CHARUSAT
CHAROTAR UNIVERSITY OF SCIENCE AND TECHNOLOGY

STUDENT INFORMATION BOOKLET FOR THE ACADEMIC YEAR 2025-26

VOLUME – 2 : M.Pharm (Regulatory Affairs)

Ramanbhai Patel College of Pharmacy

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

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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 (Regulatory Affairs)

1.1 Academic Regulation

&

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

ACADEMIC REGULATIONS & SYLLABUS

Faculty of Pharmacy
Master of Pharmacy Programme
(Regulatory Affairs)

(AS PER PCI SYLLABUS)

A. Y. 2023 - 2024

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; behavioural, 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, analyse, 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 fulfilment 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, analyse 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 behaviour 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/
II and IV	May / June	After 15 days of the declaration of the result of the end semester Examination	end of the Academic Year, which is earlier

* 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 Ist semesters till the IInd semester examinations. However, he/she shall not be eligible to attend the courses of the IIIrd semester until all the courses of the Ist and IInd 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 (REGULATORY AFFAIRS)
PROGRAMME
Schemes for internal assessments and end semester

examinations SEMESTER-I

SCHEME OF TEACHING

Course Code	Course Name	Credit Hours	Credit Points	Hrs/Week
PHRGA001	Good Regulatory Practices	4	4	4
PHRGA013	Documentation and Regulatory Writing	4	4	4
PHRGA003	Clinical Research Regulations	4	4	4
PHRGA014	Legislative Regulations of Health Products in India and IPR	4	4	4
PHRGA004	Regulatory Affairs Practical-I	12	6	12
PHRGA005	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				
PHRGA001	Good Regulatory Practices	10	15	1Hr	25	75	3Hrs	100
PHRGA013	Documentation and Regulatory Writing	10	15	1Hr	25	75	3Hrs	100
PHRGA003	Clinical Research Regulations	10	15	1Hr	25	75	3Hrs	100
PHRGA014	Legislative Regulations of Health Products in India and IPR	10	15	1Hr	25	75	3Hrs	100
PHRGA004	Regulatory Affairs Practical-I	20	30	6Hrs	50	100	6Hrs	150
PHRGA005	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 (REGULATORY AFFAIRS)
PROGRAMME
Schemes for internal assessments and end semester

examinations SEMESTER-II

SCHEME OF TEACHING

Course Code	Course Name	Credit Hours	Credit Points	Hrs/Week
PHRGA006	Regulatory Aspects of Drugs & Cosmetics	4	4	4
PHRGA015	Regulatory Aspects of Herbal and Biologicals	4	4	4
PHRGA016	Regulatory Aspects of Medical Devices	4	4	4
PHRGA017	Regulatory Aspects of Food & Nutraceuticals	4	4	4
PHRGA009	Regulatory Affairs Practical-II	12	6	12
PHRGA010	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				
PHRGA006	Regulatory Aspects of Drugs & Cosmetics	10	15	1Hr	25	75	3Hrs	100
PHRGA015	Regulatory Aspects of Herbal and Biologicals	10	15	1Hr	25	75	3Hrs	100
PHRGA016	Regulatory Aspects of Medical Devices	10	15	1Hr	25	75	3Hrs	100
PHRGA017	Regulatory Aspects of Food & Nutraceuticals	10	15	1Hr	25	75	3Hrs	100
PHRGA009	Regulatory Affairs Practical-II	20	30	6Hrs	50	100	6Hrs	150
PHRGA010	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 (REGULATORY AFFAIRS)
PROGRAMME
Schemes for internal ssessments and end semester examinations

SEMESTER-III

* Non University Exam

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
PHRGA018	Discussion / Presentation (Proposal Presentation)	2	2	2
PHRGA019	Research Work-I	28	14	28
	Total	**35**	**21**	**35**

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
PHRGA018	Discussion / Presentation (Proposal Presentation)	-	-	-	50	-	-	50
PHRGA019	Research Work- I	-	-	-	-	350	1 Hr	350
Total								525

CHAROTAR UNIVERSITY OF SCIENCE & TECHNOLOGY
MASTER OF PHARMACY (REGULATORY AFFAIRS)
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
PHRGA020	Discussion/ Presentation	3	3	3
PHRGA021	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
PHRGA020	Discussion/ Presentation	-	-	-	75	-	-	75
PHRGA021	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
PHRGA001: GOOD REGULATORY PRACTICES (Theory)

Total hours: 60 Hr

Outline of the course:

Sr. No.	Title of the unit	Minimum number of hours
1	Current Good Manufacturing Practices	12
2	Good Laboratory Practices	12
3	Good Automated Laboratory Practices	12
4	Good Distribution Practices	12
5	Quality management systems	12

Detailed Syllabus:

Sr. No.	UNIT	Hours	Weightage (%)
1.	**Current Good Manufacturing Practices**	**12**	**20%**
	Introduction, US cGMP Part 210 and Part 211.EC Principles of GMP (Directive 91/356/EEC) Article 6 to Article 14 and WHO cGMP guidelines GAMP-5; Medical device and IVDs Global Harmonization Task Force (GHTF) Guidance docs.		
2.	**Good Laboratory Practices**	**12**	**20%**
	Introduction, USFDA GLP Regulations (Subpart A to Subpart K), Controlling the GLP inspection process, Documentation, Audit, goals of Laboratory Quality Audit, Audit tools, Future of GLP regulations, relevant ISO and Quality Council of India(QCI) Standards.		
3.	**Good Automated Laboratory Practices**	**12**	**20%**
	Introduction to GALP, Principles of GALP, GALP Requirements, SOPs of GALP, Training Documentation,21 CFR Part 11, General check list of 21CFR Part 11, Software Evaluation checklist, relevant ISO and QCI Standards.		
4.	**Good Distribution Practices**	**12**	**20%**

	Introduction to GDP, Legal GDP requirements put worldwide, Principles, Personnel, Documentation, Premises and Equipment, Deliveries to Customers, Returns, Self-Inspection, Provision of information, Stability testing principles, WHO GDP, USP GDP (Supply chain integrity), relevant CDSCO guidance and ISO standards.		
5.	**Quality Management Systems**	**12**	**20%**
	Concept of Quality, Total Quality Management, Quality by design, Six Sigma concept, Out of Specifications (OOS), Change control. Validation: Types of Validation, Types of Qualification, Validation master plan (VMP), Analytical Method Validation. Validation of utilities, [Compressed air, steam, water systems, Heat Ventilation and Air conditioning (HVAC)] and Cleaning Validation. The International Conference on Harmonization (ICH) process, ICH guidelines to establish quality, safety and efficacy of drug substances and products, ISO 13485, Sch MIII and other relevant CDSCO regulatory guidance documents.		

Course Outcome (COs):

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

CO1	Prepare checklists and SOPs for various good regulatory practices
CO2	Categorize the key regulatory and compliance elements with respect to GMP
CO3	Categorize the key regulatory and compliance elements with respect to GLP
CO4	Categorize the key regulatory and compliance elements with respect to GALP and GDP
CO5	Describe the quality management system in the Pharmaceutical Industry

Course Articulation Matrix:

	PO1	PO2	PO3	PO4	PO5	PO6	PO7	PO8	PO9	PO 10	PO 11
CO1	3	-	3	-	-	-	-	-	3	-	3
CO2	3	-	3	-	-	-	-	-	3	-	3
CO3	3	-	3	-	-	-	-	-	3	-	3
CO4	3	-	3	-	-	-	-	-	3	-	3
CO5	3	-	3	-	-	-	-	-	3	-	3

Recommended Study Material:

- **Text book:**

1.Good Laboratory Practice Regulations, by Sandy Weinberg, Fourth Edition Drugs and the Pharmaceutical Sciences, Vol.168

2.Good Pharmaceutical Manufacturing practice, Rational and compliance by John Sharp, CRC Press

3.Establishing a cGMP Laboratory Audit System, A practical Guide by David M.Bleisner, Wiley Publication.

4.How to practice GLP by PP Sharma, Vandana Publications.

5.Laboratory Auditing for Quality and Regulatory compliance by Donald C.Singer, Drugs and the Pharmaceutical Sciences, Vol.150.

6.Drugs and Cosmetics Act, 1940 and its rules, published by Ministry of health and family welfare, Government of India.

7.Good Drug Regulatory Practices: a Regulatory Affairs Quality Manual (Good Drug Development Series) – Helene I. Dumitriu.

8.WHO GMP guidelines

9.FDA GMP guidelines

10.The Quality Management Sourcebook: An International Guide to Materials and Resources By Christine Avery; Diane Zabel, Routledge, 1997

11.Pharmaceutical facilities, design, layouts and validation, Manohar A. Potdar, PharmaMed Press, Hyderabad.

12.Remington: The Science and Practice of Pharmacy, Vol-I & II, Gennaro, Alfonso R.,

13.Guidelines on cGMP and Quality of Pharmaceutical Products, S.Iyer, D.K.Publications, Mumbai.

14.A manual of laboratory techniques by N.Raghuramulu

15.Good laboratory practice- the Why and the How; by Jurg P. ,Seiler,Springer.

FACULTY OF PHARMACY
MASTER OF PHARMACY
PROGRAMME
PHRGA013: DOCUMENTATION AND REGULATORY WRITING
(Theory)

Total hours: 60 Hr

Outline of the course:

Sr. No.	Title of the unit	Minimum number of hours
1	Documentation in Pharmaceutical industry	12
2	Dossier preparation and submission	12
3	Audits	12
4	Inspections	12
5	Product life cycle management	12

Detailed Syllabus:

Sr. No.	UNIT	Hours	Weightage (%)
1.	**Documentation in Pharmaceutical industry**	**12**	**20%**
	Exploratory Product Development Brief (EPDB) for Drug substance and Drug product, Product Development Plan (PDP), Product Development Report (PDR), Master Formula Record, Batch Manufacturing Record and its calculations, Batch Reconciliation, Batch Packaging Records, Print pack specifications, Distribution records, Certificate of Analysis (CoA), Site Master File and Drug Master Files		
2.	**Dossier preparation and submission**	**12**	**20%**
	Introduction and overview of dossiers, contents and organization of dossier, binders and sections, compilation and review of dossier. Paper submissions, overview and modules of CTD, electronic CTD submissions; Electronic submission: Planning electronic submission, requirements for submission, regulatory bindings and requirements, Tool and Technologies, electronic dossier submission process and validating the submission, Electronic Submission Gateway (ESG). Non eCTD electronic submissions (NeeS), Asian CTD formats (ACTD) submission. Organizing, process and validation of submission. Submission in Sugam system of CDSCO.		
3.	**Audits**	**12**	**20%**

	Introduction, Definition, Summary, Types of audits, GMP compliance audit, Audit policy, Internal and External Audits,		
	Second Party Audits, External third-party audits, Auditing strategies, Preparation and conducting audit, Auditing strategies, audit analysis, audit report, audit follow up. Auditing/inspection of manufacturing facilities by regulatory agencies. Timelines for audits/inspection. GHTF study group 4 guidance document. ISO 13485.		
4.	**Inspections**	**12**	**20%**
	Pre-approval inspections, Inspection of pharmaceutical manufacturers, Inspection of drug distribution channels, Quality systems requirements for national good manufacturing practice inspectorates, inspection report, model certificate of good manufacturing practices, Root cause analysis, Corrective and Preventive action (CAPA). GMP guidelines of Inspection.		
5.	**Product lifecycle management**	**12**	**20%**
	Prior Approval Supplement (PAS), Post Approval Changes [SUPAC], Changes Being Effected in 30 Days (CBE-30), Annual Report, Post marketing Reporting Requirements, Post approval Labelling Changes, Lifecycle Management, FDA Inspection and Enforcement, Establishment Inspection Report (EIR), Warning Letters, Recalls, Seizure and Injunctions. ISO Risk Management Standard.		

Course Outcome (COs):

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

CO1	Describe the significance of various documents pertaining to drugs in pharmaceutical industry
CO2	Narrate the basics of regulatory compilation in format laid down by Regulatory agencies
CO3	Create and assemble the regulation submission as per the requirements of agencies
CO4	Prepare the checklist of audit and to understand the guidelines of inspections.
CO5	Describe and apply follow up the submissions and post approval document requirements

Course Articulation Matrix:

	PO1	PO2	PO3	PO4	PO5	PO6	PO7	PO8	PO9	PO 10	PO 11
CO1	-	-	-	-	-	3	-	-	-	-	3
CO2	-	-	-	-	-	3	-	-	3	-	3
CO3	-	3	-	3	-	3	-	-	-	-	3
CO4	-	3	-	3	-	3	3	-	-	-	3
CO5	-	-	-	-	-	3	-	-	-	-	3

Recommended Study Material:

❖ **Textbook:**

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 Shayne Cox 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. Implementing Juran's Road Map for Quality Leadership: Benchmarks and Results, By Al Endres, Wiley, 2000
6. Understanding, Managing and Implementing Quality: Frameworks, Techniques and Cases, By Jiju Antony; David Preece, Routledge, 2002
7. 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
8. Corporate Culture and the Quality Organization By James W. Fairfield- Sonn, Quorum Books, 2001
9. The Quality Toolbox, Second Edition, Nancy R. Tague, ASQ Publications
10. Root Cause Analysis, The Core of Problem Solving and Corrective Action, Duke Okes, 2009, ASQ Publications
11. www.ich.org/
12. www.fda.gov/
13. europa.eu/index_en.htm
14. https://www.tga.gov.au/tga-basics

15. Thesis projects in Science & Engineering – Richard M. Davis. New York: St. Martin's Press, 1980.
16. Preparing for publication: A Style Book for Authors, Editors, Compilers and Typists – King Edward Hospital Fund for London.
17. A review of ―Scientist in legal Systems‖, Journal of Forensic Sciences (JOFS),21(2),1976.
18. Donald Menzel, Jones, Howard Mumford; Boyd, Lyle G., Writing a technical paper, J. Chem. Edu., 1962, 39 (6), p A500
19. Effective Business Report Writing –Leland Brown, 2nd Edition, Prentice-Hall, Englewood Cliffs, New Jersey, 1963.

FACULTY OF PHARMACY
MASTER OF PHARMACY
PROGRAMME
PHRGA003: CLINICAL RESEARCH REGULATIONS (Theory)

Total hours: 60 Hr

Outline of the course:

Sr. No.	Title of the unit	Minimum number of hours
1	Clinical Drug Development Process	12
2	Ethics in Clinical Research	12
3	Regulations governing Clinical Trials	12
4	Clinical Research Related Guidelines	12
5	USA & EU Guidance	12

Detailed Syllabus:

Sr. No.	UNIT	Hours	Weightage (%)
1.	**Clinical Drug Development Process**	**12**	**20%**
	Different types of Clinical Studies • Phases of clinical trials, Clinical Trial protocol • Phase 0 studies • Phase I and subtype studies (single ascending, multiple ascending, dose escalation, methods, food effect studies, drug – drug interaction, PK end points • Phase II studies (proof of concept or principle studies to establish efficacy) • Phase III studies (Multi ethnicity, global clinical trial, registration studies) • Phase IV studies (Post Marketing Studies; PSUR) • Clinical Investigation and Evaluation of Medical Devices & IVDs Different Types of Studies Key Concepts of Medical Device Clinical Evaluation. Key concepts of Clinical Investigation		

2.	**Ethics in Clinical Research**	**12**	**20%**
	Historical Perspectives: Nuremberg Code, Thalidomide study, Nazis Trials, Tuskegee Syphilis Study, The Belmont Report, The declaration of Helsinki • Origin of International Conference on Harmonization – Good Clinical Practice (ICH-GCP) guidelines. • The ethics of randomized clinical trials • The role of placebo in clinical trials • Ethics of clinical research in special population • Institutional Review Board/Independent Ethics Committee/Ethics Committee – composition, roles, responsibilities, review and approval process and ongoing		
	monitoring of safety data • Data safety monitoring boards. • Responsibilities of sponsor, CRO, and investigator in ethical conduct of clinical research		
3.	**Regulations Governing Clinical Trials**	**12**	**20%**
	India: Clinical Research regulations in India – Schedule Y & Medical Device Guidance USA: Regulations to conduct drug studies in USA (FDA) • NDA 505(b)(1) of the FD&C Act (Application for approval of a new drug) • NDA 505(b)(2) of the FD&C Act (Application for approval of a new drug that relies, at least in part, on data not developed by the applicant) • ANDA 505(j) of the FD&C Act (Application for approval of a generic drug product) • FDA Guidance for Industry - Acceptance of Foreign Clinical Studies • FDA Clinical Trials Guidance Document: Good Clinical Practice EU: Clinical Research regulations in European Union (EMA) • Ethical principles governing informed consent process • Patient Information Sheet and Informed Consent Form • The informed consent process and documentation		
4.	**Clinical Research Related Guidelines**	**12**	**20%**
	Good Clinical Practice Guidelines (ICH GCP E6) • Indian GCP Guidelines • ICMR Ethical Guidelines for Biomedical Research • CDSCO guidelines GHTF study group 5 guidance documents Regulatory Guidance on Efficacy and Safety ICH Guidance's • E4 – Dose Response Information to support Drug Registration • E7 – Studies in support of General Population: Geriatrics • E8 – General Considerations of Clinical Trials • E10 – Choice of Control Groups and Related Issues in Clinical Trials, • E 11 – Clinical Investigation of Medicinal Products in the Paediatric Population • General biostatics principle applied in clinical		

	research		
5.	**USA & EU Guidance**	**12**	**20%**
	USA: FDA Guidance • CFR 21Part 50: Protection of Human Subjects • CFR 21Part 54: Financial Disclosure by Clinical Investigators • CFR 21Part 312: IND Application • CFR 21Part 314: Application for FDA Approval to Market a New Drug • CFR 21Part 320: Bioavailability and bioequivalence requirements • CFR 21Part 812: Investigational Device Exemptions • CFR 21Part 822: Post-market surveillance • FDA Safety Reporting Requirements for INDs and BA/BE Studies • FDA Med Watch •		
	Guidance for Industry: Good Pharmacovigilance Practices and Pharmaco-epidemiologic Assessment European Union: EMA Guidance • EU Directives 2001 • EudraLex (EMEA) Volume 3 – Scientific guidelines for medicinal products for human use • EU Annual Safety Report (ASR) • Volume 9A – Pharmacovigilance for Medicinal Products for Human Use • EU MDD with respect to clinical research • ISO 14155		

Course Outcome (COs):

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

CO1	Know history, origin and ethics of clinical and biomedical research and evaluation.
CO2	Narrate the development process for drug and medical devices and phases of clinical trials with significance.
CO3	Appreciate and narrate appropriate process for approval of clinical trial protocols in different populations as well as in different regions of the world
CO4	Describe and apply regulatory requirements and guidance for conduct of clinical trials and clinical research as per the guidelines proposed by Indian, US and European regulatory agencies
CO5	Compare and differentiate various regulations pertaining to conduct of clinical trial protocols and studies in different countries

Course Articulation Matrix:

	PO1	PO2	PO3	PO4	PO5	PO6	PO7	PO8	PO9	PO 10	PO 11
CO1	3	-	-	-	-	3	3	-	-	-	3
CO2	3	-	-	-	-	3	3	-	-	-	3
CO3	3	-	-	-	-	3	3	-	-	-	3
CO4	3	3	-	-	-	3	-	-	3	-	3
CO5	3	3	3	-	-	3	-	-	3	-	3

Recommended Study Material:

- **Textbook:**

1. Clinical Trials and Human Research: A Practical Guide to Regulatory Compliance By Fay A. Rozovsky and Rodney K. Adams
2. HIPAA and Human Subjects Research: A Question-and-Answer Reference Guide By Mark Barnes, JD, LLM and Jennifer Kulynych, JD, PhD
3. Principles and Practices of Clinical Research, Second Edition Edited by John I. Gallin and Frederick P. Ognibene
4. Reviewing Clinical Trials: A Guide for the Ethics Committee; Johan PE Karlberg and Marjorie A Speers; Karlberg, Johan Petter Einar, Hong Kong.
5. International Pharmaceutical Product Registration: Aspects of Quality, Safety and Efficacy; Anthony C. Cartwright; Taylor & Francis Inc., USA.
6. New Drug Approval Process: The Global Challenge; Guarino, Richard A; Marcel Dekker Inc., NY.
7. FDA regulatory affairs: a guide for prescription drugs, medical devices, and biologics; Douglas J. Pisano, David Mantus; CRC Press, USA
8. Country Specific Guidelines from official websites.
9. Textbook on clinical research: A guide for Aspiring professionals and Professionals, Guru Prasad Mohanta, Pharma med press.
10. Schedule Y of Drugs and Cosmetics act
11. Clinical trials of drugs & biopharmaceuticals; Chi-Jen Lee, Lucia H. Lee, Christopher L. Wu, Benjamin R. Lee, Mei-Ling Chen, CRC press
12. Drug Screening Methods by S.K.Gupta
13. Basic Principles of clinical Research & Technology by S.K.Gupta
14. International Medical Device Regulators Forum (IMDRF) Medical Device Single Audit Program (MDSAP)

FACULTY OF PHARMACY
MASTER OF PHARMACY
PROGRAMME

PHRGA014: LEGISLATIVE REGULATIONS OF HEALTH PRODUCTS IN INDIA AND INTELLECTUAL PROPERTY RIGHTS (Theory)

Total hours: 60 Hr

Outline of the course:

Sr. No.	Title of the unit	Minimum number of hours
1	Biologicals & Herbals, and Food & Nutraceuticals Acts and Rules (with latest amendments)	12
2	Regulatory requirements and approval procedures for Drugs & Cosmetics Medical Devices, Biologicals & Herbals, and Food & Nutraceuticals	12
3	Indian Pharmacopoeia Standards, BIS standards and ISO and other relevant standards	12
4	Bioavailability and Bioequivalence data (BA &BE), BCS Classification of Drugs, Regulatory Requirements for Bioequivalence study Stability requirements: ICH and WHO	12
5	Intellectual Property Rights: Patent, Trademark, Copyright, Industrial Designs and Geographical Indications, Indian Patent Scenario. IPR vs Regulatory	12

Detailed Syllabus:

Sr. No.	UNIT	Hours	Weightage (%)
1.	Biologicals & Herbals, and Food & Nutraceuticals Acts and Rules (with latest amendments)	**12**	**20%**

	1. Drugs and Cosmetics Act 1940 and Rules 1945: DPCO and NPPA 2. Other relevant provisions (rules schedules and guidelines for approval of Drugs & Cosmetics, Medical Devices, Biologicals & Herbals, and Food & Nutraceuticals in India Other relevant Acts: Narcotics Drugs and Psychotropic Substances Act; Medicinal and Toilet Preparations (Excise Duties) Act, 1955; Pharmacy Act, 1948; Drugs and Magic Remedies (Objectionable Advertisements) Act, 1955; Prevention of Cruelty to Animals Act.		
2.	Regulatory requirements and approval procedures for Drugs & Cosmetics Medical Devices, Biologicals & Herbals, and Food & Nutraceuticals	**12**	**20%**
	CDSCO (Central Drug Standard Control Organization) and State Licensing Authority: Organization, Responsibilities • Rules, regulations, guidelines and standards for regulatory filing of Drugs & Cosmetics, Medical Devices, Biologicals & Herbals, and Food & Nutraceuticals • Format and contents of Regulatory dossier filing Clinical trial/ investigations		
3.	Indian Pharmacopoeial Standards, BIS standards and ISO and other relevant standards	**12**	**20%**
4.	Bioavailability and Bioequivalence data (BA &BE), BCS Classification of Drugs, Regulatory Requirements for Bioequivalence study Stability requirements: ICH and WHO	**12**	**20%**
	Guidelines for Drug testing in animals/Preclinical Studies Animal testing: Rationale for conducting studies, CPCSEA Guidelines Ethical guidelines for human participants ICMR-DBT Guidelines for Stem Cell Research		
5.	Intellectual Property Rights: Patent, Trademark, Copyright, Industrial Designs and Geographical Indications, Indian Patent Scenario. IPR vs Regulatory	**12**	**20%**

Course Outcome (COs):

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

CO1	Know different acts and guidelines that regulate Drugs & Cosmetics, Medical Devices, Biologicals & Herbals, and Food & Nutraceuticals industry in India.
CO2	Understand the approval process and regulatory requirements for Drugs & Cosmetics, Medical Devices, Biologicals & Herbals, and Food & Nutraceuticals

CO3	Narrate the basics of regulatory requirements for bioequivalence and stability as per ICH and WHO
CO4	Describe the standards laid down by Indian pharmacopoeia, BIS and ISO
CO5	Describe the concept of intellectual properties as per the laws, components of patent applications and requirements to obtain the patent.

Course Articulation Matrix:

	PO1	PO2	PO3	PO4	PO5	PO6	PO7	PO8	PO9	PO 10	PO 11
CO1	3	-	-	-	-	3	-	-	-	-	3
CO2	3	-	-	-	-	3	-	-	3	-	3
CO3	3	-	-	-	-	3	-	-	3	-	3
CO4	3	-	-	-	-	3	3	-	3	-	3
CO5	3	-	-	-	-	-	-	-	3	-	3

Recommended Study Material:

1) Manual of Patent Practice & Procedure, 3rd Edition, by The Patent Office of India
2) Patent Failure How Judges, Bureaucrats, and Lawyers put innovators at risk by James Bessen and Michael J. Meurer
3) Principles and Practice of Clinical Trial Medicine by Richard Chin and Bruce Y. Lee
4) Ethical Guidelines for Biomedical Research on Human Participants by Indian Council of Medical Research New delhi 2006.
5) CPCSEA Guidelines for Laboratory Animal Facility by Committee for the purpose of control and supervision on experiments on animals (CPCSEA)
6) ICH E6 Guideline ― Good Clinical Practice‖ by ICH Harmonised Tripartite
7) Guidance for Industry on Submission of Clinical Trial Application for Evaluating Safety and Efficacy by CDSCO (Central Drug Standard Control Organisation)
8) Guidance for Industry on Requirement of Chemical & Pharmaceutical Information including Stability Study Data before approval of clinical trials / BE studies by CDSCO
9) Guidelines for Import and Manufacture of Medical Devices by CDSCO
10) Guidelines from official website of CDSCO

FACULTY OF PHARMACY
MASTER OF PHARMACY
PROGRAMME
PHRGA004: REGULATORY AFFAIRS PRACTICAL-I (Practical)

Total hours: 180 Hr

Outline of the course:

Sr. No.	Title of the unit
1	Case studies (four nos.) of each good pharmaceutical practices.
2	Documentation for in-process and finished product quality control test for solid, liquid, semisolid and sterile preparations.
3	Preparation of SOPs, Analytical reports (Stability and validation)
4	Protocol preparation for documentation of various types of plan and reports (Product Development Plan (PDP), Product Development Report (PDR), Site Master File and Drug Master Files (DMF), Device master file)
5	Labelling comparison between brand & generics, Import of drugs for research and developmental activities
6	Study of Phases of clinical trials and preparation of Clinical Trial protocol
7	Patient Information Sheet and Informed Consent Form
8	Informed consent process and documentation
9	Preparation of clinical trial protocol for registering trial in India, USA and Europe
10	Registration for conducting BA/ BE studies in India, USA and Europe
11	Preparation of regulatory dossier as per CTD (ICH, WHO) and ACTD format and submission
12	Registering for different Intellectual Property Rights in India
13	GMP Audit Requirements as per WHO
14	Preparation and documentation for Indian Patent application
15	Preparation of checklist for registration of IND as per ICH CTD format
16	Preparation of checklist for registration of NDA as per ICH CTD format
17	Preparation of checklist for registration of ANDA as per ICH CTD format
18	Case studies on response with scientific rationale to USFDA Warning Letter
19	Preparation of submission checklist of IMPD for EU submission
20	Comparison study of marketing authorization procedures in EU
21	Comparative study of DMF system in US, EU and Japan
22	Preparation of regulatory submission using eCTD software
23	Preparation of Clinical Trial Application (CTA) for US submission

24	Preparation of Clinical Trial Application (CTA) for EU submission
25	Comparison of Clinical Trial Application requirements of US, EU and Japan of a dosage form
26	Regulatory requirements checklist for conducting clinical trials in India
27	Regulatory requirements checklist for conducting clinical trials in Europe
28	Regulatory requirements checklist for conducting clinical trials in USA

Course Outcome (COs):

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

CO1	Prepare the documentation requirements for product registration and able to prepare those documents
CO2	Describe the clinical trials requirements for conducting clinical trials, and able to prepare clinical trial protocol for US, EU and Japan
CO3	Categorize the requirements for the various types of submission application for US, EU and Japan and to understand the Regulatory guidance's and guidelines for filing and approval process
CO4	Prepare the regulatory dossiers as per CTD (ICH, WHO), e-CTD and ACTD format and their submission to regulatory agencies in different countries

Course Articulation Matrix:

	PO1	PO2	PO3	PO4	PO5	PO6	PO7	PO8	PO9	PO 10	PO 11
CO1	3	-	-	3	-	-	3	-	-	-	3
CO2	3	3	-	3	-	3	3	-	-	-	3
CO3	3	-	-	3	-	-	3	-	-	-	3
CO4	3	3	3	3	-	3	3	3	-	-	3

FACULTY OF PHARMACY
MASTER OF PHARMACY PROGRAMME
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* • *Pronunciation*	**06**
	• *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

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

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 be able to:

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)

FACULTY OF PHARMACY
Master of Pharmacy Programme

Syllabi Semester II

Charotar University of Science and Technology

FACULTY OF PHARMACY
MASTER OF PHARMACY
PROGRAMME
PHRGA006: REGULATORY ASPECTS OF DRUG & COSMETICS
(Theory)

Total hours: 60 Hr

Outline of the course:

Sr. No.	Title of the unit	Minimum number of hours
1	USA and CANADA	12
2	European Union and Australia	12
3	Japan	12
4	Emerging Market	12
5	Brazil, ASEAN, CIS and GCC Countries	12

Detailed Syllabus:

Sr. No.	UNIT	Hours	Weightage (%)
1.	**USA and CANADA**	**12**	**20%**
	Organization structure and functions of FDA. Federal register and Code of Federal Regulations (CFR), History and evolution of United States Federal, Food, Drug and Cosmetic Act (FFDCA), Hatch Waxman act and Orange book, Purple book, Drug Master Files (DMF) system in US, Regulatory Approval Process for Investigational New Drug (IND), New Drug Application (NDA), Abbreviated New Drug Application (ANDA), Supplemental New Drug Application (SNDA); Regulatory requirements for Orphan drugs and Combination Products, Changes to an approved NDA / ANDA. Regulatory considerations for manufacturing, packaging and labelling of pharmaceuticals in USA. Legislation and regulations for import, manufacture, distribution and sale of cosmetics in USA and Canada.		
2.	**European Union and Australia**	**12**	**20%**

	Organization and structure of EMA & EDQM, General guidelines, Active Substance Master Files (ASMF) system in EU,		
	Content and approval process of IMPD, Marketing Authorization procedures in EU (Centralized procedure, Decentralized procedure, Mutual recognition procedure and National Procedure). Regulatory considerations for manufacturing, Packaging and labelling of pharmaceuticals in EU, Eudralex directives for human medicines, Variations & extensions, Compliance of European Pharmacopoeia (CEP)/ Certificate of Suitability (CoS), Marketing Authorization (MA) transfers, Qualified Person (QP) in EU. Legislation and regulations for import, manufacture, distribution and sale of cosmetics in European Union & Australia.		
3.	**Japan**	**12**	**20%**
	Organization of the PMDA, Pharmaceutical Laws and regulations, types of registration applications, DMF system in Japan, drug regulatory approval process, Regulatory considerations for manufacturing, packaging and labelling of pharmaceuticals in Japan, Post marketing surveillance in Japan. Legislation and regulations for import, manufacture, distribution and sale of cosmetics in Japan		
4.	**Emerging Market**	**12**	**20%**
	Introduction, Countries covered, Study of the world map, study of various committees across the globe (ASEAN, APEC, EAC, GCC, PANDRH, SADC) WHO: WHO, GMP, Regulatory Requirements for registration of drugs and post approval requirements in WHO through prequalification programme, Certificate of Pharmaceutical Product (CoPP) - General and Country Specific (South Africa, Egypt, Algeria and Morocco, Nigeria, Kenya and Botswana)		
5.	**Brazil, ASEAN, CIS and GCC Countries**	**12**	**20%**

	ASIAN Countries: Introduction to ACTD, Regulatory Requirements for registration of drugs and post approval		
	requirements in China and South Korea & Association of Southeast Asian Nations (ASEAN) Region i.e. Vietnam, Malaysia, Philippines, Singapore and Thailand. CIS (Commonwealth Independent States): Regulatory prerequisites related to Marketing authorization requirements for drugs and post approval requirements in CIS countries i.e. Russia, Kazakhstan and Ukraine GCC (Gulf Cooperation Council) for Arab states: Regulatory pre-requisites related to Marketing authorization requirements for drugs and post approval requirements in Saudi Arabia and UAE Legislation and regulations for import, manufacture, distribution and sale of cosmetics in Brazil, ASEAN, CIS and GCC Countries		

Course Outcome (COs):

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

CO1	narrate the organization of drug regulatory bodies in various countries
CO2	summarize drug discovery and development and generic product development regulatory approval process and registration procedures for API and drug products in US, EU, Japan.
CO3	summarize cosmetic regulations in regulated and semi-regulated countries.
CO4	describe the comparative study of India with other regulated markets.

Course Articulation Matrix:

	PO1	PO2	PO3	PO4	PO5	PO6	PO7	PO8	PO9	PO 10	PO 11
CO1	3	-	-	-	-	-	-	-	-	-	3
CO2	3	-	-	-	-	-	-	-	-	-	3
CO3	3	-	-	-	-	-	-	-	-	-	3
CO4	3	-	-	-	-	-	-	-	-	-	3

Recommended Study Material:

- **Text book:**

1. Generic Drug Product Development, Solid Oral Dosage forms, Leon Shargel and Isader Kaufer, Marcel Dekker series, Vol.143
2. The Pharmaceutical Regulatory Process, Edited by Ira R. Berry Marcel Dekker Series, Vol.144
3. The Pharmaceutical Regulatory Process, Second Edition Edited by Ira R. Berry and Robert P. Martin, Drugs and the Pharmaceutical Sciences, Vol.185 Informa Health care Publishers.
4. New Drug Approval Process: Accelerating Global Registrations By Richard A Guarino, MD, 5th edition, Drugs and the Pharmaceutical Sciences, Vol.190.
5. Guidebook for drug regulatory submissions / Sandy Weinberg. By John Wiley & Sons. Inc.
6. Drugs: From Discovery to Approval, Second Edition By Rick Ng
7. New Drug Development: A Regulatory Overview, Eighth Edition By Mark Mathieu
8. Pharmaceutical Risk Management By Jeffrey E. Fetterman, Wayne L. Pines and Gary H. Slatko
9. Preparation and Maintenance of the IND Application in eCTD Format By William
    1. K. Sietsema
10. Country Specific Guidelines from official websites.
11. http://www.who.int/medicines/areas/quality_safety/regulation_legislation/list MRAWebsites.pdf
12. Roadmap to an ASEAN economic community Edited by Denis Hew. ISEAS Publications, Singapore 2005, ISBN981-230-347-2
13. ASEAN, Rodolfo C. Severino, ISEAS Publications, Singapore 2005, ISBN 978-981-230- 750-7
14. Building a Future with Brics: The Next Decade for Offshoring, Mark Kobayashi-Hillary, Springer
15. Outsourcing to India: The Offshore Advantage, Mark Kobayashi-Hillary, Springer Trade performance and Regional Integration of the CIS Countries, Lev Freinkman,
16. The world Bank, Washington, DC, ISBN: 0-8212-5896-0

17. Global Pharmaceutical Policy: Ensuring Medicines for Tomorrow's World By Frederick M. Abbott, Graham Dukes, Maurice Nelson Graham Dukes 139
18. The Gulf Cooperation Council: A Rising Power and Lessons for ASEAN by Linda Low and Lorraine Carlos Salazar (Nov 22, 2010)
19. Doing Business in the Asean Countries, Balbir Bhasin, Business Expert Press ISBN:13:978-1-60649-108-9
20. Realizing the ASEAN Economic Community: A Comprehensive Assessment, Michael G Plummer (Editor), Chia Siow Yue (Editor), Instute of South east asian studies, Singapore
21. Medical Product Regulatory Affairs: Pharmaceuticals, Diagnostics, Medical Devices by John J. Tobin and Gary Walsh
22. Good Drug Regulatory Practices: A Regulatory Affairs Quality Manual (Good Drug Development Series, Vol. 1) by Helene I. Dumitriu
23. FDA regulatory Affairs, edited by D. J. Pisano and D. Mantus, CRS Press, Boca Rocan, Florida.
24. Official websites of WHO, ICH and other regulatory agencies.
25. New Drug Approval process, 4th Edition, R.A.Guarino, Marcel Dekker, New York.
26. International Medicines Regulation A Forward Look to 1992 Editors: Walker, S.R., Griffin, A.R., Springer Science & Business Media, 2012.
27. Pharmacetical Applications in the European Union: A Guide Through the Registration Maze by Cheng Yee Lowe CRC Press.
28. Pharmaceutical Product Licensing: Requirements for Europe, by A. C. Cartwright, CRC Press.

FACULTY OF PHARMACY
MASTER OF PHARMACY
PROGRAMME
PHRGA015: REGULATORY ASPECTS OF HERBAL AND BIOLOGICALS (Theory)

Total hours: 60 Hr

Outline of the course:

Sr. No.	Title of the unit	Minimum number of hours
1	India	12
2	USA	12
3	European Union	12
4	Vaccine regulations in India, US and European Union	12
5	Herbal Products	12

Detailed Syllabus:

Sr. No.	UNIT	Hours	Weightage (%)
1.	India	**12**	**20%**
	Introduction, Applicable Regulations and Guidelines , Principles for Development of Similar Biologics, Data Requirements for Preclinical Studies, Data Requirements for Clinical Trial Application, Data Requirements for Market Authorization Application, Post-Market Data for Similar Biologics, Pharmacovigilance. GMP and GDP.		
2.	USA	**12**	**20%**
	Introduction to Biologics; biologics, biological and biosimilar, different biological products, difference between generic drug and biosimilar, laws, regulations and guidance on biologics/ biosimilar, development and approval of biologics and biosimilar (IND, PMA, BLA, NDA, 510(k), pre-clinical and clinical development considerations, advertising, labelling and packing of biologics		

3.	European Union	**12**	**20%**
	Introduction to Biologics; directives, scientific guidelines and guidance related to biologics in EU, comparability/ bio-similarity assessment, Plasma master file, TSE/ BSE evaluation, development and regulatory approval of biologics (Investigational medicinal products and biosimilar), pre-clinical and clinical development considerations; stability, safety, advertising, labelling and packing of biologics		
4.	Vaccine regulations in India, US and European Union	**12**	**20%**
	Clinical evaluation, Marketing authorisation, Registration or licensing, Quality assessment, Pharmacovigilance, Additional requirements Blood and Blood Products Regulations in India, US and European Union: Regulatory Requirements of Blood and/or Its Components Including Blood Products, Label Requirements, ISBT (International Society of Blood Transfusion) and IHN (International Haemovigilence Network)		
5.	Herbal Products	**12**	**20%**
	Quality, safety and legislation for herbal products in India, USA and European Union		

Course Outcome (COs):

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

CO1	Describe the biologics regulations in INDIA, USA and EUROPE
CO2	Know the pre-clinical and clinical development considerations of biologics
CO3	Describe the vaccines regulations in INDIA, USA and EUROPE
CO4	Understand the regulatory requirements of blood and/or its components including blood products and label requirements
CO5	Summarize the legislations proposed for evaluation of quality and safety of herbal products in INDIA, USA and EUROPE

Course Articulation Matrix:

	PO1	PO2	PO3	PO4	PO5	PO6	PO7	PO8	PO9	PO 10	PO 11
CO1	3	-	-	-	-	-	3	-	3	-	3
CO2	3	-	-	-	-	-	3	-	3	-	3
CO3	3	-	-	-	-	-	3	-	3	-	3
CO4	3	-	-	-	-	-	3	-	3	-	3
CO5	3	-	-	-	-	-	3	-	3	-	3

Recommended Study Material:

1. FDA Regulatory Affairs: A Guide for Prescription Drugs, Medical Devices, and Biologics, Douglas J. Pisano , David S. Mantus ; Informa ,2008
2. Biological Drug Products: Development and Strategies; Wei Wang , Manmohan Singh wiley ,2013
3. Development of Vaccines: From Discovery to Clinical Testing; Manmohan Singh , Indresh K. Srivastava ;Wiley, 2011
4. www.who.int/biologicals/en www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInfo rmation/
5. www.ihn-org.com
6. www.isbtweb.org
7. Guidelines on Similar Biologics: Regulatory Requirements for Marketing Authorization in India www.cdsco.nic.in
8. www.ema.europa.eu › scientific guidelines › Biologicals www.fda.gov/biologicsbloodVaccines/GuidanceCompliance Regulatory Information (Biologics)

FACULTY OF PHARMACY
MASTER OF PHARMACY
PROGRAMME
PHRGA016: REGULATORY ASPECTS OF MEDICAL DEVICES (THEORY)

Total hours: 60 Hr

Outline of the course:

Sr. No.	Title of the unit	Minimum number of hours
1	Medical Devices	12
2	Ethics	12
3	USA	12
4	European Union	12
5	ASEAN, China & Japan	12

Detailed Syllabus:

Sr. No.	UNIT	Hours	Weightage (%)
1.	Medical Devices	**12**	**20%**
	Introduction, Definition, Risk based classification and Essential Principles of Medical Devices and IVDs. Differentiating medical devices IVDs and Combination Products from that of pharmaceuticals, History of Medical Device Regulation, Product Lifecycle of Medical Devices and Classification of Medical Devices. IMDRF/GHTF: Introduction, Organizational Structure, Purpose and Functions, Regulatory Guidelines, Working Groups, Summary Technical Document (STED), Global Medical Device Nomenclature (GMDN)		
2.	Ethics	**12**	**20%**

	Clinical Investigation of Medical Devices, Clinical Investigation Plan for Medical Devices, Good Clinical Practice for Clinical Investigation of medical devices (ISO 14155:2011) Quality: Quality System Regulations of Medical Devices: ISO 13485, Quality Risk Management of Medical Devices: ISO 14971,		
	Validation and Verification of Medical device, Adverse Event Reporting of Medical device		
3.	USA	**12**	**20%**
	Introduction, Classification, Regulatory approval process for Medical Devices (510k) Premarket Notification, Pre-Market Approval (PMA), Investigational Device Exemption (IDE) and In vitro Diagnostics, Quality System Requirements 21 CFR Part 820, Labelling requirements 21 CFR Part 801, Post marketing surveillance of MD and Unique Device Identification (UDI). Basics of In vitro diagnostics, classification and approval process.		
4.	European Union	**12**	**20%**
	Introduction, Classification, Regulatory approval process for Medical Devices (Medical Device Directive, Active Implantable Medical Device Directive) and In vitro Diagnostics (In Vitro Diagnostics Directive), CE certification process. Basics of In vitro diagnostics, classification and approval process		
5.	ASEAN, China & Japan	**12**	**20%**
	Medical Devices and IVDs, Regulatory registration procedures, Quality System requirements and clinical evaluation and investigation. IMDRF study groups and guidance documents.		

Course Outcome (COs):

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

CO1	Narrate the basics of medical devices and IVDs, process of development, ethical and quality considerations
CO2	Describe the harmonization initiatives for approval and marketing of medical devices and IVDs
CO3	Describe the regulatory approval process for medical devices and IVDs in India, US, Canada, EU, Japan and ASEAN
CO4	Describe the clinical evaluation and investigation of medical devices and IVDs

Course Articulation Matrix:

	PO1	PO2	PO3	PO4	PO5	PO6	PO7	PO8	PO9	PO 10	PO 11
CO1	3	-	-	-	-	-	3	-	3	-	3
CO2	3	-	-	-	-	-	-	3	3	-	3
CO3	3	-	-	-	-	-	-	3	3	-	3
CO4	3	-	-	-	-	-	-	3	3	-	3

Recommended Study Material:

1. FDA regulatory affairs: a guide for prescription drugs, medical devices, and biologics by Douglas J. Pisano, David Mantus.
2. Medical Device Development: A Regulatory Overview by Jonathan S. Kahan
3. Medical Product Regulatory Affairs: Pharmaceuticals, Diagnostics, Medical Devices by John ,A. J. Tobin and Gary Walsh
4. Compliance Handbook for Pharmaceuticals, Medical Devices and Biologics by Carmen Medina
5. Country Specific Guidelines from official websites

FACULTY OF PHARMACY
MASTER OF PHARMACY
PROGRAMME
PHRGA017: REGULATORY ASPECTS OF FOOD & NUTRACEUTICALS
(Theory)

Total hours: 60 Hr

Outline of the course:

Sr. No.	Title of the unit	Minimum number of hours
1	Nutraceuticals	12
2	Global Aspects	12
3	India	12
4	USA	12
5	European Union	12

Detailed Syllabus:

Sr. No.	UNIT	Hours	Weightage (%)
1.	Nutraceuticals	**12**	**20%**
	Introduction, History of Food and Nutraceutical Regulations, Meaning of Nutraceuticals, Dietary Supplements, Functional Foods, Medical Foods, Scope and Opportunities in Nutraceutical Market.		
2.	Global Aspects	**12**	**20%**
	WHO guidelines on nutrition. NSF International: Its Role in the Dietary Supplements and Nutraceuticals Industries, NSF Certification, NSF Standards for Food And Dietary Supplements. Good Manufacturing Practices for Nutraceuticals.		
3.	India	**12**	**20%**
	Food Safety and Standards Act, Food Safety and Standards Authority of India: Organization and Functions, Regulations for import, manufacture and sale of nutraceutical products in India, Recommended Dietary Allowances (RDA) in India.		
4.	USA	**12**	**20%**

	US FDA Food Safety Modernization Act, Dietary Supplement Health and Education Act. U.S. regulations for manufacture and sale of nutraceuticals and dietary supplements, Labelling Requirements and Label Claims for Dietary Supplements, Recommended Dietary Allowances (RDA) in the U.S		
5.	European Union	**12**	**20%**
	European Food Safety Authority (EFSA): Organization and Functions. EU Directives and regulations for manufacture and sale of nutraceuticals and dietary supplements. Nutrition labelling. European Regulation on Novel Foods and Novel Food Ingredients. Recommended Dietary Allowances (RDA) in Europe		

Course Outcome (COs):

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

CO1	Define and differentiate nutraceuticals, functional foods, dietary supplements, and medical foods
CO2	Compare the global aspects of regulations in food and nutraceuticals markets
CO3	Describe the food and nutraceuticals regulations in India, USA and Europe
CO4	Describe the labelling requirements, label claims and recommended dietary allowances (RDA) of nutraceuticals and food supplements in India, USA and Europe

Course Articulation Matrix:

	PO1	PO2	PO3	PO4	PO5	PO6	PO7	PO8	PO9	PO 10	PO 11
CO1	3	-	3	-	-	-	-	3	3	-	3
CO2	3	-	3	3	-	-	-	-	3	-	3
CO3	3	-	-	-	-	3	3	-	3	-	3
CO4	3	-	-	3	-	-	-	3	3	-	3

Recommended Study Material:

1. Regulation of Functional Foods and Nutraceuticals: A Global Perspective by Clare M. Hasler (Wiley Online Library)
2. Nutraceutical and Functional Food Regulations in the United States and Around the World by Debasis Bagchi (Academic Press, Elsevier)
3. http://www.who.int/publications/guidelines/nutrition/en/
4. http://www.europarl.europa.eu/RegData/etudes/STUD/2015/536324/IPOL_ STU(2015)536324_EN.pdf
5. Handbook of Nutraceuticals by Yashwant Pathak (CRC Press)
6. Food Regulation: Law, Science, Policy and Practice by Neal D. Fortin (Wiley)
7. Country Specific Guidelines from official websites

FACULTY OF PHARMACY
MASTER OF PHARMACY
PROGRAMME
PHRGA009: REGULATORY AFFAIRS PRACTICAL-II (Practical)

Total hours: 180 Hr

Outline of the course:

Sr. No.	Title of the unit
1	Case studies on change management/change control, deviations, connective and preventive actions (CAPA)
2	Documentation of raw material analysis as per official monographs
3	Regulatory Approval Process for Investigational New Drug (IND), New Drug Application (NDA), Abbreviated New Drug Application (ANDA), Supplemental New Drug Application (SNDA)
4	Marketing Authorization procedures in EU (Centralized procedure, Decentralized procedure, Mutual recognition procedure and National Procedure)
5	Preparation of various reports and records (IPQC, BMR, BPR, MFR, COA, Specification etc.)
6	Preparation of audit checklist for various agencies
7	Preparation of submission to FDA using eCTD software
8	Preparation of submission to EMA using eCTD software
9	Preparation of submission to MHRA using eCTD software
10	Preparation of Biologics License Applications (BLA) in India, USA, Europe
11	Preparation of documents required for Vaccine Product Approval in India, USA, Europe
12	Comparison of clinical trial application requirements of US, EU and India of Biologics
13	Preparation of Checklist for Registration of Medical devices in India, USA, Europe
14	Registration requirement comparison study of medical devices and biological in regulated and emerging market
15	Registration requirement comparison study in emerging market and preparing check list for market authorization
16	Preparation of submission documents required for Herbal product Approval in India, USA, Europe
17	Preparation of submission documents required for Nutraceuticals Product Approval in India, USA, Europe

18	Registration requirement comparison study in emerging markets (ASEAN, CIS, GCC) and preparing check list for market authorization Warning Letter
19	Registration requirement comparison study in regulated markets (TGA, MCC, Health Canada, PMDA) and preparing check list for market authorization
20	Checklists for 510k and PMA for US market
21	Checklist for CE marking for various classes of devices for EU
22	STED Application for Class III Devices
23	Audit Checklist for Medical Device Facility
24	Clinical Investigation Plan for Medical Devices
25	Case studies on Topics mentioned

Course Outcome (COs):

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

CO1	Prepare the documentation required for product registration and able to prepare those documents.
CO2	Describe the requirements for the Herbal product Approval in India, USA, and Europe.
CO3	Describe the requirements for the Nutraceuticals Product Approval in India, USA, and Europe.
CO4	Prepare the documents for registering the biological product approval of various countries.
CO5	Prepare the necessary documents for the medical devices product approval of various countries.

Course Articulation Matrix:

	PO1	PO2	PO3	PO4	PO5	PO6	PO7	PO8	PO9	PO 10	PO 11
CO1	3	3	-	3	-	-	3	-	-	-	3
CO2	3	3	-	3	-	-	3	-	-	-	3
CO3	3	3	-	3	-	-	3	-	-	-	3
CO4	3	3	-	3	-	-	3	-	-	-	3
CO5	3	3	-	3	-	-	3	-	-	-	3

FACULTY OF MANAGEMENT STUDIES
DEPARTMENT OF HUMANITIES AND SOCIAL SCIENCES
HS106.02 B: ACADEMIC WRITING

I. Credits and Schemes:

Sem	Course Code	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 • Paraphrasing • Summarizing	**05**

4	**Accuracy in Academic Writing** • *Lexical Range* • *Academic Language and Structures*	**05**
	• *Elements of Writing* • *Proof Reading, Editing, and Rewriting*	
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 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	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 professional communication 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

Course Articulation Matrix:

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

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	10
2	Biostatistics	10
3	Medical Research	10
4	CPCSEA guidelines for laboratory animal facility	10
5	Declaration of Helsinki	10

Detailed Syllabus:

Sr. No.	UNIT	Hours	Weightage (%)
1.	**General Research Methodology**	**10**	**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**	**10**	**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 (Wilcoxon rank tests, analysis of variance, correlation, chi square test), null hypothesis, P values, degree of freedom, interpretation of P values.		
3.	**Medical Research**	**10**	**20%**

	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.		
4.	**CPCSEA guidelines for laboratory animal facility**	**10**	**20%**
	Goals, veterinary care, quarantine, surveillance, diagnosis, treatment and control of disease, personal hygiene, location of animal facilities to laboratories, anaesthesia, euthanasia, physical facilities, environment, animal husbandry, record keeping, SOPs, personnel and training, transport of lab animals.		
5.	**Declaration of Helsinki**	**10**	**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
PHCCC011: 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
PHRGA019: 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
PHCCC012: 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
PHRGA021: RESEARCH WORK

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	-
	09.10.2025	Thu		WD	Teaching-Learning for 1st sem M.Pharm.
	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	
5	27.10.2025	Mon	6	WD	
	28.10.2025	Tue		WD	-
	29.10.2025	Wed		WD	-

	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	
	03.11.2025	Mon		WD	-
	04.11.2025	Tue		WD	-
	05.11.2025	Wed		HD	**Guru Nanak Jayanti**
6	06.11.2025	Thu	5	WD	Teaching-Learning for 1st sem M.Pharm.
	07.11.2025	Fri		WD	-
	08.11.2025	Sat		WD	-
	09.11.2025	Sun		HD	
	10.11.2025	Mon		WD	-
	11.11.2025	Tue		WD	-
	12.11.2025	Wed		WD	-
7	13.11.2025	Thu	6	WD	Teaching-Learning for 1st sem M.Pharm.
	14.11.2025	Fri		WD	
	15.11.2025	Sat		WD	-
	16.11.2025	Sun		HD	
	17.11.2025	Mon		WD	-
	18.11.2025	Tue		WD	
	19.11.2025	Wed		WD	-
8	20.11.2025	Thu	6	WD	Teaching-Learning for 1st sem M.Pharm.
	21.11.2025	Fri		WD	
	22.11.2025	Sat		WD	
	23.11.2025	Sun		HD	
	24.11.2025	Mon		WD	-
	25.11.2025	Tue		WD	-
	26.11.2025	Wed		WD	**1st Internal Examination (T/P)**
9	27.11.2025	Thu	6	WD	Teaching-Learning for 1st sem M.Pharm.
	28.11.2025	Fri		WD	
	29.11.2025	Sat		WD	-
	30.11.2025	Sun		HD	
	01.12.2025	Mon		WD	-
	02.12.2025	Tue		WD	-
	03.12.2025	Wed		WD	**1st Internal Examination (T/P)**
10	04.12.2025	Thu	6	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	**Journal Certification**
	03.02.2026	Tue		WD	Teaching-Learning for 1st sem M.Pharm.
	04.02.2026	Wed		WD	
	05.02.2026	Thu		WD	
	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		

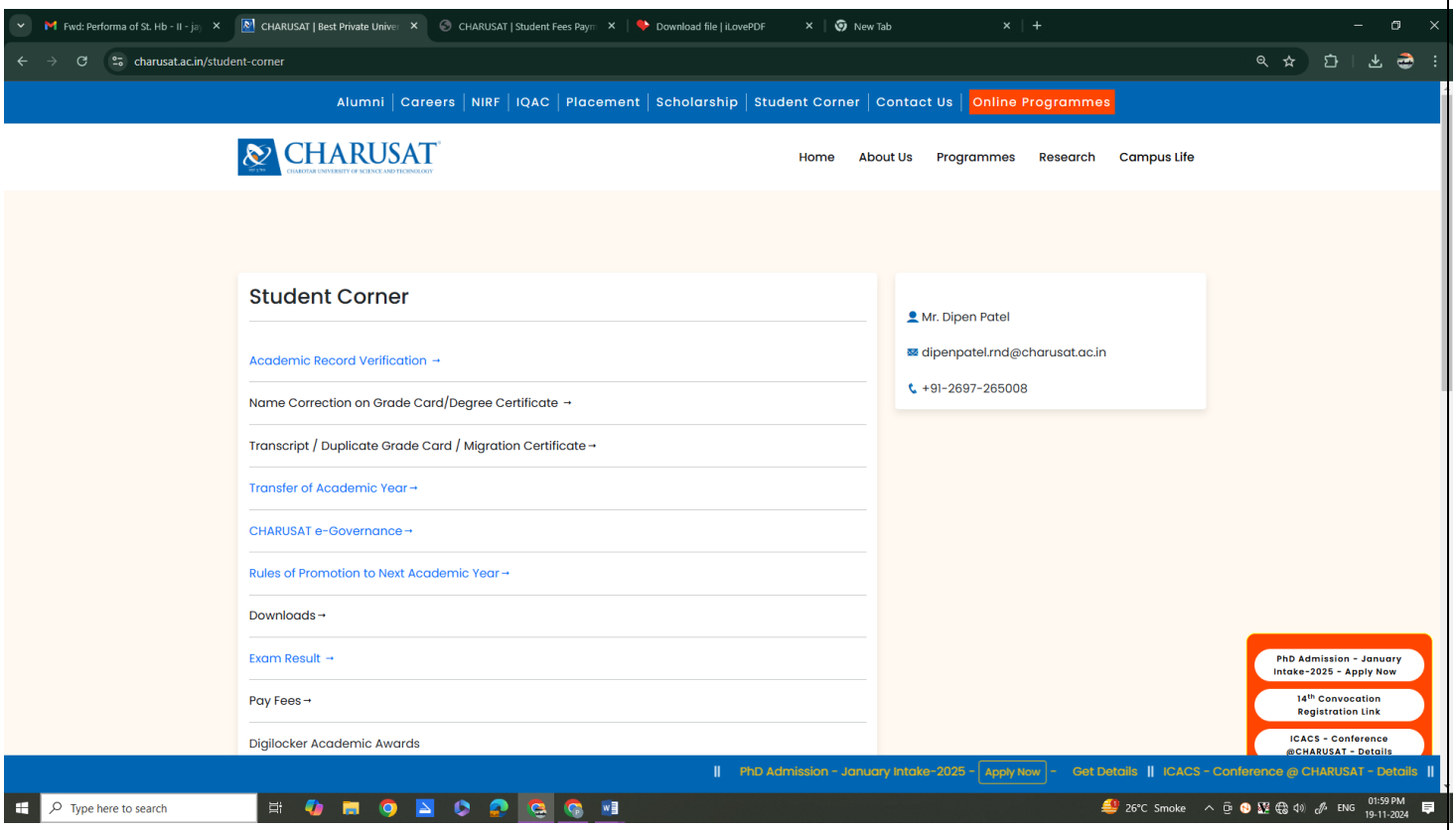
*** Schedule is tentative, subject to change**

SECTION - 2

VARIOUS ADMINISTRATIVE PROCESS

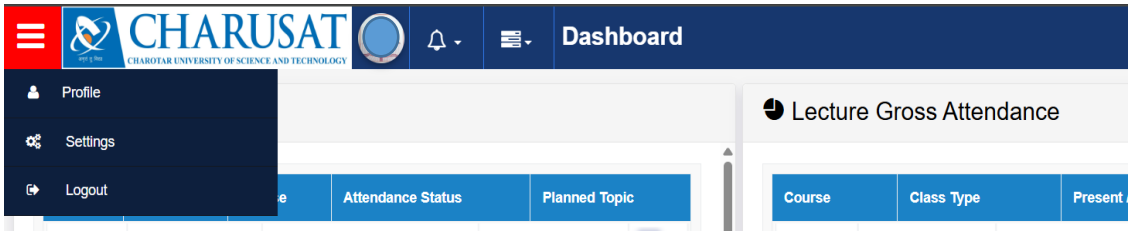
2.1 Payment of tuition fees or Other charges

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

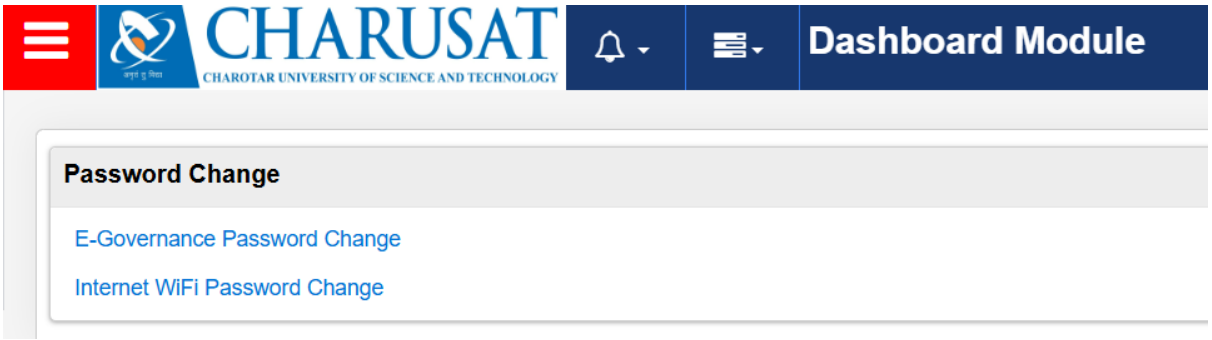


2.2 Process of Acquiring WIFI access

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

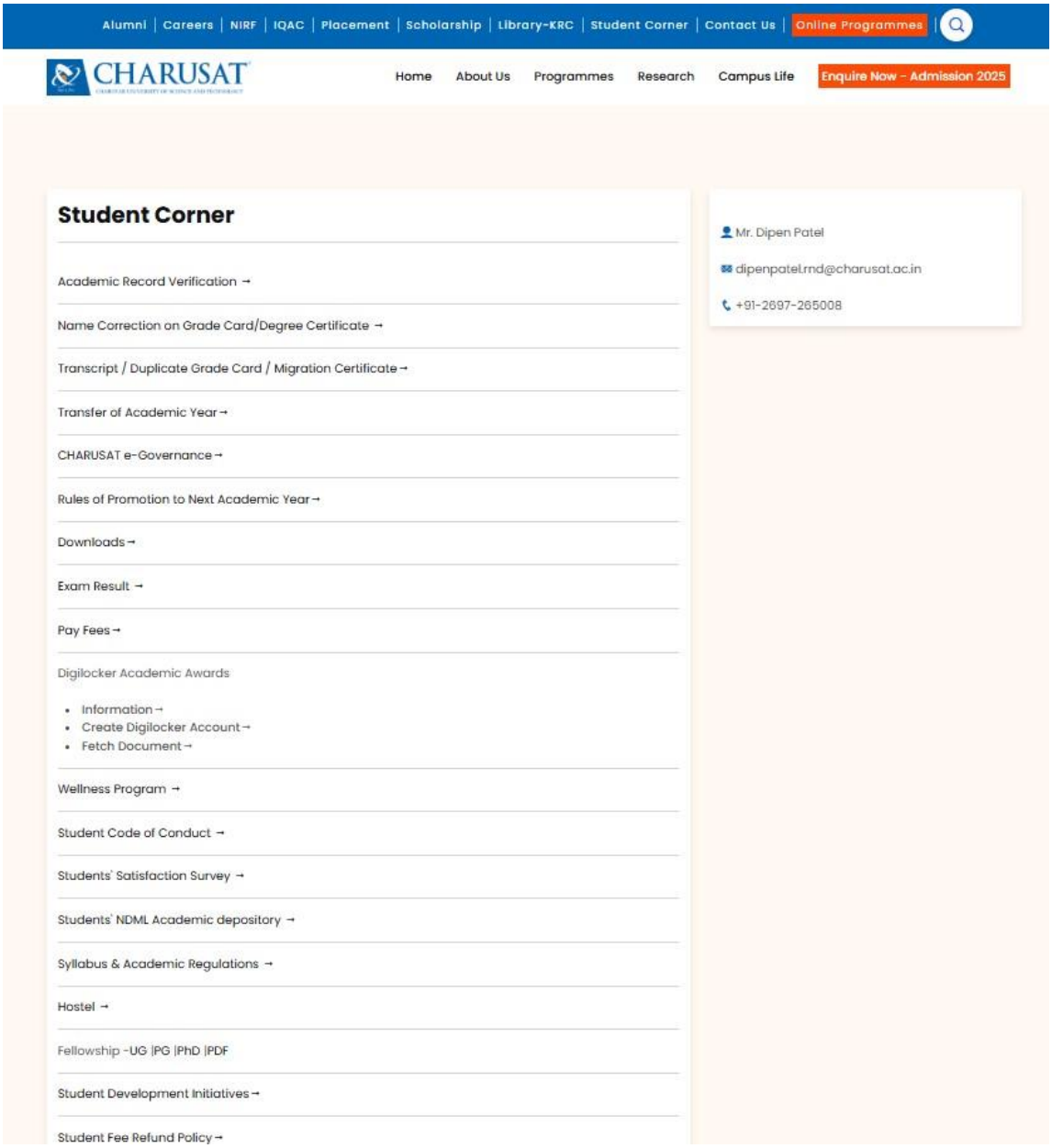
➢ Connect to wifi by authenticating your credentials on http://172.16.0.1:8090/httpclient.html

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