ACADEMIC REGULATIONS
COURSE STRUCTURE
AND
DETAILED SYLLABUS

For

M.PHARMACY

PHARMACEUTICAL ANALYSIS AND QUALITY ASSURANCE

JAWAHARLAL NEHRU TECHNOLOGY UNIVERSITY KAKINADA

KAKINADA - 533 003, Andhra Pradesh, India

ACADEMIC REGULATIONS R13 FOR M. Pharmacy (REGULAR) DEGREE COURSE

Applicable for the students of M. Pharmacy (Regular) Course from the Academic Year 2013-14 onwards

The M. Pharmacy Degree of Jawaharlal Nehru Technological University Kakinada shall be conferred on candidates who are admitted to the program and who fulfil all the requirements for the award of the Degree.

1.0 ELIGIBILITY FOR ADMISSIONS

Admission to the above program shall be made subject to eligibility, qualification and specialization as prescribed by the University from time to time.

Admissions shall be made on the basis of merit/rank obtained by the candidates at the qualifying Entrance Test conducted by the University or on the basis of any other order of merit as approved by the University, subject to reservations as laid down by the Govt. from time to time.

2.0 AWARD OF M. Pharmacy DEGREE

2.1 A student shall be declared eligible for the award of the M. Pharmacy Degree, if he pursues a course of study in not less than two and not more than four academic years.

2.2 The minimum instruction days in each semester are 90.

3.0 A. COURSES OF STUDY

The following specializations are offered at present for the M. Pharmacy course of study.

S.No	Specializations
1	Industrial Pharmacy
2	Pharmaceutical Analysis
3	Pharmaceutical Analysis & Q A
4	Pharmaceutical Analysis & QC
5	Pharmaceutical Chemistry
6	Pharmaceutical Management & Regulatory Affairs
7	Pharmaceutical Technology
8	Pharmaceutics
9	Pharmacognosy
10	Pharmacology
11	Pharmacology & Toxicology
12	Pharmacy Practices
13	Quality Assurance & Regulatory Affairs

and any other course as approved by AICTE/ PCI University from time to time.

4.0 ATTENDANCE

4.1 A student shall be eligible to write University examinations if he acquires a minimum of 75% of attendance in aggregate of all the subjects.

4.2 Condonation of shortage of attendance in aggregate up to 10% (65% and above and below 75%) in each semester shall be granted by the College Academic Committee.

4.3 Shortage of Attendance below 65% in aggregate shall not be condoned.

4.4 Students whose shortage of attendance is not condoned in any semester are not eligible to write their end semester examination of that class.

4.5 A prescribed fee shall be payable towards condonation of shortage of attendance.

4.6 A student shall not be promoted to the next semester unless he satisfies the attendance requirement of the present semester, as applicable. They may seek readmission into that semester when offered next. If any candidate fulfills the attendance requirement in the present semester, he shall not be eligible for readmission into the same class.

5.0 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.

5.1 For the theory subjects 60 marks shall be awarded based on the performance in the End Semester Examination and 40 marks shall be awarded based on the Internal Evaluation. The internal evaluation shall be made based on the **average** of the marks secured in the two Mid Term-Examinations conducted-one in the middle of the Semester and the other immediately after the completion of instruction. Each mid term examination shall be conducted for a total duration of 120 minutes with 4 questions

(without choice) each question for 10 marks. End semester examination is conducted for 60 marks for 5 questions to be answered out of 8 questions.

5.2 For practical subjects, 60 marks shall be awarded based on the performance in the End Semester Examinations and 40 marks shall be awarded based on the day-to-day performance as Internal Marks.

5.3 There shall be two seminar presentations during III semester and IV semester. For seminar, a student under the supervision of a faculty member, shall collect the literature on a topic and critically review the literature and submit it to the department in a report form and shall make an oral presentation before the Project Review Committee consisting of Head of the Department, Supervisor and two other senior faculty members of the department. For each Seminar there will be only internal evaluation of 50 marks. A candidate has to secure a minimum of 50% of marks to be declared successful.

5.4 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 semester Examination and a minimum aggregate of 50% of the total marks in the End Semester Examination and Internal Evaluation taken together.

5.5 In case the candidate does not secure the minimum academic requirement in any subject (as specified in 5.4) he has to reappear for the End semester Examination in that subject. A candidate shall be given one chance to re-register for each subject provided the internal marks secured by a candidate are less than 50% and has failed in the end examination. In such a case, the candidate must re-register for the subject(s) and secure the required minimum attendance. The candidate's attendance in the re-registered subject(s) shall be calculated separately to decide upon his eligibility for writing the end examination in those subject(s). In the event of the student taking another chance, his internal marks and end examination marks obtained in the previous attempt stand cancelled. For re-registration the candidates have to apply to the

University through the college by paying the requisite fees and get approval from the University before the start of the semester in which re-registration is required.

5.6 In case the candidate secures less than the required attendance in any re registered subject (s), he shall not be permitted to write the End Examination in that subject. He shall again re-register the subject when next offered.

5.7 Laboratory examination for M. Pharmacy. courses must be conducted with two Examiners, one of them being the Laboratory Class Teacher or teacher of the respective college and the second examiner shall be appointed by the university from the panel of examiners submitted by the respective college.

6.0 EVALUATION OF PROJECT/DISSERTATION WORK

Every candidate shall be required to submit a thesis or dissertation on a topic approved by the Project Review Committee.

6.1 A Project Review Committee (PRC) shall be constituted with Head of the Department and two other senior faculty members.

6.2 Registration of Project Work: A candidate is permitted to register for the project work after satisfying the attendance requirement of all the subjects, both theory and practical.

6.3 After satisfying 6.2, a candidate has to submit, in consultation with his project supervisor, the title, objective and plan of action of his project work for approval. The student can initiate the Project work, only after obtaining the approval from the Project Review Committee (PRC).

6.4 If a candidate wishes to change his supervisor or topic of the project, he can do so with the approval of the Project Review Committee (PRC). However, the Project Review Committee (PRC) shall examine whether or not the change of topic/supervisor leads to a major change of his initial plans of project proposal. If yes, his date of registration for the project work starts from the date of change of Supervisor or topic as the case may be.

6.5 A candidate shall submit his status report in two stages at least with a gap of 3 months between them.

6.6 The work on the project shall be initiated at the beginning of the II year and the duration of the project is two semesters. A candidate is permitted to submit Project Thesis only after successful completion of theory and practical course with the approval of PRC not earlier than 40 weeks from the date of registration of the project work. The candidate has to pass all the theory and practical subjects before submission of the Thesis.

6.7 Three copies of the Project Thesis certified by the supervisor shall be submitted to the College/School/Institute.

6.8 The thesis shall be adjudicated by one examiner selected by the University. For this, the Principal of the College shall submit a panel of 5 examiners, eminent in that field, with the help of the guide concerned and head of the department.

6.9 If the report of the examiner is not favourable, the candidate shall revise and resubmit the Thesis, in the time frame as decided by the PRC. If the report of the examiner is unfavorable again, the thesis shall be summarily rejected. The candidate has to re-register for the project and complete the project within the stipulated time after taking the approval from the University.

6.10 If the report of the examiner is favourable, Viva-Voce examination shall be conducted by a board consisting of the Supervisor, Head of the Department and the examiner who adjudicated the Thesis. The Board shall jointly report the candidate's work as one of the following:

A. Excellent
B. Good
C. Satisfactory
D. Unsatisfactory

The Head of the Department shall coordinate and make arrangements for the conduct of Viva-Voce examination.

6.11 If the report of the Viva-Voce is unsatisfactory, the candidate shall retake the Viva-Voce examination only after three months. If he fails to get a satisfactory report at the second Viva-Voce examination, the candidate has to re-register for the project and complete the project within the stipulated time after taking the approval from the University.

7.0 AWARD OF DEGREE AND CLASS

After a student has satisfied the requirements prescribed for the completion of the program and is eligible for the award of M. Pharmacy. Degree he shall be placed in one of the following four classes:

Class Awarded	% of marks to be secured
First Class with Distinction	70% and above (Without any Supplementary Appearance)
First Class	Below 70% but not less than 60%
	70% and above (With any Supplementary Appearance)
Second Class	Below 60% but not less than 50%

The marks in internal evaluation and end examination shall be shown separately in the memorandum of marks.

8.0 WITHHOLDING OF RESULTS

If the student has not paid the dues, if any, to the university or if any case of indiscipline is pending against him, the result of the student will be withheld. His degree will be withheld in such cases.

9.0 TRANSITORY REGULATIONS (for R09)

9.1 Discontinued or detained candidates are eligible for re-admission into same or equivalent subjects at a time as and when offered.

9.2 The candidate who fails in any subject will be given two chances to pass the same subject; otherwise, he has to identify an equivalent subject as per R13 academic regulations.

10. GENERAL

10.1 Wherever the words “he”, “him”, “his”, occur in the regulations, they include “she”, “her”, “hers”.

10.2 The academic regulation should be read as a whole for the purpose of any interpretation.

10.3 In the case of any doubt or ambiguity in the interpretation of the above rules, the decision of the Vice-Chancellor is final.

10.4 The University may change or amend the academic regulations or syllabi at any time and the changes or amendments made shall be applicable to all the students with effect from the dates notified by the University.

MALPRACTICES RULES

DISCIPLINARY ACTION FOR / 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	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

	(theory or practical) in which the candidate is appearing.	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.	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 imposter is an outsider, he will be handed over to the police and a case is registered against him.
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	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

	the examination.	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.	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.
6.	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	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.

	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.	
7.	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.
8.	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.
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.	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.
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: KAKINADA

KAKINADA-533003, Andhra Pradesh (India)
For Constituent Colleges and Affiliated Colleges of JNTUK

Ragging

Prohibition of ragging in educational institutions Act 26 of 1997

Salient Features

- ⇨ Ragging within or outside any educational institution is prohibited.
- ⇨ Ragging means doing an act which causes or is likely to cause Insult or Annoyance of Fear or Apprehension or Threat or Intimidation or outrage of modesty or Injury to a student

	Imprisonment upto		Fine Upto
Teasing, Embarrassing and Humiliation	6 Months	+	Rs. 1,000/-
Assaulting or Using Criminal force or Criminal intimidation	1 Year	+	Rs. 2,000/-
Wrongfully restraining or confining or causing hurt	2 Years	+	Rs. 5,000/-
Causing grievous hurt, kidnapping or Abducts or rape or committing unnatural offence	5 Years	+	Rs.10,000/-
Causing death or abetting suicide	10 Months	+	Rs. 50,000/-

In Case of Emergency CALL TOLL FREE NO. : 1800 - 425 - 1288

LET US MAKE JNTUK A RAGGING FREE UNIVERSITY

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY: KAKINADA

KAKINADA-533003, Andhra Pradesh (India)
For Constituent Colleges and Affiliated Colleges of JNTUK

Ragging

ABSOLUTELY NO TO RAGGING

1. Ragging is prohibited as per Act 26 of A.P. Legislative Assembly, 1997.
2. Ragging entails heavy fines and/or imprisonment.
3. Ragging invokes suspension and dismissal from the College.
4. Outsiders are prohibited from entering the College and Hostel without permission.
5. Girl students must be in their hostel rooms by 7.00 p.m.
6. All the students must carry their Identity Card and show them when demanded
7. The Principal and the Wardens may visit the Hostels and inspect the rooms any time.

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M.PHARMACY

PHARMACEUTICAL ANALYSIS AND QUALITY ASSURANCE

I SEMESTER

Paper 101 - Modern Analytical Techniques
Paper 102 - Research Methodologies
Paper 103 - Advanced Pharmaceutical Analysis - I
Paper 104 - Chromatographic and Other Special techniques
Paper 105 - Advanced Pharmaceutical Analysis-I - LAB
Paper 106 - Chromatographic and Other Special techniques - LAB
Paper 107 - Seminar

II SEMESTER

Paper 201 - Advanced Pharmaceutical Analysis - II
Paper 202 - Phytopharmaceutical and Biological Analysis
Paper 203 - Quality Assurance of Pharmaceuticals – I
Paper 204 - Drug Regulatory Affairs
Paper 205 - Advanced Pharmaceutical Analysis - II - LAB
Paper 206 - Phytopharmaceutical and Biological Analysis - LAB
Paper 207 - Seminar

III SEMESTER

Paper 301 - Seminar-I
Paper 302 - Project Work – I

IV SEMESTER

Paper 401 - Seminar-II
Paper 402 - Project Work – II
Paper 403 - Comprehensive Viva Voce

SCHEME OF INSTRUCTIONS AND EVALUATION PHARMACEUTICAL ANALYSIS AND QUALITY ASSURANCE

I SEMESTER

Paper No.	Title of the Paper	Evaluation / Marks				Total	Credits
		Theory		Practical			
		Mid Examination	University End Examination	Mid Examination	University End Examination		
Paper - 101	Modern Analytics Techniques	40	60			100	3
Paper - 102	Research Methodo -Igies	40	60			100	3
Paper - 101	Advanced Pharmaceutical Analysis	40	60			100	3
Paper - 102	Chromato graphic and other special Techniques	40	60			100	3
Paper - 104	Advanced Pharmaceutical Analysis I Practical			40	60	100	3
Paper - 105	Chromato graphic and other special Techniques I Practical			40	60	100	3
Paper - 106	Seminal					100	2
	Total					700	18

II SEMESTER

Paper No.	Title of the Paper	Evaluation / Marks				Total	Credits
		Theory		Practical			
		Mid Examination	University End Examination	Mid Examination	University End Examination		
Paper - 201	Advanced Pharmaceutical Analysis-II	40	60			100	3
Paper - 202	Pharmaceutical and Biological Analysis	40	60			100	3
Paper - 203	Quality Assurarance of Pharmaceutical	40	60			100	3
Paper - 204	Drug Regultory Affairs	40	60			100	3
Paper - 205	Advanced Pharmaceutical I Analysis -II Practical			40	60	100	3
Paper - 205	Phytopharmaceutical and Biological Analysis Practical			40	60	100	3
Paper - 206	Seminal					100	2
	Total					700	18

III SEMESTER

Paper No.		Marks	Credits
Paper - 301	Seminar – I	50	2
Paper - 302	Project work – I	100	14
	Total	150	16

IV SEMESTER

Paper No.		Marks	Credits
Paper - 401	Seminar – II	50	2
Paper – 402	Project work – II	100	14
Paper - 403	Comprehensive Viva Voce	100	4
	Total	250	20
Grand Total (Four Semesters)		1800	72

M.PHARM SYLLABUS FOR INDUSTRIAL PHARMACY

I – I	L	P	Credits
	-	-	3
MODERN ANALYTICAL TECHNIQUES (Paper Common for all Specializations)			

Principles, instrumentation and applications of the following Instruments and Chromatography techniques

UNIT-I

i. UV- Visible spectrophotometry

ii. Infrared spectroscopy

iii. Spectrofluorimetry

UNIT-II

i. NMR spectroscopy

ii. Electron Spin Resonance spectroscopy

iii. Atomic Emission spectroscopy

UNIT-III

i. HPLC

ii. HPTLC

iii. Exclusion chromatography

iv. Super critical fluid chromatography

UNIT-IV

i. Mass Spectroscopy including LCMS & GCMS

ii. GLC

UNIT-V

i. Plasma Emission spectroscopy

ii. X-Ray diffraction

iii. Optical Rotatory Dispersion

iv. Vapour phase chromatography

v. Affinity chromatography

vi. Ion-exchange chromatography

TEXT BOOKS

1. Practical Pharmaceutical Chemistry Vol. 1 &II by Beckett & Stenlake.

2. Instrumental Methods of Analysis by Scog and West.

3. Instrumental Methods of Analysis by B.K.Sharma

4. Vogel's text book of Quantitative Chemical Analysis.

5. Instrumental methods of Analysis by Willard & Merrit.

6. A text book of Pharmaceutical Analysis by K. A. Conners.

REFERENCE BOOKS

1. I.P.

2. B.P.

3. U.S.P.

4. Remington's Pharmaceutical Sciences.

5. Spectroscopy b Silversterin

I – I	L	P	Credits
	-	-	3

RESEARCH METHODOLOGIES
(Paper common for all Specializations)

UNIT I

Statistical Methods:

Chance Variation – Probability Distribution - Normal Distribution – Sampling Distribution

Error and its significance-Measures of Error- Control of Error in Experimental Investigations – Problem Solving.

UNIT II

Correlation and Regression., Multiple Regression - Problem Solving

UNIT III

Tests of Significance: Principles, t-test, z-test, F-ratio test, Chi-square test, Non-parametric tests- their applications in pharmacy research with examples – Problem Solving

UNIT IV

Design of Experiments

Criteria of a good design with examples.

Principles- Randomization, replication and local control.

Study of CRD, RBD, LSD and factorial designs- their applications in Pharmacy research with examples – Problem Solving

UNIT V

Analysis of Variance (ANOVA) – one way, two way and three way – principles and applications in pharmacy research- Problem Solving

Optimisation Techniques : Optimisation Techniques based on Factorial Experiments - Problem Solving.

Recommended Books:

1. Fundamentals of Biostatistics by Khan & Khanum, Ukaaz Publications, Hyderabad
2. Theory & Practice of Industrial Pharmacy by Leon Lachman and Others
3. Remingtons Practice of Pharmaceutical sciences, (Latest Edition)
4. Principles of Biostatistics by Marcello Pagnano, Published by Brooks/ Cole, (Saurabh Printers Pvt. Ltd)
5. Introduction To Biostatistics – A text book of biometry By Pranab Kumar Banerjee

I – I	L	P	Credits
	-	-	3

ADVANCED PHARMACEUTICAL ANALYSIS-I

UNIT-I

1. Good Laboratory practices (GLP), Laboratory maintenance, standard operating procedures (SOPS), Validation of analytical instruments and methods. – Quality Control Laboratory Regulatory requirements

UNIT-II

1. Theory, Instrumentation and application with regard to drug analysis, decomposition product identification and estimation and metabolite analysis based on the following:

a) Ultraviolet visible spectrophotometry

b) Infrared Spectrophotometry

c) Fluorimetry, Nephelometry and Turbidimetry

UNIT-III

1. Polarography.

2. Flame emission spectroscopy and atomic absorption spectroscopy. Principle, Instrumentation and applications in Pharmacy.

UNIT-IV

1. Thermal methods of analysis: Theory of Thermo gravimetric analysis (TGA), Differential Thermal analysis (DTA), Differential Scanning Calorimetry (DSC) and Thermo Mechanical Analysis (TMA).

2. An advanced study of non - aqueous titrations involving the following:

a) Primary, Secondary and Tertiary amines

b) Halogenated salts and bases

c) Acidic substances

d) Assays of official drugs in IP 1996 by non - aqueous titrimetry

e) Aquametry: Determination of water by titration with Karl Fischer Reagent (KFR).

UNIT-V

1. Principles and pharmaceutical applications of redox titrations involving:

a) Potassium Iodate / bromate titrations

b) Cerric ammonium sulphate titrations

c) Tannus Chloride titration

d) Examples of assays of official drugs in IP 1996.

2. Principles and Pharmaceutical applications of complexometric titrations involving:

a) Direct titration of Polymetallic system with Sodium EDTA

b) Back titration with sodium EDTA

c) titration involving the displacement of one complex by another

d) PM indicators

e) Examples of assays official drugs in IP 1996.

TEXT BOOKS

1. Practical Pharmaceutical Chemistry Vol. 1 &II by Beckett & Stenlake.
2. Instrumental Methods of Analysis by Scog and West.
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5. Spectroscopy b Silverstein

I – I	L	P	Credits
	-	-	3

CHROMATOGRAPHIC AND OTHER SPECIAL TECHNIQUES

UNIT-I

An advanced study of the following and their applications.

1. Basic principle and separation by Column chromatography, thin layer chromatography, paper chromatography and ion exchange chromatography.

UNIT-II

1. Gas Chromatography: Introduction, theory, column operation, instrumentation and detection, GCMS.

UNIT-III

1. High Pressure Liquid Chromatography: Principle, Instrumentation procedure, solvents used, elution techniques, LCMS and applications.

UNIT-IV

1. HPTLC and Supercritical Fluid Chromatography (SFC): Principle, instrumentation procedure, elution technique and pharmaceutical applications.

2. H.P.C.P.C

UNIT-V

1. Electrophoreses (gel and capillary)

2. Radio immuno assay and related immuno assays — RIA, ELISA

TEXT BOOKS

1. Instrumental Methods of Analysis by Skoog and West.
2. lnstrumental Mcthods of Analysis by B.K.Sharma
3. Instrumental methods of Analysis by Willard & Merrit.
4. High Performance Liquid Chromatography by P. D. Sethi.
5. Liquid Chromatography-Mass Spectrometry, Third Edition by by Wilfried M.A. Niessen

REFERENCE BOOKS

1. USP
2. Remington's Pharmaceutical Sciences.
3. Spectroscopy by Silversterin
4. Instrumental methods of Analysis by Hibart. H. Willard.

I – I	L	P	Credits
	-	-	2

ADVANCED PHARMACEUTICAL ANALYSIS –I

1. Use of spectrophotometer for analysis of Pharmacopoeial compounds and their formulations.
2. Use of fIuorimeter for analysis of Pharmacopoeial compounds.
3. Use of Flame photometer for analysis of Na, K & Ca etc in Biological fluids and formulations.
4. Use of Nephelo- Turbidimetric analysis of dispersions and limit tests.
5. Assays involving following procedures: Non – Aqueous, Diazotisation, Complexation and Redox titrations.
6. Official (I.P) Assays based on theory.

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I – I	L	P	Credits
	-	-	2

CHROMATOGRAPHIC AND OTHER SPECIAL TECHN1QUES LAB

1. Experiments on Electrophoresis.
2. Experiments of Chromatography:

a) Ascending technique

b) Descending technique

c) Circular technique

3. Experiments using HPLC & GC.

TEXT BOOKS

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2. lnstrumental Mcthods of Analysis by B.K.Sharma
3. Instrumental methods of Analysis by Willard & Merrit.
4. High Performance Liquid Chromatography by P. D. Sethi.

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1. USP
2. Remington's Pharmaceutical Sciences.
3. Spectroscopy by Silverstein
4. Instrumental methods of Analysis by Hibart. H. Willard.

I – I I	L	P	Credits
	-	-	3

ADVANCED PHARMACEUTICAL ANALYSIS-II

UNIT-I

1. A detailed study of the principles, instrumentation and applications of the following instrumental analysis:
   i. Nuclear Magnetic resonance spectrometry - ^{1}H NMR ,2D NMR, COSY, ^{13}CNMR, DEPT Experiments
   ii. Mass spectroscopy.

UNIT-II

1. A detailed study of the principles, instrumentation and applications of the following instrumental analysis:
   i. X-ray fluorescence spectrometry
   ii. Raman Spectroscopy
   iii. Inductively coupled plasma - atomic emission spectroscopy
   iv. Electron spin resonance spectroscopy (ESR)

UNIT-III

1. A detailed study of the various principles and procedures involved in the qualitative and quantitative analysis of pharmaceutical preparations and dosage forms containing the following groups of drugs included in IP (Biological and microbiological methods excluded)
   a) Analgesics and antipyretics
   b) l3arbiturates
   c) Sulphonamidcs
   d) Antibiotics
   e) Steroidal hormones
   f) Vitamins
   g) Alkaloids

UNIT-IV

1. A detailed study of the principles and procedures involved in the qualitative and quantitative analysis of pharmaceutical preparations and dosage forms using the following reagents and reactions.

   i) Oxidative coupling reactions using MBTH

   (3-methyl -2 benzothiazolinone hydrazone hydrochloride)

   ii) Diazotisation followed by coupling

   iii) Oxidation followed by complexation.

2. A detailed study of the principles and procedures involved in the qualitative and quantitative analysis of pharmaceutical preparations and dosage form using the following reagents and reactions

   i) Oxidation followed by charge transfer reaction.

   ii) Condensation reactions using the reagents Para Dimethyl Amino Benzaldehyde (PDAB), Para Dimethyl Amino Cinnamaldehyde (PDAC), Folin's reagent and Gibb's reagent

   iii) Folin-ciocalteu reagent (FC reagent)

UNIT-V

1. General methods for quality control of various types of official formulation- tablets, capsules, suspensions, ointments and injections.
2. Testing of containers and closures (glass, metal, rubber and plastic) for pharmaceutical preparations as per the I.P.

TEXT BOOKS

1. Instrumental methods of analysis by Skoog and West.
2. Chemical Analysis - Modem Instrumentation methods and techniques by Wiley.
3. Instrumental methods of analysis by Willard Dean & Merrit.
4. A text book of Pharmaceutical Analysis by K.A. Conners (John Wiley)
5. Pharmaceutical analysis edited by Highuchi and Brochman

REFERENCE BOOKS

1. Spectrometric identification of organic compounds by Silverstein (7th Edition) 1981
2. Hand book of Instrumental techniques for analytical chemistry edited by Frank sett by Prentice Hall Ine.
3. IP
4. BP
5. USP

I – II	L	P	Credits
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PHYTOPHARMACEUTICAL AND BIOLOGICAL ANALYSIS

UNIT-I

1. Methods of systematic phytochemical analysis including extraction and identification of constituents using chromatographic techniques.
2. Quality control of crude drugs: proximate analysis including ash and extractive values, fiber content, U.V and fluorescence analysis of powdered drugs.

UNIT-II

1. Qualitative and quantitative microscopy and chemical microscopy and micro chemical tests.
2. Detection of common adulterants and insects infestation in whole and powdered drugs.

UNIT-III

1. Blind screening and screening methods for analgesic, antipyretic, anti-inflammatory and anti -diabetic, Hepatoprotective, antiulceric and Cardiotonic activities.

UNIT-IV

1. Analysis of official formulations derived from crude drugs including some ayurvedic preparations.
2. Microbiological screening methods for antimicrobial activity.

UNIT-V

1. Official (IP) Bio assays and Toxicity studies as per IP 1985: Test for histamine like substances, test for pyrogens, test for undue toxicity, Acute, Sub acute and Chronic Toxicity Studies

TEXT BOOKS

1. Textbook of Pharmacognosy by Trease & Evans.
2. Textbook of Pharmacognosy by Titler, Brady & Robber.
3. Phytochemical methods by J.B.Haroborne.
4. Instrumental methods of Analysis by Willard, Meritt, Dean.
4. The Quantitative analysis of Drugs by D.C.Garat
5. Microbiological assays by Barton J.Wright.

REFERENCE BOOKS

I. Pharmacopoeia of India
2. Pharmacopoeial standards for ayurvedic Formulation (Council of Research in Medicine & Homeopathy)
3. Application of absorption spectroscopy in Organic compounds by J.R.Dyer.
4. Analytical Microbiology by Kavanaagh.F

I – I I	L	P	Credits
	-	-	3

QUALITY ASSURANCE OF PHARMACEUT1CALS- I

UNIT-I

1. Concept of Quality assurance, total quality management, philosophy of GMP, CGMP and GLP.

2. Organization and personnel, responsibilities, training hygiene - Premises: Location, design, plan layout, construction, maintenance and sanitations, environmental control, sterile areas, control of contamination.

UNIT-II

1. **Equipments:** Selection, purchase specifications, maintenance, clean in place, sterilize in place - Raw materials: Purchase specifications, maintenance of stores, selection of vendors, controls and raw materials.

UNIT-III

1. Manufacture and controls on dosage forms, manufacturing documents master formula, batch formula records, standard operating procedures, quality audits of manufacturing processes and facilities - In process quality control on various dosage forms: sterile, biological products and non sterile, standard operating procedures for various operations like cleaning, filling, drying, compression, coating, disinfection, sterilization, membrane filtration etc.

Guidelines for Quality Assurance of Human Blood products and large volume parenterals.

2. Packaging and labeling controls, line clearance and other packaging materials.

UNIT-IV

1. Quality Control Laboratory: Responsibilities, good laboratory practices, routine controls, instruments, protocols, non-clinical testing, controls on animal house, data generation and storage, quality control

documents, retention samples, records, audits of quality control facilities - Finished products release: quality review, quality audits, and batch release document.

UNIT-V

1. Distribution and Distribution records: Handling of returned goods, recovered materials and reprocessing.

2. Complaints and recalls, evaluation of complaints, recall procedures, related records and documents.

TEXT BOOKS

1. The International Pharmacopoeia Vol. 1,2,3,4, 3rd edition General methods of analysis quality specifications for Pharmaceutical substances, Excipients, dosage forms.

2. Quality Assurance of Pharmaceuticals: A compendium of guidelines and related material Vol. 1 and Vol. 2., WHO, (1999).

3. GMP-Mehra

4. Pharmaceutical Process validation by Berry and Nash

REFERENCE BOOKS

1. Basic tests for Pharmaceutical substances - WHO (1988)

2. Basic tests for Pharmaceutical substances - WHO (1991)

3. How to practice GMP's – P.P.Sharma

4. The Drugs and Cosmetic Act 1940- Vijay Malik

5. Q.A Manual by D.H.Shah

6. SOP Guidelines by D.H.Shah

7. Quality Assurance Guide by OPPI

I – I I	L	P	Credits
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DRUG REGULATORY AFFAIRS: (Paper Common for all Specializations)			

UNIT - I

Formulation development: Regulatory requirements involved in the preformulation studies, solid, liquid and semi-solid dosage forms, controlled release preparations, injections, ocular preparations as per the European community, United States and Indian regulatory authorities

UNIT - II

Manufacturing: Regulatory requirements as per European community, United States and Indian regulatory authorities for manufacturing information, manufacturing formula, process, validation of manufacturing process, equipment, documentation, inspection requirement of regulatory guidelines for active ingredients, data requirement for new drug, International aspects of Excipients, approval as per guidelines of all the territories. Regulatory guidelines for packaging materials, test and evaluation of packaging materials, biological test, elastometer test, microbiological test and evaluation of closures.

UNIT - III

Stability testing: Scientific and technical background to the design of stability testing regulatory requirements as per European community, United States and Indian regulatory authorities for testing of new active substances, bulk active drug substances, dosage form in their final packaging. Extension of shelf-life after authorization of drug international harmonization and current guidelines. Regulatory affairs in respect of residual solvents as per the ICH guidelines, analytical method validation, pharmacokinetic and toxicokinetic validation.

Biopharmaceutics: Different testing parameters and standards as per regulatory requirements of European community, United States and Indian regulatory authorities with respect to factors related to formulation, dosage form, manufacturing process, stability and storage.

UNIT - IV

Preclinical aspects of Biopharmaceutics: Current guidelines and developments as per regulatory requirements of European community, United States and Indian regulatory authorities in respect of clinical bioavailability , study design, presentation documentation and statistical analysis.

Clinical pharmacology and Pharmacodynamics: Regulatory guidelines as per European community, United States and Indian regulatory authorities on clinical study design, documentation, presentation and interpretation. Clinical trials: Definition, phase I, phase II, phase III and phase IV studies, design documentation, presentation and interpretation, statistical analysis of clinical data and factorial design.

UNIT - V

Intellectual property rights and patents: Introduction, purpose, international scenario and Indian scenario, guidelines as per European community, United States and Indian regulatory authorities, documentation, presentation and application, procedure for obtaining and writing a patent and patenting rules and regulations

REFERENCES:

1. Quality Assurance Guide by Organization of Pharmaceutical producers of India.
2. Drug formulation manual by D.P.S. Kohli and D.H.Shah. Eastern publishers, New Delhi.

3. How to practice GMPs by P.P.Sharma. Vandhana Publications, Agra.
4. Pharmaceutical Process Validation by Fra. R. Berry and Robert A. Nash.
5. Pharmaceutical Preformulations by J.J. Wells.
6. Applied production and operations management by Evans, Anderson, Sweeney and Williams.
7. Basic Principles of Clinical Research and Methodology by Gupta.
8. Biopharmaceutics and Clinical Pharmacokinetics-An introduction; 4th edition, Revised and expanded by Robert. E. Notari, Marcel Dekker Inc, New York and Basel, 1987

I – I I	L	P	Credits
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ADVANCED PHARMACEUTICAL ANALYSIS -II LAB

1. Estimation of following classification of drugs using different analytical methods.

a) Analgesics and Antipyretics
b) Barbiturates
c) Sulfonamide drugs
d) Antibiotics
e) Steroidal hormones
f) Vitamins
g) Alkaloids

2. Estimation of different classification of drugs using the following reagents:

a) MBTH
b) FC reagent
c) $FeCl_3$ and 1,10- phenanthroline
d) $FeCl_3$ & K_3 Fe $(CN)_6$
e) BM reagent
f) p-dimethylamine benzaldehyde
g) p-dimethylamino cinnamaldehyde
h) N-bromo succinimide- metol/sulphanilamide.

3. Quality control test for official formulations.

4. Testing of containers and closures (glass, metal, rubber and plastic) for official (IP) pharmaceutical preparations.

I – I I	L	P	Credits
	-	-	2

PHYTOPHARMACEUTICAL AND BIOLOGICAL ANALYSIS PRACTICAL

1. Spectrophotometric determination of caffeine from tea powder.
2. The estimation of curcumin from Curcuma longa by Spectrophotometric methods.
3. Determination of sugars by descending paper chromatography.
4. Determination of bitterness value of crude drugs.
5. Determination of extractive values of crude drugs.
6. Fluorometric analysis of iso-quinoline alkaloids.
7. Determination of R_f values of different amino acids and alkaloids.
8. Anti - microbial activity of some plant extracts using different pathogenic and non – pathogenic organisms.
9. Colorimetric analysis of some plant drugs.
10. Blind Screening.
11. Screening for analgesic and anti-inflammatory activities.