

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



**ACADEMIC REGULATIONS COURSE STRUCTURE
AND
DETAILED SYLLABI
OF
MASTER OF PHARMACY
IN
Pharmaceutical Analysis & Quality Control**

**(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 from 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.

RULES FOR DISCIPLINARY ACTION FOR MALPRACTICE / IMPROPER CONDUCT IN EXAMINATIONS

	Nature of Malpractices/Improper conduct	Punishment
	<i>If the candidate:</i>	
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.

2012-13**JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY ANANTAPUR****Course Structure and Syllabi for****M. Pharm- Pharmaceutical Analysis & Quality Control****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	Bio-Statistics, Intellectual Property Rights & Regulatory Affairs	4		4
3.	9S04103	Electrometric methods and spectral analysis	4		4
4.	9S04104	Chromatographic methods of analysis	4		4
5.	9S01105	Modern Pharmaceutical Analysis Practical		6	4
6.	9S04106	Electrometric and chromatographic methods of analysis-practical		6	4
7.	12S12101	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.	9S04201	Advanced Pharmaceutical Analysis	4		4
2.	9S04202	Quality Assurance of Pharmaceuticals	4		4
3.	9S04203	Analytical method development and validation	4		4
4.	9S04204	Evaluation of dosage forms	4		4
5.	9S04205	Analytical method development and Validation - Practical		6	4
6.	9S04206	Evaluation of dosage forms - Practical		6	4
7.	12S12201	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	12S12401	Seminar		2
2	12S12402	Project work		16

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(9S01101) MODERN PHARMACEUTICAL ANALYSIS

1. **UV-VISIBLE SPECTROSCOPY:** Brief review of electromagnetic spectrum, UV-Visible range, energy, wavelength and color relationships. Interaction of electromagnetic radiation (UV-visible) with matter and its effects. Chromophores and their interactions with E.M.R. Absorption spectra of organic compounds and complexes illustrating the phenomenon and its utilization in qualitative and quantitative studies of drugs. Shifts and their interpretation (including solvent effects). Empirical correlation of structure with absorption phenomena (Woodward's rules etc) Quantitative estimations, Modern instrumentation.
2. 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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(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 LD₅₀, ED₅₀.
4. **Statistical quality control** : Meaning and uses , Construction of \bar{X} , R, P, np and \bar{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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(9S04103) ELECTROMETRIC METHODS AND SPECTRAL ANALYSIS

Principles, instrumentation and applications of the following spectral and electrometric methods of analysis.

1. UV – visible & IR spectrophotometry
2. NMR Spectrometry
3. ESR Spectrometry
4. Atomic absorption Spectroscopy
5. Plasma emission Spectroscopy
6. Atomic force Microscopy & Photon co-relation spectroscopy
7. Spectrofluorometry
8. **Electrometric Methods :**
Conductometry, High frequency titrations, potentiometry, Amperometry, Polarography

REFERENCES:

1. R.M. Silverstein and G.C. Bassler, Spectrometric Identification of analysis capods.
2. Sittle: Handbook of Instrumental Techniques for Analytical Chemistry
3. Robert D Brown, Introduction to Instrumental Analysis.
4. Skoogadwest – Principles of Instrumental analysis.

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(9S04104) CHROMOTOGRAPHIC METHODS OF ANALYSIS

Introduction, Principle , Method of preparation and different types of stationary & mobile phases, Instrumentation, Interpretations, Data analysis and its applications of the following

1. Paper Chromatography & Thin layer chromatography
2. Column chromatography & Gas chromatography
3. HPLC
4. HPTLC
5. Exclusion chromatography & Super critical fluid chromatography
6. Vapour phase chromatography & Affinity chromatography
7. Ion – exchange chromatography & Centrifugal partition chromatography
8. LCMS & GCMS

REFERENCES

1. R.M. Silverstein, 'spectrometric identification of organic compounds'.
2. B.K. Sharma 'Instrumental Methods of Chemical Analysis', Goel Publications
3. Chatwal and Anand 'Instrumental Methods of Chemical Analysis', Himalaya Publications
4. H. Kaur 'Instrumental Methods of Chemical Analysis', Pragati Prakashan
5. P.D. Sethi 'Qualitative Analysis of Drugs and Pharmaceuticals
6. I.M. Kolthaf 'Quantitative Chemical Analysis'

(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.

**(9S04106) ELELCTROMETRIC & CHROMATOGRAPHIC METHODS OF
 ANALYSIS PRACTICAL**

- 1 Preparation of Mobile Phase, Standard Solution, Sample Solution, Internal Standard for Acetaminophen, Caffeine and Codeine Phosphate Tablets as per USP.
- 2 Test for Identification by using HPLC – For any Compendial Drug
- 3 Test for Assay by using HPLC – For any Compendial Drug
- 4 Test for Uniformity of Dosage Units by using HPLC – For any Tablets / Capsules as per USP.
- 5 Test for Dissolution by using Dissolution Apparatus and HPLC – For any Tablets
- 6 Test for Residual Solvents by using GC – For any Compendial Drug
- 7 Determination of Alcohol Content by using GC
- 8 Test for Assay by using GC - For any Compendial Drug
- 9 Test for Identification by using HPTLC – For any Compendial Drug
- 10 Test for Assay by using HPTLC – For any Compendial Drug
- 11 Test for Impurity Profile by using HPTLC – For any Compendial Drug
- 12 Test for Degradation compounds by using TLC – For Acetaminophen as per USP

Part-II

Determination of λ_{\max} of different drugs and preparation of calibration curve. (Ephedrine Hydrochloride, Sulphanilamide, etc.).

1. Estimation of drugs by UV Spectrophotometry Mimesulide tablets, Paracetamol, Pyridoxine, Pheniramine maleate,
2. Assay of Riboflavin, by Fluorimetry.
3. To study the quenching effect of Quinine sulphate by Fluorimetry.
4. Interpretation of IR spectra of Polystyrene, Salicylic acid, etc.

5. Assay of drugs by IR Spectrophotometry by baseline technique.
6. Interpretation of NMR spectra of pure drugs.
7. Identification of different functional groups by IR
(amino group, alcoholic group amide, ester, acid group etc)
8. Assay of Cotrimazole tablet by NMR.
9. Determination of Iodine values of natural oils.
Olive oil, Peanut oil etc.
10. Assay of total zinc in Insulin zinc suspension by Atomic Absorption Spectroscopy.
11. Assay of Sodium, Potassium and Calcium in blood serum and water by Flame Emission Spectroscopy.
12. Assay of some inorganic agents by Flame Emission Spectroscopy Sodium chloride, Potassium citrate, Magnesium acetate.
13. Assay of drugs by Potentiometric method of analysis.
Cimetidine, Nitrazepam, Clonidine etc.
14. Assay of Procainamide hydrochloride by Amperometric titration method.
15. Study of different fragments of Mass Spectra of different pure drugs.

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M.Pharm I year I semester (PA & QC)

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(12S12101) Mini Projects-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

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY ANANTAPUR
M.Pharm - Pharmaceutical Analysis & Quality Control
M.Pharm I year II semester (PA & QC)

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(9S04201) ADVANCED PHARMACEUTICAL ANALYSIS

- Principles and procedures involved in quantitative determination of the following functional groups

A. Hydroxy	B. Aldehyde	C. Ketone
D. Amine	E. Methoxy	F. Ester
- General methods for the estimation of the following

A. Proteins	B. Carbohydrates	C. Fats
D. Crude fibre	E. Moisture	F. Nitrogen
- Principles and procedures involved in the use of the following reagents in Pharmaceutical Analysis
 - 3- Methyl 1-2- benzothiozoline hydrozone (MBTH)
 - Folin - Ciocalteu Reagent
 - Paradimethyl amino benzaldehyde.
 - 2-6- Dichloro quinine chlorimide
 - 2,3,5- Triphenyl tetrazolium salt
 - Ninhydrin Reagent
- Thermal Methods of Analysis: Theory of Thermal gravimetric Analysis (TGA), Differential thermal Analysis (DTA), Differential Scanning calorimetry (DSC) and Thermal Mechanical Analysis (TMA)

5. Principles and procedures involved in the following physicochemical methods including the assays of official drugs mentioned in IP.
 - a) Non-aqueous titration
 - b) Complexometric titration
 - c) Oxidation- reduction titration
6. Principles and procedures involved in the following physicochemical methods including the assays of official drugs mentioned in IP.
 - a) Diazotization titration
 - b) Potentiometer titration
 - c) Conduct metric titration
7.
 - a. Radiometric analysis: radio activity, radioisotopes and Pharmaceutical Applications of radiopharmaceuticals
 - b. Radio Immune Assay: Principle, Procedures and applications.
 - c. ELISA Test
8. Preparation drug samples for analysis: Pharmaceutical samples, fundamental theories controlling preparation techniques, specific sample preparation techniques.

REFERENCES

- 1) Remington's Pharmaceutical Sciences by Alfonso and Gennaro
- 2) Pharmaceutical Chemistry by Becket and Stanlake
- 3) Quantitative Analysis of Drugs in Pharmaceutical Formulations by P.D. Sethi
- 4) Pharmaceutical Analysis by Higuchi, Bechmman and Hassan
- 5) Theory and Practice of Industrial Pharmacy by Lieberman and Lachman
- 6) Indian Pharmacopoeia 1996
- 7) Instrumental Methods of Chemical Analysis by B.K. Sharma
- 8) A Text Book of Pharmaceutical Analysis by Kerrenth A. Connors
- 9) Journals like Indian Drugs, IJPS etc.

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY ANANTAPUR**M.Pharm I year II semester (PA & QC)****Th C**
4 4**(9S04202) QUALITY ASSURANCE OF PHARMACEUTICALS**

1. a. Concepts of Total Quality Management (TQM) and Good Manufacturing Practices (GMP)
b. Organization and personnel – Responsibilities and Training.
2. Good Laboratory Practices (GLP): Routine controls, Instruments, Protocols, Non-Clinical Testing, Controls on Animal House, Applications of Computers in Quality Control Laboratory.
3. Finished product Release: Quality Review, Quality Audits, Batch Release document
- 4 Warehousing: Good ware housing practices Materials Management
- 5 Documentation related to Product Development, Standard operating procedures, standard test procedures, cleaning methods, quality control documents, batch release document, distribution records, complaints and recalls records, retention of records.
- 6 Regulatory Affairs - Drugs and Cosmetic Act, DPCO, Intellectual Property right and patent laws.
- 7 New Drug Development and Approval Process: Investigational New Drugs (IND), New Drug Applications (NDA), Supplemental New Drug Application (SNDA).
- 8 a. ICH requirements for registration of Pharmaceuticals
b. WHO certification scheme on the quality of pharmaceutical products.

References

- 2) Quality Assurance of Pharmaceuticals (A compendium of guidelines and selected materials) Vol I & II (Pharma Book Syndicate, Book Street, Hyd)
- 3) Basic Texts for Pharmaceutical substances WHO (1988, 1991)
- 4) A guide to Total quality management K. Maitra and S.K. Ghosh
- 5) Good Manufacturing Practice (GMP) by Mehra
- 6) How to Practice GMP by P.P. Sharma.
- 7) ISO 9000 and Total Quality Management by S.K. Ghosh.
- 8) Packaging Drugs and Pharmaceuticals W.A. Jenkins & K. R. Osborn.
- 9) The Drug and Cosmetic Act 1940 by Vijay Malik
- 10) The International Pharmacopoeia, Vol. 1-4
- 11) Web links
 - a. www.iprlawindia.org
 - b. www.indialegalguide.com
 - c. www.intelproplaw.com
 - d. www.indianpatentoffice.org
 - e. www.findlaw.com

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(9S04203) ANALYTICAL METHOD DEVELOPMENT AND VALIDATION

1. Concept of Analytical Method development, validation and calibration of various analytical instruments for drug analysis
2. Development of analytical Methods and validation of the following techniques
A. UV-Visible spectrophotometer B. IR Spectrometer C. Flourimeter
3. Development of analytical Methods and validation of the following techniques
A. HPLC B. GC-MS C. LC-MS
4. A detailed study on related substances and impurities present in drugs and their effect on drug stability and therapeutic action. ICH guidelines for impurity and related substances determination in the drugs
5. Validation Methods for the following
A. Analytical Procedures B. Analyst Validation
C. Air handling equipment and facilities in zone D. Animal house
6. Validation of sterilization methods and equipment, Dry heat sterilizations, Auto cleaving membrane filtration.
7. Validation Methods for the following
a. Water supplies
b. Water supply systems: Deionised , distilled, purified, Demineralised and water for injections
8. Accuracy, Precision and Linearity, Sources of Errors, use of significant figures and their correct usage, Intraday and interlay analysis. System suitability and ruggedness of the method

REFERENCES

- 1) Pharmaceutical Process Validation by Ira R. Berry and Robert A. Nash
- 2) Quality assurance and TQM for analytical laboratories by M. Parkany, The Royal Society of Chemistry
- 3) SOP Guidelines by D. H. Shah
- 4) GMP, by M.L. Mehra
- 5) A Guide to Total Quality Management by Kaushik Maitra and Sadhan K.Ghosh
- 6) Microbiological Assays by Barton J. Wright

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M.Pharm I year II semester (PA & QC)

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(9S04204) EVALUATION OF DOSAGE FORMS

1. Detailed study of the principles and procedures involved in various physicochemical methods of analysis of Pharmaceutical dosage forms belong to the following classes of drugs.
A. Sulphonamides B. Antibiotics C. Anti-histamines D. Vitamins
2. A detailed study on the principles and procedures involved in the determination of the dosage forms of the following group of drugs
A. Adrenergic B. Anti-malarial C. Steroids D. Analgesics and anti pyretic
3. Official methods of determination for the mentioned below pharmaceutical dosage forms of the following group of drugs
A. Local anesthetics B. Barbiturates C. Anti-diabetic D. Diuretics
4. Various in process Quality Control tests carried on the following of Dosage Forms
A. Tablets B. Capsules C. Injectables D. Liquid Orals
5. A detailed study on the biological evaluation of the following dosage forms
a. Rabbits Vaccine b. Oxytocin c. Tetanus Antitoxin
6. Microbiological evaluation of the following dosage forms
a. Neomycin Sulphate b. Cyanocobalamin c. Diphtheria Vaccine
7. Quality control of crude drugs: Proximate analysis including ash and extractive values, crude fibre content, UV and Florescence analysis of powdered drugs.
8. a. Detection of common adulterants and insects infestation in whole and powdered drugs.
b. WHO guidelines for the quality control raw materials
c. Brief study of quality control of plant products and their High throughput Screening

REFERENCES

- 1) Remington's Pharmaceutical Sciences by Alfonso and Gennaro
- 2) Microbiological Assays by Barton J. Wright
- 3) Pharmaceutical Chemistry by Becket and Stanlake
- 4) Quantitative Analysis of Drugs in Pharmaceutical Formulations by P.D. Sethi
- 5) Pharmaceutical Analysis by Higuchi, Bechmman and Hassan
- 6) Theory and Practice of Industrial Pharmacy by Lieberman and Lachman
- 7) Indian Pharmacopoeia 1996

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**(9S04205) ANALYTICAL METHOD DEVELOPMENT AND VALIDATION
PRACTICAL**

Comparison of different methods available for various dosage forms with the official methods mentioned in IP, BP, USP etc.

Method of Determination by colourimetry is compared with the official IP method for its accuracy of the following drugs

- 1) Paracetamol
- 2) Aspirin
- 3) Piperine
- 4) Gingerene
- 5) Curcuminoids
- 6) Ginsenosides
- 7) Sennoides
- 8) Strychnine and Brucine
- 9) Caffeine
- 10) Nicotine
- 11) Aspiridine
- 12) Vasicine

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(9S04206) EVALUATION OF DOSAGE FORMS -PRACTICAL

1. Assay of Ascorbic Acid Tablets.
2. Assay of Paracetamol Tablets.
3. Assay of trimethoprim and sulphamethoxazole
4. Assay of calcium Gluconate Injection
5. Assay of Penicillin Injection.
6. Assay of Acetyl Salicylic acid tablets.
7. Assay of Ibuprofen Tablets.
8. Assay of Dextrose Injection.
9. Assay of Riboflavin Tablets.
10. Assay of Rifampicin Capsules.
11. Assay of INH
12. Assay of Chloromphenicol.

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I year II semester (PA & QC)

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(12S12201) 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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IV semester (PA & QC)

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(12S12401) SEMINAR

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY
ANANTAPUR

IV semester (PA & QC)

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(12S12402) 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.