

2016

THE MASTER OF PHARMACY (M. PHARM.) COURSE REGULATION 2014

(BASED ON NOTIFICATION IN THE GAZETTE OF INDIA No. 362, DATED DECEMBER 11, 2014)

SCHEME AND SYLLABUS



PHARMACY COUNCIL OF INDIA

Combined Council's Building, Kotla Road,
Aiwan-E-Ghalib Marg, New Delhi-110 002.
Website : www.pci.nic.

COURSE STRUCTURE AND SYLLABUS
For
M. PHARM

MPH R 18 Regulations

(Applicable for batches admitted from 2018-2019)



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

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PHARMACY COUNCIL OF INDIA NOTIFICATION

New Delhi, the 10th December, 2014

The Master of Pharmacy (M.Pharm) Course Regulations, 2014

No. 14-136/ 2014-PCI.—In exercise of the powers conferred by Sections 10 and 18 of the Pharmacy Act, 1948 (8 of 1948), the Pharmacy Council of India, with the approval of the Central Government hereby makes the following regulations; namely—

CHAPTER –I: REGULATIONS

1. Short Title and Commencement

These regulations shall be called as “The Revised Regulations for the Master of Pharmacy (M. Pharm.) Degree Program - Credit Based Semester System (CBSS) of the Pharmacy Council of India, New Delhi”. They shall come into effect from the Academic Year 2016-17. The regulations framed are subject to modifications from time to time by the authorities of the university.

2. Minimum qualification for admission

A Pass in the following examinations

- a) B. Pharm Degree examination of an Indian university established by law in India from an institution approved by Pharmacy Council of India and has scored not less than 55 % of the maximum marks (aggregate of 4 years of B.Pharm.)
- b) Every student, selected for admission to post graduate pharmacy program in any PCI approved institution should have obtained registration with the State Pharmacy Council or should obtain the same within one month from the date of his/her admission, failing which the admission of the candidate shall be cancelled.

Note: It is mandatory to submit a migration certificate obtained from the respective university where the candidate had passed his/her qualifying degree (B.Pharm.)

3. Duration of the program

The program of study for M.Pharm. shall extend over a period of four semesters (two academic years). The curricula and syllabi for the program shall be prescribed from time to time by Pharmacy Council of India, New Delhi.

4. Medium of instruction and examinations

Medium of instruction and examination shall be in English.

5. Working days in each semester

Each semester shall consist of not less than 100 working days. The odd semesters shall be conducted from the month of June/July to November/December and the even semesters shall be conducted from the month of December/January to May/June in every calendar year.

6. Attendance and progress

A candidate is required to put in at least 80% attendance in individual courses considering theory and practical separately. The candidate shall complete the prescribed course satisfactorily to be eligible to appear for the respective examinations.

7. Program/Course credit structure

As per the philosophy of Credit Based Semester System, certain quantum of academic work viz. theory classes, practical classes, seminars, assignments, etc. are measured in terms of credits. On satisfactory completion of the courses, a candidate earns credits. The amount of credit associated with a course is dependent upon the number of hours of instruction per week in that course. Similarly the credit associated with any of the other academic, co/extra- curricular activities is dependent upon the quantum of work expected to be put in for each of these activities per week/per activity.

7.1. Credit assignment

7.1.1. Theory and Laboratory courses

Courses are broadly classified as Theory and Practical. Theory courses consist of lecture (L) and Practical (P) courses consist of hours spent in the laboratory. Credits (C) for a course is dependent on the number of hours of instruction per week in that course, and is obtained by using a multiplier of one (1) for lecture and a multiplier of half (1/2) for practical (laboratory) hours. Thus, for example, a theory course having four lectures per week throughout the semester carries a credit of 4. Similarly, a practical having four laboratory hours per week throughout semester carries a credit of 2.

The contact hours of seminars, assignments and research work shall be treated as that of practical courses for the purpose of calculating credits. i.e., the contact hours shall be multiplied by 1/2. Similarly, the contact hours of journal club, research work presentations and discussions with the supervisor shall be considered as theory course and multiplied by 1.

7.2. Minimum credit requirements

The minimum credit points required for the award of M. Pharm. degree is 95. However based on the credit points earned by the students under the head of co-curricular activities, a student shall earn a maximum of 100 credit points. These credits are divided into Theory courses, Practical, Seminars, Assignments, Research work, Discussions with the supervisor, Journal club and Co-Curricular activities over the duration of four semesters. The credits are distributed semester-wise as shown in Table 14. Courses generally progress in sequence, building competencies and their positioning indicates certain academic maturity on the part of the learners. Learners are expected to follow the semester-wise schedule of courses given in the syllabus.

8. Academic work

A regular record of attendance both in Theory, Practical, Seminar, Assignment, Journal club, Discussion with the supervisor, Research work presentation and Dissertation shall be maintained by the department / teaching staff of respective courses.

9. Course of study

The specializations in M.Pharm program is given in Table 1.

Table – 1: List of M.Pharm. Specializations and their Code

S. No.	Specialization	Code
1.	Pharmaceutics	MPH
2.	Industrial Pharmacy	MIP
3.	Pharmaceutical Chemistry	MPC
4.	Pharmaceutical Analysis	MPA
5.	Pharmaceutical Quality Assurance	MQA
6.	Pharmaceutical Regulatory Affairs	MRA
7.	Pharmaceutical Biotechnology	MPB
8.	Pharmacy Practice	MPP
9.	Pharmacology	MPL
10.	Pharmacognosy	MPG

The course of study for M.Pharm specializations shall include Semester wise Theory & Practical as given in Table – 2 to 11. The number of hours to be devoted to each theory and practical course in any semester shall not be less than that shown in Table – 2 to 11.

Table – 2: Course of study for M. Pharm. (Pharmaceutics)

Course Code	Course	Credit Hours	Credit Points	Hrs./wk	Marks
Semester I					
MPH101T	Modern Pharmaceutical Analytical Techniques	4	4	4	100
MPH102T	Drug Delivery System	4	4	4	100
MPH103T	Modern Pharmaceutics	4	4	4	100
MPH104T	Regulatory Affair	4	4	4	100
MPH105PA	Pharmaceutics Practical I	6	3	6	75
MPH105PB	Pharmaceutical Practical II	6	3	6	75
-	Seminar/Assignment	7	4	7	100
Total		35	26	35	650
Semester II					
MPH201T	Molecular Pharmaceutics (Nano Tech and Targeted DDS)	4	4	4	100
MPH202T	Advanced Biopharmaceutics & Pharmacokinetics	4	4	4	100
MPH203T	Computer Aided Drug Delivery System	4	4	4	100
MPH204T	Formulation Development of Pharmaceutical and Cosmetic Products	4	4	4	100
MPH205PA	Pharmaceutics Practical III	6	3	6	75
MPH205PB	Pharmaceutics Practical IV	6	3	6	75
-	Seminar/Assignment	7	4	7	100
Total		35	26	35	650

Table – 3: Course of study for M. Pharm. (Industrial Pharmacy)

Course Code	Course	Credit Hours	Credit Points	Hrs./wk	Marks
Semester I					
MIP101T	Modern Pharmaceutical Analytical Techniques	4	4	4	100
MIP102T	Pharmaceutical Formulation Development	4	4	4	100
MIP103T	Novel drug delivery systems	4	4	4	100
MIP104T	Intellectual Property Rights	4	4	4	100
MIP105PA	Industrial Pharmacy Practical I	6	3	6	75
MIP105PB	Industrial Pharmacy Practical II	6	3	6	75
-	Seminar/Assignment	7	4	7	100
Total		35	26	35	650
Semester II					
MIP201T	Advanced Biopharmaceutics and Pharmacokinetics	4	4	4	100
MIP202T	Scale up and Technology Transfer	4	4	4	100
MIP203T	Pharmaceutical Production Technology	4	4	4	100
MIP204T	Entrepreneurship Management	4	4	4	100
MIP205PA	Industrial Pharmacy Practical III	6	3	6	75
MIP205PB	Industrial Pharmacy Practical IV	6	3	6	75
-	Seminar/Assignment	7	4	7	100
Total		35	26	35	650

Table – 4: Course of study for M. Pharm. (Pharmaceutical Chemistry)

Course Code	Course	Credit Hours	Credit Points	Hrs./wk	Marks
Semester I					
MPC101T	Modern Pharmaceutical Analytical Techniques	4	4	4	100
MPC1012T	Advanced Organic Chemistry -I	4	4	4	100
MPC103T	Advanced Medicinal chemistry	4	4	4	100
MPC104T	Chemistry of Natural Products	4	4	4	100
MPC105PA	Pharmaceutical Chemistry Practical I	6	3	6	75
MPC105PB	Pharmaceutical Chemistry Practical II	6	3	6	75
-	Seminar/Assignment	7	4	7	100
Total		35	26	35	650
Semester II					
MPC201T	Advanced Spectral Analysis	4	4	4	100
MPC202T	Advanced Organic Chemistry -II	4	4	4	100
MPC203T	Computer Aided Drug Design	4	4	4	100
MPC204T	Pharmaceutical Process Chemistry	4	4	4	100
MPC205PA	Pharmaceutical Chemistry Practical III	6	3	6	75
MPC105PB	Pharmaceutical Chemistry Practical IV	6	3	6	75
-	Seminar/Assignment	7	4	7	100
Total		35	26	35	650

Table – 5: Course of study for M. Pharm. (Pharmaceutical Analysis)

Course Code	Course	Credit Hours	Credit Points	Hrs./wk	Marks
Semester I					
MPA101T	Modern Pharmaceutical Analytical Techniques	4	4	4	100
MPA102T	Advanced Pharmaceutical Analysis	4	4	4	100
MPA103T	Pharmaceutical Validation	4	4	4	100
MPA104T	Food Analysis	4	4	4	100
MPA105PA	Pharmaceutical Analysis Practical I	6	3	6	75
MPA105PB	Pharmaceutical Analysis Practical II	6	3	6	75
-	Seminar/Assignment	7	4	7	100
Total		35	26	35	650
Semester II					
MPA201T	Advanced Instrumental Analysis	4	4	4	100
MPA202T	Modern Bio-Analytical Techniques	4	4	4	100
MPA203T	Quality Control and Quality Assurance	4	4	4	100
MPA204T	Herbal and Cosmetic Analysis	4	4	4	100
MPA205PA	Pharmaceutical Analysis Practical III	6	3	6	75
MPA205PB	Pharmaceutical Analysis Practical IV	6	3	6	75
-	Seminar/Assignment	7	4	7	100
Total		35	26	35	650

Table – 6: Course of study for M. Pharm. (Pharmaceutical Quality Assurance)

Course Code	Course	Credit Hours	Credit Points	Hrs./wk	Marks
Semester I					
MQA101T	Modern Pharmaceutical Analytical Techniques	4	4	4	100
MQA102T	Quality Management System	4	4	4	100
MQA103T	Quality Control and Quality Assurance	4	4	4	100
MQA104T	Product Development and Technology Transfer	4	4	4	100
MQA105PA	Pharmaceutical Quality Assurance Practical I	6	3	6	75
MQA105PB	Pharmaceutical Quality Assurance Practical II	6	3	6	75
-	Seminar/Assignment	7	4	7	100
Total		35	26	35	650
Semester II					
MQA201T	Hazards and Safety Management	4	4	4	100
MQA202T	Pharmaceutical Validation	4	4	4	100
MQA203T	Audits and Regulatory Compliance	4	4	4	100
MQA204T	Pharmaceutical Manufacturing Technology	4	4	4	100
MQA205PA	Pharmaceutical Quality Assurance Practical III	6	3	6	75
MQA205PB	Pharmaceutical Quality Assurance Practical IV	6	3	6	75
-	Seminar/Assignment	7	4	7	100
Total		35	26	35	650

Table – 7: Course of study for M. Pharm. (Regulatory Affairs)

Course Code	Course	Credit Hours	Credit Points	Hrs./wk	Marks
Semester I					
MRA101T	Good Regulatory Practices	4	4	4	100
MRA102T	Documentation and Regulatory Writing	4	4	4	100
MRA103T	Clinical Research Regulations	4	4	4	100
MRA104T	Regulations and Legislation for Drugs & Cosmetics, Medical Devices, Biologicals & Herbals, and Food & Nutraceuticals In India and Intellectual Property Rights	4	4	4	100
MRA105PA	Regulatory Affairs Practical I	6	3	6	75
MRA105PB	Regulatory Affairs Practical II	6	3	6	75
	Seminar/Assignment	7	4	7	100
	Total	35	26	35	650
Semester II					
MRA201T	Regulatory Aspects of Drugs & Cosmetics	4	4	4	100
MRA202T	Regulatory Aspects of Herbal & Biologicals	4	4	4	100
MRA203T	Regulatory Aspects of Medical Devices	4	4	4	100
MRA204T	Regulatory Aspects of Food & Nutraceuticals	4	4	4	100
MRA205PA	Regulatory Affairs Practical III	6	3	6	75
MRA205PB	Regulatory Affairs Practical IV	6	3	6	75
	Seminar/Assignment	7	4	7	100
	Total	35	26	35	650

Table – 8: Course of study for M. Pharm. (Pharmaceutical Biotechnology)

Course Code	Course	Credit Hours	Credit Points	Hrs./wk	Marks
Semester I					
MPB101T	Modern Pharmaceutical Analytical Techniques	4	4	4	100
MPB102T	Microbial And Cellular Biology	4	4	4	100
MPB103T	Bioprocess Engineering and Technology	4	4	4	100
MPB104T	Advanced Pharmaceutical Biotechnology	4	4	4	100
MPB105PA	Pharmaceutical Biotechnology Practical I	6	3	6	75
MPB105PB	Pharmaceutical Biotechnology Practical II	6	3	6	75
-	Seminar/Assignment	7	4	7	100
Total		35	26	35	650
Semester II					
MPB201T	Proteins and protein Formulation	4	4	4	100
MPB202T	Immunotechnology	4	4	4	100
MPB203T	Bioinformatics and Computer Technology	4	4	4	100
MPB204T	Biological Evaluation of Drug Therapy	4	4	4	100
MPB205PA	Pharmaceutical Biotechnology Practical III	6	3	6	75
MPB205PB	Pharmaceutical Biotechnology Practical IV	6	3	6	75
-	Seminar/Assignment	7	4	7	100
Total		35	26	35	650

Table – 9: Course of study for M. Pharm. (Pharmacy Practice)

Course Code	Course	Credit Hours	Credit Points	Hrs./wk	Marks
Semester I					
MPP101T	Clinical Pharmacy Practice	4	4	4	100
MPP102T	Pharmacotherapeutics-I	4	4	4	100
MPP103T	Hospital & Community Pharmacy	4	4	4	100
MPP104T	Clinical Research	4	4	4	100
MPP105PA	Pharmacy Practice Practical I	6	3	6	75
MPP105PB	Pharmacy Practice Practical II	6	3	6	75
-	Seminar/Assignment	7	4	7	100
Total		35	26	35	650
Semester II					
MPP201T	Principles of Quality Use of Medicines	4	4	4	100
MPP102T	Pharmacotherapeutics II	4	4	4	100
MPP203T	Clinical Pharmacokinetics and Therapeutic Drug Monitoring	4	4	4	100
MPP204T	Pharmacoepidemiology & Pharmacoeconomics	4	4	4	100
MPP205PA	Pharmacy Practice Practical III	6	3	6	75
MPP205PB	Pharmacy Practice Practical IV	6	3	6	75
-	Seminar/Assignment	7	4	7	100
Total		35	26	35	650

Table – 10: Course of study for (Pharmacology)

Course Code	Course	Credit Hours	Credit Points	Hrs./wk	Marks
Semester I					
MPL101T	Modern Pharmaceutical Analytical Techniques	4	4	4	100
MPL102T	Advanced Pharmacology-I	4	4	4	100
MPL103T	Pharmacological and Toxicological Screening Methods-I	4	4	4	100
MPL104T	Cellular and Molecular Pharmacology	4	4	4	100
MPL105PA	Pharmacology Practical I	6	3	6	75
MPL105PB	Pharmacology Practical II	6	3	6	75
-	Seminar/Assignment	7	4	7	100
Total		35	26	35	650
Semester II					
MPL201T	Advanced Pharmacology II	4	4	4	100
MPL202T	Pharmacological and Toxicological Screening Methods-II	4	4	4	100
MPL203T	Principles of Drug Discovery	4	4	4	100
MPL204T	Experimental Pharmacology practical- II	4	4	4	100
MPL205PA	Pharmacology Practical III	6	3	6	75
MPL205PB	Pharmacology Practical IV	6	3	6	75
-	Seminar/Assignment	7	4	7	100
Total		35	26	35	650

Table – 11: Course of study for M. Pharm. (Pharmacognosy)

Course Code	Course	Credit Hours	Credit Points	Hrs./wk	Marks
Semester I					
MPG101T	Modern Pharmaceutical Analytical Techniques	4	4	4	100
MPG102T	Advanced Pharmacognosy-1	4	4	4	100
MPG103T	Phytochemistry	4	4	4	100
MPG104T	Industrial Pharmacognostical Technology	4	4	4	100
MPG105PA	Pharmacognosy Practical I	6	3	6	75
MPG105PB	Pharmacognosy Practical II	6	3	6	75
-	Seminar/Assignment	7	4	7	100
Total		35	26	35	650
Semester II					
MPG201T	Medicinal Plant biotechnology	4	4	4	100
MPG102T	Advanced Pharmacognosy-II	4	4	4	100
MPG203T	Indian system of medicine	4	4	4	100
MPG204T	Herbal cosmetics	4	4	4	100
MPG205PA	Pharmacognosy Practical III	6	3	6	75
MPG205PB	Pharmacognosy Practical IV	6	3	6	75
-	Seminar/Assignment	7	4	7	100
Total		35	26	35	650

Table – 12: Course of study for M. Pharm. III Semester
(Common for All Specializations)

Course Code	Course	Credit Hours	Credit Points
MRM301T	Research Methodology and Biostatistics*	4	4
-	Journal club	1	1
-	Discussion / Presentation (Proposal Presentation)	2	2
-	Research Work	28	14
Total		35	21

* Non University Exam

Table – 13: Course of study for M. Pharm. IV Semester
(Common for All Specializations)

Course Code	Course	Credit Hours	Credit Points
-	Journal Club	1	1
-	Research Work	31	16
-	Discussion/Final Presentation	3	3
Total		35	20

Table – 14: Semester wise credits distribution

Semester	Credit Points
I	26
II	26
III	21
IV	20
Co-curricular Activities (Attending Conference, Scientific Presentations and Other Scholarly Activities)	Minimum=02 Maximum=07*
Total Credit Points	Minimum=95 Maximum=100*

*Credit Points for Co-curricular Activities

Table – 15: Guidelines for Awarding Credit Points for Co-curricular Activities

Name of the Activity	Maximum Credit Points Eligible / Activity
Participation in National Level Seminar/Conference/Workshop/Symposium/ Training Programs (related to the specialization of the student)	01
Participation in international Level Seminar/Conference/Workshop/Symposium/ Training Programs (related to the specialization of the student)	02
Academic Award/Research Award from State Level/National Agencies	01
Academic Award/Research Award from International Agencies	02
Research / Review Publication in National Journals (Indexed in Scopus / Web of Science)	01
Research / Review Publication in International Journals (Indexed in Scopus / Web of Science)	02

Note: International Conference: Held outside India; International Journal: The Editorial Board Outside India

*The credit points assigned for extracurricular and or co-curricular activities shall be given by the Principals of the colleges and the same shall be submitted to the University. The criteria to acquire this credit point shall be defined by the colleges from time to time.

10. Program Committee

The M. Pharm. programme shall have a Programme Committee constituted by the Head of the Institution in consultation with all the Heads of the departments.

The composition of the Programme Committee shall be as follows:

A teacher at the cadre of Professor shall be the Chairperson; One Teacher from each M.Pharm specialization and four student representatives (two from each academic year), nominated by the Head of the institution.

Duties of the Programme Committee:

Periodically reviewing the progress of the classes.

Discussing the problems concerning curriculum, syllabus and the conduct of classes.

Discussing with the course teachers on the nature and scope of assessment for the course and the same shall be announced to the students at the beginning of respective semesters.

1. Communicating its recommendation to the Head of the Institution on academic matters.
2. The Programme Committee shall meet at least twice in a semester preferably at the end of each sessional exam and before the end semester exam.

11. Examinations/Assessments

The schemes for internal assessment and end semester examinations are given from Table–16.

11.1. End semester examinations

The End Semester Examinations for each theory and practical course through semesters I to IV shall be conducted by the respective university except for the subject with asterix symbol (*) for which examinations shall be conducted by the subject experts at college level and the marks/grades shall be submitted to the university.

Tables – 16: Schemes for internal assessments and end semester (Pharmaceutics- MPH)

Course Code	Course	Internal Assessment				End Semester Exams		Total Marks
		Continues Mode	Sessional Exams		Total	Marks	Duration	
			Marks	Duration				
SEMESTER I								
MPH101T	Modern Pharmaceutical Analytical Techniques	10	15	1Hr	25	75	3Hr	100
MPH102T	Drug Delivery Systems	10	15	1Hr	25	75	3Hr	100
MPH103T	Modern Pharmaceutics	10	15	1Hr	25	75	3Hr	100
MPH104T	Regulatory Affairs	10	15	1Hr	25	75	3Hr	100
MPH105PA	Pharmaceutics Practical I	10	15	3Hr	25	50	3Hr	75
MPH105PB	Pharmaceutics Practical II	10	15	3Hr	25	50	3Hr	75
-	Seminar/Assignment	-	-	-	-	-	-	100
Total								650
SEMESTER II								
MPH201T	Molecular Pharmaceutics (Nano Tech and Targeted DDS)	10	15	1Hr	25	75	3Hr	100
MPH202T	Advanced Biopharmaceutics & Pharmacokinetics	10	15	1Hr	25	75	3Hr	100
MPH203T	Computer Aided Drug Delivery System	10	15	1Hr	25	75	3Hr	100
MPH204T	Formulation Development of Pharmaceutical and Cosmetic Products	10	15	1Hr	25	75	3Hr	100
MPH205PA	Pharmaceutics Practical I	10	15	3Hr	25	50	3Hr	75
MPH205PB	Pharmaceutics Practical I	10	15	3Hr	25	50	3Hr	75
-	Seminar/Assignment	-	-	-	-	-	-	100
Total								650

Tables – 17: Schemes for internal assessments and end semester (Industrial Pharmacy- MIP)

Course Code	Course	Internal Assessment				End Semester Exams		Total Marks
		Continues Mode	Sessional Exams		Total	Marks	Duration	
			Marks	Duration				
SEMESTER I								
MIP101T	Modern Pharmaceutical Analytical Techniques	10	15	1Hr	25	75	3Hr	100
MIP102T	Pharmaceutical Formulation Development	10	15	1Hr	25	75	3Hr	100
MIP103T	Novel Drug Delivery Systems	10	15	1Hr	25	75	3Hr	100
MIP104T	Intellectual Property rights	10	15	1Hr	25	75	3Hr	100
MIP105PA	Industrial Pharmacy Practical I	10	15	3Hr	25	50	3Hr	75
MIP105PB	Industrial Pharmacy Practical II	10	15	3Hr	25	50	3Hr	75
-	Seminar/Assignment	-	-	-	-	-	-	100
Total								650
SEMESTER II								
MIP201T	Advanced Biopharmaceutics and Pharmacokinetics	10	15	1Hr	25	75	3Hr	100
MIP202T	Scale up and Technology Transfer	10	15	1Hr	25	75	3Hr	100
MIP203T	Pharmaceutical Production Technology	10	15	1Hr	25	75	3Hr	100
MIP204T	Entrepreneurship Management	10	15	1Hr	25	75	3Hr	100
MIP205PA	Industrial Pharmacy Practical III	10	15	3Hr	25	50	3Hr	75
MIP205PB	Industrial Pharmacy Practical IV	10	15	3Hr	25	50	3Hr	75
-	Seminar/Assignment	-	-	-	-	-	-	100
Total								650

Tables – 18: Schemes for internal assessments and end semester (Pharmaceutical Chemistry-MPC)

Course Code	Course	Internal Assessment				End Semester Exams		Total Marks
		Continues Mode	Sessional Exams		Total	Marks	Duration	
			Marks	Duration				
SEMESTER I								
MPC101T	Modern Pharmaceutical Analytical Techniques	10	15	1Hr	25	75	3Hr	100
MPC102T	Advanced Organic Chemistry – I	10	15	1Hr	25	75	3Hr	100
MPC103T	Advanced Medicinal Chemistry	10	15	1Hr	25	75	3Hr	100
MPC104T	Chemistry of Natural Products	10	15	1Hr	25	75	3Hr	100
MPC105PA	Pharmaceutical chemistry Practical I	10	15	3Hr	25	50	3Hr	75
MPC105PB	Pharmaceutical chemistry Practical II	10	15	3Hr	25	50	3Hr	75
	Seminar/Assignment	-	-	-	-	-	-	100
Total								650
SEMESTER II								
MPC201T	Advanced Spectral Analysis	10	15	1Hr	25	75	3Hr	100
MPC202T	Advanced Organic Chemistry II	10	15	1Hr	25	75	3Hr	100
MPC203T	Computer Aided Drug Design	10	15	1Hr	25	75	3Hr	100
MPC204T	Pharmaceutical Process Chemistry	10	15	1Hr	25	75	3Hr	100
MPC205PA	Pharmaceutical chemistry Practical III	10	15	3Hr	25	50	3Hr	75
MPC205PB	Pharmaceutical chemistry Practical IV	10	15	3Hr	25	50	3Hr	75
	Seminar/Assignment	-	-	-	-	-	-	100
Total								650

Tables – 19: Schemes for internal assessments and end semester (Pharmaceutical Analysis-MPA)

Course Code	Course	Internal Assessment				End Semester Exams		Total Marks
		Continues Mode	Sessional Exams		Total	Marks	Duration	
			Marks	Duration				
SEMESTER I								
MPA101T	Modern Pharmaceutical Analytical Techniques	10	15	1Hr	25	75	3Hr	100
MPA102T	Advanced Pharmaceutical Analysis	10	15	1Hr	25	75	3Hr	100
MPA103T	Pharmaceutical Validation	10	15	1Hr	25	75	3Hr	100
MPA104T	Food Analysis	10	15	1Hr	25	75	3Hr	100
MPA105PA	Pharmaceutical Analysis Practical I	10	15	3Hr	25	50	3Hr	75
MPA105PB	Pharmaceutical Analysis Practical II	10	15	3Hr	25	50	3Hr	75
	Seminar/Assignment	-	-	-	-	-	-	100
Total								650
SEMESTER II								
MPA201T	Advanced Instrumental Analysis	10	15	1Hr	25	75	3Hr	100
MPA202T	Modern Bio-Analytical Techniques	10	15	1Hr	25	75	3Hr	100
MPA203T	Quality Control and Quality Assurance	10	15	1Hr	25	75	3Hr	100
MPA204T	Herbal and Cosmetic Analysis	10	15	1Hr	25	75	3Hr	100
MPA205PA	Pharmaceutical Analysis Practical III	10	15	3Hr	25	50	3Hr	75
MPA205PB	Pharmaceutical Analysis Practical IV	10	15	3Hr	25	50	3Hr	75
	Seminar/Assignment	-	-	-	-	-	-	100
Total								650

Tables – 20: Schemes for internal assessments and end semester (Pharmaceutical Quality Assurance- MQA)

Course Code	Course	Internal Assessment				End Semester Exams		Total Marks
		Continues Mode	Sessional Exams		Total	Marks	Duration	
			Marks	Duration				
SEMESTER I								
MQA101T	Modern Pharmaceutical Analytical Techniques	10	15	1Hr	25	75	3Hr	100
MQA102T	Quality Management System	10	15	1Hr	25	75	3Hr	100
MQA103T	Quality Control and Quality Assurance	10	15	1Hr	25	75	3Hr	100
MQA104T	Product Development and Technology Transfer	10	15	1Hr	25	75	3Hr	100
MQA105PA	Pharmaceutical Quality Assurance Practical I	10	15	3Hr	25	50	3Hr	75
MQA105PB	Pharmaceutical Quality Assurance Practical II	10	15	3Hr	25	50	3Hr	75
	Seminar/Assignment	-	-	-	-	-	-	100
Total								650
SEMESTER II								
MQA201T	Hazards and Safety Management	10	15	1Hr	25	75	3Hr	100
MQA202T	Pharmaceutical Validation	10	15	1Hr	25	75	3Hr	100
MQA203T	Audits and Regulatory Compliance	10	15	1Hr	25	75	3Hr	100
MQA204T	Pharmaceutical Manufacturing Technology	10	15	1Hr	25	75	3Hr	100
MQA205PA	Pharmaceutical Quality Assurance Practical III	10	15	3Hr	25	50	3Hr	75
MQA205PB	Pharmaceutical Quality Assurance Practical IV	10	15	3Hr	25	50	3Hr	75
	Seminar/Assignment	-	-	-	-	-	-	100
Total								650

Tables – 21: Schemes for internal assessments and end semester (Pharmaceutical Regulatory Affairs- MRA)

Course Code	Course	Internal Assessment				End Semester Exams		Total Marks
		Continues Mode	Sessional Exams		Total	Marks	Duration	
			Marks	Duration				
SEMESTER I								
MRA101T	Good Regulatory Practices	10	15	1Hr	25	75	3Hr	100
MRA102T	Documentation and Regulatory Writing	10	15	1Hr	25	75	3Hr	100
MRA103T	Clinical Research Regulations	10	15	1Hr	25	75	3Hr	100
MRA104T	Regulations and Legislations for Drugs & Cosmetics, Medical Devices, Biologicals & Herbals, and Food & Nutraceuticals in India and Intellectual Property Rights	10	15	1Hr	25	75	3Hr	100
MRA105PA	Regulatory Affairs Practicals I	10	15	3Hr	25	50	3Hr	75
MRA105PB	Regulatory Affairs Practicals II	10	15	3Hr	25	50	3Hr	75
	Seminar/Assignment	-	-	-	-	-	-	100
Total								650
SEMESTER II								
MRA201T	Regulatory Aspects of Drugs and Cosmetics	10	15	1Hr	25	75	3Hr	100
MRA202T	Regulatory Aspects of Herbal & Biologicals	10	15	1Hr	25	75	3Hr	100
MRA203T	Regulatory Aspects of Medical Devices	10	15	1Hr	25	75	3Hr	100
MRA204T	Regulatory Aspects of Food Neutraceuticals	10	15	1Hr	25	75	3Hr	100
MRA205PA	Regulatory Affairs Practicals III	10	15	3Hr	25	50	3Hr	75
MRA205PB	Regulatory Affairs Practicals IV	10	15	3Hr	25	50	3Hr	75
	Seminar/Assignment	-	-	-	-	-	-	100
Total								650

Tables – 22: Schemes for internal assessments and end semester (Pharmaceutical Biotechnology-MPB)

Course Code	Course	Internal Assessment				End Semester Exams		Total Marks
		Continues Mode	Sessional Exams		Total	Marks	Duration	
			Marks	Duration				
SEMESTER I								
MPB101T	Modern Pharmaceutical Analytical Techniques	10	15	1Hr	25	75	3Hr	100
MPB102T	Microbial and Cellular Biology	10	15	1Hr	25	75	3Hr	100
MPB103T	Bioprocess Engineering and Technology	10	15	1Hr	25	75	3Hr	100
MPB104T	Advanced Pharmaceutical Biotechnology	10	15	1Hr	25	75	3Hr	100
MPB105PA	Pharmaceutical Biotechnology Practical I	10	15	3Hr	25	50	3Hr	75
MPB105PB	Pharmaceutical Biotechnology Practical II	10	15	3Hr	25	50	3Hr	75
	Seminar/Assignment	-	-	-	-	-	-	100
Total								650
SEMESTER II								
MPB201T	Proteins and Protein Formulation	10	15	1Hr	25	75	3Hr	100
MPB202T	Immunotechnology	10	15	1Hr	25	75	3Hr	100
MPB203T	Bioinformatics and Computer Technology	10	15	1Hr	25	75	3Hr	100
MPB204T	Biological Evaluation of Drug Therapy	10	15	1Hr	25	75	3Hr	100
MPB205PA	Pharmaceutical Biotechnology Practical III	10	15	3Hr	25	50	3Hr	75
MPB205PB	Pharmaceutical Biotechnology Practical IV	10	15	3Hr	25	50	3Hr	75
	Seminar/Assignment	-	-	-	-	-	-	100
Total								650

Tables – 23: Schemes for internal assessments and end semester (Pharmacy Practice- MPP)

Course Code	Course	Internal Assessment				End Semester Exams		Total Marks
		Continues Mode	Sessional Exams		Total	Marks	Duration	
			Marks	Duration				
SEMESTER I								
MPP101T	Clinical Pharmacy Practice	10	15	1Hr	25	75	3Hr	100
MPP102T	Pharmacotherapeutics - I	10	15	1Hr	25	75	3Hr	100
MPP103T	Hospital & Community Pharmacy	10	15	1Hr	25	75	3Hr	100
MPP104T	Clinical Research	10	15	1Hr	25	75	3Hr	100
MPP105PA	Pharmacy Practice Practical I	10	15	3Hr	25	50	3Hr	75
MPP105PB	Pharmacy Practice Practical II	10	15	3Hr	25	50	3Hr	75
	Seminar/Assignment	-	-	-	-	-	-	100
Total								650
SEMESTER II								
MPP201T	Principles of Quality Use of Medicines	10	15	1Hr	25	75	3Hr	100
MPP202T	Pharmacotherapeutics - II	10	15	1Hr	25	75	3Hr	100
MPP203T	Clinical Pharmacokinetics and Therapeutic Drug Monitoring	10	15	1Hr	25	75	3Hr	100
MPP204T	Pharmacoepidemiology & Pharmacoeconomics	10	15	1Hr	25	75	3Hr	100
MPP205PA	Pharmacy Practice Practical III	10	15	3Hr	25	50	3Hr	75
MPP205PB	Pharmacy Practice Practical IV	10	15	3Hr	25	50	3Hr	75
	Seminar/Assignment	-	-	-	-	-	-	100
Total								650

Tables – 24: Schemes for internal assessments and end semester (Pharmacology- MPL)

Course Code	Course	Internal Assessment				End Semester Exams		Total Marks
		Continues Mode	Sessional Exams		Total	Marks	Duration	
			Marks	Duration				
SEMESTER I								
MPL101T	Modern Pharmaceutical Analytical Techniques	10	15	1Hr	25	75	3Hr	100
MPL102T	Advanced Pharmacology - I	10	15	1Hr	25	75	3Hr	100
MPL103T	Pharmacology and Toxicology Screening methods- I	10	15	1Hr	25	75	3Hr	100
MPL104T	Cellular and Molecular Pharmacology	10	15	1Hr	25	75	3Hr	100
MPL105PA	Pharmacology Practical I	10	15	3Hr	25	50	3Hr	75
MPL105PB	Pharmacology Practical II	10	15	3Hr	25	50	3Hr	75
	Seminar/Assignment	-	-	-	-	-	-	100
Total								650
SEMESTER II								
MPL201T	Advanced Pharmacology - II	10	15	1Hr	25	75	3Hr	100
MPL202T	Pharmacology and Toxicology Screening methods- II	10	15	1Hr	25	75	3Hr	100
MPL203T	Principles of Drug Discovery	10	15	1Hr	25	75	3Hr	100
MPL204T	Experimental Pharmacology Practical II	10	15	1Hr	25	75	3Hr	100
MPL205PA	Pharmacology Practical III	10	15	3Hr	25	50	3Hr	75
MPL205PB	Pharmacology Practical IV	10	15	3Hr	25	50	3Hr	75
	Seminar/Assignment	-	-	-	-	-	-	100
Total								650

Tables – 25: Schemes for internal assessments and end semester (Pharmacognosy- MPG)

Course Code	Course	Internal Assessment				End Semester Exams		Total Marks
		Continues Mode	Sessional Exams		Total	Marks	Duration	
			Marks	Duration				
SEMESTER I								
MPG101T	Modern Pharmaceutical Analytical Techniques	10	15	1Hr	25	75	3Hr	100
MPG102T	Advanced Pharmacognosy - I	10	15	1Hr	25	75	3Hr	100
MPG103T	Phytochemistry	10	15	1Hr	25	75	3Hr	100
MPG104T	Industrial Pharmacognostical Technology	10	15	1Hr	25	75	3Hr	100
MPG105PA	Pharmacognosy Practical I	10	15	3Hr	25	50	3Hr	75
MPG105PB	Pharmacognosy Practical II	10	15	3Hr	25	50	3Hr	75
	Seminar/Assignment	-	-	-	-	-	-	100
Total								650
SEMESTER II								
MPG201T	Medicinal Plant Biotechnology	10	15	1Hr	25	75	3Hr	100
MPG202T	Advanced Pharmacognosy - II	10	15	1Hr	25	75	3Hr	100
MPG203T	Indian system of Medicine	10	15	1Hr	25	75	3Hr	100
MPG204T	Herbal Cosmetics	10	15	1Hr	25	75	3Hr	100
MPG205PA	Pharmacognosy Practical III	10	15	3Hr	25	50	3Hr	75
MPG205PB	Pharmacognosy Practical IV	10	15	3Hr	25	50	3Hr	75
	Seminar/Assignment	-	-	-	-	-	-	100
Total								650

Tables – 26: Schemes for internal assessments and end semester examinations (Semester III& IV)

Course Code	Course	Internal Assessment				End Semester Exams		Total Marks
		Continuous Mode	Sessional Exams		Total	Marks	Duration	
			Marks	Duration				
SEMESTER III								
MRM301T	Research Methodology and Biostatistics*	10	15	1 Hr	25	75	3 Hrs	100
-	Journal club	-	-	-	25	-	-	25
-	Discussion / Presentation (Proposal Presentation)	-	-	-	50	-	-	50
-	Research work*	-	-	-	-	350	1 Hr	350
Total								525
SEMESTER IV								
-	Journal club	-	-	-	25	-	-	25
-	Discussion / Presentation (Proposal Presentation)	-	-	-	75	-	-	75
-	Research work and Colloquium	-	-	-	-	400	1 Hr	400
Total								500

*Non University Examination

11.2. Internal assessment: Continuous mode

The marks allocated for Continuous mode of Internal Assessment shall be awarded as per the scheme given below.

Table – 27: Scheme for awarding internal assessment: Continuous mode

Theory	
Criteria	Maximum Marks
Attendance (Refer Table – 28)	8
Student – Teacher interaction	2
Total	10
Practical	
Attendance (Refer Table – 28)	10
Based on Practical Records, Regular viva voce, etc.	10
Total	20

Table – 28: Guidelines for the allotment of marks for attendance

Percentage of Attendance	Theory	Practical
95 – 100	8	10
90 – 94	6	7.5
85 – 89	4	5
80 – 84	2	2.5
Less than 80	0	0

11.2.1. Sessional Exams

Two sessional exams shall be conducted for each theory / practical course as per the schedule fixed by the college(s). The scheme of question paper for theory and practical sessional examinations is given in the table. The average marks of two sessional exams shall be computed for internal assessment as per the requirements given in tables.

12. Promotion and award of grades

A student shall be declared PASS and eligible for getting grade in a course of M.Pharm.programme if he/she secures at least 50% marks in that particular course including internal assessment.

13. Carry forward of marks

In case a student fails to secure the minimum 50% in any Theory or Practical course as specified in 12, then he/she shall reappear for the end semester examination of that course. However his/her marks of the Internal Assessment shall be carried over and he/she shall be entitled for grade obtained by him/her on passing.

14. Improvement of internal assessment

A student shall have the opportunity to improve his/her performance only once in the sessional exam component of the internal assessment. The re-conduct of the sessional exam shall be completed before the commencement of next end semester theory examinations.

15. Reexamination of end semester examinations

Reexamination of end semester examination shall be conducted as per the schedule given in table 29. The exact dates of examinations shall be notified from time to time.

Table – 29: Tentative schedule of end semester examinations

Semester	For Regular Candidates	For Failed Candidates
I and III	November / December	May / June
II and IV	May / June	November / December

16. Allowed to keep terms (ATKT):

No student shall be admitted to any examination unless he/she fulfills the norms given in 6. ATKT rules are applicable as follows:

A student shall be eligible to carry forward all the courses of I and II semesters till the III semester examinations. However, he/she shall not be eligible to attend the courses of IV semester until all the courses of I, II and III semesters are successfully completed.

A student shall be eligible to get his/her CGPA upon successful completion of the courses of I to IV semesters within the stipulated time period as per the norms.

Note: Grade AB should be considered as failed and treated as one head for deciding ATKT. Such rules are also applicable for those students who fail to register for examination(s) of any course in any semester.

17. Grading of performances

17.1. Letter grades and grade points allocations:

Based on the performances, each student shall be awarded a final letter grade at the end of the semester for each course. The letter grades and their corresponding grade points are given in Table – 30.

Table–30: Letter grades and grade points equivalent to Percentage of marks and performances.

Percentage of Marks Obtained	Letter Grade	Grade Point	Performance
90.00 – 100	O	10	Outstanding
80.00 – 89.99	A	9	Excellent
70.00 – 79.99	B	8	Good
60.00 – 69.99	C	7	Fair
50.00 – 59.99	D	6	Average
Less than 50	F	0	Fail
Absent	AB	0	Fail

A learner who remains absent for any end semester examination shall be assigned a letter grade of AB and a corresponding grade point of zero. He/she should reappear for the said evaluation/examination in due course.

18. The Semester grade point average (SGPA)

The performance of a student in a semester is indicated by a number called ‘Semester Grade Point Average’ (SGPA). The SGPA is the weighted average of the grade points obtained in all the courses by the student during the semester. For example, if a student takes five courses (Theory/Practical) in a semester with credits C₁, C₂, C₃ and C₄ and the student’s grade points in these courses are G₁, G₂, G₃ and G₄, respectively, and then students’ SGPA is equal to:

$$\text{SGPA} = \frac{C_1G_1 + C_2G_2 + C_3G_3 + C_4G_4}{C_1 + C_2 + C_3 + C_4}$$

The SGPA is calculated to two decimal points. It should be noted that, the SGPA for any semester shall take into consideration the F and ABS grade awarded in that semester. For example if a learner has a F or ABS grade in course 4, the SGPA shall then be computed as:

$$\text{SGPA} = \frac{C_1G_1 + C_2G_2 + C_3G_3 + C_4^* \text{ ZERO}}{C_1 + C_2 + C_3 + C_4}$$

19. Cumulative Grade Point Average (CGPA)

The CGPA is calculated with the SGPA of all the IV semesters to two decimal points and is indicated in final grade report card/final transcript showing the grades of all IV semesters and their courses. The CGPA shall reflect the failed status in case of F grade(s), till the course(s) is/are passed. When the course(s) is/are passed by obtaining a pass grade on subsequent examination(s) the CGPA shall only reflect the new grade and not the fail grades earned earlier. The CGPA is calculated as:

$$\text{CGPA} = \frac{C_1S_1 + C_2S_2 + C_3S_3 + C_4S_4}{C_1 + C_2 + C_3 + C_4}$$

where C_1, C_2, C_3, \dots is the total number of credits for semester I, II, III, \dots and S_1, S_2, S_3, \dots is the SGPA of semester I, II, III, \dots .

20. Declaration of class

The class shall be awarded on the basis of CGPA as follows:

First Class with Distinction = CGPA of 7.50 and above

First Class = CGPA of 6.00 to 7.49

Second Class = CGPA of 5.00 to 5.99

21. Project work

All the students shall undertake a project under the supervision of a teacher in Semester III to IV and submit a report. 4 copies of the project report shall be submitted (typed & bound copy not less than 75 pages).

The internal and external examiner appointed by the University shall evaluate the project at the time of the Practical examinations of other semester(s). The projects shall be evaluated as per the criteria given below.

Evaluation of Dissertation Book:

Objective(s) of the work done	50 Marks
Methodology adopted	150 Marks
Results and Discussions	250 Marks
Conclusions and Outcomes	50 Marks
Total	500 Marks

Evaluation of Presentation:

Presentation of work	100 Marks
Communications skills	50 Marks
Question and answer skills	100 Marks
Total	250 Marks

22. Award of Ranks

Ranks and Medals shall be awarded on the basis of final CGPA. However, candidates who fail in one or more courses during the M.Pharm program shall not be eligible for award of ranks. Moreover, the candidates should have completed the M. Pharm program in minimum prescribed number of years, (two years) for the award of Ranks.

23. Award of degree

Candidates who fulfill the requirements mentioned above shall be eligible for award of degree during the ensuing convocation.

24. Duration for completion of the program of study

The duration for the completion of the program shall be fixed as double the actual duration of the program and the students have to pass within the said period, otherwise they have to get fresh Registration.

25. Revaluation I Retotaling of answer papers

There is no provision for revaluation of the answer papers in any examination. However, the candidates can apply for retotaling by paying prescribed fee.

26. Re-admission after break of study

Candidate who seeks re-admission to the program after break of study has to get the approval from the university by paying a condonation fee.



Directorate of Academic Planning
JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY KAKINADA

Kakinada-533003, Andhra Pradesh, INDIA

(Established by AP Government Act No. 30 of 2008)

Lr. No. JNTUK/DAP/AC/I Year/M. Tech/M.Pharmacy/2023-24

Date: 25-09-2023

Dr. K. VENKATA REDDY,

M.Tech, Ph.D.,

Director i/c, Academic Planning

To

All the Principals of Affiliated Colleges,
JNTUK, Kakinada.

Academic Calendar of
I Year M.Tech/M.Pharmacy for the Academic Year 2023-24

I SEMESTER			
Description	From	To	Weeks
Commencement of Class Work	04.10.2023		
I Unit of Instruction	04.10.2023	02.12.2023	9W
I Mid Examinations	27.11.2023	02.12.2023	
II Unit of Instructions	04.12.2023	27.01.2024	8W
II Mid Examinations	22.01.2024	27.01.2024	
Preparation & Practicals	29.01.2024	03.02.2024	1W
End Examinations	05.02.2024	17.02.2024	2W
Commencement of II Semester Class Work	19.02.2024		
II SEMESTER			
I Unit of Instructions	19.02.2024	20.04.2024	9W
I Mid Examinations	15.04.2024	20.04.2024	
II Unit of Instructions	22.04.2024	04.05.2024	2W
Summer Holidays	06.05.2024	01.06.2024	4W
II Unit of Instructions	03.06.2024	13.07.2024	6W
II Mid Examinations	08.07.2024	13.07.2024	
Preparation & Practicals	15.07.2024	20.07.2024	1W
End Examinations	22.07.2024	03.08.2024	2W

Dr. K. Venkata Reddy
Director i/c

Academic Planning
Director,
Academic Planning
JNTUK Kakinada

Copy to the Secretary to the Hon'ble Vice Chancellor, JNTUK
Copy to Rector, JNTUK
Copy to Registrar, JNTUK
Copy to Director Academic Audit, JNTUK
Copy to Director of Evaluation, JNTUK
Copy to Controller of Examinations, JNTUK



Vijaya Institute of
PRINCIPAL

VIJAYA INSTITUTE OF
PHARMACEUTICAL SCIENCES FOR WOMEN
ENIKEPADU, VIJAYAWADA - 521 109

**INSTITUTIONAL EXAMINATION
COMMITTEE**

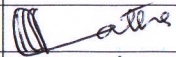
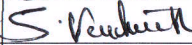

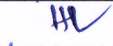
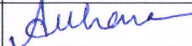
VIJAYA INSTITUTE OF PHARMACEUTICAL SCIENCES FOR WOMEN
Enikepadu, Vijayawada – 521108

Date: 26-07-2023

OFFICE ORDER

INSTITUTIONAL EXAMINATION COMMITTEE

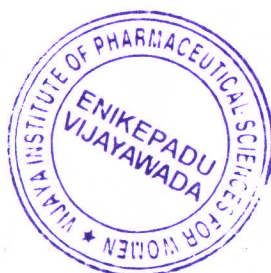
The Institutional Examination Committee has been constructed for smooth conduct of sessional / end semester examinations for the academic year 2023 – 2024 for the period of 06-09-2023 to 06-08-2024. Following staff members are appointed as Internal Squad Committee.


S.NO	NAME	DESIGNATION	POSITION	SIGNATURE
1	Dr. K. Padmalatha	Principal	President	
2	Mr. S. Venkateswara Rao	Professor	Chairman	
3	Mr. A. Jayarami Reddy	Assoc. Professor	Member	
4	Mrs. A.V.S. Hima bindu	Assoc. Professor	Member	
5	Mrs. S. Archana	Assoc. Professor	Member	

Functions and Responsibilities:

1. Ensure proper dissemination of information with regard to examination among all the stakeholders viz. students / faculty / non – teaching staff / university authorities etc.
2. Receive and submission of exam notification / schedule from JNTUK web portal.
3. To ensure proper organization of in semester assessments / sessional / end semester examination in the college.
4. Ensure proper communication with JNTUK with regards to examination and fulfillment of universities circulars.
5. Appoint alternative external senior supervisor / chairman / internal examiners/ external examiners / for conduct of end semester theory / practical examination with permission of university authorities.
6. Record and issue the answer books and other exam related stationary to the invigilators / internal examiners 30 minutes before start the exam.
7. Download and print the appropriate number of question papers at least 20 minutes before the commencement of the exam and maintaining absolute confidentiality.
8. Resolve students / faculty/ university grievances with regards to examination.
9. Uploading internal theory / practical examination marks on JNTUK web portal.
10. Maintain records with regards to conduct of examination and results.

Copy to: 1. Establishment File
2. Concerned Faculty member




Dr. K. Padmalatha
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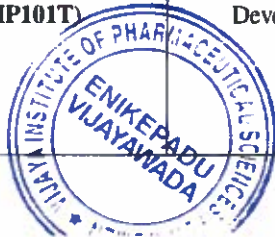
UNIVERSITY EXAMINATION CENTER, KAKINADA

M. PHARMACY I SEMESTER (PCI REGULATION) I MID EXAMINATIONS, NOVEMBER - 2023

TIME TABLE

TIME: 10:00 AM TO 12:00 NOON

BRANCH & SPECIALIZATION	28-11-2023 (Tuesday)	29-11-2023 (Wednesday)	30-11-2023 (Thursday)	01-12-2023 (Friday)
PHARMACEUTICAL CHEMISTRY (02)	Modern Pharmaceutical Analytical Techniques (MPC101T)	Advanced Organic Chemistry -I (MPC102T)	Advanced Medicinal Chemistry (MPC103T)	Chemistry of Natural Products (MPC104T)
PHARMACEUTICS (03)	Modern Pharmaceutical Analytical Techniques (MPH101T)	Drug Delivery Systems (MPH102T)	Modern Pharmaceutics (MPH103T)	Regulatory Affairs (MPH104T)
PHARMACOLOGY (06)	Modern Pharmaceutical Analytical Techniques (MPL101T)	Advanced Pharmacology-I (MPL102T)	Pharmacological and Toxicological Screening Methods-I (MPL103T)	Cellular and Molecular Pharmacology (MPL104T)
PHARMACOGNOSY (07)	Modern Pharmaceutical Analytical Techniques (MPG101T)	Advanced Pharmacognosy-I (MPG102T)	Phytochemistry (MPG103T)	Industrial Pharmacognostical Technology (MPG104T)
PHARMACY PRACTICE (08)	Clinical Pharmacy Practice (MPP101T)	Pharmacotherapeutics-I (MPP102T)	Hospital & Community Pharmacy (MPP103T)	Clinical Research (MPP104T)
INDUSTRIAL PHARMACY (09)	Modern Pharmaceutical Analytical Techniques (MIP101T)	Pharmaceutical Formulation Development (MIP102T)	Novel drug delivery systems (MIP103T)	Intellectual Property Rights (MIP104T)



Principal
PRINCIPAL

VIJAYA INSTITUTE OF
PHARMACEUTICAL SCIENCES FOR WOMEN
ENIKEPADU, VIJAYAWADA - 521 108

VIJAYA INSTITUTE OF PHARMACEUTICAL SCIENCES FOR WOMEN
 ENIKEPADU, VIJAYAWADA - 521 106

BRANCH & SPECIALIZATION	28-11-2023 (Tuesday)	29-11-2023 (Wednesday)	30-11-2023 (Thursday)	01-12-2023 (Friday)
✓ PHARMACEUTICAL REGULATORY AFFAIRS (17)	Good Regulatory Practices (MRA101T)	Documentation and Regulatory Writing (MRA102T)	Clinical Research Regulations (MRA103T)	Regulations and Legislation for Drugs & Cosmetics, Medical Devices, Biologicals & Herbals, and Food & Nutraceuticals In India and Intellectual Property Rights (MRA104T)
PHARMACY QUALITY ASSURANCE (15)	Modern Pharmaceutical Analytical Techniques (MQA101T)	Quality Management System (MQA102T)	Quality Control and Quality Assurance (MQA103T)	Product Development and Technology Transfer (MQA104T)
✓ PHARMACEUTICAL ANALYSIS (16)	Modern Pharmaceutical Analytical Techniques (MPA101T)	Advanced Pharmaceutical Analysis (MPA102T)	Pharmaceutical Validation (MPA103T)	Food Analysis (MPA104T)

NOTE: (i) If Government declares holiday on any of the above dates, the examinations will be conducted as usual
 (ii) Any omissions or clashes in this Time Table may please be informed to the Controller of Examinations immediately.
 (iii) The Principals are requested to inform the University, if any other substitute subjects that are not included in the above time table immediately.

Date: 10.11.2023



S. Venkatesh
 15/11/2023

Controller of Examinations (PG)










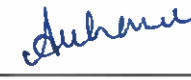

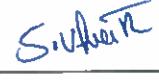
PRINCIPAL
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I M. Pharm / I Sem II Mid Exam Time Table

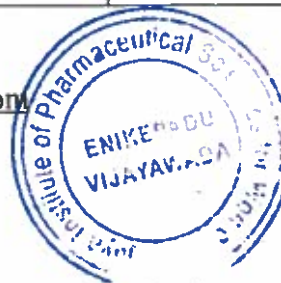
Date: 01.04.2023


Date	Pharmaceutics	Staff Sign	Ph. Analysis	Staff Sign	Ph. Cology	Staff Sign	Reg. Affairs	Staff Sign
		Staff Name		Staff Name		Staff Name		Staff Name
03.04.2023 (Monday)	Modern Pharmaceutical Analytical Techniques (MPH101T)		Modern Pharmaceutical Analytical Techniques (MPA101T)		Modern Pharmaceutical Analytical Techniques (MPL101T)		Good Regulatory Practices (MRA101T)	
		Mrs. S. Archana		Mrs. S. Archana		Mrs. S. Archana		Mrs. B. Hemalatha
04.04.2023 (Tuesday)	Drug Delivery System (MPH102T)		Advanced Pharmaceutical Analysis (MPA102T)		Advanced Pharmacology – I (MPL102T)		Documentation and Regulatory Writing (MRA102T)	
		Dr. S. Venkateswara Rao		Mrs. Ch. Anupama Swathi		Mrs. A. Bhavana		Mrs. B. Hemalatha
10.04.2023 (Monday)	Modern Pharmaceutics (MPH103T)		Pharmaceutical Validation (MPA103T)		Pharmacological & Toxicological Screening Methods-I (MPL103T)		Clinical Research Regulations (MRA103T)	
		Mrs. B. Hemalatha		Mrs. Ch. Anupama Swathi		Mrs. N. K. S. Neeraja		Mrs. A. Bhavana
11.04.2023 (Tuesday)	Regulatory Affair		Food Analysis (MPA104T)		Cellular & Molecular Pharmacology (MPL104T)		Regulation & Legislation for Drugs&Cosmetics, Medical Devices,Biological &Herbals,&Food& NIIAIPR	
		Mrs. B. Hemalatha		Mrs. S. Archana		Dr. S. Sundar		Dr. S. Venkateswara Rao

Timings: II Mid: 02.00 PM to 04.00 PM

Note: Send the Question Papers to Exam Section Mail ID: Vipwexams@gmail.com


Exams in charge
(Mr. S. Venkateswara Rao)
PHARMACEUTICAL SCIENCES FOR WOMEN
ENIKEPADU, VIJAYAWADA




Principal
(Dr. K. Padmalatha)
VIJAYA INSTITUTE OF
PHARMACEUTICAL SCIENCES FOR WOMEN
ENIKEPADU, VIJAYAWADA
PIN - 521 108

INTERNAL SQUAD COMMITTEE

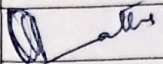
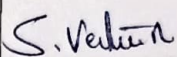
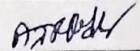

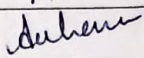
VIJAYA INSTITUTE OF PHARMACEUTICAL SCIENCES FOR WOMEN
Enikepadu, Vijayawada – 521108

Date: 25-07-2023

OFFICE ORDER

INTERNAL SQUAD COMMITTEE

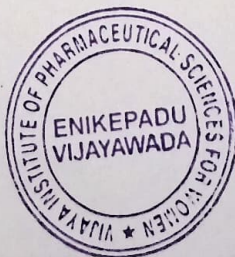
The Internal Squad Committee has been constructed for smooth conduct of sessional / end semester examinations for the academic year 2023 – 2024 for the period of 06-09-2023 to 06-08-2024. Following staff members are appointed as Internal Squad Committee.

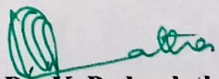
S.NO	NAME	DESIGNATION	POSITION	SIGNATURE
1	Dr. K. Padmalatha	Principal	President	
2	Mr. S. Venkateswara Rao	Assoc. Professor	Chairman	
3	Mr. A. Jayarami Reddy	Asst. Professor	Member	
4	Mrs. A.V.S. Hima bindu	Asst. Professor	Member	
5	Mrs. S. Archana	Asst. Professor	Member	

Responsibilities:

1. Strict checking of unfair means is sole responsibility of members of committee.
2. Before the start of examination, the committee members should check every student.
3. Care should be taken by committee members, that the students should not carry mobile phones, calculator or any sort of electronic material inside the examination hall.
4. Check whether students are carrying hall tickets by committee members to maintain environment of examination. Any issue related to the unfair means should immediately report to the principal or college examination officer.

Copy to: 1. Establishment File
2. Concerned Faculty member





Dr. K. Padmalatha
PRINCIPAL

**VIJAYA INSTITUTE OF
PHARMACEUTICAL SCIENCES FOR WOMEN**
ENIKEPADU, VIJAYAWADA-521 108.

II MID

ATTENDANCE SHEET FOR II MID EXAMINATIONS

COURSE: M. Pharm

Date of Examination: 24.01.24

Time: 02.00 PM TO 04.00 PM

Room No: 01

Subject Name: Pharmacological & Toxicological Screening Methods - I

Subject Code: MPL103T

No. of Students Present: 04

No. of Students Absent: 0

S.No.	Hall Ticket No.	Name of the Student	Answer Booklet Serial No.	Signature of the Student
1	237NIS0601	NALLURU JOTHIKA	7N230001	N.Jothika.
2	237NIS0602	VEEREPALLI SWETHA	7N230002	V.Swetha.
3	237NIS0603	SEETHAMRAJU SARASWATHI SAMANVITHA	7N230003	S.S.Samanvitha.
4	237NIS0604	JONNA KALYANI	7N230004	J.kalyani

Signature of the Invigilator: 

Name of the Invigilator: D. Lakshmi kumari

Designation: Assistant professor


Signature of the Principal

II MID

ATTENDANCE SHEET FOR II MID EXAMINATIONS

COURSE: M. Pharm

Date of Examination: 24.01.24

Time: 02.00 PM TO 04.00 PM

Room No: 01

Subject Name: Pharmaceutical Validation

Subject Code: MPA103T

No. of Students Present: 03

No. of Students Absent: 0

S.No.	Hall Ticket No.	Name of the Student	Answer Booklet Serial No.	Signature of the Student
1	237N1S1601	BEJJAM JAHNAVI	7N230001	B. Jahnavi
2	237N1S1602	NIMMAKURI SAMYUKTHA	7N230002	N. Samyuktha
3	237N1S1603	SARAKANAM PRAVALLIKA	7N230003	S. pravallika

Signature of the Invigilator: 

Name of the Invigilator: D. Lakshmi kumar

Designation: Assistant professor


Signature of the Principal

II MID

ATTENDANCE SHEET FOR II MID EXAMINATIONS

COURSE: M. Pharm

Date of Examination: 24.01.24

Time: 02.00 PM TO 04.00 PM

Room No: 01

Subject Name: Clinical Research Regulations

Subject Code: MRA103T

No. of Students Present: 14

No. of Students Absent: 0

S.No.	Hall Ticket No.	Name of the Student	Answer Booklet Serial No.	Signature of the Student
1	237NIS1701	TOMMANDRU PRATHYUSHA	7N230001	T. Prathyusha
2	237NIS1702	KARIMELLA NAGA RAMYA KRISHNA	7N230002	K.N. Ramya Krishna
3	237NIS1703	MALLEMPATI HAREESHA	7N230003	M. Hareesha
4	237NIS1704	KOTA LAKSHMI AMRUTHA	7N230004	K. Lakshmi Amrutha
5	237NIS1705	LAKSHMI DEVI SIGATAPU	7N230005	S. Lakshmi Devi
6	237NIS1706	NALLURI DHARANI	7N230006	Dharani. N
7	237NIS1707	ALA JYOTHI SRAVANI	7N230007	A. Jyothi Sravan
8	237NIS1708	CHALLAGALLA PRAVALLIKA	7N230008	CH. PRAVALLIKA
9	237NIS1709	YERREDDU SRAVANTHI	7N230009	Y. Sravanthi
10	237NIS1710	GOTTUMUKKALA SRI LAKSHMI	7N230010	G. Sri Lakshmi
11	237NIS1711	GARIMELLA PREETHI CHOWDARY	7N230011	G. Preethi Chowdary
12	237NIS1712	CHEREDDY GEETHA SRI	7N230012	C. Geetha Sri
13	237NIS1713	SRAVANTHI THOMMANDRU	7N230013	T. Sravanthi
14	237NIS1714	VINUTHNA RALLAPALLI	7N230014	B. Vinuthna

Signature of the Invigilator: 

Name of the Invigilator: D. Lakshmi Kumar

Designation: Assistant professor


Signature of the Principal

II MID

ATTENDANCE SHEET FOR II MID EXAMINATIONS

COURSE: M. Pharm

Date of Examination: 24.01.24

Time: 02.00 PM TO 04.00 PM

Room No: 01

Subject Name: Modern Pharmaceutics

Subject Code: MPH103T

No. of Students Present: **15**

No. of Students Absent: **0**

S.No.	Hall Ticket No.	Name of the Student	Answer Booklet Serial No.	Signature of the Student
1	237NIS0301	PEDASANAGANTI APARNA	7N230001	P. Aparna
2	237NIS0302	REBBA SOWMYA	7N230002	R. Sowmya
3	237NIS0303	PURAMSETTI SAI GEETHIKA	7N230003	P. Saigeethika
4	237NIS0304	KANCHARLA SRAVYA	7N230004	K. Sravya
5	237NIS0305	MOTUKURU DHARANI	7N230005	M. Dharami
6	237NIS0306	RAVULAPALLI THIRISALINI	7N230006	R. Thirisalini
7	237NIS0307	MUDDAMSETTY HARSHA	7N230007	M. Harsha
8	237NIS0308	TIPPASANI PAVANI	7N230008	T. Pavani
9	237NIS0309	BUDALA MOUNIKA	7N230009	B. Mounika
10	237NIS0310	GOLLAPUDI UDAYA SREE	7N230010	G. Udaya Sree
11	237NIS0311	SEELAM DEEPTHI	7N230011	S. Deepthi
12	237NIS0312	YENNABATTENA MOUNIKA	7N230012	Y. Mounika
13	237NIS0313	VALLURU SAI DURGA	7N230013	V. Sai Durga
14	237NIS0314	DARAM UDAYA PUJITHA	7N230014	D. Udaya Pujitha
15	237NIS0315	DOGUPARTHI NAGA PRATHYUSHA	7N230015	D. Naga Prathyusha

Signature of the Invigilator: 

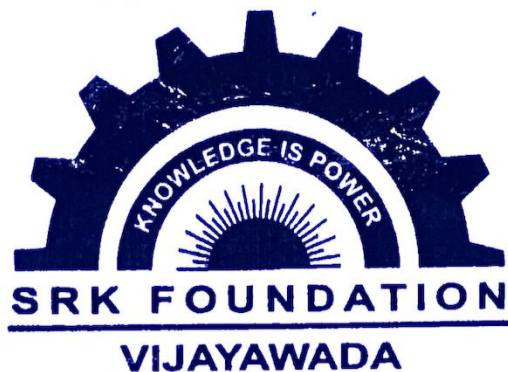
Name of the Invigilator: **D. Lakshmi Kumari**

Designation: **Asst. Prof**


Signature of the Principal

Model of Evaluated Mid Exam
Answer Script

SRK FOUNDATION'S
**VIJAYA INSTITUTE OF
PHARMACEUTICAL SCIENCES FOR WOMEN**
ENIKEPADU, VIJAYAWADA



2023 - 2024

SESSIONAL BOOK

Name : Sravanthi. Thammamdu.
Class : M. Pharmacy Regulatory Affairs (1st year 1st sem)
Roll No. : 23 TNIS17103
Subject : Good Regulatory Practices (MRA102T).

Internal	Objective	Subjective	Assignment	Total	Staff Sign	Student Sign
I		29		29		T. Sravanthi
II		28		28		T. Sravanthi

Final Average : 29

Staff Sign

HOD Sign

SECTION - 1

29/30

Sp

Good Laboratory Practices:-

- Good Laboratory Practices is a quality system concerned with the organizational process and the conditions under which non-clinical health and environmental safety studies are planned, performed, monitored, recorded, archived and reported.
- Regulations come under title 21 of the code of federal Regulations as Part 58 (21CFR58).
- GLP is an FDA regulation.
- A formal regulation that was created by the FDA in 1978.
- In early 70's poor laboratory practices were done.
- Discovered fraudulent activities and poor laboratory practices.
- Examples were like equipments not calibrated, incorrect accounts, inadequate test systems, replacement of animals and fabrication of test results.
- Hence creation of GLP.

Objectives:-

- GLP makes sure that the data submitted are a true reflection of the results obtained from the studies.
- Certifies that the every step of analysis is valid or not.
- Assures the quality and integrity of data submitted to FDA in support of the safety of regulated products.
- Makes sure that the data is traceable.
- Promotes international acceptance tests.

REPORT - A · General Provisions:

This part describes GLP for conducting non-clinical laboratory studies that support a research or marketing permits for products regulated by FDA like, food and colour additives, animal food additives, human and animal drugs, Medical devices, biological products.

Compliance with GLP is intended to assure the quality and integrity of safety data.

Test article:- Any product mentioned by FDA meant for testing.

Control article:- Any product mentioned by FDA that is administered to the test system in the course of a non-clinical laboratory study for the purpose of establishing a basis for comparison with test article.

Test system:- Means any product whereof to which the test or control article is administered or added for the study.

Test facilities:- Means a person or many establishment who actually conducts a non-clinical study. The facility includes operational units used for the study.

Sponsor:- a person who initiates and supports, by provision of financial or other resources, a non-clinical study. They submit the report of the non-clinical study to the FDA, in support of research or marketing report.

Study director:- means the individual responsible for the overall conduct of a non-clinical laboratory study.

Raw data:- Is result of original observations and activities of the study and are necessary for the reconstruction and evaluation of the report.

SUBPART B — Organisation & Personnel

- * Personnel: Each individual engaged in a non-clinical laboratory study shall have education, training and experience so that can perform the assigned functions.
- * Testing Facility Management:— For each non-clinical laboratory study, TFM shall, designate study director before the study.
 - Assure that a quality assurance unit is present.
 - Assure that test and control articles are of appropriate identity, strength, purity and stability.
- * Study director:— For each study, a scientist or professional of appropriate education, training and experience appointed as study director, who has the responsibility of - technical conduct of study, interpretation, analysis, documentation and reporting of results.
- * Quality Assurance Unit:— Responsible for monitoring each study to assure that facilities, equipments, personnel, methods, practices, records comply with the regulations.

SUBPART C — Facilities

- Animal care facilities.
- Animal supply facilities.
- Facilities for handling test and control articles.
- Laboratory operation areas.
- Specimen and data storage facilities.
- Each testing facilities shall be suitable size and construction to facilitate proper conduct of non-clinical laboratory study.
- There should be a degree of separation which prevents any adverse effects on the study.

SUPPORT D - Equipment:

- Equipments used in generation, measurement or assessment of data and equipment used for facility environmental control.
- Shall have adequate design and capacity to facility function according to the protocol.
- Shall be suitably located for operation, inspection, cleaning and maintenance.

SUPPORT - E — Testing Facilities Operation

* Standard Operating Procedures:-

- SOP's shall be established for animal room preparation, Animal care; Receipt, Identification, storage, handling, etc.
- Each laboratory shall have laboratory manuals and SOP's of the laboratory procedures being performed.
- A historical file of SOP's and all its revisions including the dates of the revisions shall be maintained.
- A testing facility shall have SOP's that the management is satisfied are adequate to ensure facility and integrity of data generated in the study.

* Reagents and Solutions:- All reagents and solutions in the laboratory areas shall be labelled to indicate identity, titre or concentration, storage requirements and expiration date.

* Animal care:- SOP's for housing, feeding, handling, and care of animals.

- All newly received animals from outside sources shall be isolated and their health status shall be evaluated with acceptable veterinary medical practice.

SUBPART - F - Test and Control Articles.

- Test and control Article characterization.
- Test and Control Article Handling.
- Mixture of Articles with Carriers.

SUBPART - G - Protocol And Conduct Of Non-clinical Study.

* Protocol of the study:- Each study shall have an approved written protocol that indicates the objective and methods to conduct the study.

- It contains a descriptive title and purpose of study.
- Identification of article by name, chemical abstract number, code number.

* Conduct of the study:-

- Conduct of study should be in accordance with the protocol.
- Test systems shall be monitored about conformity with the protocol.

SUBPART - H - Records And Reports.

- Reporting of non-clinical laboratory study results.
- Storage and retrieval of records and data.
- Retention of records.

SUBPART - I - Disqualification of Testing Facility.

- Purpose
- Grounds for Disqualification.
- Notice of and opportunity for hearing on proposed disqualification.
- Final order on disqualification.
- Actions upon disqualification.
- Public disclosure of information regarding disqualification.
- Alternative or additional actions on disqualification.
- Suspension or termination of testing facility by sponsor.

SECTION - F:

Importance of Standard Operating Procedures:-

SOP's shall be established for:

- Animal room preparation.

- Animal care.

- Receipt, identification, storage, handling, mixing and method of sampling of test and control articles.

- Test system operations.

- Laboratory test.

- Handling of animals found moribund or dead during the study.

- Necropsy of animals or postmortem examination of animals.

- Collection and identification of specimens.

- Histopathology.

- Data handling, storage, and retrieval.

- Maintenance and calibration of equipment.

- Transfer, proper placement and identification of animals.

F.1) Each Laboratory:-

- shall have laboratory manuals and SOP's of the laboratory procedures being performed.

- Published literature can also be used as supplement of the SOP's.

a) A historical file of SOP's and all its revisions including the dates of the revisions shall be maintained.

b) A testing facility shall have SOP's that the management is satisfied are adequate to ensure quality and integrity of data generated in the study.

- All deviations - from SOP's shall be authorized by the study director and documented
- Significant changes in SOP's should properly authorized in writing.
- To perform a job properly.
- To ensure that production operations are performed consistently.
- To ensure that processes continue uninterrupted and are completed on a prescribed schedule.
- To ensure that no failures occur in manufacturing and other processes for which the SOP was written.
- To ensure that approved procedures are followed in compliance with company and government regulations.
- To serve as a training document for teaching users about the process.
- To serve as a checklist for co-workers who observe job performance to reinforce proper performance.
- To serve as a checklist for auditors.
- To serve as an historical record for the change over.
- To serve as an explanation in review of accident investigations.
- Should be written by individuals knowledgeable with the activity and subject-matter experts.
- By an individual who performs the tasks routinely or someone who is directly responsible for the performance.

Good Laboratory Practices:-

- GLP is an FDA regulation.
- GLP is a formal regulation that was created by the FDA in 1978.

Good Laboratory Practice is a quality system concerned with the organisational process and the conditions under which non-clinical health and environmental safety studies are planned, performed, monitored, recorded, archived and reported.

- In the early 70's FDA became aware of cases of poor laboratory practice all over the United States.
- They discovered a lot of fraudulent activities and a lot of poor lab practices.
- Examples of some of these poor lab practices found were:-
 1. Equipment not been calibrated to standard form, therefore giving wrong measurements.
 2. Incorrect/inaccurate accounts of the actual lab study.
 3. Inadequate test systems.

Purpose of GLP's:-

- GLP is to certify that every step of the analysis is valid or not.
- Assure the quality & integrity of data submitted to FDA in support of the safety of regulated products.
- GLP's have heavy emphasis on data recording, record & specimen retention.

Scope of GTP:

- Principles of GTP apply to all non-clinical health and environmental safety studies required by regulations for the purpose of registering or licensing -

* Pharmaceuticals, Pesticides, food and food additives, Cosmetic products, Veterinary drug products and similar products, Industrial chemicals.

Organisation & Personnel - Management's Responsibilities:-

- Ensure sufficient number of qualified personnel, appropriate facilities, equipment, and materials.
- Ensure the maintenance of a record of the qualification, training, experience.
- Proper training of personnel to assigned functions
- Job description for each professional and technical individual
- To establish and follow SOP.
- Quality assurance program with designated personnel.
- Approval of protocols & the study plan including amendments
- Ensure QA personnel and study personnel are updated with study plans & SOP.
- Ensure QA personnel and study personnel are updated with study plans & SOP.
- Ensure the follow up of SOPs periodically and take appropriate corrective action.
- Archiving Raw data, supporting materials and final report
- Areas available for the diagnosis, treatment and control of diseases.

Software Evaluation Checklist of GALP:-

Unsatisfactory-1	Needs Improvement-2	Good-3	Exemplary-4
Information is inaccurate or outdated.	- Information is not always accurate; complete or current.	Information is accurate and most is complete & correct.	Information is accurate, complete & correct.
Facts do not come from reliable sources & sources are not identified.	Facts from questionable sources	Facts usually come from reliable sources	Facts come from clear identification
Little or no overall context for information.	Content is ^{not} related to larger context	Content is related to larger context	Content & context are consistently with the theme.
Little or no overall context for information Purpose is unclear	Content lacks sense of purpose or central theme.	General purpose is identified.	All information relates to the stated purpose and learning goals
National and/or state standards are not accessible within the product and there are no apparent links to be the learning activities.	National and/or state standards are not located within the product but some relation to standards is apparent.	National and/or state standards are sometimes available and may be linked to lessons.	National & state standards are accessible within the product and may be easily linked to lessons.

Unsatisfactory - 1 :-

- Graphics are absent, poorly placed, or fail to assist learning.
- Background and text are not compatible and text is difficult to read.
- Gratuitous animation with no relation to learning goals.
- Layout is confusing.

Needs Improvement - 2 :-

- Graphics minimally support learning.
- Background and text are frequently incompatible and text is often difficult to read.
- Graphics are not always consistent or appropriate.
- Colors are used somewhat ineffectively.

Good - 3 :-

- Graphics are intended to assist learning.
- Background and text are usually pleasing, compatible and legible.
- Most graphics are consistent and appropriate in design.

Exemplary - 4 :-

- Graphics are well designed and selected to enhance learning.
- Background and text are pleasing, compatible and easy to read.
- Animation always complements learning.

Quality Audit

Quality audit is defined as a systematic and independent examination to determine whether activities and related results comply with planned arrangements and whether these arrangements are implemented effectively and are suitable to achieve objectives.

Reasons for Quality auditing:-

In order to internal:-

- Determine the level of compliance.
- Build confidence (hopefully) in GMP and the QA system.
- Build interdepartmental trust, understanding, and communication (if the audit is done properly and tactfully).
- Determine measures necessary to improve; e.g.'s:
Premises, equipments, environment.
- Operations, actions, procedures.
- Personnel / training.
- Provide a stimulus for improvement.
- Recommend corrective action.
- Monitor improvement.
- Tells you the health of a quality system.
- Achieve better allocation of resources.
- Able to avoid potentially big problem.

Ties to external:

- Establish and monitor capability of supplier or contractor to deliver goods and services that are fit for purpose (and on time, and in the quantity required).
- Build mutual confidence.
- Promote understanding and communication between the parties involved (both sides can learn).
- And in general, as listed for "internal."

Scope and Objectives:-

- To ensure quality of the product.
- To assess effectiveness of QA system.
- It permits timely correction of problems.
- It established high degree of confidence.

Auditee's Responsibility:-

- Inform relevant employees about the objectives and scope of the audit.
- Appoint responsible members of staff to meet with members of the audit team.
- Provide all resources needed for the audit team in order to ensure an effective and efficient audit process.
- Co-operate with the auditors to permit the audit objectives to be achieved.
- Determine and initiate corrective actions based on the audit report.

Section - D

(24/30) N7

Stability Principles according to GDP.

- Principles of GDP are the methods or procedures that adhere to the principles of good documentation, making them a nested component of these principles.
- For instance, a good practice would be using a standardized template for all meeting minutes to ensure consistency.

16 Principles of GDP:-

1. Accuracy:-

- Every piece of information recorded should be correct and precise.
- This ensures that the document serves as a reliable source of information for decision making, process improvement, and regulatory compliance.

2. Clarity and Completeness:-

- Documentation should be clear (unambiguous and not confusing), understandable, and complete.
- Use plain language, provide context, and include all relevant details.

3. Time lines:-

- Documentation should be recorded without delays and kept up to date.

- Outdated records can block other tasks and lead decision-makers with outdated information, decreasing the performance of specific employees and the whole company.
- Finally, this can end up in missed opportunities, damaged reputation, and even legal jeopardy.

4. Traceability and audit trails:-

- Maintain document traceability by recording all the changes to your documents within a full lifecycle. To ensure this is possible, your technical writers should structure content to make information traceable and modifications easily tracked.
- This allows quality managers, auditors, and inspectors to conduct audit trails & make assessments of documentation integrity.

5. Consistency and Standardization:-

- Establishment and use consistent formats, templates and terminology across documentation whenever possible.
- You should be also add learning of relevant documentation standards to educational programs for personnel.

6. Legibility:-

- Carefully choose fonts of their sizes, leadings, the contrast ratio between the background and text layouts and other design parameters which can enhance the physical readability of your documents.

7. Authorization approval and accountability:-

Only authorized individuals should approve documents and be accountable for the accuracy of generating and storing documentation.

8. Version control and change management:-

- By keeping your documents up to date and maintaining a history of all their changes, you can implement efficient version control & change management processes.
- This will help quality assurance professionals ensure that the documents in the company meet regulatory requirements.

9. Protection, security and restricted access:-

Documents containing sensitive information must be reliably protected from unauthorized access, alteration & destruction.

10. Retention and Destruction:-

Hold your documents only for the required period and destroy them securely when no longer needed.

11. Training and awareness:-

Train and relevant personnel on practices of good documentation and ensure they are aware of why compliance is important.

- Design responsibility staff members as training professionals to control the coverage of good documentation practices and data integrity requirements in training programmes.

12. Validation:-

- Validate any systems your company uses for generating or storing documentation for data integrity.
- Instead of relying on a vendor's promises, entrust your information technology or information security personnel to conduct compliance validation at least once before starting work with a new system.

13. Review Cycles:-

- Regularly review your documents to stop and correct errors, verify their relevance and ensure compliance.

14. Risk based approach:-

- Prioritize your GDP based on risk to focus your resources where they can make the most impact.
- Risks with highest probability of occurrence and with largest potential impact get highest priority.

15. Root cause analysis:-

- By conducting root cause analysis, you can identify and address the underlying causes of documentation problems rather than just treating of symptoms.

Section - B

16. Continuous Improvement :-

- Identify and implement improvements to your documentation process over time to maintain ongoing compliance.

Section - B

Quality by Design :- [QBD]

Definition:-

- Systematic approach to development that begins with pre-defined objectives and emphasize product and process understanding and process control, based on sound science and quality risk management.

Concepts of QBD:-

- Quality by Design is a concept first outlined by Joseph M. Juran in various publications.
- He supposed that quality could be planned.
- The concept of QBD was mentioned in ICH guidelines as primarily mentioned that "Quality is not tested for the product it should be built in the product".
- For that "Zero defect theory" was also proposed.
- ICH Q9 guideline will explain the Quality of product.

Objectives of QBD:

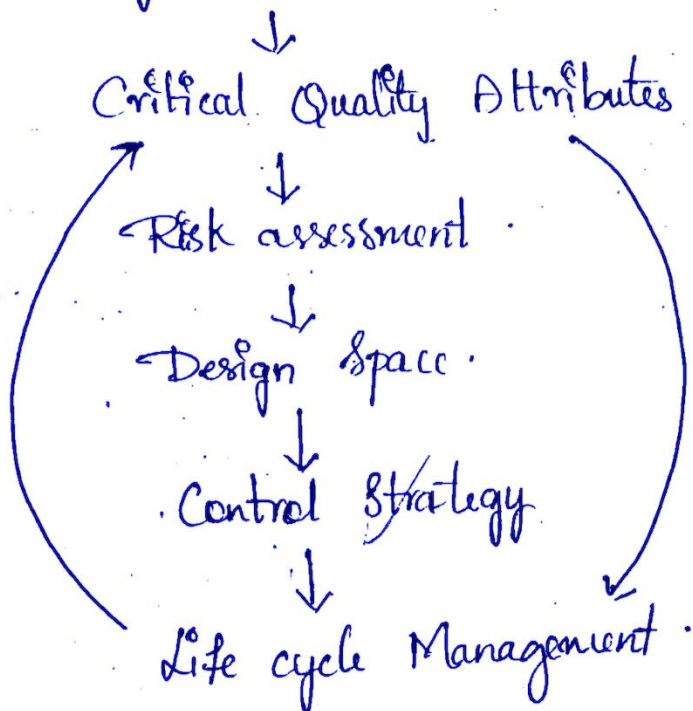
- The main objective of QBD is to ensure the quality products, for that product & process characteristics important to desired performance must be resulting from a combination of prior knowledge & new estimation during development.

ICH primarily ICH Q8 through Q11

- Q8 - Pharmaceutical development.
- Q9 - Quality Risk management.
- Q10 - Pharmaceutical Quality System.
- Q11 - Development and Manufacture of Drug Substances.

Key Aspects of QBD:-

Target Product Profile.



Out of Specifications [OOS]

Definition:-

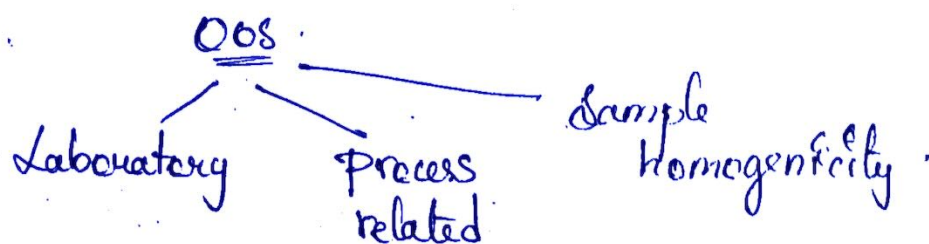
- If the analytical result (s) of a batch or material is/are falling outside of the established specification ranges is considered as out of specification.

Guidelines for OOS:-

- MHRA guideline.
- CDER guideline.
- PCIIIS guideline.

* The OOS may be observed during the analysis of.

- Stability study.
- Finished API.
- Intermediates.
- In-Process.
- Raw materials.
- Packing materials.
- Out of specifications found due to the following reasons but not limited to.



Procedures of OOS investigations:-

As per MHRA [EUGMP]

- Phase I Investigation: Primary & extended lab investigation.
- Phase II Investigation: Manufacturing Investigation.
- Phase III Investigation: Extended manufacturing, Re-sampling and re-analysis.

As per CDER (US FDA)

- Phase I Investigation: Primary & extended lab investigation.
- Phase II Investigation: Manufacturing investigation and re-sampling and re-analysis.

Re-testing:- The analysis of original sample at the time of phase
- I laboratory investigation.

Re-sampling:- The original batch is sampled by QA second time after QA lead authorization for re-analysis.

Re-analysis:-

The analysis of re-sampled material for the verification of results, if manufacturing investigation does not have root cause.

- All these activity for investigation [corrective actions] preventive actions should be recorded and reviewed and archived.

Six Sigma Concept:

Six-sigma is a disciplined, data-driven approach and methodology for eliminating defects in any process - from manufacturing to transactional and from product to service.

- Six sigma is a set of techniques, and tools for process improvement.
- The word sigma is a statistical term that measures how far a given process deviates from perfection.

Six Sigma

- Add value to organisation & stakeholder
- Technical solutions.
 - * Reduce variation.
 - * Analyze data
 - * Activity, Program & Process design.
 - * Statistical tools.
- Project Delivery & Evaluation.
- Ownership
 - * Involved.
 - * Employees.
 - * Green/Black Belt.
 - * Training/Mentoring.

- Performance & Reliability
- Organizational Direction.
 - * Identify opportunities.
 - * Voice of stakeholder & Organization.
 - * Sponsors & Champions.
 - * Team Guideliness.

Features of Six Sigma

- A six sigma process is one in which 99.999% of the products manufactured are statistically expected to be free of defects.
- Six sigma's aim to eliminate waste and inefficiency, thereby increasing customer satisfaction by delivering what the customer is expecting.
- Six sigma is a data driven methodology, and requires accurate data collection for the processes being analyzed.
- Six sigma is about putting results on financial statements.
- Six sigma follows a structured methodology, and has defined roles for the participants.
- Six sigma is a business-driven, multi-dimensional structured approach for:
 - * Improving processes.
 - * Lowering Defects.
 - * Reducing process variability.
 - * Reducing costs.
 - * Increased profits.

Principles of GDP:

- According to GDP standards, national legislation must ensure that the pharmaceutical product distribution process is under strict control.
- The distributor should be a legitimate, registered business, as they will be in charge of ensuring that the pharmaceuticals or medical devices are delivered safely.
- To import or export pharmaceutical products, one must only be authorized or work for a company that has the proper authorization.
- Distributors can only carry out a distribution of a pharmaceutical product in nations where it is legal to do so.
- Only third parties with the necessary licenses may be delegated duties and responsibilities.
- Distributors can only provide their services to businesses that are authorized to produce or interact with pharmaceutical products.
- Pharmaceutical products should only be supplied by distributors or their agents to individuals or organizations who are legally permitted to purchase them.
- The sub-contractor must have the required authorization to use the person or organization.

- Only registered and approved mail-order pharmacies or other authorized companies should be able to sell medical products online.

Quality System:-

- Document a Quality Policy with defined procedures and that are periodically reviewed.
- Appoint designated personnel to ensure a quality system with specified authority.
- Authorize procurement and release procedures
- Inspect, audit, and attain a certificate of compliance with ISO quality standards.
- Periodically evaluate your risks.

Documentation:

- Maintain appropriate documentation with written/electronic records of all activities.
- Ensure that documents are completed, approved and signed by the authorized personnel.
- Prepare documents that are sufficiently comprehensive, with clear and specific language.
- Keep records for the definite amounts of time specified by national law.

Analytical Method Validation:-

Types:-

- Identification tests.
- Quantitative tests for impurities content.
- Limit tests for the control of impurities.
- Quantitative tests of the active moiety in samples of drug.
- Substance or drug product or other selected component(s) in the drug product.

Definition:-

Validation of an analytical method is the process by which it is established, by laboratory studies, that the performance characteristics of the method meet the requirements for the intended analytical applications.

Typical Analytical performance characteristics used in method

Validation:

- Specificity.
- Linearity.
- Range.
- Accuracy.
- Precision.
- Detection Limit.
- Quantitation Limit.
- Robustness.

System Suitability Testing.

Revalidation May be necessary in the following circumstances

- changes in the synthesis of the drug substance.
- changes in the composition of the finished product.
- changes in the analytical procedure;

The degree of revalidation required depends on the nature of the changes. Certain other changes may require validation as well.

Considerations Prior to Method Validation:

- Suitability of Instrument.
- Suitability of Materials.
- Suitability of Analyst.
- Suitability of Documentation.

Submission to the competent:

- Rationale.
- Proposed Analytical Procedure.
- Data Elements.

**Mid exam marks scored by students
are entered in the Mother register**

I M. PHARM I SEM PHARMACEUTICS
Sub: MODERN ANALYTICAL TECHNIQUES (MPH101T)

95

S.No	Register No	Name of the student	Theory		Average of two	Remarks
			I Mid	II mid		
1	237N150301	Pedasanagati Aparna	24	21	23	
2	237N150302	Rebba Sowmya	24	21	23	
3	237N150303	Puramsetti Sai Geethika	25	21	23	
4	237N150304	Kancharla Sravya	25	23	24	
5	237N150305	Motukuru Dharani	21	21	21	
6	237N150306	Ravalapalli Thirsalini	25	23	24	
7	237N150307	Muddamsetty Harsha	25	21	23	
8	237N150308	Tippasani Pavani	25	23	24	
9	237N150309	Budala Mounika	23	22	23	
10	237N150310	Gollapudi Udaya Sree	25	23	24	
11	237N150311	Seelam Deepthi	25	24	25	
12	237N150312	Yennabattana Manika	24	22	23	
13	237N150313	Nalluru Sai durga	25	24	25	
14	237N150314	Naram Udaya prajitha	24	22	24	
15	237N150315	Daguparthi Naga prathyusha	25	23	24	

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 ENIKEPADU, VIJAYAWADA - 521 108

Sub: DRUG DELIVERY SYSTEM (M PH027)

96

S.No	Register No	Name of the Student	Theory		Average of two	Remarks
			Imid	Imid		
1.	237NISO301	Pedasanaganti Aparna	23	23	23	
2.	237NISO302	Rebba Sowmya	25	25	25	
3.	237NISO303	Paramsetti Sai Geethika	25	25	25	
4.	237NISO304	Kancharla Pravya	25	25	25	
5.	237NISO305	Motukuru Dharani	24	25	25	
6.	237NISO306	Ravuballi Thrisalini	25	24	25	
7.	237NISO307	Muddamsetty Harsha	24	24	24	
8.	237NISO308	Tippasani pavani	25	24	25	
9.	237NISO309	Budala Mounika	24	24	24	

10.	237NISO310	Collapudi eudaya Sree	25	25	25	
11.	237NISO311	Seelam Deepthi	25	25	25	
12.	237NISO312	Yennabattena Mounika	24	23	24	
13.	237NISO313	Valluru Sri durga	25	24	25	
14.	237NISO314	Daram eudaya priyitha	25	25	25	
15.	237NISO315	Daguparthi Naga Prathyusha	25	25	25	

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Sub: MODERN PHARMACEUTICS (MPH103T)

97

S.No	Register no	Name of the Student	Theory		Avg. of 2	Remarks
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1.	237N150301	Pedasaganti Aparna	22	20	21	
	237N150302	Rebba Sowmya	24	24	24	
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	237N150311	Seelam Deepthi	25	25	25	
	237N150312	Yennabattena Mounika	24	25	25	
	237N150313	Vallury Sai durga	23	25	24	
	237N150314	Daram udaya prajitha	24	24	24	
	237N150315	Dogiparthi Naga prathyusha	23	25	24	

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Sub: REGULATORY AFFAIRS (MPH104T)

J. 98

S.No	Register No	Name of the student	Theory		Average of two	Remarks
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1.	237N150301	Pedasanaganti Aparna	25	24	25	
2.	237N150302	Rebba Sowmya	25	25	25	
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4.	237N150304	Kancharla Sravya	25	24	25	
5.	237N150305	Motukuru Dharani	23	24	24	
6.	237N150306	Ravulapalli Thrisalini	25	24	25	
7.	237N150307	Muddamsetty Harsha	25	25	25	
8.	237N150308	Tippasani Pavani	25	25	25	
9.	237N150309	Budda Mouika	25	25	25	
10.	237N150310	Gollapudi Udaya Sree	25	25	25	
11.	237N150311	Seelam Deepthi	24	25	25	
12.	237N150312	Yennabattena Mouika	25	25	25	
13.	237N150313	Valluru Sai durga	25	25	25	
14.	237N150314	Daram Udaya pritha	25	25	25	
15.	237N150315	Doguparthi Naga Prathysa	25	25	25	

Entered by:- P. Poornima

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Date:30-03-2024

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237N1S0601	MPL101T	25	24	0	25	T
237N1S0602	MPL101T	24	23	0	24	T
237N1S0603	MPL101T	24	22	0	23	T
237N1S0604	MPL101T	24	23	0	24	T
237N1S0601	MPL102T	24	24	0	24	T
237N1S0602	MPL102T	24	24	0	24	T
237N1S0603	MPL102T	21	21	0	21	T
237N1S0604	MPL102T	22	22	0	22	T
237N1S0601	MPL103T	23	22	0	23	T
237N1S0602	MPL103T	23	22	0	23	T
237N1S0603	MPL103T	21	21	0	21	T
237N1S0604	MPL103T	21	21	0	21	T
237N1S0601	MPL104T	23	24	0	24	T
237N1S0602	MPL104T	24	24	0	24	T
237N1S0603	MPL104T	22	22	0	22	T
237N1S0604	MPL104T	20	22	0	21	T

HTNO	SUBJECT	MID_1	MID_2	SEMINAR	FINAL	SUB_TYPE
237N1S0601	MPL105PA	24	24	0	24	L
237N1S0602	MPL105PA	23	24	0	24	L
237N1S0603	MPL105PA	22	22	0	22	L
237N1S0604	MPL105PA	22	23	0	23	L
237N1S0601	MPL105PB	23	24	0	24	L
237N1S0602	MPL105PB	23	24	0	24	L
237N1S0603	MPL105PB	21	22	0	22	L
237N1S0604	MPL105PB	20	21	0	21	L
237N1S0601	MPL106S	0	0	98	98	S
237N1S0602	MPL106S	0	0	95	95	S
237N1S0603	MPL106S	0	0	95	95	S
237N1S0604	MPL106S	0	0	96	96	S
237N1S1701	MRA101T	20	22	0	21	T
237N1S1702	MRA101T	24	24	0	24	T
237N1S1703	MRA101T	24	25	0	25	T
237N1S1704	MRA101T	21	24	0	23	T
237N1S1705	MRA101T	22	22	0	22	T
237N1S1706	MRA101T	24	24	0	24	T
237N1S1707	MRA101T	21	24	0	23	T
237N1S1708	MRA101T	20	24	0	22	T
237N1S1709	MRA101T	22	25	0	24	T
237N1S1710	MRA101T	25	25	0	25	T
237N1S1711	MRA101T	23	25	0	24	T
237N1S1712	MRA101T	23	24	0	24	T
237N1S1713	MRA101T	25	24	0	25	T
237N1S1714	MRA101T	25	24	0	25	T
237N1S1701	MRA102T	23	24	0	24	T
237N1S1702	MRA102T	25	24	0	25	T
237N1S1703	MRA102T	25	25	0	25	T
237N1S1704	MRA102T	25	24	0	25	T
237N1S1705	MRA102T	24	24	0	24	T
237N1S1706	MRA102T	24	25	0	25	T
237N1S1707	MRA102T	25	25	0	25	T
237N1S1708	MRA102T	25	24	0	25	T
237N1S1709	MRA102T	24	24	0	24	T
237N1S1710	MRA102T	25	25	0	25	T
237N1S1711	MRA102T	25	25	0	25	T
237N1S1712	MRA102T	25	25	0	25	T
237N1S1713	MRA102T	25	25	0	25	T
237N1S1714	MRA102T	25	25	0	25	T
237N1S1701	MRA103T	21	22	0	22	T
237N1S1702	MRA103T	23	24	0	24	T
237N1S1703	MRA103T	24	20	0	22	T
237N1S1704	MRA103T	22	23	0	23	T
237N1S1705	MRA103T	23	23	0	23	T
237N1S1706	MRA103T	24	20	0	22	T
237N1S1707	MRA103T	23	24	0	24	T
237N1S1708	MRA103T	22	23	0	23	T
237N1S1709	MRA103T	23	24	0	24	T
237N1S1710	MRA103T	24	23	0	24	T

HTNO	SUBJECT	MID_1	MID_2	SEMINAR	FINAL	SUB_TYPE
237N1S1711	MRA103T	23	22	0	23	T
237N1S1712	MRA103T	23	24	0	24	T
237N1S1713	MRA103T	24	24	0	24	T
237N1S1714	MRA103T	24	21	0	23	T
237N1S1701	MRA104T	21	21	0	21	T
237N1S1702	MRA104T	24	22	0	23	T
237N1S1703	MRA104T	25	24	0	25	T
237N1S1704	MRA104T	24	23	0	24	T
237N1S1705	MRA104T	23	23	0	23	T
237N1S1706	MRA104T	24	24	0	24	T
237N1S1707	MRA104T	25	25	0	25	T
237N1S1708	MRA104T	24	23	0	24	T
237N1S1709	MRA104T	25	24	0	25	T
237N1S1710	MRA104T	24	24	0	24	T
237N1S1711	MRA104T	24	24	0	24	T
237N1S1712	MRA104T	25	23	0	24	T
237N1S1713	MRA104T	25	24	0	25	T
237N1S1714	MRA104T	25	25	0	25	T
237N1S1701	MRA105PA	24	24	0	24	L
237N1S1702	MRA105PA	24	24	0	24	L
237N1S1703	MRA105PA	24	23	0	24	L
237N1S1704	MRA105PA	23	24	0	24	L
237N1S1705	MRA105PA	23	23	0	23	L
237N1S1706	MRA105PA	23	24	0	24	L
237N1S1707	MRA105PA	24	24	0	24	L
237N1S1708	MRA105PA	24	24	0	24	L
237N1S1709	MRA105PA	24	23	0	24	L
237N1S1710	MRA105PA	25	23	0	24	L
237N1S1711	MRA105PA	25	24	0	25	L
237N1S1712	MRA105PA	24	25	0	25	L
237N1S1713	MRA105PA	23	24	0	24	L
237N1S1714	MRA105PA	24	23	0	24	L
237N1S1701	MRA105PB	23	24	0	24	L
237N1S1702	MRA105PB	23	24	0	24	L
237N1S1703	MRA105PB	24	23	0	24	L
237N1S1704	MRA105PB	23	23	0	23	L
237N1S1705	MRA105PB	23	24	0	24	L
237N1S1706	MRA105PB	23	24	0	24	L
237N1S1707	MRA105PB	24	24	0	24	L
237N1S1708	MRA105PB	24	23	0	24	L
237N1S1709	MRA105PB	24	24	0	24	L
237N1S1710	MRA105PB	23	24	0	24	L
237N1S1711	MRA105PB	24	24	0	24	L
237N1S1712	MRA105PB	23	24	0	24	L
237N1S1713	MRA105PB	24	25	0	25	L
237N1S1714	MRA105PB	24	24	0	24	L
237N1S1701	MRA106S	0	0	90	90	S
237N1S1702	MRA106S	0	0	92	92	S
237N1S1703	MRA106S	0	0	95	95	S
237N1S1704	MRA106S	0	0	95	95	S

HTNO	SUBJECT	MID_1	MID_2	SEMINAR	FINAL	SUB_TYPE
237N1S1705	MRA106S	0	0	94	94	S
237N1S1706	MRA106S	0	0	96	96	S
237N1S1707	MRA106S	0	0	96	96	S
237N1S1708	MRA106S	0	0	95	95	S
237N1S1709	MRA106S	0	0	96	96	S
237N1S1710	MRA106S	0	0	96	96	S
237N1S1711	MRA106S	0	0	95	95	S
237N1S1712	MRA106S	0	0	95	95	S
237N1S1713	MRA106S	0	0	96	96	S
237N1S1714	MRA106S	0	0	96	96	S



Verified by: PRINCIPAL

Controller of Examinations

Date:30-03-2024