Shri Guru Ram Rai University

[Estd. by Govt. of Uttarakhand, vide Shri Guru Ram Rai University Act no. 03 of 2017 & recognized by UGC u/s (2f) of UGC Act 1956]

Patel Nagar, Dehradun -248001, Uttarakhand.

Regulations & Syllabus

M. Pharm

(Master of Pharmacy)

2016

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

(BASED ON NOTIFICATION IN THE GAZETTE OF INDIA NO. 352, DATED DECEMBER 11, 2014)

SCHEME AND SYLLABUS

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

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PHARMACY COUNCIL OF INDIA

NOTIFICATION

New Delhi, the 10th December, 2014

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

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

CHAPTER –I:REGULATIONS

1. Short Title and Commencement

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

2. Minimum qualification for admission

A Pass in the following examinations

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

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

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

3. Duration of the program

The program of study for M.Pharm. shall extend over a period of four semesters (two academic years). The curricula and syllabi for the program shall be prescribed from time to time by Phamacy 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 semestershall consist of not less than 100 working days. The odd semesters shall be conducted from the month of June/July to November/December and the even semesters shall be conducted from the month of December/January to May/June in every calendar year.

6. Attendance and progress

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

7. Program/Course credit structure

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

7.1. Credit assignment

7.1.1. Theory and Laboratory courses

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

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

7.2. Minimum credit requirements

The minimum credit points required for the award of M. Pharm. degree is 95. However based on the credit points earned by the students under the head of co-curricular activities, a student shall earn a maximum of 100 credit points. These credits are divided into Theory courses, Practical, Seminars, Assignments,Research work, Discussions with the supervisor, Journal club and Co-Curricular activities over the duration of four semesters. The credits

are distributed semester-wise as shown in Table 14. Courses generally progress in sequence, building competencies and their positioning indicates certain academic maturity on the part of the learners. Learners are expected to follow the semester-wise schedule of courses given in the syllabus.

8. Academic work

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

9. Course of study

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

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

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

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

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

Course Code	Course	Credit Hours	Credit Points	Hrs./wk	Marks
Semester I					
MPH101T	Modern Pharmaceutical Analytical Techniques	4	4	4	100
MPH102T	Drug Delivery System	4	4	4	100
MPH103T	Modern Pharmaceutics	4	4	4	100
MPH104T	Regulatory Affair	4	4	4	100
MPH105P	Pharmaceutics Practical I	12	6	12	150
-	Seminar/Assignment	7	4	7	100
	Total	35	26	35	650
Semester II					
MPH201T	Molecular Pharmaceutics (Nano Tech and Targeted DDS)	4	4	4	100
MPH202T	Advanced Biopharmaceutics & Pharmacokinetics	4	4	4	100
MPH203T	Computer Aided Drug Delivery System	4	4	4	100
MPH204T	Cosmetic and Cosmeceuticals	4	4	4	100
MPH205P	Pharmaceutics Practical II	12	6	12	150
-	Seminar/Assignment	7	4	7	100
	Total	35	26	35	650

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

Course Code	Course	Credit Hours	Credit Points	Hrs./wk	Marks
Semester I					
MQA101T	Modern Pharmaceutical Analytical Techniques	4	4	4	100
MQA102T	Quality Management System	4	4	4	100
MQA103T	Quality Control and Quality Assurance	4	4	4	100
MQA104T	Product Development and Technology Transfer	4	4	4	100
MQA105P	Pharmaceutical Quality Assurance Practical I	12	6	12	150
-	Seminar/Assignment	7	4	7	100
Total		35	26	35	650
Semester II					
MQA201T	Hazards and Safety Management	4	4	4	100
MQA202T	Pharmaceutical Validation	4	4	4	100
MQA203T	Audits and Regulatory Compliance	4	4	4	100
MQA204T	Pharmaceutical Manufacturing Technology	4	4	4	100
MQA205P	Pharmaceutical Quality Assurance Practical II	12	6	12	150
-	Seminar/Assignment	7	4	7	100
	Total	35	26	35	650

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

Course Code	Course	Credit Hours	Credit Points	Hrs./wk	Marks
Semester I					
MPP 101T	Clinical Pharmacy Practice	4	4	4	100
MPP 102T	Pharmacotherapeutics-I	4	4	4	100
MPP 103T	Hospital & Community Pharmacy	4	4	4	100
MPP 104T	Clinical Research	4	4	4	100
MPP 105P	Pharmacy Practice Practical I	12	6	12	150
-	Seminar/Assignment	7	4	7	100
Total		35	26	35	650
Semester II					
MPP 201T	Principles of Quality Use of Medicines	4	4	4	100
MPP 102T	Pharmacotherapeutics II	4	4	4	100
MPP 203T	Clinical Pharmacokinetics and Therapeutic Drug Monitoring	4	4	4	100
MPP 204T	Pharmacoepidemiology & Pharmacoeconomics	4	4	4	100
MPP 205P	Pharmacy Practice Practical II	12	6	12	150
-	Seminar/Assignment	7	4	7	100
	Total	35	26	35	650

Table - 10: Course of study for (Pharmacology)

Course Code	Course	Credit Hours	Credit Points	Hrs./wk	Marks
Semester I					
MPL 101T	Modern Pharmaceutical Analytical Techniques	4	4	4	100
MPL 102T	Advanced Pharmacology-I	4	4	4	100
MPL 103T	Pharmacological and Toxicological Screening Methods-I	4	4	4	100
MPL 104T	Cellular and Molecular Pharmacology	4	4	4	100
MPL 105P	Pharmacology Practical I	12	6	12	150
-	Seminar/Assignment	7	4	7	100
Total		35	26	35	650
Semester II					
MPL 201T	Advanced Pharmacology II	4	4	4	100
MPL 202T	Pharmacological and Toxicological Screening Methods-II	4	4	4	100
MPL 203T	Principles of Drug Discovery	4	4	4	100
MPL 204T	Experimental Pharmacology practical- II	4	4	4	100
MPL 205P	Pharmacology Practical II	12	6	12	150
-	Seminar/Assignment	7	4	7	100
	Total	35	26	35	650

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

Course Code	Course	Credit Hours	Credit Points	Hrs./wk	Marks
Semester I					
MPG101T	Modern Pharmaceutical Analytical Techniques	4	4	4	100
MPG102T	Advanced Pharmacognosy-1	4	4	4	100
MPG103T	Phytochemistry	4	4	4	100
MPG104T	Industrial Pharmacognostical Technology	4	4	4	100
MPG105P	Pharmacognosy Practical I	12	6	12	150
-	Seminar/Assignment	7	4	7	100
Total		35	26	35	650
Semester II					
MPG201T	Medicinal Plant biotechnology	4	4	4	100
MPG102T	Advanced Pharmacognosy-II	4	4	4	100
MPG203T	Indian system of medicine	4	4	4	100
MPG204T	Herbal cosmetics	4	4	4	100
MPG205P	Pharmacognosy Practical II	12	6	12	150
-	Seminar/Assignment	7	4	7	100
	Total	35	26	35	650

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

Course Code	Course	Credit Hours	Credit Points
MRM 301T	Research Methodology and Biostatistics*	4	4
-	Journal club	1	1
-	Discussion / Presentation (Proposal Presentation)	2	2
-	Research Work	28	14
Total		35	21

* Non University Exam

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

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

Table - 14: Semester wise credits distribution

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

*Credit Points for Co-curricular Activities

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

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

Note: International Conference: Held Outside India

International Journal: The Editorial Board Outside India

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

10. Program Committee

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 eachM.Pharm specialization and four student representatives (two from each academic year), nominated by the Head of the institution.

3. Duties of the Programme Committee:
   i. Periodically reviewing the progress of the classes.
   ii. Discussing the problems concerning curriculum, syllabus and the conduct of classes.
   iii. Discussing with the course teachers on the nature and scope of assessment for the course and the same shall be announced to the students at the beginning of respective semesters.

iv. Communicating its recommendation to the Head of the institution on academic matters.

v. The Programme Committee shall meet at least twice in a semester preferably at the end of each sessionalexam and before the end semester exam.

11. Examinations/Assessments

The schemes for internal assessment and end semester examinations are given in Table - 16.

11.1. End semester examinations

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

Tables – 1616 : 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								
MPH 101T	Modern Pharmaceutical Analytical Techniques	10	15	1 Hr	25	75	3 Hrs	100
MPH 102T	Drug Delivery System	10	15	1 Hr	25	75	3 Hrs	100
MPH 103T	Modern Pharmaceutics	10	15	1 Hr	25	75	3 Hrs	100
MPH 104T	Regulatory Affair	10	15	1 Hr	25	75	3 Hrs	100
MPH 105P	Pharmaceutics Practical I	20	30	6 Hrs	50	100	6 Hrs	150
-	Seminar /Assignment	-	-	-	-	-	-	100
Total								650
SEMESTER II								
MPH 201T	Molecular Pharmaceutics(Nano Tech and Targeted DDS)	10	15	1 Hr	25	75	3 Hrs	100
MPH 202T	Advanced Biopharmaceutics & Pharmacokinetics	10	15	1 Hr	25	75	3 Hrs	100
MPH 203T	Computer Aided Drug Delivery System	10	15	1 Hr	25	75	3 Hrs	100
MPH	Cosmetic	10	15	1 Hr	25	75	3 Hrs	100

204T	and Cosmeceutic als							
MPH 205P	Pharmaceuti cs Practical I	20	30	6 Hrs	50	100	6 Hrs	150
-	Seminar /Assignment	-	-	-	-	-	-	100
Total								650

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

Course Code	Course	Internal Assessment				End Semester Exams		Total Marks
		Continuous Mode	Sessional Exams		Total	Marks	Duration	
			Marks	Duration				
SEMESTER I								
MQA101T	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 Development and 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
-	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 Quality Assurance Practical II	20	30	6 Hrs	50	100	6 Hrs	150
-	Seminar /Assignment	-	-	-	-	-	-	100
Total								650

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

Course Code	Course	Internal Assessment				End Semester Exams		Total Marks
		Continuous Mode	Sessional Exams		Total	Marks	Duration	
			Marks	Duration				
SEMESTER I								
MPP101T	Clinical Pharmacy Practice	10	15	1 Hr	25	75	3 Hrs	100
MPP102T	Pharmacotherapeutics-I	10	15	1 Hr	25	75	3 Hrs	100
MPP103T	Hospital & Community Pharmacy	10	15	1 Hr	25	75	3 Hrs	100
MPP104T	Clinical Research	10	15	1 Hr	25	75	3 Hrs	100
MPP105P	Pharmacy Practice Practical I	20	30	6 Hrs	50	100	6 Hrs	150
-	Seminar /Assignment	-	-	-	-	-	-	100
Total								650
SEMESTER II								
MPP201T	Principles of Quality Use of Medicines	10	15	1 Hr	25	75	3 Hrs	100
MPP102T	Pharmacotherapeutics II	10	15	1 Hr	25	75	3 Hrs	100
MPP203T	Clinical Pharmacokinetics and Therapeutic Drug Monitoring	10	15	1 Hr	25	75	3 Hrs	100
MPP204T	Pharmacoepidemiology & Pharmacoeconomics	10	15	1 Hr	25	75	3 Hrs	100
MPP205P	Pharmacy Practice Practical II	20	30	6 Hrs	50	100	6 Hrs	150
-	Seminar /Assignment	-	-	-	-	-	-	100
Total								650

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

Course Code	Course	Internal Assessment				End Semester Exams		Total Marks
		Continuous Mode	Sessional Exams		Total	Marks	Duration	
			Marks	Duration				
SEMESTER I								
MPL101T	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
-	Seminar /Assignment	-	-	-	-	-	-	100
Total								650
SEMESTER II								
MPL201T	Advanced Pharmacology II	10	15	1 Hr	25	75	3 Hrs	100
MPL102T	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
-	Seminar /Assignment	-	-	-	-	-	-	100
Total								650

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

Course Code	Course	Internal Assessment				End Semester Exams		Total Marks
		Continuous Mode	Sessional Exams		Total	Marks	Duration	
			Marks	Duration				
SEMESTER I								
MPG101T	Modern Pharmaceutical Analytical Techniques	10	15	1 Hr	25	75	3 Hrs	100
MPG102T	Advanced Pharmacognosy-I	10	15	1 Hr	25	75	3 Hrs	100
MPG103T	Phytochemistry	10	15	1 Hr	25	75	3 Hrs	100
MPG104T	Industrial Pharmacognostical Technology	10	15	1 Hr	25	75	3 Hrs	100
MPG105P	Pharmacognosy Practical I	20	30	6 Hrs	50	100	6 Hrs	150
-	Seminar /Assignment	-	-	-	-	-	-	100
Total								650
SEMESTER II								
MPG201T	Medicinal Plant biotechnology	10	15	1 Hr	25	75	3 Hrs	100
MPG102T	Advanced Pharmacognosy-II	10	15	1 Hr	25	75	3 Hrs	100
MPG203T	Indian system of medicine	10	15	1 Hr	25	75	3 Hrs	100
MPG204T	Herbal cosmetics	10	15	1 Hr	25	75	3 Hrs	100
MPG205P	Pharmacognosy Practical II	20	30	6 Hrs	50	100	6 Hrs	150
-	Seminar /Assignment	-	-	-	-	-	-	100
Total								650

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

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

*Non University Examination

11.2. Internal assessment: Continuous mode

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

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

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

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

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

11.2.1. Sessional Exams

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

12. Promotion and award of grades

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

13. Carry forward of marks

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

14. Improvement of internal assessment

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

15. Reexamination of end semester examinations

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

Table – 29: Tentative schedule of end semester examinations

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

16. Allowed to keep terms (ATKT):

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

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

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

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

17. Grading of performances

17.1. Letter grades and grade points allocations:

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

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

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

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

18. The Semester grade point average (SGPA)

The performance of a student in a semester is indicated by a number called 'Semester Grade Point Average' (SGPA). The SGPA is the weighted average of the grade points obtainedin 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 the 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 statusin case of F grade(s), till the course(s) is/are passed. When the course(s) is/are passedby obtaining a pass grade on subsequent examination(s) theCGPA

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 C_1, C_2, C_3,.... is the total number of credits for semester I,II,III,.... and S_1,S_2, S_3,....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 the students shall undertake a project under the supervision of a teacher in Semester III to IV and submit a report. 4 copies of the project report shall be submitted (typed & bound copy not less than 75 pages).

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

Evaluation of Dissertation Book:

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

Evaluation of Presentation:

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

22. Award of Ranks

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

23. Award of degree

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

24. Duration for completion of the program of study

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

25. Revaluation I Retotaling of answer papers

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

26. Re-admission after break of study

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

SHRI GURU RAM RAI UNIVERSITY

[Estd. by Govt. of Uttarakhand, vide Shri Guru Ram Rai University Act no. 03 of 2017 & recognized by UGC u/s (2f) of UGC Act 1956]

SCHOOL OF PHARMACEUTICAL SCIENCES

PROGRAM: M. Pharm (Pharmacy Practice)

OUTCOME BASED EDUCATION

Course Outcomes, Program Outcomes,

Program Specific Outcomes

&

Articulation Matrix

Program Outcomes- M.Pharm (Pharmacy Practice)

PO1	**Advanced Knowledge:** Possess advanced scientific knowledge of the pharmacy profession so as to apply the learning's in providing solutions for complex issues of the Pharmaceutical field.
PO2	**Scientific and Technical Skills:** Develop analytical skills for effective scientific writing/presentation, data compilation & interpretation. Obtain erudite technical skills for applying in research and development for improvement of pharmaceutical process and products.
PO3	**Multidisciplinary Collaborative Research:** Develop interdisciplinary research with other health care communities to provide innovative solutions.
PO4	**Regulatory Professional Skills** Comply and work on rules and regulations involved in the drug discovery & development, manufacture and other allied area of the field.
PO5	**Critical Thinking:** Apply critical thinking skills, including investigation, application, analysis, creativity, evaluation of information, data and documents related to research.
PO6	**Problem based learning:** Develop problem-based learning approach and analytical thinking in his/her academic and professional life.
PO7	**Professional Identity:** Demonstrate the ability to plan and implement professional activities.
PO8	**Leadership Skills:** Leadership qualities of motivation, team building, time management, organizational skills so as to take lead and responsibilities in order to face the challenges of pharmaceutical sector.
PO9	**Ethical practice and societal concern:** Exercise ethical practices and moral values in personal and professional endeavours.
PO10	**Innovations Leading Skills:** Development of novel analytical techniques for identification, characterization and quantification of drugs, formulation, Pharmacological, Pharmacognostical, and regulatory aspects of drugs and biomolecules.
PO11	**Lifelong learning:** Tackle professional challenges through lifelong learning attitude.
PO12	**Expertise on Medications:** The student should be able to provide an expert opinion on medications to health care professionals on safe and effective medication-use, relevant policies and procedures based on available evidence.

Program Specific Outcomes- M.Pharm (Pharmacy Practice)

PSO1	**Expert knowledge of medications & practice:** Possess knowledge of and ability to prepare individualized therapeutic plans based on diagnosis, monitoring therapy, through identification of alternatives, time-course of clinical and laboratory indices of therapeutic response and adverse effects.
PSO2	**Pharmaceutical Care:** Learn scientific concepts to improve patient care by understanding the need for modification of prescriptions with respect to past medical & medication history, need for therapeutic management & dose adjustments.
PSO3	**Scientific & Technical Skills:** Skill development to detect, assess, report and monitor adverse drug events and interactions, interpret selected laboratory results of specific disease states and provide patient counselling.
PSO4	**Problem Based Learning:** Application of the pharmacoepidemiological methods like drug utilization review, cohort studies, meta-analysis, prescription event monitoring and study on vaccine safety, risk management and drug-induced birth defects, pharmacoeconomic evaluation for cost-minimization, cost-benefit, cost-effectiveness, and cost-utility evaluations.

Dean
School of Pharmaceutical Sciences
SGRR University, Dehradun (Uttarakhand)

Course Outcomes- M.Pharm. (Pharmacy Practice)

Semester-I	
COURSE NAME:	Clinical Pharmacy Practice
COURSE CODE:	MPP 101T
MPP 101T: CO 1	Define the basics of clinical pharmacy services in clinical settings.
MPP 101T: CO 2	Explain the services provided by clinical pharmacists in healthcare settings.
MPP 101T: CO 3	Apply the basic concept of pharmaceutical care for providing clinical services in healthcare settings.
MPP 101T: CO 4	Examine various functions of health care professionals towards clinical services.
MPP 101T: CO 5	Explain the utility of clinical services among health care professionals.
MPP 101T: CO 6	Discuss the significance of various patient care services in drug therapy management.

Articulation matrix:

	Semester –I															
	COURSE NAME: Clinical Pharmacy Practice															
	COURSE CODE: MPP 101T															
	PO 1	**PO 2**	**PO 3**	**PO 4**	**PO 5**	**PO 6**	**PO 7**	**PO 8**	**PO 9**	**PO 10**	**PO 11**	**PO 12**	**PSO 1**	**PSO 2**	**PSO 3**	**PSO 4**
CO 1	3	2	3	1	1	1	2	1	1	1	1	1	1	3	1	1
CO 2	3	3	3	2	2	1	3	3	2	0	2	1	2	3	2	2
CO 3	3	3	3	1	2	2	3	2	2	0	3	2	3	3	2	1
CO 4	3	3	2	2	3	2	3	2	0	1	2	2	2	2	2	2
CO 5	3	1	3	0	2	2	3	1	2	0	2	2	3	3	2	1
CO 6	3	2	3	1	3	1	3	2	1	1	3	2	3	3	1	1

Semester-I.	
COURSE NAME: Pharmacotherapeutics-I	
COURSE CODE: MPP 102T	
MPP 102T: CO 1	Fundamental knowledge of various common diseases and their etiologic, diagnostic & pharmacotherapeutic factors.
MPP 102T: CO 2	Gaining basic knowledge of pathogenesis of disease and pharmacotherapeutic options available to prevent the disease progression.
MPP 102T: CO 3	Applying different pharmacological & non-pharmacological treatment approaches in managing various disease conditions.
MPP 102T: CO 4	Developing skills for establishing a desired pharmacotherapeutic outcome for each drug and disease-related problem based on pathophysiologic factors.
MPP 102T: CO 5	Improving skills in optimizing drug therapy of a patient by individualizing the treatment plan through evidence-based medicines.
MPP 102T: CO 6	Create a pharmaceutical care plan and determine rational pharmacotherapeutic alternatives.

Articulation matrix:

Semester –I															
COURSE NAME: Pharmacotherapeutics-I															
COURSE CODE: MPP 102T															
	PO 1	**PO 2**	**PO 3**	**PO 4**	**PO 5**	**PO 6**	**PO 7**	**PO 8**	**PO 9**	**PO 10**	**PO 11**	**PO 12**	**PSO 1**	**PSO 2**	**PSO 3**	**PSO 4**
CO 1	2	1	2	1	1	1	1	1	1	1	1	2	1	1	3	1
CO 2	3	3	2	1	1	2	1	1	1	1	1	3	2	2	2	2
CO 3	3	3	3	2	3	3	2	1	1	3	2	3	3	3	1	3
CO 4	3	2	2	1	2	2	2	2	3	2	2	3	3	3	2	3
CO 5	3	2	2	2	3	3	3	2	3	3	3	3	3	3	2	3
CO 6	2	2	3	1	3	3	3	2	2	3	2	3	3	3	1	3

Semester-I	
COURSE NAME: Hospital & Community Pharmacy	
COURSE CODE: MPP 103T	
MPP 103T: CO 1	Fundamental knowledge about hospitals, hospital pharmacy & its services.
MPP 103T: CO 2	Understanding & gaining knowledge about hospital policies & various hospital pharmacy services to be performed in healthcare settings.
MPP 103T: CO 3	Developing skills for identifying thrust areas and services to be performed by hospital pharmacies in healthcare settings.
MPP 103T: CO 4	Applying different professional management skills in hospital pharmacies.
MPP 103T: CO 5	Improving skills in optimizing various hospital pharmacy services to improve pharmaceutical care.
MPP 103T: CO 6	Create continuing professional development programs & practices of hospital pharmacist.

Articulation matrix:

Semester –I															
COURSE NAME: Hospital & Community Pharmacy															
COURSE CODE: MPP 103T															
	PO 1	**PO 2**	**PO 3**	**PO 4**	**PO 5**	**PO 6**	**PO 7**	**PO 8**	**PO 9**	**PO 10**	**PO 11**	**PO 12**	**PSO 1**	**PSO 2**	**PSO 3**	**PSO 4**
CO 1	3	2	2	1	1	1	2	1	1	1	1	1	1	2	1	1
CO 2	2	2	3	2	0	1	2	2	2	1	2	2	2	2	2	1
CO 3	3	3	2	2	1	3	2	2	2	2	3	1	1	2	1	2
CO 4	3	2	1	0	3	2	3	3	2	1	2	2	2	2	0	3
CO 5	3	2	2	2	2	2	2	2	2	2	2	2	2	3	1	2
CO 6	1	2	2	1	2	3	3	3	1	1	3	1	1	1	1	3

Semester-I	
COURSE NAME:	Clinical Research
COURSE CODE:	MPP 104T
MPP 104T: CO 1	Understanding of New drug Discovery & Drug development process and various terminology used in Clinical Research.
MPP 104T: CO 2	Fundamental knowledge of designing, conducting, and documenting the clinical trial process and their rationale.
MPP 104T: CO 3	Developing skills of clinical trial process viz clinical trial execution & monitoring, procurement & storage of investigational product, clinical trial data management etc.
MPP 104T: CO 4	Basic knowledge of essential clinical trial documents and roles & responsibilities of the clinical trial study team.
MPP 104T: CO 5	Apprise the various ethical & regulatory principles to be followed during Clinical trials.
MPP 104T: CO 6	Apply knowledge of Quality assurance & Quality control in clinical trials for regulatory compliance.

Articulation matrix:

Semester –I															
COURSE NAME:	Clinical Research														
COURSE CODE:	MPP 104T														
	PO 1	**PO 2**	**PO 3**	**PO 4**	**PO 5**	**PO 6**	**PO 7**	**PO 8**	**PO 9**	**PO 10**	**PO 11**	**PO 12**	**PSO1**	**PSO 2**	**PSO 3**	**PSO 4**
CO 1	2	3	2	2	2	1	2	1	0	3	2	3	2	2	2	2
CO 2	3	3	2	2	2	1	2	2	1	3	3	3	3	2	2	2
CO 3	3	3	3	3	3	3	3	3	2	3	3	3	3	3	3	3
CO 4	3	3	3	3	3	2	3	3	2	3	3	3	3	3	2	2
CO 5	3	2	3	3	3	2	1	2	3	3	2	3	2	2	3	1
CO 6	3	3	3	3	1	1	0	2	3	3	1	2	1	0	3	2

Semester-I	
COURSE NAME: Pharmacy Practice Practical-I	
COURSE CODE: MPP 105P	
MPP 105P: CO 1	Understanding & implementation of pharmaceutical care plan model for presentation & justification of clinical cases of various disease conditions.
MPP 105P: CO 2	Demonstrate skills for interpretation of medication history interview, treatment chart review & laboratory data.
MPP 105P: CO 3	Developing skills & execution of patient medication counselling & provision of drug & poison information.
MPP 105P: CO 4	Practicing methods of inventory control & drug distribution in health care settings.

Articulation matrix:

Semester –I															
COURSE NAME: Pharmacy Practice Practical-I															
COURSE CODE: MPP 105P															
	PO 1	**PO 2**	**PO 3**	**PO 4**	**PO 5**	**PO 6**	**PO 7**	**PO 8**	**PO 9**	**PO 10**	**PO 11**	**PO 12**	**PSO 1**	**PSO 2**	**PSO 3**	**PSO 4**
CO 1	3	0	3	2	2	2	1	1	2	2	1	3	3	3	2	3
CO 2	3	3	3	2	1	1	1	1	2	1	1	1	3	2	2	2
CO 3	3	1	2	1	2	1	1	2	1	2	2	2	2	2	3	2
CO 4	2	1	1	1	3	1	1	2	2	2	1	2	2	2	2	3

Semester-II	
COURSE NAME: Principles of Quality Use of Medicines	
COURSE CODE: MPP 201T	
MPP 201T: CO 1	Fundamental knowledge of the principles of Quality use of medicines (QUM).
MPP 201T: CO 2	Gaining basic knowledge, concepts & elements of Quality use of medicines.
MPP 201T: CO 3	Developing skills for identifying & defining various principles of quality use of medicines.
MPP 201T: CO 4	Applying different aspects & principles of quality use of medicines in managing various disease conditions.
MPP 201T: CO 5	Improving skills in establishing principles of quality use of medicines through evidence-based medicines & their regulatory aspects.
MPP 201T: CO 6	Apply knowledge of basic principles of quality use of medicines in various healthcare settings as per the regulatory aspects.

Articulation matrix:

Semester –II															
COURSE NAME: Principles of Quality Use of Medicines															
COURSE CODE: MPP 201T															
	PO 1	**PO 2**	**PO 3**	**PO 4**	**PO 5**	**PO 6**	**PO 7**	**PO 8**	**PO 9**	**PO 10**	**PO 11**	**PO 12**	**PSO 1**	**PSO 2**	**PSO 3**	**PSO 4**
CO 1	3	1	2	2	1	1	1	1	0	1	2	2	2	1	0	1
CO 2	3	2	2	3	1	2	1	1	1	2	2	2	2	1	0	2
CO 3	3	3	3	2	3	2	2	2	2	3	2	3	3	2	3	3
CO 4	3	3	3	2	3	3	2	3	2	2	2	3	3	3	3	3
CO 5	3	2	2	3	3	3	3	3	3	3	3	3	3	3	3	3
CO 6	2	2	2	3	3	3	2	3	3	3	3	3	3	3	3	3

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Semester-II	
COURSE NAME: Pharmacotherapeutics-II	
COURSE CODE: MPP 202T	
MPP 202T: CO 1	Fundamental knowledge of various common diseases and their etiologic, diagnostic & pharmacotherapeutic factors.
MPP 202T: CO 2	Gaining basic knowledge of pathogenesis of disease and pharmacotherapeutic options available to prevent the disease progression.
MPP 202T: CO 3	Applying different pharmacological & non-pharmacological treatment approaches in managing various disease conditions.
MPP 202T: CO 4	Developing skills for establishing a desired pharmacotherapeutic outcome for each drug and disease-related problem based on pathophysiologic factors.
MPP 202T: CO 5	Improving skills in optimizing drug therapy of a patient by individualizing the treatment plan through evidence-based medicines.
MPP 202T: CO 6	Create a pharmaceutical care plan and determine rational pharmacotherapeutic alternatives.

Articulation matrix:

Semester –II															
COURSE NAME: Pharmacotherapeutics-II															
COURSE CODE: MPP 202T															
	PO 1	**PO 2**	**PO 3**	**PO 4**	**PO 5**	**PO 6**	**PO 7**	**PO 8**	**PO 9**	**PO 10**	**PO 11**	**PO 12**	**PSO 1**	**PSO 2**	**PSO 3**	**PSO 4**
CO 1	2	1	2	1	1	1	1	1	1	1	1	2	1	1	3	1
CO 2	3	3	2	1	1	2	1	1	1	1	1	3	2	2	2	2
CO 3	3	3	3	2	3	3	2	1	1	3	2	3	3	3	1	3
CO 4	3	2	2	1	2	2	2	2	3	2	2	3	3	3	2	3
CO 5	3	2	2	2	3	3	3	2	3	3	3	3	3	3	2	3
CO 6	2	2	3	1	3	3	3	2	2	3	2	3	3	3	1	3

Semester-II	
COURSE NAME:	Clinical Pharmacokinetics & Therapeutic Drug Monitoring
COURSE CODE:	MPP 203T
MPP 203T: CO 1	Define the basic understanding and terminology relevant to clinical pharmacokinetics.
MPP 203T: CO 2	Illustrate various clinically related activities under clinical pharmacokinetics and therapeutic drug monitoring.
MPP 203T: CO 3	Identify the role of clinical pharmacokinetics and TDM in different clinical oriented services.
MPP 203T: CO 4	Analyze the importance of clinical pharmacokinetics and TDM.
MPP 203T: CO 5	Explain the purpose of various methods aligned to study clinical pharmacokinetics & TDM services.
MPP 203T: CO 6	Discuss the scientific validity and practical applications of clinical pharmacokinetics and pharmacotherapeutic drug monitoring.

Articulation matrix:

Semester –II															
COURSE NAME:	Clinical Pharmacokinetics & Therapeutic Drug Monitoring														
COURSE CODE:	MPP 203T														
	PO 1	**PO 2**	**PO 3**	**PO 4**	**PO 5**	**PO 6**	**PO 7**	**PO 8**	**PO 9**	**PO 10**	**PO 11**	**PO 12**	**PSO 1**	**PSO 2**	**PSO 3**	**PSO 4**
CO 1	3	2	0	0	1	1	0	0	0	1	3	1	1	1	0	0
CO 2	3	3	1	1	2	3	2	2	1	2	2	2	2	2	2	1
CO 3	3	3	2	0	2	2	2	3	1	3	2	2	2	1	3	1
CO 4	2	3	1	1	2	2	2	2	0	3	2	2	2	1	3	3
CO 5	2	3	2	2	3	3	2	3	1	3	2	2	2	2	3	2
CO 6	3	3	2	2	3	2	1	3	1	3	2	2	2	1	3	2

Semester-II	
COURSE NAME:	Pharmacoepidemiology & Pharmacoeconomics
COURSE CODE:	MPP 204T
MPP 204T: CO 1	Define the terminology and basic understanding of Pharmacoepidemiology and Pharmacoeconomics.
MPP 204T: CO 2	Outline the classification/ types of pharmacoepidemiological and Pharmacoeconomic methods.
MPP 204T: CO 3	Apply the knowledge to study the pharmacoepidemiological and pharmacoeconomic methods.
MPP 204T: CO 4	Analyze the origin/ history and needs of pharmacoepidemiology and pharmacoeconomics.
MPP 204T: CO 5	Explain the theoretical aspects of various methods under pharmacoepidemiological and pharmacoeconomic studies.
MPP 204T: CO 6	Discuss the various applications of pharmacoepidemiology and pharmacoeconomics.

Articulation matrix:

Semester –II															
COURSE NAME:	Pharmacoepidemiology & Pharmacoeconomics														
COURSE CODE:	MPP 204T														
	PO 1	**PO 2**	**PO 3**	**PO 4**	**PO 5**	**PO 6**	**PO 7**	**PO 8**	**PO 9**	**PO 10**	**PO 11**	**PO 12**	**PSO 1**	**PSO 2**	**PSO 3**	**PSO 4**
CO 1	2	2	1	0	1	1	0	1	1	1	1	1	3	1	1	3
CO 2	2	3	1	1	1	2	2	0	1	2	2	2	2	3	3	3
CO 3	3	3	2	1	1	1	2	1	1	1	1	2	2	2	3	3
CO 4	2	3	2	1	1	1	2	1	1	2	2	2	2	3	3	3
CO 5	3	3	2	1	1	2	1	1	1	2	2	1	3	3	2	3
CO 6	2	3	1	0	1	1	0	0	1	1	1	2	3	1	2	3

Semester-II	
COURSE NAME:	Pharmacy Practice Practical-II
COURSE CODE:	MPP 205P
MPP 205P: CO 1	Understanding & implementation of pharmaceutical care plan model for presentation & justification of clinical cases of various disease conditions.
MPP 205P: CO 2	Basic skills for the detection and management of medication errors.
MPP 205P: CO 3	Developing skill on causality assessment of Adverse drug reactions.
MPP 205P: CO 4	Knowledge & implementation of interpretation of Therapeutic Drug monitoring reports.

Articulation matrix:

Semester –II															
COURSE NAME: Pharmacy Practice Practical-II															
COURSE CODE: MPP 205P															
	PO 1	**PO 2**	**PO 3**	**PO 4**	**PO 5**	**PO 6**	**PO 7**	**PO 8**	**PO 9**	**PO 10**	**PO 11**	**PO 12**	**PSO 1**	**PSO 2**	**PSO 3**	**PSO 4**
CO 1	1	3	2	2	2	2	2	1	1	2	2	3	3	2	3	3
CO 2	2	2	1	3	2	3	3	2	2	2	2	1	2	3	2	3
CO 3	2	3	2	3	1	3	2	1	2	1	2	2	3	3	2	2
CO 4	1	2	2	1	2	2	2	3	2	2	2	2	3	2	3	3

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Semester-III	
COURSE NAME: Research Methodology & Biostatistics	
COURSE CODE:	
CO 1	Understand the various aspects of research methodology and the use of biostatistics in research.
CO 2	Compare the various statistical techniques and their applications.
CO 3	Select and perform the appropriate parametric/ non parametric tests as per the data, manually as well as using statistical software.
CO 4	Elaborate with examples the ethics involved in medical research.
CO 5	Comprehend the guidelines for the experimentation on animals.
CO 6	Know about the genesis of bioethics with special reference to Helsinki declaration.

Articulation matrix:

Semester –III															
COURSE NAME: Research Methodology & Biostatistics															
COURSE CODE:															
	PO 1	**PO 2**	**PO 3**	**PO 4**	**PO 5**	**PO 6**	**PO 7**	**PO 8**	**PO 9**	**PO 10**	**PO 11**	**PO 12**	**PSO 1**	**PSO 2**	**PSO 3**	**PSO 4**
CO 1	3	3	3	0	2	2	3	0	1	1	3	1	3	0	2	2
CO 2	3	2	0	0	2	2	3	2	1	1	3	1	2	1	3	2
CO 3	1	3	0	0	2	2	3	0	1	1	3	0	2	1	3	3
CO 4	1	1	0	0	2	1	1	0	3	0	0	0	1	2	2	3
CO 5	3	1	0	0	2	1	1	0	3	0	0	0	0	0	0	0
CO 6	1	1	0	0	2	1	1	0	3	0	0	1	0	0	1	2

Semester-III	
COURSE NAME: Research Work	
COURSE CODE:	
CO 1	Gain an understanding to identify the research question.
CO 2	Developing skills to define & determine the research problem with the peers to achieve the desired outcome.
CO 3	Gain understanding to establish the research objectives.
CO 4	Developing skills for establishing a suitable methodology to answer the research problem.
CO 5	Gain an understanding to develop a protocol & plan of work to answer the research problem.
CO 6	Demonstration of the plan of work & critically appraised research problem in appropriate forum.

Articulation matrix:

Semester –III															
COURSE NAME: Research Work															
COURSE CODE:															
	PO 1	**PO 2**	**PO 3**	**PO 4**	**PO 5**	**PO 6**	**PO 7**	**PO 8**	**PO 9**	**PO 10**	**PO 11**	**PO 12**	**PSO 1**	**PSO 2**	**PSO 3**	**PSO 4**
CO 1	2	3	2	2	3	2	1	1	0	2	2	2	3	0	0	0
CO 2	3	2	2	1	3	3	2	2	0	2	2	3	2	0	2	2
CO 3	3	0	2	1	3	1	1	1	0	2	1	3	2	1	1	2
CO 4	2	2	2	2	2	2	1	1	2	2	2	2	3	2	2	1
CO 5	2	2	2	2	2	1	1	1	2	1	2	3	2	3	3	2
CO 6	2	2	2	2	2	3	1	2	2	3	2	3	2	3	2	2

Semester-III	
COURSE NAME: Journal Club	
COURSE CODE:	
CO 1	Search articles from various scientific databases.
CO 2	Critically appraise scientific articles and assess the quality
CO 3	Develop a report on the critically appraised article
CO 4	Prepare a technical presentation for a small audience.
CO 5	Deliver a presentation and address related queries.

Articulation matrix:

Semester –III															
COURSE NAME: Journal Club															
COURSE CODE:															
	PO 1	**PO 2**	**PO 3**	**PO 4**	**PO 5**	**PO 6**	**PO 7**	**PO 8**	**PO 9**	**PO 10**	**PO 11**	**PO 12**	**PSO 1**	**PSO 2**	**PSO 3**	**PSO 4**
CO 1	2	0	3	0	1	2	1	1	1	1	3	3	1	3	1	1
CO 2	2	2	2	2	2	3	3	2	2	2	3	3	3	3	2	2
CO 3	3	2	1	1	3	2	2	2	3	1	3	3	1	2	1	2
CO 4	1	2	2	0	2	2	3	3	3	1	3	3	2	1	1	1
CO 5	2	1	1	0	1	2	3	3	2	2	3	3	1	0	0	0

Dean
School of Pharmaceutical Sciences
SGRR University, Dehradun (Uttarakhand)

Semester-IV	
COURSE NAME: Research Work & Colloquium	
COURSE CODE:	
CO 1	Ability to review scholarly articles critically to collect and formulate the data.
CO 2	Developing skills to conduct research for achieving research objectives.
CO 3	Gain understanding to stratify the collected data and formulate into the research findings.
CO 4	Ability to statistically analyse the critically formulated data and generate the research outcome.
CO 5	Developing skills to propose new ideas or outcomes for the defined research question and create research document of the findings.
CO 6	Appraise and defend the research findings with evidence-based observations.

Articulation matrix:

Semester –IV															
COURSE NAME: Research Work & Colloquium															
COURSE CODE:															
	PO 1	**PO 2**	**PO 3**	**PO 4**	**PO 5**	**PO 6**	**PO 7**	**PO 8**	**PO 9**	**PO 10**	**PO 11**	**PO 12**	**PSO 1**	**PSO 2**	**PSO 3**	**PSO 4**
CO 1	3	3	2	1	1	2	2	2	3	2	2	3	2	2	2	2
CO 2	3	3	2	2	2	2	2	2	3	2	3	2	2	3	2	2
CO 3	3	2	2	1	2	2	2	1	2	2	2	2	3	3	2	2
CO 4	2	3	3	2	2	2	2	2	2	2	1	3	2	2	2	3
CO 5	3	3	3	2	2	2	2	2	2	3	1	1	3	3	3	2
CO 6	3	2	2	2	2	2	2	1	2	2	1	1	3	2	3	2

PHARMACYPRACTICE(MPP)

CLINICAL PHARMACY PRACTICE (MPP 101T)

Scope

This course is designed to impart the basic knowledge and skills that are required to practice pharmacy including the provision of pharmaceutical care services to both healthcare professionals and patients in clinical settings.

Objectives

Upon completion of this course it is expected that students shall be able to :

- Understand the elements of pharmaceutical care and provide comprehensive patient care services
- Interpret the laboratory results to aid the clinical diagnosis of various disorders
- Provide integrated, critically analyzed medicine and poison information to enable healthcare professionals in the efficient patient management

THEORY	60 Hrs
1. Introduction to Clinical Pharmacy: Definition, evolution and scope of clinical pharmacy, International and national scenario of clinical pharmacy practice, Pharmaceutical care Clinical Pharmacy Services: Ward round participation, Drug therapy review (Drug therapy monitoring including medication order review, chart endorsement, clinical review and pharmacist interventions)	12 Hrs
2 Clinical Pharmacy Services: Patient medication history interview, Basic concept of medicine and poison information services, Basic concept of pharmacovigilance, Hemovigilance, Materiovigilance and AEFI, Patient medication counselling, Drug utilisation evaluation, Documentation of clinical pharmacy services, Quality assurance of clinical pharmacy services.	12 Hrs
3 Patient Data Analysis: Patient Data & Practice Skills: Patient's case history - its structure and significances in drug therapy management, Common medical abbreviations and terminologies used in clinical practice, Communication skills: verbal and non-verbal communications, its applications in patient care services.	12 Hrs

	Lab Data Interpretation: Hematological tests, Renal function tests, Liver function tests	
4	Lab Data Interpretation: Tests associated with cardiac disorders, Pulmonary function tests, Thyroid function tests, Fluid and electrolyte balance, Microbiological culture sensitivity tests	12 Hrs
5	Medicines & Poison Information Services Medicine Information Service: Definition and need for medicine information service, Medicine information resources, Systematic approach in answering medicine information queries, Preparation of verbal and written response, Establishing a drug information centre. Poison Information Service: Definition, need, organization and functions of poison information centre.	12 Hrs

REFERENCES

1. A Textbook of Clinical Pharmacy Practice – Essential concepts and skills – Parthasarathi G, Karin Nyfort-Hansen and Milap Nahata
2. Practice Standards and Definitions - The Society of Hospital Pharmacists of Australia
3. Basic skills in interpreting laboratory data - Scott LT, American Society of Health System Pharmacists Inc
4. Relevant review articles from recent medical and pharmaceutical literature.

PHARMACOTHERAPEUTICS-I
(MPP 102T)

Scope

This course aims to enable the students to understand the different treatment approaches in managing various disease conditions. Also, it imparts knowledge and skills in optimizing drug therapy of a patient by individualizing the treatment plan through evidence-based medicines.

Objectives

Upon completion of this course it is expected that students shall be able to:

- Describe and explain the rationale for drug therapy
- Summarize the therapeutic approach for management of various disease conditions including reference to the latest available evidence
- Discuss the clinical controversies in drug therapy and evidence based medicine
- Prepare individualized therapeutic plans based on diagnosis
- Identify the patient specific parameters relevant in initiating drug therapy, and monitoring therapy (including alternatives, time- course of clinical and laboratory indices of therapeutic response and adverse effect/s)

THEORY 60 Hrs

Etiopathogenesis and pharmacotherapy of diseases associated with following systems

1.	Cardiovascular system: Hypertension, Congestive cardiac failure, Acute coronary syndrome, Arrhythmias, Hyperlipidemias.	12 Hrs
2	Respiratory system: Asthma, Chronic obstructive airways disease, Drug induced pulmonary diseases Endocrine system: Diabetes, Thyroid diseases	12 Hrs
3	Gastrointestinal system: Peptic ulcer diseases, Reflux esophagitis, Inflammatory bowel diseases, Jaundice & hepatitis	12 Hrs
4	Gastrointestinal system: Cirrhosis, Diarrhea and Constipation, Drug-induced liver disease Hematological diseases: Anemia, Deep vein thrombosis, Drug induced hematological disorders	12 Hrs

5	Bone and joint disorders: Rheumatoid arthritis, Osteoarthritis, Gout, Osteoporosis	12 Hrs
	Dermatological Diseases: Psoriasis, Eczema and scabies, impetigo, drug induced skin disorders	
	Ophthalmology: Conjunctivitis, Glaucoma	

REFERENCES

1. Roger and Walker. Clinical Pharmacy and Therapeutics - Churchill Livingstone publication
2. Joseph T. Dipiro et al. Pharmacotherapy: A Pathophysiologic Approach- Appleton & Lange
3. Robins SL. Pathologic basis of disease -W.B. Saunders publication
4. Eric T. Herfindal. Clinical Pharmacy and Therapeutics- Williams and Wilkins Publication
5. Lloyd Young and Koda-Kimble MA Applied Therapeutics: The clinical Use of Drugs- Lippincott Williams and Wilkins
6. Chisholm- Burns Wells Schwinghammer Malone and Joseph P Dipiro. Pharmacotherapy Principles and practice-- McGraw Hill Publication
7. Carol Mattson Porth. Principles of Pathophysiology- Lippincott Williams and Wilkins
8. Harrison's. Principles of Internal Medicine - McGraw Hill
9. Relevant review articles from recent medical and pharmaceutical literature

HOSPITAL & COMMUNITY PHARMACY
(MPP 103T)

Scope

This course is designed to impart basic knowledge and skills that are required to practice pharmacy in both hospital and community settings.

Objectives

Upon completion of this course it is expected that students shall be able to:

- Understand the organizational structure of hospital pharmacy
- Understand drug policy and drug committees
- Know about procurement & drug distribution practices
- Know the admixtures of radiopharmaceuticals
- Understand the community pharmacy management
- Know about value added services in community pharmacies

THEORY		60 Hrs
1.	Introduction to Hospitals - Definition, classification, organizational structure Hospital Pharmacy: Definition, Relationship of hospital pharmacy department with other departments, Organizational structure, legal requirements, work load statistics, Infrastructural requirements, Hospital Pharmacy Budget and Hospital Pharmacy management Hospital Drug Policy: Pharmacy & Therapeutics Committee, Infection Control committee, Research & Ethics Committee, Management of Medicines as per NABH	12 Hrs
2	Hospital Formulary Guidelines and its development, Developing Therapeutic guidelines, Drug procurement process, and methods of Inventory control, Methods of Drug distribution, Intravenous admixtures, Hospital Waste Management	12 Hrs
3	Education and training: Training of technical staff, training and continuing education for pharmacists, Pharmacy students, Medical staff and students, Nursing staff and students, Formal and informal meetings and lectures, Drug and therapeutics newsletter. Community Pharmacy Practice: Definition, roles & responsibilities of community pharmacists, and their relationship with other health care providers.	12 Hrs

Community Pharmacy management: Legal requirements to start community pharmacy, site selection, lay out & design, drug display, super drug store model, accounts and audits, Good dispensing practices, Different softwares & databases used in community pharmacies. Entrepreneurship in community pharmacy.

4 Prescription – Legal requirements & interpretation, prescription related problems — 12 Hrs

Responding to symptoms of minor ailments: Head ache, pyrexia, menstrual pains, food and drug allergy,
OTC medication: Rational use of over the counter medications
Medication counseling and use of patient information leaflets
Medication adherence – Definition, factors influencing adherence behavior, strategies to improve medication adherence
Patient referrals to the doctors
ADR monitoring in community pharmacies

5 Health Promotion – Definition and health promotion activities, family planning, Health screening services, first aid, prevention of communicable and non-communicable diseases, smoking cessation, Child & mother care — 12 Hrs

National Health Programs- Role of Community Pharmacist in Malaria and TB control programs
Home Medicines review program – Definition, objectives, Guidelines, method and outcomes
Research in community pharmacy Practice

REFERENCES

1. Hospital Pharmacy - Hassan WE. Lea and Febiger publication.
2. Textbook of hospital pharmacy - Allwood MC and Blackwell.
3. Avery's Drug Treatment, Adis International Limited.
4. Community Pharmacy Practice – Ramesh Adepu, BSP Publishers, Hyderabad
5. Remington Pharmaceutical Sciences.
6. Relevant review articles from recent medical and pharmaceutical literature

CLINICAL RESEARCH
(MPP 104T)

Scope

This course aims to provide the students an opportunity to learn drug development process especially the phases of clinical trials and also the ethical issues involved in the conduct of clinical research. Also, it aims to imparts knowledge and develop skills on conceptualizing, designing, conducting and managing clinical trials.

Objectives

Upon completion of this course it is expected that students shall be able to:

- Know the new drug development process.
- Understand the regulatory and ethical requirements.
- Appreciate and conduct the clinical trials activities
- Know safety monitoring and reporting in clinical trials
- Manage the trial coordination process

THEORY	60 Hrs
1. Drug development process: Introduction, various approaches to drug discovery, Investigational new drug application submission Ethics in Biomedical Research: Ethical Issues in Biomedical Research – Principles of ethics in biomedical research, Ethical committee [institutional review board] - its constitution and functions, Challenges in implementation of ethical guidelines, ICH GCP guidelines and ICMR guidelines in conduct of Clinical trials, Drug Safety Reporting.	12 Hrs
2 Types and Designs used in Clinical Research: Planning and execution of clinical trials, Various Phases of clinical trials, Bioavailability and Bioequivalence studies, Randomization techniques (Simple randomization, restricted randomization, blocking method and stratification), Types of research designs based on Controlling Method (Experimental, Quasi experimental, and Observational methods) Time Sequences (Prospective and Retrospective), Sampling methods (Cohort study, case Control study and cross sectional study), Health outcome measures (Clinical & Physiological, Humanistic and economic) Clinical Trial Study team: Roles and responsibilities of: Investigator, Study Coordinator, Sponsor, Monitor, Contract Research Organization.	12 Hrs

3	Clinical trial Documents: Guidelines to the preparation of following documents: Protocols, Investigator's Brochure, Informed Consent Form, Case report forms, Contracts and agreements, Dairy Cards Clinical Trial Start up activities: Site Feasibility Studies, Site/Investigator selection, Pre-study visit, Investigator meeting, Clinical trial agreement execution, Ethics committee document preparation and submission	12 Hrs
4	Investigational Product: Procurement and Storage of investigation product Filing procedures: Essential documents for clinical trial, Trial Master File preparation and maintenance, Investigator Site File, Pharmacy File, Site initiation visit, Conduct, Report and Follow up Clinical Trial Monitoring and Close out: Preparation and conduct of monitoring visit: Review of source documents, CRF, ICF, IP storage, accountability and reconciliation, Study Procedure, EC communications, Safety reporting, Monitoring visit reporting and follow-up Close-Out visit: Study related documents collection, Archival requirement, Investigational Product reconciliation and destruction, Close-Out visit report.	12 Hrs
5	Quality Assurance and Quality Control in Clinical Trials: Types of audits, Audit criteria, Audit process, Responsibilities of stakeholders in audit process, Audit follow-up and documentation, Audit resolution and Preparing for FDA inspections, Fraud and misconduct management Data Management Infrastructure and System Requirement for Data Management: Electronic data capture systems, Selection and implementation of new systems, System validation and test procedures, Coding dictionaries, Data migration and archival Clinical Trial Data Management: Standard Operating Procedures, Data management plan, CRF & Data base design considerations, Study set-up, Data entry, CRF tracking and corrections, Data cleaning, Managing laboratory and ADR data, Data transfer and database lock, Quality Control and Quality Assurance in CDM, Data mining and warehousing.	12 Hrs

REFERENCES

1. Principles and practice of pharmaceutical medicine, Second edition. Authors:Lionel. D. Edward, Aadrew.J.Flether Anthony W Fos , Peter D Sloaier Publisher:Wiley;
2. Handbook of clinical research. Julia Lloyd and Ann Raven Ed. Churchill Livingstone
3. Principles of Clinical Research edited by Giovanna di Ignazio, Di Giovanna and Haynes.
4. Central Drugs Standard Control Organization. Good Clinical Practices-Guidelines for Clinical Trials on Pharmaceutical Products in India. New Delhi: Ministry of Health.
5. International Conference on Harmonisation of Technical requirements for registration of Pharmaceuticals for human use. ICH Harmonised Tripartite Guideline. Guideline for Good Clinical Practice.E6; May 1996.
6. Ethical Guidelines for Biomedical Research on Human Subjects. Indian Council of Medical Research, New Delhi.
7. Textbook of Clinical Trials edited by David Machin, Simon Day and Sylvan Green, John Wiley and Sons.
8. Clinical Data Management edited by R K Rondels, S A Varley, C F Webbs. Second Edition, Jan 2000, Wiley Publications.
9. Goodman & Gilman: JG Hardman, LE Limbard, McGraw Hill Publications.
10. Relevant review articles from recent medical and pharmaceutical literature.

PHARMACY PRACTICE PRACTICAL – I
(MPP 105P)

Pharmacy Practice practical component includes experiments covering important topics of the courses Clinical Pharmacy Practice, Pharmacotherapeutics-I, Hospital & Community Pharmacy and Clinical Research.

List of Experiments (24)

1. Treatment Chart Review (one)
2. Medication History Interview (one)
3. Patient Medication Counseling (two)
4. Drug Information Query (two)
5. Poison Information Query (one)
6. Lab Data Interpretation (two)
7. Presentation of clinical cases of various disease conditions adopting Pharmaceutical Care Plan Model (eight)
8. ABC Analysis of a given list of medications (one)
9. Preparation of content of a medicine, with proper justification, for the inclusion in the hospital formulary (one)
10. Formulation and dispensing of a given IV admixtures (one)
11. Preparation of a patient information leaflet (two)
12. Preparation of Study Protocol (one)
13. Preparation of Informed Consent Form (one)

PRINCIPLES OF QUALITY USE OF MEDICINES
(MPP 201T)

Scope:

This course is designed to impart basic knowledge and skills that are required to practice quality use of medicines (QUM) in different healthcare settings and also to promote quality use of medicines, in clinical practice, through evidence-based medicine approach.

Objectives:

Upon completion of this course it is expected that students shall be able to:

- Understand the principles of quality use of medicines
- Know the benefits and risks associated with use of medicines
- Understand regulatory aspects of quality use of medicines
- Identify and resolve medication related problems
- Promote quality use of medicines
- Practice evidence-based medicines

	THEORY	60 Hrs
1.	Introduction to Quality use of medicines (QUM): Definition and Principles of QUM, Key partners and responsibilities of the partners, Building blocks in QMC, Evaluation process in QMC, Communication in QUM, Cost effective prescribing.	12 Hrs
2	Concepts in QUM Evidence based medicine: Definition, concept of evidence based medicine, Approach and practice of evidence based medicine in clinical settings Essential drugs: Definition, need, concept of essential drug, National essential drug policy and list Rational drug use: Definition, concept and need for rational drug use, Rational drug prescribing, Role of pharmacist in rational drug use.	12 Hrs
3	QUM in various settings: Hospital settings, Ambulatory care/Residential care, Role of health care professionals in promoting the QUM, Strategies to promote the QUM, Impact of QUM on E-health, integrative medicine and multidisciplinary care. QUM in special population: Pediatric prescribing, Geriatric prescribing, Prescribing in pregnancy and lactation, Prescribing in immune compromised and organ failure patients.	12 Hrs

4	Regulatory aspects of QUM in India: Regulation including scheduling, Regulation of complementary medicines, Regulation of OTC medicines, Professional responsibility of pharmacist, Role of industry in QUM in medicine development.	12 Hrs
5	Medication errors: Definition, categorization and causes of medication errors, Detection and prevention of medication errors, Role of pharmacist in monitoring and management of medication errors Pharmacovigilance: Definition, aims and need for pharmacovigilance, Types, predisposing factors and mechanism of adverse drug reactions (ADRs), Detection, reporting and monitoring of ADRs, Causality assessment of ADRs, Management of ADRs, Role of pharmacist in pharmacovigilance.	12 Hrs

REFERENCES:

1. A Textbook of Clinical Pharmacy Practice - Essential concepts and skills - Parthasarathi G, Karin Nyfort-Hansen and Milap Nahata
2. Andrews EB, Moore N. Mann's Pharmacovigilance
3. Dipiro JT, Talbert RL, Yee GC. Pharmacotherapy: A Pathophysiologic Approach
4. Straus SE, Richardson WS, Glasziou P, Haynes RB. Evidence-Based Medicine: How to practice and teach it
5. Cohen MR. Medication Errors
6. Online:
   - http://medicinesaustralia.com.au/files/2012/05/MA_QUM_External_Reduced.pdf
   - http://curriculum.racgp.org.au/statements/quality-use-of-medicines/
   - http://www.rug.nl/research/portal/files/14051541/Chapter_2.pdf
7. Relevant review articles from recent medical and pharmaceutical literature.

PHARMACOTHERAPEUTICS II
(MPP 202T)

Scope

This course aims to enable the students to understand the different treatment approaches in managing various disease conditions. Also, it imparts knowledge and skills in optimizing drug therapy of a patient by individualizing the treatment plan through evidence-based medicines.

Objectives

Upon completion of this course it is expected that students shall be able to:

- Describe and explain the rationale for drug therapy
- Summarize the therapeutic approach for management of various disease conditions including reference to the latest available evidence
- Discuss the clinical controversies in drug therapy and evidence based medicine
- Prepare individualized therapeutic plans based on diagnosis
- Identify the patient specific parameters relevant in initiating drug therapy, and monitoring therapy (including alternatives, time- course of clinical and laboratory indices of therapeutic response and adverse effect/s)

THEORY		60 Hrs
1.	Nervous system: Epilepsy, Parkinson's disease, Stroke, Headache, Alzheimer's disease, Neuralgias and Pain pathways and Pain management.	12 Hrs
2	Psychiatric disorders: Schizophrenia, Depression, Anxiety disorders, Sleep disorders, Drug induced psychiatric disorders Renal system: Acute renal failure, Chronic renal failure, Renal dialysis, Drug induced renal disease	12 Hrs
3	Infectious diseases: General guidelines for the rational use of antibiotics and surgical prophylaxis, Urinary tract infections, Respiratory tract infections, Gastroenteritis, Tuberculosis, Malaria, Bacterial endocarditis, Septicemia.	12 Hrs
4	Infectious diseases: Meningitis, HIV and opportunistic infections, Rheumatic fever, Dengue fever, H1N1, Helmenthiasis, Fungal infections Gynecological disorders: Dysmenorrhea, Hormone replacement therapy.	12 Hrs

5	Oncology: General principles of cancer chemotherapy, pharmacotherapy of breast cancer, lung cancer, head & neck cancer, hematological malignancies, Management of nausea and vomiting, Palliative care	12 Hrs

REFERENCES

1. Roger and Walker. Clinical Pharmacy and Therapeutics - Churchill Livingstone publication.
2. Joseph T. Dipiro et al. Pharmacotherapy: A Pathophysiologic Approach- Appleton & Lange
3. Robins SL. Pathologic basis of disease -W.B. Saunders publication
4. Eric T. Herfindal. Clinical Pharmacy and Therapeutics- Williams and Wilkins Publication
5. Lloyd Young and Koda-Kimble MA Applied Therapeutics: The clinical Use of Drugs- Lippincott Williams and Wilkins
6. Chisholm- Burns Wells Schwinghammer Malone and Joseph P Dipiro. Pharmacotherapy Principles and practice-– McGraw Hill Publication
7. Carol Mattson Porth. Principles of Pathophysiology- Lippincott Williams and Wilkins
8. Harrison's. Principles of Internal Medicine - McGraw Hill
9. Relevant review articles from recent medical and pharmaceutical literature

CLINICAL PHARMACOKINETICS AND THERAPEUTIC DRUG MONITORING
(MPP 203T)

Scope

This course is designed to enable students to understand the basics principles and applications of pharmacokinetics in designing the individualized dosage regimen, to interpret the plasma drug concentration profile in altered pharmacokinetics, drug interactions and in therapeutic drug monitoring processes to optimize the drug dosage regimen. Also, it enables students to understand the basic concepts of pharmacogenetics, pharmacometrics for modeling and simulation of pharmacokinetic data.

Objectives

Upon completion of this course it is expected that students shall be able to:

- Design the drug dosage regimen for individual patients
- Interpret and correlate the plasma drug concentrations with patients' therapeutic outcomes
- Recommend dosage adjustment for patients with renal/ hepatic impairment
- Recommend dosage adjustment for paediatrics and geriatrics
- Manage pharmacokinetic drug interactions
- Apply pharmacokinetic parameters in clinical settings
- Interpret the impact of genetic polymorphisms of individuals on pharmacokinetics and or pharmacodynamics of drugs
- Do pharmacokinetic modeling for the given data using the principles of pharmacometrics

THEORY 60 Hrs

1. Introduction to Clinical pharmacokinetics: Compartmental and Non compartmental models, Renal and non-renal clearance, Organ extraction and models of hepatic clearance, Estimation and determinants of bioavailability, Multiple dosing, Calculation of loading and maintenance doses — 12 Hrs

   Designing of dosage regimens: Determination of dose and dosing intervals, Conversion from intravenous to oral dosing, Nomograms and Tabulations in designing dosage regimen.

2	Pharmacokinetics of Drug Interaction: Pharmacokinetic drug interactions, Inhibition and Induction of Drug metabolism, Inhibition of Biliary Excretion Pharmacogenetics: Genetic polymorphism in Drug metabolism: Cytochrome P-450 Isoenzymes, Genetic Polymorphism in Drug Transport and Drug Targets, Pharmacogenetics and Pharmacokinetic / Pharmacodynamic considerations Introduction to Pharmacometrics: Introduction to Bayesian Theory, Adaptive method or Dosing with feedback, Analysis of Population pharmacokinetic Data.	12 Hrs
3	Non Linier Mixed Effects Modelling: The Structural or Base Model, Modeling Random Effects, Modeling Covariate Relationships, Mixture Model, Estimation Methods, Model Building Techniques, Covariate Screening Methods, Testing the model assumptions, Precision of the parameter estimates and confidence intervals, Model misspecification and violation of the model assumptions, Model Validation, Simulation of dosing regimens and dosing recommendations, Pharmacometrics software.	12 Hrs
4	Altered Pharmacokinetics: Drug dosing in the elderly, Drug dosing in the paediatrics, Drug dosing in the obese patients, Drug dosing in the pregnancy and lactation, Drug dosing in the renal failure and extracorporeal removal of drugs, Drug dosing in the in hepatic failure.	12 Hrs
5	Therapeutic Drug monitoring: Introduction, Individualization of drug dosage regimen (Variability - Genetic, age, weight, disease and Interacting drugs), Indications for TDM, Protocol for TDM, Pharmacokinetic/Pharmacodynamic Correlation in drug therapy, TDM of drugs used in the following conditions: Cardiovascular disease: Digoxin, Lidocaine, Amiodarone; Seizure disorders: Phenytoin, Carbamazepine, Sodium Valproate; Psychiatric conditions: Lithium, Fluoxetine, Amitriptyline; Organ transplantations: Cyclosporine; Cytotoxic Agents: Methotrexate, 5-FU, Cisplatin; Antibiotics: Vancomycin, Gentamicin, Meropenem.	12 Hrs

REFERENCES

1. Leon Shargel, Susanna Wu-Pong, Andrew Yu. Applied Biopharmaceutics & Pharmacokinetics. New York: Mc Graw Hill.
2. Peter L. Bonate. Pharmacokinetic - Pharmacodynamic Modeling and Simulation. Springer Publications.
3. Michael E. Burton, Leslie M. Shaw, Jerome J. Schentag, William E.Evans. Applied Pharmacokinetics & Pharmacodynamics: Principles of Therapeutic Drug Monitoring. lippincott Williams & Wilkins.
4. Steven How-Yan Wong, Irving Sunshine. Handbook of Analytical Therapeutic Drug Monitoring and Toxicology. CRC Press, USA.
5. Soraya Dhillon, Andrzej Kostrzewski. Clinical pharmacokinetics. 1st edition. London: Pharmaceutical Press.
6. Joseph T.Dipiro, William J.Spruill, William E.Wade, Robert A.Blouin and Jane M.Pruemer .Concepts in Clinical Pharmacokinetics. American Society of Health-System Pharmacists, USA.
7. Malcolm Rowland, Thomas N. Tozer .Clinical Pharmacokinetics and pharmacodynamics: concepts and applications. lippincott Williams & Wilkins, USA.
8. Evans, Schentag, Jusko. Applied pharmacokinetics. American Society of Health system Pharmacists, USA.
9. Michael E. Winter. Basic Clinical Pharmacokinetics. lippincott Williams & Wilkins, USA.
10. Milo Gibaldi. Biopharmaceutics and Clinical Pharmacokinetics. Pharma Book Syndicate, USA.
11. Dhillon and Kostrzewski. Clinical pharmacokinetics. Pharmaceutical Press, London.
12. John E .Murphy. Clinical Pharmacokinetics. 5th edition. US: American Society of Health- System Pharmacist, USA.
13. Relevant review articles from recent medical and pharmaceutical literature

PHARMACOEPIDEMIOLOGY & PHARMACOECONOMICS
(MPP 204T)

Scope

This course enables students to understand various pharmacoepidemiological methods and their clinical applications. Also, it aims to impart knowledge on basic concepts, assumptions, terminology, and methods associated with Pharmacoeconomics and health related outcomes, and when should be appropriate Pharmacoeconomic model should be applied for a health care regimen.

Objectives

Upon completion of this course it is expected that students shall be able to:

- Understand the various epidemiological methods and their applications
- Understand the fundamental principles of Pharmacoeconomics.
- Identify and determine relevant cost and consequences associated with pharmacy products and services.
- Perform the key Pharmacoeconomics analysis methods
- Understand the Pharmacoeconomic decision analysis methods and its applications.
- Describe current Pharmacoeconomic methods and issues.
- Understand the applications of Pharmacoeconomics to various pharmacy settings.

THEORY 60 Hrs

1. Introduction to Pharmacoepidemiology: Definition, Scope, Need, Aims & Applications; Outcome measurement: Outcome measures, Drug use measures: Monetary units, Number of prescriptions, units of drug dispensed, defined daily doses, prescribed daily doses, Diagnosis and Therapy surveys, Prevalence, Incidence rate, Monetary units, number of prescriptions, unit of drugs dispensed, defined daily doses and prescribed daily doses, medications adherence measurements. Concept of risk: Measurement of risk, Attributable risk and relative risk, Time- risk relationship and odds ratio — 12 Hrs

2. Pharmacoepidemiological Methods: Qualitative models: Drug Utilization Review; Quantitative models: case reports, case series, Cross sectional studies, Cohort and case control studies, Calculation of Odds' ratio, Meta analysis models, Drug effects study in populations: Spontaneous reporting, Prescription event — 12 Hrs

monitoring, Post marketing surveillance, Record linkage systems, Applications of Pharmacoepidemiology

3	Introduction to Pharmacoeconomics: Definition, history of Pharmacoeconomics, Need of Pharmacoeconomic studies in Indian healthcare system. Cost categorization and resources for cost estimation: Direct costs. Indirect costs. Intangible costs. Outcomes and Measurements of Pharmacoeconomics: Types of outcomes: Clinical outcome, Economic outcomes, Humanistic outcomes; Quality Adjusted Life Years, Disability Adjusted Life Years Incremental Cost Effective Ratio, Average Cost Effective Ratio. Person Time, Willingness To Pay, Time Trade Off and Discounting.	12 Hrs
4	Pharmacoeconomic evaluations: Definition, Steps involved, Applications, Advantages and disadvantages of the following Pharmacoeconomic models: Cost Minimization Analysis (CMA), Cost Benefit Analysis (CBA), Cost Effective Analysis (CEA), Cost Utility Analysis (CUA), Cost of Illness (COI), Cost Consequences Analysis (COA).	12 Hrs
5	Definition, Steps involved, Applications, Advantages and disadvantages of the following: Health related quality of life (HRQOL): Definition, Need for measurement of HRQOL, Common HRQOL measures. Definition, Steps involved, Applications of the following: Decision Analysis and Decision tree, Sensitivity analysis, Markov Modeling, Software used in pharmacoeconomic analysis, Applications of Pharmacoeconomics.	12 Hrs

REFERENCES

1. Rascati K L. Essentials of Pharmacoeconomics, Woulters Kluwer Lippincott Williams & Wilkins, Philadelphia.
2. Thomas E Getzen. Health economics. Fundamentals and Flow of Funds. John Wiley & Sons, USA.
3. Andrew Briggs, Karl Claxton, Mark Sculpher. Decision Modelling for Health Economic Evaluation, Oxford University Press, London.
4. Michael Drummond, Mark Sculpher, George Torrence, Bernie O'Brien and Greg Stoddart. Methods for the Economic Evaluation of Health Care Programmes Oxford University Press, London.

5. George E Mackinnon III. Understanding health outcomes and pharmacoeconomics.
6. Graker, Dennis. Pharmacoeconomics and outcomes.
7. Walley, Pharmacoeconomics.
8. Pharmacoeconomic - ed. by Nowakowska - University of Medical Sciences, Poznan.
9. Relevant review articles from recent medical and pharmaceutical literature

PHARMACY PRACTICE PRACTICAL - II
(MPP 205P)

Pharmacy Practice practical component includes experiments covering important topics of the courses Principles of Quality Use of Medicines, Pharmacotherapeutics-II, Clinical Pharmacokinetics & Therapeutic Drug Monitoring and Pharmacoepidemiology and Pharmacoeconomics.

List of Experiments (24)

1. Causality assessment of adverse drug reactions (three)
2. Detection and management of medication errors (three)
3. Rational use of medicines in special population (three)
4. Presentation of clinical cases of various disease conditions adopting Pharmaceutical Care Plan Model (eight)
5. Calculation of Bioavailability and Bioequivalence from the given data (two)
6. Interpretation of Therapeutic Drug Monitoring reports of a given patient (three)
7. Calculation of various Pharmacoeconomic outcome analysis for the given data (two)

Semester III

MRM 301T - Research Methodology & Biostatistics

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.

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.

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.

UNIT – IV

CPCSEA guidelines for laboratory animal facility: Goals, veterinary care, quarantine, surveillance, diagnosis, treatment and control of disease, personal hygiene, location of animal facilities to laboratories, anesthesia, euthanasia, physical facilities, environment, animal husbandry, record keeping, SOPs, personnel and training, transport of lab animals.

UNIT – V

Declaration of Helsinki: History, introduction, basic principles for all medical research, and additional principles for medical research combined with medical care.