CHARUSAT
CHAROTAR UNIVERSITY OF SCIENCE AND TECHNOLOGY

STUDENT INFORMATION BOOKLET FOR THE ACADEMIC YEAR 2025-26

VOLUME – 2 : Master of Pharmacy Programme (Pharmaceutical Quality Assurance)

Ramanbhai Patel College of Pharmacy

CHARUSAT UNIVERSITY
Off. Nadiad-Petlad Highway, Changa - 388 421
Anand, Gujarat, India

CONTENT

PREAMBLE

The Handbook (Student's Information Booklet) for Students, printed in two volumes contain General Information Respectively about the CHARUSAT University and detailed information about Indukaka Ipcowala Institute of Management.

Handbook Volume-I contains information about general rules to be followed by the students on campus. It gives information about the general facilities and support available for the students on campus. It gives insight about the discipline and conduct rules of the University.

This Handbook (Student's Information Booklet) is for the purpose of providing information to the students about the University and its programmes and is not a Regulation book of the University. Hence, no claim can be made based on the information given in the book.

The University / Institute reserves the right to amend the rules and regulations mentioned in the Handbook without any prior notice. The decision of the University shall be final on all matters. For any clarification, the Student Section may be contacted.

Handbook Volume-II (Student's Information Booklet) contains academic information about the Institute, which includes the Academic Rules and Regulations regarding academic requirements and academic conduct of the students at the University including different policies and forms. Besides, it includes important information on registration, grading system, academic standards, attendance norms, discipline and the like. The students shall abide by these rules and shall, at all times, conduct in a manner so as to bring credit to the University and enhance its prestige in the society.

It is prime responsibility of the students to get familiar (themselves) with the rules and regulations

About the Institute

Ramanbhai Patel College of Pharmacy (RPCP) is a constituent Institute of Charotar University of Science and Technology (CHARUSAT). RPCP was established in the year 2004 with a view to promote excellence in Pharmacy Education and to prepare young talent to meet the challenges of Industrial Pharmacy and Pharmacy Practice. The Institute has the patronage of Zydus Cadila Health Care Ltd; patronized by Shri Pankaj Patel, CMD, Zydus Cadila Healthcare Ltd to commemorate his father, Late Shri Ramanbhai Patel. A Visionary Entrepreneur and a Philanthropist. M.Pharm Programs at RPCP are executed under the auspices of T. P. Patel Centre for PG studies in Pharmacy. The centre in patronized by Shri Jagdishbhai Patel and Shri H. T. Patel and their families to monumentalize their father, Late Shri T. P. Patel.

Vision

To Become a Premier Pharma Institute by Creating World Class Pharmacists and Researchers

Mission

To Strive for the Excellence in Pharmaceutical Sciences through Quality Education and Research

SECTION - 1

PROGRAMME SPECIFIC: M.Pharm (Pharmaceutical Quality Assurance)

1.1 Academic Regulation

1.2 B.Pharm Programme Structure (Teaching & Examination Scheme)

ACADEMIC REGULATIONS & SYLLABUS

Faculty of Pharmacy
Master of Pharmacy Programme

(Pharmaceutical Quality Assurance)

(AS PER PCI SYLLABUS)

A.Y. 2025 - 2026

Ramanbhai Patel College of Pharmacy

CHAROTAR UNIVERSITY OF SCIENCE AND TECHNOLOGY

Vision of RPCP

To Become a Premier Pharma Institute by Creating World Class Pharmacists and Researchers.

Mission of RPCP

To Strive for the Excellence in Pharmaceutical Sciences through Quality Education and Research.

PROGRAM OUTCOMES

1. Pharmacy Knowledge: Possess knowledge and comprehension of the core and basic knowledge associated with the profession of pharmacy, including biomedical sciences; pharmaceutical sciences; behavioral, social, and administrative pharmacy sciences; and manufacturing practices.

2. Planning Abilities: Demonstrate effective planning abilities including time management, resource management, delegation skills and organizational skills. Develop and implement plans and organize work to meet deadlines.

3. Problem analysis: Utilize the principles of scientific enquiry, thinking analytically, clearly and critically, while solving problems and making decisions during daily practice. Find, analyze, evaluate and apply information systematically and shall make defensible decisions.

4. Modern tool usage: Learn, select, and apply appropriate methods and procedures, resources, and modern pharmacy-related computing tools with an understanding of the limitations.

5. Leadership skills: Understand and consider the human reaction to change, motivation issues, leadership and team-building when planning changes required for fulfillment of practice, professional and societal responsibilities. Assume participatory roles as responsible citizens or leadership roles when appropriate to facilitate improvement in health and wellbeing.

6. Professional Identity: Understand, analyze and communicate the value of their professional roles in society (e.g. health care professionals, promoters of health, educators, managers, employers, employees).

7. Pharmaceutical Ethics: Honour personal values and apply ethical principles in professional and social contexts. Demonstrate behavior that recognizes cultural and personal variability in values, communication and lifestyles. Use ethical frameworks; apply ethical principles while making decisions and take responsibility for the outcomes associated with the decisions.

8. Communication: Communicate effectively with u the pharmacy community and with society at large, such as, being able to comprehend and write effective reports, make effective presentations and documentation, and give and receive clear instructions.

9. The Pharmacist and society: Apply reasoning informed by the contextual knowledge to assess societal, health, safety and legal issues and the consequent responsibilities relevant to the professional pharmacy practice.

10. Environment and sustainability: Understand the impact of the professional pharmacy solutions in societal and environmental contexts, and demonstrate the knowledge of, and need for sustainable development.

11. Life-long learning: Recognize the need for, and have the preparation and ability to engage in independent and life-long learning in the broadest context of technological change. Self-assess and use feedback effectively from others to identify learning needs and to satisfy these needs on an ongoing basis.

FACULTY OF PHARMACY

ACADEMIC REGULATIONS
MASTER OF PHARMACY (M. Pharm.) PROGRAMME
Choice Based Credit System (CBCS)

1. Short Title and Commencement

These regulations shall be called as "The Revised Academic Regulations for the postgraduate programmes under the Faculty of Pharmacy". They shall come into effect from the Academic Year 2018-19. The regulations framed are subject to modifications from time to time by the respective regulatory bodies.

2. Minimum Qualification for Admission

2.1 Candidate shall have passed 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.)

2.2 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 Programme

The course 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 a 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 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. Programme Credit Structure

As per the philosophy of Credit Based Semester System, certain quantum of academic work viz. theory classes, tutorial hours, practical classes, 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.

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 93. However based on the credit points earned by the students under the head of co-curricular activities, a student shall earn a maximum of 98 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. 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. Examinations/Assessments

The scheme for internal assessment and end semester examinations is given in Annexure II (Table – 1 to 5).

9.1. End Semester Examinations

The End Semester Examinations for each theory and practical course through semesters I to IV shall be conducted by the University for which Examinations shall be conducted by the subject experts at college level and the marks/grades shall be submitted to the university.

9.2. Internal Assessment: Continuous Mode

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

Table- 1: Scheme for awarding internal assessment: Continuous mode

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

Table- 2: 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

9.2.1. Sessional Exams

Two Sessional exams shall be conducted for each theory / practical course as per the schedule fixed by the college. The scheme of question paper for theory and practical Sessional examinations will be as prescribed by the regulatory body. The average marks of two Sessional exams shall be computed for internal assessment as per the requirements given in Annexure II. Sessional exam shall be conducted for 30 marks for theory and shall be computed for 15 marks. Similarly, Sessional exam for practical shall be conducted for 40 marks and shall be computed for 10 marks.

10. 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.

11. Carry Forward of Marks

In case a student fails to secure the minimum 50% in any Theory or Practical course as specified in 9 above, 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.

12. 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.

13. Re-examination of End Semester Examinations

Re-examination of end semester examination shall be conducted as per the schedule given in table 3. The exact dates of examinations shall be notified from time to time.

Table-3: Tentative schedule of end semester examinations

Semester	**For Regular Candidates**	**For Failed Candidates**	
		Remedial Examination-1	**Remedial Examination-2***
I and III	November / December	After 15 days of the declaration of the result of the end semester Examination	last week of June/ end of the Academic Year, which is earlier
II and IV	May / June	After 15 days of the declaration of the result of the end semester Examination	

* If student who are remain left from end semester examination and remedial examination-1.

14. Academic Progression

No student shall be admitted to any examination unless he/she fulfils the norms given in item no. 6 under the heading of attendance and progress. Academic progression rules are applicable as follows:

- **"Student will not be allowed to move to next year if she/he has not cleared all the courses of the previous year"**
- A student shall be eligible to carry forward all the courses of I^{st} semesters till the II^{nd} semester examinations. However, he/she shall not be eligible to attend the courses of the III^{rd} semester until all the courses of the I^{st} and II^{nd} 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 "NA" 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.

15. Grading of Performances (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 – 4.

Table-4: Letter grades and grade points equivalent to Percentage of marks and performances

Percentage of Marks Obtained	Letter Grade	Grade Point	Performance
90.00 – 100	AA	10	Outstanding
80.00 – 89.99	AB	9	Excellent
70.00 – 79.99	BB	8	Good
60.00 – 69.99	BC	7	Fair
50.00 – 59.99	CC	6	Average
Less than 50	FF	0	Fail
Absent	NA	0	Fail

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

16. 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, C4 and C5 and the student's grade points in these courses are G1, G2, G3, G4 and G5, respectively, and then students' SGPA is equal to:

$$\text{SGPA} = \frac{C1G1+C2G2+C3G3+C4G4}{C1+C2+C3+C4}$$

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

$$\text{SGPA} = \frac{C1G1+C2G2+C3G3+C4Zero}{C1+C2+C3+C4}$$

17. Cumulative Grade Point Average (CGPA)

The CGPA is calculated with the SGPA of all the VIII semesters to two decimal points and is indicated in final grade report card/final transcript showing the grades of all VIII semesters and their courses. The CGPA shall reflect the failed status in case of FF 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:

$$\text{CGPA} = \frac{C1S1+C2S2+C3S3+C4S4}{C1+C2+C3+C4}$$

where C1, C2, C3,…. is the total number of credits for semester I,II,III,…. and S1,S2, S3,….is the SGPA of semester I,II,III,…. .

No student will be allowed to move further if CGPA is less than 3 at the end of every academic year.

18. Declaration of Class (Table-5)

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

First Class with Distinction	= CGPA of. 7.50 to 10.0
First Class	= CGPA of 6.0 to 7.49
Second Class	= CGPA of 5.0 to 5.99
Pass Class	< CGPA of 5.00

19. 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			
Criteria	**Semester-III**	**Semester-IV**	
		Internal Evaluation (Marks)	**External Evaluation (Marks)**
Objective(s) of the work done	--	05	05
Methodology Adopted	--	25	25
Results and Discussions	--	15	15
Conclusions and Outcome	--	05	05
Total	--	50	50
Final Total		**100**	

Evaluation of Presentation				
	Semester-III		Semester-IV	
Criteria	**Internal Evaluation (Marks)**	**External Evaluation (Marks)**	**Internal Evaluation (Marks)**	**External Evaluation (Marks)**
Presentation of work	75	100	75	75
Communication skills	25	50	25	25
Question and answer skills	50	50	50	50
Total	150	200	150	150
Final Total	**350**		**300**	

20. 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.

22. Award of degree

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

23. 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.

24. Extra Credit:

An extra credit is to be offered to a student for achievements in co-curricular and extra–curricular activities. This credit shall not be counted while considering the minimum credits for completing the program. The activities and appropriate weight (points) to be allocated to award an extra credit are broadly classified as per the table below:

Sr. no.	**Name of the Activity**	**Maximum Credit Points Eligible / Activity**
1	Participation in National Level Seminar/Conference/Workshop/Symposium/ Training Programs (related to the specialization of the student)	01

2	Participation in international Level Seminar/Conference/Workshop/Symposium/ Training Programs (related to the specialization of the student)	02
3	Academic Award/Research Award from State Level/National Agencies	01
4	Academic Award/Research Award from International Agencies	02
5	Research / Review Publication in National Journals (Indexed in Scopus / Web of Science)	01
6	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.**

CHAROTAR UNIVERSITY OF SCIENCE & TECHNOLOGY
MASTER OF PHARMACY (PHARMACEUTICAL QUALITY ASSURANCE) PROGRAMME
Schemes for internal assessments and end semester examinations

SEMESTER-I
SCHEME OF TEACHING

Course Code	Course Name	Credit Hours	Credit Points	Hrs/Week
PHCCC009	Modern Pharmaceutical Analytical Techniques	4	4	4
PHPQA001	Quality Management System	4	4	4
PHPQA002	Quality Control and Quality Assurance	4	4	4
PHPQA012	Product Development and Technology Transfer	4	4	4
PHPQA003	Quality Assurance Practical-I	12	6	12
PHPQA004	Seminar/Assignment-I	2	1	2
---	DHSS Elective-I*	2	2	2
	Total	**32**	**25**	**32**

SCHEME OF EVALUATION

Course Code	Course	Internal Assessment				End Semester Exams		Total Marks
		Continuous Mode	Sessional Exams		Total	Marks	Duration	
			Marks	Duration				
PHCCC009	Modern Pharmaceutical Analytical Techniques	10	15	1Hr	**25**	**75**	3Hrs	**100**
PHPQA001	Quality Management System	10	15	1Hr	**25**	**75**	3Hrs	**100**
PHPQA002	Quality Control and Quality Assurance	10	15	1Hr	**25**	**75**	3Hrs	**100**
PHPQA012	Product Development And Technology Transfer	10	15	1Hr	**25**	**75**	3Hrs	**100**
PHPQA003	Quality Assurance Practical-I	20	30	6Hrs	**50**	**100**	6Hrs	**150**
PHPQA004	Seminar/Assignment-I	-	-	-	**100**	**-**	-	**100**
----	DHSS Elective-I*	-	-	-	**30**	**70**	-	**100**
Total								**750**

*DHSS elective courses: SCHEME OF TEACHING

Semester	Course Code	Course Name	Credit Hours	Credit Points	Hrs/Week
I	HS105.02 B	Academic Speaking and Presentation Skills	02	02	02

*DHSS elective courses: SCHEME OF EVALUATION

Course Code	Course Name	Evaluation Scheme				
		Theory		Practical		Total
		Internal	External	Internal	External	
HS105.02 B	Academic Speaking and Presentation Skills	-	-	30	70	100

CHAROTAR UNIVERSITY OF SCIENCE & TECHNOLOGY
MASTER OF PHARMACY (PHARMACEUTICAL QUALITY ASSURANCE) PROGRAMME
Schemes for internal assessments and end semester examinations

SEMESTER-II
SCHEME OF TEACHING

Course Code	Course Name	Credit Hours	Credit Points	Hrs/Week
PHPQA013	Hazards and Safety Management	4	4	4
PHPQA018	Pharmaceutical Validation	4	4	4
PHPQA006	Audit and Regulatory Compliance	4	4	4
PHPQA007	Pharmaceutical Manufacturing Technology	4	4	4
PHPQA008	Quality Assurance Practical-II	12	6	12
PHPQA009	Seminar/Assignment-II	2	1	2
---	DHSS elective-II*	2	2	2
---	University Elective-II**	2	2	2
	Total	**34**	**27**	**34**

SCHEME OF EVALUATION

Course Code	Course	Internal Assessment				End Semester Exams		Total Marks
		Continuous Mode	Sessional Exams		Total	Marks	Duration	
			Marks	Duration				
PHPQA013	Hazards and Safety Management	10	15	1Hr	25	75	3Hrs	100
PHPQA018	Pharmaceutical Validation	10	15	1Hr	25	75	3Hrs	100
PHPQA006	Audit and Regulatory Compliance	10	15	1Hr	25	75	3Hrs	100
PHPQA007	Pharmaceutical Manufacturing Technology	10	15	1Hr	25	75	3Hrs	100
PHPQA008	Quality Assurance Practical-II	20	30	6Hrs	50	100	6Hrs	150
PHPQA009	Seminar/Assignment-II	-	-	-	100	-	-	100
---	DHSS elective-II*	-	-	-	30	70	-	100
---	University Elective-II**	-	-	-	25	25	-	50
Total								**800**

*DHSS elective courses: SCHEME OF TEACHING

Semester	Course Code	Course Name	Credit Hours	Credit Points	Hrs/Week
II	HS106.02 B	Academic Writing	02	02	02

*DHSS elective courses: SCHEME OF EVALUATION

Course Code	Course Name	Evaluation Scheme				
		Theory		Practical		Total
		Internal	External	Internal	External	
HS106.02 B	Academic Writing	-	-	30	70	100

****University elective courses: SCHEME OF TEACHING - Semester-II**

Course Code	Course Name	Credit Hours	Credit Points	Hrs/Week
NRMD551	Mindfulness and Well-Being: Living With Balance and Ease	4	2	4
PTUD796	Yoga and Positive Psychology for Managing Career and Life	4	2	4
FSUD554	Plastic Waste Management	4	2	4
FSUD553	Computational Science in Engineering	4	2	4
FSUD552	Nuclear Astrophysics	4	2	4
FSUD551	Energy Resources, Economics and Sustainability	4	2	4
CAUD518	Software Project Management	4	2	4
MBUD558	Introduction to Operations Research	4	2	4
FTUD501	Blockchain and Its Applications	4	2	4
FTUD502	Sustainable Engineering Concepts and Life Cycle Analysis	4	2	4
FTUD552	Health and Safety Management	4	2	4
OCMPH1003	Introduction on Intellectual Property to Engineers and Technologists	4	2	4

****University elective courses: SCHEME OF EVALUATION- Semester-II**

Course Code	Course Name	Evaluation Scheme				
		Theory		Practical		Total
		Internal	External	Internal	External	
NRMD551	Mindfulness and Well-Being: Living With Balance and Ease	-	-	25	25	50
PTUD796	Yoga and Positive Psychology for Managing Career and Life	-	-	25	25	50
FSUD554	Plastic Waste Management	-	-	25	25	50
FSUD553	Computational Science in Engineering	-	-	25	25	50
FSUD552	Nuclear Astrophysics	-	-	25	25	50
FSUD551	Energy Resources, Economics and Sustainability	-	-	25	25	50
CAUD518	Software Project Management	-	-	25	25	50
MBUD558	Introduction to Operations Research	-	-	25	25	50
FTUD501	Blockchain and Its Applications	-	-	25	25	50
FTUD502	Sustainable Engineering Concepts and Life Cycle Analysis	-	-	25	25	50
FTUD552	Health and Safety Management	-	-	25	25	50
OCMPH1003	Introduction on Intellectual Property to Engineers and Technologists	-	-	25	25	50

CHAROTAR UNIVERSITY OF SCIENCE & TECHNOLOGY
MASTER OF PHARMACY (PHARMACEUTICAL QUALITY ASSURANCE) PROGRAMME
Schemes for internal assessments and end semester examinations

SEMESTER-III

Course Code	Course Name	Credit Hours	Credit Points	Hrs/Week
PHCCC010	Research Methodology and Biostatistics*	4	4	4
PHCCC011	Journal Club-I	1	1	1
PHPQA014	Discussion / Presentation (Proposal Presentation)	2	2	2
PHPQA015	Research Work-I	28	14	28
	Total	**35**	**21**	**35**

* Non University Exam

SCHEME OF EVALUATION

Course Code	Course	Internal Assessment				End Semester Exams		Total Marks
		Continuous Mode	Sessional Exams		Total	Marks	Duration	
			Marks	Duration				
PHCCC010	Research Methodology and Biostatistics*	10	15	1 Hr	25	75	3 Hr	100
PHCCC011	Journal Club-I	-	-	-	25	-	-	25
PHPQA014	Discussion / Presentation (Proposal Presentation)	-	-	-	50	-	-	50
PHPQA015	Research Work-I	-	-	-	-	350	1 Hr	350
Total								525

* Non University Exam

CHAROTAR UNIVERSITY OF SCIENCE & TECHNOLOGY
MASTER OF PHARMACY (PHARMACEUTICAL QUALITY ASSURANCE) PROGRAMME
Schemes for internal assessments and end semester examinations

SEMESTER-IV

Course Code	Course Name	Credit Hours	Credit Points	Hrs/Week
PHCCC012	Journal Club-II	1	1	1
PHPQA016	Discussion / Presentation	3	3	3
PHPQA017	Research Work-II	31	16	31
Total		**35**	**20**	**35**

SCHEME OF EVALUATION

Course Code	Course	Internal Assessment				End Semester Exams		Total Marks
		Continuous Mode	Sessional Exams		Total	Marks	Duration	
			Marks	Duration				
PHCCC012	Journal Club-II	-	-	-	25	-	-	25
PHPQA016	Discussion / Presentation	-	-	-	75	-	-	75
PHPQA017	Research Work-II	-	-	-	-	400	1Hr	400
Total								500

Semester wise distribution

Semester	Credit Point
I	25
II	27
III	21
IV	20
Co-curricular Activity (Attending conference, scientific presentations, publication, industry training and other scholarly activities)	Maximum-5
Total Credit Point	Minimum-93 Maximum -98*

***Credit point for co-curricular activity**

FACULTY OF PHARMACY
Master of Pharmacy Programme

Syllabi
Semester I

Charotar University of Science and Technology

FACULTY OF PHARMACY
Master of Pharmacy Programme
PHCCC009: Modern Pharmaceutical Analytical Techniques (Theory)

Total hours: 60 Hr

Outline of the course:

Sr. No.	Title of the unit	Minimum number of hours
1	UV-Visible spectroscopy	10
	IR spectroscopy	
	Spectroflourimetry	
	Flame emission spectroscopy and Atomic absorption spectroscopy	
2	NMR Spectroscopy	10
3	Mass Spectroscopy	10
	X-Ray Crystallography	
4	Chromatography	10
5	Electrophoresis	10
	Immunological Assays	
6	Potentiometry	10
	Thermal analysis	

Detailed Syllabus:

1.	**UV-Visible spectroscopy**	**10 Hours**	**16.67%**
	• UV-Visible spectroscopy: Introduction, Theory, Laws, Instrumentation associated with UV-Visible spectroscopy, Choice of solvents and solvent effect and Applications of UV Visible spectroscopy.		
	IR spectroscopy		
	• Theory, Modes of Molecular vibrations, Sample handling, Instrumentation of Dispersive and Fourier - Transform IR Spectrometer, Factors affecting vibrational frequencies and Applications of IR spectroscopy		

	Spectroflourimetry Theory of Fluorescence, Factors affecting fluorescence, Quenchers, Instrumentation and Applications of fluorescence spectrophotometer. **Flame emission spectroscopy and Atomic absorption spectroscopy** • Principle, Instrumentation, Interferences and Applications.		
2.	**NMR Spectroscopy**	**10 Hours**	**16.67%**
	• Quantum numbers and their role in NMR, Principle, Instrumentation, Solvent requirement in NMR, Relaxation process, NMR signals in various compounds, Chemical shift, Factors influencing chemical shift, SpinSpin coupling, Coupling constant, Nuclear magnetic double resonance, Brief outline of principles of FT-NMR and 13C NMR. Applications of NMR spectroscopy.		
3.	**Mass Spectroscopy**	**10 Hours**	**16.67%**
	• Mass Spectrometry: Principle, Theory, Instrumentation of Mass Spectrometry, Different types of ionization like electron impact, chemical, field, FAB and MALDI, APCI, ESI, APPI Analysers of Quadrupole and Time of Flight, Mass fragmentation and its rules, Meta stable ions, Isotopic peaks and Applications of Mass spectrometry. **X ray Crystallography** • Production of X rays, Different X ray diffraction methods, Bragg's law, Rotating crystal technique, X ray powder technique, Types of crystals and applications of X ray diffraction.		
4.	**Chromatography**	**10 Hours**	**16.67%**
	• Principle, apparatus, instrumentation, chromatographic parameters, factors affecting resolution and applications of the following: a) Paper chromatography b) Thin Layer chromatography c) Ion exchange chromatography d) Column chromatography e) Gas chromatography f) High Performance Liquid chromatography g) Affinity chromatography		

5.	**Electrophoresis**	**10 Hours**	**16.67%**
	• Principle, Instrumentation, Working conditions, factors affecting separation and applications of the following: a) Paper electrophoresis b) Gel electrophoresis c) Capillary electrophoresis d) Zone electrophoresis e) Moving boundary electrophoresis f) Iso electric focusing		
	Immunological Assays		
	• RIA (Radio Immuno assay), ELISA, Bioluminescence assays.		
6.	**Potentiometry**	**10 Hours**	**16.67%**
	• Principle, working, Ion selective Electrodes and Application of potentiometry		
	Thermal Techniques		
	• Differential Scanning Calorimetry (DSC): Principle, thermal transitions and Instrumentation (Heat flux and power-compensation and designs), Modulated DSC, Hyper DSC, experimental parameters (sample preparation, experimental conditions, calibration, heating and cooling rates, resolution, source of errors) and their influence, advantage and disadvantages, pharmaceutical applications. • Differential Thermal Analysis (DTA): Principle, instrumentation and advantage and disadvantages, pharmaceutical applications, derivative differential thermal analysis (DDTA). TGA: Principle, instrumentation, factors affecting results, advantage and disadvantages, pharmaceutical applications.		

Course Outcome (COs):

At the end of the course, the students would be able to;

CO1	describe theory and principle of various spectroscopic and chromatographic separation techniques.
CO2	describe instrumentation and application of various spectroscopic and chromatographic separation techniques with justification.
CO3	summarize approaches to be adopted for quantitative & qualitative analysis of drugs in single and combine dosage forms.
CO4	Describe use of thermal methods and potentiometry in analysis of drugs/formulations
CO5	interpret the spectra and propose the structure of organic compounds.

Course Articulation Matrix:

	PO1	PO2	PO3	PO4	PO5	PO6	PO7	PO8	PO9	PO10	PO11
CO1	-	-	-	-	-	-	-	-	-	-	3
CO2	3	3	3	-	3	-	-	3	-	3	3
CO3	3	3	3	3	-	3	-	3	-	3	3
CO4	3	3	3	3	-	-	-	3	-	-	3
CO5	3	-	3	3	-	-	-	3	-	-	3

❖ **References:**

1. Spectrometric Identification of Organic compounds - Robert M Silverstein, Sixth edition, John Wiley & Sons, 2004.
2. Principles of Instrumental Analysis - Doglas A Skoog, F. James Holler, Timothy A. Nieman, 5th edition, Eastern press, Bangalore, 1998
3. Instrumental methods of analysis – Willards, 7th edition, CBS publishers.
4. Practical Pharmaceutical Chemistry – Beckett and Stenlake, Vol II, 4th edition, CBS Publishers, New Delhi, 1997.
5. Organic Spectroscopy - William Kemp, 3rd edition, ELBS, 1991.
6. Quantitative Analysis of Drugs in Pharmaceutical formulation - P D Sethi, 3rd Edition, CBS Publishers, New Delhi, 1997.
7. Pharmaceutical Analysis- Modern methods – Part B - J W Munson, Volume 11, Marcel Dekker Series. 8. The Analysis of Drugs in Biological Fluids, Joseph Chamberlain, CRC Press

FACULTY OF PHARMACY
Master of Pharmacy Programme
PHPQA001: Quality Management System (Theory)

Outline of the course: **Total hours: 60 Hr**

Sr. No.	Title of the unit	Minimum number of hours
1	Introduction to quality	12
	Quality as a strategic design	
	Customer focus	
	Cost of quality	
2	Pharmaceutical quality Management	12
3	Six sigma inspection model	12
	Quality systems	
4	Drug stability	12
	Quality risk management	
5	Statistical process control	8
6	Regulatory Compliance through Quality Management and development of Quality Culture	4

Detailed Syllabus:

Sr. No.	UNIT	Hours	Weightage (%)
1.	**Introduction to quality, quality as a strategic design, customer focus, cost of quality**	**12**	**20%**
	Introduction to Quality: Evolution of Quality, Definition of Quality, Dimensions of Quality Quality as a Strategic Decision: Meaning of strategy and strategic quality management, mission and vision statements, quality policy, Quality objectives, strategic planning and implementation, McKinsey 7s model, Competitive analysis, Management commitment to quality Customer Focus: Meaning of customer and customer focus, Classification of customers, Customer focus, Customer perception of quality, Factors affecting customer perception, Customer requirements, Meeting customer needs and expectations, Customer satisfaction and Customer delight, Handling customer complaints, Understanding customer behavior, concept of internal and external customers. Case studies.		

	Cost of Quality: Cost of quality, Categories of cost of Quality, Models of cost of quality, Optimising costs, Preventing cost of quality.		
2.	**Pharmaceutical quality management**	**12**	**20%**
	Basics of Quality Management, Total Quality Management (TQM), Principles of Six sigma, ISO 9001:2008, 9001:2015, ISO 14001:2004, Pharmaceutical Quality Management – ICH Q10, Knowledge management, Quality Metrics, Operational Excellence and Quality Management Review. OSHAS guidelines, NABL certification and accreditation, CFR-21 part 11, WHO-GMP requirements.		
3.	**Six sigma inspection model, quality systems**	**12**	**20%**
	Six System Inspection model: Quality Management system, Production system, Facility and Equipment system, Laboratory control system, Materials system, Packaging and labeling system. Concept of self-inspection. Quality systems: Change Management/ Change control. Deviations, Out of Specifications (OOS), Out of Trend (OOT), Complaints - evaluation and handling, Investigation and determination of root cause, Corrective & Preventive Actions (CAPA), Returns and Recalls, Vendor Qualification, Annual Product Reviews, Batch Review and Batch Release. Concept of IPQC, area clearance/ Line clearance.		
4.	**Drug stability, quality risk management**	**12**	**20%**
	Drug Stability: ICH guidelines for stability testing of drug substances and drug products. Study of ICH Q8, Quality by Design and Process development report. Quality risk management: Introduction, risk assessment, risk control, risk review, risk management tools, HACCP, risk ranking and filtering according to ICH Q9 guidelines.		
5.	**Statistical process control**	**8**	**14%**
	Statistical Process control (SPC): Definition and Importance of SPC, Quality measurement in manufacturing, Statistical control charts - concepts and general aspects, Advantages of statistical control, Process capability, Estimating Inherent or potential capability from a control chart analysis, Measuring process controland quality improvement, Pursuit of decreased process variability.		
6.	**Regulatory Compliance through Quality Management and development of Quality Culture**	**4**	**6%**

	Regulatory Compliance through Quality Management and development of Quality Culture Benchmarking: Definition of benchmarking, Reasons for benchmarking, Types of Benchmarking, Benchmarking process, Advantages of benchmarking, Limitations of benchmarking.		

Course Outcome (COs):

At the end of the course, the students would be able to;

CO1	summarize importance of Quality, tools to improve the quality and analyze the issues in Quality of Pharmaceutical Products.
CO2	narrate the concept of Total Quality Management, Quality systems Approach with reference to pharmaceutical manufacturing.
CO3	describe the importance and application of Quality Risk Management concept in pharmaceutical manufacturing processes.
CO4	describe and compare ICH guidelines for stability testing of drug substances and drug products with reference to similar guidelines issued by other competent authorities.
CO5	describe statistical approaches and benchmarking for quality of pharmaceuticals.

Course Articulation Matrix:

	PO1	PO2	PO3	PO4	PO5	PO6	PO7	PO8	PO9	PO10	PO 11
CO1	3	-	-	-	-	-	-	-	-	-	3
CO2	3	-	-	-	-	-	-	-	-	-	3
CO3	3	-	-	-	-	-	-	-	-	-	3
CO4	3	-	-	-	-	-	-	-	-	-	3
CO5	3	-	-	-	-	-	-	-	-	-	3

- **REFERENCES**

1. Implementing Juran's Road Map for Quality Leadership: Benchmarks and Results, By Al Endres, Wiley, 2000
2. Understanding, Managing and Implementing Quality: Frameworks, Techniques and Cases, By Jiju Antony; David Preece, Routledge, 2002
3. Organizing for High Performance: Employee Involvement, TQM, Reengineering, and Knowledge Management in the Fortune 1000: The CEO Report By Edward E. Lawler; Susan Albers Mohrman; George Benson, Jossey-Bass, 2001
4. Corporate Culture and the Quality Organization By James W. Fairfield- Sonn, Quorum Books, 2001

5. The Quality Management Sourcebook: An International Guide to Materials and Resources By Christine Avery; Diane Zabel, Routledge, 1997
6. The Quality Toolbox, Second Edition, Nancy R. Tague, ASQ Publications
7. Juran's Quality Handbook, Sixth Edition, Joseph M. Juran and Joseph A. De Feo, ASQ Publications
8. Root Cause Analysis, The Core of Problem Solving and Corrective Action, Duke Okes, 2009, ASQ Publications.

FACULTY OF PHARMACY
Master of Pharmacy Programme
PHPQA002: Quality Control & Quality Assurance (Theory)

Outline of the course: **Total hours: 60 Hr**

Sr. No.	Title of the unit	Minimum number of hours
1	Introduction	12
2	cGMP guideline	12
	USFDA	
	Pharmaceutical Inspection Convention	
	WHO	
	EMEA	
3	Analysis of raw materials, finished products, packaging Materials	12
	In-process quality control	
	Developing & Purchase specifications	
	Maintenance of stores for raw materials	
4	Documentation in pharmaceutical industry	12
5	Manufacturing operations & controls	12

Detailed Syllabus:

Sr. No.	UNIT	Hours	Weightage (%)
1.	**Introduction**	**12**	**20%**
	Concept and evolution and scopes of Quality Control and Quality Assurance, Good Laboratory Practice, GMP, Overview of ICH Guidelines - QSEM, with special emphasis on Q-series guidelines. Good Laboratory Practices: Scope of GLP, Definitions, Quality assurance unit, protocol for conduct of non-clinical testing, control on animal house, report preparation and documentation. CPCSEA guidelines.		
2.	**cGMP guidelines according to schedule M, USFDA (inclusive of CDER and CBER) Pharmaceutical Inspection Convention (PIC), WHO and EMEA covering**	**12**	**20%**
	Organization and personnel responsibilities, training, hygiene and personal records, drug industry location, design, construction and plant lay out, maintenance, sanitation, environmental control, utilities and maintenance of sterile areas, control of contamination		

	and Good Warehousing Practice.		
3.	**Analysis of raw materials, finished products, packaging materials, in process quality control (IPQC), Developing specification (ICH Q6 and Q3), purchase specifications and maintenance of stores for raw materials**	**12**	**20%**
	In process quality control and finished products quality control for following dosage forms in Pharma industry according to Indian, US and British pharmacopoeias: tablets, capsules, ointments, suppositories, creams, parenterals, ophthalmic and surgical products (How to refer pharmacopoeias).		
4.	**Documentation in pharmaceutical industry**	**12**	**20%**
	Three tier documentation, Policy, Procedures and Work instructions, and records (Formats), Basic principles- How to maintain, retention and retrieval etc. Standard operating procedures (How to write), Master Batch Record, Batch Manufacturing Record, Quality audit plan and reports. Specification and test procedures, Protocols and reports. Distribution records. Electronic data handling. Concepts of controlled and uncontrolled documents. Submission documents for regulators DMFs, as Common Technical Document and Electronic Common Technical Documentation (CTD, eCTD). Concept of regulated and non-regulated markets.		
5.	**Manufacturing operations & Controls**	**12**	**20%**
	Sanitation of manufacturing premises, mix-ups and cross contamination, processing of intermediates and bulk products, packaging operations, IPQC, release of finished product, process deviations, charge-in of components, time limitations on production, drug product inspection, expiry date calculation, calculation of yields, production record review, change control, sterile products, aseptic process control, packaging, reprocessing, salvaging, handling of waste and scrap disposal. Introduction, scope and importance of intellectual property rights. Concept of trade mark, copyright and patents.		

Course Outcome (COs):

At the end of the course, the students would be able to;

CO1	summarize the roles and responsibilities of QC and QA department
CO2	describe the cGMP concept and would be able to compare various cGMP guidelines used in pharmaceutical industry
CO3	suggest the IPQC and FPQC tests in pharmaceutical industry
CO4	describe documentation in pharmaceutical industry
CO5	narrate various manufacturing operations along with their controls

Course Articulation Matrix:

	PO1	PO2	PO3	PO4	PO5	PO6	PO7	PO8	PO9	PO10	PO11
CO1	3	-	-	-	-	-	-	-	-	-	3
CO2	3	-	-	-	-	-	-	-	-	-	3
CO3	3	-	-	-	-	-	-	-	-	-	3
CO4	3	-	-	3	-	-	-	3	-	-	3
CO5	3	-	-	-	-	-	-	-	-	-	3

❖ REFERENCES

1. Quality Assurance Guide by organization of Pharmaceutical Procedures of India,3 rd revised edition, Volume I & II, Mumbai, 1996. Anatomy and Physiology in Health and Illness by Kathleen J.W. Wilson, Churchill, Livingstone, New York
2. Good Laboratory Practice Regulations, 2nd Edition, Sandy Weinberg Vol. 69, Marcel Dekker Series, 1995.
3. T Quality Assurance of Pharmaceuticals- A compendium of Guide lines andRelated materials Vol I & II, 2nd edition, WHO Publications, 1999. Principles of Anatomy and Physiology by Tortora Grabowski. Palmetto, GA, U.S.A.
4. How to Practice GMP's – P P Sharma, Vandana Publications, Agra, 1991. 126
5. The International Pharmacopoeia – vol I, II, III, IV & V - General Methods of Analysis and Quality specification for Pharmaceutical Substances, Excipients and Dosage forms, 3 rd edition, WHO, Geneva, 2005.
6. Good laboratory Practice Regulations – Allen F. Hirsch, Volume 38, Marcel Dekker Series, 1989.
7. ICH guidelines.
8. ISO 9000 and total quality management.
9. The drugs and cosmetics act 1940 – Deshpande, Nilesh Gandhi, 4th edition,Susmit Publishers, 2006.

10. QA Manual – D.H. Shah, 1 st edition, Business Horizons, 2000.
11. Good Manufacturing Practices for Pharmaceuticals a plan for total quality control
– Sidney H. Willig, Vol. 52, 3 rd edition, Marcel Dekker Series.
12. Steinborn L. GMP/ISO Quality Audit Manual for Healthcare Manufacturers and Their Suppliers, Sixth Edition, (Volume 1 - With Checklists and Software Package). Taylor & Francis; 2003. Sarker DK. Quality Systems and Controls for Pharmaceuticals. John Wiley & Sons; 2008.
13. Packaging of Pharmaceuticals.
14. Schedule M and Schedule N.

FACULTY OF PHARMACY
Master of Pharmacy Programme
PHPQA012: Product Development & Technology Transfer (Theory)

Outline of the course: **Total hours: 60 Hr**

Sr. No.	Title of the unit	Minimum number of hours
1	Principal of drug discovery and development	12
2	Pre formulation study	12
3	Pilot plant scale up	12
4	Pharmaceutical packaging	12
5	Technology transfer	12

Detailed Syllabus:

Sr. No.	UNIT	Hours	Weightage (%)
1.	**Principal of drug discovery and development**	**12**	**20%**
	Introduction, Clinical research process. Development and informational content for Investigational New Drugs Application (IND), New Drug Application (NDA), Abbreviated New Drug Application (ANDA), Supplemental New Drug Application (SNDA), Scale Up Post Approval Changes (SUPAC) and Bulk active chemical Post approval changes (BACPAC), Post marketing surveillance, Product registration guidelines – CDSCO, USFDA. Submission documents for regulators DMFs, as Common Technical Document and Electronic Common Technical Documentation (CTD, eCTD). Concept of regulated and non-regulated markets.		
2.	**Pre formulation study**	**12**	**20%**
	Introduction/concept, organoleptic properties, purity, impurity profiles, particle size, shape and surface area. Solubility, Methods to improve solubility of Drugs: Surfactants & its importance, co-solvency. Techniques for the study of Crystal properties and polymorphism. Pre-formulation protocol, Stability testing during product development.		
3.	**Pilot plant scale up**	**12**	**20%**
	Concept, Significance, design, layout of pilot plant scale up study, operations, large scale manufacturing techniques (formula, equipment, process, stability and quality control) of solids, liquids,		

	semisolid and parenteral dosage forms. New era of drug products: opportunities and challenges.		
4.	**Pharmaceutical packaging**	**12**	**20%**
	Pharmaceutical dosage form and their packaging requirements, Pharmaceutical packaging materials, Medical device packaging, Enteral Packaging, Aseptic packaging systems, Container closure systems, Issues facing modern drug packaging, Selection and evaluation of Pharmaceutical packaging materials. Quality control test: Containers, closures and secondary packing materials.		
5.	**Technology transfer**	**12**	**20%**
	Development of technology by R & D, Technology transfer fromR & D to production, Optimization and Production, Qualitative and quantitative technology models. Documentation in technology transfer: Development report, technology transfer plan and Exhibit.		

Course Outcome (COs):

At the end of the course, the students would be able to;

CO1	narrate the new product development process with significance.
CO2	describe scale up activities and justify the operations.
CO3	summarize the packaging requirements for different pharmaceutical dosage forms.
CO4	justify pre-formulation studies in pharmaceutical product development.
CO5	apply concept of technology transfer in pharmaceutical development.

Course Articulation Matrix:

	PO1	PO2	PO3	PO4	PO5	PO6	PO7	PO8	PO9	PO10	PO11
CO1	3	-	-	-	-	-	-	-	-	-	3
CO2	3	-	-	-	-	-	-	-	-	-	3
CO3	3	-	-	-	-	-	-	-	-	-	3
CO4	3	-	-	-	-	-	-	-	-	-	3
CO5	3	-	-	-	-	-	-	-	-	-	3

REFERENCES

1. The process of new drug discovery and development. I and II Edition (2006) by Charles G. Smith, James T and O. Donnell. CRC Press, Group of Taylor and Francis. Leon Lac Lachman, Herbert A. Liberman, Theory and Practice of Industrial Pharmacy. Marcel Dekker Inc. New York.

2. Sidney H Willing, Murray M, Tuckerman. Williams Hitchings IV, Good manufacturing of pharmaceuticals (A Plan for total quality control) 3rd Edition. Bhalani publishing house Mumbai.

3. Tablets Vol. I, II, III by Leon Lachman, Herbert A. Liberman, Joseph B. Schwartz, 2nd Edn. (1989) Marcel Dekker Inc. New York Anatomy and Physiology in Health and Illness by Kathleen J.W. Wilson, Churchill, Livingstone, New York.

4. Text book of Bio-Pharmaceutics and clinical Pharmacokinetics by Milo Gibaldi, 3rd Edn, Lea & Febriger, Philadelphia.

5. Pharmaceutical product development. Vandana V. Patrevale. John I. Disouza. Maharukh T.Rustomji. CRC Press, Group of Taylor and Francis.

6. Dissolution, Bioavailability and Bio-Equivalence by Abdou H.M, Mack Publishing company, Eastern Pennsylvania.

7. Remingtons Pharmaceutical Sciences, by Alfonso & Gennaro, 19th Edn.(1995)OO2C Lippincott; Williams and Wilkins A Wolters Kluwer Company, Philadelphia.

8. The Pharmaceutical Sciences; the Pharma Path way 'Pure and applied Pharmacy' by D. A Sawant, Pragathi Books Pvt. Ltd.

9. Pharmaceutical Packaging technology by D.A. Dean. E.R. Evans, I.H. Hall. 1st Edition (Reprint 2006). Taylor and Francis. London and New York.

FACULTY OF PHARMACY
Master of Pharmacy Programme
PHPQA003: Pharmaceutical Quality Assurance Practical-I (Practical)

Outline of the course: **Total hours: 180 Hr**

Sr. No.	Title of the unit
1	Analysis of Pharmacopoeial compounds in bulk and in their formulations (tablet/ capsules/ semisolids) by UV Vis spectrophotometer
2	Simultaneous estimation of multi-drug component containing formulations by UV spectrophotometry
3	Experiments based on HPLC
4	Experiments based on Gas Chromatography
5	Estimation of riboflavin/quinine sulphate by fluorimetry
6	Estimation of sodium/potassium by flame photometry or AAS Corrective
7	Case Studies on: • Total Quality Management • Six Sigma • Change Management/ Change control. Deviations, & Deviations • Out of Specifications (OOS) • Out of Trend (OOT) • Corrective & Preventive Actions (CAPA) • Deviations
8	Development of Stability study protocol
9	Estimation of process capability
10	In process and finished product quality control tests for tablets, capsules, parenteral and semisolid dosage forms
11	Assay of raw materials as per official monographs
12	Testing of related and foreign substances in drugs and raw materials
13	To carry out pre formulation study for tablets, parenteral (2 experiment)
14	To study the effect of pH on the solubility of drugs, (1 experiment)
15	Quality control tests for Primary and secondary packaging materials
16	Accelerated stability studies (1 experiment)
17	Improved solubility of drugs using surfactant systems (1 experiment)
18	Improved solubility of drugs using co-solvency method (1 experiment)
19	Determination of pKa and Log P of drugs

Course Outcome (COs):

At the end of the course, the students would be able to;

CO1	estimate the pharmaceuticals compounds form bulk and its formulation by UV-Vis spectrophotometry and fluorimetry
CO2	estimate multi-drug component containing formulations by UV spectrophotometry simultaneously.
CO3	separate the components of pharmaceutical mixture by various chromatographic techniques
CO4	perform in process and finished product quality control tests for tablets, capsules, parenterals and semisolid dosage forms
CO5	analyze the problem, communicate suggested solution and interpret the results.

Course Articulation Matrix:

	PO1	PO2	PO3	PO4	PO5	PO6	PO7	PO8	PO9	PO10	PO11
CO1	-	3	-	-	3	3	3	3	3	3	-
CO2	-	3	-	-	3	3	3	3	3	3	-
CO3	-	3	-	-	3	3	3	3	3	3	-
CO4	-	3	-	-	3	3	3	3	3	3	-
CO5	-	3	-	-	3	3	3	3	3	3	-

REFERENCE

1. Principles of Instrumental Analysis, Skoog, Hollar and Nieman, Saunders College Publishers, Philadelphia.
2. Instrumental Methods of Analysis, Willard, Merritt, Dean and Settle, CBSpublishers and Distributers, Delhi.
3. strumental Methods of Chemical Analysis, G. W. Ewing, McGraw Hill BookCo, NY.
4. Instrumental Methods of Chemical Analysis, B.K. Sharma, Goel PublicationHouse, Meerut, India.
5. John H. Kennedy, Principles of Analytical Chemistry, 2nd Edition, SaundersCollege Publishing, New York.
6. Higuchi, Bechmman and Hassan: Pharmaceutical Analysis, John Wiley and Sons,New York.
7. D. C. Garratt, The Quantitative Analysis of Drugs, CBS Publishers, New Delhi.
8. P. D. Sethi, Quantitative Analysis of Drugs in Pharmaceutical Formulation, CRC press.

9. J. W. Munson, Pharmaceutical Analysis – Modern Methods, Part – A & B, 2001.
10. United States Pharmacopoeia, United State of Pharmacopeial convention.
11. British Pharmacopoeia, 2010, The British Pharmacopoeia commission office.
12. Indian Pharmacopoeia-2007, Indian pharmacopoeia commission.
13. ICH Q2 R1: Validation of analytical procedures: text and methodology, EMEA, June 25.
14. FDA guidelines For Validation of analytical Method.

CHAROTAR UNIVERSITY OF SCIENCE &TECHNOLOGY
FACULTY OF MANAGEMENT STUDIES DEPARTMENT OF HUMANITIES AND SOCIAL SCIENCES
HS105.02 B:ACADEMIC SPEAKING AND PRESENTATION SKILLS (Sem-I)

I. Credits and Schemes:

Sem	Course Code	Course Name	Credits	Teaching Scheme	Evaluation Scheme				
				Contact Hours/ Week	Theory		Practical		Total
					Internal	External	Internal	External	
1	HS105.02 B	Academic Speaking and Presentation Skills	02	02	--	--	30	70	100

II. Course Outline

Module No.	Title/Topic	Classroom Contact Hours
1	**Foundations of Advance Communication** • *Meaning and Definition of Advance Communication* • *Advance Communication in Digital, Social, Mobile World* • *Strategies for Advance Communication* • Meaning and Concept of Academic Language • High Frequency Academic Vocabulary	**04**
2	**Art of Conversation** • *Describing people, places and things* • *Expressing opinions* • *Making suggesting* • *Persuading someone* • *Interpreting and Summarizing*	**06**
3	***Science of Power Speaking*** • *Phonemes* • *Word Stress*	**06**

	• *Pronunciation* • *Intonation* • *Pause* • *Register* • *Fluency* • *Prosody* • *Lexical Range*	
4	***Academic Speaking Application – Part I*** • *Art of Oratory* • *Formal Presentation* • *Speech Analysis – Decoding Best Speeches*	**08**
5	**Academic Speaking Application – Part II** • *Job Interview* • *Group Discussion* • *Meeting*	**06**
	Total	**30**

III. Instruction Methods and Pedagogy

The course is based on practical learning. Teaching will be facilitated by reading material, discussion, task-based learning, projects, assignments and various interpersonal activities like case studies, group work, independent and collaborative research, presentations etc.

IV. Evaluation

The students will be evaluated continuously in the form of their consistent performance throughout the semester. There is no theoretical evaluation. There is just practical evaluation. The evaluation (practical) is schemed as 30 marks for internal evaluation and 70 marks for external evaluation.

Internal Evaluation

The students' performance in the course will be evaluated on a continuous basis through the following components:

Sl. No.	Component	Number	Marks per incidence	Total Marks
1	I-Talk	1	10	25
2	Situational Speaking	1	05	
3	Case Study - Speech Analysis	2	10	
4	Attendance and Class Participation	-		05
			Total	**30**

External Evaluation

Sl. No.	Component	Number	Marks per incidence	Total Marks
1	Viva / Practical	-	70	70
			Total	**70**

Course Outcome (COs):

After completion of the course the student would:

CO1	understand and demonstrate advance communication skills and academic speaking.
CO2	demonstrate linguistic competence
CO3	demonstrate performing ability at group discussion and personal interview.
CO4	demonstrate the formal presentation skills.
CO5	demonstrate ability to communicate in diverse situations

Course Articulation Matrix:

	PO1	PO2	PO3	PO4	PO5	PO6	PO7	PO8	PO9	PO10	PO11
CO1	-	-	-	-	-	-	-	3	-	-	-
CO2	-	-	-	-	-	-	-	3	-	-	-
CO3	-	-	-	-	3	-	-	3	-	-	-
CO4	-	-	-	-	-	-	-	3	-	-	-
CO5	-	2	-	-	3	-	-	3	-	-	-

Correlation levels 1, 2 or 3 are as defined below:

1: Slight (Low) 2: Moderate (Medium) 3: Substantial (High)

V. Reference Books

- Headway Academic Skills - Level 1: Listening, Speaking and Study Skills Student's Book Paperback

VI. Reading

- **Unit 1:** Business communication Today (Thirteenth Edition) by Courtland L. Bovee,

John V. Thill and Roshan Lal Raina

- **Unit 2:** Effective Speaking Skills by Terry O' Brien **Unit 2:** Speak Better Write Better by Norman Lewis
- **Unit 2:** Well Spoken: Teaching Speaking to All Students by Erik Palmer
- **Unit 3:** Let Us Hear Them Speak : Developing Speaking – Listening Skills in English by Jayshree Mohanraj (Publisher – Sage Publication)
- **Unit 4:** The craft of scientific presentations: Critical steps to succeed and critical errors to avoid. New York: Springer by Michael Alley
- **Unit 4:** Presentation Skills in English by Bob Dignen (Publisher: Orient Black Swan)

The University Practical Examination will be for 70 marks and will test the advance communication skills and academic speaking.

FACULTY OF PHARMACY
Master of Pharmacy Programme

Syllabi
Semester II

Charotar University of Science and Technology

FACULTY OF PHARMACY
Master of Pharmacy Programme
PHPQA013: Hazard and Safety Management (Theory)

Outline of the course: Total hours: 60

Sr. No.	Title of the unit	Minimum number of hours
1	Multidisciplinary nature of environmental studies	12
2	Air based hazards	12
3	Chemical based hazards	12
4	Fire and Explosion	12
5	hazard and risk management	12

Detailed Syllabus

Sr. No.	UNIT	Hours	Weightage (%)
1.	**Multidisciplinary nature of environmental studies**	**12**	**20%**
	• Natural Resources, Renewable and non-renewable resources, Natural resources and associated problems, a) Forest resources; b) Water resources; c) Mineral resources; d) Energy resources; e) Land resources • Ecosystems: Concept of an ecosystem and Structure and function of an ecosystem. Environmental hazards: Hazards based on Air, Water, Soil and Radioisotopes.		
2.	**Air based hazards**	**12**	**20%**
	• Sources, Types of Hazards, Air circulation maintenance industry for sterile area and non-sterile area, Preliminary Hazard Analysis (PHA) Fire protection system: Fire prevention, types of fire extinguishers and critical Hazard management system.		
3.	**Chemical-based hazards**	**12**	**20%**
	• Sources of chemical hazards, Hazards of Organic synthesis, sulphonating hazard, Organic solvent hazard, Control measures for chemical hazards, Management of combustible gases, Toxic gases and Oxygen displacing gases management, Regulations for chemical hazard, Management of over-Exposure to chemicals and TLV concept.		

4.	**Fire and Explosion**	**12**	**20%**
	• Introduction, Industrial processes and hazards potential, mechanical electrical, thermal and process hazards. Safety and hazards regulations, Fire protection system: Fire prevention, types of fire extinguishers and critical Hazard management system mechanical and chemical explosion, multiphase reactions, transport effects and global rates. Preventive and protective management from fires and explosion- electricity passivation, ventilation, and sprinkling, proofing, relief systems -relief valves, flares, scrubbers.		
5.	**Hazard and risk management**	**12**	**20%**
	• Self-protective measures against workplace hazards. Critical training for risk management, Process of hazard management, ICH guidelines on risk assessment and Risk management methods and Tools Factory act and rules, fundamentals of accident prevention, elements of safety programme and safety management, Physicochemical measurements of effluents, BOD, COD, Determination of some contaminants, Effluent treatment procedure, Role of emergency services.		

Course Outcome (COs):

At the end of the course, the students would be able to;

CO1	describe the environment and related issues and suggest probable mitigation plans.
CO2	enumerate various hazards associated with the pharmaceutical industries, their management and prevention techniques.
CO3	exhibit comprehensive knowledge on the safety issues associated with the working area and suggest the practices to provide safe working environment.
CO4	describe various ways for hazard management and factory act

Course Articulation Matrix:

	PO1	PO2	PO3	PO4	PO5	PO6	PO7	PO8	PO9	PO10	PO11
CO1	-	-	-	-	-	-	-	-	3	3	3
CO2	3	3	3	3	-	-	-	-	-	-	3
CO3	3	3	-	3	-	-	3	-	-	-	3
CO4	3	3	3	3	-	-	-	-	-	-	3

REFERENCES

1. Y.K. Singh, Environmental Science, New Age International Pvt, Publishers, Bangalore
2. "Quantitative Risk Assessment in Chemical Process Industries" American Institute of Chemical Industries, Centre for Chemical Process safety.
3. Bharucha Erach, The Biodiversity of India, Mapin Pu blishing Pvt. Ltd., Ahmedabad – 380 013, India,
4. Hazardous Chemicals: Safety Management and Global Regulations, T.S.S. Dikshith, CRC press

FACULTY OF PHARMACY
Master of Pharmacy Programme
PHPQA018-Pharmaceutical Validation (Theory)

Outline of the course:

Sr. No.	Title of the unit	Minimum number of hours
1	Introduction of validation	10
	Qualification	
2	Qualification of manufacturing equipment	10
	Qualification of analytical instruments	
3	Qualification of laboratory equipment	10
4	Process validation	10
5	Cleaning validation	10
6	General Principles of Intellectual Property	10

Detailed Syllabus:

Sr. No.	UNIT	Hours	Weightage (%)
1.	**Introduction of validation**	**10**	**16.67%**
	• Definition of Calibration, Qualification and Validation, Scope, frequency and importance. Difference between calibration and validation. Calibration of weights and measures. Advantages of Validation, scope of Validation, Organization for Validation, Validation Master plan, Types of Validation, Streamlining of qualification & Validation process and Validation Master Plan.		
	Qualification		
	• User requirement specification, Design qualification, Factory Acceptance Test (FAT)/Site Acceptance Test (SAT),		

	Installation qualification, Operational qualification, Performance qualification, Re-Qualification (Maintaining status-Calibration Preventive Maintenance, Change management).		
2.	**Qualification of manufacturing equipment**	**10**	**16.67%**
	• Dry Powder Mixers, Fluid Bed and Tray dryers, Tablet Compression (Machine), Dry heat sterilization/Tunnels, Autoclaves, Membrane filtration, Capsule filling machine.		
	(b) Qualification of analytical instruments		
	• UV-Visible spectrophotometer, FTIR, DSC, GC, HPLC, HPTLC, LC-MS.		
3.	**Qualification of laboratory equipment**	**10**	**16.67%**
	• Hardness tester, Friability test apparatus, tap density tester, Disintegration tester, Dissolution test apparatus • Validation of Utility systems: Pharmaceutical water system & pure steam, HVAC system, Compressed air and nitrogen.		
4.	**Process Validation**	**10**	**16.67%**
	• Concept, Process and documentation of Process Validation. Prospective, Concurrent & Retrospective Validation, Re validation criteria, Process Validation of various formulations (Coated tablets, Capsules, Ointment/Creams, Liquid Orals and aerosols.), Aseptic filling: Media fill validation, USFDA guidelines on Process Validation- A life cycle approach. • Analytical method validation: General principles, Validation of analytical method as per ICH guidelines and USP.		
5.	**Cleaning Validation**	**10**	**16.67%**
	• Cleaning Method development, Validation of analytical method used in cleaning, Cleaning of Equipment, Cleaning of Facilities. Cleaning in place (CIP).		

	• Validation of facilities in sterile and non-sterile plant. • Computerized system validation: Electronic records and digital signature - 21 CFR Part 11 and GAMP		
6.	**General Principles of Intellectual Property**	**10**	**16.67%**
	• Concepts of Intellectual Property (IP), Intellectual Property Protection (IPP), Intellectual Property Rights (IPR); Economic importance, mechanism for protection of Intellectual Property –patents, Copyright, Trademark; Factors affecting choice of IP protection; Penalties for violation; Role of IP in pharmaceutical industry; Global ramification and financial implications. Filing a patent applications; patent application forms and guidelines. Types patent applications-provisional and non provisional, PCT and convention patent applications; International patenting requirement procedures and costs; Rights and responsibilities of a patentee; Practical aspects regarding maintaining of a Patent file; Patent infringement meaning and scope. Significance of transfer technology (TOT), IP and ethics-positive and negative aspects of IPP; Societal responsibility, avoiding unethical practices.		

Course Outcome (COs):

At the end of the course, the students would be able to

CO1	describe the concept and preparation aspect of validation and qualification in pharmaceutical industry.
CO2	differentiate qualification and validation process and narrate the process for validating various pharmaceutical instruments and equipment.
CO3	summarize the process validation for pharmaceutical dosage forms.
CO4	narrate the implementation of digital processes and cleaning process in pharmaceutical industry.

CO5	describe the concepts of Intellectual Property, patenting requirements, procedures rights & responsibilities of a patentee.

Course Articulation Matrix:

	PO1	PO2	PO3	PO4	PO5	PO6	PO7	PO8	PO9	PO 10	PO11
CO1	3	3	3	-	-	-	-	-	-	-	3
CO2	3	3	3	-	-	-	-	-	-	-	3
CO3	3	3	3	3	-	-	-	-	-	-	3
CO4	3	3	3	-	-	-	-	-	-	-	3
CO5	3	3	3	-	-	-	-	-	-	-	3

❖ **References:**

1. T. Loftus & R. A. Nash, "Pharmaceutical Process Validation", Drugs and Pharm Sci. Series, Vol. 129, 3rd Ed., Marcel Dekker Inc., N.Y.
2. The Theory & Practice of Industrial Pharmacy, 3rd edition, Leon Lachman, Herbert A. Lieberman, Joseph. L. Karig, Varghese Publishing House, Bombay.
3. Validation Master Plan by Terveeks or Deeks, Davis Harwood International publishing.
4. Validation of Aseptic Pharmaceutical Processes, 2nd Edition, by Carleton & Agalloco, (Marcel Dekker).
5. Michael Levin, Pharmaceutical Process Scale-Up‖, Drugs and Pharm. Sci. Series, Vol. 157,2nd Ed., Marcel Dekker Inc., N.Y.
6. Validation Standard Operating Procedures: A Step by Step Guide for Achieving Compliance in the Pharmaceutical, Medical Device, and Biotech Industries, Syed Imtiaz Haider.
7. Pharmaceutical Equipment Validation: The Ultimate Qualification Handbook, Phillip A. Cloud, Interpharm Press.
8. Validation of Pharmaceutical Processes: Sterile Products, Frederick J. Carlton (Ed.) and James Agalloco (Ed.), Marcel Dekker.
9. Analytical Method validation and Instrument Performance Verification by Churg Chan, Heiman Lam, Y.C. Lee, Yue. Zhang, Wiley Interscience.

10. Huber L. Validation and Qualification in Analytical Laboratories. Informa Healthcare.
11. Wingate G. Validating Corporate Computer Systems: Good IT Practice for Pharmaceutical Manufacturers. Interpharm Press.
12. LeBlanc DA. Validated Cleaning Technologies for Pharmaceutical Manufacturing. Interpharm Press.

FACULTY OF PHARMACY
Master of Pharmacy Programme
PHPQA006: Audit & Regulatory Compliance (Theory)

Outline of the course: **Total hours: 60 Hr**

Sr. No.	Title of the unit	Minimum number of hours
1	Introduction	12
2	Role of quality systems and audits in pharmaceutical manufacturing environment	12
3	Auditing of vendors and production department	12
4	Auditing of microbiology laboratory	12
5	Auditing of Quality Assurance and engineering	12

Detailed Syllabus:

Sr. No.	UNIT	Hours	Weightage (%)
1.	**Introduction**	**12**	**20%**
	Introduction: Objectives, Management of audit, Responsibilities, Planning process, information gathering, administration, Classifications of deficiencies		
2.	**Role of quality systems and audits in pharmaceutical manufacturing environment:**	**12**	**20%**
	cGMP Regulations, Qualityassurance functions, Quality systems approach, Management responsibilities, Resource, Manufacturing operations, Evaluation activities, Transitioning to quality system approach, Audit checklist for drug industries.		
3.	**Auditing of vendors and production department**	**12**	**20%**
	Bulk Pharmaceutical Chemicals and packaging material Vendor audit, Warehouse and weighing, Dry Production: Granulation, tableting, coating, capsules, sterile production and packaging.		
4.	**Auditing of microbiology laboratory**	**12**	**20%**
	Auditing the manufacturing process, Product and process information, General areas of interest in the building raw materials, Water, Packaging materials.		

5	**Auditing of Quality Assurance and engineering**	**12**	**20%**
	Quality Assurance Maintenance, Critical systems: HVAC, Water, Water for Injection systems, ETP.		

Course Outcome (COs):

At the end of the course, the students would be able to;

CO1	narrate the roles of quality system and audits in pharmaceutical environment and propose the steps of audits with significance.
CO2	describe the audit process for vendors and production department
CO3	prepare the auditing report and the check list for auditing

Course Articulation Matrix:

	PO1	PO2	PO3	PO4	PO5	PO6	PO7	PO8	PO9	PO10	PO11
CO1	3	-	-	-	-	-	-	-	-	-	3
CO2	3	-	-	-	-	-	-	-	-	-	3
CO3	3	-	-	-	-	-	-	-	-	-	3

REFERENCES

1. Compliance auditing for Pharmaceutical Manufacturers. Karen Ginsbury and Gil Bismuth, Interpharm/CRC, Boca Raton, London New York, Washington D.C.
2. Pharmaceutical Manufacturing Handbook, Regulations and Quality by ShayneCox Gad. Wiley Interscience, A John Wiley and sons, Inc., Publications.
3. Handbook of microbiological Quality control. Rosamund M. Baird, Norman A.Hodges, Stephen P. Denyar. CRC Press. 2000.
4. Laboratory auditing for quality and regulatory compliance. Donald C. Singer, Raluca-loana Stefan, Jacobus F. Van Staden. Taylor and Francis (2005).
5. ICH guideline for method validation.
6. EMEA for Bioanalytical method validation. Industrial guidelines for Bioanalytical method validation

FACULTY OF PHARMACY
Master of Pharmacy Programme
PHPQA007: Pharmaceutical Manufacturing Technology (Theory)

Total hours: 60 Hr

Outline of the course:

Sr. No.	Title of the unit	Minimum number of hours
1	Pharmaceutical industry developments	12
	Plant layout	
2	Aseptic process technology	12
3	Non sterile manufacturing process technology	12
4	Containers and closures for pharmaceuticals	12
5	Quality by design (QbD) and process analytical technology (PAT)	12

Detailed Syllabus:

Sr. No.	UNIT	Hours	Weightage (%)
1.	**Pharmaceutical industry developments, Plant layout**	**12**	**20%**
	Legal requirements and Licenses for API and formulation industry, Plant location- Factors influencing. Plant layout: Factors influencing, Special provisions, Storage space requirements, sterile and aseptic area layout. Production planning: General principles, production systems, calculation of standard cost, process planning, routing, loading, scheduling, dispatching of records, production control.		
2.	**Aseptic process technology**	**12**	**20%**
	Manufacturing, manufacturing flowcharts, in process-quality control tests for following sterile dosage forms: Ointment, Suspension and Emulsion, Dry powder, Solution (Small Volume & large Volume). Advanced sterile product manufacturing technology: Area planning & environmental control, wall and floor treatment, fixtures and machineries, change rooms, personnel flow, utilities & utilities equipment location, engineering and maintenance. Process Automation in Pharmaceutical Industry: With specific reference to manufacturing of sterile semisolids, Small Volume Parenterals & Large Volume Parenterals (SVP & LVP), Monitoring of Parenteral manufacturing facility, Cleaning in Place (CIP),		

	Sterilization in Place (SIP), Prefilled Syringe, Powdered Jet, Needle Free Injections, and Form Fill Seal Technology (FFS). Lyophilization technology: Principles, process, equipment.		
3.	**Non sterile manufacturing process technology:**	**12**	**20%**
	Manufacturing, manufacturing flowcharts, in process-quality control tests for following Non-Sterile solid dosage forms: Tablets (compressed & coated), Capsules (Hard & Soft). Advance non-sterile solid product manufacturing technology: Process Automation in Pharmaceutical Industry with specific reference to manufacturing of tablets and coated products, Improved Tablet Production: Tablet production process, granulation and palletization equipment, continuous and batch mixing, rapid mixing granulators, rota granulators, spheronizers and marumerisers, and other specialized granulation and drying equipments. Problems encountered. Coating technology: Process, equipments, particle coating, fluidized bed coating, application techniques. Problems encountered.		
4	**Containers and closures for pharmaceuticals**	**12**	**20%**
	Types, performance, assuring quality of glass; types of plastics used, Drug plastic interactions, biological tests, modification of plastics by drugs; different types of closures and closure liners; film wrapper; blister packs; bubble packs; shrink packaging; foil / plastic pouches, bottle seals, tape seals, breakable seals and sealed tubes; quality control of packaging material and filling equipment, flexible packaging, product package compatibility, transit worthiness of package, Stability aspects of packaging. Evaluation of stability of packaging material.		
5	**Quality by design (QbD) and process analytical technology (PAT):**	**12**	**20%**
	Current approach and its limitations. Why QbD is required, Advantages, Elements of QbD, Terminology: QTPP. CMA, CQA, CPP, RLD, Design space, Design of Experiments, Risk Assessment and mitigation/minimization. Quality by Design, Formulations by Design, QbD for drug products, QbD for Drug Substances, QbD for Excipients, Analytical QbD. FDA initiative on process analytical technology. PAT as a driver for improving quality and reducing costs: quality by design (QbD), QA, QC and GAMP. PAT guidance, standards and regulatory requirements.		

Course Outcome (COs):

At the end of the course, the students would be able to;

CO1	narrate pharmaceutical industry developments, plant layout and production planning
CO2	describe the principles and practices of aseptic process technology, non-sterile manufacturing technology and packaging technology with justification for adaptation.
CO3	summarize the principles of packaging and suggest various packages for pharmaceuticals with justifications.
CO4	describe principles of Quality by design (QbD) and process analytical technology (PAT) in pharmaceutical manufacturing and apply those principles in prototype conditions.

Course Articulation Matrix:

	PO1	PO2	PO3	PO4	PO5	PO6	PO7	PO8	PO9	PO10	PO11
CO1	3	3	-	-	-	-	-	-	-	-	3
CO2	3	-	-	-	-	-	-	-	3	-	3
CO3	3	-	-	-	-	-	-	-	3	-	3
CO4	3	-	-	3	-	-	-	-	-	-	3

Recommended Study Material:

- **Textbook:**

1. Lachman L, Lieberman HA, Kanig JL. The theory and practice of industrial pharmacy, 3rd ed., Varghese Publishers, Mumbai 1991.
2. Sinko PJ. Martin's physical pharmacy and pharmaceutical sciences, 5th ed., B.I. Publications Pvt. Ltd, Noida, 2006.
3. Lieberman HA, Lachman L, Schwartz JB. Pharmaceutical dosage forms: tablets Vol. I-III, 2nd ed., CBS Publishers & distributors, New Delhi, 2005.
4. Banker GS, Rhodes CT. Modern Pharmaceutics, 4th Ed. Inc, New York, 2005. Marcel Dekker
5. Sidney H Willing, Murray M, Tuckerman. Williams Hitchings IV, Good manufacturing of pharmaceuticals (A Plan for total quality control) 3rd Edition. Bhalani publishing house Mumbai.
6. Indian Pharmacopoeia. Controller of Publication. Delhi, 1996.
7. British Pharmacopoeia. British Pharmacopoeia Commission Office, London, 2008.
8. United States Pharmacopoeia. United States Pharmacopeial Convention, Inc, USA, 2003.
9. Dean D A, Evans E R and Hall I H. Pharmaceutical Packaging Technology.London, Taylor & Francis, 1st Edition. UK.
10. Edward J Bauer. Pharmaceutical Packaging Handbook. 2009. Informa Health careUSA Inc. Newyork.
11. Shaybe Cox Gad. Pharmaceutical Manufacturing Handbook. John Willey andSons, New Jersey, 2008.

FACULTY OF PHARMACY
Master of Pharmacy Programme
PHPQA008: Pharmaceutical Quality Assurance Practical-II (Practical)

Outline of the course: **Total hours: 180 Hr**

Sr. No.	Title of the unit
1	Organic contaminants residue analysis by HPLC
2	Estimation of Metallic contaminants by Flame photometer
3	Identification of antibiotic residue by TLC
4	Estimation of Hydrogen Sulphide in Air.
5	Estimation of Chlorine in Work Environment.
6	Sampling and analysis of SO2 using Colorimetric method
7	Qualification of following Pharma • Autoclave • Hot air Oven • Powder Mixer (Dry) • Tablet Compression Machine
8	Validation of an analytical method for a drug
9	Validation of a processing area
10	Qualification of at least two analytical instruments
11	Cleaning validation of one equipment
12	Qualification of Pharmaceutical Testing Equipment (Dissolution testingapparatus, Friability Apparatus, Disintegration Tester)
13	Check list for Bulk Pharmaceutical Chemicals vendors
14	Check list for tableting production
15	Check list for sterile production area
16	Check list for water for injection
17	Design of plant layout: Sterile and non-sterile
18	Case study on application of QbD
19	Case study on application of PAT

Course Outcome (COs):

At the end of the course, the students would be able to;

CO1	summarize the concept of pharmaceutical validation and carry out validation of selected equipment/instruments.
CO2	apply basic instrumental techniques in pharmaceutical analysis for assessing the quality of formulations.
CO3	apply routine statistical tools in field of pharmaceutical analysis.
CO4	qualify pharmaceutical testing instruments and manufacturing equipment.

Course Articulation Matrix:

	PO1	PO2	PO3	PO4	PO5	PO6	PO7	PO8	PO9	PO10	PO11
CO1	3	-	-	-	-	-	-	-	-	-	3
CO2	3	-	-	-	-	-	-	-	-	-	3
CO3	3	3	-	-	-	-	-	-	-	-	3
CO4	3	-	-	-	-	-	-	-	-	-	3

❖ REFERENCES

1. Principles of Instrumental Analysis, Skoog, Hollar and Nieman, Saunders CollegePublishers, Philadelphia.
2. Instrumental Methods of Analysis, Willard, Merritt, Dean and Settle, CBSpublishers and Distributers, Delhi.
3. Instrumental Methods of Chemical Analysis, G. W. Ewing, McGraw Hill Book Co, NY.
4. Instrumental Methods of Chemical Analysis, B.K. Sharma, Goel Publication House, Meerut, India.
5. John H. Kennedy, Principles of Analytical Chemistry, 2nd Edition, Saunders College Publishing, New York.
6. Higuchi, Bechmman and Hassan : Pharmaceutical Analysis, John Wiley and Sons, New York.
7. D. C. Garratt, The Quantitative Analysis of Drugs, CBS Publishers, New Delhi.
8. P. D. Sethi, Quantitative Analysis of Drugs in Pharmaceutical Formulation, CRC press.
9. J. W. Munson, Pharmaceutical Analysis – Modern Methods, Part – A & B, 2001.
10. United States Pharmacopoeia, United State of Pharmacopeal convention.
11. British Pharmacopoeia, 2010, The British Pharmacopoeia commission office.
12. Indian Pharmacopoeia-2007, Indian pharmacopoeia commission.
13. ICH Q2 R1: Validation of analytical procedures: text and methodology, EMEA, June 25.
14. FDA guidelines For Validation of analytical Method.

15. WHO guidelines For Validation of analytical Method.
16. How to perform GMP, P P Sharma, Vandana Publications, New Delhi.
17. Handbook of cosmetics: Formulation, Manufacturing and quality control, by PP sharma, Vandana Publications, New Delhi.
18. Pearson's Composition and analysis offoods, R.S.Kirk, R.sawyer, Addson Weskey, England.
19. Handbook of Forensic analysis, Fedrick P, Academic Press.

CHAROTAR UNIVERSITY OF SCIENCE &TECHNOLOGY
FACULTY OF MANAGEMENT STUDIES DEPARTMENT OF HUMANITIES AND SOCIAL SCIENCES
HS106.02 B: ACADEMIC WRITING

I. Credits and Schemes:

Sem	CourseCode	Course Name	Credits	Teaching Scheme	Evaluation Scheme				
				Contact Hours/Week	Theory		Practical		Total
					Internal	External	Internal	External	
II	HS106.02 B	Academic Writing	02	02	--	--	30	70	100

II. Course Outline

Module No.	Title / Topic	Classroom Contact Hours
1	**Academic Writing and Research Process** • *Introduction to Academic Writing* • *Academic Writing as a Part of Research* • *Types of Academic Writing* • *Features of Academic Writing* • *Importance of Good Academic Writing in various Academic Works*	**05**
2	**Anatomy of Academic Writing** • *Academic Vocabulary* • *Simple and Complex Sentences* • *Organizing Paragraphs* • *The Writing Process* • *Adopting Academic Writing Style*	**05**
3	**Key Academic Skills** • Note – taking • Note – making	**05**

	• Paraphrasing • Summarizing	
4	**Accuracy in Academic Writing** • *Lexical Range* • *Academic Language and Structures* • *Elements of Writing* • *Proof Reading, Editing, and Rewriting*	**05**
5	**Using and Citing Sources of Ideas** • *Academic Texts and their Types* • *Intellectual Honesty in Academic Writing* • *Avoiding Plagiarism – Idea Theft* • *Degrees of Plagiarism* • *Types of Borrowing* • *Anatomy of Citations* • *Common Citation Styles*	**05**
6	**Contemporary Practices in Academic Writing** • Analytical Essays • Graph / Table / Process Interpretation and Description • Writing Reports • Writing Research / Concept Papers	**05**
Total		**30**

III. Instruction Methods and Pedagogy

The course is based on practical learning. Teaching will be facilitated by reading material, discussion, task-based learning, projects, assignments and various interpersonal activities like writing, group work, independent and collaborative research, etc.

IV. Evaluation

The students will be evaluated continuously in the form of their consistent performance throughoutthe semester. There is no theoretical evaluation. There is just practical evaluation.

The evaluation (practical) is schemed as 30 marks for internal evaluation and 70 marks for external evaluation.

Internal Evaluation

The students' performance in the course will be evaluated on a continuous basis through thefollowing components:

Sl. No.	Component	Number	Marks per incidence	Total Marks
1	Paragraph Writing	1	3	03
2	Note-taking / Note-making	1	3	03
3	Paraphrasing / Summarizing	1	4	04
4	Essay Writing	1	5	05
5	Concept Paper Writing	1	10	10
5	Attendance and Class Participation			05
			Total	**30**

External Evaluation

The University Practical Examination will be for 70 marks and will test the professionalcommunication skills and academic writing skills of the students.

Sl. No.	Component	Number	Marks per incidence	Total Marks
1	Viva / Practical /Quiz/ Project / Academic Writing	-	70	70
			Total	**70**

Course Outcome (COs):

After completion of the course, the student would:

CO1	have sound understanding of the concept and applications of academic writing
CO2	have acquired enough knowledge of academic writing style, strategy and approach
CO3	be able to demonstrate error free and effective academic writing
CO4	be able to demonstrate ability to work on project/report/paper writing
CO5	understand the concept of plagiarism and learn to use different citation styles as a part of referencing

	PO1	PO2	PO3	PO4	PO5	PO6	PO7	PO8	PO9	PO10	PO11
CO1	-	-	-	-	-	-	-	3	-	-	-
CO2	-	-	-	-	-	-	-	3	-	-	-
CO3	-	-	-	-	-	-	-	3	-	-	-
CO4	-	-	-	-	-	-	-	3	-	-	-
CO5	-	-	-	-	-	-	2	-	-	-	-

Course Articulation Matrix:

Correlation levels 1, 2 or 3 are as defined below:

1: Slight (Low) 2: Moderate (Medium) 3: Substantial (High)

V. Reference Books / Reading

Essential Reading for
Concepts

- Academic Writing for International Students, Routledge
- Academic Writing: A Guide for Management Students and Researchers. Monipally, M. M. &Pawar, B. S. Sage. 2010. New Delhi

Essential Reading for Activity and Teacher Resource

- ***Effective Academic Writing Level - 1,2,3,4 (Second Edition) By:*** Alice Savage, Patricia Mayer,Masoud Shafiei, Rhonda Liss, & Jason Davis; *Publisher: Oxford*

Additional Reading

- Writing Your Thesis (2nd Edition) by Paul Oliver, Sage
- Development Communication In Practice by Vilanilam V J, Sage
- Intercultural Communication by Mingsheng Li, Patel Fay, Sage
- www.owl.perdue.edu.

FACULTY OF PHARMACY
Master of Pharmacy Programme

Syllabi
Semester III

Charotar University of Science and Technology

FACULTY OF PHARMACY
Master of Pharmacy Programme
PHCCC010: Research Methodology & Biostatistics (Theory)

Total hours: 60 Hr

Outline of the course:

Sr. No.	Title of the unit	Minimum number of hours
1	General Research Methodology	12
2	Biostatistics	12
3	Medical Research	12
4	CPCSEA guidelines for laboratory animal facility	12
5	Declaration of Helsinki	12

Detailed Syllabus:

Sr. No.	UNIT	Hours	Weightage (%)
1.	**General Research Methodology**	**12**	**20%**
	Research, objective, requirements, practical difficulties, review of literature, study design, types of studies, strategies to eliminate errors/bias, controls, randomization, crossover design, placebo, blinding techniques		
2.	**Biostatistics**	**12**	**20%**
	Definition, application, sample size, importance of sample size, factors influencing sample size, dropouts, statistical tests of significance, type of significance tests, parametric tests(students “t” test, ANOVA, Correlation coefficient, regression), non-parametric tests (wilcoxan rank tests, analysis of variance, correlation, chi square test), null hypothesis, P values, degree of freedom, interpretation of P values.		
3.	**Medical Research**		

	History, values in medical ethics, autonomy, beneficence, non-maleficence, double effect, conflicts between autonomy and beneficence/non-maleficence, euthanasia, informed consent, confidentiality, criticisms of orthodox medical ethics, importance of communication, control resolution, guidelines, ethics committees, cultural concerns, truth telling, online business practices, conflicts of interest, referral, vendor relationships, treatment of family members, sexual relationships, fatality.	**12**	**20%**
4.	**CPCSEA guidelines for laboratory animal facility**	**12**	**20%**
	Goals, veterinary care, quarantine, surveillance, diagnosis, treatment and control of disease, personal hygiene, location of animal facilities to laboratories, anesthesia, euthanasia, physical facilities, environment, animal husbandry, record keeping, SOPs, personnel and training, transport of lab animals.		
5.	**Declaration of Helsinki**	**12**	**20%**
	History, introduction, basic principles for all medical research, and additional principles for medical research combined with medical care.		

Course Outcome (COs):

At the end of the course, the students would be able to

CO1	narrate hierarchy of continue research by proper fundamental methodology.
CO2	summarize the guidelines and ethical values in medical research.
CO3	prepare protocol for Animal study.
CO4	apply the concept of design of experiments in pharmaceutical research.

Course Articulation Matrix:

	PO1	PO2	PO3	PO4	PO5	PO6	PO7	PO8	PO9	PO 10	PO11
CO1	3	-	-	-	-	-	-	-	-	-	3
CO2	3	-	-	-	-	-	-	-	-	-	3
CO3	3	-	-	-	-	-	-	-	-	-	3
CO4	3	-	-	-	-	-	-	3	-	-	3

Recommended Study Material:

❖ **References:**

1. Research In Education- John V. Best, John V. Kahn 7th edition, Published by: Phi Learning Pvt. Ltd
2. Research Methodology: Methods and Techniques. C.R. Kothari and Gaurav Garg, New Age International Publications.
3. Essentials of Research Methodology and Dissertation Writing. Kanan Yelikar, Jaypee Publishers
4. ICMR Ethical Guidelines for Biomedical Research (http://icmr.nic.in/ethical_guidelines.pdf)
5. A review of ―Scientist in legal Systems‖, Journal of Forensic Sciences (JOFS),21(2),1976.
6. Donald Menzel, Jones, Howard Mumford; Boyd, Lyle G., Writing a technical paper, J. Chem. Edu., 1962, 39 (6), p A500.
7. Mitchell, K. and Glover, T. 2001. Introduction to Biostatistics. McGraw Hill, Publishing Co.

FACULTY OF PHARMACY
Master of Pharmacy Programme
PHCCC11: Journal Club -I

Total hours: 15

Course Outcome (COs):

At the end of the course, the students would be able to

	CO
CO1	present scientific literature and interpret the finding

Course Articulation Matrix:

	PO1	PO2	PO3	PO4	PO5	PO6	PO7	PO8	PO9	PO10	PO11
CO1	3	-	3	3	-	-	-	3	-	-	3

FACULTY OF PHARMACY
Master of Pharmacy Programme
PHPQA015: Research work -I

Total hours: 420

Course Outcome (COs):

At the end of the course, the students would be able to

CO1	define and describe research problem.
CO2	illustrate project management skills such as project design, scientific information and literature access, project implementation, data analysis, and interpretation.
CO3	present a dissertation report integrating appropriate written and verbal communicative skills.
CO4	efficiently use communication and information technology tools.

Course Articulation Matrix:

	PO1	PO2	PO3	PO4	PO5	PO6	PO7	PO8	PO9	PO10	PO11
CO1	3	-	-	-	-	-	-	-	-	-	3
CO2	3	3	3	3	-	-	-	-	-	-	3
CO3	3	-	3	3	-	-	-	-	-	-	3
CO4	3	-	-	-	-	-	3	3	-	-	3

FACULTY OF PHARMACY
Master of Pharmacy Programme

Syllabi
Semester IV

CHAROTAR UNIVERSITY OF SCIENCE AND TECHNOLOGY

FACULTY OF PHARMACY
Master of Pharmacy Programme
PHCCC12: Journal Club -II

Total hours: 15

Course Outcome (COs):

At the end of the course, the students would be able to

	CO
CO1	present scientific literature and interpret the finding

Course Articulation Matrix:

	PO1	PO2	PO3	PO4	PO5	PO6	PO7	PO8	PO9	PO10	PO11
CO1	3	-	3	3	-	-	-	3	-	-	3

FACULTY OF PHARMACY
Master of Pharmacy Programme
PHPQA017: Research Work-II

Total hours: 465

Course Outcome (COs):

At the end of the course, the students would be able to

CO1	define and describe research problem.
CO2	illustrate project management skills such as project design, scientific information and literature access, project implementation, data analysis, and interpretation.
CO3	present a dissertation report integrating appropriate written and verbal communicative skills.
CO4	efficiently use communication and information technology tools.

Course Articulation Matrix:

	PO1	PO2	PO3	PO4	PO5	PO6	PO7	PO8	PO9	PO10	PO11
CO1	3	-	-	-	-	-	-	-	-	-	3
CO2	3	3	3	3	-	-	-	-	-	-	3
CO3	3	-	3	3	-	-	-	-	-	-	3
CO4	3	-	-	-	-	-	3	3	-	-	3

1.3 Learning Resources

Students can utilize library at RPCP or CHARUSAT Knowledge Resource Centre (situated in building A1)

1.4 Academic Calendar:

Ramanbhai Patel College of Pharmacy					
Charotar University of Science & Technology					
Tentative Planning for **Academic Year: 2025-2026 (Odd semester-1st Sem M.Pharm.)**					
Week	**Date**	**Day**	**No. of working days**	**WD/HD**	**Activity**
1	03.10.2025	Fri	2	WD	**COMMENCEMENT OF 1st SEMESTER OF M.Pharm.**
	04.10.2025	Sat		WD	Teaching-Learning for 1st sem M.Pharm.
	05.10.2025	Sun		HD	
2	06.10.2025	Mon	6	WD	-
	07.10.2025	Tue		WD	-
	08.10.2025	Wed		WD	Teaching-Learning for 1st sem M.Pharm.
	09.10.2025	Thu		WD	
	10.10.2025	Fri		WD	
	11.10.2025	Sat		WD	-
	12.10.2025	Sun		HD	
3	13.10.2025	Mon	5	WD	-
	14.10.2025	Tue		WD	-
	15.10.2025	Wed		WD	-
	16.10.2025	Thu		WD	Teaching-Learning for 1st sem M.Pharm.
	17.10.2025	Fri		WD	-
	18.10.2025	Sat		HD	
	19.10.2025	Sun		HD	
4	20.10.2025	Mon	0	HD	**Diwali vacation**
	21.10.2025	Tue		HD	
	22.10.2025	Wed		HD	-
	23.10.2025	Thu		HD	
	24.10.2025	Fri		HD	-
	25.10.2025	Sat		HD	

	26.10.2025	Sun		HD	
	27.10.2025	Mon	6	WD	
	28.10.2025	Tue		WD	-
	29.10.2025	Wed		WD	-
5	30.10.2025	Thu		WD	Teaching-Learning for 1st sem M.Pharm.
	31.10.2025	Fri		WD	-
	01.11.2025	Sat		WD	-
	02.11.2025	Sun		HD	
6	03.11.2025	Mon	5	WD	-
	04.11.2025	Tue		WD	-
	05.11.2025	Wed		HD	**Guru Nanak Jayanti**
	06.11.2025	Thu		WD	Teaching-Learning for 1st sem M.Pharm.
	07.11.2025	Fri		WD	-
	08.11.2025	Sat		WD	-
	09.11.2025	Sun		HD	
7	10.11.2025	Mon	6	WD	-
	11.11.2025	Tue		WD	-
	12.11.2025	Wed		WD	-
	13.11.2025	Thu		WD	Teaching-Learning for 1st sem M.Pharm.
	14.11.2025	Fri		WD	
	15.11.2025	Sat		WD	-
	16.11.2025	Sun		HD	
8	17.11.2025	Mon	6	WD	-
	18.11.2025	Tue		WD	
	19.11.2025	Wed		WD	-
	20.11.2025	Thu		WD	Teaching-Learning for 1st sem M.Pharm.
	21.11.2025	Fri		WD	
	22.11.2025	Sat		WD	
	23.11.2025	Sun		HD	
9	24.11.2025	Mon	6	WD	-
	25.11.2025	Tue		WD	-
	26.11.2025	Wed		WD	**1st Internal Examination (T/P)**
	27.11.2025	Thu		WD	Teaching-Learning for 1st sem M.Pharm.
	28.11.2025	Fri		WD	
	29.11.2025	Sat		WD	-
	30.11.2025	Sun		HD	
10	01.12.2025	Mon	6	WD	-

	02.12.2025	Tue		WD	-
	03.12.2025	Wed		WD	**1st Internal Examination (T/P)**
	04.12.2025	Thu		WD	Teaching-Learning for 1st sem M.Pharm.
	05.12.2025	Fri		WD	
	06.12.2025	Sat		WD	
	07.12.2025	Sun		HD	
11	08.12.2025	Mon	6	WD	-
	09.12.2025	Tue		WD	-
	10.12.2025	Wed		WD	-
	11.12.2025	Thu		WD	Teaching-Learning for 1st sem M.Pharm.
	12.12.2025	Fri		WD	-
	13.12.2025	Sat		WD	-
	14.12.2025	Sun		HD	-
12	15.12.2025	Mon	6	WD	-
	16.12.2025	Tue		WD	-
	17.12.2025	Wed		WD	-
	18.12.2025	Thu		WD	Teaching-Learning for 1st sem M.Pharm.
	19.12.2025	Fri		WD	-
	20.12.2025	Sat		WD	
	21.12.2025	Sun		HD	
13	22.12.2025	Mon	5	WD	-
	23.12.2025	Tue		WD	-
	24.12.2025	Wed		WD	Teaching-Learning for 1st sem M.Pharm.
	25.12.2025	Thu		HD	**Christmas**
	26.12.2025	Fri		WD	
	27.12.2025	Sat		WD	
	28.12.2025	Sun		HD	
14	29.12.2025	Mon	6	WD	-
	30.12.2025	Tue		WD	-
	31.12.2025	Wed		WD	-
	01.01.2026	Thu		WD	Teaching-Learning for 1st sem M.Pharm.
	02.01.2026	Fri		WD	-
	03.01.2026	Sat		WD	-
	04.01.2026	Sun		HD	-
15	05.01.2026	Mon	6	WD	-
	06.01.2026	Tue		WD	-
	07.01.2026	Wed		WD	-

	08.01.2026	Thu		WD	Teaching-Learning for 1st sem M.Pharm.
	09.01.2026	Fri		WD	-
	10.01.2026	Sat		WD	-
	11.01.2026	Sun		HD	-
16	12.01.2026	Mon	4	WD	-
	13.01.2026	Tue		WD	**2nd Internal Examination (P)**
	14.01.2026	Wed		HD	**Makar Sankranti (Uttarayan)**
	15.01.2026	Thu		HD	
	16.01.2026	Fri		WD	Teaching-Learning for 1st sem M.Pharm.
	17.01.2026	Sat		WD	-
	18.01.2026	Sun		HD	-
17	19.01.2026	Mon	6	WD	-
	20.01.2026	Tue		WD	-
	21.01.2026	Wed		WD	**2nd Internal Examination (T)**
	22.01.2026	Thu		WD	Teaching-Learning for 1st sem M.Pharm.
	23.01.2026	Fri		WD	-
	24.01.2026	Sat		WD	-
	25.01.2026	Sun		HD	-
18	26.01.2026	Mon	5	HD	**Republic Day**
	27.01.2026	Tue		WD	-
	28.01.2026	Wed		WD	-
	29.01.2026	Thu		WD	Teaching-Learning for 1st sem M.Pharm.
	30.01.2026	Fri		WD	-
	31.01.2026	Sat		WD	-
	01.02.2026	Sun		HD	-
19	02.02.2026	Mon	6	WD	-
	03.02.2026	Tue		WD	-
	04.02.2026	Wed		WD	**Journal Certification**
	05.02.2026	Thu		WD	Teaching-Learning for 1st sem M.Pharm.
	06.02.2026	Fri		WD	-
	07.02.2026	Sat		WD	-
	08.02.2026	Sun		HD	-
20	09.02.2026	Mon	6	WD	**CHARUSAT EXAMINATION (T/P)**
	10.02.2026	Tue		WD	
	11.02.2026	Wed		WD	
	12.02.2026	Thu		WD	
	13.02.2026	Fri		WD	
	14.02.2026	Sat		WD	

	15.02.2026	Sun		HD	
21	16.02.2026	Mon	6	WD	
	17.02.2026	Tue		WD	
	18.02.2026	Wed		WD	
	19.02.2026	Thu		WD	
	20.02.2026	Fri		WD	
	21.02.2026	Sat		WD	
	22.02.2026	Sun		HD	
22	16.02.2026	Mon	6	WD	
	17.02.2026	Tue		WD	
	18.02.2026	Wed		WD	
	19.02.2026	Thu		WD	
	20.02.2026	Fri		WD	
	21.02.2026	Sat		WD	
	22.02.2026	Sun		HD	
			116		

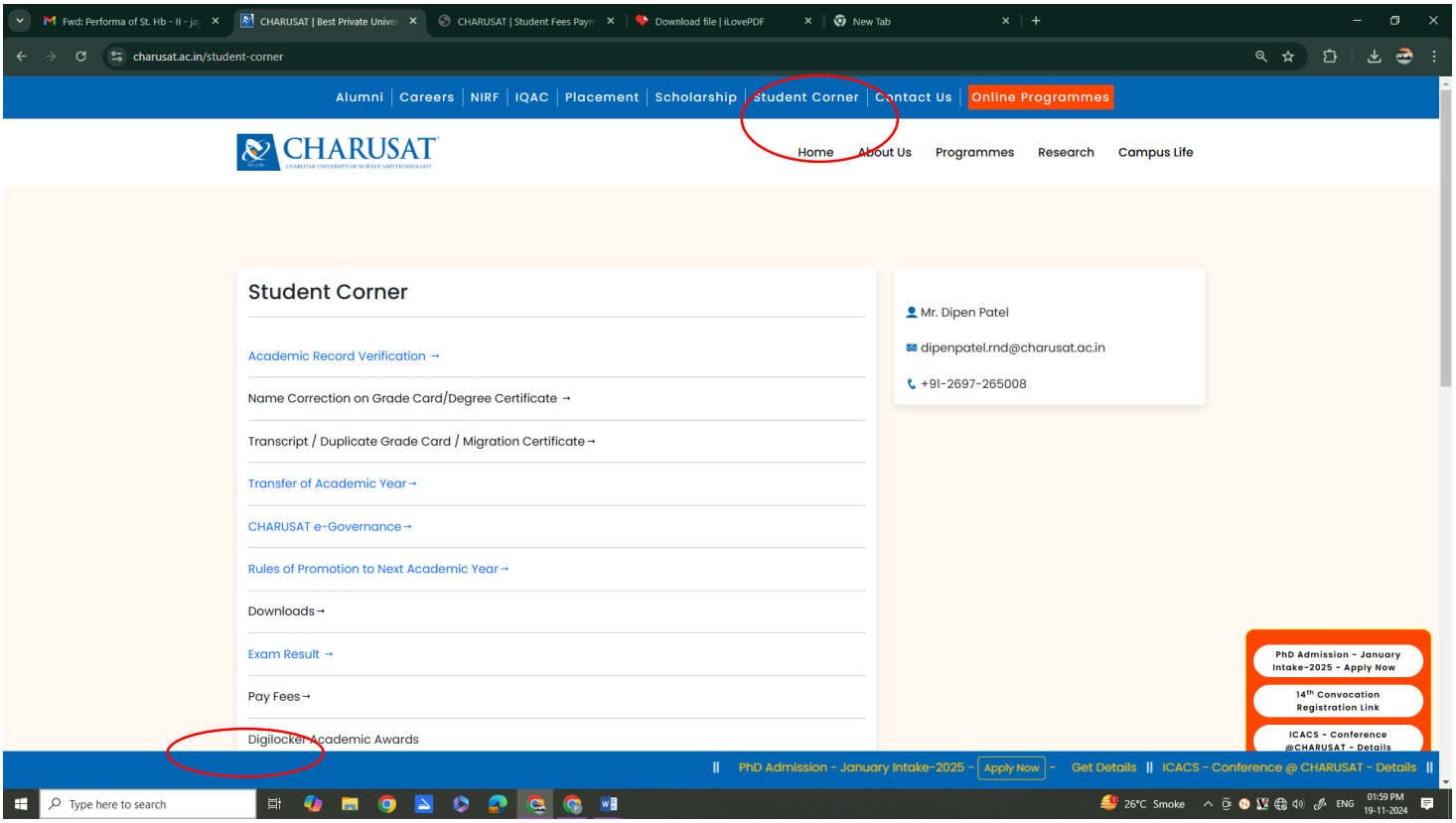
*** Schedule is tentative, subject to change**

SECTION - 2

VARIOUS ADMINISTRATIVE PROCESS

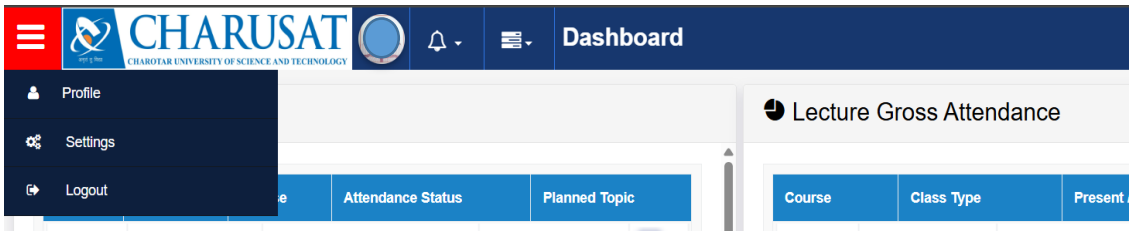
2.1 Payment of tuition fees or Other charges

Step:1	Visit University web-portal click on Pay Fees: https://charusat.edu.in:912/FeesPaymentApp/
Step:2	Enter your Student ID and Pay your Fees
Step:3	Download your fees receipt

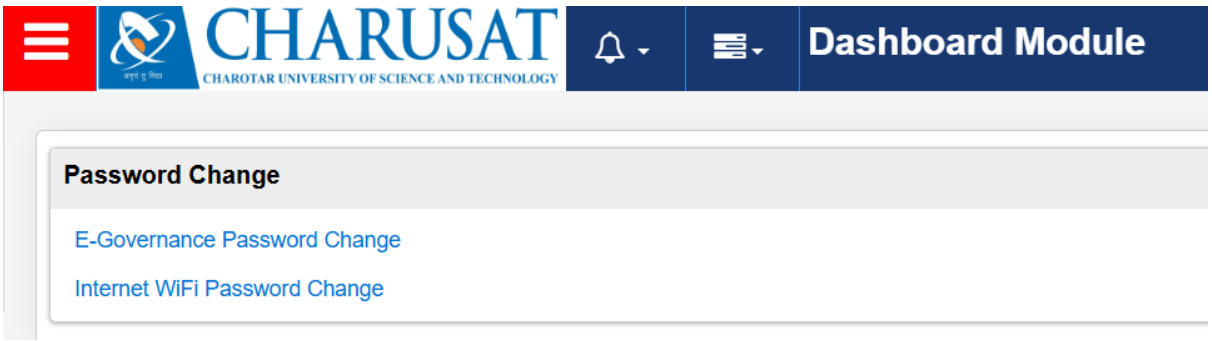


2.2 Process of Acquiring WIFI access

1. Go to e-governance website
    a. http://egov.charusat/
2. Login into your student account using e-governance login credentials
3. Go to settings tab as how in picture below



4. Click on Internet WiFi password change



5. Change the password to get access to WiFi
6. Save and remember your password

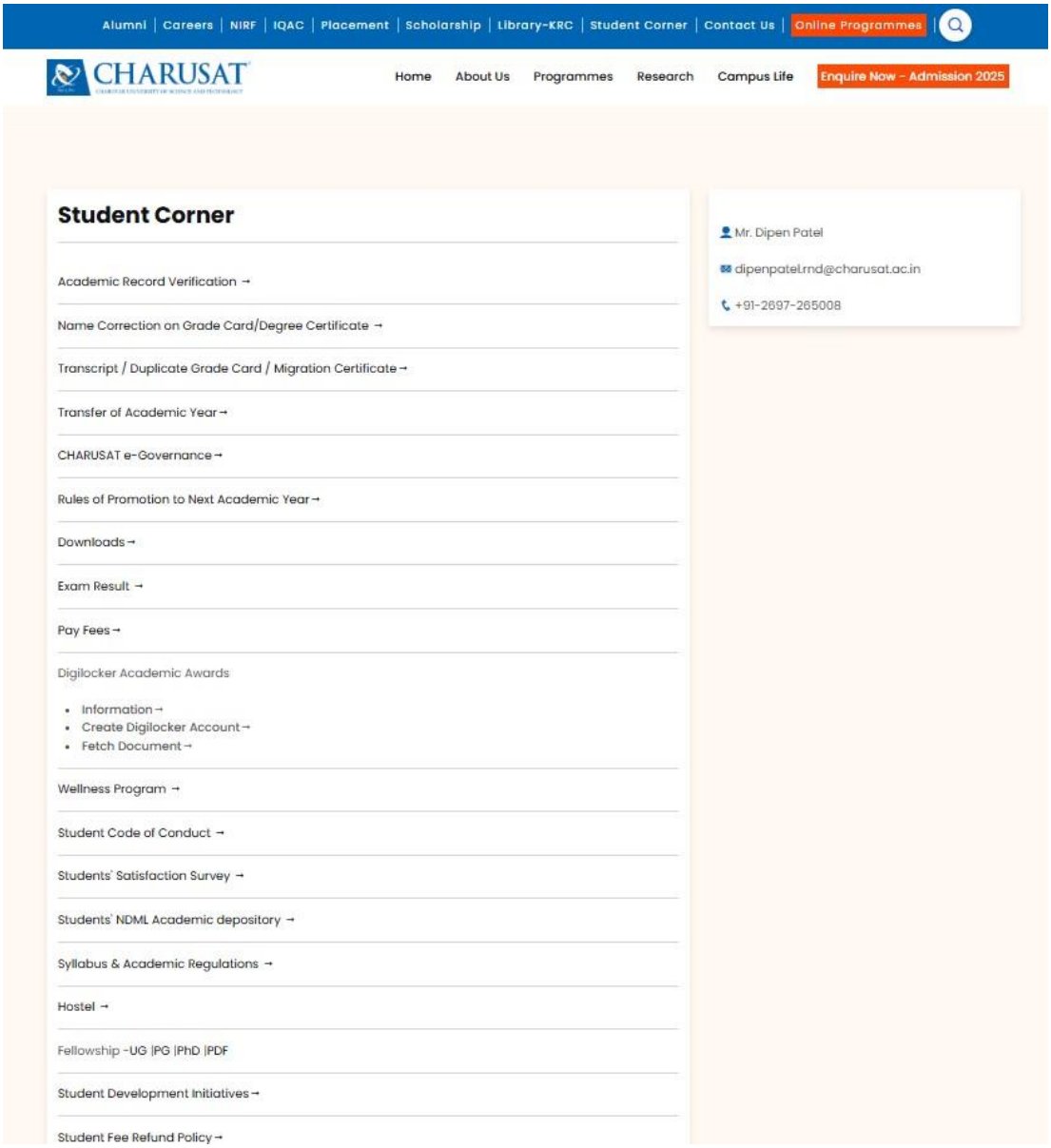
➢ Connect to wifi by authenticating your credentials on http://172.16.0.1:8090/httpclient.html

2.3 Process to obtain required Certificate from the institute

Step:1	Visit Administrative office of RPCP
Step:2	Submit an application as per your requirement along with your ID Number (via Email: principal.rpcp@charusat.ac.in)
Step:3	Collect certificate form Administrative office (Room no: 129A, RPCP)

2.4 Process to obtain required Certificate from the university office

- In order to obtain the required certificate at the University Level, students need to visit the Student Corner of the CHARUSAT University website. They can choose to apply online or offline and should ensure to include all necessary enclosures with their application. The application must be submitted to the Student Section of the University and should be duly attested by the relevant institute's HoD / Principal/ Dean. Once all the necessary procedures are completed, the certificate will be issued at the University office. (As per the below):



2.5 to 2.7 Process to obtain Duplicate Grade Card / Name Correction in Grade Card / Transcript OR E-transcript / Migration Certificate

Step:1	Online Application Request through CHARUSAT Web Portal https://www.charusat.ac.in/student-corner Select Transcript / Duplicate Grade Card / Migration Certificate Select Document Type **Migration Certificate** **Transcript/E-Transcript / WES** **Duplicate Grade Card** Enter CHARUSAT Student ID
Step:2	Pay fees at online Download Payment Receipt (for further Communication)
	University will get request after successful Payment (Time is depend on clearing of payment)
Collect the certificate within 15 days	

OR

Scan the below QR code

CHARUSAT®

CHAROTAR UNIVERSITY OF SCIENCE AND TECHNOLOGY

अमृतं तु विद्या

SCAN TO APPLY FOR

e-transcript

Duplicate Grade Card

Migration Certificate

Student will get an e-copy of the transcript on his/her CHARUSAT e-mail id withing 48 hs working after the successful payment

2.8 Process for Academic Document Verification by External Agency

Step:1	Online Application Request through CHARUSAT Web Portal https://www.charusat.ac.in/student-corner
Step:2	Select Academic Record Verification menu
Step:3	Fill required Information
Step:4	Make Payment
Step:5	Please email Transaction receipt, Student Academic Verification Details (Transcript / Degree Certificate/ Marksheet(s)) after completing the payment process.
Email ID: ***studentservices@charusat.ac.in*** **Email Subject: Academic Document Verification : < Student ID > : < Student Name >**	

SECTION - 3

UNDERTAKINGS

AND

DECLARATIONS

UNDERTAKING

(Observing Rules and Regulations of the University)

Roll No. _____

I, Mr./Ms. _____

son/daughter of _____ have secured admission at the Indukaka Ipcowala Institute of Management of CHARUSAT University in the academic year _____ for the _____ Programme. We hereby confirm that we have gone through the academic rules and regulations of the Institute very carefully and we assure you that we will abide by the same.

Student Signature : _____

Name of the Parent/Guardian : 1. _____

2. _____

Signature of the Parent/Guardian : 1. _____ 2. _____

DECLARATION
(Code of Conducts and Disciplinary Rules)

I ..... bearing roll no. …… admitted in ..... (programme) of the Institute of....., CHARUSAT University, Changa do hereby declare and undertake that I will abide by the Code of Conduct, including rules for misconduct/indiscipline by the students, provisions like dress code on the campus, rules for maintaining vehicles on the campus, public display of affection (PDA), etiquette on the campus etc.

I will abide by all the rules and regulations as and when intimated by the university and if I am found violating any rules then, I shall be subjected to the major/minor penalties as may deemed fit by the university.

Signature : _____

Name of the Parent/Guardian : 1. _____

2. _____

Signature of the Parent/Guardian : 1. _____ 2. _____

UNDERTAKING
(Observing Rules & Regulations of the Examination)

I, ... Roll No..... studying in the First year of ..... programme at Institute of ....., CHARUSAT University, Changa do hereby undertake that I have read and understood all the Rules & Regulations related to Academic Dishonesty at examinations/tests/assignments and punishment in case of using unfair means, I have also gone through the Academic Regulations related to Granting of Term and Cancellation of admission, and I shall observe, follow and abide by all these rules and regulations.

I shall abide by all the rules and regulations and if I am found violating any rules then, I shall be subjected to the necessary action/penalties as per provision of rules/regulations of the university.

Signature : _____

Name : _____

Address : _____

_____

_____

Signature of the Parent/Guardian : 1. _____ 2. _____

UNDERTAKING
(To Refrain from Consumption of Drugs and Alcohol)

I, _____ bearing Roll No._____ admitted in _____ (programme) at Institute of _____ do hereby declare and undertake that I will refrain myself from possession / consumption of Drugs and Alcohol.

I know that the use/possession of narcotics drugs and alcohol is a punishable offence under the law of the Government of Gujarat and if I am found guilty of using such thing/s, then it will amount to a criminal offence and I am liable for the appropriate penalty as per laws and also liable to cancel my admission from the university.

I hereby give an undertaking to the Institute that I will refrain myself from possession or consumption of Drugs and Alcohol in and around the campus.

Date :

Place :

_____

Signature of Student

I undertake that I will take utmost care to see that my ward does not get involved in any such incident.

Name of the Parent/Guardian : 1. _____

2. _____

Signature of the Parent/Guardian : 1. _____ 2. _____

Address of Parent/ Guardian : _____

_____

Contact no of Parent/ Guardian : 1. _____ 2. _____

4. IMPORTANT CONTACTS

+91-02697-265011 (Last 4 digits: Extension number)

Name and Designation	Extension number & Email-id
Dr. Samir Patel Dean - Faculty of Pharmacy,	5161 dean.fph@charusat.ac.in
Dr. Manan Raval Principal, RPCP	5141 principal.rpcp@charusat.ac.in
Mr. Jaydeep Parmar P.A to Principal	5151 jaydeepparmar.ph@charusat.ac.in
Dr. Meghna Mehta Librarian	5145 meghanamehta.ph@charusat.ac.in
Mr. Jaydeep Parmar Student Section, RPCP	5151 jaydeepparmar.ph@charusat.ac.in
Shri Mukesh Yadav Dy. Registrar, Academic Section	5029 mukeshyadav.adm@charusat.ac.in
Ms. Manisha Patel Chief Finance Officer, Accounts Section	5007 cfo@charusat.ac.in
Shri Mitesh Patel Assistant Registrar, Students Section (University office)	5038 studentservices@charusat.ac.in
Dr. Abhilash Shukla Examination Section	----- abhilashshukla.mca@charusat.ac.in
Dr. Ritesh Patel Coordinator, E-governance	5251 coordinator.egov@charusat.ac.in
Shri Ritesh Bhatt WIN Cell Coordinator	5106 riteshbhatt.win@charusat.ac.in
Mr. Sujal Dadhaniya Corporate Development & Placement Cell	5213 tpo@charusat.ac.in,tnp@charusat.ac.in
Dr. Dilip Gosai Head, Charusat Rural Education Development Programme	5160 head.credp@charusat.ac.in
Dr. Gayatri Dave Chairperson, Women Development Cell	5197 gayatridave.bt@charusat.ac.in
Dr. Mrunali Patel Chairperson, Internal Complaint Committee	5163 chairperson.icc@charusat.ac.in
Dr. Vijay Panchal Head, Equal Opportunity Cell	5081 vijaypanchal.cv@charusat.ac.in
Shri Mukesh Patel Nodal Officer of Student Grievance Redressal Cell	5029 nodalofficergrc@charusat.ac.in
Dr. Vijaykumar Chaudhary Convenor, Anti-ragging Cell	5221 vijaychaudhary.me@charusat.ac.in