Academic Regulations-M.Pharm. 2009-10

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY ANANTAPUR
ACADEMIC REGULATIONS FOR THE AWARD OF FULL TIME
M. Pharm. DEGREE
(WITH EFFECT FROM THE ACADEMIC YEAR 2009-10)

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 from 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 Analysis
for affiliated and constituent Pharmacy Colleges 2009-10

I YEAR I SEMESTER

S. No	Course code	Subject	Theory	Lab.	Credits
1	9S01101	Modern Pharmaceutical Analysys	4		4
2	9S01102	Biostatistics, Intellectual property rights & regulatory affairs	4		4
3	9S07103	Quality control and validation	4		4
4	9S07104	Analytical methodology	4		4
5	9S01105	Modern Pharmaceutical Analysis-Practical		6	4
6	9S07106	Analytical methodology Practical		6	4
7	9S07107	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	9S07201	Advanced pharmaceutical analysis	4		4
2	9S07202	Chemical and biological evaluation	4		4
3	9S07203	Drug analysis	4		4
4	9S07204	Formulation and cosmetic analysis	4		4
5	9S07205	Advanced pharmaceutical analysis - Practical		6	4
6	9S07206	Formulation and cosmetic analysis - Practical		6	4
7	9S07207	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	9S07401	Seminar		2
2	9S07402	Project work		16

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M.Pharm I year I semester Pharmaceutical Analysis **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, 5/e.
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.

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M.Pharm I year I semester Pharmaceutical Analysis **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}.

Statistical quality control : Meaning and uses , Construction of $\overline{X}$, R, P, ηp and Ċ chart-s.

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.

REFERENCES:

1. 'Biostatistics', KS Negi, AITB Publishers, Delhi.
2. 'Fundamentals of Biostatistics',Irfan Alikhan, Ukaaz Publications
3. 'Biostatistics for Pharmacy', Khan and Khanum, Ukaaz Publications
4. 'Basic statistics and Pharmaceutical applications', J.E, Demuth,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', S.N. Katju, Law Publications.
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

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY ANANTAPUR

M.Pharm I year I semester Pharmaceutical Analysis **Th 4** **C 4**

(9S07103) QUALITY CONTROL AND VALIDATION

1. Quality control, layout, responsibilities, good laboratory practice, training, Calibration of instruments, sampling techniques, Specifications, SOPs. Documentation review and batch release. Vendor and batch release. Vender and where house audit. Working references and pharmacopeial standards.
2. Retention of active pharmaceutical ingredients and finished formulations and quality review. Schedule M of drug rules and WHO certification for export of pharmaceuticals. Salving of returned good and reprocessing.
3. Application of computers in quality control laboratory.
4. Validation: Method validation, Cleaning Validation, Personal validation.
5. Development of drug information profiles.
6. Enzyme immunoassay. Concepts and Methodology.
7. Concept of QA requirements of CGMP, GLP, ISO 9000 Series.
8. Analysis of industrial samples: lead in paint Hg container pharmaceuticals, heavy metals in fertilizers, determination of Pb in gasoline and steel air, copper compound in human serum.

REFERENCES:

1. GMP'S Vo1 78 Dekker's Series
2. Schedule M (Govt. of India.)
3. Drug and Cosmetics Act – 1940.(Govt. of India)
4. Duality Assurance (by shah)
5. I.C.H guidelines (www.ich.org.in) Export policy & India.(Govt. of India.)

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M.Pharm I year I semester Pharmaceutical Analysis **Th 4** **C 4**

(9S07104) ANALYTICAL METHODOLOGY

1. Application of instrumental methods in the development and use of medicines: Introduction, Product characterization for drug development, product development, production and pharmacopoeial controls, concept of analytical method development.

2. Analysis of drugs and excipients in the solid state introduction, Particle size analysis, importance of particle size in various dosage forms, methods of practical size analysis. X-ray powder diffraction

3. light scattering methods in quantitative analysis
   a. Turbidometry b. Nephlometry.

4. Light emission methods in quantitative analysis
   a. Flourimetry b. Flame photometry.

5. Analytical method validation parameters: Spectrophotometric, HPLC and GC methods statistical analysis and significance in analytical methods.

6 Quality control of radiopharmaceutical and radiochemical methods in analysis.

7. Preparation of drug samples for analysis: Pharmaceutical samples, fundamental theories, controlling preparation techniques, specific sample techniques.

8. Precipitation titration: Titration curves, feasibility of precipitation titration, factors affecting shape –titrant and analyte concentration, selection and evaluation of external and adsorption indicators of end points. Quantitative application of precipitation titrations.

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. 'Organnic 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. 'TLC', by Wagner

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY ANANTAPUR

M.Pharm I year I semester Pharmaceutical Analysis	**L**	**C**
	6	**4**

(9S01105) MODERN PHARMACEUTICAL ANALYSIS - PRACTICALS

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

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M.Pharm I year I semester Pharmaceutical Analysis **L** **C**
6 **4**

(9S07106) ANALYTICAL METHODOLOGY - PRACTICALS

1. Determination of chloride and sulfate in calcium gluconate by nephloturbidometric analysis

2. Estimation of following drugs by fluorimetry
   a. Doxazosin mesylate.
   b. Riboflavin
   c. Thiamine.
   d. Terazocin.

3. Study of the quenching in fluorimetry- eg. quenching of quinine fluorescence by iodide ions.

4. Determination of sodium/ potassium by flame photometry.

5. Colorimetric estimation of sulphadiazine/sulphaacetamide using N-(1-naphthyl) ethylenediamine di HCl.

6. Quantitative determination of following groups.
   a. Hydroxyl b. carboxyl c. Methoxyl d. Amine e. Aldehyde f. Esters.

7. Quantitative colorimetric determination of any drug by using paradimethylaminocinamaldehyde reagent.

8. Quantitative colorimetric determination of any drug by using MBTH reagent.

9. Colorimetric estimations of ferrous ions using 1, 10-phenanthroline.

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M.Pharm I year I semester Pharmaceutical Analysis **St** **C**
3 **2**

(9S07107) 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.

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY ANANTAPUR

M.Pharm I year II semester Pharmaceutical Analysis	**Th**	**C**
	4	**4**

(9S07201) ADVANCED PHARMACEUTICAL ANALYSIS

1. A detailed study of principles and procedures involved in various physico-chemical methods of analysis including instrumental methods of analysis of pharmaceutical dosage forms containing the following classes of drugs.
    a. Sulphonamides.
    b. Barbiturates.
    c. Adrenergic drugs.
    d. Anti tubercular drugs.
    e. Diuretics.
    f. Anti-malarials
    g. Local anesthetics.
    h. General anesthetics.
    i. Analgesics and anti pyretics.
    j. Antihelmentics.

2. Principles and procedures involved in the analysis of pharmaceutical preparations and dosage forms containing the following groups of substances.
    a. Alkaloids
    b. Glycosides
    c. Vitamins.
    d. Antibiotics.
    e. Steroid hormones

3. a) Elementary analysis –non-metals and metals
    b) Principles and procedures involved in the quantitative determination of following groups
        a. Hydroxyl
        b. Carboxylic acid.
        c. Aldehydes
        d. Ketones.
        e. Methoxyl
        f. Esters
        g. Amines
        h. Nitrates.

4. Principles and procedures involver in the use of the following reagents in pharmaceutical analysis.

    a. MBTH (3-methyl-2-benzothiazolone hydrazone) reagent.
    b. FC reagent
    c. 2,6 - dichloroquinine monoamine reagent.
    d. 1,2 napthaquinone-4-sulfonate reagent
    e. 2, 3, 5-tri phenyl tetrazonium salt.
    f. PDAB (paramethyle aminobenzaldehyde) reagent
    g. PDACA (paradimethyleamino cinnamaldehyde) reagent
    h. Ninhydrine Reagent
    i. Carr-Price reagent
    j. Baratton-Marshal reagent.
    k. 2, 6-dicholroquinone chloride

5. Assay of official compounds by HPLC, GC, and IP1996

6. Interpretation of spectral data of Infrared spectroscopy, H^{1} N.M.R & C^{13} N.M.R and Mass spectroscopy for structural elucidation of organic molecules.

7. A detaile study of principles, instrumentation and application in drug analysis of: GC-MS, LC-MS with drug metabolism, toxicological and forensic studies, diagnosis of disease state, quantification of dugs in biological samples, super critical fluid chromatography and size exclusion chromatography.

8. Brief study of the theory, instrumentation and application of the following analytical techniques: Atomic force microscopy, plasma atomic emission spectroscopy, photon correlation spectroscopy.

REFERENCES:

1. A.I.Vogel text book of inorganic chemistry , 4^{th} edition, ELBS publication, London
2. Becket and Stanlake pharmaceutical chemistry, 3/e, Vol-I & II, CBS publishers, New Delhi.
3. K.A.Connors text book of pharmaceutical analysis, 3/e, Willey Interscience publication Newyork.
4. Instrumental methods of analysis by Willard, Merit, Dean, Settle.
5. Instrumental methods of analysis by Skoog.

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M.Pharm I year II semester Pharmaceutical Analysis	**Th**	**C**
	4	**4**

(9S07202) CHEMICAL AND BIOLOGIACL EVALUATION THEORY

1. Sterility testing methodology and interpretation
2. Tests for effectiveness of antimicrobial preservatives.
3. Detailed study of principles and procedures involved in the biological assay of the following:
   a) Adsorbed Diphtheria vaccine.
   b) Absorbed Tetanus vaccine.
   c) Chorionic Gonandrotrophin.
   d) Diphtheria antitoxin
   e) Gas Gangrene antitoxin.
   f) Heparin sodium.
   g) Human anti hemophilic fraction.
   h) Japanese encephalitis vaccine
   i) Oxytocin
   j) Pertussis vaccine.
   k) Plague vaccine.
   l) Rabies vaccine.
   m)Streptokinase.
   n)Tetanus Antitoxin
   o) Tuberculin purified protein derivative.
   p) Typhus vaccine
   q) Urokinase.
   r) Vasopressin activity.
4. Pyrogens-Production, chemistry and properties of bacterial Pyrogens and endotoxins. Pyrogens testion: IP,BP and USP methods. Interpretation of data comparison with other official pyrogen tests.
5. Microbial assay of Vitamins and antibiotics.
6. Chemical and bacteriological analysis of portable water, Purified water and water for injection.
7. Clinical analysis: clinical analysis of the composition of blood collection and preservation of the sample, clinical analysis of blood glucose, blood urea nitrogen, immuno assay, the blood gas analyzer, trace elements in the body.
8. Forensic analysis: general discussion of poisons, organophosphates and snake venom, estimation of poisonous materials such as lead, mercury and barbiturates in biological materials.

REFERENCES:

1.Biotechnology. Principles and Application, I.J. Higgins, D.J. Best, J. Jones, Blackwell Scientific Publications, Oxford, London 1988.

1. 'A guide to quality management', by Koushik Maithra & Shadan.K.Gosh.
2. 'How to practice GMP', by P.P.Sharma.
3. 'QA manual', by D.H.Shah
4. Basic test for pharmaceutical substances WHO 1988.
5. 'Elements in biotechnology', by P. K. Gupta.
6. 'Molecular biology and biotechnology', by J. M Walker and E. D. Gingold.
7. 'Pharmaceutical biotechnology', by S. P. Vyas and V. K. Dixit.
8. 'Biotechnological applications to tissue culture', by Shargool.
9. 'Immunology, An Introduction',-Tizard, 4th Edn. Saunders College Publication, 1995

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M.Pharm I year II semester Pharmaceutical Analysis	**Th**	**C**
	4	**4**

(9S07203) DRUGS ANALYSIS

1. Classification of reactions in Titrimetric analysis, standard solutions, preparations of standard solutions, primary and secondary standard substances. Theory of acid base titration. Neutralization indicators, mixed and universal indicators, neutralization curve and displacement titrations.
2. Non aqueous titrations involving the following.
   a. Primary, secondary and tertiary amines.
   b. Halogenated salts of bases.
   c. Acidic substances.
   d. Assay of official drugs in IP1996 by non aqueous titrimetry.

   C). Aquametry: determination of water by titration with Karl Fischer Reagents (KFR)
3. Principles and pharmaceutical applications of complexometric titrations involving:
   a. Potassium Iodate/Bromate titrations
   b. Ceric ammonium sulphate titrations
   c. Titanus chloride titration
4. Principles and pharmaceutical applications of complex-metric titrations involving:
   a. Direct titration of polymetalic system with sodium editate.
   b. Back titration with sodium editate.
   c. Titration involving the displacement of one complex by another.
   d. P^M indicators

5. a) Principles and procedures involved in gravimetric and argentimetric analysis with examples official in IP1996.
   b) Diazotization titration.
6. Thermo - analytical methods of analysis
   a. Thermo gravimetric analysis
   b. Differential thermal analysis.
7. Quality control of crude drugs- ash value, extraction value, fiber content, powder analysis quantitative microscopy and micro chemical tests.
8. Techniques in the estimation of enzyme and the endogenious substances in the body fluids in the physiological and pathological condition.

REFERENCES:

1. Vogels, Pharmaceutical Analysis.
2. Pharmacopeias.
3. Becket and Stanlake Pharmaceutical Chemistry

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M.Pharm I year II semester Pharmaceutical Analysis	**Th**	**C**
	4	**4**

(9S07204) FORMULATION AND COSMETICAL ANALYSIS

1. Principles and pharmaceutical applications of electro-analytical methods-I.
   i. Potentiometry
   ii. pH measurements.
   iii. Polarography
2. Principles and pharmaceutical applications of electro-analytical methods-II
   i. Amperometry
   ii. High frequency titrations
   iii. Conductometric titrations.
3. Identifications and quantitative determination of preservatives, antioxidants, coloring materials, emulsifiers and stabilizers in pharmaceutical formulations.
4. Quality control of tablets, capsules, liquid dosage forms, parental preparations, ointments and creams suppositories and controlled release products.
5. Quality control of containers, closures, caps and secondary packing materials like paper and board for pharmaceuticals.
6. a). Quality control of cosmetic products- Hair care products, skin care products, color cosmetics, baby care products, ethnic products, dental products, personal hygiene products, color makeup preparations, lipsticks, hair setting locations and eye shadows.
   b). Toxicity testing in cosmetic industry, Safety and legislation in cosmetic industry

7. a) Various types of raw materials used in the cosmetic industry for the manufacture of finished products.
   b) Methods of analysis to determine the quality of raw materials used in cosmetic industry.
8. The study of sources and description of herbal origin used like fixed oils, gums, hydrophilic colloids, clours, perfumes, protective agents, preservatives, anti oxidants and ancillary agents.

REFERENCES:

1. W.A.Poucher: Poucher's perfumes, Cosmetics and soaps. Vol.3,9th edition, Chapman and Hill , London
2. J.B.Wilkinson and R.J.Moore: Herry's Cosmeticology, Longman Scientific and Technical Publishers,SIngaore.
3. The controller of publications; New Delhi, Govt.of India Pharmacopeia, Vol.I and II,1996

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M.Pharm I year II semester Pharmaceutical Analysis **L 6** **C 4**

(9S07205) ADVANCED PHARMACEUTICAL ANALYSIS - PRACTICALS

1. Assay of reserpine injection, IP1996

2. Quantitative analysis of drugs in the following multicomponent dosage forms.
   a. Ibuprofen, paracetamol and chlorzoxazone.
   b. Amoxicillin and probenecid
   c. Diazepam and diphenylhydramine HCL
   d. Clotrimazole and tinidazole
   e. Cloxacillin and ampicillin

3. Assay of paracetamol tablets, IP1996
4. Assay of phenylephrine injection IP1996
5. Assay of Atropine sulphate tablets, IP1996
6 Assay of Benzhexol hydrochloride tablets.
7. Identification and verification of standards for a sample of caster oil, IP1996
8. Identification and verification of standards for a sample cetyl alcohol, IP1996
9. Validation of analytical instruments.
10 Validation of pharmaceutical manufacturing machinery
11. Validation of pharmaceutical manufacturing process.
12. Validation of analytical methods
13 Standard operating procedures- for analytical instrumentation.
14 Standard operating procedures- cleaning process.

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(9S07206) FORMULATION AND COSMETICAL ANALYSIS - PRACTICAL

1. Assay of bisacodyl suppositories, IP1996
2. Assay of Sodium diatrizoate injection, IP1996
3. Determination of moisture content in the following drugs using Karl-Fischer Reagent.
    a. Ampicillin trihydrate.
    b. Fructose
    c. Gentamycin sulphate
    d. Calcium lactate or gluconate / emetin dihydrochloride
4. Assay of cephalexin capsule, IP1996
5. Assay of calcium gluconate injection, IP1996
6. Assay of sodium aurothiomalate injection, IP1996
7. Quality control test for Ointments and creams.
8. Quality control test for pessaries, suppositories and controlled release products.
9. Detection and Quantitative determination of preservatives.
10. Detection and Quantitative determination of antioxidants.
11. Quality control tests for pharmaceutical containers.
12. Quality control testing of pharmaceutical containers.
13. Quality control of some cosmetic preparations.

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M.Pharm I year II semester Pharmaceutical Analysis **St** **C**
3 **2**

(9S07207) 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.

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(9S07401) SEMINAR

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(9S07402) PROJECT WORK

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

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