Ref. AVCoP/588

Date: 13/10/2025

Academic Program Regualtions-2025-26:M.Pharm

The Master of Pharmacy (M.Pharm) program being offered at Amrutvahini College of Pharmacy, Sangamner (An Autonomous College) under the title "Academic Program Regualtions-2025 has been duly approved by the Academic Council of Amrutvahini Sheti & Shikshan Vikas Sanstha's, Amrutvahini College of Pharmacy, Sangamner (An Autonomous College)

Dr.M.J.Chavan
Chairman-Academic Council & Principal

Amrutvahini College of Pharmacy ★ Sangamner ★

AMRUTVAHINI®
Since 1978

Amrutvahini Sheti & Shikshan Vikas Sansth's

Amrutvahini College of Pharmacy, Sangamner

(An Autonomous College)

Academic Program Regulations-2025

[Framed under Regulation THE MASTER OF PHARMACY (M. PHARM.) COURSE REGULATION 2014 (BASED ON NOTIFICATION IN THE GAZETTE OF INDIA NO. 362, DATED DECEMBER 11.
2014)]

MASTER OF PHARMACY

Academic
Year 2025-26
[Revision Zero 0.0]

Amrutvahini Sheti & Shikshan Vikas Sanstha's

Amrutvahini College of Pharmacy, Sangamner

Nashik-Pune Highway, Ghulewadi, Amrutnagar,
Tal. Sangamner, Dist-Ahilynagar, Pin Code:-422608

Vision

Our college will be recognized as socially cautious centre of excellence in innovative education through its contribution in training, scholarly research in pharmacy profession and services to society.

Mission

For translation of our vision into reality college is striving to:

M1: Provide value based student centric and sustained quality pharmaceutical education.

M2: Foster advanced and innovative research that benefits pharmaceutical industry and community.

M3: Encourage and strengthen leadership, competitiveness, ethical reasoning and intellectual curiosity.

Program Educational Objectives

PEO 1: Graduates of the program will be having strong background and skills in pharmaceutical sciences and able to use these tools in Pharmaceutical industry and/or institutes wherever necessary for success.

PEO 2: Technically sound and mentally robust with critical thinking abilities to excel in career.

PEO 3: Professional and ethical attitude and have ability to address healthcare issues of community.

PROGRAM OUTCOMES

PO	Title	Statement
PO1	**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.
PO2	**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
PO2	**Problem analysis**	Utilize the principles of scientific enquiry, thinking analytically, clearly and critically, while solving problems and making decisions during daily practice. Find, analyze, evaluate and apply information systematically and shall make defensible decisions
PO4	**Modern tool usage**	Learn, select, and apply appropriate methods and procedures, resources, and modern pharmacy-related computing tools with an understanding of the limitations.
PO5	**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 well-being.

PO6	**Professional Identity**	Understand, analyze and communicate the value of their professional roles in society (e.g. health care professionals, promoters of health, educators, managers, employers, employees)
PO7	**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
PO8	**Communication**	Communicate effectively with 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.
PO9	**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.
PO10	**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.
PO11	**Lifelong 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.

TABLE OF CONTENT

INTRODUCTION

RECOMMENDATIONS OF NATIONAL REGULATORY AUTHORITIES

The University Grants Commission (UGC), the National Assessment and Accreditation Council (NAAC), the Distance Education Council (DEC) and the Indian Knowledge System (IKS), have time and again come out with recommendations for improving the quality and effectiveness of Higher education provisions in the country. The ministry of Human Resource Development at the Central level and the Ministry of Higher & Technical Education, Government of Maharashtra have also repeatedly stressed on the need for universities to pay prompt attention to improve the quality of education. The NEP 2020 incorporates IKS principles to enhance interdisciplinary learning, integrate traditional wisdom with modern knowledge, and foster a more inclusive and holistic educational experience. An important concern voiced more strongly in recent times, is the need to develop a Choice-Based Credit System (CBCS) in tune with global trends and the adoption of a sound grading system for reflecting learner performance. This is in line with the recommendation of the UGC in its Action Plan for Academic and Administrative Reforms (Ref. UGC letters January 2008; March 2009) "Curricular flexibility and learners' mobility are issues that warrant our urgent attention. These can be addressed by introducing credit based courses and credit accumulation. In order to provide with some degree of flexibility to learners, we need to provide flexibility in course selection and also a minimum as well as a maximum permissible span of time in which a course can be completed by a learner… The Choice-Based Credit System (CBCS) imminently fits into the emerging socioeconomic milieu and could effectively respond to the educational and occupational aspirations of the upcoming generations. In view of this, institutions of higher education in India would do well to invest thought and resources into introducing CBCS. Aided by modern communication and information technology, CBCS has a high probability to be operationalized efficiently and effectively — elevating learners, institutions and higher education system in the country to newer height".

RATIONALE FOR INTRODUCTION OF CREDIT AND GRADING SYSTEM

The UGC while outlining the several unique features of the Choice-Based Credit System (CBCS) has, in fact, given in a nutshell, the rationale for its introduction. Among the features highlighted by the UGC are: Enhanced learning opportunities, ability to match learners' scholastic needs and aspirations, inter- institution transferability of learners (following the completion of a semester), part-completion of an academic programme in the institution of enrolment and part-completion in a specialized (and recognized) institution, improvement in educational quality and excellence, flexibility for working learners to complete the programme over an extended period of time, standardization and comparability of educational programmes across the country, etc. This Choice Based Credit System enables a much- required shift in focus from teacher-centric to learner-centric education since the workload estimated is based on the investment of time in learning, not in teaching. It also focuses on continuous evaluation which will enhance the quality of education. It can be concluded from the above discussion that it is very much essential to implement the Choice Based

Credit System in higher education in India. Course credit structure, examination/assessment and grading are mainly focused aspects of this manual and discussed in subsequent chapters.

DIRECTIVES OF PHARMACY COUNCIL OF INDIA

The Pharmacy Council of India (PCI) in exercise of the powers conferred to it under the sections 10 and 18 of the Pharmacy Act 1948 (8 of 1948), with the approval of the Central Government, had made the Bachelor of Pharmacy (B. Pharm.) Course Regulations, 2014 and Master of Pharmacy (M. Pharm.) Course regulations vide Gazette dated December 10, 2014. Further as per regulations 6 and 8 of the above course regulations the PCI has also prescribed the Rules and Syllabus for B. Pharm. course and Scheme and Syllabus for M. Pharm., its letter Ref 14-136/2016-PCI and Ref 14- 154/2015 PCI dated December 21, 2016, with the subject heading "Statutory Scheme/Rules and syllabus for B. Pharm and M. Pharm. courses". It is thus mandatory to implement the directives of PCI with regard to the Rules/Regulations/Syllabus for recognition and extension of approval of B. Pharm. and M. Pharm. programs of institutes/Universities by the PCI

CHAPTER - I: REGULATIONS

1. Short Title and Commencement

These regulations shall be called as "The Revised Regulations for the Master of Pharmacy (M. Pharm.)Degree Program – Credit Based Semester System (CBSS) of the Pharmacy Council of India, New Delhi". The program regulations are based on the PCI notification in the Gazette of India, No. 362, dated 11 December 2014.They shall come into effect from the Academic Year 2025-26.The regulations framed are subject to modifications from time to time by the authorities of Amrutvahini Sheti & Shikshan Vikas Sanstha's, Amrutvahini College of Pharmacy, Sangamner as per the directions of the Pharmacy Council of India.

2. Minimum qualification for admission

A. Pass in the following examinations -

a) B.Pharm Degree examination of an Indian university established by law in India from an institution approved by Pharmacy Council of India and has scored not less than 55 % of the maximum marks (aggregate of 4 years of B.Pharm.)

b) Every student, selected for admission to post graduate pharmacy program in any PCI approved institution should have obtained registration with the State Pharmacy Council or should obtain the same within one month from the date of his/her admission, failing which the admission of the candidate shall be cancelled.

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

3. Duration of the program

The program of study for M.Pharm. shall extend over a period of four semesters (two academic years). The curricula and syllabi for the program shall be prescribed from time to time by Amrutvahini Sheti & Shikshan Vikas Sanstha's, Amrutvahini College of Pharmacy, Sangamner as per the directions of the Pharmacy Council of India, New Delhi.

4. Medium of instruction and examinations

Medium of instruction and examination shall be in English.

5. Working days in each semester

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

6. Attendance and progress

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

7. Program / Course credit structure

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

curricular activities is dependent upon the quantum of work expected to be put in for each of these activities per week / per activity.

7.1 Credit assignment

7.1.1 Theory and Laboratory courses

Courses are broadly classified as Theory and Practical. Theory courses consist of lecture (L) and Practical (P) courses consist of hours spent in the laboratory. Credits
(C) for a course is dependent on the number of hours of instruction per week in that course, and is obtained by using a multiplier of one (1) for lecture and a multiplier of half (1/2) for practical (laboratory) hours. Thus, for example, a theory course having four lectures per week throughout the semester carries a credit of 4. Similarly, a practical having four laboratory hours per week throughout semester carries a credit of 2.The contact hours of seminars, assignments and research work shall be treated as that of practical courses for the purpose of calculating credits. i.e., the contact hours shall be multiplied by 1/2. Similarly, the contact hours of journal club, research work presentations and discussions with the supervisor shall be considered as theory course and multiplied by 1.

7.1.2 Minimum credit requirements

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

8. Academic work

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

9. Course of study

The specializations in M.Pharm program is given in Table 1.**Table – 1: List of M.Pharm. Specializations and their Code**

Sr. No.	Specialization	Code
1.	Pharmaceutics	MPH
2.	Pharmaceutical Quality Assurance	MQA
3.	Pharmacognosy	MPG

The course of study for M.Pharm specializations shall include Semester wise Theory & Practical as given in Table - 2 to 4. The number of hours to be devoted to each theory and practical course in any semester shall not be less than that shown in Table - 2 to 4.

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

Course Code	Course	Credit Hours	Credit Points	Hrs./wk.	Marks
SEMESTER I					
MPAT101T	Modern Pharmaceutical Analytical Techniques	4	4	4	100
MPH102T	Drug Delivery System	4	4	4	100
MPH103T	Modern Pharmaceutics	4	4	4	100
MPH104T	Regulatory Affair	4	4	4	100
MPH105P	Pharmaceutics Practical I	12	6	12	150
-	Seminar/Assignment	7	4	7	100
	Total	**35**	**26**	**35**	**650**
SEMESTER II					
MPH201T	Molecular Pharmaceutics (Nano Tech and Targeted DDS)	4	4	4	100
MPH202T	Advanced Biopharmaceutics & Pharmacokinetics	4	4	4	100
MPH203T	Computer Aided Drug Development	4	4	4	100
MPH204T	Cosmetic & Cosmeceuticals	4	4	4	100
MPH205P	Pharmaceutics Practical II	12	6	12	150
-	Seminar/Assignment	7	4	7	100
	Total	**40**	**26**	**35**	**650**

Table - 3: Course of study for M. Pharm. (Pharmaceutical Quality Assurance)

Course Code	Course	Credit Hours	Credit Points	Hrs./wk	Marks
SEMESTER I					
MPAT101T	Modern Pharmaceutical Analytical Techniques	4	4	4	100
MQA102T	Quality Management System	4	4	4	100
MQA103T	Quality Control and Quality Assurance	4	4	4	100
MQA104T	Product Development and Technology Transfer	4	4	4	100
MQA105P	Pharmaceutical Quality Assurance Practical I	12	6	12	150
-	Seminar/Assignment	7	4	7	100
	Total	**35**	**26**	**35**	**650**
SEMESTER II					
MQA201T	Hazards and Safety Management	4	4	4	100
MQA202T	Pharmaceutical Validation	4	4	4	100
MQA203T	Audits and Regulatory Compliance	4	4	4	100
MQA204T	Pharmaceutical Manufacturing Technology	4	4	4	100
MQA205P	Pharmaceutical Quality Assurance Practical II	12	6	12	150
-	Seminar/Assignment	7	4	7	100
	Total	**40**	**26**	**35**	**650**

Table - 4: Course of study for M. Pharm. (Pharmacognosy)

Course Code	Course	Credit Hours	Credit Points	Hrs./wk	Marks
SEMESTER I					
MPAT101T	Modern Pharmaceutical Analytical Techniques	4	4	4	100
MPG102T	Advanced Pharmacognosy–1	4	4	4	100
MPG103T	Phytochemistry	4	4	4	100
MPG104T	Industrial Pharmacognostical Technology	4	4	4	100
MPG105P	Pharmacognosy Practical I	12	6	12	150
-	Seminar/Assignment	7	4	7	100
	Total	**35**	**26**	**35**	**650**
SEMESTER II					
MPG201T	Medicinal Plant biotechnology	4	4	4	100
MPG202T	Advanced Pharmacognosy – II	4	4	4	100
MPG203T	Indian system of medicine	4	4	4	100
MPG204T	Herbal cosmetics	4	4	4	100
MPG205P	Pharmacognosy Practical II	12	6	12	150
-	Seminar/Assignment	7	4	7	100
	Total	**40**	**26**	**35**	**650**

* *Non University Exam*

Table - 5: Course of study for M. Pharm. III Semester
(Common for All Specializations)

Course Code	Course	Credit Hours	Credit Points	Marks
MRM 301T	Research Methodology and Biostatistics*	4	4	100
MPH/MQA/MPG302P	Journal club	1	1	25
MPH/MQA/MPG303P	Discussion / Presentation (Proposal Presentation)	2	2	50
MRW304P	Research Work*	28	14	350
	Total	**35**	**17**	**525**

** Non University Exam*

Table - 6: Course of study for M. Pharm. IV Semester
(Common for All Specializations)

Course Code	Course	Credit Hours	Credit Points	Marks
MPH/MQA/MPG401P	Journal Club	1	1	25
MPH/MQA/MPG402P	Discussion / Presentation (Proposal Presentation)	31	16	75
MRW403P	Research Work and Colloquium	3	3	400
	Total	**35**	**20**	**500**

Table – 7: Semester wise credits distribution

Semester	Credit Points
I	26
II	26
III	21
IV	20
Co-curricular Activities (Attending Conference, Scientific Presentations and Other Scholarly Activities)	Minimum=02 Maximum=07*
Certificate courses	02
Total Credit Points	Minimum=97 Maximum=102*

**Credit Points for Co–curricular Activities*

*Credit points for co-curricular activities (Table 8A) and choice based courses (Table 8B).

Table 8B Certificate courses

Sr. No.	Certificate courses
1	• AI in preformulation & Formulation • AI in drug design & Discovery and Bioinformatics • AI in pharmacology & Drug safety • AI in pharmacognosy & Biotechnology • AI in pharmacy practice & patient care as decided from BOS time to time (The syllabus of each course is provided in Annexure-I-V)

Table – 8 A: Guidelines for Awarding Credit Points for Co-curricular Activities

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

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

*The credit points assigned for extracurricular and or co–curricular activities shall be given by the Principal of the college. The criteria to acquire this credit point shall be defined by the college from time to time.

10. Program Committee

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

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

3. Duties of the Programme Committee:
   i. Periodically reviewing the progress of the classes.
   ii. Discussing the problems concerning curriculum, syllabus and the conduct of classes.
   iii. Discussing with the course teachers on the nature and scope of assessment for the course and the same shall be announced to the students at the beginning of respective semesters.
   iv. Communicating its recommendation to the Head of the institution on academic matters.
   v. The Programme Committee shall meet at least twice in a semester preferably at the end of each sessional exam and before the end semester exam.

11. Examinations/Assessments

The schemes for internal assessment and end semester examinations are given in Table – 9-12

Tables - 9: Schemes for internal assessments and end semester (Pharmaceutics - MPH)

Course Code	Course	Internal Assessment				End Semester Exams		Total Marks
		Continuous Mode	Sessional Exams		Total	Marks	Duration	
			Marks	Duration				
SEMESTER I								
MPAT 101T	Modern Pharmaceutical Analytical Techniques	10	15	1 Hr.	25	75	3 Hrs.	100
MPH 102T	Drug Delivery System	10	15	1 Hr.	25	75	3 Hrs.	100
MPH 103T	Modern Pharmaceutics	10	15	1 Hr.	25	75	3 Hrs.	100
MPH 104T	Regulatory Affair	10	15	1 Hr.	25	75	3 Hrs.	100
MPH 105P	Pharmaceutics Practical I	20	30	6 Hrs.	50	100	6 Hrs.	150
-	Seminar /Assignment	–	–	–	–	–	–	100
							Total	**650**
SEMESTER II								
MPH 201T	Molecular Pharmaceutics(Nano Tech and Targeted DDS)	10	15	1 Hr.	25	75	3 Hrs.	100
MPH 202T	Advanced Biopharmaceutics & PharmacoKinetics	10	15	1 Hr.	25	75	3 Hrs.	100
MPH 203T	Computer Aided Drug Development	10	15	1 Hr.	25	75	3 Hrs.	100
MPH 204T	Cosmetic and Cosmeceuticals	10	15	1 Hr.	25	75	3 Hrs.	100
MPH 205P	Pharmaceutics Practical II	20	30	6 Hrs.	50	100	6 Hrs.	150
-	Seminar Assignment	–	–	–	–	–	–	100
							Total	**650**

Tables - 10: Schemes for internal assessments and end semester examinations (Pharmaceutical Quality Assurance–MQA)

Course Code	Course	Internal Assessment				End Semester Exams		Total Marks
		Continuous	Sessional Exams		Total	Marks	Duration	
		Mode	Marks	Duration				
SEMESTER I								
MPAT 101T	Modern Pharmaceutical Analytical Techniques	10	15	1 Hr.	25	75	3 Hrs.	100
MQA 102T	Quality Management System	10	15	1 Hr.	25	75	3 Hrs.	100
MQA 103T	Quality Control and Quality Assurance	10	15	1 Hr.	25	75	3 Hrs.	100
MQA 104T	Product Development and Technology Transfer	10	15	1 Hr.	25	75	3 Hrs.	100
MQA 105P	Pharmaceutical Quality Assurance Practical I	20	30	6 Hrs.	50	100	6 Hrs.	150
-	Seminar /Assignment	–	–	–	–	–	–	100
							Total	**650**
SEMESTER II								
MQA 201T	Hazards and Safety Management	10	15	1 Hr.	25	75	3 Hrs.	100
MQA 202T	Pharmaceutical Validation	10	15	1 Hr.	25	75	3 Hrs.	100
MQA 203T	Audits and Regulatory Compliance	10	15	1 Hr.	25	75	3 Hrs.	100
MQA 204T	Pharmaceutical Manufacturing Technology	10	15	1 Hr.	25	75	3 Hrs.	100
MQA 205P	Pharmaceutical Quality Assurance Practical II	20	30	6 Hrs.	50	100	6 Hrs.	150
-	Seminar /Assignment	–	–	–	–	–	–	100
							Total	**650**

Tables - 11: Schemes for internal assessments and end semester examinations (Pharmacognosy–MPG)

Course Code	Course	Internal Assessment				End Semester Exams		Total Marks
		Continuous Mode	Sessional Exams		Total	Marks	Duration	
			Marks	Duration				
SEMESTER I								
MPAT 101T	Modern Pharmaceutical Analytical Techniques	10	15	1 Hr.	25	75	3 Hrs.	100
MPG 102T	Advanced Pharmacognosy – 1	10	15	1 Hr.	25	75	3 Hrs.	100
MPG 103T	Phytochemistry	10	15	1 Hr.	25	75	3 Hrs.	100
MPG 104T	Industrial Pharmacognostical Technology	10	15	1 Hr.	25	75	3 Hrs.	100
MPG 105P	Pharmacognosy Practical I	20	30	6 Hrs.	50	100	6 Hrs.	150
-	Seminar /Assignment	–	–	–	–	–	–	100
							Total	**650**
SEMESTER II								
MPG 201T	Medicinal Plant biotechnology	10	15	1 Hr.	25	75	3 Hrs.	100
MPG 202T	Advanced Pharmacognosy– II	10	15	1 Hr.	25	75	3 Hrs.	100
MPG 203T	Indian system of medicine	10	15	1 Hr.	25	75	3 Hrs.	100
MPG 204T	Herbal cosmetics	10	15	1 Hr.	25	75	3 Hrs.	100
MPG 205P	Pharmacognosy Practical II	20	30	6 Hrs.	50	100	6 Hrs.	150
-	Seminar /Assignment	–	–	–	–	–	–	100
							Total	**650**

Tables - 12: Schemes for internal assessments and end semester examinations (Semester III& IV)

Course Code	Course	Internal Assessment				End Semester Exams		Total Marks
		Continuous Mode	Sessional Exams		Total	Marks	Duration	
			Marks	Duration				
SEMESTER III								
MRM30 1T	Research methodology and Biostatistics*	10	15	1 Hr.	25	75	3 Hrs.	100
MPH/MQA/ MPG302P	Journal club	–	–	–	25	–	–	25
MPH/MQA/ MPG303P	Discussion / Presentation (Proposal Presentation)	–	–	–	50	–	–	50
MRW304P	Research work*	–	–	–	–	350	1 Hr.	350
							Total	**525**
SEMESTER IV								
MPH/MQA/ MPG401P	Journal club	–	–	–	25	–	–	25
MPH/MQA/ MPG402P	Discussion / Presentation (Proposal Presentation)	–	–	–	75	–	–	75
MRW403P	Research work and Colloquium	–	–	–	–	400	1 Hr.	400
							Total	**500**

*Non University Examination

11.1 Internal assessment: Continuous mode

The marks allocated for continuous mode of internal assessment of theory courses shall be awarded based on the students' performance in the assignments/surprise tests, etc., while in the lab course it is based on the practical record, regular viva-voce etc.

Table - 13: Scheme for awarding internal assessment: Continuous mode

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

Table - 14: Guidelines for the allotment of marks for attendance

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

11.2 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 is given in the table. The sessional exam will be conducted for 30 marks and computed for 15 marks. The average marks of two sessional exams shall be computed for internal assessment as per the requirements given in following tables.

Scheme for theory Sessional examination

I. Objective Type Questions (Answer all the questions)	05Q x 2M= 10M
II. Short Answers (Answer 2 out of 3)	2Q x 5M = 10M
III. Long Answers (Answer 1 out of 2)	1Q x 10M = 10M
Total	**30 marks**

Scheme for Practical Sessional examination

I. Synopsis	05 M
II. Experiments	20 M
III. Viva voce	05 M
Total	**30 marks**

Seminar/Assignment/Journal Club/Proposal Presentation/Discussion Presentation/Research Work

1. **Seminar:** The evaluation of seminar for semester I & II shall be carried out as per following scheme.
   a. Reference work and scientific contents---------- 10 marks
   b. Communication skill---------- 05 marks
   c. Discussion/defense---------- 05 marks
   d. Presentation---------- 30 marks
   Total ---------- 50 marks

2. **Assignment:** one assignment related to any topic from the specialization shall be conducted in semester I and II.
   Evaluation criteria for assignment are as follows:

a. Structure, organization and content ---------- 20 marks
b. Creativity and originality---------- 05 marks
c. Compilation of information---------- 10 marks
d. Literature resources---------- 10 marks
e. Reference style ---------- 05 marks
Total ---------- 50 marks

3. Journal club

The evaluation of Journal Club for Semester III & IV shall be carried out as per following scheme

a. Selection of research topic and their applicability--------- 05 marks
b. Objectives ---------- 05 marks
c. Reference work and scientific contents ---------- 05 marks
d. Reading research papers---------- 05 marks
e. Skill in oral presentation ---------- 05marks
Total ---------- 25 marks

4. Discussion / Presentation (Proposal Presentation)

The evaluation of Discussion / Presentation (Proposal Presentation) for Semester III shall be carried out as per following scheme

a. Selection of research topic and their applicability--------- 10 marks
b. Objectives ---------- 10 marks
c. Reference work and scientific contents ---------- 10 marks
d. Methodology Adopted---------- 10 marks
e. Skill in oral presentation---------- 10 marks
Total ---------- 50 marks

5. Research Work

The evaluation of Research Work for Semester III shall be carried out as per following scheme

a. Selection of research topic and their applicability--------- 30 marks
b. Objectives ---------- 40 marks
c. Plan of Work ---------- 50 marks
d. Methodology Adopted---------- 100 marks
e. Reference work and scientific contents ---------- 50 marks
f. Reading research papers ---------- 50
g. Skill in oral presentation ---------- 30
Total ---------- 350 marks

6. Discussion / Presentation (Proposal Presentation)

The evaluation of Discussion / Presentation (Proposal Presentation) for Semester IV shall be carried out as per following scheme

a. Reference work and scientific contents---------- 15 marks
b. Communication Skills---------- 15 marks
c. Discussion/Defence---------- 10 marks
d. Presentation---------- 35 marks
Total ---------- 75 marks

11.3 End semester examinations

End-semester examinations are conducted for eligible students twice at the end of the semester, namely, the main examination for regular students and the supplementary examinations for the failed students only before the commencement of the next semester (Table 15). In case a failed student could not clear the course in the supplementary examination, the student would have his next examination along with the regular students only in the main examination.

Table-15: Tentative schedule of end semester examinations

Semester	For Regular Candidates	For Failed Candidates
I and III	November/December (exact dates will be announced at the beginning of the Academic Year). For those students who have been declared "failed", there will be a supplementary exam after fifteen days of the declaration of the results	December/January (exact dates will be announced at the beginning of the Academic Year)
II & IV	May/June (exact dates will be announced at the beginning of the Academic Year). For those students who have been declared "failed" there will be a supplementary exam after fifteen days of the declaration of the results.	June/July (exact dates will be announced at the beginning of the Academic Year)

Question paper pattern for end semester theory examinations (ESE)

For 75 marks paper

I	Short answer questions (solve 5 out of 7)	5Q x 3M = 15M
II	Medium Length answers (Solve 8 out of 10)	8Q x 5 M= 40M
III	Long answer questions (solve 2 out of 3)	2Q x 10M= 20M
	Total	**75 marks**

Question paper pattern for end semester practical examination

I. Synopsis	15M
II. Experiments	70M
III. Viva voce	15M
Total	**100 marks**

12 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 BOS 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.

Note: If any candidate fails to submit the dissertation on or before the date prescribed, the end-semester examination of such candidate shall be at a later date, which shall not be earlier than 6 months from the date fixed in the first instance.

The performance of student in the dissertation work is assessed as per the scheme given in the Table 16.

Table 16. M Pharm dissertation evaluation scheme								
Internal Assessment			**University Examination**					**Grand Total**
Presentation 1 (III semester)	**Presentation 2 (IV semester)**	**Total**	**Dissertation Evaluation (250) by Examiners**		**Viva Voce Joint Evaluation by Internal and External Examiners (150)**		**Total**	
			Internal	External	Presentation	Viva-voce		
i	ii	i+ii=A	i	ii	iii	iv	i+ii+iii+iv =B	A+B
350	**75**	**425**	**125**	**125**	**75**	**75**	**400**	**825**

The internal and external examiners appointed by the university shall evaluate the dissertation of the research project separately as per the following evaluation criteria.

Evaluation of Dissertation Book:

- Objective(s) of the work done 25 Marks
- Methodology adopted 75 Marks
- Results and Discussions 125Marks
- Conclusions and Outcomes 25 Marks

Total 250 Marks

Evaluation of Presentation:

- Presentation of work 75 Marks
- Communication skills 50 Marks
- Question and answer skills 25 Marks

Total 150 Marks

12.1 M. Pharm. Semester III and Semester IV

Research work related to the title of the thesis.

The student will be allotted a Research Supervisor while in Semester I. The Research Supervisor (Guiding Teacher) along with the student may plan the research area to be pursued during Semesters III and IV. The title of the thesis should be communicated to the Chairman of the Board of Studies before the commencement of Sem. III. Request for change in the title of the thesis, at a later time, should have a valid reason and will be considered under the existing rules for title change (minor or major). Any request for change in title should be communicated to the Chairman of the Board of Studies by the student through the Research Guide and forwarded by the Principal. The student is expected to work a minimum of 40 hrs/week in Research to be entitled for 24 Credits each in Semester III and IV. The Guiding Teacher (Research Supervisor) will sign a statement to this effect at the conclusion of Semesters III and IV, which may be communicated to the Chairman of the Exam committee at the conclusion of each semester. Before completing the course, the

student will be required to give a Colloquium on the research work carried out by him/her during Semesters III and IV. The Colloquium will follow an open structure and will be assessed besides others by the Head of the Department, the Guide and the Principal. A Statement that the student has delivered a Colloquium will be mandated before the conduct of the viva-voce examination and such a statement should be part of the thesis. Students should attend conferences, seminars where they may present their research work and should publish a review paper (along with the research supervisor) in any one of the UGC approved research journals before submission of the thesis.

Weightage in evaluation of the thesis (vide infra) will be given if the work reported in the thesis has been published in any one of the UGC approved research journals. There will be no ESE at the end of Semester III. A student will be permitted to submit his/her synopsis no earlier than 20 months (after 20 months) from the beginning of the M. Pharm program as announced by the Government/Regulatory Authority for the respective year, BUT will have to submit the final thesis by the end of 24 months from the beginning of the M. Pharm program as announced by the Government/Regulatory Authority. The time between submission of synopsis and thesis should be at least one month. Any late submission of synopsis or thesis will result in the student requiring to keep terms for the next semester and any subsequent semester/s (with payment of all applicable fees) till the student finishes his/her degree.

At the end of Semester IV the student will submit a thesis to the College. This will jointly be evaluated by the guiding teacher and an external examiner appointed by the Board of Studies. The thesis will be evaluated as per guidelines given by Pharmacy council of India, New Delhi.

The submission of synopsis and the holding of the viva voce examination shall be done independent of the fact whether the student has successfully cleared semester I and Semester II. However, the result of the viva voce of M. Pharm. Examination will be declared only if the student has successfully cleared Semester I and Semester II examinations

13. Improvement of internal assessment

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

14. Promotion and award of grades

A student shall be declared PASS and eligible for getting grade in a course of M. Pharm. Program. The minimum for a pass in a course shall be 50% of the maximum marks (IA + End Semester Examination marks put together) allotted for a course. For example, to be declared as PASS and to get grade, the student has to secure a minimum of 50 marks for the total of 100 including continuous mode of assessment and end semester theory examination and has to secure a minimum of 25 marks for the total 50 including internal assessment and end semester practical examination. Hence, a student shall be declared PASS, if the student secures D-Grade and above, in the course concerned, on Grading-Scheme.

15. Award of performance grades

The marks obtained in the end semester and internal assessment in a course is added together and a Grading-Scheme is used to allot an appropriate grade to the student's performance in that course.

Grading-Scheme

Final evaluation of the performance of a student in each course (theory and lab separately) will be carried out on a Grading-Scheme corresponding to the marks obtained in that course. Eventually each letter grade of the course is converted into a specific grade point associated with the letter grade as given in the Table 17 for SGPA calculations

Table-17: Grading-Scheme

Letter Grade	Grade Points	Performance
O	10	Outstanding
A	9	Excellent
B	8	Good
C	7	Fair
D	6	Average
F	0	Fail
DT/AB	0	Fail
PP	-	Passed (Only for Extra course)
NP	-	Not passed (Only for extra course)
DT: Detained, AB: Absent		

Note the following:

1. Internal assessment marks and end semester examination marks put together are taken into account for the Grading-Scheme in each course separately.

2. Appropriate letter grades, from D to O, are awarded, in each theory and lab courses, to only such candidate who has passed the course in first attempt. However, grades D to B are only awarded to a student who makes multiple attempts to pass a course; except in case of I-grade.

3. A candidate who is eligible and registers for the end semester examination but fails to appear in the end semester examination gets a grade 'AB', indicating failure.

4. The grade DT is given to a candidate who fails to put in the minimum required attendance for appearing the end semester examination for a course.

5. A student, who appears for the end semester examination could not secure 'D" or above grade in the grading scheme in a course is granted 'F' grade indicating failure in a course (subject) concerned.

5. A student who earns a grade 'D' or above in a course is declared to have successfully completed the course and earns the credits assigned to that particular course. A course successfully completed cannot be repeated for the purpose of improving the grade.

16. Carry forward of marks

In case, a student fails to secure D-grade in any theory or practical courses, he/she shall reappear for the end semester examination of that course. However, the candidates with DT-grade will also be allowed to take this examination provided they meet the eligibility criteria laid for the candidates to appear in the end semester examinations of the courses of the programs.

Important to note: In case a candidate with DT-grade re- registers for the course to repeat the entire education process in the subsequent academic year, after paying the required course fee, the DT status in that particular course is removed and he/she is allowed to retain the grades that he/she secures in the end semester examination. After the results are declared, grade cards will be issued to each student, which will contain the list of courses for that semester and the grades obtained by the student.

17. Academic Progression

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. Academic progression rules are applicable as follows:

1. A student shall be eligible to carry forward all the courses of I, II and III semesters till the IV semester examinations. However, he/she shall not be eligible to attend the courses of IV semester until all the courses of I and II semesters are successfully completed.
2. A student shall be eligible to get his/her CGPA upon successful completion of the courses of I to IV semesters within the stipulated time period as per the norms.

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

18. Grading of performances

18.1. Letter grades and grade points allocations:

Based on the performances, each student shall be awarded a final letter grade at the end of the semester for each course. The letter grades and their corresponding grade points are given in Table – 18.

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

Table – 18: Letter grades and grade points equivalent Percentage of marks and performances

Percentage of Marks Obtained	Letter Grade	Grade Point	Performance
90.00 – 100	O	10	Outstanding
80.00 – 89.99	A	9	Excellent
70.00 – 79.99	B	8	Good
60.00 – 69.99	C	7	Fair
50.00 – 59.99	D	6	Average
Less than 50	F	0	Fail
Absent	AB/DT	0	Fail
-	PP	-	Passed (Only for Extra course)
-	NP	-	Not passed (Only for Extra course)

18.2 The Semester grade point average (SGPA)

Note: For the SGPA/ CGPA calculation, the credit points of the courses that are having university examinations are only considered.

However, a candidate has to earn the credit points of non-university examination and extracurricular activities along with the credit points of the courses of the university examination to qualify for the award of degree.

The performance of a student in a semester is indicated by a number called Semester Grade Point Average' (SGPA). The SGPA is the weighted average of the grade points obtained in all the courses by the student during the semester.

For example, if a student takes five courses (Theory/Practical) in a semester with credits C1, C2, C3 and C4 and the student's grade points in these courses are G1, G2, G3 and G4, respectively, and then students' SGPA is equal to:

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

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

$$SGPA = \frac{C1G1 + C2G2 + C3G3 + C4* ZERO}{C1 + C2 + C3 + C4}$$

18.3 Cumulative Grade Point Average (CGPA)

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

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

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,….

18.4 Conversion of GPA/CGPA into percentage

The performance of students who are pursuing pharmacy programs in Amrutvahini College of Pharmacy, Sangamner Dist. Ahilyanagar is awarded on a Grading-Scheme. In this system, the top band (top 10%) of students who score highest marks are placed at O which is equivalent to 10 grade point (maximum). Thus, 10 GPA or CGPA is equivalent to 100%. Accordingly, 1 GPA or CGPA is

equivalent to 10%. Based on this, the following formula is applied to convert GPA or CGPA to an appropriate percentage:

Percentage secured by the candidate = GPA or CGPA × 10

19. Declaration of class

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

First Class with Distinction	CGPA of. 7.50 and above
First Class	CGPA of. 6.00 to 7.49
Second Class	CGPA of. 5.00 to 5.99

20. Award of degree

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

21. 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.

22. Revaluation and retotaling of answer papers

There is provision for re-totaling and revaluation of the answer papers in any examination. The candidates can apply for revaluation/ re-totaling by paying prescribed fee.

23. Re-admission after break of study

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

24. Addendum

Wherever an issue has not been covered by these Autonomy Rules of the College, the Rules and Statutes of the Savitribai Phule Pune University, Pune would apply, as long as the latter does not go against the spirit of the College Autonomy arrangements.

NOTE: UNIVERSITY GRANTS COMMISSION (PROMOTION OF ACADEMIC INTEGRITY AND \PREVENTION OF PLAGIARISM IN HIGHER EDUCATIONAL INSTITUTIONS) REGULATIONS, 2018 New Delhi, the 23rd July, 2018, shall be applicable to all project reports/ all written reports that have to be submitted as part of the B. Pharm. program. The details of the regulations may be accessed at www.ugc.ac.in

Annexure-I

AI IN PREFORMULATION & FORMULATION

Total Credits 2 **Hours / Week: 2** **30 HR**

COURSE OBJECTIVES

1. Explain how AI supports decision-making in pre-formulation studies.
2. Teach AI methods to improve solubility and predict key physicochemical properties.
3. Train students to model fluid dynamics, particle behavior, and rheology with machine learning.
4. Show how AI optimizes processes, prevents equipment failures, and safeguards product quality.
5. Enable learners to build models that forecast degradation, shelf life, and drug-release kinetics.

COURSE OUTCOMES

Upon successful completion of this course, the students will be able to:

1. Describe the role of AI across pre-formulation workflows.
2. Generate regression models to estimate solubility, melting point, and boiling point using molecular descriptors.
3. Apply machine learning tools to analyze fluid flow, particle separation, and predict viscosity behavior.
4. Implement AI-based control strategies for early detection of process faults.
5. Develop neural network models to predict drug stability and release profiles under various conditions.

COURSE CONTENTS

Unit 1: Introduction to AI in Preformulation Studies 6 Hours

- Overview of artificial intelligence in pharmaceutical sciences
- Role of AI in decision-making during preformulation workflows
- Importance of predictive modeling in early-stage drug development

Unit 2: AI-Driven Physicochemical Property Prediction 6 Hours

- Strategies to enhance solubility and bioavailability using AI
- Regression models for predicting melting and boiling points from molecular descriptors
- Data sources and feature selection in predictive property modelling

Unit 3: AI for Fluid Dynamics and Rheology 6 Hours

- Machine learning in fluid dynamics analysis
- Prediction of particle behavior and separation techniques
- AI/ML algorithms for modeling viscosity and rheological profiles

Unit 4: AI-Based Process Optimization and Control 6 Hours

- Role of AI in pharmaceutical process optimization
- Predictive maintenance and equipment failure prevention
- AI systems for ensuring consistent product quality and compliance

Unit 5: Stability, Shelf Life, and Drug Release Prediction 6 Hours

- Neural network models for degradation pathway and shelf-life prediction under varying conditions
- Machine learning for modeling drug-release kinetics
- Case studies of AI applications in formulation design and lifecycle management

RECOMMENDED BOOKS

1. Pharmaceutical Preformulation and Formulation by Mark Gibson.
2. A Handbook of Artificial Intelligence in Drug Delivery edited by Abhay S. Shukla and Reinhold Kesharwani.
3. Artificial Intelligence for Drug Product Lifecycle Applications by Alexander Pais and José M. Martínez.
4. Machine Learning in Materials Science (ACS In Focus series) by the American Chemical Society
5. Artificial Intelligence in Manufacturing: Applications and Case Studies edited by O. Pierson and colleagues.

AI IN DRUG DESIGN & DISCOVERY AND BIOINFORMATICS - THEORY

Total Credits 2 **Hours / Week: 2** **30 HR**

COURSE OBJECTIVES

1. To introduce the fundamental principles of drug discovery and the evolution of scientific approaches across its stages.
2. To explain the role of biological targets, disease pathways, and screening strategies in early- stage drug development.
3. To familiarize students with computational methods used in structure prediction, virtual screening, pharmacokinetic, and toxicity profiling.
4. To develop an understanding of in silico modeling techniques and their integration into rational drug design.
5. To provide insights into regulatory frameworks and ethical considerations associated with modern drug development processes.

COURSE OUTCOMES

Upon successful completion of the course, students will be able to:

1. Know about various biological targets, Drug – receptor interactions, Molecular descriptors.
2. Interpret structural and biological data to assess target relevance
3. Describe the stages of drug discovery and the data-driven strategies used in target identification and druggability.
4. Analyze 2D and 3D-QSAR to optimize lead compounds.
5. Apply computational methodologies to simulate molecular interactions, evaluate compound properties, and predict pharmacokinetics

COURSE CONTENTS

Unit-I: Introduction to Drug Discovery and Development 10 Hours

1. Historical evolution and milestones in drug discovery
2. Role of Artificial intelligence (AI) in accelerating drug discovery Disease linkage and types of biological targets
3. Introduction to Databases and Resources for major repository of biological data to carry out protein structure predictions.
4. 2D & 3D representations of chemical structure
5. Artificial Intelligence in ADMET prediction, Insilico prediction of activity, Drug design, QSAR studies, Drug Repurposing,
6. Computer Aided Drug Design (CADD) and Its applications
7. Various software and modules used in CADD and its applications (Both open source and commercial)
8. Chemical and Biological databases including natural, small molecule and protein databases like PubChem, ChEMBL, DrugBank, Zinc, Coconut, RCSB, NCBI etc.
9. Energy minimization and force fields
10. Drug – receptor interactions

Unit-II: Drug Design, Discovery and Lead Identification 10 Hours

1. Artificial Intelligence in Bioinformatics: Algorithms, Applications, and Advances, Deep learning-based methods to drug discovery
2. Target identification, Protein structure prediction, protein preparation using open

source or commercial software
3. Ligand preparation using open source or commercial software
4. Principles of Molecular Docking studies using open source or commercial software
5. Virtual screening
6. Structure-based and Ligand-Based drug design
7. In-silico ADMET & Drug-Likeness Prediction using open source or commercial software

Unit-III: Lead Optimization & AI/ML Applications 10 Hours

1. 2D & 3D-QSAR
2. Pharmacophore modeling
3. Prediction of binding energy of ligand-receptor complex
4. Molecular similarity and similarity searching
5. Molecular dynamics
6. Drug repurposing
7. Reaction Prediction & Synthesis Planning
8. Artificial Intelligence in Interpretation of Advanced Spectroscopic and Chromatographic Data, Interpretation of NMR spectra for structural elucidation using AI
9. Demonstration of CADD modules using open-access or commercial software

Stage	**Tool/Platform**
Target Validation & Data Mining	KNIME, DrugBank, PubChem, STITCH, MolProphet
Structure Prediction	AlphaFold (AI-based), SWISS-MODEL
Molecular Docking	AutoDock, MZDock (open-source), iGemDock, GLIDE*, GOLD*
Pharmacophore Modeling	PharmaGist, PHASE*, MOE*
QSAR / Machine Learning	AutoQSAR*, KNIME, QSAR Toolbox, DTC QSAR, MolProphet
ADMET Prediction & Drug-likeness	SwissADME, pkCSM, Qikprop*, ProTox 3.0

*Commercial tools that may be demonstrated based on access and availability

REFERENCE BOOKS

1. Patrick, G. L. – An Introduction to Medicinal Chemistry
2. Silverman, R., Holladay, M. – The Organic Chemistry of Drug Design and Drug Action
3. Liu, X., Altman, R. – Drug Discovery and Development: Technology in Transition
4. Artificial Intelligence in Drug Discovery — Nathan Brown — Royal Society of Chemistry, 2020
5. Deep Learning for the Life Sciences — Bharath Ramsundar, Peter Eastman, Patrick Walters, Vijay Pande — O'Reilly Media, 2019
6. Machine Learning in Chemistry: The Impact of Artificial Intelligence — Hugh M. Cartwright (ed.) — Royal Society of Chemistry, 2020
7. Drug Design and Development: From Practice to Concept – Robin Ganellin

AI IN PHARMACOLOGY & DRUG SAFETY - THEORY

Total Credits 2 **Hours / Week: 2** **30 HR**

COURSE OBJECTIVES

1. Teach students to use AI tools for 3-D visualization, anatomical mapping, and virtual physiology simulations.
2. Introduce AI models that predict pharmacokinetic properties and protein–ligand interactions across species.
3. Equip learners with AI platforms that accelerate drug discovery, candidate selection, and preclinical testing.
4. Familiarize students with AI techniques for predicting adverse drug reactions and chemical toxicity.
5. Explore how AI enables personalized medicine and shapes the future of pharmacology.

COURSE OUTCOMES

Upon successful completion of this course, the students will be able to:

1. Create AI-generated anatomical or physiological visualizations and explain the underlying models.
2. Apply AI algorithms to forecast ADME profiles and map target interactions for small molecules in human, rat, and mouse systems.
3. Run an AI-driven workflow to identify, rank, and justify potential drug candidates.
4. Predict adverse drug reactions or toxicities for a given compound set and interpret the safety implications.
5. Design a personalized treatment concept using AI insights and discuss emerging pharmacology trends.

COURSE CONTENTS:

Unit 1 – AI-Enhanced Anatomy & Physiology 6 Hours

- AI-Based 3D Visualization of Human Anatomy
- AI-based anatomical mapping and physiological functions
- AI-driven simulations showing real-time physiological responses
- AI-based virtual dissection and physiology simulation

Unit 2 – AI for Pharmacokinetics & Molecular Interaction 6 Hours

- AI models predict drug absorption, distribution, metabolism, and excretion (ADME)
- Molecular interactions between target protein and small molecules
- Target Prediction of small molecules in Human, Rat, Mice model

Unit 3 – AI in Drug Discovery & Development 6 Hours

- Introduction to AI applications in drug discovery and development
- Use of AI platforms to identify novel drug candidates
- Analysis of molecular and omics data using machine learning
- Prediction of drug-target interactions to assess efficacy
- AI-driven tools in preclinical testing and compound optimization

Unit 4 – AI in Drug Safety & Toxicology 6 Hours

- AI applications in drug safety and pharmacovigilance
- Platforms for predicting adverse drug reactions (ADRs) and drug-drug interactions
- Machine learning models for early toxicity prediction of small molecules based on chemical structure
- Role of AI in enhancing drug safety profiles and optimizing treatment regimens

Unit 5 – AI in Personalized Medicine & Future Pharmacology 6 Hours

- AI-driven approaches in personalized medicine and individualized therapy design
- Genomic data integration for precision drug recommendations
- Future trends in AI-powered pharmacology and therapy optimization
- Ethical, legal, and implementation challenges in AI-based personalized healthcare

RECOMMENDED BOOKS

1. Artificial Intelligence in Drug Discovery — Nathan Brown — Royal Society of Chemistry, 2020
2. Deep Learning for the Life Sciences — Bharath Ramsundar, Peter Eastman, Patrick Walters, Vijay Pande — O'Reilly Media, 2019
3. Machine Learning and Artificial Intelligence in Toxicology and Environmental Health — Zhoumeng Lin & Wei-Chun Chou (eds.) — Elsevier, 2024
4. Artificial Intelligence in Medical Imaging: Opportunities, Applications and Risks — Erik R. Ranschaert, Sergey Morozov, Paul Algra (eds.) — Springer, 2019
5. Deep Learning in Personalized Healthcare and Decision Support — Abhinav Garg (ed.) — Elsevier, 2023

AI IN PHARMACOGNOSY & BIOTECHNOLOGY

Total Credits 2 **Hours / Week: 2** **30 HR**

COURSE OBJECTIVES

The course aims to:

1. Introduce students to core AI and ML tools used across nutrition, agriculture, herbal medicine, genomics, and microbiology.
2. Show how AI designs personalized diets, discovers nutraceutical actives, and checks their safety and efficacy.
3. Teach AI methods that optimize crop growth, conserve medicinal plants, and predict plant secondary metabolites.
4. Train learners to apply AI for crude-drug recognition, natural-product drug discovery, and regulatory intelligence.
5. Equip students to analyze genomic, proteomic, and microbial data with AI—covering phylogenetics, non-coding RNA, and enzyme engineering.

COURSE OUTCOMES

Upon successful completion of this course, the students will be able to:

1. Produce an AI-generated diet plan and justify its predicted health benefits.
2. Build an ML model that forecasts plant growth or metabolite yield from soil, climate, or genomic inputs.
3. Classify a crude drug image set with AI and flag potential herb-drug interactions.
4. Run an AI pipeline to identify microbes or non-coding RNAs from sequence data and display a phylogenetic tree.
5. Create an AI-guided strategy to improve enzyme immobilization or automate cell- structure detection and present the results.

COURSE CONTENTS:

Unit 1 – Nutrition & Nutraceuticals 6 Hours

- AI in nutrition planning and personalized diet recommendations.
- AI assistance in linking food components with disease phenotypes.
- AI in Nutraceutical Discovery and Personalization Machine learning for bioactive compound Screening, AI-guided formulation of personalized supplements
- Predictive analytics in efficacy and safety assessment of nutraceuticals.

Unit 2 – Agriculture & Plant Science 6 Hours

- AI in agriculture for optimizing plant growth conditions via soil and climate analysis,
- Greenhouse automation.
- AI in Conservation of Medicinal Plants: GIS, Remote Sensing & Prediction Models.
- Prediction of Plant secondary metabolites using genomes.
- AI driven prediction of secondary metabolite structures.

Unit 3 – Herbal Medicine & Natural Products 6 Hours

- AI in Classification of Crude Drugs using Image Recognition (Microscopy, Morphology).
- AI-driven techniques for identification of crude drugs.
- AI driven drug discovery from natural product.
- Herb Identification, Herb-Drug Interactions, Herbal formulations
- AI for Regulatory Intelligence: Machine learning to track updates in EU, ICH, and WHO herbal guidelines (T).
- AI in studying secondary metabolite production through pathways like the Shikimic acid pathway and Acetate pathway.

Unit 4 – Genomics & Molecular Biology 6 Hours

- Introduction to AI & ML in Biology, AI in Genomics and Molecular Data Analysis
- Machine Learning in Protein Structure Prediction,
- ML-based identification of non-coding RNAs (miRNA, lncRNA, etc.).
- Basic differences between DNA, RNA, and proteins.

Unit 5 – Microbial & Cellular Informatics and Enzyme Engineering 6 Hours

- Identification of microorganisms using gene sequences through BLAST.
- Open-Source AI Tool for Microbial Identification.
- Introduction and hands-on training on Phylogenetic tree construction.
- Prediction of secondary metabolite biosynthetic gene clusters.
- Use of deep learning for analyzing cell structures and identifying organelles automatically (T-1HRS).
- ML for optimizing enzyme loading, immobilization matrices.

RECOMMENDED BOOKS

1. Artificial Intelligence in Food Science: Transforming Food and Bioprocess Development — Tanmay Sarkar & Anandakumar Haldorai, Academic Press (Elsevier), 1st ed., 2025
2. Artificial Intelligence in Agriculture — Rajesh Singh, Anita Gehlot, Mahesh Kumar Prajapat & Bhupendra Singh, CRC Press (Taylor & Francis), 1st ed., 2022.
3. Artificial Intelligence in Drug Discovery — Nathan Brown, Royal Society of Chemistry, 1st ed., 2020
4. Deep Learning in Bioinformatics: Techniques and Applications in Practice — Habib Izadkhah, Academic Press (Elsevier), 1st ed., 2022
5. Bioinformatics, AI, and Machine Learning in Microbial Drug Development — Vagish Dwibedi, Nancy George, Santosh Kumar Rath & Swapnil Kajale (eds.), Academic Press (Elsevier), 1st ed., 2025

Annexure-V

AI IN PHARMACY PRACTICE & PATIENT CARE - THEORY

Total Credits 2 **Hours / Week: 2** **30 HR**

COURSE OBJECTIVES

The course aims to:

1. Introduce AI-driven simulation technologies—covering student and teacher modeling—to enhance pharmacy education.
2. Familiarize learners with key AI simulation and content-creation platforms such as Body Interact, SimX, IBM Watson Health, Synthesia, Pictory, and Animoto.
3. Explain how AI supports pharmacy automation, medication dispensing, and adherence monitoring through wearables and mobile apps.
4. Teach AI techniques for adverse drug-reaction prediction and for monitoring the safety of medicines and vaccines.
5. Develop the ability to apply AI-based big-data analytics for public-health surveillance and decision-making.

COURSE OUTCOMES

Upon successful completion of this course, the students will be able to:

1. Students will design a simple AI-guided simulation scenario that adapts to learner performance and objectives.
2. Students will compare two AI simulation platforms and justify their choice for a specific pharmacy teaching case.
3. Students will map an automated dispensing workflow and recommend AI tools to improve accuracy and patient adherence tracking.
4. Students will build and interpret a basic machine-learning model that flags potential adverse drug reactions from clinical data.
5. Students will analyze public-health datasets with AI techniques to detect emerging trends and propose evidence-based interventions.

COURSE CONTENTS

Unit 1 – AI-Driven Simulation-Based Learning 6 Hours

- Introduction to AI in healthcare and education
- Concept of simulation-based learning in pharmacy education
- **Student modeling**: adaptive feedback systems, personalized learning trajectories
- **Teacher modeling**: intelligent tutoring systems and performance prediction
- Role of Natural Language Processing (NLP) in conversational agents for learning
- Case studies: Use of AI-driven simulators in pharmacology and clinical pharmacy labs

Unit 2 – Simulation & Content-Creation Platforms 6 Hours

- Overview of simulation platforms: design, integration, and outcomes
- **Body Interact**: virtual patient cases, clinical decision-making
- **SimX**: AR/VR-based immersive clinical training
- **IBM Watson Health**: real-time decision support and AI in disease management
- **Synthesia, Pictory, Animoto**: automated video generation for microlearning
- Applications of AI-generated content in patient counseling and drug education
- Ethics and accuracy in AI-generated educational material

Unit 3 – Pharmacy Automation & Adherence 6 Hours

- Pharmacy Automation & Medication Dispensing
- Medication Adherence Monitoring (AI-enabled wearables, apps)
- Fundamentals of pharmacy automation systems: dispensing robots, smart carts

- AI in prescription validation, drug labeling, and inventory management
- Medication adherence tools: AI-enabled **wearables**, reminder apps, digital pills
- Case examples: Proteus Digital Health, Medisafe, and smart pill organizers
- Challenges in implementation: interoperability, privacy, and user compliance
- Role of pharmacists in interpreting AI recommendations and alerts

Unit 4 – Pharmacovigilance & Safety Monitoring 6 Hours

- Adverse Drug Reaction (ADR) Prediction
- Leveraging AI for medicines and vaccines safety monitoring
- Introduction to pharmacovigilance and its challenges in manual reporting
- AI for signal detection in large ADR databases (e.g., VigiBase, FAERS)
- Algorithms for **ADR prediction** based on EHR, genomic, and prescription data
- Safety monitoring of **vaccines and biologics** using machine learning and real-world data
- NLP in mining social media and forums for adverse event tracking
- Integration of AI tools in national pharmacovigilance programs (e.g., PvPI)

Unit 5 – Public Health Analytics 6 Hours

- Introduction to **AI in public health**: disease outbreak prediction, surveillance systems
- Sources of real-world health data: EHRs, claims data, mobile health apps, IoT
- Machine learning models for predicting epidemics, health risks, and patient outcomes
- Role of AI in health policy, vaccination forecasting, and healthcare resource planning
- Introduction to big-data tools (e.g., Hadoop, R, Python, Power BI) for pharmacists
- Case studies: AI for COVID-19 surveillance, antimicrobial resistance mapping

RECOMMENDED BOOKS

1. Artificial Intelligence in Education: Promises and Implications for Teaching and Learning — Wayne Holmes, Maya Bialik & Charles Fadel, Routledge/CCR, 2019 (1st ed.)
2. Pharmacy Automation — Fouad Sabry, Independently Published (Apple Books), 2025 (1st ed.)
3. Artificial Intelligence in Pharmacovigilance: A New Era for Drug Safety — Julia Appelskog, Kindle Direct Publishing, 2024 (1st ed.)
4. AI for Disease Surveillance and Pandemic Intelligence: Intelligent Disease Detection in Action — Arash Shaban-Nejad, Martin Michalowski & Simone Bianco (eds.), Springer, 2022 (1st ed.)
5. Data Science and Predictive Analytics: Biomedical and Health Applications Using R — Ivo D. Dinov, Springer, 2023 (2nd ed.)

Abbreviations

- **SGPA-**Semester Grade Point average
- **CGPA-** Cumulative Grade Point Average
- **MPAT101T*-**Modern Pharmaceutical Analytical Techniques-First Semester-First Subject-Theory
- **MPH102T*-**M.Pharm Pharmaceutics-First Semester-Second Subject-Theory
- **MPH105P*-**M.Pharm Pharmaceutics-First Semester-Fifth Subject-Practical
- **MQA102T*-**M.Pharm Quality Assurance-First Semester-Second Subject-Theory
- **MQA105P*-**M.Pharm Quality Assurance-First Semester-Fifth Subject-Practical
- **MPG102T*-**M.Pharm Pharmacognosy-First Semester-Second Subject-Theory
- **MPG105P*-**M.Pharm Pharmacognosy-First Semester-Fifth Subject-Practical

  (*Applicable to all subject codes likewise)

Syllabus

Program : M. Pharmacy (Common for All Branches)

Class: First Year **Semester :** 1

Modern Pharmaceutical Analytical Technique (Theory)

Course Code : MPAT101T **Credits :** 4 **Contact Hours:**60 Hrs.

Scope : This subject deals with various advanced analytical instrumental techniques for identification, characterization and quantification of drugs. Instruments dealt are UV, IR, NMR, Mass spectrometer, HPLC, GC etc. Simple structure elucidation problems may be included based on UV-IR-NMR data.

Objectives : Upon completion of the course the student shall be able to

- Understand analytical techniques for identification, characterization and quantification of drugs
- Learn theoretical and practical skills of instrument handling and use.
- Carryout Structural Elucidation of organic compounds using spectroscopic tools

Course Outcome (CO):

Upon completion of course student will able to

CO number	Course Outcome (CO) statement
MPAT101T.01	Understand the principles, theory, instrumentation, and applications of UV-Visible spectroscopy, IR spectroscopy, spectrofluorimetry, flame emission spectroscopy, and atomic absorption spectroscopy for qualitative and quantitative analysis of pharmaceutical substances
MPAT101T.02	Interpret the principles, instrumentation, and applications of NMR and Mass Spectrometry and analyze the structural features of organic compounds using integrated spectroscopic techniques
MPAT101T.03	Demonstrate automated analytical methods and chromatographic techniques, and evaluate their suitability for separation and analysis of pharmaceutical compounds
MPAT101T.04	Apply the principles of electrophoresis and X-ray crystallography in the characterization and purity assessment of pharmaceutical substances and biological molecules
MPAT101T.05	Utilize thermal analytical techniques such as TGA and DSC for the identification, characterization, and quantification of drugs and formulation components

Course Content:

Unit	Topic	Hours
I	**a) UV-Visible spectroscopy:** Introduction, Theory, Laws, Instrumentation associated with UV-Visible spectroscopy, Choice of solvents and solvent effect and Applications of UV Visible spectroscopy. **b) IR spectroscopy:** Theory, Modes of Molecular vibrations, Sample handling, Instrumentation of Dispersive and Fourier - Transform IR Spectrometer, Factors affecting vibrational frequencies and Applications of IR spectroscopy, Data Interpretation. **c) Spectrofluorimetry:** Theory of Fluorescence, Factors affecting	10 Hrs.

	fluorescence, Quenchers, Instrumentation and Applications of fluorescence spectroscopy. **d) Flame emission spectroscopy and Atomic absorption spectroscopy:** Principle, Instrumentation, Interferences and Applications.	
II	**NMR spectroscopy:** Quantum numbers and their role in NMR, Principle, Instrumentation, Solvent requirement in NMR, Relaxation process, NMR signals in various compounds, Chemical shift, Factors influencing chemical shift, Spin-Spin coupling, Coupling constant, Nuclear magnetic double resonance, Brief outline of principles of FT-NMR and 13C NMR. Applications of NMR spectroscopy.	10 Hrs.
III	**Mass Spectrometry:** Principle, Theory, Instrumentation of Mass Spectrometry, Different types of ionization like electron impact, chemical, field, FAB and MALDI, APCI, ESI, APPI Analyzers of Quadrupole and Time of Flight, Mass fragmentation and its rules, Meta stable ions, Isotopic peaks and Applications of Mass spectrometry, Structural elucidation- problems based on UV, IR, NMR and Mass data	12 Hrs.
IV	**Chromatography:** Principle, instrumentation, chromatographic parameters, factors affecting resolution and applications of the following: a) Thin Layer chromatography b) Column chromatography c) High Performance Liquid chromatography d) High Performance Thin Layer Chromatography e) Ion exchange chromatography f) Gas chromatography g) Ultra High Performance Liquid chromatography h) Affinity chromatography i) Gel Chromatography j) Hyphenated techniques- LC-MS, GC-MS	10 Hrs.
V	**a) Electrophoresis:** Principle, Instrumentation, Working conditions, factors affecting separation and applications of the following: a) Paper electrophoresis b) Gel electrophoresis c) Capillary electrophoresis d) Zone electrophoresis e) Moving boundary electrophoresis f) Iso electric focusing **b) X ray Crystallography:** Production of X rays, Different X ray diffraction methods, Bragg's law, Rotating crystal technique, X ray powder technique, Types of crystals and applications of X ray diffraction.	10Hrs.
VI	**Thermal Techniques:** **a) Thermogravimetric analysis (TGA):** Principle, instrumentation, factors affecting results, advantage and disadvantages, pharmaceutical applications. **b) Differential scanning calorimetry (DSC):** Principle, thermal transitions and Instrumentation (Heat flux and power-compensation and designs), Modulated DSC, Hyper DSC, experimental parameters (sample preparation, experimental conditions, calibration, heating and cooling rates, resolution, source of errors) and their influence, advantage and disadvantages, pharmaceutical applications. **c) Differential Thermal Analysis (DTA):** Principle, instrumentation and advantage and disadvantages, pharmaceutical applications, derivative differential thermal analysis (DDTA).	08 Hrs.

Recommended Books (Latest editions):-

1. Spectrometric Identification of Organic compounds - Robert M Silverstein, Sixth edition, John Wiley & Sons, 2004.
2. Principles of Instrumental Analysis - Doglas A Skoog, F. James Holler, Timothy A. Nieman, 5th edition, Eastern press, Bangalore, 1998.
3. Instrumental methods of analysis – Willards, 7th edition, CBS publishers.
4. Practical Pharmaceutical Chemistry – Beckett and Stenlake, Vol II, 4th edition, CBS Publishers, New Delhi, 1997.
5. Organic Spectroscopy - William Kemp, 3rd edition, ELBS, 1991.
6. Quantitative Analysis of Drugs in Pharmaceutical formulation - P D Sethi, 3rd Edition, CBS Publishers, New Delhi, 1997.
7. Pharmaceutical Analysis- Modern methods – Part A and B - J W Munson, Volume 11, Marcel Dekker Series
8. Introduction to Spectroscopy, Donald L. Pavia, Gary M. Lampman, George S. Kriz, James A. Vyvyan, Cengage Learning, 2008.
9. Solving spectroscopy problems: A basic approach by Nazmalnamdar (Career publications).

Program : M. Pharmacy (Pharmaceutics) **Class:** First Year **Semester :** 1

Drug Delivery Systems

Course Code : MPH 102T **Credits :** 4 **Contact Hours:** 60 Hrs (Theory)

Scope : This course is designed to impart knowledge on the area of advances in novel drug delivery systems.

Objectives : Upon completion of the course, student shall be able to understand

- ✓ The various approaches for development of novel drug delivery systems.
- ✓ The criteria for selection of drugs and polymers for the development of delivering system
- ✓ The formulation and evaluation of Novel drug delivery systems.

Course Outcome (CO):

Upon completion of course student will able to

CO number	Course Outcome (CO) statement
MPH102.1	Compare polymers used in dosage forms, develop sustained and controlled release formulation; and explain dosage forms for personalized and customized medicines.
MPH102.2	Investigate the rate controlled drug delivery systems and determine activation mechanism and justify feedback regulation.
MPH102.3	Explore the concept of gastro-retentive drug delivery systems and formulate buccal delivery system.
MPH102.4	Predict the methodology for drug delivery across ocular barrier; and design transdermal drug delivery system with enhanced drug penetration through skin.
MPH102.5	Articulate problems in delivery of peptide, proteins and vaccines as well as illustrate the strategy for their formulation.

Course Content:

Unit	Topic	Hours
I	**Sustained Release (SR) and Controlled Release (CR) formulations**: Introduction & basic concepts, advantages/ disadvantages, factors influencing, Physicochemical & biological approaches for SR/CR formulation, Mechanism of Drug Delivery from SR/CR formulation. Difference between IR, CR and SR. **Polymers:** introduction, definition, classification, properties and application, smart polymers/intelligent polymer. **Dosage Forms for Personalized Medicine:** Introduction, Definition, Pharmacogenetics, Categories of Patients for Personalized Medicines: Customized drug delivery systems, Bioelectronic Medicines, 3D printing of pharmaceuticals, Telepharmacy.	12 Hrs

II	**Rate Controlled Drug Delivery Systems:** Principles & Fundamentals, Types, Activation; Modulated Drug Delivery Systems; Mechanically activated, pH activated, Enzyme activated, and Osmotic activated Drug Delivery Systems Feedback regulated Drug Delivery Systems; Principles & Fundamentals.	10 Hrs
III	**Gastro-Retentive Drug Delivery Systems:** Principle, approaches of GRDDS, concepts advantages and disadvantages, Modulation of GI transit time approaches to extend GI transit, **Buccal Drug Delivery Systems**: Principle of mucoadhesion, advantages and disadvantages, mechanism of drug permeation, permeation enhancers, methods of formulation and its evaluations.	12 Hrs
IV	**Ocular Drug Delivery Systems:** Anatomy of eye, advantages and disadvantages of ocular route, Barriers of drug permeation, Methods to overcome barriers, types of ocular drug delivery systems, Evaluation, ocular delivery to posterior segment of eye. **Transdermal Drug Delivery Systems:** Structure of skin and barriers, Penetration enhancers, Transdermal Drug Delivery Systems, Formulation and evaluation. Advancements of transdermal drug delivery.	12 Hrs
V	**Protein and Peptide Delivery:** Barriers for protein delivery. Formulation and Evaluation of delivery systems of proteins and other macromolecules. Stability of protein DDS **Vaccine delivery systems:** Vaccines, classification of vaccines, uptake of antigens, adjuvants used in vaccines, single shot vaccines, mucosal and transdermal delivery of vaccines.	14 Hrs

References:

1. Y W. Chien, Novel Drug Delivery Systems, second edition, revised and expanded, Marcel Dekker, Inc., New York, 1992.
2. Robinson, J. R., Lee V. H. L, Controlled Drug Delivery Systems, Marcel Dekker, Inc, New York, 1992.
3. Encyclopedia of controlled delivery, Editor- Edith Mathiowitz, Published by Wiley Interscience Publication, John Wiley and Sons, Inc, New York! Chichester/Weinheim
4. N.K. Jain, Controlled and Novel Drug Delivery, CBS Publishers & Distributors, New Delhi, First edition 1997 (reprint in 2001).
5. S.P. Vyas and R.K. Khar, Controlled Drug Delivery - concepts and advances, Vallabh Prakashan, New Delhi, First edition 2002

Program : M. Pharmacy (Pharmaceutics) **Class:** First Year **Semester :** 1

Modern Pharmaceutics

Course Code : MPH 103T **Credits :** 4 **Contact Hours:** 60 Hrs (Theory)

Scope : Course designed to impart advanced knowledge and skills required to learn various aspects and concepts at pharmaceutical industries.

Objectives : Upon completion of the course, student shall be able to understand

- ✓ The elements of preformulation studies.
- ✓ The Active Pharmaceutical Ingredients and Generic drug Product development
- ✓ Industrial Management and GMP Considerations.
- ✓ Optimization Techniques & Pilot Plant Scale Up Techniques
- ✓ Stability Testing, sterilization process & packaging of dosage forms.

Course Outcome (CO):

Upon completion of course student will able to

CO number	Course Outcome (CO) statement
MPH103T.1	Evaluate preformulation parameter and assess stability of drug and formulation; summarize theories of dispersed system; and critically explain large and small volume parenteral.
MPH103T.2	Identify independent and dependent variables, choose appropriate design of experiment and optimize pharmaceutical formulations.
MPH103T.3	Evaluate and justify validation strategies including master plan, protocols, and reports, for compliance with regulatory guidelines in pharmaceutical process and systems.
MPH103T.4	Apply and analyze current Good Manufacturing Practices (cGMP) in relation to plant layout, equipment and services while evaluating production management strategies, quality system and technology transfer.
MPH103T.5	Interpret the physics of tablet compression; determine diffusion and dissolution parameters; and assess drug release mechanisms.

Course Content:

Unit	Topic	Hours
I	**a) Preformation:** Concepts, Solubility, Drug Excipient interactions, - different methods of interpretation, Compatibility study, Drug degradation, kinetics of stability, Shelf life, Stability testing as per ICH Q guidelines. **b) Disperse system:** Theories of dispersion and pharmaceutical Dispersion (Emulsion and Suspension, SMEDDS) preparation and stability **c) Parenteral System:** Large and small volume parental – physiological and formulation consideration, Manufacturing and evaluation.	14 Hrs
II	**Optimization techniques in Pharmaceutical Formulation:** Concept and parameters of optimization, Optimization techniques in pharmaceutical formulation and processing. Statistical design,	10 Hrs

	Response surface method, Contour designs, Factorial designs and application in formulation	
III	**Validation:** Introduction to Pharmaceutical Validation, Scope & merits of Validation, Validation and calibration, Validation Master plan, ICH & WHO guidelines for calibration and validation of equipments, Validation of specific dosage form, Types of validation. Government regulation, Manufacturing Process Model, URS facility/ instrument/ equipment, DQ, IQ, OQ & PQ of facilities, Sterile process validation.	12 Hrs
IV	**cGMP & Industrial Management:** Objectives and policies of current good manufacturing practices, layout of buildings, services, equipments and their maintenance **Production management:** Production organization, materials management, handling and transportation, inventory management and control, production and planning control, Sales forecasting, budget and cost control, industrial and personal relationship. Concept of Total Quality Management,	12 Hrs
V	**Compression and compaction:** Physics of tablet compression, compression, consolidation, effect of friction, distribution of forces, compaction profiles. **Study of consolidation parameters;** Diffusion parameters, Dissolution parameters and Pharmacokinetic parameters, IVIVC Heckel plots, Similarity factors – f2 and f1, Higuchi and Peppas plot.	12 Hrs

References:

1. Theory and Practice of Industrial Pharmacy by Lachmann and Liberman.
2. Pharmaceutical dosage forms: Tablets Vol. 1-3 by Leon Lachmann.
3. Pharmaceutical Dosage forms: Disperse systems, Vol, 1-2; By Leon Lachmann.
4. Pharmaceutical Dosage forms: Parenteral medications Vol. 1-2; By Leon Lachmann.
5. Modern Pharmaceutics; By Gillbert and S. Banker.
6. Remington' s Pharmaceutical Sciences.
7. Advances in Pharmaceutical Sciences Vol. 1-5; By H.S. Bean & A.H. Beckett.
8. Physical Pharmacy; By Alfred martin
9. Bentley' s Textbook of Pharmaceutics – by Rawlins.
10. Good manufacturing practices for Pharmaceuticals: A plan for total quality control, Second edition; By Sidney H. Willig.
11. Quality Assurance Guide; By Organization of Pharmaceutical producers of India.
12. Drug formulation manual; By D.P.S. Kohli and D.H. Shah. Eastern publishers, New Delhi.
13. How to practice GMPs; By P.P. Sharma. Vandhana Publications, Agra.
14. Pharmaceutical Process Validation; By Fra. R. Berry and Robert A. Nash.
15. Pharmaceutical Preformulations; By J.J. Wells.
16. Applied production and operations management; By Evans, Anderson, Sweeney and Williams.
17. Encyclopaedia of Pharmaceutical technology, Vol I – III.

Program : M. Pharmacy (Pharmaceutics) **Class:** First Year **Semester :** 1

Regulatory Affairs

Course Code : MPH 104T **Credits :** 4 **Contact Hours:** 60 Hrs (Theory)

Scope : Course designed to impart advanced knowledge and skills required to learn the concept of generic drug and their development, various regulatory filings in different countries, different phases of clinical trials and submitting regulatory documents filing.

- ✓ To know the approval process of IND, NDA and ANDA
- ✓ To know the chemistry, manufacturing controls and their regulatory importance.
- ✓ To learn the documentation requirements for regulatory filling and approvals.
- ✓ To learn the importance and relevance of global regulatory guidelines and compliance.

Objectives : Upon completion of the course, it is expected that the students will be able to understand

- ✓ The Concepts of innovator and generic drugs, drug development process
- ✓ The Regulatory guidance's and guidelines for filing and approval process
- ✓ Preparation of Dossiers and their submission to regulatory agencies in process in different countries.
- ✓ Post approval regulatory requirements for actives and drug products.
- ✓ Submission of global documents in CTD/ eCTD formats
- ✓ Clinical trials requirements for approvals for conducting clinical trials
- ✓ Pharmacovigilance and process of monitoring in clinical trials.

Course Outcome (CO):

Upon completion of course student will able to

CO number	Course Outcome (CO) statement
MPH104T.1	Analyze pharmaceutical documentation and regulatory processes for generic and branded drug product approvals.
MPH104T.2	Interpret and identify the regulatory requirements for approval of APIs, biologics, novel therapies, medical devices, cosmeceuticals, nutraceuticals, and US registration of foreign drugs.
MPH104T.3	Evaluate the role of CMC requirements, post-approval regulations, CTD/eCTD formats, ICH guidelines, and global regulatory frameworks in drug approval submissions.
MPH104T.4	Examine non-clinical drug development process and regulatory submissions of IND, IMPD, and Investigator Brochure.
MPH104T.5	Demonstrate clinical trial protocols, regulatory requirements including ethics, consent, HIPAA and pharmacovigilance in clinical research.

Course Content:

Unit	Topic	Hours
I	**Documentation in Pharmaceutical industry:** Master formula record, DMF (Drug Master File), distribution records. Generic drugs product development Introduction, Hatch Waxman act and amendments, CFR (CODE OF FEDERAL REGULATION), drug product performance, in-vitro, ANDA regulatory approval process, NDA approval process, BE and drug product assessment, in–vivo, scale up process approval changes, post marketing surveillance, outsourcing BA and BE to CRO.	12 Hr
II	**Regulatory requirement for product approval:** API, biologics, novel therapies, obtaining NDA, ANDA for generic drugs ways and means of US registration for foreign drugs. Regulatory approaches and criteria for approval of biotech and medical devices.	12 Hr
III	CMC, post approval regulatory affairs. Regulation for combination products and medical devices. CTD and eCTD format, industry and FDA liaison. ICH Guidelines - Q, S, E, M. Regulatory requirements of USFDA, EMA, MHRA, TGA and ROW countries.	12 Hr
IV	**Non clinical drug development:** Global submission of IND. Investigation of medicinal products dossier (IMPD) and investigator brochure (IB).	12 Hr
V	**Clinical trials:** Developing clinical trial protocols. Institutional review board/ independent ethics committee, Formulation and working procedures, informed Consent process and procedures. HIPAA- new requirement to clinical study process, Pharmacovigilance safety monitoring in clinical trials.	12 Hr

References:

1. Generic Drug Product Development, Solid Oral Dosage forms, Leon Shargel and IsaderKaufer, Marcel Dekker series, Vol.143
2. 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.
3. New Drug Approval Process: Accelerating Global Registrations by Richard A Guarino, MD,5th edition, Drugs and the Pharmaceutical Sciences, Vol.190.
4. Guidebook for drug regulatory submissions / Sandy Weinberg. By John Wiley & Sons.Inc.
5. FDA regulatory affairs: a guide for prescription drugs, medical devices, and biologics/edited By Douglas J. Pisano, David Mantus.
6. Clinical Trials and Human Research: A Practical Guide to Regulatory Compliance by Fay A. Rozovsky and Rodney K. Adams
7. www.ich.org/
8. www.fda.gov/
9. europa.eu/index_en.htm
10. https://www.tga.gov.au/tga-basics

Program : M. Pharmacy (Pharmaceutics) **Class:** First Year **Semester :** 1

Pharmaceutics Practical I

Course Code : MPH 105T **Credits :** 4 **Contact Hours:** 180 Hrs (Practical) 12 Hr/week

Scope : To provide students with foundational skills in pharmaceutical formulation, evaluation, and quality assessment, preparing them for advanced research, development, and industry applications in drug delivery and manufacturing.

Objectives : Upon completion of the course, the students shall be able to

- ✓ Apply principles of pharmaceutical formulation to prepare dosage forms like tablets
- ✓ Perform basic analytical tests for quality control.
- ✓ Identify and solve formulation problems.
- ✓ Collaborate effectively in laboratory settings and communicate scientific observations

Course Outcome (CO):

Upon completion of course student will able to

CO number	Course Outcome (CO) statement
MPH105P.1	Evaluate the drug substances and pharmaceutical formulation using advanced analytical techniques such as UV-visible spectroscopy, HPLC and flame photometry.
MPH105P.2	Perform and interpret preformulation studies to generate data supporting rational tablet development
MPH105P.3	Formulate and evaluate advanced drug delivery systems – including sustained release, osmotic, floating, mucoadhesive and transdermal drug delivery system
MPH105P.4	Justify impact of material attributes and process parameters on tablets.
MPH105P.1	Evaluate the drug substances and pharmaceutical formulation using advanced analytical techniques such as UV-visible spectroscopy, HPLC and flame photometry.

Course Content:

1. Analysis of pharmacopoeial compounds and their formulations by UV Vis spectrophotometer
2. Simultaneous estimation of multi component containing formulations by UV spectrophotometry
3. Experiments based on HPLC / Gas Chromatography
4. Estimation of riboflavin/quinine sulphate by fluorimetry
5. Estimation of sodium/potassium by flame photometry
6. To perform In-vitro dissolution profile of CR/ SR marketed formulation
7. Formulation and evaluation of sustained release matrix tablets
8. Formulation and evaluation osmotically controlled DDS
9. Preparation and evaluation of Floating DDS hydro dynamically balanced DDS
10. Formulation and evaluation of Mucoadhesive tablets.
11. Formulation and evaluation of transdermal patches.
12. To carry out preformulation studies of tablets.
13. To study the effect of compressional force on tablets disintegration time.
14. To study Micromeritic properties of powders and granulation.
15. To study the effect of particle size on dissolution of a tablet.
16. To study the effect of binders on dissolution of a tablet.
17. To plot Heckal plot, Higuchi and peppas plot and determine similarity factors.
18. To plot the ternary phase diagram in the formulation development of emulsion.

Program : M. Pharmacy (Pharmaceutics) **Class:** First Year **Semester :** 2

Molecular Pharmaceutics (Nano Technology & Targeted DDS)

Course Code : MPH 201T **Credits :** 4 **Contact Hours:** 60 Hrs (Theory)

Scope : This course is designed to impart knowledge on the area of advances in novel drug delivery systems.

Objectives : Upon completion of the course student shall be able to understand

- ✓ The various approaches for development of novel drug delivery systems.
- ✓ The criteria for selection of drugs and polymers for the development of NTDS
- ✓ The formulation and evaluation of novel drug delivery systems.

Course Outcome (CO):

Upon completion of course student will able to

CO number	Course Outcome (CO) statement
MPH201T.1	Explain the concepts, events, and biological processes involved in drug targeting, and analyze approaches for tumor targeting and brain-specific drug delivery
MPH201T.2	Describe and analyze targeting methods, and design nanoparticle and liposomal drug delivery systems through preparation, evaluation, and application studies.
MPH201T.3	Apply formulation techniques to develop microcapsules, microspheres, monoclonal antibodies, niosomes, aquasomes, phytosomes, and resealed erythrocytes; and assess their suitability as advanced drug delivery carriers.
MPH201T.4	Demonstrate formulation approaches for pulmonary aerosols and intranasal drug delivery systems, examine their components, preparation, and evaluation methods, and appraise their potential for therapeutic applications.
MPH201T.5	Summarize gene therapy and explore applications in inherited disorder; and review therapeutic antisense molecules and aptamers as drugs of future.

Course Content:

Unit	Topic	Hours
I	**Targeted Drug Delivery Systems:** Concepts, Events and biological process involved in drug targeting. Tumor targeting and Brain specific delivery.	12 Hrs
II	**Targeting Methods:** introduction preparation and evaluation. Nano Particles, Liposomes and Niosomes: Types, preparation and evaluation, application.	12 Hrs
III	**Micro Capsules / Micro Spheres:** Types, kinetics of release, preparation and evaluation, Monoclonal Antibodies; preparation and application, Phytosomes, Resealed erythrocytes	12 Hrs
IV	**Pulmonary Drug Delivery Systems:** Aerosols, propellents, Containers, Types, preparation and evaluation, Intra Nasal Route Delivery systems; Types, preparation and evaluation.	12 Hrs
V	**Nucleic acid based therapeutic delivery system:** Gene therapy, introduction (ex-vivo & in-vivo gene therapy). Potential target diseases for gene therapy (inherited disorder and cancer). Vectors for gene transfer. Liposomal gene delivery systems (Lipoplexes and polyplexes). Biodistribution and Pharmacokinetics**.** knowledge of therapeutic antisense molecules and aptamers as drugs of future.	12 Hrs

References:

1. Y W. Chien, Novel Drug Delivery Systems, second edition, revised and expanded, Marcel Dekker, Inc., New York, 1992.
2. S.P. Vyas and R.K. Khar, Controlled Drug Delivery - concepts and advances, Vallabh Prakashan, New Delhi, First edition 2002.
3. N.K. Jain, Controlled and Novel Drug Delivery, CBS Publishers & Distributors, New Delhi, First edition 1997 (reprint in 2001).

Program : M. Pharmacy (Pharmaceutics) **Class:** First Year **Semester :** 2

Advanced Biopharmaceutics and Pharmacokinetics

Course Code : MPH 202T **Credits :** 4 **Contact Hours:** 60 Hrs (Theory)

Scope : This course is designed to impart knowledge and skills necessary for dose calculations, dose adjustments and to apply biopharmaceutics theories in practical problem solving. Basic theoretical discussions of the principles of biopharmaceutics and pharmacokinetics are provided to help the students to clarify the concepts.

Objectives : Upon completion of this course, it is expected that students will be able to understand

- ✓ The basic concepts in biopharmaceutics and pharmacokinetics
- ✓ The use raw data and derive the pharmacokinetic models and parameters the best describe the process of drug absorption, distribution, metabolism and elimination.
- ✓ The critical evaluation of biopharmaceutic studies involving drug product equivalency.
- ✓ The design and evaluation of dosage regimens of the drugs using pharmacokinetic and biopharmaceutic parameters.
- ✓ The potential clinical pharmacokinetic problems and application of basics of pharmacokinetic.

Course Outcome (CO):

Upon completion of course student will able to

CO number	Course Outcome (CO) statement
MPH202T.1	Analyze the mechanisms and factors affecting drug absorption and dissolution from various dosage forms in the gastrointestinal tract.
MPH202T.2	Evaluate biopharmaceutic principles influencing drug product design and evaluate *in vitro* drug performance and IVIVC.
MPH202T.3	Apply pharmacokinetic models to understand drug absorption, distribution, metabolism, including non-linear kinetics and drug interactions.
MPH202T.4	Design and evaluate bioavailability and bioequivalence studies, including permeability assessment and application of bioavailability enhancement techniques.
MPH202T.5	Describe the pharmacokinetic and pharmacodynamic principles related to modified-release formulations and biotechnological drug products.

Course Content:

Unit	Topic	Hours
I	**Drug Absorption from the Gastrointestinal tract:** Gastrointestinal tract, Mechanisms of drug absorption, Factors affecting drug absorption, pH partition theory of drug absorption. Formulation and physicochemical factors: Dissolution rate, Dissolution process, Noyes–Whitney equation and drug dissolution, Factors affecting the dissolution rate. Gastrointestinal absorption: role of the dosage form: Solution (elixir, syrup and solution) as a dosage form, Suspension as a dosage form, Capsule as a dosage form, Tablet as a dosage form, Dissolution methods, Formulation and processing factors, Correlation of *in vivo* data with *in vitro* dissolution data. Transport model: Permeability-Solubility-Charge State and the pH Partition hypothesis, Properties of the Gastrointestinal Tract (GIT), pH Microclimate Intracellular pH Environment, Tight - Junction Complex.	12 Hr
II	**Biopharmaceutic Considerations in Drug Product Design and *In Vitro* Drug Product Performance:** Introduction, biopharmaceutic factors affecting drug bioavailability, rate-limiting steps in drug absorption, physicochemical nature of the drug, formulation factors affecting drug product performance *in vitro*: dissolution and drug release testing, compendial methods of dissolution, alternative methods of dissolution testing, meeting dissolution requirements, problems of variable control in dissolution testing performance of drug products. *In vitro–in vivo* correlation, dissolution profile comparisons, drug product stability, considerations in the design of a drug product.	12 Hr
III	**Pharmacokinetics:** Basic considerations, pharmacokinetic models, compartment modelling: one compartment model- IV bolus, IV infusion, extra-vascular. Multi compartment model: two compartment model in brief, non-linear pharmacokinetics: cause of non-linearity, Michaelis–Menten equation, estimation of K_{max} and V_{max}. Drug interactions: introduction, the effect of protein-binding interactions, the effect of tissue-binding interactions, cytochrome p450-based drug interactions, drug interactions linked to transporters	12 Hr
IV	**Drug Product Performance, *in vivo*: Bioavailability and Bioequivalence:** drug product performance, purpose of bioavailability studies, relative and absolute availability. Methods for assessing bioavailability, bioequivalence studies, design and evaluation of bioequivalence studies, study designs, crossover study designs, evaluation of the data, bioequivalence example, study submission and drug review process. Biopharmaceutics classification system, methods. Permeability: *In-vitro*, *in-situ* and *In-vivo* methods, Bioavailability enhancement techniques. Generic biologics (Biosimilar drug products), clinical significance of bioequivalence studies, special concerns in bioavailability and bioequivalence studies, generic substitution.	12 Hr
V	**Application of Pharmacokinetics:** Modified-Release Drug Products, Targeted Drug Delivery Systems and Biotechnological Products. Introduction to Pharmacokinetics and pharmacodynamic, drug interactions. Pharmacokinetics and pharmacodynamics of biotechnology drugs. Introduction, Proteins and peptides, Monoclonal antibodies, Oligonucleotides, Vaccines (immunotherapy), Gene therapies.	12 Hr

References:

1. Biopharmaceutics and Clinical Pharmacokinetics by Milo Gibaldi, 4th edition, Philadelphia, Lea and Febiger, 1991
2. Biopharmaceutics and Pharmacokinetics, A. Treatise, D.M. Brahmankar and Sunil B. Jaiswal., Vallabh Prakashan, Pitampura, Delhi
3. Applied Biopharmaceutics and Pharmacokinetics by Shargel. Land Yu ABC, Second edition, Connecticut Appleton Century Crofts, 1985
4. Textbook of Biopharmaceutics and Pharmacokinetics, Dr. Shobha Rani R. Hiremath, Prism Book
5. Pharmacokinetics by Milo Gibaldi and D. Perrier, Second edition, Marcel Dekker Inc., New York, 1982
6. Current Concepts in Pharmaceutical Sciences: Biopharmaceutics, Swarbrick. J, Lea and Febiger, Philadelphia, 1970
7. Clinical Pharmacokinetics, Concepts and Applications third edition by Malcolm Rowland and Thom N. Tozer, Lea and Febiger, Philadelphia, 1995
8. Dissolution, Bioavailability and Bioequivalence, Abdou. H.M, Mack Publishing Company, Pennsylvania 1989
9. Biopharmaceutics and Clinical Pharmacokinetics, An Introduction, 4th edition, revised and expanded by Robert. E. Notari, Marcel Dekker Inc, New York and Basel,1987.
10. Biopharmaceutics and Relevant Pharmacokinetics by John. G Wagner and M. Pemarowski, 1st edition, Drug Intelligence Publications, Hamilton, Illinois, 1971.
11. Encyclopedia of Pharmaceutical Technology, Vol 13, James Swarbrick, James. G. Boylan, Marcel Dekker Inc, New York, 1996.
12. Basic Pharmacokinetics, first edition, Sunil S Jambhekar and Philip J Breen, pharmaceutical press, RPS Publishing,2009.
13. Absorption and Drug Development- Solubility, Permeability, and Charge State, Alex Avdeef, John Wiley & Sons, Inc,2003.

Program : M. Pharmacy (Pharmaceutics) **Class:** First Year **Semester :** 2

Computer Aided Drug Development

Course Code : MPH 203T **Credits :** 4 **Contact Hours:** 60 Hrs (Theory)

Scope : This course is designed to impart knowledge and skills necessary for computer Applications in pharmaceutical research and development. It is intended for individuals who want to understand the application of computers across the entire drug research and development process. The course provides basic theoretical discussions of the principles of more integrated and coherent use of computerized information (informatics) in the drug development process that can help the students to clarify the concepts.

Objectives : Upon completion of this course it is expected that students will be able to understand,

- ✓ History of Computers in Pharmaceutical Research and Development
- ✓ Computational Modeling of Drug Disposition
- ✓ Computers in Preclinical Development
- ✓ Optimization Techniques in Pharmaceutical Formulation
- ✓ Computers in Market Analysis
- ✓ Computers in Clinical Development
- ✓ Artificial Intelligence (AI) and Robotics
- ✓ Computational fluid dynamics (CFD)

Course Outcome (CO):

Upon completion of course student will able to

CO number	Course Outcome (CO) statement
MPH203T.1	Analyze the role of computers and statistical modeling in pharmaceutical research and development and apply Quality-by-Design principles in line with regulatory guidelines to pharmaceutical development.
MPH203T.2	Employ computational modeling to predict ADME properties and examine the contribution of transporters including P-gp, BCRP, hPEPT1, ASBT, OCT, OATP, and BBB transporters in drug disposition.
MPH203T.3	Apply computer-aided optimization and screening designs in pharmaceutical formulation development; and discuss the ethical considerations and legal aspects of computer applications in pharmaceutical R&D and market analysis.
MPH203T.4	Illustrate computer-aided approaches in biopharmaceutical characterization and PK/PD simulations, and practice computational tools in clinical data collection
MPH203T.5	Describe the principles of AI, robotics, and computational fluid dynamics, and articulate their concepts to pharmaceutical automation and applications

Course Content:

Unit	Topic	Hours
I	**Computers in Pharmaceutical Research and Development:** A general overview: History of computers in pharmaceutical research and development, Statistical modeling in pharmaceutical research and development, Descriptive versus Mechanistic modeling, Statistical Parameters, Estimation, Confidence Regions, Nonlinearity at the Optimum, Sensitivity Analysis, Optimal Design, Population Modeling. **Quality-by-Design in Pharmaceutical Development:** Introduction, ICH Q8 guideline, Regulatory and industry views on QbD, scientifically based QbD - Pharmaceutical formulation examples and applications.	12 Hrs
II	**Computational Modeling of Drug Disposition**: Introduction, Modeling Techniques: Drug Absorption, Solubility, Intestinal Permeation, Drug Distribution, Drug Excretion, Active Transport; P-gp, BCRP, Nucleoside Transporters, hPEPT1, ASBT, OCT, OATP, BBB-Choline Transporter.	12 Hrs
III	**Computer-aided formulation development:** Concept of optimization, Optimization parameters, Factorial design, Optimization technology & Screening design. Computers in pharmaceutical formulation: Development of pharmaceutical emulsions, microemulsions, drug carriers. Legal protection of innovative uses of computers in R&D, The ethics of computing in pharmaceutical research, Computers in market analysis.	12 Hrs
IV	**Computer-aided biopharmaceutical characterization:** Gastrointestinal absorption simulation, Introduction, Theoretical background, Model construction, Parameter sensitivity analysis, Virtual trial, Fed vs. fasted state, *In vitro* dissolution and *in vitro* in *vivo* correlation, Biowaiver considerations. **Computer Simulations in Pharmacokinetics and Pharmacodynamics:** Introduction, Computer simulation: Whole Organism, Isolated Tissues, Organs, Cell, Proteins and Genes. **Computers in Clinical Development:** Clinical data collection and management, Regulation of computer systems in clinical research.	12 Hrs
V	Artificial Intelligence (AI), Robotics and Computational fluid dynamics: general overview, Pharmaceutical Automation, Pharmaceutical applications, advantages and disadvantages, current challenges and future directions.	12 Hrs

References:

1. Computer Applications in Pharmaceutical Research and Development, Sean Ekins, 2006, John Wiley & Sons.
2. Computer-Aided Applications in Pharmaceutical Technology, First Edition, Jelena Djuris, Woodhead Publishing.
3. Encyclopedia of Pharmaceutical Technology, Vol. 13, James Swarbrick, James. G. Boylan, Marcel Dekker Inc, New York, 1996.

Program : M. Pharmacy (Pharmaceutics) **Class:** First Year **Semester :** 2

Cosmetics and Cosmeceuticals

Course Code : MPH 204T **Credits :** 4 **Contact Hours:** 60 Hrs (Theory)

Scope : This course is designed to impart knowledge and skills necessary for the fundamental need for cosmetic and cosmeceutical products.

Objectives : Upon completion of the course, the students shall be able to understand

- ✓ Key ingredients used in cosmetics and cosmeceuticals.
- ✓ Key building blocks for various formulations.
- ✓ Current technologies in the market
- ✓ Various key ingredients and basic science to develop cosmetics and cosmeceuticals
- ✓ Scientific knowledge to develop cosmetics and cosmeceuticals with desired Safety, stability, and efficacy.

Course Outcome (CO):

Upon completion of course student will able to

CO number	Course Outcome (CO) statement
MPH204T.1	Apply Indian regulatory requirements for labeling, import, and manufacture of cosmetics, and assess compliance and potential legal implications in the industry.
MPH204T.2	Describe the structure of skin, hair, and oral cavity; express common cosmetic problems and investigate cleansing and care requirements for different body regions.
MPH204T.3	assess the role of key ingredients, including surfactants, emollients, preservatives, and perfumes; and develop cosmetic product
MPH204T.4	Interpret cosmetic care needs and design cosmeceutical products for skin, hair, and oral health, including sunscreens and anti-acne treatments.
MPH204T.5	Allocate herbal ingredients in hair, skin, and oral care, evaluate formulation guidelines from bodies like COSMOS, and develop herbal cosmetic products addressing formulation challenges.

Course Content:

Unit	Topic	Hours
I	**Cosmetics – Regulatory:** Definition of cosmetic products as per Indian regulation. Indian regulatory requirements for labelling of cosmetics Regulatory provisions relating to import of cosmetics., Misbranded and spurious cosmetics. Regulatory provisions relating to manufacture of cosmetics - Conditions for obtaining license, prohibition of manufacture and sale of certain cosmetics, loan license, offences and penalties.	12
II	**Cosmetics** - **Biological aspects:** Structure of skin relating to problems like dry skin, acne, pigmentation, prickly heat, wrinkles and body odor. Structure of hair and hair growth cycle. Common	12

	problems associated with oral cavity. Cleansing and care needs for face, eye lids, lips, hands, feet, nail, scalp, neck, body and under–arm.	
III	**Formulation Building blocks:** Classification of Cosmetics, Building blocks for different product formulations of cosmetics/cosmeceuticals. Surfactants - Classification and application. Emollients and its application, rheological additives: classification and application. Antimicrobial used as preservatives, their merits and demerits. Factors affecting microbial preservative efficacy. Building blocks for formulation of a moisturizing cream, vanishing cream, cold cream, shampoo and toothpaste. Soaps and syndetbars **Perfumes:** Advantages and Disadvantages of Perfume, Notes of Perfume, Classification of perfumes. Perfume ingredients listed as allergens in EU regulation. **Controversial ingredients**: Parabens, formaldehyde liberators, dioxane.	14
IV	**Design of cosmeceutical products**: Sun protection, sunscreens classification, SPF value. Addressing dry skin, acne, sun–protection, pigmentation, prickly heat, wrinkles, body odor, dandruff, dental cavities, bleeding gums, mouth odor and sensitive teeth through cosmeceutical formulations.	12
V	**Herbal Cosmetics:** Definition of Herbal Cosmetics, Advantages and Disadvantages of Herbal Cosmetics, Herbal ingredients used in Hair care, skin care and oral care. Review of guidelines for herbal cosmetics by private bodies like cosmos with respect to preservatives, emollients, foaming agents, emulsifiers and rheology modifiers. Challenges in formulating herbal cosmetics.	10

References:

1. Harry's Cosmeticology, eighth edition.
2. Poucher's perfume cosmetics and Soaps, tenth edition.
3. Cosmetics – Formulation, Manufacture and quality control, PP. Sharma,4th edition
4. Handbook of cosmetic science and Technology A.O. Barel, M. Paye and H.I. Maibach. third edition
5. Cosmetic and Toiletries recent suppliers‟ catalogue.
6. CTFA directory.

Program : M. Pharmacy (Pharmaceutics) **Class:** First Year **Semester :** 2

Pharmaceutics Practical II

Course Code : MPH 205T **Credits :** 4 **Contact Hours:** 180 Hrs (Practical) 12 Hr/week

Scope : This course is designed to equip students with advanced formulation, analytical, and quality control skills for research, development, regulatory compliance, and industry roles in pharmaceutical sciences.

Objectives : Upon completion of the course, the students shall be able to understand

- ✓ Design, optimize and analyze novel pharmaceutical products
- ✓ Key ingredients used in cosmetics and cosmeceuticals.
- ✓ Computer aided drug design and development
- ✓ Biopharmaceutical aspects of product

Course Outcome (CO):

Upon completion of course student will able to

CO number	Course Outcome (CO) statement
MPH205P.1	Prepare and evaluate microparticles
MPH205P.2	Analyze and compare solubility, dissolution, protein binding
MPH205P.3	Assess bioavailability, and pharmacokinetic data using experimental and computational methods
MPH205P.4	Apply statistical DoE, QbD
MPH205P.5	Exercise formulation principles to develop and evaluate cosmeceuticals and herbal cosmetics

Course Content:

1. To study the effect of temperature change, nonsolvent addition, incompatible polymer addition in microcapsules preparation.
2. Preparation and evaluation of Alginate beads
3. Formulation and evaluation of gelatin /albumin/Ethyl cellulose microspheres
4. Formulation and evaluation of liposomes / niosomes / polymeric nanoparticles.
5. Formulation and evaluation of spherules / pellets
6. Improvement of dissolution characteristics of slightly soluble drug by Solid dispersion technique (inclusion complex Beta Cyclodextrin)
7. Comparison of dissolution of two different marketed products /brands (F1 and F2 determination).
8. Protein binding studies of a highly protein bound drug & poorly protein bound drug
9. Bioavailability studies of Paracetamol in animals.
10. Estimation of Pharmacokinetic and IVIVC data analysis by Winnoline® software or any suitable tool.
11. *In vitro* cell studies for permeability and metabolism
12. DoE Using Design Expert® Software
13. Formulation data analysis Using Design Expert® Software
14. Quality-by-Design in Pharmaceutical Development
15. Computer Simulations in Pharmacokinetics and Pharmacodynamics
16. Computational Modeling of Drug Disposition
17. To develop Clinical Data Collection manual
18. To carry out Sensitivity Analysis, and Population Modeling.
19. Development and evaluation of Creams
20. Development and evaluation of Shampoo and Toothpaste base
21. To incorporate herbal and chemical actives to develop products
22. To address Dry skin, acne, blemish, Wrinkles, bleeding gums and dandruff

Program : M. Pharmacy [Pharmaceutical Quality Assurance (MQA)] **Class:** First Year **Semester :** 1

QUALITY MANAGEMENT SYSTEM (THEORY)

Course Code : MQA102T	**Credits :** 4	**Contact Hours:**60 Hrs.

Scope : This course is designed to impart fundamental knowledge and concepts about various quality management principles and systems utilized in the manufacturing industry. It also aids in understanding the quality evaluation in the Pharmaceutical industries

Objectives : Upon completion of the course the student shall be able to

- Understand the importance of quality
- Know tools for quality improvement
- Analyze issues in quality
- Perform quality evaluation of pharmaceuticals
- Understand stability testing of drug and drug substances
- Understand statistical approaches for quality

Course Outcome (CO):

Upon completion of course student will be able to

CO number	Course Outcome (CO) statement
MQA102T.1	Understand the concepts and gain knowledge about the importance of quality, analysis of issues in quality
MQA102T.2	Acquire knowledge on tools for quality improvement pharmaceutical quality Management
MQA102T.3	Understand and explain Quality evaluation of pharmaceuticals using Six System Inspection model, Quality systems, Complaints, CAPA
MQA102T.4	Study, understand and explain Stability testing of drug and drug substances, Statistical Process control (SPC)
MQA102T.5	Understand and explain Regulatory Compliance through Quality Management and development of Quality Culture Benchmarking

Course Content:

Unit	Topic	Hours
I	**Introduction to Quality**: Definition of Quality, Evolution of Quality, Dimensions of Quality, Quality culture metrics **Quality as a Strategic Decision:** Meaning of strategy and strategic quality management, mission and vision statements, quality policy, Quality objectives, strategic planning and implementation, McKinsey 7s model, Competitive analysis, Management commitment to quality, Customer Focus: Meaning of customer and customer focus, Classification of customers, Customer focus, Customer perception of quality, Factors affecting customer perception, Customer requirements, Meeting customer needs and expectations, Customer satisfaction and Customer delight, Handling customer complaints, Understanding customer behaviour, concept of internal and external customers, Case studies **Cost of Quality:** Meaning, Categories of cost of Quality, Models of cost of quality, Optimizing costs, preventing cost of quality.	08 Hrs.
II	**Pharmaceutical quality Management:** Basics of Quality Management, Total Quality Management (TQM), Principles of Six	16 Hrs.

	sigma, ISO 9001:2008, 9001:2015, ISO 14001:2004, Pharmaceutical Quality Management-ICH Q10, Knowledge management, Quality Metrics, Operational Excellence and Quality Management Review. OSHAS guidelines, NABL certification and accreditation, CFR-21 part 11 with case study, WHO-GMP requirements.	
III	**Six System Inspection model:** Quality Management system, Production system, Facility and Equipment system, Laboratory control system, Materials system, Packaging and labelling system. Concept of self-inspection **Quality systems:** Change Management / Change control. Deviations, Out of Specifications (OOS), Out of Trend (OOT) **Complaints**- evaluation and handling, Investigation and determination of root cause, Corrective & Preventive Actions (CAPA), Returns and Recalls, Vendor Qualification, Annual Product Reviews, Batch Review and Batch Release. Concept of IPQC, area clearance/ Line clearance	12 Hrs.
IV	**Drug Stability:** ICH guidelines for stability testing of drug substances and drug products. **Study of ICH Q8, Quality by Design and Process development report** **Quality risk management:** Introduction, risk assessment, risk control, risk review, risk management tools, HACCP, risk ranking and filtering according to ICH Q9 guidelines. **Data Integrity**	12 Hrs.
V	**Statistical Process control (SPC):** Definition and Importance of SPC, Quality measurement in manufacturing, Statistical control charts- concepts and general aspects, Advantages of statistical control, Process capability, Estimating Inherent or potential capability from a control chart analysis, Measuring process control and quality improvement, Pursuit of decreased process variability.	08 Hrs.
VI	**Regulatory Compliance through Quality Management and development of Quality Culture Benchmarking:** Definition of benchmarking, Reasons for benchmarking, Types of Benchmarking, Benchmarking process, Advantages of benchmarking, Limitations of benchmarking.	04 Hrs.

Recommended books (Latest editions):-

1. Al Endres, Implementing Juran's Road Map for Quality Leadership: Benchmarks and Results, Wiley, 2000.
2. Jiju Antony; David Preece, Routledge, Understanding, Managing and Implementing Quality: Frameworks, Techniques and Cases, 2002.
3. Edward E. Lawler, Organizing for High Performance: Employee Involvement, TQM, Reengineering, and Knowledge Management in the Fortune 1000: The CEO Report, 2001.
4. James W. Fairfield- Sonn, Corporate Culture and the Quality Organization, Quorum Books, 2001.
5. Christine Avery; Diane Zabel, Routledge, the Quality Management Sourcebook: An International Guide to Materials and Resources 1997.
6. Nancy R. Tague, the Quality Toolbox, Second Edition, ASQ Publications.
7. Joseph M. Juran and Joseph A., De Feo, Juran's Quality Handbook, Sixth Edition, ASQ Publications.
8. Duke Okes, Root Cause Analysis, the Core of Problem Solving and Corrective Action, 2009, ASQ Publications.

Program : M. Pharmacy (Pharmaceutical Quality Assurance) **Class:** First Year **Semester :** 1

QUALITY CONTROL & QUALITY ASSURANCE (THEORY)

Course Code: MQA103T	**Credits:** 4	**Contact Hours:** 60 Hrs.

Scope : This course deals with the various aspects of quality control and quality assurance aspects of pharmaceutical industries. It covers the important aspects like cGMP, QC tests, documentation, quality certifications, GLP and regulatory affairs.

Objectives : Upon completion of the course student shall be able to:

- Understand the cGMP aspects in a pharmaceutical industry.
- Learn the documentation process.
- Understand the scope of quality certifications applicable to Pharmaceutical industries.
- Understand the responsibilities of QA & QC departments.

Course Outcome (CO):

Upon completion of course student will able to

CO number	Course Outcome (CO) statement
MQA103T.1	Understand & explain a concepts, responsibilities and scope of quality control (QC) and quality assurance (QA) and regulatory compliance for pharmaceutical products.
MQA103T.2	Explain & implement Good Laboratory Practices (GLP), Good Manufacturing Practices (GMP), C-GMP including M-schedule, ICH guidelines to assess quality system in pharmaceutical operation.
MQA103T.3	Understand & explain the role of various regulatory body guidelines in maintaining compliance in pharmaceutical manufacturing.
MQA103T.4	Demonstrate quality analysis for raw materials, finished products, and packaging materials as per IP, USP & BP.
MQA103T.5	Prepare, maintain & implement documentation practices in Pharmaceutical Industry for both regulated & non-regulated market.
MQA103T.6	Explain & implement how to control & validate manufacturing environment to prevent cross contamination & ensure sterile production.

Course Content:

Unit	Topic	Hours
I	**Introduction:** Concept and evolution and scopes of Quality Control and Quality Assurance, Good Laboratory Practice, GMP, Overview of ICH Guidelines - QSEM, with special emphasis on Q-series guidelines. **Good Laboratory Practices:** Scope of GLP, Definitions, Quality assurance unit, protocol for conduct of nonclinical testing, control on animal house, report preparation and documentation. CPCSEA guidelines **GDP Guidelines**- ALCOA practices & SOPs	12 Hrs.
II	**cGMP guidelines according to schedule M, USFDA (inclusive of CDER and CBER) Pharmaceutical Inspection Convention(PIC),**	12 Hrs.

	WHO and EMEA covering: Organization and personnel responsibilities, training, hygiene and personal records, drug industry location, design, construction and plant lay out, maintenance, sanitation, environmental control, utilities and maintenance of sterile areas, control of contamination and Good Warehousing Practice	
III	Analysis of raw materials, finished products, packaging materials, in process quality control (IPQC), Developing specification (ICH Q6 and Q3), purchase specifications and maintenance of stores for raw materials. In process quality control and finished products quality control for following dosage forms in Pharma industry according to Indian, US and British pharmacopoeias: tablets, capsules, ointments, suppositories, creams, parenterals, ophthalmic and surgical products (How to refer pharmacopoeias)	12 Hrs.
IV	**Documentation in pharmaceutical industry:** Three tier documentation, Policy, Procedures and Work instructions, and records (Formats), Basic principles- How to maintain, retention and retrieval etc. Standard operating procedures (How to write), Master Batch Record, Batch Manufacturing Record, Quality audit plan and reports. Specification and test procedures, Protocols and reports. Distribution records. Electronic data handling. Concepts of controlled and uncontrolled documents. Submission documents for regulators DMFs, as Common Technical Document and Electronic Common Technical Documentation (CTD, eCTD). Concept of regulated and non-regulated markets.	16 Hrs.
V	**Manufacturing operations and controls:** Sanitation of manufacturing premises, mix-ups and cross contamination, processing of intermediates and bulk products, packaging operations, IPQC, release of finished product, process deviations, charge-in of components, time limitations on production, drug product inspection, expiry date calculation, calculation of yields, production record review, change control, sterile products, aseptic process control, packaging, reprocessing, salvaging, handling of waste and scrap disposal.	08 Hrs.

Recommended books (Latest editions):-

1. Quality Assurance Guide by organization of Pharmaceutical Procedures of India, 3rd revised edition, Volume I & II, Mumbai, 1996.
2. Sandy Weinberg, Good Laboratory Practice Regulations, 2nd Edition, Vol. 69, Marcel Dekker Series, 1995.
3. Quality Assurance of Pharmaceuticals- A compendium of Guide lines and related materials Vol I & II, 2nd edition, WHO Publications, 1999.
4. Sharma P. P., How to Practice GMP"s Vandana Publications, Agra, 1991, 127.
5. The International Pharmacopoeia – Vol I, II, III, IV & V - General Methods of Analysis and Quality specification for Pharmaceutical Substances, Excipients and Dosage forms, 3rd edition, WHO, Geneva, 2005.
6. Allen F. Hirsch, Good laboratory Practice Regulations, Volume 38, Marcel Dekker Series, 1989.
7. ICH guidelines
8. ISO 9000 and total quality management.
9. Deshpande, Nilesh Gandhi, The Drugs and Cosmetics Act 1940, 4th edition, Susmit Publishers, 2006.

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

Program : M. Pharmacy (Pharmaceutical Quality Assurance) **Class:** First Year **Semester :** 1

PRODUCT DEVELOPMENT AND TECHNOLOGY TRANSFER (THEORY)

Course Code: MQA104T	**Credits:** 4	**Contact Hours:** 60Hrs.

Scope : This deal with technology transfer covers the activities associated with Drug Substance, Drug Product and analytical tests and methods, required following Candidate drug selection to completion of technology transfer from R&D to the first receiving site and technology transfer related to post-marketing changes in Manufacturing places.

Objectives: Upon completion of this course the student should be able to

- Understand the new product development process
- Understand the necessary information to transfer technology from R&D to actual manufacturing by sorting out various information obtained during R&D
- Elucidate necessary information to transfer technology of existing products between various manufacturing places

Course Outcome (CO):

Upon completion of course student will able to

CO number	Course Outcome (CO) statement
MQA104T.1	Explain and distinguish the principles of drug discovery and development
MQA104T.2	Discuss pre-formulation studies and explain methods to improve solubility of drug
MQA104T.3	Sketch and Describe the pilot plant scale up for various dosage forms
MQA104T.4	Classify the pharmaceutical packaging and explain quality control test for containers, closure and secondary packaging material
MQA104T.5	Elaborate the technology transfer concepts and prepare the documentation in technology transfer

Course Content:

Unit	Topic	Hours
I	**Principles of Drug discovery and development:** Basics of Drug Regulations: Introduction, Clinical research process. Development and informational content for Investigational New Drugs Application (IND), New Drug Application (NDA), Abbreviated New Drug Application (ANDA), Supplemental New Drug Application (SNDA), Scale Up Post Approval Changes (SUPAC) and Bulk active chemical Post approval changes (BACPAC), Post marketing surveillance, Concepts of Bioavailability (BA), Bioequivalence (BE) and Bio waivers, IVIVC	12 Hrs.
II	**Pre-formulation studies:** Introduction / concept, organoleptic properties, purity, impurity profiles, particle size, shape and surface area. **Solubility, Methods to improve solubility of Drugs**: Surfactants &its importance, co-solvency. Techniques for the study of Crystal properties and polymorphism. Pre-formulation protocol, Stability testing during product development.	12 Hrs.
III	**Pharmaceutical packaging:** Pharmaceutical dosage form and their packaging requirements, Pharmaceutical packaging materials, Medical device packaging, Enteral Packaging, Aseptic packaging	12 Hrs.

	systems, Container closure systems, Issues facing modern drug packaging, Selection and evaluation of Pharmaceutical packaging materials. **Quality control test:** Containers, closures and secondary packing materials.	
IV	**Pilot plant scale up :** Concept, Significance, design, layout of pilot plant scale up study, operations, large scale manufacturing techniques (formula, equipment, process, stability and quality control) of solids, liquids, semisolid and parenteral dosage forms. New era of drug products: opportunities and challenges.	
V	**Technology transfer:** Development of technology by R & D, Technology transfer from R & D to production, Optimization and Production, Qualitative and quantitative technology models. **Documentation in technology transfer:** Development report, technology transfer plan and Exhibit.	12 Hrs.

Recommended books (Latest editions):-

1. Charles G. Smith, James T and O. Donnell, The process of new drug discovery and development. I and II Edition (2006) CRC Press, Group of Taylor and Francis.
2. Leon Lac Lachman, Herbert A. Liberman, Theory and Practice of Industrial Pharmacy. Marcel Dekker Inc. New York.
3. Sidney H Willing, Murray M, Tuckerman. Williams Hitchings IV, Good manufacturing of pharmaceuticals (A Plan for total quality control) 3rd E/d Bhalani publishing house Mumbai.
4. Leon Lachman, Herbert A. Liberman, Joseph B. Schwartz, Tablets Vol. I, II, III, 2nd E/d. (1989), Marcel Dekker Inc. New York.
5. Milo Gibaldi, Text book of Bio- Pharmaceutics and clinical Pharmacokinetics 3rd E/d Lea &Febriger, Philadelphia.
6. Vandana V. Patrevale. John I. Disouza. MaharukhT.Rustomji, Pharmaceutical product development. CRC Press, Group of Taylor and Francis.
7. Abdou H. M., Dissolution, Bioavailability and Bio-Equivalence, Mack Publishing company, Eastern Pennsylvania.
8. Alfonso &Gennaro, Remingtons Pharmaceutical Sciences, 19thEdn. (1995) OO2C Lippincott; Williams and Wilkins A Wolters Kluwer Company, Philadelphia.
9. D. A Sawant, The Pharmaceutical Sciences; the Pharma Path way Pure and applied Pharmacy, Pragathi Books Pvt. Ltd.
10. D. A. Dean. E.R. Evans, Pharmaceutical Packaging technology, I.H. Hall. 1st E/d (Reprint 2006). Taylor and Francis. London and New York.130

Program : M. Pharmacy (Pharmaceutical Quality Assurance) **Class:** First Year **Semester :** 1

PHARMACEUTICAL QUALITY ASSURANCE (PRACTICAL-I)

Course Code : MQA105P **Credits :** 4 **Contact Hours:** 12 Hrs./Week

Scope : This course is designed to gain practical skills on assay of drugs, formulations, quality control of packaging materials, pre-formulation studies and QA case studies.

Objectives : Upon completion of this course the student should be able to:

- Analyze the API and formulations using various analytical instruments
- Solve the case studies on QA related issues
- Perform the Pre-formulation studies

Course Outcome (CO):

Upon completion of course student will able to

CO number	Course Outcome (CO) statement
MQA105P.1	Demonstrate proficiency in handling analytical instruments and perform drug estimation using various analytical techniques.
MQA105P.2	Explain the principles of Total Quality Management (TQM) and develop protocols for conducting stability studies.
MQA105P.3	Apply the concepts and procedures of In-Process Quality Control (IPQC) in pharmaceutical manufacturing.
MQA105P.4	Perform solubility determination and conduct accelerated stability studies to assess drug product stability.

Course Content: 12 Hrs./week

1. Analysis of Pharmacopoeial compounds in bulk and in their formulations (tablet/ capsules/ semisolids) by UV Visible spectrophotometer
2. Simultaneous estimation of multi-drug component containing formulations by UV spectrophotometry
3. Experiments based on HPLC
4. Experiments based on Gas Chromatography
5. Estimation of riboflavin/quinine sulfate by fluorimetry
6. Estimation of sodium/potassium by flame photometry or AAS
7. Case studies on

- Total Quality Management
- Six Sigma
- Change Management/ Change control. Deviations,
- Out of Specifications (OOS)
- Out of Trend (OOT)
- Corrective & Preventive Actions (CAPA)
- Deviations

8. Development of Stability study protocol
9. Estimation of process capability
10. In process and finished product quality control tests for tablets, capsules, parenteral and semisolid dosage forms.
11. Assay of raw materials as per official monographs
12. Testing of related and foreign substances in drugs and raw materials
13. To carry out pre formulation study for tablets, parenteral (2 experiments)
14. To study the effect of pH on the solubility of drugs (1 experiment)
15. Quality control tests for Primary and secondary packaging materials
16. Accelerated stability studies (1 experiment)
17. Improved solubility of drugs using surfactant systems (1 experiment)
18. Improved solubility of drugs using co-solvency method (1 experiment)
19. Determination of Pka and Log p of drugs
20. Case Studies

Program : M. Pharmacy (Quality assurance) **Class:** First Year **Semester :** 2

HAZARDS AND SAFETY MANAGEMENT (THEORY)

Course Code : MQA201T **Credits :** 4 **Contact Hours:**60 Hrs.

Scope : This course is designed to convey the knowledge necessary to understand issues related to different kinds of hazard and their management. Basic theoretical and practical discussions integrate the proficiency to handle the emergency situation in the pharmaceutical product development process and provide the principle based approach to solve the complex tribulations

Objectives : Upon completion of the course student shall be able to:

- Understand about environmental problems among learners.
- Gain basic knowledge about the environment and its allied problems.
- Develop an attitude of concern for the industry environment.
- Ensure safety standards in pharmaceutical industry
- Provide comprehensive knowledge on the safety management
- Empower an ideas to clear mechanism and management in different kinds of hazard management system
- Teach the method of Hazard assessment, procedure, methodology for provide safe industrial atmosphere.

Course Outcome (CO):

Upon completion of course student will able to

CO number	Course Outcome (CO) statement
MQA201T.1	Understand the Environment and its allied problems
MQA201T.2	Define and Explain the compliance of safety standards and safety management in industry
MQA201T.3	Learn and Explain safety standards in pharmaceutical industry, applications of Air circulation system for sterile area, non-sterile area, and fire protection system
MQA201T.4	Gain comprehensive knowledge on the safety management& State the control measures for chemical hazards. Regulatory aspects in chemical hazard
MQA201T.5	Explain the importance of industrial processes, potential hazards, regulatory aspects of safety and hazards .control and approaches of preventive and protective management from various hazards
MQA201T.6	Ensure safety standards in pharmaceutical industry through various regulatory guidelines and safety management tool.

Course Content:

Unit	Topic	Hours
I	• Multidisciplinary nature of environmental studies, Natural Resources and associated problems, Renewable and non-renewable resources, a) Forest resources; b) Water resources; c) Mineral resources; d) Energy resources; e) Land resources • **Ecosystems:** Concept of an ecosystem, Structure and function of an ecosystem. Environmental hazards: Hazards based on Air, Water, Soil and Radioisotopes.	12 Hrs.

II	• Air based hazards Sources, Types of Hazards, Air circulation, Air handling system, HVAC system, air maintenance in industry for sterile area and non-sterile area.	12 Hrs.
III	• GHS Classification and labeling • **Chemical based hazards:** Sources of chemical hazards, Hazards of Organic synthesis, sulphonating hazard, Organic solvent hazard. Control measures for chemical hazards. Management of combustible gases, Toxic gases and Oxygen displacing gases management, Regulations for chemical hazard, MSDS, Management of over Exposure to chemicals and TLV concept, Disposal of hazardous material.	12 Hrs.
IV	• **Fire and Explosion:** Introduction, Industrial processes and hazards potential, Mechanical, electrical, thermal and process hazards, mechanical and chemical explosion, multiphase reactions. Safety and hazards regulations • **Fire protection system:** Fire prevention, types of fire extinguishers and critical Hazard management system, Preventive and protective management from fires and explosion- electricity passivation, ventilation, and sprinkling, proofing, fire walls, bunds, relief systems - relief valves, flares, scrubbers	12Hrs.
V	• **Hazard and risk management:** Self-protective measures against workplace hazards. Critical training for risk management, Process of hazard management, ICH guidelines on risk assessment and Risk management methods and Tools, Preliminary hazard analysis • **Factory act and rules,** fundamentals of accident prevention, elements of safety programme and safety management, Physicochemical measurements of effluents, BOD, COD, Determination of some contaminants, Effluent treatment procedure- Mock emergency drill and case study, Role of emergency services. • Microbial Hazards	12 Hrs.

Recommended books (Latest editions):-

1. Y. K. Sing, Environmental Science, New Age International Pvt. Publishers, Bangalore
2. Quantitative Risk Assessment in Chemical Process Industries, American Institute of Chemical Industries, Centre for Chemical Process safety
3. T. S. S. Dikshith, Hazardous Chemicals: Safety Management and Global Regulations, CRC press
4. M. N. Vyas, Safety and hazard management in chemical industries, Atlantic Publisher
5. Daniel A. Crowl, Joseph F. Louvar, Chemical Process Safety: Fundamentals with Applications, 3rd Edition, Prentice Hall, 2011
6. H. H. Fawcett and W.S. Wood, Safety and Accident Prevention in Chemical Operations, 2nd E/d, John Wiley & Sons, New York 1982
7. C.S. Rao, Environmental Pollution Control Engineering, New Age international Publisher
8. Phillip Carson, Clive Mumford, Butterworth-Heinemann, Hazardous Chemicals Handbook, Second edition, an imprint of Elsevier Science.
9. RavikiranSuryawanshi and R. C. Patel Hazards and Safety Management,Publisher: S. Vikas and Company

Program : M. Pharmacy (Pharmaceutical Quality Assurance) **Class:** First Year **Semester :** 2

PHARMACEUTICAL VALIDATION (THEORY)

Course Code : MQA202T	**Credits :** 4	**Contact Hours:**60 Hrs.

Scope : The main purpose of the subject is to understand about validation and how it can be applied to industry and thus improve the quality of the products. The subject covers the complete information about validation, types, methodology and application.

Objectives : At completion of this course, it is expected that students will be able to:

- Understand the concepts of calibration, qualification and validation
- Learn the qualification of various equipments and instruments
- Understand process validation of different dosage forms
- Understand validation of analytical method for estimation of drugs
- Learn cleaning validation of equipments employed in the manufacture of pharmaceuticals

Course Outcome (CO):

Upon completion of course student will able to

CO number	Course Outcome (CO) statement
MQA202T.1	Explain the concepts and regulatory importance of calibration, qualification, and validation in pharmaceutical quality assurance.
MQA202T.2	Describe the qualification process for laboratory equipment and its significance in ensuring data integrity and compliance.
MQA202T.3	Outline the steps and types of validation processes used in pharmaceutical manufacturing and testing.
MQA202T.4	Apply the principles and procedures involved in cleaning validation to ensure compliance with regulatory guidelines.
MQA202T.5	Explain the general principles of intellectual property rights (IPR) and their relevance in pharmaceutical research and innovation.

Course Content:

Unit	Topic	Hours
I	**Introduction to validation:** Definition of Calibration, Qualification and Validation, Scope, frequency and importance. Difference between calibration and validation. Calibration of weights and measures. Advantages of Validation, scope of Validation, Organization for Validation, Validation Master plan, Types of Validation, Streamlining of qualification & Validation process and Validation Master Plan	10 Hrs.
II	**Qualification of manufacturing equipment:** Dry Powder Mixers, Fluid Bed and Tray dryers, Tablet Compression (Machine), Dry heat sterilization/Tunnels, Autoclaves, Membrane filtration, Capsule filling machine. Qualification of analytical instruments: UV-Visible spectrophotometer, FTIR, DSC, GC, HPLC, HPTLC, LC-MS.	10 Hrs.
III	**Qualification of laboratory equipments:** Hardness tester, Friability test apparatus, tap density tester, Disintegration tester, Dissolution test apparatus, and Validation of Utility systems: Pharmaceutical water system & pure steam, HVAC system, Compressed air and nitrogen.	10 Hrs.

IV	**Process Validation:** Concept, Process and documentation of Process Validation. Prospective, Concurrent & Retrospective Validation, Re validation criteria, Process Validation of various formulations (Coated tablets, Capsules, Ointment/Creams, Liquid Orals and aerosols.), Aseptic filling: Media fill validation, USFDA guidelines on Process Validation- A life cycle approach. Analytical method validation: General principles, Validation of analytical method as per ICH guidelines and USP.	10 Hrs.
V	**Cleaning Validation:** Cleaning Method development, Validation of analytical method used in cleaning, Cleaning of Equipment, Cleaning of Facilities. Cleaning in place (CIP). Validation of facilities in sterile and non-sterile plant. Computerized system validation: Electronic records and digital signature -21 CFR Part 11 and GAMP	10 Hrs.
VI	General Principles of Intellectual Property: Concepts of Intellectual Property (IP), Intellectual Property Protection (IPP), Intellectual Property Rights (IPR); Economic importance, mechanism for protection of Intellectual Property -patents, Copyright, Trademark; Factors affecting choice of IP protection; Penalties for violation; Role of IP in pharmaceutical industry; Global ramification and financial implications. Filing a patent applications; patent application forms and guidelines. Types patent applications-provisional and non-provisional, PCT and convention patent applications; International patenting requirement procedures and costs; Rights and responsibilities of a patentee; Practical aspects regarding maintaining of a Patent file; Patent infringement meaning and scope. Significance of transfer technology (TOT), IP and ethics-positive and negative aspects of IPP; Societal responsibility, avoiding unethical practices.	10 Hrs.

Recommended books (Latest editions):-

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

Program : M. Pharmacy [Pharmaceutical Quality Assurance (MQA)] **Class:** First Year **Semester :** 2

AUDITS AND REGULATORY COMPLIANCE (THEORY)

Course Code : MQA203T **Credits :** 4 **Contact Hours:** 60Hrs.

Scope : This course deals with the understanding and process for auditing in pharmaceutical industries. This subject covers the methodology involved in the auditing process of different in pharmaceutical industries.

Objectives : Upon completion of this course the student should be able to:

- Understand the importance of auditing
- Understand the methodology of auditing
- Carry out the audit process
- Prepare the auditing report
- Prepare the check list for auditing

Course Outcome (CO):

Upon completion of course student will able to

CO number	Course Outcome (CO) statement
MQA203T.1	Understand, state and explain importance of auditing and explain audit process
MQA203T.2	Understand and explain role of quality systems and audits in pharmaceutical manufacturing environment
MQA203T.3	Understand and explain auditing of vendors and production department
MQA203T.4	Understand and explain auditing of microbiological laboratory
MQA203T.5	Understand and explain auditing of Quality assurance and engineering department

Course Content:

Unit	Topic	Hours
I	**Introduction**: Objectives, Management of audit, Responsibilities, Planning process, information gathering, administration, Classifications of deficiencies	12 Hrs.
II	**Role of quality systems and audits in pharmaceutical manufacturing environment**: cGMP Regulations, Quality assurance functions, Quality systems approach, Management responsibilities, Resource, Manufacturing operations, Evaluation activities, transitioning to quality system approach, Audit checklist for drug industries.	12 Hrs.
III	**Auditing of vendors and production department:** Bulk Pharmaceutical Chemicals and packaging material Vendor audit, Warehouse and weighing, Dry Production: Granulation, tableting, coating, capsules, sterile production and packaging	12 Hrs.
IV	**Auditing of Microbiological laboratory**: Auditing the manufacturing process, Product and process information, General areas of interest in the building raw materials, Water, Packaging materials	12 Hrs.
V	**Auditing of Quality Assurance and engineering department**: Quality Assurance Maintenance, Critical systems: HVAC, Water, Water for Injection systems, ETP	12 Hrs.

Recommended books (Latest editions):-

1. B.T. Loftus & R. A. Nash, "Pharmaceutical Process Validation", Drugs and PharmSci.Series, Vol.129, 3rd Ed.,MarcelDekkerInc.,N.Y.
2. The Theory & Practice of IndustrialPharmacy, 3rd edition,LeonLachman, Herbert A. Lieberman, Joseph. L. Karig, Varghese Publishing House, Bombay.
3. Validation Master plan byTerveeksorDeeks,Davis Harwood International publishing.
4. ValidationofAsepticPharmaceutical Processes, 2nd Edition,by Carleton &Agalloco, (Marcel Dekker). Michael Levin, Pharmaceutical Process Scale-Up",DrugsandPharm. Sci. Series, Vol.157, 2nd Ed.,Marcel Dekker Inc.,N.Y.
5. Validation Standard Operating Procedures: AStep byStep Guide for Achieving Compliance in the Pharmaceutical, Medical Device, and Biotech Industries,SyedImtiazHaider
6. Pharmaceutical Equipment Validation: The Ultimate Qualification Handbook,Phillip A.Cloud, InterpharmPress
7. Validation of PharmaceuticalProcesses:SterileProducts,FrederickJ. Carlton (Ed.) andJamesAgalloco(Ed.),MarcelDekker
8. Analytical Method validation and Instrument Performance Verification by Churg Chan,Heiman Lam,Y.C.Lee,Yue.Zhang,WileyInterscience.
9. HuberL.ValidationandQualificationinAnalyticalLaboratories.InformaHealthcare
10. Wingate G. Validating Corporate Computer Systems: Good IT Practice for PharmaceuticalManufacturers.InterpharmPress
11. LeBlanc DA. Validated Cleaning Technologies for Pharmaceutical Manufacturing.InterpharmPress

Program : M. Pharmacy [Pharmaceutical Quality Assurance (MQA)] **Class:** First Year **Semester:** 2

PHARMACEUTICAL MANUFACTURING TECHNOLOGY (THEORY)

Course Code : MQA204T **Credits :** 4 **Contact Hours:**60Hrs.

Scope : This course is designed to impart knowledge and skills necessary to train the students with the industrial activities during Pharmaceutical Manufacturing

Objectives : At completion of this course it is expected that students will be able to:

- Understand the common practice in the pharmaceutical industry developments, plant layout and production planning
- Be familiar with the principles and practices of aseptic process technology, non-sterile manufacturing technology and packaging technology.
- Understand principles and implementation of
- Understand Quality by design (QbD) and process analytical technology (PAT) in pharmaceutical manufacturing

Course Outcome (CO):

Upon completion of course student will able to

CO number	Course Outcome (CO) statement
MQA 204T.1	Describe the common practices in pharmaceutical industry development, including plant layout and production planning.
MQA 204T.2	Explain the principles and practices of aseptic processing and sterile manufacturing technologies.
MQA 204T.3	Demonstrate understanding of non-sterile manufacturing operations and pharmaceutical packaging technologies.
MQA 204T.4	Analyze different types of pharmaceutical packaging materials, techniques, and regulatory requirements.
MQA 204T.5	Evaluate the implementation of Quality by Design (QbD) and Process Analytical Technology (PAT) in pharmaceutical manufacturing processes.

Course Content:

Unit	Topic	Hours
I	**Pharmaceutical industry developments:** Legal requirements and Licenses for API and formulation industry, Plant location- Factors influencing. **Plant layout:** Factors influencing, Special provisions, Storage space requirements, sterile and aseptic area layout. Schedule M **Production planning:** General principles, production systems, calculation of standard cost, process planning, routing, loading, scheduling, dispatching of records, production control.	12 Hrs.
II	**Aseptic process technology:** Manufacturing, manufacturing flowcharts, in process-quality control tests for following sterile dosage forms: Ointment, Suspension and Emulsion, Dry powder, Solution (Small Volume & large Volume). **Advanced sterile product manufacturing technology :** Area planning & environmental control, wall and floor treatment, fixtures and machineries, change rooms, personnel flow, utilities & utilities equipment location, engineering and maintenance. **Process Automation in Pharmaceutical Industry:** With specific	12 Hrs.

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

Recommended Books (Latest Editions):-

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

10. Edward J Bauer. Pharmaceutical Packaging Handbook. 2009. Informa Health care USA Inc. New york.
11. Shaybe Cox Gad.Pharmaceutical Manufacturing Handbook. John Willey and Sons, New Jersey, 2008.

Program : M. Pharmacy (Pharmaceutical Quality Assurance) **Class:** First Year **Semester :** 2

PHARMACEUTICAL QUALITY ASSURANCE (PRACTICAL-II)

Course Code : MQA205P **Credits :** 4 **Contact Hours:** 12 Hrs./Week

Scope : This course is designed to gain practical skills on qualification of analytical instruments, estimation of contaminants, and design of audit check lists.

Objectives : Upon completion of this course the student should be able to

- Analyze the contamination in pharmaceutical products using various analytical instruments
- Design audit check list for various pharmaceutical activities
- Understand the Qualification of analytical instruments, and importance of QbD and PAT

Course Outcome (CO):

Upon completion of course student will able to

CO number	Course Outcome (CO) statement
MQA205P.1	Demonstrate the determination of impurities in organic compounds and environmental samples using appropriate analytical techniques.
MQA205P.2	Perform qualification and validation procedures for various analytical instruments used in the pharmaceutical industry.
MQA205P.3	Identify and explain the functional and documentation requirements of the production department in the pharmaceutical industry.
MQA205P.4	Apply the principles of Quality by Design (QbD) and Process Analytical Technology (PAT) in pharmaceutical development and manufacturing.

Course Content:	**12 Hrs./week**
1) Organic contaminants residue analysis by HPLC	
2) Estimation of Metallic contaminants by Flame photometer	
3) Identification of antibiotic residue by TLC	
4) Estimation of Hydrogen Sulfide in Air	
5) Estimation of Chlorine in Work Environment	
6) Sampling and analysis of SO2 using Colorimetric method	
7) Qualification of following Pharma equipment	
a) Autoclave	
b) Hot air oven	
c) Powder Mixer (Dry)	
d) Tablet Compression Machine	
8) Validation of an analytical method for a drug	
9) Validation of a processing area	
10) Qualification of at least two analytical instruments	

11) Cleaning validation of one equipment

12) Qualification of Pharmaceutical Testing Equipment (Dissolution testing apparatus, Friability Apparatus, Disintegration Tester)

13) Check list for Bulk Pharmaceutical Chemicals vendors

14) Check list for tableting production.

15) Check list for sterile production area

16) Check list for Water for injection

17) Design of plant layout: Sterile and non- sterile

18) Case study on application of QbD

19) Case study on application of PAT

Program: M. Pharmacy (Pharmacognosy) **Class:** First Year **Semester :** 1

Advanced Pharmacognosy-I

Course Code: MPG102T **Credits:** 4 **Contact Hours:** 60 Hrs (Theory)

Scope : This course is designed to impart knowledge in the area of advances in pharmacognosy.

Objectives : Upon completion of the course, student shall be able to understand

- The course will cover various aspects of cultivation, collection, and conservation practices in drug production.
- The course will also cover the source, utilization, and medicinal value of phytopharmaceuticals.
- Understand the application of nutraceuticals and their potential health benefits.
- This course will cover the use, extraction, and application of marine sources in drug development.
- The student will gain knowledge about the pharmacovigilance of drugs that are derived from natural sources.

Course Outcome (CO):

Upon completion of the course, the student will be able to:

CO number	Course Outcome (CO) statement
MPG102T.1	Understand and apply the knowledge of cultivation, collection, and conservation practices in the production of drugs.
MPG102T.2	Identify sources and methods for purification of drugs of marine origin, its classification problems faced in marine research, and their solutions.
MPG102T.3	Apply knowledge of various nutraceuticals and herbs and their health benefits.
MPG102T.4	Analyzes various phytopharmaceuticals and their source, their utilization, and their medicinal value.
MPG102T.5	Apply the WHO and AYUSH guidelines for safety monitoring and reporting.

Course Content:

Unit	Topic	Hours
I	**Plant drug cultivation:** Importance of Pharmacognosy in herbal drug industry, Indian Council of Agricultural Research, Current Good Agricultural Practices of medicinal Plants, Conservation of medicinal plants—ex-situ and in-situ conservation of medicinal plants.	10 Hrs
II	**Marine natural products:** General methods of isolation and purification, Study of Marine toxins, Recent advances in research in marine drugs, Challenges in research on marine drugs.	10 Hrs
III	**Nutraceuticals:** Introduction, current trends, future scope, classification and examples. Inorganic mineral supplements, Vitamin supplements, Digestive enzymes, Dietary fibers, Antioxidants, Polyunsaturated fatty acids, Herbs as functional foods, Formulation and standardization of nutraceuticals, Regulatory aspects, FSSAI guidelines, Sources, name of marker compounds and their chemical nature, medicinal uses and health benefits of nutraceuticals for	12 Hrs

	Gastrointestinal health, cardiovascular health, reproductive health and PCOS, anti-ageing, mental wellbeing, nutraceuticals for sports and athletes, and space nutraceuticals.	
IV	**Phytopharmaceuticals:** Occurrence, isolation and characteristic features (Chemical nature, uses in pharmacy, medicinal and health benefits) of following. a) Carotenoids – i) α and β – Carotene, ii) Astaxanthin ii) Xanthophyll Lutein, zeaxanthin b) Limonoids – i) d-Limonene ii) α – Terpineol c) Saponins – i) Shatavarins d) Flavonoids – i) Resveratrol ii) Rutin iii) Hesperidin iv) Naringin v) Quercetin e) Phenolic acids- Ellagic acid f) Vitamins g) Tocotrienols and Tocopherols h) Andrographolide, Gugulipids, Withanolides, Vasicine, Taxol, Baccatin III	16 Hrs
V	**Pharmacovigilance of drugs of natural origin**: Introduction to Pharmacovigilance, Adverse event terminology, WHO guidelines and AYUSH guidelines for safety monitoring of natural medicine, Spontaneous and aggregate reporting schemes for bio-drug adverse reactions, bio drug-drug and bio drug-food interactions with suitable examples. Software use in PV and challenges.	12 Hrs

References:

1. Pharmacognosy - G. E. Trease and W.C. Evans. Saunders Edinburgh,New York.
2. Pharmacognosy-Tyler, Brady, Robbers
3. Modem Methods of Plant Analysis- Peach & M.V. Tracey, Vol. I&II
4. Text Book of Pharmacognosy by T.E. Wallis
5. Marine Natural Products-Vol.I to IV.
6. Natural products: A lab guide by Raphael Ikan , Academic Press 1991.
7. Glimpses of Indian Ethano Pharmacology, P. Pushpangadam. Ulf Nyman.V.George Tropical Botanic Garden & Research Institute, 1995.
8. Medicinal natural products (a biosynthetic approach), Paul M. Dewick, John Wiley & Sons Ltd., England, 1998.
9. Chemistry of Marine Natural Products- Paul J. Schewer 1973.
10. Herbal Drug Industry by RD. Choudhary, Eastern Publisher, New Delhi,1996.
11. Cultivation of Medicinal Plants by C.K. Atal & B.M. Kapoor.
12. Cultivation and Utilization of Aromatic Plants, C.K. Atal & B.M. Kapoor
13. Cultivation of medicinal and aromatic crops, AA Farooqui and B.S.Sreeramu. University Press, 2001
14. Natural Products from Plants, 1st edition, by Peter B. Kaufman, CRC Press, New York, 1998
15. Recent Advances in Phytochemistry—Vol. 1&4: Scikel Runeckles-::Appleton Century Crofts.
16. Textbook of Pharmacognosy, C.K.Kokate, Purohit, Ghokhale, Nirali Prakasshan, 1996.
17. Pharmacognosy and Pharmacobiotechnology, Ashutoshkar, New Age Publications, New Delhi.

Program: M. Pharmacy (Pharmacognosy) **Class:** First Year **Semester :** 1

Phytochemistry

Course Code: MPG103T **Credits:** 4 **Contact Hours:** 60 Hrs (Theory)

Scope : This course is designed to impart knowledge in the area of natural product drug discovery, extraction, isolation, and identification.

Objectives : Upon completion of the course, student shall be able to understand

- The course will cover different classes of phytoconstituents and their biosynthetic pathways.
- Students will be able to understand the properties, extraction methods, general processes of natural product drug discovery, phytochemical fingerprinting, and structure elucidation of phytoconstituents.

Course Outcome (CO):-

Upon completion of the course, the student will be able to:

CO number	Course Outcome (CO) statement
MPG103T.1	To study biosynthetic pathways of different classes of phytoconstituents.
MPG103T.2	To understand the natural product drug discovery and development process.
MPG103T.3	To study and apply methods of phytochemical extraction and isolation.
MPG103T.4	To analyze phytochemicals by fingerprinting of the natural products.
MPG103T.5	To predict and identify the structure of phytochemicals by instrumental methods.

Course Content:

Unit	Topic	Hours
I	**Biosynthetic pathways and radio tracing techniques:** Constituents & their biosynthesis, isolation, characterization, and purification with a special reference to their importance in herbal industries of the following phyto-pharmaceuticals containing drugs: a) **Alkaloids**: Berberine, Taxol b) **Glycosides**: Digitoxin, Bacosides c) **Steroids**: Guggulosterone and withanolides. d) **Coumarin**: Umbelliferone. e) **Terpenoids**: Cucurbitacin.	12 Hrs
II	**Drug discovery and development:** History of herbs as source of drugs, drug discovery, the lead structure selection, structure development, product discovery process and drug registration. Selection and optimization of lead compound Andrographolides. Clinical studies emphasising on phases of clinical trials, protocol design for lead molecules.	12 Hrs
III	**Extraction and Phytochemical studies:** Recent advances in extractions with emphasis on selection of method and choice of solvent for extraction, successive and exhaustive extraction and other methods of extraction commonly used like microwave assisted	12 Hrs

	extraction, Methods of fractionation. Separation of phytoconstituents by latest CCCET, SCFE techniques including preparative HPLC and Flash column chromatography.	
IV	Phytochemical finger printing: HPTLC and LCMS/GCMS applications in the characterization of herbal extracts. Structure elucidation of phytoconstituents such as Berberine, Bacosides, Withanolides, Umbelliferone and Cucurbitacin.	12 Hrs
V	Structure elucidation of the following compounds by spectroscopic techniques like UV, IR, MS, NMR (1H, 13C): Citral, Kaempferol, Glycyrrhizin.	12 Hrs

References:

1. Organic chemistry by I.L. Finar Vol.II
2. Pharmacognosy by Trease and Evans, ELBS.
3. Pharmacognosy by Tylor and Brady.
4. Textbook of Pharmacognosy by Wallis.
5. Clark's isolation and identification of drugs by A.C. Mottal.
6. Plant Drug Analysis by Wagner & Bladt.
7. Wilson and Gisvold's Textbook of Organic Medicinal and Pharmaceutical Chemistry by Deorge. R.F.
8. The Chemistry of Natural Products, Edited by R.H. Thomson, Springer International Edn. 1994.
9. Natural Products Chemistry Practical Manual: For Science & Pharmacy Courses by Anees A Siddiqui and Seemi Siddiqui
10. Organic Chemistry of Natural Products, Vol. 1&2. Gurdeep R Chatwal.
11. Chemistry of Natural Products- Vol. 1 onwards IWPAC.
12. Modern Methods of Plant Analysis- Peach & M.V. Tracey, Vol. I&II
13. Medicinal Natural products – a biosynthetic approach, Dewick PM, John Wiley & Sons, Toronto, 1998.
14. Chemistry of Natural Products, Bhat SV, Nagasampagi BA, Meenakshi S, Narosa Publishing House, New Delhi.
15. Pharmacognosy & Phytochemistry of Medicinal Plants, 2nd edition, Bruneton J, Interceptt Ltd., New York, 1999.

Program: M. Pharmacy (Pharmacognosy) **Class:** First Year **Semester :** 1

Industrial Pharmacognostical Technology

Course Code: MPG104T **Credits:** 4 **Contact Hours:** 60 Hrs (Theory)

Scope : This course is designed to impart knowledge about herbal industrial technology.

Objectives : Upon completion of the course, student shall be able to understand

- The course will cover various aspects of setting up an herbal drug industry.
- Also, the regulatory and quality assurance requirements for herbal drug industry, and testing of natural products.
- The course will cover the process of patenting, IPR laws, amendments, and processes applicable to herbal/natural products.

Course Outcome (CO):

Upon completion of the course, the student will be able to:

CO number	Course Outcome (CO) statement
MPG104T.1	To understand the industrial and commercial requirement of drugs of natural origin and integrate traditional Indian systems of medicine with modern medicine.
MPG104T.2	To understand the regulatory requirements and quality assurance for setting up the herbal/natural drug industry and trade of herbal drugs.
MPG104T.3	To study the general parameters for monographs and WHO guidelines in quality assessment of herbal drugs.
MPG104T.4	To understand the protocols for testing of natural products.
MPG104T.5	To gain the knowledge of patenting/IPR laws, amendments, and processes applicable to herbal/natural products.

Course Content:

Unit	Topic	Hours
I	**Herbal Drug Industry:** Infrastructure of the herbal drug industry involved in the production of standardized extracts and various dosage forms. Current challenges in upgrading and modernizing herbal formulations. Entrepreneurship development, project selection, project reports, technical knowledge, capital ventures, plant design, layout, and construction. Pilot plant scale-up techniques and case studies of herbal extracts. Formulation and production management of herbals.	12 Hrs
II	**Regulatory requirements for setting up the herbal drug industry:** Regulatory framework, types of license, and document requirements. Global marketing management. Indian and international patent law as applicable to herbal drugs and natural products. Export-Import (EXIM) policy, TRIPS. Quality assurance in	12 Hrs

	herbal/natural drug products. Concepts of TQM, GMP, GLP, NABL	
III	**Monographs of herbal drugs:** General parameters of monographs of herbal drugs and comparative studies in IP, USP, Ayurvedic Pharmacopoeia, Siddha and Unani Pharmacopoeia, American Herbal Pharmacopoeia, British Herbal Pharmacopoeia, and WHO guidelines in quality assessment of herbal drugs.	12 Hrs
IV	**Testing of natural products and drugs:** Herbal medicines—Good Clinical Practices (GCP). Stability testing of natural products and protocols. Examples of dossiers containing testing protocol.	12 Hrs
V	**Patents:** Indian and international patent laws and proposed amendments as applicable to herbal/natural products and processes. Geographical indication, Copyright, Patentable subject matter, novelty, non-obviousness, utility, enablement and best mode, procedure for Indian patent filing, patent processing, grant of patents, rights of patents, cases of patents, opposition and revocation of patents, patent search and literature, Controllers of patents.	12 Hrs

References:

1. Pharmacognosy—G. E. Trease and W. C. Evans. Saunders Edinburgh, New York.
2. Pharmacognosy—Tyler, Brady, Robbers
3. Modem Methods of Plant Analysis—Peach & M.V. Tracey, Vol. I&II
4. Text Book of Pharmacognosy by T.E. Wallis
5. Marine Natural Products-Vol.I to IV.
6. Natural products: A lab guide by Raphael Ikan , Academic Press 1991.
7. Glimpses of Indian Ethano Pharmacology, P. Pushpangadam. Ulf Nyman.V.George Tropical Botanic Garden & Research Institute, 1995.
8. Medicinal natural products (a biosynthetic approach), Paul M. Dewick, John Wiley & Sons Ltd., England, 1998.
9. Chemistry of Marine Natural Products- Paul J. Schewer 1973.
10. Herbal Drug Industry by RD. Choudhary, Eastern Publisher, New Delhi,1996.
11. Cultivation of Medicinal Plants by C.K. Atal & B.M. Kapoor.
12. Cultivation and Utilization of Aromatic Plants, C.K. Atal & B.M. Kapoor
13. Cultivation of medicinal and aromatic crops, AA Farooqui and B.S.Sreeramu. University Press, 2001
14. Natural Products from Plants, 1st edition, by Peter B. Kaufman, CRC Press, New York, 1998
15. Recent Advances in Phytochemistry-Vol. 1&4: Scikel Runeckles- Appleton Century Crofts.
16. Textbook of Pharmacognosy, C.K. Kokate, Purohit, Ghokhale, Nirali Prakasshan, 1996.
17. Pharmacognosy and Pharmacobiotechnology, Ashutoshkar, New Age Publications, New Delhi.

Program: M. Pharmacy (Pharmacognosy) **Class:** First Year **Semester :** 1

Pharmacognosy Practicals-I

Course Code: MPG105P **Credits:** 6 **Contact Hours:** 90 Hrs (Practical)

Scope : This course is designed to impart practical knowledge on pharmacognosy and phytochemistry.

Objectives : Upon completion of the course, student shall be able to understand

- The course will cover practical aspects of analyzing herbals and their formulations.
- Students will be able to perform extraction, phytochemical screening, and drug monograph analysis.
- The course will cover the formulation, evaluation, and standardization of herbal and natural products.

Course Outcome (CO):

Upon completion of the course, the student will be able to:

CO number	Course Outcome (CO) statement
MPG105P.1	Understand, apply, and analyze using the different analytical techniques used in herbal formulations, development, and evaluation.
MPG105P.2	Understand, apply, and utilize the methods for extraction and phytochemical screening.
MPG105P.3	Understand the monograph analysis of herbal drugs.
MPG105P.4	Able to apply and evaluate herbal dosage forms and their standardization.

Course Content:

Sr. No.	Topic
1	Methods of extraction and optimization
2	Physico-chemical study and Phytochemical screening (As per WHO Guidelines)
3	Spectroscopic analysis of natural compounds and their formulations by UV Vis spectrophotometer.
4	Analysis of recorded spectra of natural compounds.
5	Estimation of sodium and potassium in herbal drugs by flame photometry.
6	Development of TLC fingerprint of medicinal plant extracts.
7	Estimation of Quinine, Caffein and Resveratrol by HPLC.
8	Monograph analysis of clove oil.
6	Monograph analysis of castor oil.
7	Identification of bioactive constituents from plant extracts.
8	Formulation of different dosage forms and their standardization.

References:

1. Indian Pharmacopoeia, 2017.
2. Florey K., “Analytical Profiles of Drug Substances”, Academic press, Harcourt Brace Publishers, New York.
3. Skoog D.A., “Principles of Instrumental Analysis”, 5th edition, 1998, Estern Press, Banglore.
4. Wagner H., Baldt S., “Plant Drug Analysis”, Springer Publications, Berlin.
5. Deore S.L., Khadbadi S.S., et.al. “Experimental Phytopharmacognosy-A Comprehensive Guide”, Nirali Prakashan, Mumbai,
6. Indian Herbal Pharmacopoeia, IDMA, Delhi.
7. Rangari V.D., “Pharmacognosy & Phytochemistry”, Vol I &II, 3rd edition, Career Publications, Pune.
8. Kaushik A., et.al. “Formulation and Evaluation of Herbal Cough Syrup”, European Journal of Pharmaceutical and Medical Research, Department of Pharmacy/Teerthankar Mahaveer University, Moradabad, India.

Program: M. Pharmacy (Pharmacognosy) **Class:** First Year **Semester :** 2

Medicinal Plant Biotechnology

Course Code: MPG201T **Credits:** 4 **Contact Hours:** 60 Hrs (Theory)

Scope : To explore the knowledge of biotechnology and its application in the improvement of the quality of medicinal plants.

Objectives : Upon completion of the course, student shall be able to understand

- Know the process, like genetic engineering in medicinal plants, a higher yield of phytopharmaceuticals.
- The course will also cover the application of biotechnological techniques to enhance the quality of natural products and medicinal plants.

Course Outcome (CO):

Upon completion of the course, the student will be able to:

CO number	Course Outcome (CO) statement
MPG201T.1	Understand the fundamental principles of plant biotechnology and its applications.
MPG201T.2	Demonstrate competence in plant tissue culture techniques and related methodologies.
MPG201T.3	Analyze immobilization techniques and their significance in plant systems.
MPG201T.4	Evaluate biotransformation and transgenic plant technology in medicinal applications.
MPG201T.5	Apply fermentation technology for the production of plant-based pharmaceuticals.

Course Content:

Unit	Topic	Hours
I	**Introduction to Plant Biotechnology:** Historical perspectives and prospects of plant biotechnology as a source of medicinal agents. Applications in pharmacy and allied fields. Genetic and molecular biology as applied to pharmacognosy, the study of DNA, RNA, and protein replication, genetic code, regulation of gene expression, structure and complexity of the genome, cell signaling, and DNA recombinant technology.	12 Hrs
II	**Different tissue culture techniques:** organogenesis and embryogenesis, synthetic seed and monoclonal variation, protoplast fusion, hairy root multiple shoot cultures and their applications. Micropropagation of medicinal and aromatic plants. Sterilization methods involved in tissue culture, gene transfer in plants, and their applications.	12 Hrs
III	**Immobilization techniques & secondary metabolite production:** Immobilization techniques of plant cells and its application on secondary metabolite Production. Cloning of plant cells: Different methods of cloning and its applications. Advantages and disadvantages of plant cell cloning. Secondary metabolism in tissue cultures with emphasis on production of medicinal agents. Precursors and elicitors on production of secondary metabolites..	12 Hrs

IV	Biotransformation and Transgenesis: Biotransformation bioreactors for pilot and large scale cultures of plant cells and Hrs retention of biosynthetic potential in cell culture. Transgenic plants, methods used in gene identification, localization and sequencing of genes. Application of PCR in plant genome analysis.	12 Hrs
V	Fermentation technology: Application of Fermentation technology, Production of ergot alkaloids, single cell proteins, enzymes of pharmaceutical interest.	12 Hrs

References:

1. Plant tissue culture, Bhagwani, vol 5, Elsevier Publishers.
2. Plant cell and Tissue Culture (Lab. Manual), JRMM. Yeoman.
3. Elements in biotechnology by PK. Gupta, Rastogi Publications, New Delhi.
4. An introduction to plant tissue culture by MK. Razdan, Science Publishers.
5. Experiments in Plant Tissue Culture by John HD and Lorin WR., Cambridge University Press.
6. Pharmaceutical biotechnology by SP. Vyas and VK. Dixit, CBS Publishers.
7. Plant cell and tissue culture by Jeffrey W. Pollard and John M Walker, Humana press.
8. Plan tissue culture by Dixon, Oxford Press, Washington DC, 1985
9. Plant tissue culture by Street.
10. Pharmacognosy by G. E. Trease and WC. Evans, Elsevier.
11. Biotechnology by Purohit and Mathur, Agro-Bio, 3rd revised edition.
12. Biotechnological applications to tissue culture by Shargool, Peter D, Shargoal, CKC Press.
13. Pharmacognosy by Varo E. Tyler, Lynn R. Brady and James E. Robberrt, That Tjen, NGO.
14. Plant Biotechnology, Ciddi Veerasham

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Program: M. Pharmacy (Pharmacognosy) **Class:** First Year **Semester :** 2

Advanced Pharmacognosy-II

Course Code: MPG202T **Credits:** 4 **Contact Hours:** 60 Hrs (Theory)

Scope : This course is designed to impart knowledge on the area of advances in Pharmacognosy.

Objectives : Upon completion of the course, student shall be able to understand

- The different aspects of the toxicity of herbal drugs and conventional drugs, and how to use drugs rationally.
- The course will also emphasize the significance of raw material purity and methods for detecting adulteration.
- The course will explore the various sources of herbal drugs through ethnobotanical and ethnopharmacological research and drug development.
- Various analytical methods are employed to establish standards for herbal drug quality.
- Aware of the biological and *in-vitro* screening methods of herbal extracts and herbal drugs.

Course Outcome (CO):

Upon completion of the course, the student will be able to:

CO number	Course Outcome (CO) statement
MPG202T.1	Understand and analyze toxicity issues and regulations for herbal drugs and their validation.
MPG202T.2	Understand and apply methods for detecting adulteration and evaluating techniques for herbal drugs.
MPG202T.3	Understand, apply, and analyze the ethnobotanical and ethnopharmacological knowledge in research.
MPG202T.4	Able to apply the knowledge and evaluate the analytical studies of herbal drugs.
MPG202T.5	Be able to understand and apply methods of screening herbals for various biological properties.

Course Content:

Unit	Topic	Hours
I	**Herbal remedies-**Toxicity and Regulations: Herbals vs Conventional drugs, Efficacy of Herbal medicine products, Validation of herbal therapies, Pharmacodynamic and Pharmacokinetic issues.	12 Hrs
II	**Adulteration and Deterioration :** Introduction, Types of Adulteration/ Substitution of Herbal drugs, Causes and Measures of Adulteration, Sampling Procedures, Determination of Foreign Matter, DNA Finger printing techniques in identification of drugs of natural origin, detection of heavy metals, pesticide residues, phytotoxin, microbial contamination in herbs and their formulations.	12 Hrs
III	**Ethnobotany and Ethnopharmacology:** Ethnobotany in herbal drug evaluation, Impact of Ethnobotany in traditional medicine, New development in herbals, Bio-prospecting tools for drug discovery, Role of Ethnopharmacology in drug evaluation, Reverse Pharmacology.	12 Hrs

IV	**Analytical Profiles of herbal drugs:** *Andrographis paniculata, Boswellia serata, Coleus forskholii, Curcuma longa, Embelica officinalis, and Psoralea corylifolia.*	12 Hrs
V	**Biological screening of herbal drugs:** Introduction and Need for Phyto-Pharmacological Screening, New Strategies for evaluatingNatural Products, In vitro evaluation techniques for Antioxidants, Antimicrobial and Anticancer drugs. In vivo evaluation techniques for Anti-inflammatory, Antiulcer, Anticancer, Wound healing, Antidiabetic, Hepatoprotective, Cardio protective, Diuretics and Antifertility, Toxicity studies as per OECD guidelines.	12 Hrs

References:

1. Glimpses of Indian Ethano Pharmacology by P. Pushpangadam. Ulf Nyman. V.George Tropical Botanic Garden & Research Institute.
2. Natural products: A lab guide by Raphael Ikan, Academic Press.3. Pharmacognosy - G. E. Trease and W.C. Evans. WB. Saunders Edinburgh, New York.
4. Pharmacognosy-Tyler, Brady, Robbers, Lee & Fetiger.
5. Modem Methods of Plant Analysis- Peach & M.V. Tracey, Vol. I & II, Springer Publishers.
6. Herbal Drug Industry by RD. Choudhary, Eastern Publishers, New Delhi.
7. Text book of Pharmacognosy by C.K.Kokate, Purohit, Ghokhale, Nirali Prakashan.
8. Text Book of Pharmacognosy by T.E. Wallis, J & A Churchill Ltd., London.
9. Quality control of herbal drugs by Pulok K Mukherjee, Business Horizons Pharmaceutical Publishers, New Delhi.
10. Indian Herbal Pharmacopoeia, IDMA, Mumbai.
11. Text book of Pharmacognosy and Phytochemistry by Vinod D. RangarI, Part I & II, Career Publication, Nasik, India.
12. Plant drug analysis by H.Wagner and S.Bladt, 2nd edition, Springer, Berlin.
13. Standardization of Botanicals. Testing and extraction methods of medicinal herbs by V. Rajpal (2004), Vol.I, Eastern PublisherS, New Delhi.
14. Herbal Medicine. Expanded Commission E Monographs, M.Blumenthal

Program: M. Pharmacy (Pharmacognosy) **Class:** First Year **Semester :** 2

Indian System of Medicine

Course Code: MPG203T **Credits:** 4 **Contact Hours:** 60 Hrs (Theory)

Scope : This course is designed to impart knowledge on the area of the Indian System of Medicines and related GMP practices.

Objectives : Upon completion of the course, student shall be able to understand

- Understand the thoroughly the basic principles of various Indian systems of medicine
- Understand the basic principles and treatment modalities of Naturopathy, Yoga and Aromatherapy practices
- Understand the preparations, formulation development, standardization and stability studies of medicines of various Indian systems of medicine
- Understand Good Manufacturing Practice (GMP), quality assurance, safety monitoring, and regulations of Indian systems of medicine.

Course Outcome (CO):

Upon completion of the course, the student will be able to:

CO number	Course Outcome (CO) statement
MPG203T.1	Understand and analyze toxicity issues and regulations for herbal drugs and their validation.
MPG203T.2	Understand and apply methods for detecting adulteration and evaluating techniques for herbal drugs.
MPG203T.3	Understand, apply, and analyze the ethnobotanical and ethnopharmacological knowledge in research.
MPG203T.4	Able to apply the knowledge and evaluate the analytical studies of herbal drugs.
MPG203T.5	Be able to understand and apply methods of screening herbals for various biological properties.

Course Content:

Unit	Topic	Hours
I	Fundamental concepts of Ayurveda, Siddha, Unani and Homoeopathy systems of medicine Different dosage forms of the ISM. **Ayurveda**: Ayurvedic Pharmacopoeia, Analysis of formulations and bio crude drugs with references to: Identity, purity and quality. **Siddha:**Gunapadam (Siddha Pharmacology), raw drugs/Dhatu/Jeevam in Siddha system of medicine, Purification process (Suddhi).	12 Hrs
II	Naturopathy, Yoga and Aromatherapy practices a) Naturopathy - Introduction, basic principles and treatment modalities. b) Yoga - Introduction and Streams of Yoga. Asanas, Pranayama, Meditations and Relaxation techniques. c) Aromatherapy – Introduction, aroma oils for common problems,	12 Hrs

	carrier oils.	
III	Formulation development of various systems of medicine Salient features of the techniques of preparation of some of the important class of Formulations as per Ayurveda, Siddha, Homeopathy and Unani Pharmacopoeia and texts. Standardization, Shelf life and Stability studies of ISM formulations.	12 Hrs
IV	Schedule T – Good Manufacturing Practice of Indian systems of medicine. Components of GMP (Schedule – T) and its objectives Infrastructural requirements, working space, storage area machinery and equipments, standard operating procedures health and hygiene, documentation and records. Quality assurance in ISM formulation industry GAP GMP and GLP. Preparation of documents for new drug application and export registration. Challenges in monitoring the safety of herbal medicines. Regulation , Quality assurance and control National/Regional pharmcopeias.	12 Hrs
V	TKDL, Geographical indication Bill, Government bills in AYUSH, ISM, CCRAS, CCRS, CCRH, CCRU	12 Hrs

References:

1. Ayurvedic Pharmacopoeia, the Controller of Publications, Civil Lines, Govt. of India, New Delhi.
2. Hand Book on Ayurvedic Medicines, H. Panda, National Institute of Industrial Research, New Delhi.
3. Ayurvedic System of Medicine, Kaviraj Nagendranath Sengupata, Sri Satguru Publications, New Delhi.
4. Ayurvedic Pharmacopoeia. Formulary of Ayurvedic Medicines, IMCOPS, Chennai.
5. Homeopathic Pharmacopoeia. Formulary of Homeopathic Medicines, IMCOPS, Chennai.
6. Homeopathic Pharmacy: An introduction & Hand book, Steven B. Kayne, Churchill Livingstone, and New York.
7. Indian Herbal Pharmacopoeia, IDMA, Mumbai.
8. British Herbal Pharmacopoeia, British Herbal Medicine Association, UK.
9. GMP for Botanicals - Regulatory and Quality issues on Phytomedicine, Pulok K Mukharjee, Business Horizons, New Delhi.
10. Indian System of Medicine and Homeopathy in India, Planning and Evaluation Cell, Govt. of India, New Delhi.
11. Essential of Food and Nutrition, Swaminathan, Bappco, Bangalore.
12. Clinical Dietetics and Nutrition, F.P. Antia, Oxford University Press, Delhi.
13. Yoga - The Science of Holistic Living by V.K.Yoga, Vivekananda Yoga Prakashna Publishing, Bangalore.

Program: M. Pharmacy (Pharmacognosy) **Class:** First Year **Semester :** 2

Herbal Cosmetics

Course Code: MPG204T **Credits:** 4 **Contact Hours:** 60 Hrs (Theory)

Scope : This course is designed to impart knowledge about the herbal cosmetics, design, development, formulation, and standardization.

Objectives : Upon completion of the course, student shall be able to understand

- Understand thoroughly the basic principles of regulatory aspects of herbal cosmetics.
- Analyze commonly used herbal raw materials, the design of herbal formulations, and possible interactions among them.
- Understand the physiology of skin & hair and preparation. Evaluate and standardize different herbal skin care cosmetics.
- Design, analyze, and control the quality and toxicity of herbal cosmetics as per the Drug & Cosmetics Act.

Course Outcome (CO):

Upon completion of the course, the student will be able to:

CO number	Course Outcome (CO) statement
MPG203T.1	Understand the basic principles & regulatory aspects of herbal cosmetics.
MPG203T.2	Analyze commonly used herbal raw material, the design of herbal formulation, herbal raw material, and possible interactions.
MPG203T.3	Demonstrate physiology of skin & hair and preparation. Evaluate and standardize different herbal skin care cosmetics.
MPG203T.4	Design different herbal hair care and skin care cosmetics.
MPG203T.5	Analysis, quality control, and toxicity of herbal cosmetics as per the Drug & Cosmetics Act.

Course Content:

Unit	Topic	Hours
I	**Introduction to Herbal/Natural Cosmetics:** Classification & Economic Aspects. Regulatory provisions related to the manufacture of cosmetics: license, GMP, offenses & penalties, import & export of herbal/natural cosmetics, and industries involved in the production of herbal/natural cosmetics.	12 Hrs
II	**Commonly used herbal cosmetics, raw materials**, preservatives, surfactants, humectants, oils, colors, and some functional herbs; preformulation studies; compatibility studies; possible interactions between chemicals and herbs, design of herbal cosmetic formulation.	12 Hrs
III	Herbal Cosmetics : Physiology and chemistry of skin and pigmentation, hairs, scalp, lips and nails; cleansing cream, lotions, face powders, face packs, Lipsticks, Bath products, soaps and baby products. Preparation and standardization of the following : Tonic, Bleaches, dentifrices and mouthwashes & toothpastes, and cosmetics for nails.	12 Hrs
IV	Cosmeceuticals of herbal and natural origin: Hair growth formulations, Shampoos, Conditioners, Colorants & hair oils, Hrs	12 Hrs

	Fairness formulations, vanishing & foundation creams, anti-sun burn preparations, moisturizing creams, and deodorants.	
V	Analysis of Cosmetics, Toxicity Screening, and Test Methods: Quality control and toxicity studies as per Drug and Cosmetics Act.	12 Hrs

References:

1. Panda H. Herbal Cosmetics (Hand book), Asia Pacific Business Press Inc, New Delhi.
2. Thomson EG. Modern Cosmetics, Universal Publishing Corporation, Mumbai.
3. P.P.Sharma. Cosmetics - Formulation, Manufacturing & Quality Control, Vandana Publications, New Delhi.
4. Supriya K B. Handbook of Aromatic Plants, Pointer Publishers, Jaipur.
5. Skaria P. Aromatic Plants (Horticulture Science Series), New India Publishing Agency, New Delhi.
6. Kathi Keville and Mindy Green. Aromatheraphy (A Complete Guide to the Healing Art), Sri Satguru Publications, New Delhi.
7. Chattopadhyay PK. Herbal Cosmetics & Ayurvedic Medicines (EOU), National Institute of Industrial Research, Delhi.
8. Balsam MS & Edward Sagarin. Cosmetics Science and Technology, Wiley Interscience, New York.

Program: M. Pharmacy (Pharmacognosy) **Class:** First Year **Semester :** 2

Pharmacognosy Practicals-II

Course Code: MPG205P **Credits:** 6 **Contact Hours:** 90 Hrs (Practical)

Scope : This course is designed to impart practical knowledge on pharmacognosy and phytochemistry.

Objectives : Upon completion of the course, student shall be able to understand

- The course will cover practical aspects of analyzing herbals and their formulations.
- Able to perform extraction, phytochemical screening, and drug monograph analysis.
- The course will cover the formulation, evaluation, and standardization of herbal and natural products.

Course Outcome (CO):

Upon completion of the course, the student will be able to:

CO number	Course Outcome (CO) statement
MPG205P.1	Understand, apply, and analyze using the different analytical techniques used in herbal formulations, development, and evaluation.
MPG205P.2	Understand, apply, and utilize the methods for extraction and phytochemical screening.
MPG205P.3	Understand the monograph analysis of herbal drugs.
MPG205P.4	Able to apply and evaluate herbal dosage forms and their standardization.

Course Content:

Sr. No.	Content
1	Estimation of aldehyde contents of volatile oils
2	Estimation of total phenolic content in herbal raw materials
3	Estimation of total alkaloid content in herbal raw materials
4	Estimation of total flavonoid content in herbal raw materials
5	Estimation of total tannin content in herbal raw materials
6	Preparation and standardization of various simple dosage forms from traditional formulations.
7	Formulation & standardization of herbal cough syrup.
8	Preparation of cosmetic formulations of herbal hair and skin care products
9	Evaluation of herbal tablets and capsules
10	Immobilization technique
11	Isolation of nucleic acid

References:

1. Dubey R.C., “A Textbook of Biotechnology”, 1st edition, 1993, S. Chand Publication, New Delhi.
2. Indian Pharmacopoeia, Vol I & II, 2017

3. Deore S.L., Khadbadi S.S., et.al. “Experimental Phytopharmacognosy-A Comprehensive Guide”, 1st edition, Nirali Prakashan, Mumbai, may 2011.
4. Ayurvedic Pharmacopeia of India
5. Worwood A.V., “The complete Book of Essential oil and Aromatherapy”, Sept.1991, New World Liabrary, Calofornia.
6. Sharma P.P., “Cosmetics Formulation, Manufacturing & Quality control”, 3rd edition, 2005, Vandana Publications, Delhi.
7. Gupta S., “Herbal Cosmetics and Beauty Products with Formulations”, Engineers India Research Institute, Delhi