# ACADEMIC EGULATIONS COURSE STRUCTURE AND DETAILED SYLLABUS

# For M.PHARMACY

Pharmaceutical analysis & Quality Control



JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY KAKINADA KAKINADA - 533 003, Andhra Pradesh, India



### ACADEMIC REGULATIONS R13 FOR M. Tech (REGULAR) DEGREE COURSE

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

The M. Tech 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. Tech DEGREE

- 2.1 A student shall be declared eligible for the award of the M. Tech Degree, if he pursues a course of study in not less than two and not more than four academic years.
- 2.2 The student shall register for all 80 credits and secure all the 80 credits.
- 2.3 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. Tech course of study.

- 1. M.Tech- Structural Engineering
- 2. M.Tech- Transportation Engineering
- 3. M.Tech- Infrastructure Engineering & Management
- 4. ME- Soil Mechanics and Foundation Engineering
- 5. M.Tech- Power Electronics
- 6. M.Tech- Power & Industrial Drives
- 7. M.Tech- Power Electronics & Electrical Drives
- 8. M.Tech- Power System Control & Automation
- 9. M.Tech- Power Electronics & Drives
- 10. M.Tech- Power Systems
- 11. M.Tech- Power Systems Engineering
- 12. M.Tech- High Voltage Engineering
- 13. M.Tech- Power Electronics and Power Systems
- 14. M.Tech- Power System and Control
- 15. M.Tech- Power Electronics & Systems
- 16. M.Tech- Electrical Machines and Drives
- 17. M.Tech- Advanced Power Systems
- 18. M.Tech- Power Systems with Emphasis on High Voltage Engineering
- 19. M.Tech- Control Engineering
- 20. M.Tech- Instrumentation & Control
- 21. M.Tech- Control Systems
- 22. M.Tech- Thermal Engineering
- 23. M.Tech- CAD/CAM
- 24. M.Tech- Machine Design
- 25. M.Tech- Computer Aided Design and Manufacture
- 26. M.Tech- Advanced Manufacturing Systems
- 27. M.Tech- Systems and Signal Processing
- 28. M.Tech- Digital Electronics and Communication Systems



- 29. M.Tech- Electronics & Communications Engineering
- 30. M.Tech- Communication Systems
- 31. M.Tech- Communication Engineering & Signal Processing
- 32. M.Tech- Microwave and Communication Engineering
- 33. M.Tech-Telematics
- 34. M.Tech- Digital Systems & Computer Electronics
- 35. M.Tech- Embedded System
- 36. M.Tech- VLSI
- 37. M.Tech- VLSI Design
- 38. M.Tech- VLSI System Design
- 39. M.Tech- Embedded System & VLSI Design
- 40. M.Tech- VLSI & Embedded System
- 41. M.Tech- VLSI Design & Embedded Systems
- 42. M.Tech- Computer Science & Engineering
- 43. M.Tech- Computer Science
- 44. M.Tech- Computer Science & Technology
- 45. M.Tech- Image Processing
- 46. M.Tech- Digital Image Processing
- 47. M.Tech- Computers & Communication
- 48. M.Tech- Computers & Communication Engineering
- 49. M.Tech- Computer Networks
- 50. M.Tech- Computer Networks & Information Security
- 51. M.Tech- Information Technology
- 52. M.Tech- Software Engineering
- 53. M.Tech- Neural Networks
- 54. M.Tech- Chemical Engineering
- 55. M.Tech- Biotechnology
- 56. M.Tech- Nano Technology
- 57. M.Tech- Remote Sensing
- 58. M.Tech- Food Processing
- 59. M.Tech- Avionics

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



### 3.0 B. <u>Departments offering M. Tech Programmes with specializations are noted below:</u>

Civil Engg.	1.	M.Tech- Structural Engineering
	2.	M.Tech- Transportation Engineering
	3.	M.Tech- Infrastructure Engineering & Management
	4.	ME- Soil Mechanics and Foundation Engineering
EEE	1.	M.Tech- Power Electronics
	2.	M.Tech- Power & Industrial Drives
	3.	M.Tech- Power Electronics & Electrical Drives
	4.	M.Tech- Power System Control & Automation
	5.	M.Tech- Power System Control & Automation  M.Tech- Power Electronics & Drives
	6.	
	-	M.Tech- Power Systems
	7.	M.Tech- Power Systems Engineering
	8.	M.Tech- High Voltage Engineering
	9.	M.Tech- Power Electronics and Power Systems
		M.Tech- Power System and Control
		M.Tech- Power Electronics & Systems
		M.Tech- Electrical Machines and Drives
		M.Tech- Advanced Power Systems
		M.Tech- Power Systems with Emphasis on High Voltage Engineering
		M.Tech- Control Engineering
		M.Tech- Instrumentation & Control
	17.	M.Tech- Control Systems
ME	1.	M.Tech- Thermal Engineering
	2.	M.Tech- CAD/CAM
	3.	M.Tech- Machine Design
	4.	M.Tech- Computer Aided Design and Manufacture
	5.	M.Tech- Advanced Manufacturing Systems
ECE	1.	M.Tech- Systems and Signal Processing
	2.	M.Tech- Digital Electronics and Communication Systems
	3.	M.Tech- Electronics & Communications Engineering
	4.	M.Tech- Communication Systems
	5.	M.Tech- Communication Engineering & Signal Processing
	6.	M.Tech- Microwave and Communication Engineering
	7.	M.Tech- Telematics
	8.	M.Tech- Digital Systems & Computer Electronics
	9.	M.Tech- Embedded System
	10.	M.Tech- VLSI
	11.	M.Tech- VLSI Design
	12.	M.Tech- VLSI System Design
	13.	M.Tech- Embedded System & VLSI Design
	14.	M.Tech- VLSI & Embedded System
	15.	M.Tech- VLSI Design & Embedded Systems
	16.	M.Tech- Image Processing
		M.Tech- Digital Image Processing
	18.	M.Tech- Computers & Communication
		M.Tech- Computers & Communication Engineering
CSE	1.	M.Tech- Computer Science & Engineering
	2.	M.Tech- Computer Science
	3.	M.Tech- Computer Science & Technology
	4.	M.Tech- Computer Networks
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	5.	M.Tech- Computer Networks & Information Security
	6.	M.Tech- Information Technology
	7.	M.Tech- Software Engineering
	8.	M.Tech- Neural Networks
Others	M.Tech- Chemical Engineering	
	2.	M.Tech- Biotechnology
	3.	M.Tech- Nano Technology
	4.	M.Tech- Remote Sensing
	5.	M.Tech- Food Processing
	6.	M.Tech- Avionics

### 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.

- 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.
- 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.
- 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.
- 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. Tech. 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. Tech. 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.

### 8.0 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.
- 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	Punishment
	conduct	
1 (a)	If the candidate:  Possesses or keeps accessible in	Expulsion from the examination hall and
1. (a)	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.	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 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.	Uses objectionable, abusive or offensive	Cancellation of the performance in that subject.



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	language in the answer paper or in letters to the examiners or writes to the examiner requesting him to award pass marks.	
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 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.
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.
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.	The candidate is also debarred and forfeits the seat.  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

- Punishments to the candidates as per the above guidelines.
- 1. 2. Punishment for institutions: (if the squad reports that the college is also involved in encouraging malpractices)
  - A show cause notice shall be issued to the college. (i)
  - (ii) Impose a suitable fine on the college.
  - Shifting the examination centre from the college to another college for a specific period (iii) of not less than one year.





For Constituent Colleges and Affiliated Colleges of JNTUK



# 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

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

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

LET US MAKE JNTUK A RAGGING FREE UNIVERSITY



For Constituent Colleges and Affiliated Colleges of JNTUK



- 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 Cards and show them when demanded
- 7. The Principal and the Wardens may visit the Hostels and inspect the rooms any time.

Jawaharlal Nehru Technological University Kakinada

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### PHARMACEUTICAL ANALYSIS AND QUALITY CONTROL

### **I SEMESTER**

Paper 101 -	<b>Modern Analytical Techniques</b>
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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	-	Quality Control of Pharmaceuticals
Dames 202		Quality Assurance of Dharmacouticals I

Paper 203 - Quality Assurance of Pharmaceuticals – I

Paper 204 - Drug Regulatory Affairs

Paper 205 - Advanced Pharmaceutical Analysis - II - LAB
Paper 206 - Quality Control of Pharmaceuticals - 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 CONTROL

	I SEMESTER						
	Evaluation / Marks						
Paper No.	Title of the Paper	Th	eory	Practical		Total	Credits
140.		Mid Examinatio n	University End Examination	Mid Examination	University End Examination		
Paper – 101	Modern Analytical Techniques	40	60	01		100	3
Paper - 102	Research Methodologies	40	.60			100	3
Paper - 101	Advanced Pharmaceutical Analysis-I	40	60			100	3
Paper – 102	Chromatographic and Other Special Techniques	40	60			100	3
Paper - 104	Advanced Pharmaceutical Analysis-I Practical			40	60	100	2
Paper – 105	Chromatographic and Other Special Techniques Practical			40	60	100	2
Paper – 106	Seminar					100	2
	TOTAL					700	18



			II SEMEST	ER				
			Evaluatio	n / Marks				
Paper	Title of the	The	eory	Practical		Tot	Credi	
No.	Paper	Mid Examinati on	University End Examinati on	Mid Examinati on	University End Examinati on	al	ts	
Paper – 201	Advanced Pharmaceu tical Analysis-II	40	60			100	3	
Paper –202	Quality Control of Pharmaceu ticals	40	60		RI	100	3	
Paper – 203	Quality Assurance of Pharmaceu ticals-I	40	60			100	3	
Paper – 204	Drug Regulatory affairs	40	60			100	3	
Paper – 205	Advanced Pharmaceu tical Analysis-II Practical			40	60	100	2	
Paper – 206	Quality Control of Pharmaceu ticals			40	60	100	2	
Paper – 207	Seminar					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 PHARMACEUTICAL ANALYSIS AND QUALITY CONTROL

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

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. Phase Emission Spectroscopy
- ii. X-Ray Diffractometry
- iii. Optical Rotatory Diffusion
- 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.

- 1. I.P.
- 2. B.P.
- 3. U.S.P.
- 4. Remington's Pharmaceutical Sciences.
- 5. Spectroscopy B Silversterin



I-I RESEARCH METHODOLOGIES L/P/Credits (Paper common for all Specializations) --/--/3

### **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 ADVANCED PHARMACEUTICAL ANALYSIS-I L/P/Credits --/--/3

### **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) Fluoremetry, 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 lodate / bromate titrations
- h) Ceric ammonium sulphate titrations
- c) Tanus 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.
- 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.

- 1. I.P.
- 2. B.P.
- 3. U.S.P.
- 4. Remington's Pharmaceutical Sciences.
- 5. Spectroscopy b Silversterin



# I-I CHROMATOGRAPHIC AND OTHER L/P/Credits SPECIAL TECHNIQUES --/--/3

### **UNIT-I**

An advanced study of the following and their applications.

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

### **UNIT-II**

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

### **UNIT-III**

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

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



# I-I ADVANCED PHARMACEUTICAL ANALYSIS –I L / P / Credits -- / -- / 2

- 1. Use of spectrophotometer for analysis of Pharmacopoeial compounds and their formulations.
- 2. Use of fluorimeter 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.

### **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.

- 1. I.P.
- 2. B.P.
- 3. U.S.P.
- 4. Remington's Pharmaceutical Sciences.
- 5. Spectroscopy b Silversterin



# I-I CHROMATOGRAPHIC AND OTHER SPECIAL L/P/Credits TECHN1QUES LAB --/--/2

- 1. Experiments on Electrophoresis.
- 2. Experiments of Chromatography:
  - a) Ascending technique
  - b) Descending technique
  - c) Circular technique
- 3. Experiments using HPLC & GC.

### **TEXT BOOKS**

- 1. Instrumental Methods of Analysis by Scog and West.
- 2. Instrumental Mcthods of Analysis by B.K.Sharma
- 3. Instrumental methods of Analysis by Willard & Merrit.
- 4. High Performance Liquid Chromatography by P. D. Sethy.

- 1. USP
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