PROGRESSIVE EDUCATION SOCIETY'S MODERN COLLEGE OF PHARMACY, MOSHI, PUNE

(AUTONOMOUS)

AFFILIATED TO

SAVITRIBAI PHULE PUNE UNIVERSITY

FACULTY OF SCIENCE AND TECHNOLOGY

RULES & SYLLABUS

MASTER OF PHARMACY (M. Pharm.) COURSE

(WITH EFFECT FROM ACADEMIC YEAR 2026-2027)



PHARMACIST'S OATH

I swear by the code of ethics of Pharmacy Council of India, in relation to the community and shall act as an integral part of health care team.

I shall uphold the laws and standards governing my profession.

I shall strive to perfect and enlarge my knowledge to contribute to the advancement of pharmacy and public health.

I shall follow the system which I consider best for pharmaceutical care and counselling of patients.

I shall endeavour to discover and manufacture drugs of quality to alleviate sufferings of humanity.

I shall hold in confidence the knowledge gained about the patients in connection with my professional practice and never divulge unless compelled to do so by the law.

I shall associate with organizations having their objectives for betterment of the profession of Pharmacy and make contribution to carry out the work of those organizations.

While I continue to keep this oath unviolated, may it be granted to me to enjoy life and the practice of pharmacy respected by all, at all times !

Should I trespass and violate this oath, may the reverse be my lot !

GRADUATE ATTRIBUTES (GA's)

Graduate Attributes (GAs) represent the key competencies and professional qualities expected from every pharmacy graduate, irrespective of the program such as D. Pharm, B. Pharm, Pharm.D or M.Pharm.

While the level of mastery may vary, these attributes remain common and guide the overall outcomes of pharmacy education.

1. Pharmaceutical Knowledge Proficiency – Strong grounding in core and applied pharmaceutical sciences and practice.

2. Scientific and Analytical Thinking – Ability to critically analyze data, processes, and clinical information.

3. Ethical and Professional Integrity – Commitment to ethical conduct, patient safety, and regulatory compliance.

4. Patient-Centered Orientation – Sensitivity to patient needs, cultural diversity, and healthcare outcomes.

5. Industry and Practice Readiness – Preparedness for roles in industry, hospitals, community pharmacy, research, and regulation.

6. Digital and Technological Awareness – Familiarity with AI, data analytics, automation, and modern pharmaceutical technologies.

7. Effective Communication Skills – Clear, empathetic, and professional interaction across healthcare settings.

8. Teamwork and Leadership Skills – Ability to collaborate, lead, and contribute constructively in teams.

9. Innovation and Problem-Solving Mindset – Capability to identify problems and develop practical, evidence-based solutions.

10. Lifelong Learning Orientation – Motivation for continuous professional development and higher education.

PROGRAM SPECIFIC OUTCOMES (PSOs)

PHARMACEUTICAL QUALITY ASSUARANCE

After completion of the program students are able to,

PSO1: acquire advanced knowledge with scientific background in the specialization of Quality Assurance like validation, documentation, regulatory submissions etc.

PSO2: successfully complete short term research project individually/ independently by acquiring research skills and handling sophisticated instruments/equipment in Quality Assurance and Quality Control based on emerging Quality building concepts in product manufacturing.

PHARMACEUTICS

After completion of the program students should be able to,

PSO1: acquire advanced knowledge with background of Pharmaceutics, Physical Pharmacy and Pharmaceutical Engineering area to apply it in development, evaluation and characterization of dosage form.

PSO2: successfully complete short term research project individually/independently by acquiring research skills and high competency in designing of novel drug delivery to cater the need of pharmaceutical industry and patient community.

PHARMACOLOGY

PSO 1: The students should be able to design and execute independent preclinical research projects using advanced in-vivo and in-vitro models to elucidate drug mechanisms and validate novel therapeutic targets.

PSO 2: At the end of this programme, the students should be able to critically analyze complex experimental data to contribute to global drug safety and innovation while adhering to international regulatory and ethical standards.

Program Outcomes (POs)

PO1 Proficiency in Subject domain

Students should be able to demonstrate a degree of mastery over the area as per the specialization of the program. The mastery should be at a level higher than the requirements in the appropriate bachelor program

PO2 Communication

Students should be able to Communicate effectively with public as well as with professionals, demonstrating the ability to comprehend, write effective reports, make effective presentations and documentation.

PO3 Problem Analysis and Resolution

Students should be able to, successfully complete research project independently by acquiring research skills and handling sophisticated instruments.

PO4 Pharmaceutical Ethics

Students should honour personal values and apply ethical principles while making decisions and take responsibility for the outcomes associated with the decisions.

PO5 Entrepreneurship

Students should develop entrepreneurship skills that support the growth of Pharmaceutical Industry / Pharmaceutical Services leading to economic development.

PO6 Environment and sustainability

Students should understand the impact of the professional pharmacy solutions in societal and environmental contexts, and demonstrate the knowledge of, and need for sustainable development.

PO7 Lifelong learning

Students should recognize the need for, and have the preparation and ability to engage in independent and lifelong learning and develop an aptitude of continuous professional development and demonstrate the knowledge of Research and Development in different disciplines of pharmaceutical sciences.

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CHAPTER-I: REGULATIONS

1. Short Title and Commencement

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

2. Minimum qualification for admission

A. Pass in the following examinations –

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

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

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

3. Duration of the program

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

4. Medium of instruction and examinations

Medium of instruction and examination shall be in English.

5. Working days in each semester

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

6. Attendance and progress

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

7. Program / Course credit structure

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

7.1 Credit assignment 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 seminar-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.

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 6. 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.	Pharmacology	MPL

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
MSA106	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
MSA206	Seminar/Assignment	7	4	7	100
	Total	**35**	**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
MSA106	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
MSA206	Seminar/Assignment	7	4	7	100
	Total	**35**	**26**	**35**	**650**

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

Course Code	Course	Credit Hours	Credit Points	Hrs./wk	Marks
SEMESTER I					
MPAT101T	Modern Pharmaceutical Analytical Techniques	4	4	4	100
MPL102T	Advanced Pharmacology - I	4	4	4	100
MPL103T	Pharmacological and Toxicological Screening Methods–I	4	4	4	100
MPL104T	Cellular and Molecular Pharmacology	4	4	4	100
MPL105P	Pharmacology Practical I	12	6	12	150
MSA106	Seminar/Assignment	7	4	7	100
	Total	**35**	**26**	**35**	**650**
SEMESTER II					
MPL201T	Advanced Pharmacology II	4	4	4	100
MPL202T	Pharmacological and Toxicological Screening Methods–II	4	4	4	100
MPL203T	Principles of Drug Discovery	4	4	4	100
MPL204T	Clinical Research and Pharmacovigilance	4	4	4	100
MPL205P	Pharmacology Practical II	12	6	12	150
MSA206	Seminar/Assignment	7	4	7	100
	Total	**35**	**26**	**35**	**650**

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

Course Code	Course	Credit Hours	Credit Points
MRM 301	Research Methodology and Biostatistics	4	4
MJC 302	Journal club	1	1
MDP 303	Discussion/ Proposal Presentation	2	2
MRW 304	Research Work	28	14
MIC 305	Introduction to Constitution*	-	-
	Total	**35**	**21**

* **Additional course as per UGC guidelines.**

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

Course Code	Course	Credit Hours	Credit Points
MJC 401	Journal club	1	1
MDP 402	Discussion / Final Presentation	3	3
MRW 403	Research Work	31	16
	Total	**35**	**20**

Table -6: Semester wise credits distribution

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

*Credit Points for Co–curricular Activities

Table –7: Guidelines for Awarding Credit Points for Co-curricular Activities

Sr. No.	Name of activity	Maximum credit points eligible/activity
1.	Participation in National/International level seminar/conference/workshop/symposium (at least 2)	01
2.	Poster presentation in Participation in National/ International level seminar/ conference/ workshop/ symposium/training program (at least 1)	01
3.	Academic/Research/Co-curricular/Extra-curricular award in intercollegiate competitions	01
4.	Research/Review paper publication in Journal	1-2 (depending upon quality)
5.	Successful completion of NPTEL/ SWAYAM/ MOOCS/ Online course (min 30 H) (at least 2)	01
6.	Successful completion of Training program of at least 15 days (Industry/research lab/Retail Pharmacy/Hospital Pharmacy) (at least 1)	01
7.	**Total**	**07**

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 sh all 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 se ssionalexam and before the end semester exam.

11. Examinations/Assessments

The schemes for internal assessment and end semester examinations are given in Table – 8-10.

11.1 End semester examinations

The End Semester Examinations for each theory and practical course throug semesters I to IV shall be conducted at the end of each semester.

Question paper pattern for end semester theory examination

I. Long answer questions (solve 1 out of 2)	1 X 15=15
II. Medium Length answers (Solve 2 out of 4)	2 X 7.5=15
III. Short answer questions (solve 3 out of 5)	3 X 5=15
IV. Long answer questions (solve 1 out of 2)	1 X 15=15
V. Short notes (Solve 3 out of 5)	3 X5= 15
	Total Marks= 75

Question paper pattern for end semester practical examination

I. Synopsis	15
II. Experiment(s)	70
III. Viva voce	15
Total Marks = 100	

Table - 8: 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								
MPAT101T	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
MPH104T	Regulatory Affair	10	15	1 Hr	25	75	3 Hrs	100
MPH105P	Pharmaceutics Practical I	20	30	6 Hrs	50	100	6 Hrs	150
MSA106	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 & Pharmaco Kinetics	10	15	1 Hr	25	75	3 Hrs	100
MPH 203T	Computer Aided Drug Development	10	15	1 Hr	25	75	3 Hrs	100
MPH204T	Cosmetic and Cosmeceuticals	10	15	1 Hr	25	75	3 Hrs	100
MPH205P	Pharmaceutics Practical II	20	30	6 Hrs	50	100	6 Hrs	150
MSA206	Seminar /Assignment	–	–	–	–	–	–	100
Total								**650**

Table - 9: Schemes for internal assessments and end semester examinations (Pharmaceutical Quality Assurance–MQA)

Course Code	Course	Internal Assessment				End Semester Exams		Total Marks
		Contin-uous Mode	Sessional Exams		Total	Marks	Duration	
			Marks	Duration				
SEMESTER I								
MPAT101T	Modern Pharmaceutical Analytical Techniques	10	15	1 Hr	25	75	3 Hrs	100
MQA102T	Quality Management System	10	15	1 Hr	25	75	3 Hrs	100
MQA103T	Quality Control and Quality Assurance	10	15	1 Hr	25	75	3 Hrs	100
MQA104T	Product Developmentand Technology Transfer	10	15	1 Hr	25	75	3 Hrs	100
MQA105P	Pharmaceutical Quality Assurance Practical I	20	30	6 Hrs	50	100	6 Hrs	150
MSA106	Seminar /Assignment	–	–	–	–	–	–	100
Total								650
SEMESTER II								
MQA201T	Hazards and Safety Management	10	15	1 Hr	25	75	3 Hrs	100
MQA202T	Pharmaceutical Validation	10	15	1 Hr	25	75	3 Hrs	100
MQA203T	Audits and Regulatory Compliance	10	15	1 Hr	25	75	3 Hrs	100
MQA204T	Pharmaceutical Manufacturing Technology	10	15	1 Hr	25	75	3 Hrs	100
MQA205P	Pharmaceutical QualityAssurance Practical II	20	30	6 Hrs	50	100	6 Hrs	150
MSA206	Seminar /Assignment	–	–	–	–	–	–	100
Total								650

Table - 10: Schemes for internal assessments and end semester examinations (Pharmacology–MPL)

Course Code	Course	Internal Assessment				End Semester Exams		Total Marks
		Contin-uous Mode	Sessional Exams		Total	Marks	Duration	
			Marks	Duration				
SEMESTER I								
MPAT101T	Modern Pharmaceutical Analytical Techniques	10	15	1 Hr	25	75	3 Hrs	100
MPL102T	Advanced Pharmacology–I	10	15	1 Hr	25	75	3 Hrs	100
MPL103T	Pharmacological and Toxicological Screening Methods–I	10	15	1 Hr	25	75	3 Hrs	100
MPL104T	Cellular and Molecular Pharmacology	10	15	1 Hr	25	75	3 Hrs	100
MPL105P	Experimental Pharmacology – I	20	30	6 Hrs	50	100	6 Hrs	150
MSA106	Seminar /Assignment	–	–	–	–	–	–	100
Total								**650**
SEMESTER II								
MPL201T	Advanced Pharmacology II	10	15	1 Hr	25	75	3 Hrs	100
MPL202T	Pharmacological and Toxicological Screening Methods–II	10	15	1 Hr	25	75	3 Hrs	100
MPL203T	Principles of Drug Discovery	10	15	1 Hr	25	75	3 Hrs	100
MPL204T	Clinical research and pharmacovigilance	10	15	1 Hr	25	75	3 Hrs	100
MPL205P	Experimental Pharmacology– II	20	30	6 Hrs	50	100	6 Hrs	150
MSA206	Seminar /Assignment	–	–	–	–	–	–	100
Total								**650**

Seminar/Assignment

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**

Table - 11: Schemes for internal assessments and end semester examinations (Semester III & IV)

Course Code	Course	Internal Assessment				End Semester Exams		Total Marks
		Contin-uous Mode	Sessional Exams		Total	Marks	Duration	
			Marks	Duration				
SEMESTER III								
MRM301	Research methodology and Biostatistics	10	15	1 Hr	25	75	3 Hrs	100
MJC302	Journal club	–	–	–	25	–	–	25
MDP303	Discussion / Presentation (Proposal Presentation)	–	–	–	50	–	–	50
MRM304	Research work	–	–	–	–	350	1 Hr	350
MIC305	Introduction to * Constitution	–	–	–	25	–	–	25
Total								**525**
SEMESTER IV								
MJC401	Journal club	–	–	–	25	–	–	25
MDP402	Discussion / Presentation (Proposal Presentation)	–	–	–	75	–	–	75
MRM403	Research work and Colloquium	–	–	–	–	400	1 Hr	400
Total								**500**

*Additional course as per UGC guilines

11.2 Internal assessment: Continuous mode

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

Table - 12: Scheme for awarding internal assessment: Continuous mode

Theory	
Criteria	**Maximum Marks**
Attendance (Refer Table – 13)	8
Student – Teacher interaction	2
Total	**10**
Practical	
Attendance (Refer Table – 13)	10
Based on Practical Records, Regular viva voce, etc.	**10**
Total	**20**

Table - 13: 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

Sessional Exams

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

Scheme for theory Sessional examination

Question no.		Particulars	Marks (30)
1	A	Attempt any three out of four questions (Objective Type questions)	3×2 = 06
	B	Attempt Following questions (Short answer questions)	5×2 = 10 or 5×2 = 10
2	A	Attempt any two out of three questions (Objective Type questions)	2×2 = 04
	B	Long Answer Attempt any one out of two (Long answer questions)	10×1 =10

Scheme for Practical Sessional examination

I. Synopsis	05
II. Experiment(s)	20
III. Viva voce	05
Total Marks=	**30**

12. Promotion and award of grades

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

13. Carry forward of marks

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

14. Improvement of internal assessment

A student shall have the opportunity to improve his/her performance 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.

15. Re examination of end semester examinations

Reexamination of end semester examination shall be conducted as per the schedule given in table 14. The exact dates of examinations shall be notified from time to time.

Table – 13: Tentative schedule of end semester examinations

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

16. Allowed to keep terms (ATKT):

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

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

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

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

17. Grading of performances

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-14.

Table–14: Letter grades and grade points equivalent to Percentage of marks and performances

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

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

18. The Semester grade point average (SGPA)

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

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

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

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

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

19. Cumulative Grade Point Average (CGPA)

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

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

where C1, C2, C3,…. is the total number of credits for semester I, II, III, …. and S 1, S2, S3, ….is the SGPA of semester I, II, III, ….

20. Declaration of class

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

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

21. Project work

All th e 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 exainer appointed by the University shall evaluate the project at the time of the Practical examinations of other semester(s). The projects shall be evaluated as per the criteria given below.

Evaluation of Dissertation Book:

□ Objective(s) of the work done		25 Marks
□ Methodology adopted		75 Marks
□ Results and Discussions		125 Marks
□ 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**

22. Award of Ranks

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

23. Award of degree

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

24. Duration for completion of the program of study

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

25. Revaluation 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.

26. Re-admission after break of study

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

Common subject for all specializations

MODERN PHARMACEUTICAL ANALYTICAL TECHNIQUES (MPAT101T)		**THEORY 60 Hrs**
Scope This subject deal 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. **Course Outcomes** Upon completion of the course the student shall be able to, • identify and quantify drugs using UV and Flame photometry. • perform structural elucidation, identification of compounds using spectroscopic tools like NMR and Mass Spectrometry. • perform separation of organic compounds using electrophoresis and chromatography. • Understand theoretical concepts and applications of IR Spectroscopy, Atomic absorption spectroscopy and Fluorimetry.		
UNIT-1	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 affecti ng vibrational frequencies and Applications of IR spectroscopy, Data Interpretation. **c) Spectroflourimetry:** Theory of Fluorescence, Factors affecting fluorescence, Quenchers, Instrumentation and Applications of fluorescence spectroscopy. **d) Flame emission spectroscopy and atomic absorption spectroscopy:** Principle, Instrumentation, Interferences and Applications.	**10 Hrs**
UNIT-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**
UNIT-III	a) **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	**12 Hrs**

	and Applications of Mass spectrometry b) Simple structure elucidation problems based on UV, IR, NMR and Mass data.	
UNIT-IV	**Chromatography:** Principle, instrumentation, chromatographic parameters, factors affecting resolution and applications of the following: a) High-Performance Liquid chromatography b) High-Performance Thin Layer Chromatography c) Ion exchange chromatography d) Gas chromatography e) Ultra High-Performance Liquid chromatography f) Affinity chromatography g) Gel Chromatography	**10 Hrs**
UNIT-V	**a) Electrophoresis:** Principle, Instrumentation, working conditions, factors affecting separation and applications of the following: a) Paper electrophoresis b) Gel electrophoresis c) Capillary electro phoresis 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.	**10 Hrs**
UNIT - 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**

References

1. Spectrometric Identification of Organic compounds - Robert M Silverstein, Sixth edition, John Wiley & Sons, 2004.
2. Principles of Instrumental Analysis - Doglas A Skoog, F. James Holler, Timothy A. Nieman, 5th edition, Eastern press, Bangalore, 1998.
3. Instrumental methods of analysis – Willards, 7th edition, CBS publishers.
4. Practical Pharmaceutical Chemistry – Beckett and Stenlake, Vol II, 4 th 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, 3 rd 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 Nazma Inamdar (Career publications).

PHARMACEUTICS (MPH)

DRUG DELIVERY SYSTEM (MPH 102T)		THEORY 60 Hrs
Scope This course is designed to impart knowledge on the area of advances in novel drug delivery systems. **Course Outcomes** Upon completion of the course, student shall be able to • describe the fundamental concept of modified drug release prerequisites of drug candidate for modified release and polymers. • Provide knowledge regarding recent development approaches of mucoadhesive dosage forms. • create awareness of different personalized drug delivery system. • learn ocular protein and vaccine drug delivery system.		
UNIT 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. Polymers: introduction, definition, classification, propert ies and application Dosage Forms for Personalized Medicine: Introduction, Definition, Pharmacogenetics, and Categories of Patients for Personalized Medicines: Customized drug delivery systems, Bioelectronic Medicines, 3D printing of pharmaceuticals, Telepharmacy.	**10 Hrs**
UNIT 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**
UNIT III	**Gastro-Retentive Drug Delivery Systems:** Principle, concepts advantages and disadvantages, Modulation of GI transit time approaches to extend GI transit. Buccal Drug Delivery Systems: Principle of muco adhesion, advantages and disadvantages, Mechanism of drug permeation, Methods of formulation and its evaluations.	**10 Hrs**
UNIT IV	**Occular Drug Delivery Systems:** Barriers of drug permeation, Methods to overcome barriers	**06 Hrs**
UNIT V	**Transdermal Drug Delivery Systems:** Structure of skin and barriers, Penetration enhancers, Transdermal Drug Delivery Systems, Formulation and evaluation.	**10 Hrs**

UNIT VI	**Protein and Peptide Delivery:** Barriers for protein delivery. Formulation and Evaluation of delivery systems of proteins and other macromolecules.	**08 Hrs**
UNIT VII	**Vaccine delivery systems:** Vaccines, uptake of antigens, single shot vaccines, mucosal and transdermal delivery of vaccines.	**06 Hrs**

REFERENCES

1. Y W. Chien, Novel Drug Delivery Systems, 2nd 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 WileyInterscience 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

JOURNALS

1. Indian Journal of Pharmaceutical Sciences (IPA)
2. Indian drugs (IDMA)
3. Journal of controlled release (Elsevier Sciences) desirable
4. Drug Development and Industrial Pharmacy (Marcel & Decker) desirable

MODERN PHARMACEUTICS (MPH 103T)		THEORY 60 Hrs
Scope Course designed to impart advanced knowledge and skills required to learn various aspects and concepts at pharmaceutical industries **Course Outcomes** Upon completion of the course, student shall be able to • Describe preformulation parameters, stability testing and understanding of theories of dispersed systems with preparation of SVP and LVP formulation. • Apply optimization techniques, experimental design in dosage form development. • Analyze physics of compression and consolidation of powder mass with determination of consolidation parameters. • Explain necessity of validation, its types and cGMP in research, Manufacturing, distribution of dosage form.		
UNIT I	**Preformation Concepts** – Drug Excipient interactions different methods, kinetics of stability, Stability testing. Theories of dispersion and pharmaceutical Dispersion (Emulsion and Suspension, SMEDDS) prepa ration and stability. Large and small volume parental – physiological and formulation consideration, Manufacturing and evaluation.	**12 Hrs**
UNIT II	**Optimization techniques in Pharmaceutical Formulation:** Concept and parameters of optimization, Optimization techniques in pharmaceutical formulation and processing. Statistical design, Response surface method, Contour designs, Factorial designs and application in formulation.	**10 Hrs**
UNIT III	**Validation:** Introduction to Pharmaceutical Valid ation, Scope & merits of Validation, ICH & WHO guidelines for validation of equipments, Validation of cone blender, mixer granulator and tablet compression machine, URS, DQ, IQ, OQ & P.Q. of facilities, Types of process validation. Process validation of a ny one dosage form. Technology transfer from R & D to pilot plant to plant scale.	**12 Hrs**
UNIT IV	**GMP & Industrial Management:** Objectives and policies of current good manufacturing practices, layout of buildings, services, equipment 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.	**10 Hrs**
UNIT V	**Compression and compaction:** Physics of tablet compression, compression, consolidation, effect of friction, distribution of forces, compaction profiles, Study of consolidation parameters, Heckel plots.	**10 Hrs**

UNIT V	Diffusion parameters, Dissolution parameters and Pharmacokinetic parameters, Similarity factors – f2 and f1, Dissolution models including Higuchi, Peppas plot, zero order, first order and Hixson Crowell.	**06 Hrs**

REFERENCES

1. Theory and Practice of Industrial Pharmacy By Lachmann and Libermann
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. Sha h. 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 man agement; By Evans, Anderson, Sweeney and Williams.
17. Encyclopaedia of Pharmaceutical technology, Vol I – III.

REGULATORY AFFAIRS (MPH 104T)		THEORY 60 Hrs
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 process of IND, NDA and ANDA. **Course Outcomes** Upon completion of the course, it is expected that the students will be able to • Describe concepts of innovator, generic drugs, drug development process and the Regulatory guidance's and guidelines for filing and approval process. • Prepare Dossiers and their submission to regulatory agencies in different countries. • Understand and Prepare Post approval regulatory requirements for actives and drug products and submission of global documents in CTD/ eCTD formats. • Explain Clinical trials requirements for approvals for conducting clinical trials and Pharmaco-vigilence and process of monitoring in clinical trials.		
UNIT 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 Hrs**
UNIT II	**Regulatory requir ement for product approval:** API, biologics, novel, therapies obtaining NDA, ANDA for generic drugs ways and means of US registration for foreign drugs.	**12 Hrs**
UNIT III	**CMC, post approval regulatory affairs:** Regulation for combination products and medical devices. CTD and ECTD format, industry and FDA liaison. ICH – Guidelines of ICH –Q, S E, M. Regulatory requirements of EU, MHRA, TGA and ROW countries.	**12 Hrs**
UNIT IV	**Non clinical drug development:** Global submission of IND, NDA, ANDA. Investigation of medicinal products dossier, dossier (IMPD) and investigator brochure (IB).	**12 Hrs**
UNIT 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, pharmaco-vigilance safety monitoring in clinical trials.	**12 Hrs**

REFERENCES

1. Generic Drug Product Development, Solid Oral Dosage forms, Leon Shargel and Isader Kaufer, 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: Accel erating 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 d rugs, 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

PHARMACEUTICS PRACTICALS – I
(MPH 105P)

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
4. Experiments based on Gas Chromatography
5. Estimation of riboflavin/quinine sulphate by fluorimetry
6. Estimation of sodium/potassium by flame photometry
7. To perform In-vitro dissolution profile of CR/ SR marketed formulation
8. Formulation and evaluation of sustained release matrix tablets
9. Formulation and evaluation osmotically controlled DDS
10. Preparation and evaluation of Floating DDS– hydro dynamically balanced DDS
11. Formulation and evaluation of Muco adhesive tablets.
12. Formulation and evaluation of Trans dermal patches.
13. To carry out preformulation studies of tablets.
14. To study the effect of compressional force on tablets disintegration time.
15. To study Micromeritic properties of powders and granulation.
16. To study the effect of particle size on dissolution of a tablet.
17. To study the effect of binders on dissolution of a tablet.
18. To plot Heckal plot, Higuchi and peppas plot and determine similarity factors.

MOLECULAR PHARMACEUTICS (NANO TECHNOLOGY & TARGETED DDS) (MPH 201T)	THEORY 60 Hrs

Scope

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

Course Outcomes

Upon completion of the course student shall be able to

- Describe various approaches of targeted drug delivery system, microencapsulation system.
- Explain aerosol dosage form and intranasal delivery system.
- Compare liposomes, phytosome, electrosome, niosomes drug delivery systems.
- Learn various gene therapy techniques.

UNIT I	**Targeted Drug Delivery Systems:** Concepts, Events and biological process involved in drug targeting. Tumor targeting and Brain specific delivery.	**10 Hrs**
UNIT II	**Targeting Methods:** introduction preparation and evaluation. Nano Particles & Liposomes: Types, preparation and evaluation	**10 Hrs**
UNIT III	**Micro Capsules / Micro Spheres:** Types, preparation and evaluation, Monoclonal Antibodies; preparation and application, preparation and application of Niosomes, Aquasomes, Phytosomes, Electrosomes.	**10 Hrs**
UNIT IV	**Pulmonary Drug Delivery Systems:** Aerosols, propellents, ContainersTypes, preparation and evaluation, Intra Nasal Route Delivery systems; Types, preparation and evaluation.	**10 Hrs**
UNIT 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). Gene expression systems (viral and nonviral gene transfer). Liposomal gene delivery systems	**10 Hrs**
UNIT VI	**Biodistribution and Pharmacokinetics:** knowledge of therapeutic antisense molecules and aptamers as drugs of future.	**10 Hrs**

REFERENCES

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

ADVANCED BIOPHARMACEUTICS & PHARMACOKINETICS (MPH 202T)		THEORY 60 Hrs

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.

Course Outcomes

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

- Explain the concept of absorption, physicochemical properties and its importance for the development of a dosage form.
- Analyze In-Vitro drug product performance, concept of IVIVC in design of drug products.
- Learn various pharmacokinetic parameters from plasma concentration or urinary excretion data for drug based on compartment modelling and differentiation between linear and non-linear pharmacokinetics behaviour of drug.
- Discuss concept of absolute and relative bioavailability, its measurement and to design BA-BE study protocol as per regulatory requirements and Application of Pharmacokinetics in development.

UNIT I	**Drug Absorption from the Gastrointestinal Tract:** Gastrointestinal tract, Mechanism 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 –unction Complex.	**12 Hrs**
UNIT 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 Hrs**
UNIT 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	**12 Hrs**

	non –linearity, Michaelis- Menten equation, estimation of k max and vmax. 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.	
UNIT 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 sub mission and drug review process. biopharmaceutics classification system, methods. Permeability: In –vitro, in –situ and In –vivo methods. generic biologics (biosimilar drug products), clinical significance of bioequivalence studies, special concerns in bioavailability and bioequivalence studies, generic substitution.	**12 Hrs**
UNIT 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 Hrs**

REFERENCES

1. Biopharmaceutics a nd 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., VallabPrakashan, Pitampura, Delhi
3. Applied Biopharmaceutics and P harmacokinetics by Shargel. Land YuABC, 2nd 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, 2nd edition, Marc el Dekker Inc., New York, 1982
6. Current Concepts in Pharmaceutical Sciences: Biopharmaceutics, Swarbrick. J, Leaand Febiger, Philadelphia, 1970
7. Clinical Pharmacokinetics, Concepts and Applications 3rd 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 expande 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,1 st edition, Sunil S JambhekarandPhilip J Breen, pharmaceutical press, RPS Publishing,2009.
13. Absorption and Drug Development – Solubility, Permeability, and Charge State, Alex Avdeef, John Wiley & Sons, Inc,2003.

COMPUTER AIDED DRUG DEVELOPMENT (MPH 203T)	THEORY 60 Hrs

Scope

This course is designed to impart knowledge and skills necessary for computer Applications in pharmaceutical research and development who want to understand the application of computers across the entire drug research and development process. Basic theoretical discussions of the principles of more integrated and coherent use of computerized information (informatics) in the drug development process are provided to help the students to clarify the concepts.

Course Outcomes

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

- Explain the role of CADD and quality by design in drug discovery.
- Apply optimization design in pharmaceutical formulations and computational modelling in drug disposition.
- Remember the computer aided biopharmaceutical characterization.
- Discuss overview of artificial intelligence, computational fluid dynamics, role and ethics of computers in Clinical Development, R & D and market analysis.

UNIT I	**a) 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 **b) Quality-by-Design in Pharmaceutical Development:** Introduction, ICH Q8 guideline, Regulatory and industry views on QbD, scientifically based QbD – examples of application.	**12 Hrs**
UNIT II	**Computational Modeling of Drug Disposition:** Introduction, Modeling Techniques: Drug Absorption, Solubility, Intes tinal Permeation, Drug Distribution, Drug Excretion, Active Transport; P–gp BCRP, Nucleoside Transporters, hPEPT1, ASBT, OCT, OATP, BBB – Choline Transporter.	**12 Hrs**
UNIT III	**Computer-aided formulation development:** Concept of optimization, Optimization parameters, Factorial design, Optimization technology & Screening design. Computers in Pharmaceutical Formulation: Development of pharmaceutical emulsions, microemulsion 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**
UNIT IV	**a) 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	**12 Hrs**

	b) Computer Simulations in Pharmacokinetics and Pharmacodynamics: Introduction, Computer Simulation: Whole Organism, Isolated Tissues, Organs, Cell, Proteins and Genes. **c) Computers in Clinical Development:** Clinical Data Collection and Management, Regulation of Computer Systems	
UNIT 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, 1st Edition, Jelena Djuris, Woodhead Publishing
3. Encyclopedia of Pharmaceutical Technology, Vol 13, James Swarbrick, James. G. Boylan, Marcel Dekker Inc, New York, 19

COSMETICS AND COSMECEUTICALS (MPH 204T)		THEORY 60 Hrs
Scope This course is designed to impart knowledge and skills necessary for the fundamental need for cosmetic and cosmeceutical products. **Course Outcomes** Upon completion of the course, the students shall be able to • Explain key building blocks for various formulations. • Describe the regulatory provisions of cosmetics as per drug and cosmetics act 1940 and the rules 1945. • Elaborate Key ingredients, regulation of herbal cosmetics and scientific knowledge for design of cosmeceutical with desired safety, stability and efficacy. • Discuss biological aspects of cosmetics, cleansing and care needs for face, eye lids, lips, hands, feet, nail, scalp, neck, body and under arm.		
UNIT I	**Cosmetics – Regulatory:** Definition of cosmetic products as per Indian regul ation. Indian regulatory requirements for labeling of cosmetics Regulatory provisions relating to import of cosmetics., Misbranded and spurious cosmetics. Regulatory provisions relating to manufacture of cosmetics - Conditions for obtaining license, prohib ition of manufacture and sale of certain cosmetics, loan license, offences and penalties.	**12 Hrs**
UNIT II	**Cosmetics - Biological aspects:** Structure of skin relating to problems like dry skin, acne, pigmentation, prickly heat, wrinkles and body odor. Structur e of hair and hair growth cycle. Common problems associated with oral cavity. Cleansing and care needs for face, eye lids, lips, hands, feet, nail, scalp, neck, body and under–arm.	**12 Hrs**
UNIT III	**Formulation Building blocks:** Building blocks for different produc t formulations of cosmetics/cosmeceuticals. Surfactants - Classification and application. Emollients, rheological additives: classification and application. Antimicrobial used as preservatives, their merits and demerits. Factors affecting microbial preserv ative efficacy. Building blocks for formulation of a moisturizing cream, vanishing cream, cold cream, shampoo and toothpaste. Soaps and syndetbars. Perfumes; Classification of perfumes. Perfume ingredients listed as allergens in EU regulation. Controversial ingredients: Parabens, formal - ehyde liberators, dioxane.	**12 Hrs**
UNIT IV	**Design of cosmeceutical products:** Sun protection, sunscreens classification and regulatory aspects. 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 Hrs**
UNIT V	**Herbal Cosmetics:** Herbal ingredients used in Hair care, skin care and oral care. Review of guidelines for herbal cosmetics by private	**12 Hrs**

	bodies like cosmos with respect to preservatives, emollients, foaming agents, emulsifiers and rheology modifiers. Challenges in formulating herbal cosmetics.	

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1. Harry's Cosmeticology. 8th edition.
2. Poucher'sperfumecosmeticsandSoaps,10th 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. 3 rd edition
5. Cosmetic and Toiletries recent suppliers‟ catalogue.
6. CTFA directory.

PHARMACEUTICS PRACTICALS - II
(MPH 205P)

1. To study the effect of temperature change, non solvent addition, incompatible polymer addition in microcapsules preparation
2. Preparation and evaluation of Alginate beads
3. Formulation and evaluation of gelatin /albumin microspheres
4. Formulation and evaluation of liposomes/niosomes
5. Formulation and evaluation of spherules/microparticles
6. Improvement of dissolution characteristics of slightl y soluble drug by Solid dispersion technique.
7. Comparison of dissolution of two different marketed products /brands
8. Protein binding studies of a highly protein bound drug & poorly protein bound drug
9. Case studies of Bioavailability studies of Paracetamol in animals.
10. Case studies of Pharmacokinetic and IVIVC data analysis
11. Case studies of In vitro cell studies for permeability and metabolism
12. Design of Experiment for any formulation using Design Expert® Software (Only formulation DOE is expected)
13. Formulation data analysis Using Design Expert® Software (Data analysis and interpretation of the previous experiment is expected)
14. Quality-by-Design in Pharmaceutical Development
15. Case studies of Computer Simulations in Pharmacokinetics and Pharmacodynamics
16. Case studies of Computational Modeling of Drug Disposition
17. Case studies of Developing Clinical Data Collection manual
18. Case studies of 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 to address Dry skin, acne, blemish, Wrinkles, bleeding gums and dandruff

PHARMACEUTICAL QUALITY ASSURANCE (MQA)

QUALITY MANAGEMENT SYSTEMS (MQA 102T)		THEORY 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. **Course Outcomes** Upon completion of the course the student shall be able to • Explain the concept and importance of quality in pharmaceutical industry. • Apply various regulations and tools to analyze and resolve quality issues. • Implement ICH guidelines with focus on stability testing, Pharmaceutical development, quality and Risk management. • Use statistical approaches to quality and develop quality culture benchmarking.		
UNIT-I	**Introduction to Quality:** Evolution of Quality **Definition of Introduction to Quality :** Evolution of Quality, Definition of Quality, Dimensions of Quality **Quality a s 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 satisfact ion and Customer delight, Handling customer complaints, Understanding customer behaviour, concept of internal and external customers. Case studies. **Cost of Quality:** Cost of quality, Categories of cost of Quality, Models of cost of quality, optimising costs, preventing cost of quality.	**08 Hrs**
UNIT-II	**Pharmaceutical quality Management:** Basics of Quality Management, Total Quality Management (TQM), Principles of Six sigma, ISO 9001:2008, 9001:2015, ISO 14001:2004, Pharmaceutical Quality Management-ICH Q10, Kno wledge management, Quality Metrics, Operational Excellence and Quality Management Review. OSHAS guidelines, NABL certification and accreditation, CFR -21 part 11, WHO-GMP requirements.	**16 Hrs**
UNIT-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	**12 Hrs**

	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.	
UNIT-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 assessm ent, risk control, risk review, risk management tools, HACCP, risk ranking and filtering according to ICH Q9 guidelines.	**12 Hrs**
UNIT-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**
UNIT-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**

REFERENCES

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.

QUALITY CONTROL AND QUALITY ASSURANCE (MQA 103T)		THEORY 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. **Course Outcomes** Upon completion of this course the student should be able to • Explain the concept of quality control and quality assurance including of GMP/GLP, and ICH guidelines in pharmaceutical industry. • Describe the importance of documentation including USFDA, PIC, WHO, EMEA in pharmaceutical industry and CPCSEA guidelines. • Apply different quality control parameters as per specifications and pharmacopoeias. • Elaborate various manufacturing-operations, control parameters, documentation records and audit plan in pharmaceutical industry.		
UNIT-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 non clinical testing, control on animal house, report preparation and documentation. CPCSEA guidelines.	**12 Hrs**
UNIT-II	**cGMP guidelines** according to schedule M, USFDA (inclusive ofCDER and CBER) Pharmaceutical Inspection Convention (PIC), WHO, EMEA, GMP 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.	**12 Hrs**
UNIT-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**
UNIT-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,	**16 Hrs**

	as Common Technical Document and Electronic Common Technical Documentation (CTD, eCTD). Concept of regulated and non regulated markets.	
UNIT-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**

REFERENCES

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 compedium of Guide lines and related materials Vol I & II, 2nd edition, WHO Publications, 1999.
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5. The International Pharmacopoeia – Vol I, II, III, IV & V - General Methods of Analysis and Quality specification for Pharmaceutical Substances, Excepients and Dosage forms, 3rd edition, WHO, Geneva, 2005.
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8. ISO 9000 and total quality management.
9. Deshpande, Nilesh Gandhi, The Drugs and Cosmetics Act 1940, 4 th 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.
9. 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.
12. Sarker DK. Quality Systems and Controls for Pharmaceuticals. John Wiley & Sons; 2008.
13. Schedule M and Schedule N.

PRODUCT DEVELOPMENT AND TECHNOLOGY TRANSFER (MQA 104T)		THEORY 60 Hrs
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. **Course Outcomes** Upon completion of this course the student should be able to • Describe the new product development process. • Analyze the need of preformulation studies, importance of solubility studies and method to improve solubility of poorly soluble drugs. • Explain the necessary information and documentation of pilot plant scale up technique and technology transfer from R & D to manufacturing unit. • Discuss various pharmaceutical packaging systems and analyze their quality control testing.		
UNIT-I	**Principles of Drug discovery and development:** Introduction, Clinical research process. Development and informational content for Investigational New Drugs Application (IND), New Drug Application (NDA), Abbreviated New Drug Application (AND A), Supplemental New Drug Application (SNDA), Scale Up Post Approval Changes (SUPAC) and Bulk active chemical Post approval changes (BACPAC), Post marketing surveillance, Product registration guidelines – CDSCO, USFDA.	**12 Hrs**
UNIT-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 proper ties and polymorphism. Pre -formulation protocol, Stability testing during product development.	**12 Hrs**
UNIT-III	**Pilot plant scale up:** Concept, Significance, design, layout of pilotplant 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.	**12 Hrs**
UNIT-IV	**Pharmaceutical packaging:** Pharmaceutical dosage form and their packaging requirments, Pharmaceutical packaging materials, Medical device packaging, Enteral Packaging, Aseptic packaging systems, Container closure systems, Issues facing modern drug packaging, Selection and evaluation of Pharmaceutical packaging materials. Quality control test: Containers, closures and secondary packing materials.	**12 Hrs**
UNIT-V	**Technology transfer:** Development of technology by R & D, Technology transfer from R & D to production, Optimization and	**12 Hrs**

	Production, Qualitative and quantitative technology models. Documentation in technology transfer: Development report, technology transfer plan and Exhibit.	

REFERENCES

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) 3 rd E/d Bhalani publishing house Mumbai.
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5. Milo Gibaldi, Text book of Bio- Pharmaceutics and clinical Pharmacokinetics 3rd E/d Lea & Febriger, Philadelphia.
6. Vandana V. Patrevale. John I. Disouza. Maharukh T.Rustomji, Pharmaceutical product development. CRC Press, Group of Taylor and Francis.
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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

QUALITY ASSURANCE PRACTICAL - I
(MQA 105P)

1. Analysis of Phar macopoeial compounds in bulk and in their formulations (tablet / capsules / semisolids) by UV Vis spectrophotometer
2. Simultaneous estimation of multi -drug component containing formulations by UV spectrophotometry
3. Experiments based on HPLC
4. Experiments based on Gas Chromatography
5. Estimation of riboflavin/quinine sulphate by fluorimetry
6. Estimation of sodium/potassium by flame photometry or AAS
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, parenterals 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, parenterals (2 experiment).
14. To study the effect of pH on the solubility of drugs, (1 experiment)
15. Quality control tests for Primary and secondary packaging materials
16. Accelerated stability studies (1 experiment)
17. Improved solubility of drugs using surfactant systems (1 experiment)
18. Improved solubility of drugs using co-solvency method (1 experiment)
19. Determination of Pka and Log p of drugs.

HAZARDS AND SAFETY MANAGEMENT (MQA 201T)		THEORY 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 provides the principle-based approach to solve the complex tribulations. **Course Outcomes** Upon completion of this course the student should be able to, • explain environmental sciences, problems associated with environment and to ensure safety standards in pharmaceutical industry. • apply factory act and rules, regulatory guidelines for risk assessment and management. • analyze chemical based hazards and apply safety management in industry. • analyze fire and explosion hazards with understanding of protection system and safety management.		
UNIT-I	**Multidisciplinary nature of environmental studies:** Natural Resources and associated problems, Renewable and 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**
UNIT-II	**Air based hazards:** Sources, Types of H azards, Air circulation, Air handling system, HVAC system, air maintenance in industry for sterile area and non sterile area.	**12 Hrs**
UNIT-III	**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, Labelling guidelines, Management of over -Exposure to chemicals and TLV concept, Disposal of hazardous material.	**12 Hrs**
UNIT-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 wa lls, bunds, relief systems -relief valves, flares, scrubbers.	**12 Hrs**
UNIT-V	• **Hazard and risk management:** Self-protective measures against	**12 Hrs**

	workplace hazards. Critical training for risk management, Process of hazard management, ICH guidelines on risk assess ment 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 s ome contaminants, Effluent treatment procedure, Role of emergency services.	

REFERENCES

1. Y.K. Sing, Environmental Science, New Age International Pvt, Publishers, Bangalore
2. Quantitative Risk Assessment in Chemical Process Industries, American I nstitute 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.

PHARMACEUTICAL VALIDATION (MQA 202T)		THEORY 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.

Course Outcomes

Upon completion of this course the student should be able to

- Explain validation and demonstrate the qualification of instruments and Equipment's.
- Differentiate between various types of Intellectual properties, Rights, patents and their filing procedures.
- Describe process validation and computer system validation.
- Perform validation of Analytical method and cleaning method.

UNIT-I	**Introduction to validation:** Definition of Calibration, Qualification and Validation, Sco pe, frequency and importance. Difference between calibration and validation. Calibration of weights and measures. Advantages of Validation, scope of Validation, Organization for Validation, Validation Master plan, Types of Validation, Streamlining of qualification & Validation process and Validation Master Plan. **Qualification:** User requirement specification, Design qualification, Factory Acceptance Test (FAT)/Site Acceptance Test (SAT), Installation qualification, Operational qualification, Performance qualification, Re -Qualification (Maintaining status - Calibration Preventive Maintenance, Change management).	**10 Hrs**
UNIT-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, GC, HPLC, HPTLC.	**10 Hrs**
UNIT-III	**Qualification of laboratory equipments:** Hardness tester, Friability test apparatus, tap density tester, Disintegration tester, Dissolution test apparatus **Validation of Utility systems:** Pharmaceutical water system & pure steam, HVAC system, Compressed air and nitrogen.	**10 Hrs**
UNIT-IV	**Process Validation:** Concept, Process and documentation of ProcessValidation. Prospective, Concurrent & Retrospective Validation, Revalidation 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**

UNIT-V	**Cleaning Validation:** Cleaning Method development, Va lidation 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**
UNIT-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 Intelle ctual 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 application; 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**

REFERENCES

1. B. T. Loftus & R. A. Nash, "Pharmaceutical Process Validation", Drugs and Pharm Sci. Series, Vol. 129, 3rd Ed., Marcel Dekker Inc., N.Y.
2. Leon Lachman, Herbert A. Lieberman, Joseph. L. Karig, The Theory & Practice of Industrial Pharmacy, 3rd edition, Varghese Publishing House, Bombay.
3. Terveeks, Validation Master plan Davis Harwood International publishing.
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7. Phillip A. Cloud, Pharmaceutical Equipment Validation: The Ultimate Qualification Handbook, Interpharm Press.
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9. Churg Chan, Heiman Lam, Y.C. Lee, Yue. Zhang, Analytical Method validation and Instrument Performance Verification, Wiley Interscience.
10. Huber L. Validation and Qualification in Analytical Laboratories. Informa Healthcare
11. Wingate G. Validating Corporate Computer Systems: Good IT Practice for Pharmaceutical Manufacturers. Interpharm Press.
12. LeBlanc D. A. Validated Cleaning Technologies for Pharmaceutical Manufacturing, Interpharm Press.

AUDITS AND REGULATORY COMPLIANCE (MPA 203T)		THEORY 60 Hrs
Scope This course deals with the understanding and process for aud iting in pharmaceutical industries. This subject covers the methodology involved in the auditing process of different in pharmaceutical industries. **Course Outcomes** Upon completion of this course the student should be able to • Discuss briefly about audit objectives, their management and methodology of auditing. • Describe the role of quality systems and audits in pharmaceutical manufacturing environment. • Carry out the audit process and prepare the auditing report for various depatments. • Prepare the check list for auditing of Quality Assurance and engineering department.		
UNIT-I	**Introduction:** Objectives, Management of audit, Responsibilities, Planning process, information gathe ring, administration, Classifications of deficiencies	**12 Hrs**
UNIT-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**
UNIT-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**
UNIT-IV	**Auditing of Microbiological laboratory:** Auditing the manufacturing process, Product and process information, Gener al areas of interest in the building raw materials, Water, Packaging materials.	**12 Hrs**
UNIT-V	**Auditing of Quality Assurance and engineering department:** Quality Assurance Maintenance, Critical systems: HVAC, Water, Water for Injection systems, ETP.	**12 Hrs**

REFERENCES

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-loana Stefan, Jacobus F. Van Staden, Laboratory auditing for quality and regulatory compliance. Donald Taylor and Francis (2005).

PHARMACEUTICAL MANUFACTURING TECHNOLOGY (MQA 204T)		THEORY 60 Hrs
Scope This course is designed to impart knowledge and skills necessary to train the students with the industrial activities during Pharmaceutical Manufacturing. **Course Outcomes:** Upon completion of this course the student should be able to • Describe the common practice in the pharmaceutical industry developments, plant layout, production planning etc. • Explain various container closure systems used in pharmaceutical packaging as well as able to understand and implement concept of quality by design, PAT and its various applications. • Discuss the concept related to aseptic process technology and advanced sterile product manufacturing technology. • Describe the various activities performed in non-sterile product manufacturing technology.		
UNIT-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. Production planning: General principles, production systems, calculation of standard cost, process planning, routing, loading, scheduling, dispatching of records, production control.	**12 Hrs**
UNIT-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 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 Injec tions, and Form Fill Seal Technology (FFS). Lyophilization technology: Principles, process, equipment.	**12 Hrs**
UNIT-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 pelletization equipments, continuous and batch mixing, rapid mixing granulators,	**12 Hrs**

	rota granulators, spheronizers and marumerisers, and other specialized granulation and drying equipments. Problems encountered. Coating technology: Process, equipments, particle coating, fluidized bed coating, application techniques. Problems encountered.	
UNIT-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**
UNIT-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 Experi ments, 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**

REFERENCES

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, 5 th 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) 3 rd 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 Manu facturing Handbook. John Willey and Sons, New Jersey, 2008.

QUALITY ASSURANCE PRACTICAL – II PRACTICALS (MQA 205P)

1. Organic contaminants residue analysis by HPLC
2. Identification of antibiotic residue by TLC
3. Estimation of Chlorine in Work Environment.
4. Sampling and analysis of SO2 using Colorimetric method
5. Qualification of following Pharma equipment

a) Autoclave b) Hot air oven
c) Powder Mixer (Dry) d) Tablet Compression Machine

6. Validation of an analytical method for a drug
7. Process validation of any non-sterile or sterile dosage form
8. Validation of a processing area
9. Qualification of at least two analytical instruments
10. Cleaning validation of one equipment
11. Qualification of Pharmaceutical Testing Equipment (Dissolution testing apparatus, Friability Apparatus, Disintegration Tester)
12. Check list for Bulk Pharmaceutical Chemicals vendors
13. Check list for tableting production.
14. Check list for sterile production area
15. Check list for Water for injection.
16. Design of plant layout: Sterile and non-sterile
17. Case study on application of QbD
18. Case study on application of PAT

PHARMACOLOGY (MPL)

ADVANCED PHARMACOLOGY – I (MPL 102T)		THEORY 60 Hrs
Scope The subject is designed to strengthen the basic knowledge in the field of pharmacology and to impart recent advances in the drugs used for the treatment of various diseases. In addition, this subject helps the students to understand the concepts of drug action and mechanisms involved **Course Outcomes** Upon completion of the course the student shall be able to: • Explain advanced pharmacokinetic and pharmacodynamic principles, drug–receptor interactions, and molecular mechanisms underlying drug action. • Analyze the pathophysiology of cardiovascular disorders and critically evaluate the mechanisms of action, therapeutic applications, and adverse effects of drugs used in their management. • Evaluate the pathophysiology and advanced pharmacotherapy of central nervous system disorders, including neurological and psychiatric conditions, with emphasis on molecular mechanisms, therapeutic applications, and drug safety. • Analyze the physiological and pathological roles of autacoids and evaluate the pharmacological mechanisms, therapeutic applications, and adverse effects of drugs the autonomic nervous system, neuromuscular junction and hematological systems.		
Unit-I	**General Pharmacology pharmacokinetics:** The dynamics of drug absorption, distribution, biotransformation and elimination. Concepts of linear and non –linear compartment models. Significance of Protein binding. **Pharmacodynamics:** Mechanism of drug action and the relationship between drug concentration and effect. Receptors, structural and functional families of receptors, quantitation of drug receptors interaction and elicited effects.	**12 Hrs**
Unit -II	**Neurotransmission:** General aspects and steps involved in neurotransmission. Neurohumoral transmission in autonomic nervous system (Detailed study about neurotransmitters– Adrenaline and Acetyl choline). Neurohumoral transmission in central nervous system (Detailed study about neurotransmitter histamine, serotonin, dopamine, GABA, glutamate and glycine). Non adrenergic non cholinergic transmission (NANC). Co–transmission Systemic Pharmacology A detailed study on pathophysiology of diseases, mechanism of action, pharmacology and toxicology of existing as well as novel drugs used in the following systems. Autonomic Pharmacology Parasympathomimetics and lytics, sympathomimetics and lytics, agents affecting neuromuscular junction.	**12 Hrs**
Unit-III	**Central nervous system Pharmacology** General anesthetics Sedatives and hypnotics, anti-anxiety drugs. Depression, psychosis, mania, epilepsy, neurodegenerative diseases Parkinsonism and Alzheimer‟s).	**12 Hrs**

	Narcotic and non–narcotic analgesics.	
Unit-IV	**Cardiovascular Pharmacology** Diuretics, anti-hypertensives, anti-ischemics, anti -arrhythmics, drugs for heart failure and hyperlipidemia. Hematinics, coagulants and anticoagulants, fibrinolytics and anti – platelet drugs.	**12 Hrs**
Unit-V	**Autocoid Pharmacology** The physiological and pathological role of Histamine, Serotonin, Kinins Prostaglandins Opioid autocoids. Pharmacology of antihistamines, 5HT antagonists.	**12 Hrs**

REFEERENCES

1. The Pharmacological Basis of Therapeutics, Goodman and Gillman,,s.
2. Principles of Pharmacology. The Pathophysiologic basis of drug Therapy by David E Golan, Armen H, Tashjian Jr, Ehrin J, Armstrong, April W, Armstrong, Wolters, Kluwer–Lippincott Williams & Wilkins Publishers.
3. Basic and Clinical Pharmacology by B.G Katzung.
4. Hand book of Clinical Pharmacokinetics by Gibaldi and Prescott.
5. Applied biophar maceutics and Pharmacokinetics by Leon Shargel and Andrew B.C.Yu.
6. Graham Smith. Oxford textbook of Clinical Pharmacology.
7. Avery Drug Treatment.
8. Dipiro Pharmacology, Pathophysiological approach.
9. Green Pathophysiology for Pharmacists.

PHARMACOLOGICAL AND TOXICOLOGICAL SCREENING METHODS - I (MPL 103T)		THEORY 60 Hrs
Scope This subject is designed to impart the knowledge on preclinical evaluation of drugs and recent experimental techniques in the drug discovery and development. The subject content helps the student to understand the maintenance of laboratory animals as per the guidelines, basic knowledge of various in-vitro and in-vivo preclinical evaluation processes **Course Outcomes** Upon completion of the course the student shall be able to, • Evaluate the ethical and regulatory frameworks (CPCSEA, GLP) governing the maintenance, handling, and application of common and transgenic laboratory animals. • Execute and demonstrate standardized in-vivo and in-vitro screening protocols for drugs acting on the Central Nervous System (CNS) and Autonomic Nervous System (ANS). • Analyze and compare the pharmacological screening methods for diverse therapeutic areas, including Respiratory, Gastrointestinal, Cardiovascular, and Metabolic disorders. • Synthesize preclinical data through immunoassay principles and alternative experimental models to predict and extrapolate safety and efficacy results to human clinical contexts.		
Unit-I	**Laboratory Animals** Common Laboratory animals: Description, handling and applications of different species and strains of animals. Transgenic animals: Production, maintenance and applications. CPCSEA Guidelines for experimental animals. Anesthesia and euthanasia of experimental animals Maintenance and breeding of laboratory animals. Good laboratory Practice.	**12 Hrs**
Unit -II	**Preclinical screening of new substances for the pharmacological activity using in vivo, in vitro and other possible alternative m ethods in animals.** CNS Pharmacology: General principles of preclinical screening, screening of behavioral and muscle coordination, CNS stimulants and depressants, anxiolytics, anti -psychotics, anti-epileptics, nootropics, Parkinsonism and Alzheimer"s. Drugs acting on Autonomic nervous system.	**12 Hrs**
Unit-III	**Preclinical screening of new substances for the pharmacological activity using in vivo, in vitro and other possible alternative methods in animals.** Respiratory Pharmacology: Anti-asthmatics, drugs for COPD and anti-allergic. Reproductive Pharmacology: Aphrodisiacs and ant-fertility agents Gastrointestinal drugs: Anti-ulcer, anti-emetic, anti-diarrheal and laxatives Analgesic, anti-inflammatory and anti-pyretic drugs.	**12 Hrs**

Unit-IV	**Preclinical screening of new substances for the pharmacological activity using in vivo, in vitro and other possible alternative methods in animals.** Cardiovascular Pharmacology: Anti-hypertensive, anti -arrhythmic, anti -anginals, anti -atherosclerotic, and diuretics. Drugs for metabolic disorders: Anti-diabetic, anti-hyperlipidemic and anti-cancer drugs. Methods for screening of Hepatoprotective drugs.	**12 Hrs**
Unit-V	**Preclinical screening of new substances for the pharmacological activity using in vivo, in vitro and other possible alternative methods in animals.** Immunosuppressant‟s and immunomodulators General principles of immunoassay: Theoretical basis and optimization of immunoassay, heterogeneous and homogenous immunoassay system. Immunoassay methods evaluation; protocol outline, objectives and preparation. Immunoassay for digoxin and insulin. Limitation of animal experimentation and alternate animal experiments. Extrapolation of in vitro data to preclinical and preclinical to humans.	**12 Hrs**

REFERENCES

1. Biological standardization by J.H. Burn D.J. Finney and I.G. Goodwin.
2. Screening methods in Pharmacology by Robert Turner. A.
3. Evaluation of drugs activities by Laurence and Bachrach.
4. Methods in Pharmacology by Arnold Schwartz.
5. Fundamentals of experimental Pharmacology by M. N. Ghosh.
6. Pharmacological experiment on intact preparations by Churchill Livingstone.
7. Drug discovery and Evaluation by Vogel H.G.
8. Experimental Pharmacology by R. K. Goyal.
9. Preclinical evaluation of new drugs by S. K. Gupta.
10. Handbook of Experimental Pharmacology, S. K. Kulkarni.
11. Practical Pharmacology and Clinical Pharmacy, S. K. Kulkarni, 3rd Edition.
12. David R. Gross. Animal Models in Cardiovascular Research, 2nd Edition, Kluwer Academic Publishers, London, UK.
13. Rodents for Pharmacological Experiments, Dr. Tapan Kumar Chatterjee.
14. Practical Manual of Experimental and Clinical Pharmacology by Bikash Medhi , Ajay Prakash.

CELLULAR AND MOLECULAR PHARMACOLOGY (MPL 104T)		THEORY 60 Hrs
Scope This subject imparts a fundamental knowledge on the structure and functions of cellular components and helps to understand the interaction of these components with drug. This information will further help the student to apply the knowledge in drug discovery. **Course Outcomes** Upon completion of the course the student shall be able to: • Explain the concept on genome organization, regulation mapping and more on Cell cycles regulation, apoptosis program, Necrosis and autophagy. • Describe the various receptors and their secondary messengers and focusing on various signaling pathways. • Discuss recombinant DNA technology, techniques involved in gene therapy, applications and advances in it. • elaborate Genetic variation and its effects in drug metabolism, Gene mapping and cloning of disease gene.		
Unit-I	**Cell biology** Structure and function of cell and is organelles. Genome organization. Gene expression and its regulation, importance of siRNA and micro-RNA, gene mapping and gene sequencing. Cell cycle and its regulation. Cell death events, regulators intrinsic and extrinsic pathways of apoptosis. Necrosis and autophagy.	**12 Hrs**
Unit -II	**Cell signaling:** Intercellular and intracellular signaling pathways. Classification of receptor family and molecular structure of: Ligand gated ion channels, G -protein coupled rece ptors, tyrosine kinase receptor and nuclear receptor. **Secondary messengers:** cyclic AMP, cyclic GMP, calcium ion, inositol 1,4,5 -triphosphte (IP3), NO and diacylglycerol (DAG). **Detailed study of following intracellular signaling pathways:** cyclic AMP signaling pathway, mitogen -activated protein kinase (MAPK) signaling, Janus kinase (JAK) / signal transducer and activator of transcription (STAT) signaling pathway.	**12 Hrs**
Unit-III	**Principle and application of genomic and proteomic tools:** DNA electrophore sis, PCR (reverse transcriptase and real time), Gene sequencing, microarray technique, SDS page, ELISA and western blotting. **Basic principles of recombinant DNA technology:** Restriction enzymes, various types of vectors. Applications of various recombinant DNA technology. **Gene therapy:** various types of gene transfer techniques, clinical applications and recent advances in gene therapy.	**12 Hrs**
Unit IV	**Pharmacogenomics:** Gene mapping and cloning of disease gene.	**12 Hrs**

	Gene variation and its role in health / pharmacology. Polymorphism affecting drug metabolism. Genetic variation in drug transporters. Genetic variation in G-protein coupled receptors. **Application of proteomic science:** Genomics, proteomics, metbolomics, functionomics, nutrigenomics. **Immunotherapeutics:** Types of immunotherapeutics, humanisation, antibody therapy, Immunotherapeutics in clinical practice.	
Unit V	**Cell culture techniques:** Basic equipments used in cell culture lab. Cell culture media, various types of cell culture, gen eral procedure for cell culture, isolation of cells subculture, cryopreservation, characterization of cells and their application. Principles and applications of cell viability assays, glucose uptake assay, Calcium influx assays. Principles and application of flow cytometry. Introduction and applications of Biosimilars	**12 Hrs**

REFERENCES

1. The Cell, A Molecular Approach. Geoffrey M Cooper.
2. Pharmacogenomics: The Search for Individualized Therapies. Edited by J. Licinio and M L. Wong.
3. Handbook of Cell Signaling (Second Edition) Edited by Ralph A. et.al.
4. Molecular Pharmacology: From DNA to Drug Discovery. John Dickenson et.al.
5. Basic Cell Culture protocols by Cheril D. Helgason and Cindy L. Miller.
6. Basic Cell Culture (Practical Approach) by J. M. Davis.
7. Animal Cell Culture: A Practical Approach by John R. Masters.
8. Current protocols in molecular biology Vol I to VI edited by Frederick M. Ausuvel et la.

PHARMACOLOGICAL PRACTICAL -I
(MPL 105P)

1. Analysis of pharmacopoeial compounds & their formulations by UV -Vis spectrophotometer.
2. Simultaneous estimation of multi component containing formulations by UV Spectrophotometry.
3. Experiments based on HPLC.
4. Experiments based on Gas Chromatography.
5. Estimation of riboflavin/quinine sulphate by Fluorimetry.
6. Estimation of sodium/potassium by flame photometry.

LABORATORY ANIMAL EXPERIMENTS

1. Various routes of drug administration.
2. Techniques of blood sampling, anesthesia and euthanasia of experimental animals.
3. Functional observation battery tests (modified Irwin test)
4. Evaluation of CNS stimulant, depressant, anxiogenics and anxiolytic, anticonvulsant activity.
5. Evaluation of analgesic, anti –inflammatory, local anesthetic, mydriatic and miotic activity.
6. Evaluation of diuretic activity.
7. Evaluation of antiulcer activity by pylorus ligation method.
8. Oral glucose tolerance test.
9. Isolation and identification of DNA from various sources (Bacteria, Cauliflower, onion, Goat liver).
10. Isolation of RNA from yeast
11. Estimation of proteins by Braford/Lowry's in biological samples.
12. Estimation of RNA/DNA by UV Spectroscopy
13. Gene amplification by PCR.
14. Protein quantification Western Blotting.
15. Enzyme based in-vitro assays (MPO, AChEs, a -amylase, a- glucosidase).
16. Cell viability assays (MTT/Trypan blue/SRB).
17. DNA fragmentation assay by agarose gel electrophoresis.
18. DNA damage study by Comet assay.
19. Apoptosis determination by fluorescent imaging studies.
20. Pharmacokinetic studies and data analysis of drugs given by different routes of administration using softwares.
21. Enzyme inhibition and induction activity
22. Extraction of drug from various biological samples and estimation of drugs in biological fluids using different analytical techniques (UV)
23. Extraction of drug from various biological samples and estimation of drugs in biological fluids using different analytical techniques (HPLC)

REFERENCES

1. CPCSEA, OECD, ICH, USFDA, Schedule Y, EPA guidelines.
2. Fundamentals of experimental Pharmacology by M. N. Ghosh.
3. Handbook of Experimental Pharmacology by S.K. Kulkarni.
4. Drug discovery and Evaluation by Vogel H.G.

5. Spectrometric Identification of Organic compounds – Robert M Silverstein,
6. Principles of Instrumental Analysis – Doglas A Skoog, F. James Holler, Timothy A. Nieman.
7. Vogel's Text book of quantitative chemical analysis –Jeffery, Basset, Mendham, Denney.
8. Basic Cell Culture protocols by Cheril D. Helgason and Cindy L. Mille.
9. Basic Cell Culture (Practical Approach) by J. M. Davis.
10. Animal Cell Culture: A Practical Approach by John R. Masters.
11. Practical Manual of Experimental and Clinical Pharmacology by Bikash Medhi, Ajay Prakash Jaypee brothers' medical publishers Pvt. Ltd

ADVANCED PHARMACOLOGY-II (MPL201T)		THEORY 60 Hrs

Scope

The subject is designed to strengthen the basic knowledge in the field of pharmacology and to impart recent advances in the drugs used for the treatment of various diseases. In addition, the subject helps the student to understand the concepts of drug action and mechanism involved.

Course Outcomes

- Upon completion the course the student shall be able to:
  Explain the molecular and cellular mechanisms of hormone action and evaluate the pharmacological actions, therapeutic applications, and adverse effects of drugs used in endocrine disorders.
- Analyze the mechanisms of action and drug resistance of antimicrobial, antifungal, antiviral, antitubercular, antiprotozoal, anthelmintic, and anticancer agents, and evaluate their therapeutic applications.
- Evaluate the mechanisms of inflammation, immune responses, allergy, and hypersensitivity, and analyze the pharmacotherapy of asthma, COPD, gastrointestinal disorders, and immune-related conditions, including the applications of chronopharmacology and chronotherapy.
- Explain the generation and pathological roles of free radicals in various diseases and critically evaluate the protective mechanisms and therapeutic potential of antioxidants.

Unit-I	**Endocrine Pharmacology** Molecular and cellular mechanism of action of hormones such as growth hormone, prolactin, thyroid, insulin and sex hormone. Anti-thyroid drugs, oral hypoglycemic agents, oral contraceptives, corticosteroids and drugs affecting on calcium regulation.	**12 Hrs**
Unit -II	**Chemotherapy** Cellular and molecular mechanism of actions and resistance of antimicrobial agents such as β -lactams, aminoglycosides, quinolones, Macrolides antibiotics. Antifungal, antiviral and anti-TB drugs.	**12 Hrs**
Unit-III	**Chemotherapy** Drugs used in Protozoal infections, Helminthiasis and cancer. Cellular and biochemical mediators of inflammation and immune response, allergy or hypersensitivity reactions, Pharmacotherapy of asthma and COPD. Immunosuppressants and immunomodulators.	**12 Hrs**
Unit-IV	**GIT Pharmacology** Anti-ulcer drugs, Prokinetics, anti -emetics, anti -diarrheals and drugs for constipation and irritable bowel syndrome. Chronopharmacology Biological and circadian rhythms, applications of chronotherap y in various diseases like cardiovascular disease, diabetes, asthma and peptic	**12 Hrs**

	ulcer.	
Unit-V	**Free Radical Pharmacology** Generation of free radicals, role of free radicals in etiopathology of various diseases such as diabetes, neurodegenerative diseases and cancer. Protective activity of certain important antioxidants such as Vitamin E, Vitamin C, Curcumin, CoQ10, Lipoic acid etc. Recent advances in the treatment of Alzheimer‟s disease, Parkinson‟s disease, cancer and diabetes mellitus.	**12 Hrs**

REFERENCES

1. The Pharmacological basis of therapeutics-Goodman and Gill man,,s
2. Principles of Pharmacology. The Pathophysiologic basis of drug therapy by David E Golan et al.
3. Basic and Clinical Pharmacology by B.G-Katzung.
4. Pharmacology by H.P. Rang and M.M. Dale.
5. Hand book of Clinical Pharmacokinetics by Gibaldi and Prescott.
6. Text book of Therapeutics, drug and disease management by E T. Herfindal and Gourley.
7. Applied biopharmaceutics and Pharmacokinetics by Leon Shargel and Andrew B.C.Yu.
8. Handbook of Essential Pharmacokinetics, Pharmacodynamics and Drug Metabolism for Industrial Scientists.
9. Robbins and Cortan Pathologic Basis of Disease, 9th Ed. (Robbins Pathology)
10. A Complete Textbook of Medical Pharmacology by Dr. S.K Srivastava published by APC Avichal Publishing Company.
11. K. D. Tripathi. Essentials of Medical Pharmacology
12. Principles of Pharmacology. The Pathophysiologic basis of drug Therapy by David E Golan, Armen H, Tashjian Jr, Ehrin J, Armstrong, April W, Armstrong, Wolters, Kluwer–Lippincott Williams & Wilkins Publishers.

PHARMACOLOGICAL AND TOXICOLOGICAL SCREENING METHODS-II (MPL202T)		THEORY 60 Hrs
Scope This subject imparts knowledge on the preclinical safety and toxicological evaluation of drug and new chemical entity. This knowl edge will make the student competent in regulatory toxicological evaluation. **Course Outcomes** Upon completion of the course the student shall be able to: • Explain the foundational branches of toxicology, principles of Good Laboratory Practice (GLP), and analyze international regulatory guidelines (OECD, ICH, EPA, and Schedule Y) essential for drug development. • Apply specific OECD protocols to design, execute, and evaluate acute, sub-acute, and chronic systemic toxicity profiles, including specialized dermal, ocular, and sensitization assessments. • Assess complex toxicological profiles by evaluating reproductive toxicity, teratogenicity, in vivo carcinogenicity, and standard genotoxicity assays like the Ames and micronucleus tests. • Evaluate safety pharmacology tiers (CVS, CNS, respiratory) and toxicokinetic parameters required for IND submissions, while justifying the integration of valid alternative methods to animal testing.		
Unit-I	**Basic definition and types of toxicology** (general, mechanistic, regulatory and descriptive) Regulatory guidelines for conducting toxicity studies OECD, ICH, EPA and Schedule Y OECD principles of Good laboratory practice. History, concept and its importance in drug development	**12 Hrs**
Unit -II	Acute, Sub-acute and chronic -oral, dermal and inhalation al studies as per OECD guidelines. Acute eye irritation, skin sensitization, dermal irritation & dermal toxicity studies. Test item characterization - importance and methods in regulatory toxicity studies.	**12 Hrs**
Unit-III	**Reproductive toxicity studies**, Male reproductive toxicity studies, Female reproductive studies (segment I and III), teratogenicity studies (segment II) Genotoxicity studies (Ames Test, in vitro and in vivo Micronucleus and Chromosomal aberrations studies) In vivo carcinogenicity studies	**12 Hrs**
Unit-IV	**IND enabling studies** (IND studies): Definition of IND, importance of IND, industry perspective, list of studies needed for IND submission. Safety pharmacology studies: origin, concepts and importance of safety pharmacology Tier 1- CVS, CNS and respiratory safety pharmacology, HERG assay. Tier 2- GI, renal and other studies.	**12 Hrs**

Unit-V	**Toxicokinetics** – Toxicokinetic evaluation in preclinical studies, saturation kinetics. Importance and applications of toxicokinetic studies. Alternative methods to animal toxicity testing.	**12 Hrs**

References

1. Hand book on GLP, Quality practices for regulated non –clinical research and development (http://www.who.int/tdr/publications/documents/glp– handbook.pdf).
2. Schedule Y Guideline: drugs and cosmetics (second amendment) rules,2005, ministry of health and family welfare (department of health) New Delhi.
3. Drugs from discovery to approval by Rick NG.
4. Animal Models in Toxicology, 3rd Edition, Lower and Bryan.
5. OECD test guidelines.
6. Principles of toxicology by Karen E. Stine, Thomas M. Brown.
7. Guidance for Industry M3(R2) Nonclinical Safety Studies for the Conduct of Human Clinical Trials and Marketing Authorization for Pharmaceuticals (http://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm073246.pdf)

PRINCIPLES OF DRUG DISCOVERY (MPL203T)		THEORY 60 Hrs
Scope: The subject imparts basic knowledge of drug discovery process. This information will make the student competent in drug discovery process. **Course Outcomes:** Upon completion of the course, the student shall be able to, • Explain modern drug discovery stages and target validation approaches. • Describe lead identification techniques and protein structure analysis. • Differentiate rational drug design approaches and explain molecular docking techniques. • Analyse SAR/QSAR methods and explain QSAR statistical approaches and prodrug design.		
Unit-I	**An overview of modern drug discovery process:** Target identification, target validation, lead identification and lead His Optimization Economics of drug discovery. Target Discovery and validation - Role of Genomics, Proteomics and Bioinformatics. Role of Nucleic acid microarrays, Protein microarrays, Antisense technologies, siRNAs oligonucleotides, Zinc finger proteins Role of transgenic animals in target validation.	**12 Hrs**
Unit -II	**Lead Identification** Combinatorial chemistry & high throughput screening in silico lead discovery techniques, Assay development for hit identification. Protein structure Levels of protein structure, Domains, motifs, and folds in protein structure. Computational prediction of protein structure Threading and homology modeling methods, Application of NMR and X -ray crystallography in protein structure prediction	**12 Hrs**
Unit-III	**Rational Drug Design** Structure and pharmacophore-based approaches, virtual screening technique, rational approaches for reperfusing of existing molecules for new therapeutic target. Introduction to molecular docking and QSAR statistical method and product concept.	**12 Hrs**
Unit-IV	**Classical Targets, Translational Medicine and Biomarkers in Drug Discovery** Enzymes and Enzymes Inhibition, G -Protein-Coupled Receptors (GPCRs), Ion Channels, Membrane Transport Proteins (Transporters), Emerging Targets. Definition of a Biomarker and Their Classification, Characteristics and Impact of Biomarkers, Biomarkers versus Surrogate End Points, Imaging Technologies, The Practical Application of Biomarkers. Biomarkers for cancer (breast, lung, skin), diabetes, CVs etc.	**12 Hrs**
Unit-V	**In vitro screening systems** The Language of Screening: Basic Terms, Biochemical versus Cellular Assays, Assay Systems and Methods of Detection, Radioligand Assay	**12 Hrs**

	Systems (RIA), Enzyme-Linked Immunosorbent Assay (ELISA), Fluorescence-Based Assay Systems, Reporter Gene Assays, Kinetic Fluorescent Measurement Systems, Label-Free Assay Systems, Electrophysiological Patch Clamp, General Consideration for All Screening Methods.	

REFERENCES

1. Mouldy Sioud. Target Discovery and Validation Reviews and Protocols: Volume 2 Emerging Molecular Targets and Treatment Options. 2007 Humana Press Inc.
2. Darryl León. Scott Markel In. Silico Technologies in Drug Target Identification and Validation. 2006 by Taylor and Francis Group, LLC.
3. Johanna K. DiStefano. Disease Gene Identification. Methods and Protocols. Springer New York Dordrecht Heidelberg London.
4. Hugo Kubiny. QSAR: Hansch Analysis and Related Approaches. Methods and Principles in Medicinal Chemistry. Publisher Wiley–VCH
5. Klaus Gubernator, Hans Joachin Bohm. Structure –Based Ligand Design. Methods and Principles in Medicinal Chemistry. Publisher Wiley–VCH
6. Abby L . Parrill. M . Rami Reddy. Rational Drug Design. Novel Methodology and Practical Applications. ACS Symposium Series; American Chemical Society: Washington, DC, 1999.
7. J. Rick Turner. New drug development d esign, methodology and, analysis. John Wiley & Sons, Inc., New Jersey.
8. Benjamin Blass. Basic Principles of Drug Discovery and Development.1 st Edition, Academic Press.

CLINICAL RESEARCH AND PHARMACOVIGILANCE (MPL204T)		THEORY 60 Hrs
Scope: This subject will provide a value addition and current requirement for the students in clinical research and pharmacovigilance. It will reach the students on conceptualizing, designing, conducting, managing and reporting of clinical trials. This subject also focuses on global scenario of Pharmacovigilance in different methods that can be used to generate safety data. It will teach the students in developing drug safety data in Pre-clinical, Clinical phases of Drug development and post market surveillance. **Course Outcomes:** Upon completion of the course, the student shall be able to: • Exlain Clinical trials Regulatory perspectives like Good Clinical Practice (ICH-GCP) guidelines, - Schedule Y and ICMR. • Describe Cohort, case control, cross sectional clinical trial study - Team roles and responsibilities of clinical trial personnel and to gain knowledge on Pharmacoepidimology and pharmacoeconomics. • Prepare Clinical trial documents like protocol, Investigator Brochure, Case Report Forms, Clinical Study Report etc. and to study Clinical trial monitoring Safety, adverse drug reactions, Severity and seriousness assessment. • Discuss Basic terminologies of pharmacovigilance, WHO international drug monitoring programme, WHO and Regulatory terminologies of ADR, Statistical methods for evaluating medication safety data.		
Unit-I	**Regulatory Perspective of Clinical Trials:** Origin and Principles of International Conference on Harmonizati on-Good Clinical Practice (ICH-GCP) guidelines. Ethical Committee: Institutional Review Board, Ethical guidelines for Biomedical Research and Human Participant Schedule Y, ICMR. Inform Consent Process: Structure and content of an Inform Consent Process Ethical principles governing informed consent process.	12 Hrs
Unit -II	**Clinical Trials:** Types and Design Experimental Study- RCT and Non RCT Observation Study: Cohort, Case control, Cross sectional Clinical trial Study Team Roles and responsibilities of Clinical Trial Personnel: Investigator, Study Coordinator, Sponsor, Contract Research Organization and its management	12 Hrs
Unit-III	**Clinical Trial Documentation** – Guidelines to the preparation of documents, Preparation of protocol, Investigator Brochure, Case Report Forms, Clinical Study Report Clinical Trial Monitoring Safety monitoring in CT Adverse Drug Reactions: definition and types. Detection and reporting methods. Severity and seriousness assessment. Predictability and preventability assessment, Management of adverse drug reactions; terminologies of ADR	12 Hrs

Unit-IV	**Basic aspects, terminologies and establishment of Pharmacovigilance** History and progress of Pharmacovigilance, Significant of safety monitoring, pharmacovigil ance in India and international aspects, WHO international drug monitoring programme, WHO and Regulatory terminologies of ADR, evaluation of medication safety, Establishing pharmacovigilance centers in Hospitals, Industry and National programmes related t o pharmacovigilance. Roles and responsibilities in Pharmacovigilance	12 Hrs
Unit-V	**Methods, ADR reporting and tools used in Pharmacovigilance** International classification of diseases, International Non - proprietary names for drugs, Passive and Active s urveillance, Comparative observational studies, Targeted clinical investigations and Vaccine safety surveillance. Spontaneous reporting system and Reporting to regulatory authorities, Guidelines for ADRs reporting. Arugs, Aris G Pharmacovigilance, Vigiflow, Statistical methods for evaluating medication safety data. Introduction to pharmaco-epidemiology and pharmacoeconomics.	12 Hrs

References

1. Central Drugs Standard Control Organization – Good Clinical Practices, Guidelines for Clinical Trials on Pharmaceutical Products in India. New Delhi: Ministry of Health; 2001.
2. International Conference on Harmonization of Technical requirements for registration of Pharmaceuticals for human use. ICH Harmonized Tripartite Guideline. Guideline for Good Clinical Practice.E6; May 1996.
3. Ethical guidelines for Biomediical Research on Human Subjects 2000. Indian Council of Medical Research, New Delhi.
4. Textbook of Clinical trials by David Machin, Simon Day and Sylvan Green. 2005. John Wiley and Sons.
5. Clinical Data management edited by R. K. Rondels, S A Varley, C F Webbs. Second edition, 2000. Wiley Publications.
6. Handbook of Clinical research. Julia Lloyd and Ann Raven Ed. Churchill Livingstone.
7. Principles of Clinical Research edited by Giovanna di lgnazio, di Giovanna and Haynes.

PHARMACOLOGICAL PRACTICAL – II (MPL 205P)
1. To record the DRC of agonist using suitable isolated tissues preparation. 2. To study the effects of antagonist/potentiating agents on DRC of agonist using suitable isolated tissue preparation. 3. To determine to the strength of unknown sample by matching bioassay by using suitable tissue preparation. 4. To determine to the strength of unknown sample by interpolation bioassay by using suitable tissue preparation 5. To determine to the strength of unknown sample by bracketing bioassay by using suitable tissue preparation 6. To determine to the strength of unknown sample by multiple point bioassay by using suitable tissue preparation. 7. Estimation of PA2 values of various antagonists using suitable isolated tissue preparations. 8. To study the effects of various drugs on isolated heart preparations 9. Recording of rat BP, heart rate and ECG. 10. Recording of rat ECG 11. Drug absorption studies by averted rat ileum preparation. 12. Acute oral toxicity studies as per OECD guidelines. 13. Acute dermal toxicity studies as per OECD guidelines. 14. Repeated dose toxicity studies– Serum biochemical, haematological, urine analysis, functional observation tests and histological studies. 15. Drug mutagenicity study using mice bone–marrow chromosomal aberration test. 16. Protocol design for clinical trial (3 Nos.) 17. Design of ADR monitoring protocol. 18. In-silico docking studies. (2 Nos.) 19. In-silico pharmacophore based screening. 20. In-silico QSAR studies. 21. ADR reporting

REFERENCES

1. Fundamentals of experimental Pharmacology–by M.N. Ghosh
2. Hand book of Experimental Pharmacology–S.K. Kulkarni
3. Text book of in-vitro practical Pharmacology by Ian Kitchen
4. Bioassay Techniques for Drug Development by Atta–ur–Rahman, Iqbal choudhary and William Thomsen
5. Applied biopharmaceutics and Pharmacokinetics by Leon Shargel and Andrew B.C.Yu.
6. Handbook of Essential Pharmacokinetics, Pharmacodynamics and Drug Metabolism for Industrial Scientists.

SEMESTER III

Research Methodology & Biostatistics MRM 301T		THEORY 60 Hrs
Course Outcomes: Upon completion of the course, the student shall be able to: • Develop the ability to apply the methods while working on a research project work. • Apply the appropriate statistical methods required for a particular research design. • Choose the appropriate research design and develop appropriate research hypothesis for a research project including clinical testing methodologies. • Develop appropriate framework for research studies including preclinical testing methodologies.		
UNIT – I	**General Research Methodology:** Research, objective, requirements, practical difficulties, review of literature, study design, types of studies, strategies to eliminate errors/bias, controls, randomization, crossover design, placebo, blinding techniques.	**12 Hrs**
UNIT – II	**Biostatistics:** Definition, application, sample size, importance of sample size, factors influencing sample size, dropouts, statistical tests of significance, type of significance tests, parametric tests (students "t" test, ANOVA, Correlation coefficient, regression), non–parametric tests (wilcoxan rank tests, analysis of variance, correlation, chi square test), null hypothesis, P values, degree of freedom, interpretation of P values.	**12 Hrs**
UNIT – III	**Medical Research:** History, values in medical ethics, autonomy, beneficence, non –maleficence, double effect, conflicts between autonomy and beneficence/non –maleficence, euthanasia, informed consent, confidentiality, criticisms of orthodox medical ethics, importance of communication, control resolution, guidelines, ethics committees, cultural concerns, truth telling, online business practices, conflicts of interest, referral, vendor relationships, treatment of family members, sexual relationships, fatality.	**12 Hrs**
UNIT – IV	**CPCSEA guidelines for laboratory animal facility:** Goal s, veterinary care, quarantine, surveillance, diagnosis, treatment and control of disease, personal hygiene, location of animal facilities to laboratories, anesthesia, euthanasia, physical facilities, environment, animal husbandry, record keeping, SOPs, pe rsonnel and training, transport of lab animals.	**12 Hrs**
UNIT – V	Declaration of Helsinki: History, introduction, basic principles for all medical research, and additional principles for medical research combined with medical care.	**12 Hrs**

REFERENCES

1. WMA Declaration of Helsinki – Ethical Principles for Medical Research Involving Human Participants – WMA – The World Medical Association
2. ACTS, RULES AND GUIDELINES: Committee for the Purpose of Control And Supervision of Experiments on Animals

INTRODUCTION TO CONSTITUTION MIC 302T		THEORY 30 Hrs

Scope:

This course introduces students to the Constitution of India. The Constitution, being supreme law of the land, must be known to every citizen of India. It begins with the Preamble, which indicates the source and objects of it. We, the people of India, are the source of the Constitution and have resolved to constitute India into a sovereign, socialist, secular, democratic and republic. The Course has been designed for everyone to make acquaint themselves with their fundamental rights and of others. No right is absolute one; it is subject to others right, as well. Directive Principles of State Policy are nothing but rights, though not enforceable by any court. These Directive Principles are basically 'Fundamental Principles' in the governance of the country. Powers and freedoms come with responsibility, State's responsibility to implement Directive Principles and citizens must perform their duties towards others, society and nation.

Course Outcomes:

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

- Explain the philosophy of constitution of India.
- Describe their fundamental rights.
- Discuss the system of Government and the directive principles governing its organization.
- Fulfil fundamental duties of Indian citizen towards nation and society.

UNIT 1	**PHILOSOPHY OF THE INDIAN CONSTITUTION** a) Constitutional History of India b) Role of Dr. B.R. Ambedkar in Constituent Assembly c) Preamble – Source and Objects d) Sovereign and Republic e) Socialist and Secular f) Democratic – Social and Economic Democracy g) Justice – Social, Economic and Political h) Liberty – Thought, Expression, Belief, Faith and Worship i) Equality – Status and Opportunity j) Fraternity, Human Dignity, Unity and Integrity of the Nation	**5 Hours**
UNIT 2	**FUNDAMENTAL RIGHTS** a) Right to equality b) Right to freedoms c) Right against exploitation d) Right to freedom of religion e) Cultural and educational rights f) Right to property g) Right to constitutional remedies	**10 Hours**
UNIT 3	**DIRECTIVE PRINCIPLES OF STATE POLICY** a) Equal Justice and free legal aid b) Right to work and provisions for just and humane conditions of work c) Provision for early childhood, Right to education and SC, ST, weaker section d) Uniform Civil Code	**10 Hours**

	e) Standard of Living, nutrition and public health f) Protection and improvement of environment g) Separation of Judiciary from executive h) Promotion of International peace and security	
UNIT 4	**FUNDAMENTAL DUTIES** a) Duty to abide by the Constitution b) Duty to cherish and follow the noble ideals c) Duty to defend the country and render national service d) Duty to value and preserve the rich heritage of our composite culture e) Duty to develop scientific temper, humanism, the spirit of inquiry & reform f) Duty to safeguard public property and abjure violence g) Duty to strive towards excellence	**5 Hours**

Text/Reference Books:

a) D. D. Basu, Introduction to the Constitution of India, LexisNexis
b) Granville Austin, The Constitution of India: Cornerstone of a Nation, Oxford University Press
c) Subhash Kashyap, Our Constitution, National Book Trust
d) M.P. Jain, Indian Constitutional Law, LexisNexis
e) V.N.Shukla, Constitution of India, Eastern Book Company
f) P.M. Bakshi, The Constitution of India, Universal Law Publishing
g) M.V.Pylee, Constitutional Government in India, S. Chand
h) V. S. Khare, Dr. B.R.Ambedkar and India's National Security