

# JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY ANANTAPUR Draft Academic Regulations for the Award of Full Time M.Tech. P.G. Degree (WITH EFFECT FROM THE ACADEMIC YEAR 2017-18 ONWARDS)

The Jawaharlal Nehru Technological University Anantapur shall confer M. Tech. Post Graduate degree to candidates who are admitted to the Master of Technology Programs and fulfill all the requirements for the award of the degree.

## 1.0 ELIGIBILITY FOR ADMISSIONS:

Admission to the above programmes shall be made subject to the eligibility, qualifications and specialization prescribed by the University for each Programme, from time to time.

Admissions shall be made either on the basis of merit rank obtained by the qualified candidates at an Entrance Test conducted by the University or on the basis of GATE/PGECET score, subject to reservations prescribed by the University or Government policies from time to time.

## 2.0 **COURSE WORK:**

- 2.1 A Candidate after securing admission must pursue the M.Tech. course of study for Four semesters duration.
- 2.2 Each semester shall be of 20 weeks duration including all examinations.
- 2.3 A candidate admitted to a programme should complete it within a period equal to twice the prescribed duration of the programme from the date of admission.
- 2.4 The medium of instruction shall be English for all theory and practical courses, examinations, Seminar, Teaching Assignments, Comprehensive Viva-Voce and project thesis/dissertation reports.

### **3.0 ATTENDANCE:**

- 3.1 A candidate shall be deemed to have eligibility to write end semester examinations if he/she has put in atleast 75% of attendance on cumulative basis of all subjects/courses in the semester.
- 3.2 Condonation of shortage of attendance up to 10% i.e., from 65% and above and less than 75% may be given by the college on the recommendation of the Principal.
- 3.3 Condonation of shortage of attendance shall be granted only on genuine and valid reasons on representation by the candidate with supporting evidence.
- 3.4 If the candidate does not satisfy the attendance requirement he/she is detained for want of attendance and shall reregister for that semester. He/she shall not be promoted to the next semester.

#### 4.0. EVALUATION:

The performance of the candidate in each semester program shall be evaluated subject wise, with a maximum of 100 marks for theory and 100 marks for practical examination, on the basis of Internal Evaluation and End Examination.

4.1. There shall be five units in each of the theory subjects. For the theory subjects 60% of the marks will be for the End Examination and 40% of the marks will be for Internal Evaluation.

- 4.2. Two Internal Examinations shall be held during the semester for 20 marks. First internal examination shall be conducted for half of the syllabus and second internal examination shall be conducted for remaining half of the syllabus. In each internal exam, a student shall answer all three questions in 2 hours of time without seeking any choice. Final Internal marks for a total of 20 marks shall be arrived at by considering the marks secured by the student in both the internal examinations with 70% weightage to the better internal exam and 30% to the other.
- 4.3. For the remaining 20 marks in internal evaluation, the University shall conduct one online examination.
- 4.4. The following pattern shall be followed in the End Examination.
  - a) Five questions shall be set from each of the five units with either/or type for 12 marks each.
  - b) All the questions have to be answered compulsorily.
  - c) Each question may consist of one, two or more bits.
- 4.5. For practical subjects, 60 marks shall be for the End Semester Examinations and 40 marks will be for internal evaluation based on the day to day performance.
- 4.6. For **Comprehensive Viva-Voce** and **Seminar** there will be an internal evaluation of 100 marks in each. A candidate has to secure a minimum of 50% (in each) to be declared successful. The assessment will be made by a board consisting of HOD and two senior internal experts at the end of **III** semester instruction.
- 4.7. For **Teaching Assignments** there will be an internal evaluation of 100 marks. A candidate has to secure a minimum of 50% to be declared successful. Student has to teach 10 Hours in his/her interesting subject/subjects in the entire III Semester instruction period for his juniors at PG level or Under Graduate students who are available on the campus. For each teaching hour maximum of 10 marks are allotted. The assessment will be made by the faculty allotted by the HOD.
- 4.8. Mandatory MOOCs course is introduced in III Semester as an elective without any credits. A student can choose any subject of his/her choice that has more than 30 hours duration from any MOOCs provider and should obtain satisfactory certificate. An Open Elective is introduced in III semester.
- 4.9. A candidate shall be deemed to have secured the minimum academic requirement in a subject if he secures a minimum of 40% of marks in the End Examination and a minimum aggregate of 50% of the total marks in the End Semester Examination and Internal Evaluation taken together. In case the candidate does not secure the minimum academic requirement in any of the subjects (as specified above) he has to reappear for the Semester Examination either supplementary or regular in that subject, or repeat the course when next offered or do any other specified subject as may be required.
- 4.10. In case the candidate does not secure the minimum academic requirement in any of the subjects (as specified in 4.9.) he has to reappear for the Semester Examination either supplementary or regular in that subject, or repeat the course when next offered or do any other specified subject as may be required.

## 5.0 RE-REGISTRATION FOR IMPROVEMENT OF INTERNAL EVALUATION MARKS.

Following are the conditions to avail the benefit of improvement of internal evaluation marks.

- 5.1 The candidate should have completed the course work and obtained examinations results for **I**, **II** and **III** semesters.
- 5.2 He should have passed all the subjects for which the Internal Evaluation marks secured are more than 50%.
- 5.3 Out of the subjects the candidate has failed in the examination due to Internal Evaluation marks secured being less than 50%, the candidate shall be given one chance for each Theory subject and for a maximum of **three** Theory subjects for Improvement of Internal evaluation marks.
- 5.4 The candidate has to re-register for the chosen subjects and fulfill the academic requirements.
- 5.5 For each subject, the candidate has to pay a fee equivalent to one third of the semester tuition fee and the amount is to be remitted in the form of D.D. in favour of the Registrar, JNTUA payable at Ananthapuramu along with the requisition through the Principal of the respective college.
- 5.6 In the event of availing the Improvement of Internal evaluation marks, the internal evaluation marks as well as the End Examinations marks secured in the previous attempt(s) for the reregistered subjects stand cancelled.

### **6.0 EVALUATION OF PROJECT WORK:**

Every candidate shall be required to submit thesis or dissertation after taking up a topic approved by the college/institute.

- 6.1 **Registration of Project work:** A candidate is permitted to register for the project work after satisfying the attendance requirement of all the courses (theory and practical courses of I & II Semester)
- An Internal Departmental Committee (I.D.C) consisting of HOD, Supervisor and one internal senior expert shall monitor the progress of the project work.
- 6.3 The **first phase of the project work** on the project shall be initiated in the third semester and **second phase of the project work will be** continued in the final semester. The duration of the project is for two semesters. The candidate can submit Project thesis with the approval of I.D.C. after 36 weeks from the date of registration at the earliest and one calendar year from the date of registration for the project work. Extension of time within the total permissible limit for completing the programme is to be obtained from the Head of the Institution.
- 6.4 The student must submit status report by giving seminar in three different phases (one in III semester and another two in IV semester) during the project work period. These seminar reports must be approved by the I.D.C before submission of the Project Report.
- 6.5 A candidate shall be allowed to submit the thesis/dissertation only after obtaining plagiarism report with less than 30% and passing in all the prescribed subjects (both theory and practical), and then take viva-voce examination of the project. The viva-voce examination may be conducted once in two months for all the candidates submitted during that period.
- 6.6 Three copies of the Thesis/Dissertation certified in the prescribed format by the supervisor & HOD shall be presented to the HOD. One copy is to be forwarded to the University and one copy to be sent to the examiner.
- 6.7 The college shall submit a panel of three experts for a maximum of **five** students at a time. However, the thesis/dissertation will be adjudicated by one examiner nominated by the University.

6.8 If the report of the examiner is favorable viva-voce examination shall be conducted by a board consisting of the Supervisor, Head of the Department and the examiner who adjudicated the thesis/dissertation. The board shall jointly report candidates work as:

1. Satisfactory Grade A

2. Not satisfactory Grade B

If the report of the viva-voce is not satisfactory (Grade B) the candidate will retake the viva-voce examination after three months. If he fails to get a satisfactory report at the second viva-voce examination he will not be eligible for the award of the degree unless the candidate is permitted to revise and resubmit the thesis.

## 7.0 GRADING

After each subject is evaluated for 100 marks, the marks obtained in each subject will be converted to a corresponding letter grade as given below, depending on the range in which the marks obtained by the student fall.

Letter Grade	Marks Range	Grade Point
S	91-100	10
A	81-90	9
В	70-80	8
С	60-69	7
D	55-59	6
Е	50-54	5
F	< 50	0
Absent	Ab (Absent)	0

A student obtaining Grade F shall be considered failed and will be required to reappear for that subject when the next supplementary examination offered.

## Semester Grade Point Average (SGPA) and Cumulative Grade Point Average (CGPA):

The Semester Grade Point Average (SGPA) is the ratio of sum of the product of the number of credits with the grade points scored by a student in all the courses taken by a student and the sum of the number of credits of all the courses undergone by a student, i.e.

$$SGPA = \sum_{i=1}^{n} (Ci \times Gi) / \sum_{i=1}^{n} Ci$$

Where, Ci is the number of credits of the i<sup>th</sup> subject, Gi is the grade point scored by the student in the i<sup>th</sup> course and n is the no. of subjects.

The Cumulative Grade Point Average (CGPA) will be computed in the same manner taking into account all the courses undergone by a student over all the semesters of a program, i.e.

$$CGPA = \sum_{i=1}^{n} (Ci \times Si) / \sum_{i=1}^{n} Ci$$

Where 'Si' is the SGPA of the i<sup>th</sup> semester, Ci is the total number of credits in that semester and n is the no. of semesters.

Both SGPA and CGPA shall be rounded off to 2 decimal points and reported in the transcripts.

While computing the SGPA the subjects in which the student is awarded Zero grade points will also be included.

*Grade Point:* It is a numerical weight allotted to each letter grade on a 10-point scale.

*Letter Grade:* It is an index of the performance of students in a said course. Grades are denoted by letters as mentioned in the above table.

### 8.0 AWARD OF DEGREE AND CLASS:

A candidate shall be eligible for the award of respective degree if he/she satisfies the minimum academic requirements in every subject and secures 'satisfactory' or higher grade report on his/her thesis/dissertation and viva-voce. Based on overall percentage of marks obtained, the following class is awarded.

Class Awarded	CGPA Secured
First class with Distinction	>= 8
First class	>= 7  and  < 8
Second class	>= 5  and  < 7

### 9.0 WITH – HOLDING OF RESULTS:

If the candidate has not paid dues to the university or if any case of in-discipline is pending against him, the result of the candidate shall be withheld and he will not be allowed/promoted into the next higher semester. The issue of degree is liable to be withheld in such cases.

### 10.0 TRANSITORY REGULATIONS:

Candidates who have discontinued or have been detained for want of attendance or who have failed after having undergone the course in earlier regulations and wish to continue the course are eligible for admission into the unfinished semester from the date of commencement of class work with the same or equivalent subjects as and when subjects are offered, subject to 4.10 and 2.3 sections. Whereas they continue to be in the academic regulations they were first admitted.

## 11.0 GENERAL:

- i. The academic regulations should be read as a whole for purpose of any interpretation.
- ii. Disciplinary action for Malpractice/improper conduct in examinations is appended.
- iii. There shall be no places transfer within the constituent colleges and affiliated colleges of Jawaharlal Nehru Technological University Anantapur.
- iv. Where the words "he", "him", "his", occur in the regulations, they include "she", "her", "hers".
- v. In the case of any doubt or ambiguity in the interpretation of the above rules, the decision of the Vice-Chancellor is final.
- vi. The University may change or amend the academic regulations or syllabi at any time and the changes or amendments shall be made applicable to all the students on rolls with effect from the dates notified by the University.

## RULES FOR DISCIPLINARY ACTION FOR MALPRACTICE / IMPROPER CONDUCT IN EXAMINATIONS

	Nature of Malpractices/Improper conduct	Punishment			
	If the candidate				
	Possesses or keeps accessible in examination hall, any paper, note book, programmable calculators, Cell phones, pager, palm computers or any other form of material concerned with or related to the subject of the examination (theory or practical) in which he is appearing but has not made use of (material shall include any marks on the body of the candidate which can be used as an aid in				
(b)	it from any other candidate orally or by any other body language methods or communicates through cell phones with	Expulsion from the examination hall and cancellation of the performance in that subject only of all the candidates involved. In case of an outsider, he will be handed over to the police and a case is registered against him.			
2.	Has copied in the examination hall from any paper, book, programmable calculators, palm computers or any other form of material relevant to the subject of	Expulsion from the examination hall and cancellation of the performance in that subject and all other subjects the candidate has already appeared including practical examinations and project work and shall not be permitted to appear for the remaining examinations of the subjects of that Semester/year.  The Hall Ticket of the candidate is to be cancelled and sent to the University.			
3.	Comes in a drunken condition to the examination hall.	Expulsion from the examination hall and cancellation of the performance in that subject and all other subjects the candidate has already appeared including practical examinations and project work and shall not be permitted for the remaining examinations of the subjects of that semester/year.			
4.	additional sheet or takes out or arranges	Expulsion from the examination hall and cancellation of performance in that subject and all the other subjects the candidate has already appeared including practical examinations and project work and shall not be permitted for the remaining examinations of the subjects of that semester/year. The candidate is also debarred for two consecutive semesters from class work and all University			

		examinations. The continuation of the course by the candidate is subject to the academic regulations in connection with forfeiture of seat.
5.	script or intentionally tears of the script or	Expulsion from the examination hall and cancellation of performance in that subject and all the other subjects the candidate has already appeared including practical examinations and project work and shall not be permitted for the remaining examinations of the subjects of that semester/year. The candidate is also debarred for two consecutive semesters from class work and all University examinations. The continuation of the course by the candidate is subject to the academic regulations in connection with forfeiture of seat.
6.	Possess any lethal weapon or firearm in the examination hall.	Expulsion from the examination hall and cancellation of the performance in that subject and all other subjects the candidate has already appeared including practical examinations and project work and shall not be permitted for the remaining examinations of the subjects of that semester/year. The candidate is also debarred and forfeits the seat.
7.	Impersonates any other candidate in connection with the examination.	The candidate who has impersonated shall be expelled from examination hall. The candidate is also debarred and forfeits the seat. The performance of the original candidate, who has been impersonated, shall be cancelled in all the subjects of the examination (including practicals and project work) already appeared and shall not be allowed to appear for examinations of the remaining subjects of that semester/year. The candidate is also debarred for two consecutive semesters from class work and all University examinations. The continuation of the course by the candidate is subject to the academic regulations in connection with forfeiture of seat. If the impostor is an outsider, he will be handed over to the police and a case is registered against him.
8.	Superintendent/Assistant – Superintendent / any officer on duty or misbehaves or creates disturbance of any kind in and	In case of students of the college, they shall be expelled from examination halls and cancellation of their performance in that subject and all other subjects the candidate(s) has (have) already appeared and shall not be permitted to appear for the remaining

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		examination hall of any injury to his person or to any of his relations whether	semester/year. The candidates also are debarred and forfeit their seats. In case of outsiders, they will be handed over to the police and a police case is registered against them.
		to disrupt the orderly conduct of the examination.	
ŀ			Student of the colleges expulsion from the
	·	candidate for the particular examination	examination hall and cancellation of the performance in that subject and all other
			subjects the candidate has already appeared including practical examinations and project
		to 8.	work and shall not be permitted for the remaining examinations of the subjects of that semester/year. The candidate is also debarred and forfeits the seat.
			Person(s) who do not belong to the
			College will be handed over to police and, a police case will be registered against them.
f	10.	Uses objectionable, abusive or offensive	Cancellation of the performance in that
		language in the answer paper or in letters	
		to the examiners or writes to the	
		examiner requesting him to award pass	
		marks.	
ſ	11.		Cancellation of the performance in that
			subject and all other subjects the candidate has
		during special scrutiny.	appeared including practical examinations and
			project work of that semester/year
ļ	1.0		examinations.
	12.	If any malpractice is detected which is	
		not covered in the above clauses 1 to 11	
		shall be reported to the University for	
		further action to award suitable	

punishment.

## Malpractices identified by squad or special invigilators

- 1. Punishments to the candidates as per the above guidelines.
- 2. Punishment for institutions: (if the squad reports that the college is also involved in encouraging malpractices)
  - (i) A show cause notice shall be issued to the college.
  - (ii) Impose a suitable fine on the college.
  - (iii) Shifting the examination centre from the college to another college for a specific period of not less than one year.

# JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY ANANTAPUR 18Course Structure and Syllabi for M.Pharm-Pharmacy Practice 18(JNTUA-Affiliated Pharmacy Colleges 2017-18)

## I YEAR - I Semester

S.	Course	Subjects	T	Т	P	C
No	Code	Subjects	L	1	P	
1	17S09101	Clinical Pharmacy Practice	4	_	-	4
2	17S09102	Pharmacotherapeutics-I	4	-	-	4
3	17S09103	Hospital &Community Pharmacy	4	-	-	4
4	17S09104	Clinical Research	4	-	-	4
5	17S09105	Pharmacy Practice Practical I	-	-	6	3
6	17S09106	Pharmacy Practice Practical II	_	-	6	3
7	17S09107	Seminar/Assignment	_	-	7	4
		Total	16	-	19	26

## I YEAR II Semester

S.	Course	Subject	L	T	P	C
No	Code					
1	17S09201	Principles of Quality Use of Medicines	4	-	-	4
2	17S09202	Pharmacotherapeutics II	4	-	-	4
3	17S09203	Clinical Pharmacokinetics and Therapeutic Drug Monitoring	4	-	-	4
4	17S09204	Pharmacoepidemiology & Pharmacoeconomics	4	-	-	4
5	17S09205	Pharmacy Practice Practical III	-	-	6	3
6	17S09206	Pharmacy Practice Practical IV	-	-	6	3
7	17S09207	Seminar/Assignment	-	-	7	4
	•	Total	16	-	19	26

## III SEMESTER

S.No	Subject Code	Subject	L	T	P	С
1.	17S01301	Research Methodology and Biostatistics	4	-	-	4
2.	17S09301	Journal Club	1	-	-	1
3.	17S09302	Teaching Assignment	10	-	-	2
4.	17S09303	Comprehensive viva voce	-	-	-	2
5.	17S09304	Discussion / Presentation (Proposal presentation)	-	-	2	2
6.	17S09305	Research Work	-	-	28	14
		Total	15	-	30	25

## IV SEMESTER

S.No	Subject Code	Subject	L	Т	P	С
1.	17S09401	Journal Club	1	-	-	1
2.	17S09402	Research work	31	-	-	16
3.	17S09403	Discussion/ Final Presentation	3	-	-	3
		Total	35	-	-	20

M. Pharm – I year I Sem. (Pharmacy Practice) L T P C 4 0 0 4

## (17S09101) CLINICAL PHARMACY PRACTICE

Scope

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

Objectives

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

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

THEORY 60

Hrs

1. 12Hrs

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)

2 12Hrs

Clinical Pharmacy Services: Patient medication historyinterview, Basic concept of medicine and poison informationservices, Basic concept of pharmacovigilance, Hemovigilance, Materiovigilance and AEFI, Patient medication counseling, Drugutilization evaluation, Documentation of clinical pharmacyservices, Quality assurance of clinical pharmacy services.

3 12Hrs

Patient Data Analysis: Patient Data & Practice Skills: Patient's case history – itsstructure 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

4 12Hrs

Lab Data Interpretation: Tests associated with cardiacdisorders, Pulmonary function tests, Thyroid function tests, Fluidand electrolyte balance, Microbiological culture sensitivity tests

5 12Hrs

Medicines & Poison Information Services Medicine Information Service: Definition and need for medicineinformation service, Medicine information resources, Systematicapproach in answering medicine information queries, Preparationof verbal and written response, Establishing a drug informationcentre.

Poison Information Service: Definition, need, organization and functions of poison information centre.

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

M. Pharm – I year I Sem. (Pharmacy Practice)

L T P C
4 0 0 4

## (17S09102) PHARMACOTHERAPEUTICS-I

Scope

This course aims to enable the students to understand the different treatmentapproaches in managing various disease conditions. Also, it imparts knowledgeand skills in optimizing drug therapy of a patient by individualizing the treatmentplan through evidence-based medicines. Objectives

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

• Describe and explain the rationale for drug therapy

Arrhythmias, Hyperlipidemias.

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

THEORY

60 Hrs

Etiopathogenesis and pharmacotherapy of diseasesassociated with following systems

1.

Cardiovascular system: Hypertension, Congestive cardiacfailure, Acute coronary syndrome,

2 12Hrs Respiratory system: Asthma, Chronic obstructive airways disease, Drug induced pulmonary diseasesEndocrine system: Diabetes, Thyroid diseases

3
Gastrointestinal system: Peptic ulcer diseases, Refluxesophagitis, inflammatory bowel diseases, Jaundice & hepatitis

4 12Hrs
Gastrointestinal system: Cirrhosis, Diarrhea and Constipation, Drug-induced liver disease
Hematological diseases: Anemia, Deep vein thrombosis, Druginduced hematological disorders

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

- 1. Roger and Walker. Clinical Pharmacy and Therapeutics ChurchillLivingstone 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 Useof 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 Williamsand Wilkins
- 8. Harrison's. Principles of Internal Medicine McGraw Hill
- 9. Relevant review articles from recent medical and pharmaceutical literature

## M. Pharm – I year I Sem. (Pharmacy Practice) L T P C 4 0 0 4

## (17S09103) HOSPITAL & COMMUNITY PHARMACY

Scope

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

Objectives

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

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

THEORY 60

Hrs

1. 12Hrs

Introduction to Hospitals – Definition, classification,organizational structureHospital Pharmacy: Definition, Relationship of hospitalpharmacy department with other departments, Organizationalstructure, legal requirements, work load statistics, Infrastructuralrequirements, Hospital Pharmacy Budget and Hospital Pharmacymanagement Hospital Drug Policy: Pharmacy & Therapeutics Committee,Infection Control committee, Research & Ethics Committee,Management of Medicines as per NABH

2 Hospital Formulary Guidelines and its development, DevelopingTherapeutic guidelines, Drug procurement process, and methodsof Inventory control, Methods of Drug distribution, Intravenousadmixtures, Hospital Waste Management

3 12Hrs

Education and training: Training of technical staff, training and continuing education for pharmacists, Pharmacy students, Medical staff and students, Nursing staff and students, Formaland informal meetings and lectures, Drug and therapeuticsnewsletter. Community Pharmacy Practice: Definition, roles &responsibilities of community pharmacists, and their relationshipwith other health care providers. Community Pharmacy management: Legal requirements tostart community pharmacy, site selection, lay out & design, drugdisplay, super drug store model, accounts and audits, Gooddispensing practices, Different softwares & databases used incommunity pharmacies. Entrepreneurship in communitypharmacy.

4 12Hrs

Prescription – Legal requirements & interpretation, prescriptionrelated problemsResponding to symptoms of minor ailments: Head ache,pyrexia, menstrual pains, food and drug allergy,OTC medication: Rational use of over the counter medicationsMedication counseling and use of patient information leafletsMedication adherence – Definition, factors influencing adherencebehavior, strategies to improve medication adherencePatient referrals to the doctorsADR monitoring in community pharmacies

5 12Hrs

Health Promotion – Definition and health promotion activities, family planning, Health screening services, first aid, prevention of communicable and non-communicable diseases, smokingcessation, Child & mother careNational 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

- 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

M. Pharm – I year I Sem. (Pharmacy Practice)

L T P C
4 0 0 4

## (17S09104) CLINICAL RESEARCH

Scope

This course aims to provide the students an opportunity to learn drugdevelopment process especially the phases of clinical trials and also the ethicalissues involved in the conduct of clinical research. Also, it aims to impartsknowledge and develop skills on conceptualizing, designing, conducting andmanaging clinical trials.

## Objectives

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

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

THEORY 60

Hrs

1. 12Hrs

Drug development process: Introduction, various approaches todrug discovery, Investigational new drug application submissionEthics in Biomedical Research: Ethical Issues in BiomedicalResearch – Principles of ethics in biomedical research, Ethicalcommittee [institutional review board] - its constitution and functions, Challenges in implementation of ethical guidelines, ICHGCP guidelines and ICMR guidelines in conduct of Clinical trials, Drug Safety Reporting.

12Hrs Types and Designs used in Clinical Research: Planning and execution of clinical trials, Phases of clinical trials, Bioavailability and Bioequivalence Randomizationtechniques (Simple randomization, restricted randomization, blocking method and stratification), Types of research designsbased on Controlling Method (Experimental, experimental, and Observational Sequences methods) Time (Prospective andRetrospective), Sampling methods (Cohort study, case Controlstudy and cross sectional measures(Clinical & Physiological, study), Health outcome Humanistic economic)Clinical Trial Study team: Roles and responsibilities of:Investigator, Study Coordinator, Sponsor, Monitor, ContractResearch Organization.

Clinical trial Documents: Guidelines to the preparation of following documents: Protocols, Investigator's Brochure, InformedConsent Form, Case report forms, Contracts and agreements, Dairy CardsClinical 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

4 I2Hrs
Investigational Product: Procurement and Storage of investigation product Filing procedures:
Essential documents for clinical trial, TrialMaster File preparation and maintenance,
Investigator Site File, Pharmacy File, Site initiation visit, Conduct, Report and Follow

upClinical Trial Monitoring and Close out:Preparation and conduct of monitoring visit: Review of sourcedocuments, CRF, ICF, IP storage, accountability andreconciliation, Study Procedure, EC communications, Safetyreporting, Monitoring visit reporting and follow-upClose-Out visit: Study related documents collection, Archivalrequirement, Investigational Product reconciliation anddestruction, Close-Out visit report.

5 12Hrs

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 DataManagement: Electronic data capture systems, Selection and implementation of new systems, System validation and testprocedures, Coding dictionaries, Data migration and archival

Clinical Trial Data Management: Standard OperatingProcedures, Data management plan, CRF & Data base designconsiderations, Study set-up, Data entry, CRF tracking and corrections, Data cleaning, Managing laboratory and ADR data, Data transfer and database lock, Quality Control and QualityAssurance in CDM, Data mining and warehousing.

- 1. Principles and practice of pharmaceutical medicine, Second edition.Authors:Lionel. D. Edward, Aadrew.J.Flether Anthony W Fos , Peter DSloaierPublisher:Wiley;
- 2. Handbook of clinical research. Julia Lloyd and Ann Raven Ed. ChurchillLivingstone
- 3. Principles of Clinical Research edited by Giovanna di Ignazio, Di Giovannaand Haynes.
- 4. Central Drugs Standard Control Organization. Good Clinical Practices-Guidelines for Clinical Trials on Pharmaceutical Products in India. NewDelhi: Ministry of Health.
- 5. International Conference on Harmonisation of Technical requirements forregistration of Pharmaceuticals for human use. ICH HarmonisedTripartiteGuideline. Guideline for Good Clinical Practice.E6; May 1996.
- 6. Ethical Guidelines for Biomedical Research on Human Subjects. IndianCouncil of Medical Research. New Delhi.
- 7. Textbook of Clinical Trials edited by David Machin, Simon Day and SylvanGreen, 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.

M. Pharm – I year I Sem. (Pharmacy Practice)

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## (17S09105) PHARMACY PRACTICE PRACTICAL – I

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. ABC Analysis of a given list of medications (one)
- 8. Preparation of content of a medicine, with proper justification, for theinclusion in the hospital formulary (one)
- 9. Formulation and dispensing of a given IV admixtures (one)

M. Pharm – I year I Sem. (Pharmacy Practice)

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## (17S09106) PHARMACY PRACTICE PRACTICAL – II

- 1. Presentation of clinical cases of various disease conditions adopting Pharmaceutical Care Plan Model (eight)
- 2. Preparation of a patient information leaflet (two)
- 3. Preparation of Study Protocol (one)
- 4. Preparation of Informed Consent Form (one)

#### M. Pharm – I year II Sem. (Pharmacy Practice) 4 0 0 4

## (17S09201) PRINCIPLES OF QUALITY USE OF MEDICINES

Scope:

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

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

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

60 **THEORY** 

Hrs

12Hrs 1.

Introduction to Quality use of medicines (QUM): Definition and Principles of QUM, Key partners and responsibilities of thepartners, Building blocks in QMC, Evaluation process in QMC, Communication in QUM, Cost effective prescribing.

2 12Hrs

Concepts in QUM Evidence based medicine: Definition, concept of evidencebased medicine, Approach and practice of evidence basedmedicine 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 druguse, Rational drug prescribing, Role of pharmacist in rational druguse.

3 12Hrs

QUM in various settings: Hospital settings, Ambulatorycare/Residential care, Role of health care professionals inpromoting 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 inimmune compromised and organ failure patients.

Regulatory aspects of QUM in India: Regulation includingscheduling, Regulation of complementary medicines, Regulation of OTC medicines, Professional responsibility of pharmacist, Roleof industry in QUM in medicine development.

12Hrs

Medication errors: Definition, categorization and causes ofmedication errors, Detection and prevention of medication errors, Role of pharmacist in monitoring and management of medicationerrors Pharmacovigilance: Definition, aims and need forpharmacovigilance, Types, predisposing factors and mechanismof adverse drug reactions (ADRs), Detection,

reporting andmonitoring of ADRs, Causality assessment of ADRs, Management of ADRs, Role of pharmacist in pharmacovigilance.

- $1.\ A\ Textbook\ of\ Clinical\ Pharmacy\ Practice-Essential\ concepts\ and\ skills\ -Parthasarathi$
- G, Karin Nyfort-Hansen and MilapNahata
- 2. Andrews EB, Moore N. Mann's Pharmacovigilance
- 3. Dipiro JT, Talbert RL, Yee GC. Pharmacotherapy: A PathophysiologicApproach
- 4. Straus SE, Richardson WS, Glasziou P, Haynes RB. Evidence-BasedMedicine: 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.

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## (17S09202) PHARMACOTHERAPEUTICS II

Scope

This course aims to enable the students to understand the different treatmentapproaches in managing various disease conditions. Also, it imparts knowledgeand skills in optimizing drug therapy of a patient by individualizing the treatmentplan through evidence-based medicines. Objectives

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

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

THEORY 60 Hrs

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1. 12Hrs

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

2 12Hrs

Psychiatric disorders: Schizophrenia, Depression, Anxietydisorders, Sleep disorders, Drug induced psychiatric disordersRenal system: Acute renal failure, Chronic renal failure, Renaldialysis, Drug induced renal disease

3 Infectious diseases: General guidelines for the rational use ofantibiotics and surgical

prophylaxis, Urinary tract infections, Respiratory tract infections, Gastroenteritis, Tuberculosis, Malaria, Bacterial endocarditis, Septicemia.

4 12Hrs

Infectious diseases: Meningitis, HIV and opportunistic infections,Rheumatic fever, Dengue fever, H1N1, Helmenthiasis, FungalinfectionsGynecological disorders: Dysmenorrhea, Hormonereplacement therapy.

5 Oncology: General principles of cancer chemotherapy, pharmacotherapy of breast cancer, lung cancer, head & neckcancer, hematological malignancies, Management of nausea andvomiting, Palliative care

- 1. Roger and Walker. Clinical Pharmacy and Therapeutics –ChurchillLivingstone 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 Useof 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 Williamsand Wilkins
- 8. Harrison's. Principles of Internal Medicine McGraw Hill
- 9. Relevant review articles from recent medical and pharmaceutical literature

## M. Pharm – I year II Sem. (Pharmacy Practice) L T P C 4 0 0 4

## (17S09203) CLINICAL PHARMACOKINETICS AND THERAPEUTIC DRUGMONITORING

## Scope

This course is designed to enable students to understand the basics principlesand applications of pharmacokinetics in designing the individualized dosageregimen, to interpret the plasma drug concentration profile in alteredpharmacokinetics, drug interactions and in therapeutic drug monitoringprocesses to optimize the drug dosage regimen. Also, it enables students tounderstand the basic concepts of pharmacogenetics, pharmacometrics formodeling and simulation of pharmacokinetic data.

## **Objectives**

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

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

THEORY 60 Hrs

1. 12Hrs

Introduction to Clinical pharmacokinetics: Compartmental andNon compartmental models, Renal and non-renal clearance,Organ extraction and models of hepatic clearance, Estimation anddeterminants of bioavailability, Multiple dosing, Calculation ofloading and maintenance dosesDesigning of dosage regimens: Determination of dose anddosing intervals, Conversion from intravenous to oral dosing,Nomograms and Tabulations in designing dosage regimen.

Pharmacokinetics of Drug Interaction: Pharmacokinetic druginteractions, Inhibition and Induction of Drug metabolism, Inhibition of Biliary Excretion Pharmacogenetics: Genetic polymorphism in Drug metabolism: Cytochrome P-450 Isoenzymes, Genetic Polymorphism in DrugTransport and Drug Targets, Pharmacogenetics and Pharmacokinetic / Pharmacodynamic considerations Introduction to Pharmacometrics: Introduction to Bayesian Theory, Adaptive method or Dosing with feedback, Analysis of Population

12Hrs

pharmacokinetic Data.

3 Non Linier Mixed Effects Modelling: The Structural or BaseModel, Modeling Random Effects, Modeling CovariateRelationships, Mixture Model, Estimation Methods, ModelBuilding Techniques, Covariate Screening Methods, Testing themodel assumptions, Precision of the parameter estimates and confidence intervals, Model misspecification and

violation of themodel assumptions, Model Validation, Simulation of dosingregimens and dosing recommendations, Pharmacometricssoftware.

4 12Hrs

Altered Pharmacokinetics: Drug dosing in the elderly, Drugdosing in the paediatrics, Drug dosing in the obese patients, Drugdosing in the pregnancy and lactation, Drug dosing in the renalfailure and extracorporeal removal of drugs, Drug dosing in the inhepatic failure.

5

Therapeutic Drug monitoring: Introduction, Individualization ofdrug dosage regimen (Variability – Genetic, age, weight, diseaseand Interacting drugs), Indications for TDM, Protocol for TDM, Pharmacokinetic/Pharmacodynamic Correlation in drug therapy, TDM of drugs used in the following conditions:

Cardiovasculardiseases: Digoxin, Lidocaine, Amiodarone;

Seizure disorders:Phenytoin, Carbamazepine, Sodium Valproate;

Psychiatric conditions: Lithium, Fluoxetine, Amitriptyline;

Organtransplantations: Cyclosporine;

Cytotoxic Agents: Methotrexate,5-FU, Cisplatin; Antibiotics: Vancomycin, Gentamicin, Meropenem.

- 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 TherapeuticDrug Monitoring. Iippincott Williams & Wilkins.
- 4. Steven How-Yan Wong, Irving Sunshine. Handbook of AnalyticalTherapeutic Drug Monitoring and Toxicology. CRC Press, USA.
- 5. SorayaDhillon, Andrzej Kostrzewski. Clinical pharmacokinetics. 1<sup>st</sup>edition. London: Pharmaceutical Press.
- 6. Joseph T.Dipiro, William J.Spruill, William E.Wade, Robert A.BlouinandJaneM.Pruemer .Concepts in Clinical Pharmacokinetics. AmericanSociety 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 ofHealth system Pharmacists, USA.
- 9. Michael E. Winter. Basic Clinical Pharmacokinetics. Iippincott Williams & Wilkins, USA.
- 10. Milo Gibaldi. Biopharmaceutics and Clinical Pharmacokinetics. PharmaBook Syndicate, USA.
- 11. Dhillon and Kostrzewski. Clinical pharmacokinetics. Pharmaceutical Press, London.
- 12. John E .Murphy. Clinical Pharmacokinetics. 5th edition. US: AmericanSociety of Health-System Pharmacist, USA.
- 13. Relevant review articles from recent medical and pharmaceutical literature

M. Pharm – I year II Sem. (Pharmacy Practice)

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## (17S09204) PHARMACOEPIDEMIOLOGY & PHARMACOECONOMICS

Scope

This course enables students to understand various pharmaco-epidemiologicalmethods and their clinical applications. Also, it aims to impart knowledge onbasic concepts, assumptions, terminology, and methods associated withPharmacoeconomics and health related outcomes, and when should beappropriate Pharmacoeconomic model should be applied for a health careregimen.

## Objectives

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

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

THEORY 60 Hrs

1. 12Hrs

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

2 12Hrs

Pharmacoepidemiological Methods: Qualitative models: DrugUtilization Review; Quantitative models: case reports, case series, Cross sectional studies, Cohort and case control studies, Calculation of Odds' ratio, Meta analysis models, Drug effectsstudy in populations: Spontaneous reporting, Prescription eventmonitoring, Post marketing surveillance, Record linkage systems, Applications of Pharmacoepidemiology

3 12Hrs

Introduction to Pharmacoeconomics: Definition, history of Pharmacoeconomics, Need of Pharmacoeconomic studies in Indian healthcare system. Cost categorization and resources for cost estimation: Directcosts. Indirect costs. Intangible costs. Outcomes and Measurements of Pharmacoeconomics: Typesof outcomes: Clinical outcome, Economic outcomes, Humanisticoutcomes; 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.

4 12Hrs

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), CostUtility Analysis (CUA), Cost of Illness (COI), Cost Consequences Analysis (COA).

5 12Hrs

Definition, Steps involved, Applications, Advantages and disadvantages of the following: Health related quality of life (HRQOL): Definition, Need formeasurement of HRQOL, Common HRQOL measures.

Definition, Steps involved, Applications of the following:

Decision Analysis and Decision tree, Sensitivity analysis, MarkovModeling, Software used in pharmacoeconomic analysis, Applications of Pharmacoeconomics.

- 1. Rascati K L. Essentials of Pharmacoeconomics, WoultersKluwerLippincott 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 HealthEconomic 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 MedicalSciences, Poznan.
- 9. Relevant review articles from recent medical and pharmaceutical literature

M. Pharm – I year II Sem. (Pharmacy Practice)

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## (17S09205) PHARMACY PRACTICE PRACTICAL - III

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. Interpretation of Therapeutic Drug Monitoring reports of a given patient(three)

## (17S09206) PHARMACY PRACTICE PRACTICAL - IV

- 1. Presentation of clinical cases of various disease conditions adopting Pharmaceutical Care Plan Model (eight)
- 2. Calculation of Bioavailability and Bioequivalence from the given data (two)
- 3. Calculation of various Pharmacoeconomic outcome analysis for the given, data (two)

M. Pharm – III Sem. (Pharmacy Practice)

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## (17S01301) RESEARCH METHODOLOGY & BIOSTATISTICS

## UNIT - I

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

#### UNIT – II

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

#### UNIT – III

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

## UNIT - IV

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

## UNIT - V

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