ADMISSION & EXAMINATION BYE-LAWS

FOR

MASTER OF PHARMACY IN PHARMACY PRACTICE

Program Code: MPP

SCHOOL OF PHARMACEUTICAL EDUCATION AND RESEARCH
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BOS MEETING DETAILS

- **Approval date of the BOS/School Board meeting for the present syllabus:**

Name of the program	Department	Board of School (BOS) Approval Date
M. Pharm	Pharmacy Practice	21.04.2017

- **Approval date of the Academic Council meeting for the present syllabus**

Name of the program	Program Code	Dates of Revision
M. Pharm	MPP	31.05.2017

VISION AND MISSION STATEMENTS

Vision Statement: To train and develop competent clinical pharmacists with rigorous scientific attitude who can become academicians, professionals and researchers and generate useful and contemporary knowledge to meet the needs of society, industry and research organizations in India and abroad.

Mission Statements:

MS1: To impart knowledge of pharmacotherapeutics to meet the academic, industrial and public health requirements

MS 2: To inculcate research skills in the students to make them intellectual contributors to address healthcare challenge through creation of new knowledge.

MS 3: To provide a platform for students to develop critical thinking, teamwork and communication abilities so as to become a competent professional.

PROGRAM EDUCATIONAL OBJECTIVES (PEOs)

After completion of the M. Pharm (Pharmacy Practice), the postgraduates will be able to:

PEO1: Apply knowledge in solving industry-relevant programs.

PEO2: Carry out quality research in different facets of the program including higher education.

PEO3: Foster abilities to design and fabricate new products or techniques, benefiting the society at large.

PEO4: Combine practical pharmaceutical knowledge and abilities with research ability for a better output.

PEO5: Inculcate entrepreneurial skills in aspiring pharmacy professionals

PEO6: Develop leadership skills to be applied in R&D, production, and other facets of the profession

Mapping Program Educational Objectives (PEOs)with Mission Statements (MS)

	MS-1	MS-2	MS-3
PEO-1	3	3	3
PEO-2	3	3	3
PEO-3	1	2	2
PEO-4	2	3	3
PEO-5	1	2	3
PEO-6	3	3	3

Level of Mapping: '3' is for 'high-level' mapping, 2 for 'Medium-level' mapping, 1 for 'Low-level' mapping.

PROGRAMME SPECIFIC OUTCOME (PSO)

After completion of the M. Pharm (Pharmacy Practice), the postgraduates will be able to:

PSO1: Analyze and critically evaluate the role of clinical pharmacy and pharmacotherapeutics in relation to other branches of biomedical sciences.

PSO2: Demonstrate skills related to practice of pharmacy in hospital and clinical settings and recommend pharmaceutical care services including approaches for design of drug dosage regimen and dosage adjustment through application of pharmacokinetic models.

PSO3: Demonstrate understanding of safety aspects of drugs in relation to public health.

PSO4: Demonstrate skills to design and conduct research experiments for drug discovery and development

PSO5: Communicate effectively on the scientific aspects of drugs both at community and professional levels.

PROGRAM OUTCOMES (POs)

After going through the two years Master Program in Pharmacy Practice, graduates will exhibit the ability to:

PO1: **Pharmacology Knowledge:** Apply the knowledge of pharmacotherapeutics to assist in rational and scientific pharmaceutical care.

PO2: **Planning Abilities:** Apply the principles of pharmacokinetics for finding effective doses and dosage regiments for effective treatment of special populations using appropriate models.

PO3: **Problem Analysis:** Develop scientific temperament and critical reasoning abilities to Identify and evaluate challenges and gaps in the drug therapy and formulate solutions for the effective pharmaceutical care.

PO4: **Modern tool Usage:** Demonstrate understanding of clinical research, apply the modern methods and tools for therapeutic drug monitoring and carry out pharmacoeconomic analysis and outcome research.

PO5: **Leadership Skills:** Participate effectively and demonstrate leadership skills in multidisciplinary and multicultural teams.

PO6: **Professional Identity:** Appreciate and analyze the role of medicines in improving public health and understand the responsibility of pharmacists in the same through scientific research and community engagement.

PO7: **Pharmaceutical Ethics:** Demonstrate ethics in one's practices in personal, professional and social spheres of life.

PO8: **Communication:** Demonstrate ability to effectively communicate on challenges and solution of medicines and therapeutics related aspects of healthcare using available verbal and written media at local as well as global level.

PO9: **The Pharmacist and Society**: Demonstrate understanding of role of clinical pharmacists in promoting rational use of medicines and carry out community engagement and outreach activities to promote public health through optimal use of medicines and prevent development of antimicrobial resistance.

PO10: **Environment and Sustainability:** Understand the importance of sustainable development and develop perspective on role of pharmacists towards sustainable development

PO11: **Lifelong Learning:** Understand the importance of and use available resources for lifelong learning and continuing professional development for advancement of science in general and clinical pharmacy in particular for the benefit of mankind.

Mapping of Program Outcomes (POs) and Program Specific Outcomes (PSOs) with Program Educational Objectives (PEOs)

	PEO-1	PEO-2	PEO-3	PEO-4	PEO-5	PEO-6
PO-1	3	3	2	3	3	2
PO-2	3	2	2	3	3	2
PO-3	3	3	2	3	3	2
PO-4	3	3	2	3	3	2
PO-5	3	3	2	3	3	3
PO-6	3	3	2	3	2	3
PO-7	3	2	2	3	2	1
PO-8	3	2	2	3	2	3
PO-9	2	2	2	3	2	3
PO-10	2	2	2	3	2	2
PO-11	3	3	2	3	3	3
PSO-1	3	3	2	3	3	3

PSO-2	3	3	2	3	3	3
PSO-3	3	3	2	2	2	3
PSO-4	3	3	2	3	3	3
PSO-5	3	3	2	2	2	3

Level of Mapping: '3' is for 'high-level' mapping, 2 for 'Medium-level' mapping, 1 for 'Low-level' mapping.

CONSOLIDATED SEMESTER WISE PROGRAMME DETAILS

Tables-I: Schemes for internal assessments and end semester examinations semester wise

Semester I

Course code	Name of the course	Internal Assessment				End Semester Exams		Total Marks	Credit points
		Continuous mode	Sessional Exams		Total	Marks	Duration		
			Marks	Duration					
MPP101T	Clinical Pharmacy Practice	10	15	1 Hr	25	75	3 Hrs	100	4
MPP102T	Pharmacotherapeutics - I	10	15	1 Hr	25	75	3 Hrs	100	4
MPP 103T	Hospital & Community Pharmacy	10	15	1 Hr	25	75	3 Hrs	100	4
MPP 104T	Clinical Research	10	15	1 Hr	25	75	3 Hrs	100	4
MPP 105P	Pharmacy Practice Practical I	20	30	6 Hrs	50	100	6 Hrs	150	6
-	Seminar/Assignment	-	-	-	-			100	4
	Total							650	26

Semester II

Course code	Name of the course	Internal Assessment				End Semester Exams		Total Marks	Credit point
		Continous Mode	Sessional Exams		Total	Marks	Duration		
			Marks	Duration					
MPP201T	Principles of Quality use of Medicines	10	15	1 Hr	25	75	3 Hrs	100	4
MPP 202T	Pharmacotherapeutics - II	10	15	1 Hr	25	75	3 Hrs	100	4
MPP 203T	Clinical Pharmacokinetics and Therapeutic Drug Monitoring	10	15	1 Hr	25	75	3 Hrs	100	4
MPP 204T	Pharmacoepidemiology & Pharmacoeconomics	10	15	1 Hr	25	75	3 Hrs	100	4
MPP 205P	Pharmacy Practice Practical II	20	30	6 Hrs	50	100	6 Hrs	150	6
	Seminar/Assignment							100	4
Total								**650**	**26**

Semester III

Course code	Name of the course	Internal Assessment				End Semester Exams		Total Marks	Credit points
		Continuous Mode	Sessional Exams		Total	Marks	Duration		
			Marks	Duration					
MRM 301T	Research Methodology and Biostatistics*	10	15	1 Hr	25	75	3 Hrs	100	4
-	Journal club	-	-	-	25		3 Hrs	25	1
-	Discussion / Presentation (Proposal Presentation)	-	-	-	50		3 Hrs	50	2
-	Research Work	-	-	-	-	350	1 Hrs	350	14
Total								**525**	**21**

* Non University Exam

Semester IV

Course code	Name of the course	Internal Assessment				End Semester Exams		Total Marks	Credit points
		Continuous Mode	Sessional Exams		Total	Marks	Duration		
			Marks	Duration					
-	Journal club	-	-	-	25	-	-	25	1
-	Discussion / Presentation (Proposal Presentation	-	-	-	75	-	-	75	16
-	Research work and Colloquium	-	-	-	-	400	1 Hr	400	3
Total								**500**	**20**

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

8 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 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.

9. 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 3 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.

10. 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.

11. Course ofstudy

The course of study for M. Pharm shall include Semester Wise Theory & Practical as given in Table– II-III. 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 –II-III

Table II-: Course of study for Semester I

Course code	Name of the course	No. of hours	Tutorial	Credit points
MPP101T	Clinical Pharmacy Practice	4	-----	4
MPP102T	Pharmacotherapeutics - I	4	-----	4
MPP 103T	Hospital & Community Pharmacy	4	----	4
MPP 104T	Clinical Research	4	----	4
MPP 105P	Pharmacy Practice Practical I	12	----	6
-	Seminar/Assignment	7	----	4
	Total	**35**		**26**

Table III-: Course of study for Semester II

Course code	Name of the course	No. of hours	Tutorial	Credit points
MPP201T	Principles of Quality use of Medicines	4	-	4
MPP 202T	Pharmacotherapeutics – II	4		4
MPP 203T	Clinical Pharmacokinetics and Therapeutic Drug Monitoring	4	-	4
MPP 204T	Pharmacoepidemiology & Pharmacoeconomics	4	-	4
MPP 205P	Pharmacy Practice Practical II	12	-	6
	Seminar/Assignment	7	-	4
	Total	**35**		**26**

Table-IV: 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=10*

* Credit Points for Co-curricular Activities

12. Program Committee

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

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

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

13. Examinations/Assessments

The scheme for internal assessment and end semester examinations is given in Table IV- VII

End semester examinations

The End Semester Examinations for each theory and practical course through semesters I to IV shall beconducted by the university except for the subjects 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.

Internal assessment: Continuous mode

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

Table IV: Scheme for awarding internal assessment: Continuous mode

Theory	
Criteria	**Maximum Marks**
Attendance (Refer Table – V)	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 V: 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 average marks of two sessional exams shall be computed for internal assessment as per the requirements given in tables.

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.

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.

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.

Reexamination of end semester examinations

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

Table VI: Tentative schedule of end semesterexaminations

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

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.

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 – VII.

Table VII: 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.

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:

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

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) theCGPAshall 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 S1,S2, S3,….is the SGPA of semester I,II,III,…. .

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

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

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, thecandidates should have completed the M. Pharm program in minimum prescribed number of years, (two years) for the award of Ranks.

Award of degree

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

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 freshRegistration.

Revaluation I Re-totaling 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.

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.

SYLLABUS

M.PHARM. SEMESTER I	
Course Code MPP 101T	**Title of the course: Clinical Pharmacy Practice (Theory)**
Course Code: MPP 102T	**Title of the Course: Pharmacotherapeutics – I (Theory)**
Course Code: MPP 103T	**Title of the Course: Hospital & Community Pharmacy (Theory)**
Course Code: MPP 104T	**Title of the Course: Clinical Research (Theory)**
Course Code: MPP 105P	**Title of the Course: Pharmacy Practice Practical I**

Name of the Academic Program: M Pharm Pharmacy Practice

Course Code: MPP 101T.

Title of the Course: Clinical Pharmacy Practice

L-T-P: 4-0-0 **Credits: 4**

(L=Lecture hours, T=Tutorial hours, P=Practical hours)

COURSE OUTCOMES (COs)

After completing this Course, the students should be able to

CO-1 : Understand the elements of pharmaceutical care and provide comprehensive patient care services **(Cognitive Level: Understand)**

CO-2 : Understand the basic concept of pharmacovigilance, hemovigilance materiovigilance AEFI etc **(Cognitive Level: Understand)**

CO-3 : Interpret the laboratory results to aid the clinical diagnosis of various disorders **(Cognitive Level: Evaluate)**

CO-4 : Provide effective counseling to pateints on medication usage **(Cognitive Level: Create)**

CO-5 : Provide integrated, critically analyzed medicine and poison information to enable healthcare professionals in the efficient patient management **(Cognitive Level: create)**

Mapping of Course Outcomes (COs) with Program Outcomes (POs) and Program Specific Outcomes (PSOs)

	PO1	PO2	PO3	PO4	PO5	PO6	PO7	PO8	PO9	PO10	PO11	PSO1	PSO2	PSO3	PSO4	PSO5
CO1	2	2	2			2	1	1	2		3	3	3	3	2	2
CO2	2		1		2		2	2	3	3	3	2	3	3	2	2
CO3	3	2	2	3	2		2		1		2	3	3	2	3	3
CO4		3		2	3	3	1	3	3		2	3	2	2	1	1
CO5	1	2	1	3	2	2		3	2	2	3	3	2	3	2	2

Each Course Outcome (CO) may be mapped with one or more Program Outcomes (POs). Write '3' in the box for 'High-level'mapping, 2 for 'Medium-level'mapping, 1 for 'Low'-level'mapping.

Mapping with PSOs, where applicable.

Detailed Syllabus:

UNIT 1 **12 Hrs**

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)

UNIT 2 **12Hrs**

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.

UNIT 3 **12 Hrs**

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.

Lab Data Interpretation: Hematological tests, Renal function tests, Liver function tests

UNIT 4 **12 Hrs**

Lab Data Interpretation: Tests associated with cardiac disorders, Pulmonary function tests, Thyroid function tests, Fluid and electrolyte balance, Microbiological culture sensitivity tests

UNIT 5 **12 Hrs**

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.

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.

Teaching-Learning Strategies in Brief

The teaching learning strategies, followed are board and chalk teaching, Learning through discussion among the peer group, classroom interaction, discussion of research papers of Journals related to topics, power point presentation, Q & A session and reflective learning.

Assessment methods and weightages in brief

There are two components of assessment: Internal assessment (25 marks) and End semester examination (75 marks). Internal assessment consists of continuous mode (10 marks) and sessional examinations (15 marks). There are two Sessional exams (each conducted for 30 marks and computed for 15 marks) and one improvement exam. The average marks of two best sessional exams are computed out of 15 marks. Continuous mode evaluation is of 10 marks comprising of attendance- 8 marks (calculated as: Percentage of Attendance: Allotment of marks- Less than 80: 0 marks; 80-84: 2 marks; 85-89: 4 marks; 90-94: 6 marks and 95-100: 8 marks) and Student-Teacher interaction: 2 marks.
Total Marks are 100 for the subject (Internal Assessment: 25 marks and End Semester Examination: 75 Marks).

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Name of the Academic Program: M Pharm (Pharmacy Practice)

Course Code: MPP 102T.

Title of the Course: Pharmacotherepeutics I

L-T-P 4-0-0 **Credits:** 4

(L=Lecture hours, T=Tutorial hours, P=Practical hours)

COURSE OUTCOMES (COs)

After completing this Course, the students should be able to:

CO-1: Describe and explain the rationale for drug therapy **(Cognition level: Understanding)**

CO-2: Summarize the therapeutic approach for management of various disease conditions including reference to the latest available evidence **(Cognition level: Create)**

CO-3: Discuss the clinical controversies in drug therapy and evidence based medicine **(Cognition level: Understanding)**

CO-4: Prepare individualized therapeutic plans based on diagnosis **(Cognition level: Apply)**

CO-5: 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) **(Cognition level: Understanding)**

Mapping of Course Outcomes (COs) with Program Outcomes (POs) and Program Specific Outcomes (PSOs)

	PO1	PO2	PO3	PO4	PO5	PO6	PO7	PO8	PO9	PO10	PO11	PSO1	PSO2	PSO3	PSO4
CO1	3			2					2		2			3	
CO2	3		3	3		2			2					3	
CO3	3	2	3	3	2				2		2			3	
CO4	3	2	3	2		2			2					3	
CO5	3	2	3	2					2					3	

Each Course Outcome (CO) may be mapped with one or more Program Outcomes (POs). Write '3' in the box for 'High-level'mapping, 2 for 'Medium-level'mapping, 1 for 'Low'-level'mapping.

Mapping with PSOs, where applicable.

Detailed Syllabus:

Etiopathogenesis and pharmacotherapy of diseases associated with following systems:

Unit I: Cardiovascular system **12Hrs**

Hypertension, Congestive cardiac failure, Acute coronary syndrome, Arrhythmias, Hyperlipidemias

Unit II: **12Hrs**

Respiratory system: Asthma, Chronic obstructive airways disease, Drug induced pulmonary diseases.

Endocrine system: Diabetes, Thyroid diseases

Unit III: **12Hrs**

Gastrointestinal system: Peptic ulcer diseases, Reflux esophagitis, Inflammatory bowel diseases, Jaundice &hepatitis

Unit IV: **12Hrs**

Gastrointestinal system: Cirrhosis, Diarrhea and Constipation, Drug-induced liver disease

Hematological diseases: Anemia, Deep vein thrombosis, Drug induced hematological disorders

Unit V: **12Hrs**

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

Reference Books:

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

Teaching-Learning Strategies in Brief

The teaching learning strategies, followed are board and chalk teaching, Learning through discussion among the peer group, classroom interaction, discussion of research papers of Journals related to topics, power point presentation, Q & A session and reflective learning.

Assessment methods and weightages in brief

There are two components of assessment: Internal assessment (25 marks) and End semester examination (75 marks). Internal assessment consists of continuous mode (10 marks) and sessional examinations (15 marks). There are two Sessional exams (each conducted for 30 marks and computed for 15 marks) and one improvement exam. The average marks of two best sessional exams are computed out of 15 marks. Continuous mode evaluation is of 10 marks comprising of attendance- 8 marks (calculated as: Percentage of Attendance: Allotment of marks- Less than 80: 0 marks; 80-84: 2 marks; 85-89: 4 marks; 90-94: 6 marks and 95-100: 8 marks) and Student-Teacher interaction: 2 marks.
Total Marks are 100 for the subject (Internal Assessment: 25 marks and End Semester Examination: 75 Marks).

…….

Name of the Academic Program: M Pharm Pharmacy Practice Semster I

Course Code: MPP 103 T

Title of the Course: Hospital and Community Pharmacy

L-T-P: 4-0-0 **Credits: 4**

(L=Lecture hours, T=Tutorial hours, P=Practical hours)

COURSE OUTCOMES (COs)

After completing this Course, the students should be able to:

CO-1: Understand the organizational structure of hospital pharmacy **(Cognitive Level: Understand)**

CO-2: Understand drug policy and drug committees **(Cognitive Level: Understand)**

CO-3: Know about procurement & drug distribution practices **(Cognitive Level: Knowledge)**

CO-4: Know the admixtures of radiopharmaceuticals **(Cognitive Level: Knowledge)**

CO-5: Understand the community pharmacy management **(Cognitive Level: Understand)**

CO-6: Apply various value added services in community pharmacies **(Cognitive Level: Apply)**

Mapping of Course Outcomes (COs) with Program Outcomes (POs) and Program Specific Outcomes (PSOs)

	PO1	PO2	PO3	PO4	PO5	PO6	PO7	PO8	PO9	PO10	PO11	PSO1	PSO2	PSO3	PSO4	PSO5
CO1	2		3	3	2	2	3			1		3	2			2
CO2		3	2	2		2	2	2	3	2	2	2	3	3	3	3
CO3		2	3	2	3		1	2				3	2			
CO4									3	3				3		
CO5					2	3	3	2	3		2	2	2	2	2	2
CO6	2	1		3				1	2		3	1	3	2	1	1

Each Course Outcome (CO) may be mapped with one or more Program Outcomes (POs). Write '3' in the box for 'High-level'mapping, 2 for 'Medium-level'mapping, 1 for 'Low'-level'mapping.

Mapping with PSOs, where applicable.

Detailed Syllabus:

UNIT I **12 Hrs**

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

UNIT II **12 Hrs**

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

UNIT III **12 Hrs**

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.

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.

UNIT IV **12 Hrs**

Prescription – Legal requirements & interpretation, prescription related problems

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

UNIT V **12 Hrs**

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

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

Teaching-Learning Strategies in Brief

The teaching learning strategies, followed are board and chalk teaching, Learning through discussion among the peer group, classroom interaction, discussion of research papers of Journals related to topics, power point presentation, Q & A session and reflective learning.

Assessment methods and weightages in brief

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Total Marks are 100 for the subject (Internal Assessment: 25 marks and End Semester Examination: 75 Marks).

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Name of the Academic Program: M. Pharm. (Pharmacy Practice)

Course Code: MPP 104T

Title of the Course: Clinical Research

L-T-P: 4-0-0 Credits: 4

(L=Lecture hours, T=Tutorial hours, P=Practical hours)

COURSE OUTCOMES (COs)

After completing this Course, the students should be able to:

CO-1: Understand, the new drug development process **(Cognitive level: Understand)**

CO-2: Understand the regulatory and ethical requirements for clinical drug development **(Cognitive level: Apply)**

CO-3: Design and plan the activities related to a clinical trial **(Cognitive level: Apply)**

CO-4: Understand and apply the concepts of safety monitoring in clinical studies **(Cognitive level: Analyze)**

CO-5: Manage and coordinate the clinical trials **(Cognitive level: Analyze)**

Mapping of Course Outcomes (COs) with Program Outcomes (POs) and Program Specific Outcomes (PSOs)

	PO1	PO2	PO3	PO4	PO5	PO6	PO7	PO8	PO9	PO10	PO11	PSO1	PSO2	PSO3	PSO4	PSO5
CO1	3									2	1	3		1	2	2
CO2	2		3			2					2					
CO3	1	3			3			1		2					3	
CO4	1		1	1		2	3					2		3		
CO5	1	3		2	3	1		3		1	2					3

Each Course Outcome (CO) may be mapped with one or more Program Outcomes (POs). Write '3' in the box for 'High-level'mapping, 2 for 'Medium-level'mapping, 1 for 'Low'-level'mapping.

Detailed Syllabus

Unit I **12Hr**

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.

Unit II: **12Hr**

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.

Unit III: **12Hr**

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

Unit IV: **12Hr**

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.

Unit V: **12Hr**

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.

Reference Books

1. Principles and practice of pharmaceutical medicine, Second edition. Authors:Lionel. D. Edward, Aadrew.J.Flether Anthony W Fos , Peter D SloaierPublisher:Wiley;
2. Handbook of clinical research. Julia Lloyd nd 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.

Teaching-Learning Strategies in Brief

The teaching learning strategies, followed are board and chalk teaching, Learning through discussion among the peer group, classroom interaction, discussion of research papers of Journals related to topics, power point presentation, Q & A session and reflective learning.

Assessment methods and weightages in brief

There are two components of assessment: Internal assessment (25 marks) and End semester examination (75 marks). Internal assessment consists of continuous mode (10 marks) and sessional examinations (15 marks). There are two Sessional exams (each conducted for 30 marks and computed for 15 marks) and one improvement exam. The average marks of two best sessional exams are computed out of 15 marks. Continuous mode evaluation is of 10 marks comprising of attendance- 8 marks (calculated as: Percentage of Attendance: Allotment of marks- Less than 80: 0 marks; 80-84: 2 marks; 85-89: 4 marks; 90-94: 6 marks and 95-100: 8 marks) and Student-Teacher interaction: 2 marks.

Total Marks are 100 for the subject (Internal Assessment: 25 marks and End Semester Examination: 75 Marks).

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Name of the Academic Program: M. Pharm. (Pharmacy Practice)

Course Code: MPP 105P

Title of the Course: Pharmacy Practice Practical -I

L-T-P: 0-0-12 Credits: 6

(L=Lecture hours, T=Tutorial hours, P=Practical hours)

COURSE OUTCOMES (COs)

After completing this Course, the students should be able to:

CO-1: Understand treatment chart and Laboratory Data at tertiary care level setting **(Cognitive level: Understand)**

CO-2: Conduct Patient medication history interview and counselling **(Cognitive level: Apply)**

CO-3: Understand and answer drug information and poison information query **(Cognitive level: Apply)**

CO-4: Review Pharmaceutical Care Plan **(Cognitive level: Analyze)**

CO-5: Develop content for the hospital and patient information leaflets for pharmaceutical products **(Cognitive level: Create)**

CO-6: Develop study protocol and informed consent form for a clinical study **(Cognitive level: Create)**

Mapping of Course Outcomes (COs) with Program Outcomes (POs) and Program Specific Outcomes (PSOs)

	PO1	PO2	PO3	PO4	PO5	PO6	PO7	PO8	PO9	PO10	PO11	PSO1	PSO2	PSO3	PSO4	PSO5
CO1	3			2							1		3	2	2	
CO2	2	2	3				3		3			2	3			3
CO3	2			3		3		3		2	2	2		3		3
CO4	3		2		2								3			2
CO5	1															
CO6		3	3		3	2				3	3	3	2		3	

Each Course Outcome (CO) may be mapped with one or more Program Outcomes (POs). Write '3' in the box for 'High-level'mapping, 2 for 'Medium-level'mapping, 1 for 'Low'-level'mapping.

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)

Teaching-Learning Strategies in Brief

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Assessment methods and weightages in brief

There are two components of assessment: Internal assessment (25 marks) and End semester examination (75 marks). Internal assessment consists of continuous mode (10 marks) and sessional examinations (15 marks). There are two Sessional exams (each conducted for 30 marks and computed for 15 marks) and one improvement exam. The average marks of two best sessional exams are computed out of 15 marks. Continuous mode evaluation is of 10 marks comprising of attendance- 8 marks (calculated as: Percentage of Attendance: Allotment of marks- Less than 80: 0 marks; 80-84: 2 marks; 85-89: 4 marks; 90-94: 6 marks and 95-100: 8 marks) and Student-Teacher interaction: 2 marks.

Total Marks are 100 for the subject (Internal Assessment: 25 marks and End Semester Examination: 75 Marks).

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M.PHARM. SEMESTER II	
Course Code MPP201T	**Title of the course: Principles of Quality use of Medicines (Theory)**
Course Code: MPP202T	**Title of the Course: Pharmacotherapeutics - II (Theory)**
Course Code: MPP203T	**Title of the Course: Clinical Pharmacokinetics and Therapeutic Drug Monitoring (Theory)**
Course Code: MPP204T	**Title of the Course: Pharmacoepidemiology & Pharmacoeconomics (Theory)**
Course Code: MPP205P	**Title of the Course: Pharmacy Practice Practical II**

Name of the Academic Program: M. Pharm. Pharmacy Practice

Course Code: MPP-201T

Title of the Course: Principles of Quality Use of Medicines (Theory)

L-T-P: 3-1-0 Credits: 04

(L=Lecture hours, T=Tutorial hours, P=Practical hours)

COURSE OUTCOMES (COs)

After completing this Course, the students should be able to:

CO-1: Understand the principles of quality use of medicines **(Cognitive level: Understand)**

CO-2: Know the benefits and risks associated with use of medicines **(Cognitive level: Evaluate)**

CO-3: Understand regulatory aspects of quality use of medicines **(Cognitive level: Understand)**

CO-4: Identify and resolve medication related problems **(Cognitive level: Analyse)**

CO-5: Promote quality use of medicines **(Cognitive level: Apply)**

CO-6: Practice evidence-based medicines **(Cognitive level: Apply)**

Mapping of Course Outcomes (COs) with Program Outcomes (POs) and Program Specific Outcomes (PSOs)

	PO1	PO2	PO3	PO4	PO5	PO6	PO7	PO8	PO9	PO10	PO11	PSO1	PSO2	PSO3	PSO4	PSO5
CO1	3	1	1	1	1	3	3	2	3	1	3		3	3		3
CO2	3	1	1	1	1	2	3	1	3	1	3	3	3	3		3
CO3	1	2	1	1	1	2	3	1	3	1	2	3	3	3	1	3
CO4	3	3	3	2	1	2	1	2	3	1	2	3	3	3		2
CO5	1	3	1	2	3	3	2	3	3	1	2	3	2	3		2
CO6	3	3	2	2	3	3	2	3	3	1	3	3	3	2		2

Each Course Outcome (CO) may be mapped with one or more Program Outcomes (POs).
Write '3' in the box for 'High-level' mapping, 2 for 'Medium-level' mapping, 1 for 'Low'-level' mapping.
Mapping with PSOs, where applicable.

Detailed Syllabus:

Unit I: Introduction to Quality use of medicines (QUM) 12Hrs

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.

Unit II: Concepts in QUM 12Hrs

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.

Unit III: QUM in various settings **12Hrs**

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.

Unit IV: Regulatory aspects of QUM in India **12Hrs**

Regulation including scheduling, Regulation of complementary medicines, Regulation of OTC medicines, Professional responsibility of pharmacist, Role of industry in QUM in medicine development.

Unit V **12Hrs**

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.

Reference Books

1. A Textbook of Clinical Pharmacy Practice – Essential concepts and skills – Parthasarathi G, Karin Nyfort-Hansen and MilapNahata
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.

Teaching-Learning Strategies in Brief

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Total Marks are 100 for the subject (Internal Assessment: 25 marks and End Semester Examination: 75 Marks).

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Name of the Academic Program: M Pharm Pharmacy Practice Semester II

Course Code: MPP 202 T

Title of the Course: Pharmacotherapeutics II

L-T-P: 4-0-0 **Credits: 4**

(L=Lecture hours, T=Tutorial hours, P=Practical hours)

COURSE OUTCOMES (COs)

After completing this Course, the students should be able to:

CO-1: Describe and explain the rationale for drug therapy **(Cognitive Level: Understand)**

CO-2: Summarize the therapeutic approach for management of various disease conditions including reference to the latest available evidence **(Cognitive Level: Understand)**

CO-3: Discuss the clinical controversies in drug therapy and evidence based medicine **(Cognitive Level: Understand)**

CO-4 : 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) **(Cognitive Level: Knowledge)**

CO-5: Prepare individualized therapeutic plans based on diagnosis **(Cognitive Level: Apply)**

Mapping of Course Outcomes (COs) with Program Outcomes (POs) and Program Specific Outcomes (PSOs)

	PO1	PO2	PO3	PO4	PO5	PO6	PO7	PO8	PO9	PO10	PO11	PSO1	PSO2	PSO3	PSO4	PSO5
CO1	3	2	3	1	2			3			3	3	3	3	2	3
CO2	3	3	2			3		2	2	2		2	3	2	1	2
CO3	2	3	1				3	3	1		2	3	2	2	3	3
CO4	3	3	2	3	2		3	1	2			1	3	3	1	3
CO5	3	3	3	3	1	3	3	2	3	1	3	2	3	3	3	3

Each Course Outcome (CO) may be mapped with one or more Program Outcomes (POs). Write '3' in the box for 'High-level'mapping, 2 for 'Medium-level'mapping, 1 for 'Low'-level'mapping.

Mapping with PSOs, where applicable.

Detailed Syllabus:

UNIT I **12 Hrs**

Nervous system: Epilepsy, Parkinson's disease, Stroke, Headache, Alzheimer's disease, Neuralgias and Pain pathways and Pain management.

UNIT II **12 Hrs**

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

UNIT III **12 Hrs**

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.

UNIT IV **12 Hrs**

Infectious diseases: Meningitis, HIV and opportunistic infections, Rheumatic fever, Dengue fever, H1N1, Helmenthiasis, Fungal infections, Gynecological disorders: Dysmenorrhea, Hormone replacement therapy.

UNIT 5 **12 Hrs**

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

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

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Total Marks are 100 for the subject (Internal Assessment: 25 marks and End Semester Examination: 75 Marks).

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Name of the Academic Program: M. Pharm. (Pharmacy Practice)

Course Code: MPP 203T

Title of the Course: Clinical Pharmacokinetics and Therapeutic Drug Monitoring

L-T-P: 4-0-0 Credits: 4

(L=Lecture hours, T=Tutorial hours, P=Practical hours)

COURSE OUTCOMES (COs)

CO-1: Design drug dosage regimen for individualised therapy **(Cognitive level: Apply)**

CO-2: Understand and analyze the correlation between plasma drug concentrations and therapeutic outcome **(Cognitive level: Analyze)**

CO-3: Recommend dose adjustment for special population **(Cognitive level: Apply)**

CO-4: Understand and recommend management of pharmacokinetic interactions and therapeutic level in patients with genetic polymorphism **(Cognitive level: Evaluate)**

CO-5: Carry out pharmacokinetic modelling using the principles of pharmacometrics **(Cognitive level: Analyze)**

Mapping of Course Outcomes (COs) with Program Outcomes (POs) and Program Specific Outcomes (PSOs)

	PO1	PO2	PO3	PO4	PO5	PO6	PO7	PO8	PO9	PO10	PO11	PSO1	PSO2	PSO3	PSO4	PSO5
CO1	1			2	3			2	1		2	2				3
CO2	2												3			
CO3	3	3	1	2	2		3						3	2		
CO4	3		2			2		2	3				1			1
CO5	2			3	3						2					3

Each Course Outcome (CO) may be mapped with one or more Program Outcomes (POs). Write '3' in the box for 'High-level'mapping, 2 for 'Medium-level'mapping, 1 for 'Low'-level'mapping.

Detailed Syllabus:

Unit I **12Hr**

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.

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

Unit II **12Hr**

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.

Unit III **12Hr**

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.

Unit IV **12Hr**

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.

Unit V **12Hr**

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.

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. Iippincott 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. Iippincott Williams & Wilkins, USA.
8. Evans, Schentag, Jusko. Applied pharmacokinetics. American Society of Health system Pharmacists, USA.
9. Michael E. Winter. Basic Clinical Pharmacokinetics. Iippincott 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.

Relevant review articles from recent medical and pharmaceutical literature

Teaching-Learning Strategies in Brief

The teaching learning strategies, followed are board and chalk teaching, Learning through discussion among the peer group, classroom interaction, discussion of research papers of Journals related to topics, power point presentation, Q & A session and reflective learning.

Assessment methods and weightages in brief

There are two components of assessment: Internal assessment (25 marks) and End semester examination (75 marks). Internal assessment consists of continuous mode (10 marks) and sessional examinations (15 marks). There are two Sessional exams (each conducted for 30 marks and computed for 15 marks) and one improvement exam. The average marks of two best sessional exams are computed out of 15 marks. Continuous mode evaluation is of 10 marks comprising of attendance- 8 marks (calculated as: Percentage of Attendance: Allotment of marks- Less than 80: 0 marks; 80-84: 2 marks; 85-89: 4 marks; 90-94: 6 marks and 95-100: 8 marks) and Student-Teacher interaction: 2 marks.
Total Marks are 100 for the subject (Internal Assessment: 25 marks and End Semester Examination: 75 Marks).

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Name of the Academic Program: M Pharm Pharmacy Practice Semester II

Course Code: MPP 204 T

Title of the Course: Pharmcoepidemilogy & Pharmacoeconomics

L-T-P: 4-0-0 **Credits: 4**

(L=Lecture hours, T=Tutorial hours, P=Practical hours)

COURSE OUTCOMES (COs)

After completing this Course, the students should be able to:

CO-1: Understand the various epidemiological methods and their applications **(Cognitive Level: Understand)**

CO-2: Understand the fundamental principles of Pharmacoeconomics. **(Cognitive Level: Understand)**

CO-3: Identify and determine relevant cost and consequences associated with pharmacy products and services. **(Cognitive Level: Knowledge)**

CO-4: Understand the applications of Pharmacoeconomics to various pharmacy settings. **(Cognitive Level: Understand)**

CO-5: Understand the Pharmacoeconomic decision analysis methods and its applications. **(Cognitive Level: Understand)**

CO-6: Describe current Pharmacoeconomic methods and issues. **(Cognitive Level: Knowledge)**

CO-7: Perform the key Pharmacoeconomics analysis methods **(Cognitive Level: Apply)**

Mapping of Course Outcomes (COs) with Program Outcomes (POs) and Program Specific Outcomes (PSOs)

	PO1	PO2	PO3	PO4	PO5	PO6	PO7	PO8	PO9	PO10	PO11	PSO1	PSO2	PSO3	PSO4	PSO5
CO1	2	3	2	3	1	3	1		3	2	2	3	2	3	2	3
CO2	1			3		2		2					2			2
CO3	1	1		3			3	1		1	1	2		1		2
CO4				3	2	3			1				1		2	2
CO5			1	3							2	1				3
CO6				3		1		3								2
CO7	1	2	2	3	1		3		3	2	3	3	3	1	1	2

Each Course Outcome (CO) may be mapped with one or more Program Outcomes (POs). Write '3' in the box for 'High-level'mapping, 2 for 'Medium-level'mapping, 1 for 'Low'-level'mapping.**Mapping with PSOs, where applicable**.

Detailed Syllabus:

UNIT I **12 Hrs**

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

UNIT II **12 Hrs**

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

UNIT III **12 Hrs**

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.

UNIT IV **12 Hrs**

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).

UNIT V **12 Hrs**

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.

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

Teaching-Learning Strategies in Brief

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Assessment methods and weightages in brief

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Total Marks are 100 for the subject (Internal Assessment: 25 marks and End Semester Examination: 75 Marks).

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Name of the Academic Program: M. Pharm. (Pharmacy Practice)

Course Code: MPP 205P,

Title of the Course: Pharmacy Practice Practical -II

L-T-P: 0-0-12 Credits: 6

(L=Lecture hours, T=Tutorial hours, P=Practical hours)

COURSE OUTCOMES (COs)

After completing this Course, the students should be able to:

CO-1: Understand, identify, collate and report Adverse Drug Reactions **(Cognitive level: Apply)**

CO-2: Identify and report medication errors **(Cognitive level: Apply)**

CO-3: Understand the concept of bioavailability and bioequivalence and apply it to the clinical studies **(Cognitive level: Evaluate)**

CO-4: Develop and Review Pharmaceutical Care Plan **(Cognitive level: Analyze)**

CO-5: Carry out therapeutic drug monitoring and suggest dose adjustments **(Cognitive level: Analyze)**

CO-6: Carry out cost benefit analysis based on principles of pharmacoeconomics and outcome research **(Cognitive level: Evaluate)**

Mapping of Course Outcomes (COs) with Program Outcomes (POs) and Program Specific Outcomes (PSOs)

	PO1	PO2	PO3	PO4	PO5	PO6	PO7	PO8	PO9	PO10	PO11	PSO1	PSO2	PSO3	PSO4	PSO5
CO1	3			2		2	2	2	3	2	1	2		3		
CO2	2		1				1		1	1				3		2
CO3	2	2		3											3	1
CO4	2				2	1		3			2	3	2			2
CO5	2	1		1	2			1					3	1		
CO6	1	2	3	3			2			3	2		1		2	

Each Course Outcome (CO) may be mapped with one or more Program Outcomes (POs). Write '3' in the box for 'High-level'mapping, 2 for 'Medium-level'mapping, 1 for 'Low'-level'mapping.

Detailed Syllabus

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)

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Total Marks are 100 for the subject (Internal Assessment: 25 marks and End Semester Examination: 75 Marks).

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