publishers & Distributors, New Delhi, First edition 1997 (reprint in 2001). (reprint 2010)
5. Controlled Drug Delivery – by **S.P.Vyas and R.K.Khar,**concepts and advances, Vallabh Prakashan, New Delhi, First edition 2002. (reprint 2010)

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY ANANTAPUR

M.Pharm I year II semester (Industrial Pharmacy) **Th 4** **C 4**

(9S08202) PACKING TECHNOLOGY

1. **Introduction :** Purpose of packaging, prerequisites of an ideal package, various types of inner and outer packages used for different pharmaceutical dosage forms, selection of a suitable package, storage temperature, hazards encountered by the package during storage and distribution.

2. **Glass containers for pharmaceuticals:** Glass types, their manufacture, chemical performance, testing and quality control. **Plastics containers for pharmaceuticals:** Classification of plastics, plastic polymersand their physico-chemical, mechanical and biological properties; Additives and fabrication processes. Plastic container for parenterals and transfusion sterile drip kits. Quality control testing and biological toxicity.

3. **Paper and paper board:** Types of paper, folding cartons, quality control testing of paper and paper board. **Metal containers**: Aluminum and tinplate, drums, collapsible tubes and aerosol containers, lacquering, coating and lining.

4. **Caps and closures:** Types; caps, closures, liners, child resistant caps. Elastomeric closures for parenterals, classification of elastomers, physical, chemical and biological properties and their quality control.

5. **Flexible packaging:** Types of films, co-extruded films, foils, coating and laminates,shrink and stretch films. **Product-package compatibility**: Stability of product, packaging selection and development criteria.

6. **Corrugated and solid fiber boards and boxes:** Type of corrugation methods. **Packaging machinery:** Introduction, strip packaging machinery, form, fill and Seal machines, liquid and solid filling machines, capping machines, machinery employed for liquid formulation packaging. **Sterile product packaging:** General principles of packaging of sterile products. Various types of containers used for sterile products including small volume and large volume parenterals. Types of closures used for the sterile products. Sterile product filling and sealing machinery i.e. ampoule filling and sealing machine. Limitations and merits of various packages. Evaluation of the sterile product packages.

7. **Advances in packaging technology:** Blister packaging, tamper evident packaging systems, child resistant packaging, aerosol packaging, etc.

8. **Labels and labeling:** Objectives and contents of a pharmaceutical label. Types of label (including bilingual label, bar code label, radiofrequency (RF) label, structured program label, in-mould label and decorative labels), legal requirements of labeling, packaging inserts and outserts. Adhesives and machinery employed for labeling. Concept of paperless labeling and new developments in labeling technologies.

Recommended Books

1. Pharmaceutical Packaging Technology. **Dean D.A., Evans E.R. Hall I.H.** Taylor & Francis. London and N.Y., 2000
2. Pharmaceutical Packaging Technology. **Jain U.K., Goupale D.C., Nayak S.** PharmaMed Press. (2008)
3. Kirwan M.J. Paper and Paper Board Packaging Technology. Blackwell Publishing Ltd. 1st edition, 2010.
4. Walter Soroka. Fundamentals of Packaging Technology. Institute of Packaging Professionals 2009, DES-Tech publications, 4th edition.
5. Packaging of Pharmaceuticals and Healthcare Products. **Lockhart H., Paine F.A.** Blackie Academic & Professional. 1st edition (1996)
6. Institute of Packaging. **Paine F.A. Packaging Materials and Containers.** Blackie Academic Professional 1967
7. The Science and Practice of Pharmacy, **Hendrickson R. Remington** Lippincott Williams & Wilkins, 21st edition. 2007
8. Pharmaceuticals. **Ross C.F. Packaging of** Newnes-Butterworths. 1975
9. Drug Products, Labeling, Packaging, Regulation. **Herrick A.D.** General Books, LLC. (2009)
10. The Wiley Encyclopedia of Packaging Technology. **Yam K.L.** John Wiley & Sons. 3rd edition, 2009.
11. Understanding Plastic Packaging Technology. **Selke S.E.M.** Hanser Gardner Publications, 1997.
12. Handbook of Package Engineering. **Hanlon J.F., Kelsey R.J., Forcinio H.E.** 3rd edition, CRC Press, Newyork, 1998.
13. Handbook of Packaging Technology. **Eiri.** Engineers India Research, In, 2005.

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY ANANTAPUR

M.Pharm I year II semester (Industrial Pharmacy) **Th 4** **C 4**

(9S08203) Drug regulatory Affairs

1. **Aims, objects and salient features of following legislations affecting pharmaceutical industry:** Industrial Development and Regulation Act 1951. Consumer Protection Act. USF FD and ICH regulation on Quality , safety

2. **Australian TGA guidelines**

3. **US-FDA, CDER guidelines (5 hrs)**

4. **New Drug Application, ANDA and SUPAC**

6. **Pollution and Environmental Control Act, Drug and Cosmetics Act 1940**, **Prevention of Food Adulteration Act**

7. **Validation procedures as per** I.P, B.P, U.S.P. ICH and USFSA.
Cleaning Validation : Process validation and Manufacturing and Computer System Validation Prospective, concurrent, retrospective & revalidation.
Process validation of following formulations
   - Coated tablets
   - Capsules
   - Ampoules & Vials
   - Ointment/Creams
   - Liquid Orals

8. **Global regulatory status of herbal medicines.**
Patents: Indian and international patent laws, Recent amendments as applicable to herbal/ natural products and processes Plant breeders right.

Recommended Books

1. Official Pharmacopoeias of USP, I.P (1996, 2007,2010), BP, NF
2. www.ich.org.in
3. www.usfda.org
4. Indian cosmetic Act 1948, Pub Indian gov
5. Industrial development and Regulation act 1951.
6. Pharmaceutical Production and Management **Subrahmanyam CVS**, 2005, Vallabh Prakashan, New Delhi.
7. New Drug approval Process **Gaarino R.A,** 4th edition Vol 139, Marcel Dekker Inc., New York, 2004.
8. Protection of Industrial Property right **Das P. Das G,**
9. Laws and drugs. **Kakju SN** Law Publisher
10. Pharmaceutical Process scale-up by **Michael Levin**, pub Informa health care 3rd edition 2011.

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M.Pharm I year II semester (Industrial Pharmacy) **L** **C**
6 **4**

(9S08204) Biopharmaceutics and Pharmacokinetics (Lab)

Suggested Practical Exercises: (At least 15 experiments to be conducted)

1. Improvement of dissolution characteristics of slightly soluble drugs by Various Solid dispersion techniques and solvent deposition systems.
2. Comparison of dissolution of two different marketed products /brands.
3. Influence of polymorphism on solubility and dissolution.
4. Protein binding studies of a highly protein bound drug & poorly protein bound drug.
5. Bioavailability studies of Paracetamol by salivary data .
6. Calculation of Ka, Ke, t 1/2, Cmax and Tmax for two sets of data.
7. Calculation of bioavailability from the given urinary excretion data for two drugs.
8. Calculation of *AUC* and bioequivalence from the given data for two drugs.

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M.Pharm I year II semester (Industrial Pharmacy) **L** **C**
6 **4**

(9S08205) Advanced Drug Delivery Systems (Lab)

Suggested practical experiments (at least 15 experiments to conducted)

1. Preparation and evaluation of albumin microspheres.
2. Preparation and evaluation of microcapsules by different microencapsulation technique.
3. Preparation and evaluation of matrix tablets using various polymers.
4. Study on diffusion of drugs through various polymeric membranes.
5. Preparation and in vitro evaluation of buccal mucoadhesives.
6. Preparation and evaluation of transdermal films.
7. Preparation and evaluation of hydrodynamically balanced tablets.
8. Study of in vitro dissolution of various sustained release formulations of marketed Products.

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M.Pharm I year II semester (Industrial Pharmacy)

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(9S08206) Mini Project-II:

The mini projects can be taken up as industrial visit/ training and report submission.
OR
A suitable project shall be carried out in the college

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY ANANTAPUR

M.Pharm IV Semester (Industrial Pharmacy)

(9S08401) Seminar

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2

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY ANANTAPUR

M.Pharm IV Semester (Industrial Pharmacy)

(9S08402) Project Work

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16

The project work should be on a contemporarary topic relevant to the core subjects of the course. It should be the original work of the candidate.