ANDHRA UNIVERSITY

MASTER OF PHARMACY

(2020)

Regulations and Syllabus

Four semester pattern

With effect from 2020-21

M.PHARM (2020) REGULATIONS AND SYLLABUS

INDEX:

1. Admission, instruction and attendance

The degree of Master of Pharmacy of the Andhra University will be conferred on a candidate who has satisfied the following conditions:

The candidate must have passed the B.Pharm. Degree examination of this University or B.Pharm. Degree examinations of any other University recognized by the Academic Council as equivalent thereto in First or Second class; and must have qualified in any entrance examination, if prescribed.

Every student, selected for admission to PG 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.

The candidate should have undergone a regular course of study as prescribed hereunder extending over a period of four semesters, ordinarily consecutive, and satisfied the academic requirements as prescribed hereinafter. The course of instruction and periods of study shall be as given in the scheme of instruction and in the syllabus.

The subjects of specializations for Master of Pharmacy Course shall be as follows:

1. Pharmaceutical Analysis
2. Pharmaceutical Chemistry
3. Pharmaceutics
4. Pharmaceutical Biotechnology
5. Pharmacology
6. Pharmacognosy
7. Pharmaceutical Regulatory Affairs
8. Pharmaceutical Quality Assurance
9. Industrial Pharmacy
10. Pharmacy Practice

Instruction and examination in each academic year is spread over two semesters with a minimum of 96 working days in each semester (192 in any given academic year). The odd semesters shall be conducted from the month of July to November and the even semesters shall be conducted from the month of December to April.

Each period of instruction is of 45 minutes duration. Eight periods of instruction are provided on each day and there are six working days in a week (Monday to Saturday).

Attendance Requirements: A regular course of study during an academic semester means a minimum of average attendance of 80% of all the courses of the semester computed by totaling the number of periods of lectures and practicals, as the case may be, held in every course. In special cases where sufficient causes were shown, the Vice-

Chancellor may on the recommendation of the Principal concerned condone the deficiency in the average attendance to an extent of 9% for reasons such as ill health, if the application for condonation is submitted at the time of actual illness and is supported by certificate of; authorized Medical officer approved by the Principal. However, in the case of students, who participate in activities like N.S.S., N.C.C., Inter-Collegiate tournaments conducted by Andhra University, Inter-University tournaments conducted by Inter-university Board and any such other activities involving the representation of the College/University with the prior approval of the principal, the candidate may be deemed to have attended the college during the period solely for the purpose of the examination.

A candidate who cannot satisfy the attendance requirements in clause 1.5 because of late admission under special circumstances reasonable and acceptable to the University on the basis of document, shall fulfill the following conditions; Average attendance: A candidate shall have attended at least a total of 90% of the periods-lectures/practicals as the case may be held from the date of admission and also shall attend at least 50% ofthe total working days during that academic semester (Late admission means, admissions made after 45 days from date of commencement of the academic semester for the course).

If any candidate fails to satisfy the regulation under 1.5 or 1.6 she/he shall not be allowed for the University Examinations at the end of the semester, and he/she shall not be allowed for promotion to the next higher class of study. He/she shall be required to repeat the regular course of study of that academic semester along with the next regular batch.

A regular record of attendance 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.

2. Examinations – Internal assessment and Semester-end

Assessment for the award of degree shall consists of (a) internal assessment for 30 marks in each of the theory and practical courses separately. (b) Semester-end examination as detailed in the scheme of examination for 70 marks in each of the theory and practical separately.

Regulations concerning internal assessment: Internal assessment consist of continuous mode (10 marks for theory and 15 marks for practical) and sessional examinations (20 marks for theory and 15 marks for practical)

Scheme for awarding continuous mode marks for theory and practical

Theory-Criteria	**Marks**
Attendance	5
Student-Teacher Interaction	5
Theory sessional examination	20
Total theory internal assessment	**30**
Practical-Criteria	
Attendance	5
Record + Viva-voce	10
Practical sessional examination	15
Total practical internal assessment	**30**

Guidelines for the allotment of marks for attendance

Percentage of Attendance	Theory/Practical
95 -100	5
90-94	4
85-89	3
80-84	2
Less than 80	0

Guidelines for allotment of marks for Student-Teacher interaction

The teacher shall create some interactive sessions for theory topics and every student shall interact on the given topic relating to its application in pharmacy. The teacher should assess the student capacity for understanding of the concept taught. It shall not be like seminars.

Guidelines for allotment of marks Record + Viva-voce

The teacher should conduct viva-voce at the end of each practical and evaluate the record on continuous mode and shall award these marks.

2.2.4. Guidelines for sessional examinations

Two sessional examinations shall be conducted for each theory/practical course. The average marks of the two shall be computed.

The teacher who teaches the subject shall ordinarily to be the internal examiner.

There shall be no provision for the improvement of the sessional marks.

There is no minimum mark prescribed for sessional examination for pass in the end semester examination.

If any student is absent for a single or both sessional examinations, the candidate will be awarded "ZERO" in the respective examination.

The theory average sessional mark shall be finally computed for 20 marks and average practical sessional mark shall be finally computed for 15 marks.

Regulations concerning M.Pharm I and II semester evaluation pattern:

There shall be one semester end examination in each theory course based on the question paper set by an external paper setter and there shall be single valuation. There shall be one semester end examination in each practical course as per the scheme of examination and valuation shall be done by examiner. The duration of the practical examination is of 6 hours as prescribed.

However the student may apply for revaluation of any subject in theory papers after declaring the results as per University examination guide lines.

Seminar

A seminar at the end of first and second semesters is separately conducted keeping in view of the enrichment of required communication, presentation and explanatory skills. A minimum of four seminars shall be given during the semester before the Program Committee and other students and documented separately for record in a Semester Seminar Register.

Comprehensive viva

At the end of II Semester comprehensive viva will be conducted for all the subjects

covering the theory subjects of I & II semesters by the external examiner and eligible internal examiners (at least two from the college) who taught these subjects. The candidate should obtain minimum of 50% marks for passing the examination.

Journal Club

In case of Journal Club, based on the research proposal, each student shall collect a minimum of 5 research papers (published in a reputed journal with impact factor of Thomson & Reuters of not less than 1.0) and should discuss in a Programme Committee (consisting of Head of the Department, Research Supervisor and other Senior faculty members) and documented separately for record in a Journal Club Register.

A student shall be eligible to carry forward all the courses of I, II semesters. However, he/she shall not be eligible to attend the courses of IV semester until the candidate clears III semester Midterm Project Review.

Regulations concerning M. Pharm. III and IV Semester evaluation pattern:

Evaluation of the seminar on the objectives and work plan of the proposed project is to be completed within one month from the commencement of the project date with three examiners from the same college consisting of research guide, another teacher in the concerned specialization and third teacher from different specialization. These teachers must fulfill the eligibility criteria laid down in Section 3.

Evaluation of the M.Pharm III Semester Mid-term project review and seminar on selected topic will be done by the research guide and external examiner. The seminar on the selected topic shall not be the one connected with the topic of the thesis work but should be related to concerned specialization.

A candidate shall submit four copies of his/her thesis either printed or typed, embodying the results of research work done by him under direction of an approved research director following the specific guidelines as stipulated under Section 5. All the candidates must submit their thesis within the prescribed date as per the academic calendar.

The thesis submitted by the candidate shall be examined by a Board of Examiners consisting of an External Examiner and the research director and shall have to be approved after holding a viva voce examination to test the knowledge of the candidate in the subject. The thesis will be evaluated independently by the external examiner and research director and in case the difference between examiners is more than 20%, the thesis shall be sent to a second external examiner whose award shall be the final. The viva-voce examination will be jointly conducted both by the external examiner and research director. A candidate can re-submit the thesis in a revised form after further work, if required to do so.

A candidate desires of improving his/her class shall take either or both of the first two semesters as a whole.

Guidelines for writing the thesis

The thesis should have the following pages in order:

1. Title page highlighting the title, name of the candidate, reg. no., guide name, college name and month and year of submission.
2. The inner title page containing the same details on white background.
3. Certificate from the Head of the institution
4. Certificate from the Research Director
5. Certificate from the ethical committees for approval of study, if any

6. Declaration by the student
7. Acknowledgements
8. Index highlighting chapter titles and sections titles
9. Index for tables, figures and plates, if any
10. Abbreviations and symbols
11. Materials used in the investigation with their procurement details like name of the company, batch number etc.
12. Equipment used in the study with the model number and other details
13. The thesis should contain the following chapters:
    a) Aim and objectives of the investigation
    b) Introduction and literature survey
    c) Description: Methods and Materials, etc.
    d) Experimental work
    e) Results and discussion
    f) Summary and conclusions
    g) References (The references may be included at the end of each chapter or at the end of the thesis according to the convenience)

The thesis should be typed in times new roman in 12 font size with 1.5 line spacing from the beginning of the thesis including titles to the chapters and sections. Bold font may be used wherever necessary. The students are expected to follow scientific grammar for writing *in vivo* etc. which should be in italics.

The citation of references should be done carefully by citing the complete reference i.e. name of all the authors. Usage of et al. is not allowed in the citation of reference. The students are expected to give the primary references rather than secondary or higher levels of references. The presentation of reference must be in Vancouver style.

No code names or numbers are allowed to be written in the thesis for the materialsused in the project.

The examiners of thesis evaluation are expected to verify all this and appropriate corrections are to be made before conducting the viva-voce examination.

2.5.5 Project Work/IV Semester Assessment – Division of Marks:

Course 402 -Thesis Evaluation (Max. Marks – 150)

Criteria of Evaluation	**Marks**
Seminar/Presentation of work	20
Objective(s) of the work done	20
Methodology adopted	40
Results and Discussion	40
Conclusions and Outcomes	30
Total	**150**

The division of marks shall be clearly indicated for every candidate in the marks statement being sent to the University.

End Semester examinations

The End Semester examination for each theory, practical and other courses through

semesters I to IV shall be conducted by the University except for the subject with asterisk symbol (*) in the tables of the each specialization courses (Non University Examinations) for which examinations shall be conducted by the subject experts at college level and the marks/grades shall be submitted to the University. In case of theory examinations, the question paper of the corresponding subject shall be mailed (Official mail id) to the Controller of Examinations and Chairman, BOS with signature of the Head of the Institute in PDF format within twenty four hours after completion of the examination.

3. Eligibility criteria for appointment as examiner for M.Pharm examination

In order to eligible to be appointed as an internal examiner for the semester end examination in the respective specialization, a teacher shall have M. Pharm. or Ph.D. in the respective specialization with at least three years of M.Pharm teaching experience for the course concerned.

The eligibility of a teacher for guiding the M.Pharm III and IV semester project is as follows:

The teacher must have M.Pharm/Ph.D. in the respective specialization with an experience of minimum 3 years of Post Graduate teaching in the respective specialization.

The eligibility of such teachers qualified for guiding M.Pharm projects must be ratified by the Board of Studies before commencement of M.Pharm guidance.

The recognized M.Pharm guides are not eligible to guide more than **6** students in one academic year including joint guidance.

4. Regulations for pursuing M.Pharm III and IV Semester project

Students desirous of pursuing M.Pharm III and IV semester projects outside college are required to get the approval from the college before one month from the commencement of the project work. The research work can be carried out in a GMP compliant industry (as approved by WHO, USFDA etc.) and Central research laboratories like IICT, CDRI, NIH etc. or DSIR and Drug Control Administration recognized laboratories. A certificate to that effect must be incorporated in the M.Pharm thesis indicating the duration of stay. If the duration of stay is less than nine months the remaining period of stay in the college should be certified by the research supervisor and the Principal.

All the students should present a seminar on the objectives of their work, work plan, etc. within one month from the commencement of the project. The students should attend a mid-term review seminar in the presence of a committee consisting of one external examiner, research director. The suggestions made by the committee are to be taken into consideration for further work and should be presented in the thesis.

5. Declaration of results and classification:

A candidate shall be declared to have passed the examination held at the end of each semester if obtains i) not less than 40% in the each theory and 50% in each practical, seminar, comprehensive viva, thesis and thesis viva-voce at the end of each semester end examination and ii) an aggregate of 50% of all examinations of that semester including sessoinals. There are no minimum marks prescribed for sessional examination.

A candidate who has successfully completed the examination in a course by securing not less than 50% of marks shall not be permitted to retake the examination in that course.

A candidate who fails to secure 50% of marks on the aggregate but secures 50% or

more in some courses and between 40-49% in the other courses, he/she shall be required to retake the semester and supplementary examination in one or more of the courses in which he/she secures less than 50% of marks as per his/her choice to satisfy the requirement of 50% aggregate.

Declaration of class

The classes 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

6. Grading system:

Appropriate letter grades are awarded in each theory and practical subject to only such candidates who have passed in the university examinations. Internal assessment marks and university examination marks put together will be taken into account for the letter grading system in each subject separately.

A candidate registered for the university examination but fails to appear or fails to scorethe minimum required 40% marks in the university examination will get a grade 'F', indicating failure or grade of incompletion.

A subject successfully completed cannot be repeated. Final evaluation of each subject (theory and practical separately) will be carried out on a 10- point grading system corresponding to the marks obtained in that subject. Each subject letter grade is converted into a specific grade value associated with the letter grade as given below (Table).

Grading of performances

Based on the performance, 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 below.

10-Point grading system

Percentage of marks	Grade	Grade points
90.00 - 100	O	10.0
80.00 - 89.99	A	9.0
70.00 – 79.99	B	8.0
60.00 – 69.99	C	7.0
50.00 – 59.99	D	6.0
40.00 – 49.99	E	5.0
< 40.00	F (Fail)	0.0
The grade W represents failure due to insufficient attendance in the semester or year	W	0.0
Incomplete (subsequently to be changed into pass or E or O or F grade in the same semester)	I	0.0

6.5 The Semester grade point average (SGPA):

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

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

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

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

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

The credits allotted to each course are given in the respective specialization **Tables 1-10**.

6.6. Cumulative Grade Point Average (CGPA)

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

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

Where C_1,C_2,C_3, C4.... is the total number of credits for semester I, II, III and IV and S1, S2, S3 and S4 are the SGPA of semester I, II, III and IV.

7. Guidelines for paper setting and model papers.

Guidelines for theory paper setting for semester end examinations

The semester end question paper in each theory course is to be set for a total of 70 marks by an external paper setter as per the general model given below.

Question paper consists of 5 questions each carrying 5 marks out of which 4 questions are to be answered by the candidate and 7 questions each carrying 10 marks out of which 5 questions are to be answered by the candidate for a total of 70 marks. Each main question may contain subsections like a, b, c etc.

The questions given should be spread over the entire syllabus in an even manner covering all the units as per the pattern of the question paper given below.

Model question paper for theory course:

Course No.

Specialization Name:

Title of the course:

Time: 3 Hours **Max. Marks: 70**

Part A (Question Numbers 1-5)

Answer any **four** questions out of five questions 4X5=20

One question has to be set from each unit.

Part B

Answer any **five** questions out of **seven** questions (Question Numbers 6-12) 5X10=50

Five questions are to be set from five units and the remaining two should cover at least four out of five units. The main questions may contain sub question like 6(a), 6(b) etc.

Guidelines for practical paper setting for semester end examination

The question paper in each semester end practical examination is to be set jointly by two examiners and evaluated, one external and one internal as per the general model provided below.

Model question paper for practical course:

Course No.

Title of the course

Time: 6 hrs.

1. Synopsis	10 marks
2. Major experiment	30 marks
3. Minor experiment	20 marks
4. Viva voce	10 marks
	Total: 70 marks

Guidelines for theory/practical sessional examination paper setting:

Question paper pattern for theory Sessional examinations

Max. Marks: 30

Time: 2 Hours

Part A

Answer any **two** questions out of three questions 2X5=10

Part B

Answer any **two** questions out of three questions 2X10=20

Each of the sessional examination question paper should cover at least half the units of the syllabus.

Question paper pattern for practical sessional examinations

Max. Marks: 30

Time: 4 hours

1. Synopsis	5 Marks
2. Experiment	20 Marks
3. Viva	5 Marks
	Total: 30 Marks

Table 10: Pharmacy Practice (MPP)

Code	Course	Credits	Hours/ week	Internal Assessment			Semester End Exam	Total
				Continuous mode	Sessional Exam	Total		
I Semester								
MPP 101T	Clinical Pharmacy Practice	4	4	10	20	30	70	100
MPP 102T	Pharmacotherapeutics I	4	4	10	20	30	70	100
MPP 103T	Hospital & Community Pharmacy	4	4	10	20	30	70	100
MPP 104T	Clinical Research	4	4	10	20	30	70	100
MPP 105P	Pharmacy Practice Practical - I	2	6	15	15	30	70	100
MPP 106P	Pharmacy Practice Practical - II	2	6	15	15	30	70	100
MPP 107	Seminar*	2	4	50	---	---	---	50
	Total	**22**	**32**	**---**	**---**	**---**	**---**	**650**
II Semester								
MPP 201T	Principles of Quality Use of Medicines	4	4	10	20	30	70	100
MPP 202T	Pharmacotherapeutics - II	4	4	10	20	30	70	100
MPP 203T	Clinical Pharmacokinetics and Therapeutic Drug Monitoring	4	4	10	20	30	70	100
MPP 204T	Pharmacoepidemiology & Pharmacoeconomics	4	4	10	20	30	70	100
MPP 205P	Pharmacy Practice Practical - III	2	6	15	15	30	70	100
MPP 206	Comprehensive Viva	2	---	---	---	---	---	50
MPP 207	Seminar*	2	2	50	---	---	---	50
	Total	**22**	**26**	**---**	**---**	**---**	**---**	**600**

Table 10: Pharmacy Practice (MPP) continued

III Semester								
MRM 301T	Research Methodology and Biostatistics*	2	4	10	20	30	70	100
MPP 302	Journal Club*	2	2	50	---	---	---	50
MPP 303	Discussion /Presentation (Dissertation Title & Project Proposal)*	2	---	50	---	---	---	50
MPP 304	Seminar on selected topic	4	4	---	---	---	100	100
MPP 305	Research Work Progress (Mid Term Report)	10	20	---			200	100
	Total:	**20**	**30**	**---**	**---**	**---**	---	**400**
IV Semester								
MPP 401	Journal Club*	2	2	50	**---**	**---**	---	50
MPP 402	Thesis evaluation	12	20	---	**---**	**---**	150	150
MPP 403	Thesis viva	4	---	---	**---**	**---**	50	50
	Total:	**20**	**22**	**---**	**---**	**---**	---	**250**

* Non-University Examination

PHARMACY PRACTICE

PROGRAM OUTCOMES

The program outcomes of Pharmacy practice are designed to

PO1: Make learner to know about the organization structure of the hospital

PO2: Make learner to understand the organizational structure and functions of hospital pharmacy

PO3: Make the learner aware of various drug policies in drug committees and their functions

PO4: Make the learner in acquiring the skills of reading and understanding the prescription

PO5: Make learner to know about the importance of safety monitoring and reporting in clinical trials

PO6: Make learner to understand the responsibilities of various stakeholders involved in clinical trials

PO7: Make learner to understand the importance and application of epidemiology in pharmacy

PO8: Make learner to understand the importance and application of health economics in pharmacy services

PO9: Help learner to Understand the Pharmacoeconomic decision analysis methods and its applications

PO10: Make learner to identify the patient specific parameters relevant in initiating drug therapy, and monitoring therapy

PO11: Make learner to Recommend dosage adjustment for paediatrics and geriatrics

PO12: Make learner to discuss the clinical controversies in drug therapy and evidence-based medicine

PROGRAM SPECIFIC OUTCOMES

After completion of the program, the outcomes are framed to

PSO1: Make learner to understand about the various methods of drug distribution in hospital and effective implementation of the same in hospital settings

PSO2: Make learner to understand the various ethical principles in conducting the biomedical research

PSO3: Make learner in understanding of various regulatory requirements for conduct of clinical trials in human participants

PSO4: Help learner to therapeutic approach for management of various disease conditions including reference to the latest available evidence

PSO5: Assist the learner in participation in evidence-based approach

PROGRAM EDUCATIONAL OBJECTIVES

Upon completion of the program, the objectives will

1. Make learner in understanding the legal requirements and functioning of drug store

2. Enhance the skills of ward round participation and effective communication for collaboration with healthcare professionals for doing their job better
3. Make learner to identify various sources of drug information and helps in information retrieval
4. Make learner to understand the elements of Pharmaceutical Care and provide comprehensive patient care services

M. PHARM PHARMACY PRACTICE

Subject: Clinical Pharmacy Practice

Subject Code: (MPP101T)

Course Outcomes:

1. Make learner to understand the elements of Pharmaceutical Care and provide comprehensive patient care services.
2. Make learner to acquire the skills to Interpret the laboratory results to aid the clinical diagnosis of various disorders.
3. Make learner in active participation of providing Drug Information Services to healthcare professionals and to customers.
4. Make learner to identify various sources of drug information and helps in information retrieval.
5. Engage learner in active participation of providing poison information.
6. Make learner to understand the importance of Pharmacovigilance, Hemovigilance and Materiovigilance.
7. Enhance the skills of ward round participation and effective communication for collaboration with healthcare professionals for doing their job better.
8. Make learner in engagement of efficient patient management by maximum utilization of clinical pharmacy services.

M. PHARM PHARMACY PRACTICE

Subject: Pharmacotherapeutics-I

Subject Code: (MPP102T)

Course Outcomes:

1. Make learner to know about the aetiology of various diseases associated with Cardiovascular, Respiratory, Gastrointestinal, Endocrine and Haematological Systems.
2. Make learner to understand the pathophysiology of various diseases associated with Cardiovascular, Respiratory, Gastrointestinal, Endocrine and Haematological Systems.
3. Make learner in participation of promotion of the rational drug therapy.
4. Help learner to therapeutic approach for management of various disease conditions including reference to the latest available evidence.
5. Make learner to discuss the clinical controversies in drug therapy and evidence based medicine.
6. Make learner to Prepare individualized therapeutic plans based on diagnosis.
7. Make learner to identify the patient specific parameters relevant in initiating drug therapy, and monitoring therapy.
8. Help learner in selection of optimal therapeutic regimen and also in selection of alternative therapeutic approach to the patient according to their clinical needs.

M. PHARM PHARMACY PRACTICE

Subject: Hospital and Community Pharmacy

Subject Code: (MPP103T)

Course Outcomes:

1. Make learner to know about the organization structure of the hospital.
2. Make learner to understand the organizational structure and functions of hospital pharmacy.
3. Make the learner aware of various drug policies in drug committees and their functions.
4. Make learner in active participation of effective drug procurement practices.
5. Make learner to understand about the various methods of drug distribution in hospital and effective implementation of the same in hospital settings.
6. Make learner to acquire skills in safe administration of radiopharmaceuticals.
7. Make learner in understanding the legal requirements and functioning of drug store.
8. Make learner in effective participation of community pharmacy services.
9. Make the learner in acquiring the skills of reading and understanding the prescription.

M. PHARM PHARMACY PRACTICE

Subject: Clinical Research

Subject Code: (MPP104T)

Course Outcomes:

1. Make learner to know about the drug development process and its importance in pharmaceutical industry.
2. Make learner to understand the various ethical principles in conducting the biomedical research.
3. Make the learner to overcome the various challenges in practicing the ethical concerns in conducting the biomedical research.
4. Make learner in understanding of various regulatory requirements for conduct of clinical trials in human participants.
5. Learner shall appreciate and conduct the clinical trial activities.
6. Make learner in better understanding of various phases and various clinical study designs.
7. Make learner to improve the knowledge on management of clinical trial coordination process.
8. Make learner to know about the importance of safety monitoring and reporting in clinical trials.
9. Make learner to understand the responsibilities of various stakeholders involved in clinical trials.

M. PHARM PHARMACY PRACTICE

Subject: Principles of Quality Use of Medicines

Subject Code: (MPP201T)

Course Outcomes:

1. Make learner to understand the principles of quality use of medicines.
2. Make learner to know the importance of practice of quality use of medicines.
3. Guide learner in effective participation in promotion of rational drug therapy.
4. Assist the learner in participation in evidence based approach.
5. Make learner aware of benefits and risks associated with use of medicines.
6. Make learner to understand the regulatory aspects of quality use of medicines.
7. Engage learner in identification and management of medication errors.
8. Help learner in establishment and promotion of quality use of medicine approaches at various settings.

M. PHARM PHARMACY PRACTICE

Subject: Pharmacotherapeutics-II

Subject Code: (MPP202T)

Course Outcomes:

1. Make learner to know about the aetiology of diseases associated with Nervous, Renal Systems and various infectious diseases.
2. Make learner to understand the pathophysiology of diseases associated with Nervous, Renal Systems and various infectious diseases.
3. Make learner aware of various principles of cancer chemotherapy.
4. Help learner to therapeutic approach for management of various disease conditions including reference to the latest available evidence.
5. Make learner to discuss the clinical controversies in drug therapy and evidence based medicine.
6. Make learner to Prepare individualized therapeutic plans based on diagnosis.
7. Make learner to identify the patient specific parameters relevant in initiating drug therapy, and monitoring therapy.
8. Help learner in selection of optimal therapeutic regimen and also in selection of alternative therapeutic approach to the patient according to their clinical needs.
9. Make learner in selection of appropriate chemotherapeutic regimen and improve skills in prevention and management of chemotherapy related complications.

M. PHARM PHARMACY PRACTICE

Subject: Clinical Pharmacokinetics and Therapeutic Drug Monitoring

Subject Code: (MPP203T)

Course Outcomes:

1. Help learner in design the drug dosage regimen for individual patients.
2. Improve the skills of learner in Interpretation and correlation of the plasma drug concentrations with patients' therapeutic outcomes.
3. Aid the learner in Recommending the dosage adjustment for patients with renal/ hepatic impairment.
4. Make learner to Recommend dosage adjustment for paediatrics and geriatrics.
5. Help learner in Management of pharmacokinetic drug interactions.
6. Improve the skills of learner in Application of pharmacokinetic parameters in clinical settings.
7. Make learner in Interpretation and understanding the impact of genetic polymorphisms of individuals on pharmacokinetics and or pharmacodynamics of drugs.
8. Help learner in design of pharmacokinetic modelling for the given data using the principles of pharmacometrics.

M. PHARM PHARMACY PRACTICE

Subject: Pharmacoepidemiology and Pharmacoeconomics

Subject Code: (MPP204T)

Course Outcomes:

1. Make learner to understand the importance and application of epidemiology in pharmacy.
2. Make learner to understand the importance and application of health economics in pharmacy services.
3. Make learner Understand the various epidemiological methods and their applications.
4. Make learner to know the fundamental principles of Pharmacoeconomics.
5. Help the learner in Identification and determination of relevant cost and consequences associated with pharmacy products and services.
6. Improve the learner skills in performing the key Pharmacoeconomics analysis methods.
7. Help learner to Understand the Pharmacoeconomic decision analysis methods and its applications.
8. Make learner to gain knowledge in current Pharmacoeconomic methods and issues.

PHARMACY PRACTICE (MPP)

First Semester

CLINICAL PHARMACY PRACTICE (MPP 101T)

Unit 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 Hours**

Unit 2:

Clinical pharmacy services: Patient medication history interview, basic concept of medicine and poison information services. Basic concept of pharmacovigilance, hemovigilance, materiovigilance and active surveillance of adverse events following immunization (AEFI). Patient medication counselling, drug utilization evaluation. Documentation of clinical pharmacy services, quality assurance of clinical pharmacy services. **12 Hours**

Unit 3:

Patient data analysis & 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, their applications in patient care services. **12 Hours**

Unit 4:

Lab data interpretation: Hematological tests, renal function tests, liver function tests. Tests associated with cardiac disorders, pulmonary function tests, thyroid function tests. Fluid and electrolyte balance, microbiological culture sensitivity tests. **12 Hours**

Unit 5:

Medicines information services: 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 Hours**

REFERENCES

1. A Textbook of Clinical Pharmacy Practice – Essential Concepts and Skills – G. Parthasarathi, Karin Nyfort-Hansen & Milap Nahata.
2. Practice Standards and Definitions - The Society of Hospital Pharmacists of Australia
3. Basic Skills in Interpreting Laboratory Data – L.T. Scott. American Society of Health System Pharmacists Inc.
4. Relevant review articles from recent medical and pharmaceutical literature.

PHARMACOTHERAPEUTICS-I (MPP 102T)

Etiopathogenesis and pharmacotherapy of diseases associated with following systems:

Unit 1:

Cardiovascular system: Hypertension, congestive cardiac failure, acute coronary syndrome, arrhythmias, hyperlipidemias. **12 Hours**

Unit 2:

Respiratory system: Asthma, chronic obstructive airways disease, drug induced pulmonary diseases

Endocrine system: Diabetes, thyroid diseases **12 Hours**

Unit 3:

Gastrointestinal system: Peptic ulcer diseases, reflux esophagitis, inflammatory bowel diseases, jaundice & hepatitis. **12 Hours**

Unit 4:

Gastrointestinal system: Cirrhosis, diarrhea and constipation, drug-induced liver disease.

Hematological diseases: Anemia, deep vein thrombosis, drug induced hematological disorders. **12 Hours**

Unit 5:

Bone and joint disorders: Rheumatoid arthritis, Osteoarthritis, Gout, Osteoporosis

Dermatological Diseases: Psoriasis, eczema and scabies, impetigo, drug induced skin disorders

Ophthalmology: Conjunctivitis, glaucoma **12 Hours**

REFERENCES

1. Clinical Pharmacy and Therapeutics - Roger & Walker. Churchill Livingstone Publication
2. Pharmacotherapy: A Pathophysiologic Approach - Joseph T DiPiro et al. Appleton & Lange.
3. Robbins and Cotran Pathologic Basis of Disease – Kumar, Abbas & Fausto. 8th ed. Elsevier Publications.
4. Clinical Pharmacy and Therapeutics - Eric T Herfindal. Williams and Wilkins Publications.
5. Koda-Kimble & Young's Applied Therapeutics: The clinical Use of Drugs - K.A. Brian et al. Lippincott Williams and Wilkins.
6. Pharmacotherapy Principles and Practice – M.A. Chisholm-Burns, T.L. Schwinghammer B.G. Wells, P.M. Malone, J.M. Kolesar & Joseph P Dipiro. McGraw Hill Publications.
7. Essentials of Pathophysiology: Concepts of Altered Health States - Carol Mattson Porth. Lippincott Williams and Wilkins
8. Harrison's. Principles of Internal Medicine - McGraw Hill Publication.
9. Relevant review articles from recent medical and pharmaceutical literature

HOSPITAL & COMMUNITY PHARMACY (MPP 103T)

Unit 1:

Hospital pharmacy: Definition, classification, organizational structure. Relationship of hospital pharmacy department with other departments. 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 Hours**

Unit 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 Hours**

Unit 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.

Community pharmacy management: Legal requirements to start community pharmacy, site selection, layout and design, drug display, super drug store model, accounts and audits. Good dispensing practices, different software and databases used in community pharmacies. Entrepreneurship in community pharmacy. **12 Hours**

Unit 4:

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. **12 Hours**

Unit 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.

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. **12 Hours**

REFERENCES

1. Hospital Pharmacy – W.E. Hassan. Lea and Febiger Publications.
2. Textbook of Hospital Pharmacy – M.C. Allwood & Blackwell.
3. Avery's Drug Treatment. Adis International Limited.
4. Community Pharmacy Practice – Ramesh Adepu. BSP Publishers, Hyderabad
5. Remington – The Science and Practice of Pharmacy – Loyd V Allen. 22nd ed.
6. Relevant review articles from recent medical and pharmaceutical literature

CLINICAL RESEARCH (MPP 104T)

Unit 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 Hours**

Unit 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 Hours**

Unit 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 Hours**

Unit 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

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 Hours**

Unit 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

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 Hours**

REFERENCES

1. Principles and Practice of Pharmaceutical Medicine - Lionel D Edward, Aadrew J Flether, Anthony W Fos & Peter D Sloaier. 2nd ed. Wiley Publications.
2. Handbook of Clinical Research - Julia Lloyd & Ann Raven. Churchill Livingstone.
3. Principles of Clinical Research - Giovanna di Ignazio, Di Giovanna & Haynes.
4. Textbook of Clinical Trials - David Machin, Simon Day & Sylvan Green. John Wiley & Sons.
5. Clinical Data Management – R.K. Rondels, S.A. Varley & C.F. Webbs. 2nd ed. Wiley Publications, 2000.
6. Goodman and Gillman's: The Pharmacological Basis of Therapeutics - Laurence L Brunton, Randa Hilal-Dandan, Björn C Knollmann, 13th ed. Mc Graw Hill Education.
7. Central Drugs Standard Control Organization. Good Clinical Practices - Guidelines for Clinical Trials on Pharmaceutical Products in India. New Delhi: Ministry of Health & Family Welfare.
8. International Council for Harmonization of Technical requirements for Pharmaceuticals

for human use - ICH Harmonized Tripartite Guideline - Guideline for Good Clinical Practice. E6; May 1996.

9. Ethical Guidelines for Biomedical Research on Human Subjects. Indian Council of Medical Research, New Delhi.
10. Relevant review articles from recent medical and pharmaceutical literature.

PHARMACY PRACTICE PRACTICAL – I (MPP 105P)

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. ABC Analysis of a given list of medications (one)

PHARMACY PRACTICE PRACTICAL – II (MPP 106P)

1. Presentation of clinical cases of various disease conditions adopting pharmaceutical Care Plan Model (eight)
2. Preparation of content of a medicine, with proper justification, for the inclusion in the hospital formulary (one)
3. Formulation and dispensing of a given IV admixtures (one)
4. Preparation of a patient information leaflet (two)
5. Preparation of study protocol(one)
6. Preparation of informed consent form(one)

Second Semester

PRINCIPLES OF QUALITY USE OF MEDICINES (MPP 201T)

Unit 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 QUM, communication in QUM, cost effective prescribing. **12 Hours**

Unit 2:

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 Hours**

Unit 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 Hours**

Unit 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 Hours**

Unit 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 Hours**

REFERENCES

1. A Textbook of Clinical Pharmacy Practice – Essential Concepts and Skills – G. Parthasarathi, Karin Nyfort-Hansen & Milap Nahata.
2. Mann's Pharmacovigilance – E.B. Andrews & N. Moore.
3. Pharmacotherapy: A Pathophysiologic Approach – J.T. Dipiro, R.L. Talbert & G.C. Yee.
4. Evidence-Based Medicine: How to Practice and Teach It – S.E. Straus, W.S. Richardson, P. Glasziou & R.B. Haynes.
5. Medication Errors – M.R. Cohen.
6. Online:
   - http://medicinesaustralia.com.au/files/2012/05/MA_QUM_External_Red uced.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)

Unit 1:

Nervous system: Epilepsy, Parkinson's disease, stroke, headache, Alzheimer's disease, neuralgias and pain pathways and pain management. **12 Hours**

Unit 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 Hours**

Unit 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 Hours**

Unit 4:

Infectious diseases: meningitis, HIV and opportunistic infections, rheumatic fever, dengue fever, H1N1, helmenthiasis, fungal infections, gynecological disorders, dysmenorrhea, hormone replacement therapy. **12 Hours**

Unit 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 Hours**

REFERENCES

1. Clinical Pharmacy and Therapeutics - Roger & Walker. Churchill Livingstone Publication

2. Pharmacotherapy: A Pathophysiologic Approach - Joseph T. DiPiro et al. Appleton & Lange.
3. Pathologic basis of disease – S.L. Robins. W.B. Saunders Publication.
4. Clinical Pharmacy and Therapeutics - Eric T. Herfindal. Williams and Wilkins Publication.
5. Koda-Kimble & Young's Applied Therapeutics: The clinical Use of Drugs - K.A. Brian et al. Lippincott Williams and Wilkins.
6. Pharmacotherapy Principles and Practice – M.A. Chisholm-Burns, T.L. Schwinghammer B.G. Wells, P.M. Malone, J.M. Kolesar & Joseph P Dipiro. McGraw Hill Publications.
7. Essentials of Pathophysiology: Concepts of Altered Health States - Carol Mattson Porth. Lippincott Williams and Wilkins
8. Harrison's. Principles of Internal Medicine - McGraw Hill Publication.
9. Relevant review articles from recent medical and pharmaceutical literature

CLINICAL PHARMACOKINETICS AND THERAPEUTIC DRUG MONITORING (MPP 203T)

Unit 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.

Designing of dosage regimens: Determination of dose and dosing intervals, conversion from intravenous to oral dosing, nomograms and tabulations in designing dosage regimen.

12 Hours

Unit 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 Hours**

Unit 3:

Non linier mixed effects modeling: 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 Hours**

Unit 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 Hours

Unit 5:

Therapeutic Drug Monitoring (TDM): 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-flouro uracil, cisplatin;

Antibiotics: Vancomycin, gentamicin, meropenem. **12 Hours**

REFERENCES

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

PHARMACOEPIDEMIOLOGY & PHARMACOECONOMICS (MPP 204T)

Unit 1:

Introduction to pharmacoepidemiology: Definition, scope, need, aims & applications; 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 Hours**

Unit 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 monitoring, post marketing surveillance, record linkage systems, applications of pharmacoepidemiology. **12 Hours**

Unit 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 Hours**

Unit 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 Hours**

Unit 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 Hours**

REFERENCES

1. Essentials of Pharmacoeconomics – K.L. Rascati. Woulters Kluwer Lippincott Williams & Wilkins, Philadelphia.
2. Health economics: Fundamentals and Flow of Funds - Thomas E Getzen. John Wiley & Sons, USA.
3. Decision Modelling for Health Economic Evaluation - Andrew Briggs, Karl Claxton & Mark Sculpher. Oxford University Press, London.
4. Methods for the Economic Evaluation of Health Care Programmes - Michael Drummond, Mark Sculpher, George Torrence, Bernie O'Brien & Greg Stoddart. Oxford University Press, London.
5. Understanding Health Outcomes and Pharmacoeconomics - George E Mackinnon III.
6. Pharmacoeconomics and outcomes: Applications for patient care – D.W. Grauer & Thomas S Jane. American College of Clinical Pharmacy.
7. Pharmacoeconomics – Tom Walley, Allan Haycox & Angela Boland. Elsevier Publications.
8. Pharmacoeconomics – E. Nowakowska. University of Medical Sciences, Poznan.
9. Relevant review articles from recent medical and pharmaceutical literature

PHARMACY PRACTICE PRACTICAL - III (MPP 205P)

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)

Third Semester

RESEARCH METHODOLOGY & BIOSTATISTICS (MRM 301T)

(Note: Common Paper for all specializations)

Unit 1:

General research methodology: Research, objective, requirements, practical difficulties, review of literature, study design, types of studies, strategies to eliminate errors/bias, controls, randomization, crossover design, placebo, blinding techniques. **12 Hours**

Unit 2:

Biostatistics: Definition, application, sample size, importance of sample size, factors influencing sample size, dropouts, statistical tests of significance, type of significance tests, parametric tests (students "t" test, ANOVA, Correlation coefficient, regression), non-parametric tests (Wilcoxan rank tests, analysis of variance, correlation, Chi-square test), null hypothesis, P values, degree of freedom, interpretation of P values. **12 Hours**

Unit 3:

Medical Research: History, values in medical ethics, autonomy, beneficence, non-maleficence, double effect, conflicts between autonomy and beneficence/non-malfeasance, euthanasia, informed consent, confidentiality, criticisms of orthodox medical ethics, importance of communication, control resolution, guidelines, ethics committees, cultural concerns, truth telling, online business practices, conflicts of interest, referral, vendor relationships, treatment of family members, sexual relationships, fatality. **12 Hours**

Unit 4:

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. **12 Hours**

Unit 5:

Declaration of Helsinki: History, introduction, basic principles for all medical research, and additional principles for medical research combined with medical care. **12 Hours**

REFERENCES

1. Pharmaceutical Statistics: Practical and Clinical Applications - Stanford Bolton & Charles Bon. 5th ed. CRC Press.
2. Biostatistics: A Foundation for Analysis in the Health Sciences - Wayne W Daniel. 10th ed. John Wiley & Sons.
3. Introduction to Research in the Health Sciences - Stephen Polgar & Shane Thomas. 7th ed. Elsevier.
4. www.cpcsea.nic.in
5. www.wma.net