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

ACADEMIC REGULATIONS COURSE STRUCTURE AND DETAILED SYLLABI OF MASTER OF PHARMACY IN

Pharmaceutics – Drug Regulatory Affairs

(Regular Two Years P.G. Degree Course Applicable for the batches admitted from 2012-13)

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY ANANTAPUR
ACADEMIC REGULATIONS FOR THE AWARD OF FULL TIME
M. Pharm. DEGREE
(WITH EFFECT FROM THE ACADEMIC YEAR 2012-13)

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- Pharmaceutics & Drug regulatory Affairs

Offered by Department of Pharmacy

for affiliated Pharmacy Colleges 2012-13

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.	9S03103	Advanced pharmaceutical and formulation Technology	4		4
4.	1211101	Drug Regulatory affairs - I	4		4
5.	9S01105	Modern Pharmaceutical Analysis Practical		6	4
6.	9S03106	Advanced pharmaceutical and formulation tech. and physical Pharmaceutics practical		6	4
7.		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	Bio pharmaceutics and pharmacokinetics	4		4
2.	12S11201	Novel drug delivery system	4		4
3.	12S11202	Drug Regulatory affairs - II	4		4
4.	12S11203	GMP, Quality Assurance & Process Validation	4		4
5.	9S03205	Bio pharmaceutics and Pharmacokinetics practical		6	4
6.	9S03206	Novel drug delivery system practical		6	4
7.	12S11204	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	1211401	Seminar		2
2	1211402	Project work		16

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M.Pharm I year - I semester (P & DRA) **Th 4** **C 4**

(9S01101) MODERN PHARMACEUTICAL ANALYSIS

1. **UV-VISIBLE SPECTROSCOPY**: Brief review of electromagnetic spectrum, UV-Visual 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. a) **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.

   b) **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 and 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. Column chromatography, column materials, merits and demerits. 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 Vandeemeter equation, Resolution, liquid stationary phase, derivatization 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 micro bore 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, Iontophoresis, PAGE, 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.

REFERENCES:

1. Instrumental methods of chemical analysis by Chatwal. K, Anand, 5th edition.
2. Vogel's text book of quantitative chemical analysis by G.H.Jeffery, J.Bassett, J.Mendhan, R.C.Denny.
3. Instrumental methods of analysis by Willard, Merit, Dean, Settle.
4. Organic spectroscopy by Y.R.Sharma.
5. Spectrometric identification of organic compounds by Silverstein, Webster.
6. Spectroscopy by B.K.Sharma
7. Fundamentals of analytical chemistry by Skoog
8. Instrumental methods of analysis by Skoog.
9. Text book of pharmaceutical analysis by S.Ravishankar.
10. Organic spectroscopy by William kemp
11. Spectroscopic methods in Organic chemistry by Dudley William and Ian Flemming, Tata Mc Graw Hill.

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M.Pharm I year - I semester (P & DRA) **Th 4** **C 4**

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

I. 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, ηp and C charts.

II. 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.

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REFERENCES:

1. KS Negi 'Biostatistics' ,AITB Publishers, Delhi.
2. Irfan Alikhan 'Fundamentals of Biostatistics', Ukaaz Publications
3. Khan and Khanum 'Biostatistics for Pharmacy', Ukaaz Publications
4. J.E, Demuth 'Basic statistics and Pharmaceutical applications' ,Mercel & Dekker.
5. Applied statistics by S.C.Gupta & V.K.Kapoor
6. Fundamentals of mathematical statistics by S.C.Gupta & V.K.Kapoor

7. Good Manufacturing Practices for Pharmaceuticals, S.H. Wiling, Vol. 78, Marcel Decker.
8. Protection of Industrial Property rights, P. Das & Gokul Das
9. Law and Drugs, Law Publications. S.N. Katju
10. Original Laws Published By Govt. of India
11. Laws of drugs in India, Hussain
12. New Drug Approval Process, R.A.Guarino,Vol 100, Marcel Decker, NY
13. fda.org, wipo.int, patentlawlinks.com, hc-sc.gc.ca, ich.org, cder.org

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M.Pharm I year I semester (P & DRA) **Th 4** **C 4**

(9S03103) ADVANCED PHARMACEUTICAL AND FORMULATION TECHNOLOGY

1. Preformulation Studies:

a) Goals of preformulation, preformulation parameters, methodology, Solid state properties, Solubility and Partition coefficient, drug excipient compatability.

b) Excipients used in pharmaceutical dosage forms:Properties and selection criteria for various excipients like surfactant, viscosity promoters, diluents, coating materials, plasticizers, preservatives, flavours and colours

2. Tablets: Improved production techniques for tablets: New materials, process, equipments like high shear mixers, compression machines, coating machines, coating techniques in tablet technology for product development, computerization for in process quality control of tablets, types of tablets and their manufacture.

3. Powder dosage forms: Formulation development and manufacture of powder dosage forms for internal and external use including inhalations dosage forms, Formulations, production and evaluation of hard and soft gelatin capsules.

4. **Liquid dosage forms:** Recent advances in formulation aspects and manufacturing of monophasic dosage forms. Recent advances in formulation aspects and manufacturing of suspensions and dry syrups

5. **Aerosols**: Advances in propellants, metered dose inhaler designs, dry powder inhalers, selection of containers and formulation aspects in aerosol formulation, Manufacture and quality control.

6. **Aseptic processing operation:** Introduction, contamination control, microbial environmental monitoring, microbiological testing of water, microbiological air testing, characterization of aseptic process, media and incubation condition. Theoretical evaluation of aseptic operations.

7. Parenteral dosage forms: Advances in materials and production techniques, filling machines, sterilizers and aseptic processing. Manufacturing of small and large volume Parenterals and quality control.

8. **Pilot plant scale of techniques**: Significance, phase two effect an orderly setup from laboratory procedures and formulations to routine production procedures.

REFERENCES

1. Liberman, HA & lachman L Pharmaceutical dosage forms: Tablets vol I, II & III.
2. Liberman, HA & lachman L Pharmaceutical dosage forms: Disperse systems
3. vol I , II & III.
4. Avis, Lachman I & liberman HA; Pharmaceutical dosage forms: Pareneteral medication Vol I & II.
5. Turco S and King RF Sterile dosage forms, Lea & Febiger, Philadelphia.
6. Remintons pharmaceutical sciences.
7. Martin AN, Swarbrick J & Cammarata A Physical Pharmacy Lea & Febiger, Philadelphia.
8. Carstensen JT, Theory of Pharmaceutical systems academic press New York and London.

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M.Pharm I year - I semester (P & DRA) **Th 4** **C 4**

(1211101) Regulatory Affairs - I

Unit I. **Pharmaceutical legislations in India:** I. Origin, development, scope, objectives and nature of Pharmaceutical legislation in India. History and ethics of profession of Pharmacy. A study of regulatory aspects that affect drug product design, manufacture and distribution in India with special emphasis on the following Acts / Laws (with latest amendments)

- The Drugs and Cosmetics Act, 1940 and Rules there under.
- The Narcotics Drugs and Psychotropic Substances Act.
- Medicinal and Toilet Preparations (Excise Duties) Act, 1955.
- Drugs (Price Control) Order in force.
- Copy Right Act, Trade Mark Act, and Biodiversity Act,
- The Drugs and Magic Remedies (Objectionable Advertisements) Act, 1955.
- Prevention of Cruelty to Animals Act.
- Factory's Act.
- The Environmental Protection Act
- Consumer Protection Act
- Law of Torts and Law of Contracts
- Monopolistic & Restrictive Trade Practices Act

Unit II : Globalization of drug industries: Export - Import Policy of drugs in India, US and Europe, WHO –certification, Trademarks and copyrights.

Unit III: Schedule M & U requirements : Product development stage documentation, factory procedures – Standard operating procedures (SOPs) and standard test Procedures (STPs).

Unit IV: Legal Environment of Business: Need for government regulations; financial regulations, SEBI, BIFR, FEMA and others, Contract Act and Sale of Goods Act, Company Act, Corporate tax laws – Direct and Indirect.

Unit V: Pharmaceutical Regulatory Process in India: Hierarchy and working flow of FDA in
India, Roles of DCGA and CDSCO in drug control, Drug Control Authority and its documentation in the state.

Unit VI. Introduction to US FDA: A detailed study of Federal Food, Drugs and Cosmetics Act of USA, restricted to human drugs, cosmetics and biotechnological products, with special emphasis on the following,

- Organization and functions of FDA, including historical developments, · General definitions.
- Adulterated & misbranded drugs/cosmetics/biotechnological products.
- OTC drugs, Orphan drugs, Orange Book and Fast Track Products.
- General penalties as applicable to drugs, cosmetics and biotechnological products.

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Unit VII: US FDA-I: A detailed study of Federal Food, Drugs and Cosmetics Act of USA,
restricted to human drugs, cosmetics and biotechnological products, with special emphasis on the following,

- General drug approval process
- Investigational New Drug application (INDA).
- New Drug Application (NDA) and BLA.
- ANDA.
- SNDA, SUPAC and BACPAC.
- Post marketing surveillance.

Unit VIII: US FDA- II: A detailed study of Federal Food, Drugs and Cosmetics Act of USA,
restricted to human drugs, cosmetics and biotechnological products, with special emphasis on the following,

- Labelling and advertising requirements for drugs, cosmetics and biotechnological products.
- Introduction to environmental protection laws, as applicable to drugs, cosmetics and
- biotechnological products, including EPA and OSHA.
- Common Technical Document and Drug Master Files.
- Factory Inspection.

Recommended books: (Latest edition of the books should be referred)

1.Drugs and Cosmetics Act, 1940 and its rules, published by Ministry of health and family welfare, Government of India.
2. Pharmaceutical Jurisprudence, G.K. Jani.
3. The Pharmaceutical Regulatory Process, 2nd ed. – Ira R. Berry, Robert P. Martin
4. Medical Product Regulatory Affairs: Pharmaceutical , Diagnostics, Medical Devices – John J. Tobin and Gary Walsh.
5. FDA Regulatory Affairs: A Guide for Prescription Drugs, Medical Devices and Biologics, 2nd ed. – Douglas J. Pisano and David S. Mantus
6. Good Drug Regulatory Practices: a Regulatory Affairs Quality Manual (Good Drug Development Series) – Helene I. Dumitriu.
7. Pharmaceutical Patent Law – John R. Thomas.
8. http://cdsco.nic.in
9. Original laws published by Govt. of India.
10. Text Book of Forensic Pharmacy by Mithal B. M.; Vallabh Prakashan, New Delhi.
11. Laws of Drugs in India by Hussain.
12. Text Book of Forensic Pharmacy by Jain N. K.; Vallabh Prakashan, New Delhi.
1. Medical Product Regulatory Affairs: Pharmaceuticals, Diagnostics, Medical Devices By John J. Tobin and Gary Walsh
2. FDA Regulatory Affairs: A Guide for Prescription Drugs, Medical Devices, and Biologics, Second Edition by Douglas J. Pisano and David S. Mantus
3. Good Drug Regulatory Practices: A Regulatory Affairs Quality Manual (Good Drug Development Series, Vol 1) by Helene I. Dumitriu
4. Encyclopedia of Pharmaceutical Technology, Jasmes Swarbrick and James C. Boylan, Marcel Dekker Inc., New York.
5. Guidelines for Developing National Drug Policies; WHO Publications, 1998.
6. Export Marketing by Cherian and Parab; Himalaya Publishing House, Delhi

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY ANANTAPUR

M.Pharm I year - I semester (P & DRA)

L	C
6	4

(9S01105) MODERN PHARMACEUTICAL ANALYSIS - PRACTICAL

1. Simultaneous estimation of Paracetamol and Ibuprofen, Rifampicin and INH, Aspirin and Caffeine.
2. UV-Visible spectrum scanning of certain organic compounds- absorption and co-relation of structures, comparisons. Ex: a. Chloramphenicol
   b. Sulphadiazine
   c. Analgin
3. Effect of pH and solvent on 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.(PAGE and agarose Gel electrophoresis)
7. Experiments based on HPLC and GC.
8. IR, NMR and Mass spectroscopy of 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 (P & DRA) **L** **C**

6 **4**

(9S03106) ADVANCED PHARMACEUTICAL AND FORMULATION TECHNOLOGY PHYSICAL PHARMACEUTICS PRACTICAL

1. Preparation and evaluation of Oral suspensions.
2. Preparation and evaluation of Effervescent tablets.
3. Preparation and evaluation of Gel based formulations.
4. Design and evaluation of Aerosol based formulations.
5. Effect of compression force on tablet hardness and disintegration time.
6. Effect of pH of dissolution medium on release rate profile of a drug.
7. Effect of various disintegrating agents and super disintegratants on hardness, disintegration and dissolution of drug from dosage form
8. Comparison of drug release from tablets prepared by dry granulation, wet granulation and slugging.
9. Comparison of intrinsic dissolution rate with dissolution rate profile of dosage form.
10. Diffusion study of drugs through various polymeric membranes
11. Determination of shelf life of a drug using accelerated stability studies (Temperature, pH and humidity).
12. Formulation and evaluation of multiple and micro emulsions.
13. Enhancement of solubulization of Non- electrolytes by
    a) Surfactants
    b) Co-solvents
    c) Complexation
    d) Solid dispersion
14. Effect of compression force on tablet strength, Friability and lamination
15. Effect of various blends of glidants on flow properties of powder, granules.
16. Measurement of rheological properties of some polymers and study the influence of plasticizers.
17. Measurement of surface tension / interfacial tension to determine the CMC of surfactants.
18. Preparation of polymer solutions & studying the rheological behaviour.
19. Drug- excipient interaction study using differential scanning calorimeter
20. Determination of log P value.

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY ANANTAPUR

M.Pharm I year - I semester (P & DRA) **St 3** **C 2**

(12S11102) 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.

The Project Work:

Separate guidelines will be issued

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M.Pharm I year - II semester (P & DRA) **Th 4** **C 4**

(9S01201) BIO PHARMACEUTICS AND PHARMACOKINETICS

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.

REFERENCES:

1. Gibaldi M., Pharmacokinetics, Marcel Decker Inc, New York.
2. Abtou, H.M., Dissolution, Bioavailability and bioequivalence, Mack publishing Co, Easton, PA.
3. Smith, RV & Stewart JT, Text book of Biopharmaceutical Analysis, Lea and Febiger, Philadelphia.
4. Wagner JG, Fundamentals of Clinical Pharmacokinetics, Drug intelligence Pub. Hamilton.
5. Welling, P.G., Tse, FIS & Dighe, S.V. (eds), Bioequivalence, Marcel & Decker Inc, New York.
6. Gibaldi,M., Pirrier, D, Pharmacokitics, Marcel Dekker Inc, New York.
7. Rowland, M & Tozer, T.N. Clinical Pharmacokinetics- Concept and Applications, Lea & febiger, USA.
8. Shargel, L & Yu, ABC, Applied Biopharmaceutics & Pharmacokinetics, Appleton and Lange, Connecticut, USA.
9. Hotari, RE, Biopharmaceutics and Clinical Pharmacokinetics, Marcel Dekker Inc, New York and Basel.
10. XComputer applications in Pharmaceutical research and development Seaqn Ekins Wily Interscience

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY ANANTAPUR

M.Pharm I year - II semester (P & DRA) **Th 4** **C 4**

(12S11201) NOVEL DRUG DELIVERY SYSTEMS

1. **Review of fundamentals of controlled drug delivery system:** Fundamentals, rationale of sustained / controlled drug delivery, factors influencing the design and performance of sustained / controlled release products, pharmacokinetic / pharmacodynamic basis of controlled drug delivery. Use of synthetic polymers and biocompatible polymers in controlled release dosage forms.
2. **Design and fabrication of controlled release drug delivery system:** Principle involved and formulation of: Oral dosage forms- Diffusion system, reservoir devices, systems utilizing ion exchange resins.
3. **Gastroretentive drug delivery systems:** Floating, High density, mucoadhesive, Expandable, modified shape, prolonged memory, magnetic systems and super porous hydrogels.
4. **Transmucosal drug delivery systems:** Buccal, Nasal, Vaginal, Ocular drug delivery systems.
5. **Transdermal drug delivery systems:** Permeation across skin, Matrix and reservoir systems, Enhancement of drug permeation through skin by permeation enhancers, Iontophoresis, Electrophoresis, ultra sound and micro needles.
6. **Colon specific systems:** Factors to be considered in design, Azo & glucuronide conjugates, Cyclodextrin conjugates, drug release based on microflora, In vitro & In vivo evaluation.
7. **Prodrugs:** Types, purposes, approaches to prodrugs – with lipoproteins, with block copolymers, pharmacosomes. Site specific prodrug approaches – By chemical modification, Targeting through antibodies.
8. **Miscellaneous:** Pressure controlled drug delivery systems like Osmotic, Vapour and hydrodynamic pressure controlled drug delivery systems. Medicated chewing gums, Medicated wafers, Delivery of protein and Peptide based drugs.

REFERENCES:

1. Robinson, JR & Lee VHI., Controlled and Novel drug delivery Marcel Dekker New York.
2. Jain NK. Controlled and Novel drug delivery, CBS New Delhi.
3. Chein YW, Novel drug delivery systems, Marcel Dekker New York
4. Roseman TJ, Controlled release drug delivery systems, Marcel dekker New York.
5. Bruck, SD : Controlled drug delivery, Vol I & II
6. Juliano RL, Drug delivery systems.
7. Novel drug delivery systems, Everest publishing house.
8. Kewal K Jain, Drug delivery systems, Humana press
9. Design of controlled drug delivery systems: Xialo Ling McGraw Hill

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY ANANTAPUR

M.Pharm I year - II semester (P & DRA) **Th 4** **C 4**

(12S11202) Regulatory Affairs – II

Unit I. **Drug regulatory authorities in European Union (EU) with special reference to EMA and UKMHRA:** Introduction, Organization and General Guidelines. Regulatory consideration for pre-clinical testing and clinical testing in EU. Registration application for marketing approval (IND, NDA, ANDA) in EU, Drug Master Files in EU, Regulatory considerations for manufacturing, packaging and labelling of pharmaceuticals in EU.

Unit II: The WHO Guidelines: The WHO Guidelines and their relevance in international registration. The WHO certification scheme on the quality of pharmaceutical product moving in international commerce. Introduction to Pharmacovigilance. Plant Layout as per WHO Guidelines.

Unit III: Guidelines for Rest of World (ROW): African countries (MCC), Australia (TGA),
Brazil (ANVISA), Japan, CIS countries, Gulf countries etc.

Unit IV:
a) Auditing of manufacturing facilities by International regulatory agencies. The ISO 9000 series of quality systems standards.
b) Status of pharmaceutical industry with special reference to post GATT scenario. Project planning and implementation.

Unit V: Development of orphan drug: Introduction, Designation process, tax credit, PDUFA (Prescription drug user fee act) and Orphan products development, Clinical trial design for rare disease treatment.

Unit VI: International Conference On Harmonisation Of Technical Requirements For Registration of Pharmaceuticals For Human Use: History, structure and process for hormonisation.

Unit VII: ICH guidelines on quality: Stability Testing of New Drug Substances and Products Stability Testing : Photostability Testing of New Drug Substances and Products, Stability Testing for New Dosage Forms, Bracketing and Matrixing Designs for Stability Testing of New Drug Substances and Products, Evaluation of Stability Data, Impurities in

New Drug Substances, Impurities in New Drug Products, Impurities: Guideline for Residual Solvents,

Unit VIII.

a) **ICH guidelines on efficacy**: ICH guidelines on clinical trial and Good Clinical Practice.
b) **ICH Guidelines on safety**: Carcinogenicity Studies - Need for Carcinogenicity Studies of Pharmaceuticals and Testing for Carcinogenicity of Pharmaceuticals. Genotoxicity: A Standard Battery for Genotoxicity Testing of Pharmaceuticals.

Recommended books: (Latest edition of the books should be referred)

1. Medical Product Regulatory Affairs: Pharmaceuticals, Diagnostics, Medical Devices By John J. Tobin and Gary Walsh
2. FDA Regulatory Affairs: A Guide for Prescription Drugs, Medical Devices, and Biologics, Second Edition by Douglas J. Pisano and David S. Mantus
3. Good Drug Regulatory Practices: A Regulatory Affairs Quality Manual (Good Drug Development Series, Vol 1) by Helene I. Dumitriu
4. Encyclopedia of Pharmaceutical Technology, Jasmes Swarbrick and James C. Boylan, Marcel Dekker Inc., New York.
5. Guidelines for Developing National Drug Policies; WHO Publications, 1998.
6. www.ich.org (official website for current updates in ICH guidelines)
7. www.ema.europa.eu (official website for current updates in European guidelines)

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY ANANTAPUR

M.Pharm I year - II semester (P & DRA) **Th 4** **C 4**

(12S11203) GMP, Quality Assurance & Process Validation

Unit I: Quality Assurance: · Role of raw material testing, finished product testing and in process quality control in assuring quality of the following drug products to consumers.

a. Tablets
b. Capsule
c. Oral liquids
d. Injectables

Unit II: Concept of TQM, Role of quality audit & quality circle in quality assurance. Application of Process Analytical Technology (PAT) in quality assurance. Quality by Design (QbD).

Unit III. Good Manufacturing Practices (GMP) : Role of GMP in quality assurance, General provisions related to finished pharmaceuticals, Provisions of GMP with respect to followings,

a) Basic requirements of design, ISO clasification of environmental conditions.
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 and plant design
f) Heating Ventilation and Air Conditioning System (HVAC)

Unit IV: Provision of cGMP on Equipments, Containers & closures, Production & process control, Packaging & labeling controls, Records & reports.

Unit V: Documentation related to manufacturing and product development, SOP, STP, cleaning methods, retention samples and records, quality control documents, batch release documents, distribution records, complaints and recalls, WHO certification scheme.

Unit VI: Process Validation : Regulatory basis, Terminology: validation, qualification, calibration, Prospective process validation, Retrospective validation,Concurrent validation, re-validation, Validation of sterilization processes (Heat & Filtration), Validation of tablets & capsules manufacturing processes, Qualification of water systems, Qualification of Air-Handling systems.

Unit VII:

a) Cleaning validation: Regulatory basis, sample collection, Validation & verification of cleaning process,

b) Computer system validation Vs Analytical instrument Qualification (as per 21CFR).

c) validation of analytical procedure and validation of analyst.

d) Equipment qualifications, user requirement specifications, DQ, IQ, OQ, PQ.

Unit VIII: GLP-ICH and OECD guidelines. Non Clinical testing, controls on animal house, animal house validation, IAEC, regulatory requirement for clinical trials and informed consent, schedule Y, CRO and its role, schdule L 1 and NABL Accredation.

Recommended Study material: (Latest edition of the books should be referred)

1. How to practice GMPs; P.P.Sharma, 5th Edition, Vandhana Publications, New Delhi.
2. Pharmaceutical process validation, Bernard T. L. and Robert A. Nash, Volumes 23, Marcel Decker.
3. Good Manufacturing Practice for pharmaceuticals, Sidney H. Willing, Mercel Decker Inc.
4. Validation of Pharmaceutical Process, James Agalloco, 3rd Edition, Information Healthcare USA
5. Validation of Pharmaceutical Processes, Sterile Products, F.J.Carleton, Marcel Dekker Inc.
6. Guidelines on cGMP & Quality of Pharmaceutical Products, S. Iyer, D.K. Publication, Mumbai.
7. Validation in Pharmaceutical Industry (Concept, Approches & Guidelines), P.P. Sharma, Vandhana Publications, New Delhi.
8. Good manufacturing practices for Pharmaceuticals: A plan for total quality control, Second edition; By Sidney H. Willig.
9. Applied production and operations management; By Evans, Anderson, Sweeney and Williams.
10. A Text of Pharmacy management, HW Tomski, Kogan Page ltd. London.
11. ISO 9000 and 14000 Series
12. Pharmaceutical Production and management by C.V.S. Subrahmanyam, Vallabh Prakashan.
13. Pilot plants model and scale-up methods, Johnstone and Thring.
14. Chemical Engineering Plant Design, Vibrant.
15. Drug and Cosmetic Act 1940 & Rules
16. Pharmaceutical Production Facilities, design and applications, by G.C. Cole, Taylor and
Francis.
17. Pharmaceutical Project Management, T.Kennedy, Vol 86, Marcel Dekker, NY
18. Theory and Practice of Industrial Pharmacy, Liberman, Lachman
19. Pharmaceutical production facilities: design and applications. Cole,Graham
20. Safety assessment for pharmaceuticals, Gad,Shayne.
21. From Bench to Pilot plant:Process research in thepharmaceutical industries,Mehdi Nafissi,John a Ragan,Keith M Devries.

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M.Pharm - (Pharmaceutics & Drug regulatory affairs)

M.Pharm I year - II semester (P & DRA) **L** **C**
6 **4**

(9S03205) BIOPHARMACEUTICS AND PHARMACOKINETICS- PRACTICAL

1. Improvement of dissolution characteristics of slightly soluble drugs by various solid dispersion technique and solvent deposition system (4experiments).

2. Comparison of dissolution of two different marketed products/brands (2 experiments)

3. Influence of polymorphism and complexation on solubility and dissolution.(2experiments)

4. Protein binding studies of a highly protein bound drug and poorly protein bound drug. (2experiments)

5. Bioavailability studies and bio equivalence studies of Paracetamol by salivary data (1experiment)

6. Calculation of Ka, Ke, $t_{1/2}$, C_{max}, T_{max} for two sets of data (2experiments)

7. Calculation of bioavailability curve from the given urinary excretion data for two drugs.(2experiments)

8. Calculation of AUC and Bioequivalence from the given data from two drugs (2experiments)

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M.Pharm I year - II semester (P & DRA) **L** **C**

6 **4**

(9S03206) NOVEL DRUG DELIVERY SYSTEMS-PRACTICALS

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

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M.Pharm I year II semester (P & DRA) **St** **C**

3 **2**

(12S11204) Mini Projects-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.

The Project Work:

Separate guidelines will be issued

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M.Pharm IV semester (P & DRA) **C**

2

(12S11401) SEMINAR

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY ANANTAPUR

M.Pharm IV semester (P & DRA) **C**

16

(12S11402) PROJECT WORK

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