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

ACADEMIC REGULATIONS COURSE STRUCTURE AND DETAILED SYLLABI

MASTER OF PHARMACY

PHARMACEUTICAL TECHNOLOGY

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-Pharmaceutical Technology

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.	9S10101	Pharmaceutical Product Development	4		4
4.	9S10102	Novel Drug Delivery Systems - I	4		4
5.	9S01105	Modern Pharmaceutical Analysis - Lab		6	4
6.	9S10103	Novel Drug Delivery Systems – I (Lab)		6	4
7.	9S10104	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.	9S10201	Novel Drug Delivery Systems - II	4		4
3.	9S10202	Pharmaceutical Production Management and Technology	4		4
4.	9S10203	QA, GMP and Process Validation	4		4
5.	9S10204	Biopharmaceutics and Pharmacokinetics – (Lab)		6	4
6.	9S10205	Novel Drug Delivery Systems – II (Lab)		6	4
7.	9S10206	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	9S10401	Seminar		2
2	9S10402	Project work		16

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M.Pharm I year I semester (Pharmaceutical Technology) **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 with matter and its effects. Chromophores and their interactions with UV 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 IR radiation with IR molecules and effects on bonds. Molecular Infrared Spectra. Brief outline of classical IR 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 (Signals., 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. Ionization 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 Hyphanatul techniques: 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. HPTLC and applications.

6. **Gas Chromatography**: Instrumentation packed and open tubular column, Column efficiency parameters, the Vandeemter 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, SST and Efficiency parameters, resolution, detectors in HPLC. Comparison of sensitivity, selectivity and field of applications of these detectors.

8. **(a) Electrophoresis:** Moving boundary electrophoresis, Zone electrophoresis, Isotacophoresis and applications in pharmacy.

   (b) 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.

   (c) 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. 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 (Pharmaceutical Technology) **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 hypotheses – 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, np and C charts.

Intellectual Property Rights & Regulatory Affairs

5. 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.

6. 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).

7. 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.

8. 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

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M.Pharm I year I semester (Pharmaceutical Technology) **Th 4** **C 4**

(9S10101) Pharmaceutical Product Development

1. **Preformulation:** Detailed study of physical, chemical and pharmaceutical parameters influencing formulation of drugs.

2. **Polymorphism in pharmaceutical solids:** Application of phase rule to the characterization of polymorphic systems, structural aspect of polymorphism, hydrates and solvents, generation of polymorphs, hydrates, solvates and amorphous solids, methods for the characterization of polymorphs and solvates, effect of polymorphism on solubility and dissolution rate, effect of pharmaceutical processing on drug polymorphs and solvates, impact of polymorphism on quality of lyophilized products.

3. **Excipients for Pharmaceutical formulations:** Factors affecting the selection(including safety considerations), drug-excipient and excipient- package interactions, Study of newer excipients like cyclodextrin, ion exchange resins, film coating materials, superdisintegrants, directly compressible vehicles, surfactants, thickeners. Co-processed excipients.

4. **Biomaterials:** Types, applications of biomaterials in pharmaceutical formulations & medicine, safety considerations of biomaterials, mechanism of biodegradation.

5. **Stability of drug & dosage forms:** Degradation of drug in solid state & solid dosage forms, stabilization methods, importance of stability indicating assay in stability evaluation, stability evaluation of disperse systems. Brief introduction to FDA and WHO guidelines. Detail study of ICH guidelines (Q1A (R2), Q1B, Q1C, Q1D, Q1E, Q1F, Q5C). Kinetic principles applied for stability evaluation and their applications in predicting shelf life and half life of pharmaceutical formulations. Importance of accelerated stability study.

6. **Drug Diffusion & Dissolution:** Drug diffusion: steady state diffusion, diffusion principles in biological systems, thermodynamics of diffusion, Fick's Law of diffusion. Theory of dissolution, factors influencing dissolution, interpretation of dissolution rate data, Comparison of dissolution profile by model independent (similarity and dissimilarity factor) and dependent methods. Biopharmaceutical

classification system (BCS), its significance in context of dissolution study and dosage form development. Selection of dissolution media. Pharmacopoeial & Non- Pharmacopoeial dissolution testing devises, Automation in dissolution testing, Dissolution of immediate release and modified release dosage forms

7. **Formulation development of solid and powder dosage forms:** Improved production techniques for tablets, new materials, processes, equipment improvements, high shear mixers, compression machines, coating machines, coating techniques in tablet technology for product development and computerization for in process quality control of tablets. Formulation development and manufacture of powder dosage form for internal and external use including inhalation dosage forms. **Formulation development of soft and hard gelatin capsules :**Introduction, production and methods of manufacture, filling equipment and filling operations, formulations, finishing, special techniques, the nature of the capsule shell and capsule, advances in capsule manufacture, processing and control including pharmaceutical aspects, physical stability and packaging.

8. **Comlplexation:** Classification, application of complexation in product Development **C**omplexation with cyclodextrin, types of cyclodextrins, Host – guest relationship of inclusion complex, methods of analysis (Phase solubility study & characterization of inclusion complex). **Formulation development of liquid dosage forms:** Recent advances in formulation aspects and manufacturing of monophasic dosage forms as well as suspensions.

Recommended Books

1. Drug Stability, **J.T. Carstensen**, Marcel Dekker, New York 3rd edition, vol 107, 2000
2. Theory & Practice of Industrial Pharmacy, **L.Lachman** Pub-Varghese Publication Bombay, 1991.
3. Modern Pharmaceutics, **G.S. Banker and C.T.Rhode**s, Marcel Dekker, NY 1996, 3rd edition.
4. Physical Characterization of Pharmaceutical Solids. **H.G. Brittain, Marcel Dekker,** NY-vol 70, 1995.
5. Physical Pharmacy, **A. Martin, Lea and Febiger,** Philadelphia. Lippin Cott, 4th edition 1993.
6. Pharmaceutical dissolution testing, **U.V. Banaker, Marcel Dekker**, Inc., New York 1991, 1st edition.
7. Pharmaceutical Dosage Forms: Parenteral Medications, **Avis K.E. Leon Lachman and H.Lieberman,** Marcel Dekker, New York 1984
8. Pharmaceutical Dosage Forms:tablets, **Lierberman H.A. and Leon Lachman**, Marcel Dekker, New York vol-1, 3rd edition, 1989.
9. Oral lipid based formulations: **D.J. Hauss, Informa Healthcare**, New York 2009.
10. Polymorphism in Pharmaceutical solids: **H.G.Brittain, Marcel Dekk**er, New York 1st edition, 1999
11. Biodegradable polymers as drug delivery systems, edited by **M.Chasin, R.langer**, Marcel Dekker, New York 1st edition, 1990.
12. Handbook of Preformulations, **S.K.Niazi,** Informa Healthcare, New York 1st edition 2006.
13. Pharmaceutical Preformulations & Formulation, edition, edited by **Marks Gibson, Interpharm/CRC, Boca Raton, Florida**, USA. 2nd edition-2009.

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M.Pharm I year I semester (Pharmaceutical Technology) **Th 4** **C 4**

(9S10102) Novel Drug Delivery Systems–I (Theory)

1. **Drug Carrier Delivery Systems:** Structure, stability, composition, methods of preparation, applications in drug delivery, drug targeting and commercial aspects of following: Particulate Carriers, Vesicular carriers, Cellular carriers, Monoclonal antibodies and other Carriers.

2. **Oral sustained release Drug Delivery Systems (DDS) including Gastro Retentive DDS:** Physico chemical and Biological factors influencing design, dissolution controlled systems, Diffusion controlled systems, Bioerodible systems, Osmotically controlled systems, Ion Exchange systems

3. **Mucoadhesive Drug Delivery Systems:** Delivery through Gastro intestinal, buccal, rectal and vaginal routes, Physiology of mucosa, mechanism of transmucosal permeation. In-vitro, ex-vivo and in-vivo methods of evaluation (for each route).

4. **Transdermal Drug Delivery Systems:** Fundamental of skin permeation, Approach for development, kinetic evaluation, formulation design & optimization, iontophoresis and other latest developments in skin delivery systems

5. **Implants and Inserts:** Reaction of Host to Implant, Reaction of Implant to Host, subcutaneous Implants, Intra muscular implants, Intra ocular implants, Intra vaginal Inserts, Intra uterine implants. **Immediate Release Novel Dosage Forms:** Fast dissolving tablets including Effervescent Tablets, Oral Films.

6. **Protein & peptide drug delivery system:** Physical aspects, biochemistry of protein drug (structure, properties & stability- Mechanisms of destabilization. Techniques of stabilization of Proteins and Peptides.) General methods of analysis of protein & peptide drugs, barrier to transport & Pharmacokinetics, different route of delivery, practical considerations. Importance of pre-formulation & formulation considerations, toxicity immunogenicity, stability & regulatory perspective.

7. **Novel Emulsion systems:** Microemulsion & Nanoemulsion, Self emulsifying drug Delivery system (SEDDS), Self microemulsifying drug delivery system(SM EDDS)

8. **Miscellaneous sustained Drug Delivery Systems:** Pulsatile Drug Delivery Systems, Liquid sustained release systems (Sol to gel system) etc.

Recommended books:

1. Protein Formulation & Delivery, edited by **E. J. Mcnally and J. E. Hastedt**, Informa Healthcare, New York 2nd edition, 2007
2. Pharmaceutical coating Technology, **G. Cole, J. Hogan and M. Alton**, Informa Health care, New York. 1st edition 1995.
3. FDA regulatory Affairs, edited by **D. J. Pisano and D. Mantus,** CRS Press, Boca Rocan,Florida. 2008, 1st edition, 2008.
4. Encyclopedia of Pharmaceutical Technology, **Jasmes Swarbrick and James C. Boylan**, Marcel Dekker Inc., New York. 1996 1st edition.
5. Theory and Practice of Industrial Pharmacy, **L. Lachman**, Vargish Publication, Bombay. 1991
6. Modern Pharmaceutics, **G.S. Banker and C.T. Rhodes**, Marcel Dekker, Inc., New York. 3rd edition, 1996.
7. Controlled Drug Delivery: **J. R. Robinson and V. H. Lee**, Marcel Dekker, Inc., New York. 1987, 2nd edition illustrated
8. Novel Drug Delivery Systems, **Y.W. Chien**, Marcel Dekker, Inc., New York. 2nd edition, 1992, 2nd edition, vol:50
9. Progress in Controlled and Novel Delivery Systems, edited by **N.K. Jain**, CBS Publishers &Distributors, New Delhi. 2008
10. Targeted & Controlled Drug Delivery, **S. P. Vyas and R. K. Khar**, CBS Publishers & Distributors, New Delhi. 2006
11. Advances in Controlled and Novel Drug Delivery, Edited by **N.K. Jain**, CBS Publishers & Distributors, New Delhi. 2008

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY ANANTAPUR

M.Pharm I year I semester (Pharmaceutical Technology) **L** **C**
6 **4**

(9S01105) Modern Pharmaceutical Analysis - Lab

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. Chloromphenicol
   b. Sulphadiaz ine
   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 (Pharmaceutical Technology) **L** **C**
6 **4**

(9S10103) Novel Drug Delivery Systems - Lab

Suggested Practical Exercises: (At least 15 experiments to be 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 evaluation of transdermal patches of a drug.
6. Preparation and evaluation of liposomal drug delivery systems.
7. Preparation and evaluation of bioadhesive oral dosage forms.

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(9S10104) 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 (Pharmaceutical Technology) **Th 4** **C 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 of 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.

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M.Pharm I year II semester (Pharmaceutical Technology) **Th 4** **C 4**

(9S10201) Novel Drug Delivery Systems–II (Theory)

1. **Drug targeting: Basic Concepts** Rationale of targeted drug delivery system; Biological processes & events involved in drug targeting; 1st order, 2nd order & 3rd order targeting, Active & Passive targeting.

2. **Ophthalmic Pharmaceutical Products :** Anatomy of the eye & admexa, Pharmacology & therapy of ophthalmic medication, Occular drug transport & delivery, Novel Ophthalmic products (Non errodable ocular inserts, errodable , ocular inserts, Intraoccular irrigation solution, Intraoccular injection, Intravitrial injection & implants)

3. **Nasal Drug delivery:** Anatomy, physiology and histology of nasal cavity Factors affecting nasal drug absorption, Strategies to increase the nasal drug absorption , Applications of intranasal drug delivery : Local delivery, Systemic delivery, Nasal vaccines, CNS delivery.

4. **Pulmonary Drug Delivery: Delivery to and Through the Lung:** Physicochemical, Physiological & Anatomical factors affecting lung deposition, Mechanism of drug clearance & pharmacokinetics of disposition, Drug absorption *via* the lung **,** Formulations for Nebulizers, Dry powder inhalers and other inhalation products**,** In vitro particle size analysis and deposition measurements**,** In vitro and in vivo deposition efficacy of inhalation systems Targeting drugs to the lungs via the bloodstream

5. **Design of Colon-specific Drug Delivery Systems** Physiological characteristics of the colon, Pathological processes in the colon, Approaches to colon-specific drug delivery

6. **Brain-Specific Drug Targeting :** Biology and Pharmacology Blood Brain Barrier (BBB), A brief background of pathophysiology of some CNS diseases and their effect on BBB In vitro and in vivo techniques for measurement of brain uptake Drug delivery strategies.

7. **Drug Targeting to Tumor cells** Cancer pathology, Barriers in tumour-directed therapies/strategies, Strategies to deliver drugs to targets within the tumour (cells), Animal models and their predictive value.

8. **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.

Recommended Books

1. Novel Drug Delivery Systems, **Y.W.Chien**, Marcell Dekker, New York. 1992 vol 50, 2nd edition
2. Controlled release Delivery Systems of Pesticides, **Scher H. B.,** Marcel Dekker, New York. Illustrated, 1999.
3. Controlled Release Dosage form Design, **Kim. C., CRC Press, Boca Raton**, Florida, USA. Technomic Pub, Co, 2000
4. Bioadhesive Drug Delivery Systems, **E. Mathiowitz**, Vol 98, Marcel Dekker, NY. 1999, vol,98
5. Nasal Systemic Drug Delivery, **Y. W. Chien and K.S.E. Su**, Vol 39, Marcel Dekker, NY. 1989
6. Drug Delivery Devices, Vol 32**, P Tyle**, Marcel Dekker, NY.
7. Polymers for Controlled Drug Delivery, **P.J. Tarcha, CRC Press**, Boca Raton, Florida, USA. 1991, edu-illustrated.
8. Drug Targeting, Strategies, Principles and applications, **Francies G.E.,** Delgado Cristina, Humana Press, New Jersey, 2000.
9. Drug Targeting, Organ Specific Strategies (Methods and principles in medicina chemistry volume 12, E. R. Monnhod, H. Kubiny, H. Timmerman), **Molana Grietie, Dirk K.F. Meijer,** Willey-VCH verley GmbH, 2001.
10. Biodegradable polymers as drug delivery systems, **M. Chasin, R. langer, Marcel Dekker**, New York. 1st edition, 1990.
11. Targeted & controlled drug delivery (Novel Carrier Sysytem), **S.P.Vyas & R.K.Khar,** CBC Publisher & Distributors, New Delhi. 2006
12. Advance in Controled & Novel Drug Delivery , **N.K.Jai**n, CBC Publisher & Distributors, New Delhi. 2008
13. Controlled Drug Delivery, **J. R. Robinson and V. H. Lee**, Marcel Dekker, Inc., New York. 1987- 2nd edition-illustrated.

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M.Pharm I year II semester (Pharmaceutical Technology) **Th 4** **C 4**

(9S10202) Pharmaceutical Production Management & Technology

Part I: Pharmaceutical Technology

1. **Manufacturing, manufacturing flowcharts, in process-quality control tests for following sterile dosage forms:** Ointment**,** Suspension and Emulsion**,** Dry powder**,** Solution(Small Volume & large Volume)**Advance Sterile Product Manufacturing Technology :** Area planning & environmental control, wall and floor treatment, fixtures and machineries, change rooms, personnel flow, utilities & utilities equipment location, engineering and maintenance. Process Automation in Pharmaceutical Industry with specific reference to manufacturing of sterile semisolids, Small Volume Parenterals & Large Volume Parenterals (SVP & LVP), Monitoring of Parenteral manufacturing facility, Cleaning in Place (CIP), Sterilization in Place (SIP), Prefilled Syringe, Powdered Jet, Needle Free Injections, and Form Fill Seal Technology (FFS), Lyophilization Technology: Principles, process, equipment.

2. **Manufacturing, manufacturing flowcharts, in process-quality control tests for following Non-Sterile solid dosage forms:** Tablets (compressed & coated)**,** Capsules (Hard & Soft) **Advance Non-Sterile Solid Product Manufacturing Technology:** Process Automation in Pharmaceutical Industry with specific reference to manufacturing of tablets and coated products, Improved Tablet Production: Tablet production process, granulation and pelletization equipments, continuous and batch mixing, rapid mixing granulators, rota granulators, spheronizers and marumerisers, and other specialized granulation and drying equipments. Problems encountered. Coating Technology: Process, equipments, particle coating, fluidized bed coating, application techniques. Problems encountered.

3. **Packaging Technology:** Unit dose packaging**,** Strip packaging materials Packaging of solid, parenterals, and ophthalmic dosage forms**,** Stability aspects of packaging Evaluation of packaging material**,** Evaluation of stability of packaging material.

Part II: Pharmaceutical Production Management

4. **Plant Design: a)** Basic requirements of design **b)** Plant layout **c)** Design of large scale manufacturing unit for sterile and nonsterile products (with special reference to tablets, capsules As per Schedule M), The emphasis be also given to design of facilities & utilities **d)** Design of Pilot Plant for tablets, capsules **e)** Equipment selection vis a vis plant design **f)**Heating Ventilation and Air Conditioning System (HVAC)

5. **Scale up:** Importance, Technology transfer from R & D to pilot plant to plant scale, process scale up for tablets, capsules, liquid orals, semisolids, parenteral, NDDS products – stress on formula, equipments, product uniformity, stability, raw materials, physical layout, input, in- process and finished product specifications, problems encountered during transfer of technology. SUPAC Guidelines for Scale up

6. **Industrial safety**: Hazards – fire, mechanical, electrical, chemical and pharmaceutical, Monitoring & prevention systems

7. **Waste Management:** Sewage water treatments (waste water treatment), treatments of other waste from pharma industry, Industrial effluent testing & treatment. Control of environmental pollution

8. Production planning and inventory control:- Methods for market forecasting, role of market forecasting in production planning, role of production planning in inventory management Methods of inventory management.

Recommended Books:

1. Good manufacturing Practices for Pharmaceuticals: A plan fir total quality control by **Sidney H, Willig** 2000, 5th edition.
2. Applied production and operations management: by **Evans, Anderson, Sweeney and Williams.** 3rd edition west publish company ldt.st.paul USA 1985
3. A Text of Pharmacy management, **HW Tomski,Logan** Page ltd. London
4. ISO 9000 and 14000 series **brian Rothery** Gower pub company 3rd edition, 1985
5. Pharmaceutical Production and management by **C.V.S.Subrahmanyam**, Vallabh Prakashan 2005.
6. Pilot plant model and scale up methods, **Johnstone and Thring** 1995, McGraw Hill
7. Chemical Engineering Plant Design, **Vibrant**-1959 McGraw Hill 4th edition
8. Drug and Cosmetic Act 1940 rules. Govt of India
9. Pharmaceutical Production Facilities, design and applications, by **G.C.Cole. Taylor and Francis**, 1998-2nd edition illustrated
10. Pharmaceutical Project Management. **T.Kennedy,** vol 86, Marcel Dekker, NY 2008,edition 2nd edition illustrated
11. Theory & Practice of Industrial Pharmacy, **L.Lachman**,Varghese Publication, Bomay-2008, 3rd edition.
12. Safety assessment for pharmaceuticals, **Gad, Shayne**-John wiley & sons, 2000
13. From Bench to pilot plant: Process research in the pharmaceutical industries. Mehdi Nafissi John a **Ragan, Keith M Devries** edu-ill, pub-American chemical society 2002.
14. Pharmaceutical Process Scale up. **Michael Levin**, Marcel Dekker, 2001
15. Pharmaceutical Process engineering, **David Ganderton & Anthony** Hickey vol, 195 2nd edition illustrate, Taylor and Franics 2009
16. Remington: The Science and Practice of Pharmacy, **Gennaro AR,** 2nd edition, Vol: 1&II, Ippincott Williams & Wilkins, Philadelphia, USA 2007
17. Indian 1996 IP(2007-2010) Pharmacopoeia, British Pharmacopoeia and United States Pharmacopoeia

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M.Pharm I year II semester (Pharmaceutical Technology) **Th 4** **C 4**

(9S10203)Quality Assurance, GMP & Process Validation (Theory)

1. **Quality Assurance:** Role of raw material testing, finished product testing, in process quality control in assuring quality of drug products to consumers**,** Role of quality audit & quality circle in quality assurance**,** Application of Process Analytical Technology (PAT) in quality assurance
2. **Process Validation** Regulatory basis, Terminology: validation, qualification, calibration, Prospective process validation, Retrospective validation, Validation of sterilization processes (Heat & Filtration), Validation of tablets & capsules manufacturing processes, Qualification of water systems, Qualification of Air-Handling systems, Qualification of Equipments Qualification of Facility ,Validation & verification of cleaning process, Computer system validation.
3. **Good Manufacturing Practices (GMP) :** Role of GMP in quality assurance, Provisions of GMP with respect to followings, General provisions related to finished pharmaceuticals, Building & facilities, Equipments, Containers & closures, Production & process control Packaging & labeling controls, Records & reports
4. Quality control, layout, responsibilities, good laboratory practice, training, Calibration of instruments, sampling techniques, Specifications, SOPs. Documentation review and batch release. Vendor and batch release. Vendox and warehouse audit. Working references and pharmacopoeia standards and TQM.
5. **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, pelletization and containerization, types of material handling systems. Classification of maintenance, corrective (breakdown) maintenance, scheduled

6. **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.

7. Concept of QA requirements of CGMP, GLP, ISO 9000 Series .
8. ICH Guidelines: Quality topics 7 Q7: Good manufacturing practices for Active Pharmaceutical Ingredients,Q8: Pharmaceutical Development, Q9: Quality Risk Management, Q10: Pharmaceutical Quality System

Recommended Books:

1. How to practice GMP:P.P.Sharma, 5th Edition, Vandhana Publications, New Delhi.
2. Pharmaceutical Process validation, Bernard T.L. and Robert A.Nash Volumes 23, Marcel Decker. 2003 3rd edition illustrated vol:129
3. Good Manufacturing Practice for pharmaceuticals, Sidney H.Willing, Mercel Decker Inc. 5th edition, 2000
4. Validation of Pharmaceutical Process, James Agalloco, 3rd Edition, Informa Healthcare USA 3rd edition, 2007.
5. Validation of Pharmaceutical Processes, Sterile Products, F.J.Carleton, Marcel Dekker Inc. 2nd edition illustrated 1999.
6. Guidelines on cGMP & Quality of Pharmaceutical Products, S.Lyer, Career Publication, 2003.
7. Validation in Pharmaceutical Industry (Concept, Approaches & Guidelines) P.P. Sharma, Vandhana Publications, New Delhi.

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M.Pharm I year II semester (Pharmaceutical Technology) **L** **C**
6 **4**

(9S10204) 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 (4 experiments).
2. Comparison of dissolution of two different marketed products /brands (2 experiments).
3. Influence of polymorphism on solubility and dissolution (2 experiments).
4. Protein binding studies of a highly protein bound drug & poorly protein bound drug. (2 experiments).
5. Bioavailability studies of Paracetamol by salivary data (1 experiment).
6. Calculation of Ka, Ke, t 1/2, Cmax and Tmax for two sets of data (2 experiments).
7. Calculation of bioavailability from the given urinary excretion data for two drugs (2 experiments)
8. Calculation of *AUC* and bioequivalence from the given data for two drugs (2 experiment).

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M.Pharm I year II semester (Pharmaceutical Technology) **L** **C**
6 **4**

(9S10205) Novel Drug Delivery Systems-II-Lab

1. Preparation and evaluation of buccal drug delivery systems.
2. Design of protein and peptide drug delivery systems.
3. Development of matrix type sustained release drug delivery.
4. Development of controlled released dosage form for oral use(Elementary osmotic pump).
5. Preparation and evaluation of ODT.
6. Preparation and evaluation of GRDDS.
7. Preparation and evaluation of a drug-immuno conjugate.
8. Preparation and evaluation of solid lipid nanoparticles.
9. Studying the drug transport across porcine buccal mucosa / skin (hydrophilic lipophilic drugs).
10. Preparation and evaluation of stability of protein formulation by gel electrophoresis.
11. Studying the role of permeation enhancers in drug transport across biological membranes.

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M.Pharm I year II semester (Pharmaceutical Technology)

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(9S10206) 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

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M.Pharm IV Semester (Pharmaceutical Technology)

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(9S10401) SEMINAR

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY ANANTAPUR

M.Pharm IV Semester (Pharmaceutical Technology)

(9S10402) PROJECT WORK

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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.