Sri Indu Institute of Pharmacy

(An Autonomous Institution Under UGC, New Delhi)
Accredited by NAAC (Grade "A")
Recognized Under Section 2(f) of UGC Act 1956
Approved by PCI – New Delhi, Affiliated to JNTUH- Hyderabad.
Sheriguda (V), Ibrahimpatnam (M), R.R. Dist-501510, Telangana State, India.
Website: www.siip.ac.in. Email: siipoffice@siip.ac.in., Phone: +91-9391537555

MASTER OF PHARMACY (M.PHARMACY) COURSE

PHARMACY PRACTICE SPECIALISATION

R25-ACADEMIC REGULATIONS, COURSE STRUCTURE AND DETAILED SYLLABUS

FOR

I & II YEAR M.PHARM COURSE

(Batches Admitted from 2025-26 Academic Year)

PRINCIPAL
SRI INDU INSTITUTE OF PHARMACY
(An Autonomous Institution Under JNTUH)
Sheriguda (V), Ibrahimpatnam (M),
Sheriguda (V), Ibrahimpatnam (M), Hyderabad-501510

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MASTER OF PHARMACY (M.PHARMACY) COURSE

PHARMACY PRACTICE SPECIALISATION

CHOICE BASED CREDIT SYSTEM (CBCS)

R-25 REGULATIONS AS PER JNTUH, Hyderabad.

ACADEMIC REGULATIONS, COURSE STRUCTURE AND DETAILED SYLLABUS FOR M.PHARMACY I & II Years Course

UNDER AUTONOMOUS STATUS FOR THE BATCHES ADMITTED FROM THE ACADEMIC YEAR 2025-2026

Note: Academic Regulations here under are subjected to amendments as may be made by the Academic Council of the Institute from time to time as per the JNTUH directives. Any or all such Amendments will be effective from such date and to such batches of Students (including those already undergoing the Program) as may be decided by the Academic Council timely.

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VISION

- To inculcate excellence in various fields of Pharmacy and mould the Institution as Center of Excellence in terms of Academics and Advanced Pharmaceutical Research"
- To evolve into a center of excellence in Science and Technology through creative and innovative practices in teaching, learning, promoting academic achievement & research excellence to produce internationally accepted, competitive and world class professionals, who are psychologically strong and emotionally balanced imbibed with social consciousness and ethical values.

MISSION

- Committed to impart quality Pharmacy Education and Research for Students to be competent globally"
- To provide high quality academic programs, training activities, research facilities and opportunities supported by incessant "Industry – Institute" interaction which is aimed at promoting Employability, Entrepreneurship, Leadership and Research aptitude among students that can contribute to the economic and technological development of the Region, State and the Nation.

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PROGRAM OUTCOMES (PO's)

PO'S OF M.PHARM (PHARMACY PRACTICE)	
PO1	To gain knowledge in preparation of rationale for drug therapy.
PO2	To train the students and develop their technical skill knowledge.
PO3	To create a talent pool by involving students in research projects.

PROGRAM SPECIFIC OUTCOMES (PSO'S)

PSO'S OF M.PHARMACY COURSE	
PSO1	To set forth theoretical and practical knowledge among students in the various fields of pharmaceutical sciences , pharmaceutics , pharmaceutical chemistry , pharmacology and pharmacognosy.
PSO2	To ameliorate practical skills of students through industrial training and research to confront the pharmaceutical field.
PSO3	To acquaint the students with fundamental regulatory aspects of pharmaceutical Professionals, Industry, Education and Practice.
PSO4	To boost knowledge and skills on criteria for selection of drugs, dose calculations, dose adjustments by applying biopharmaceutics theory, pharmacokinetic and bioequivalence models which gives technical skill knowledge, invitro invivo studies using computer simulations and population modellings.
PSO5	To expand the knowledge in technical and professional careers in various pharmaceutical industry/institution/health care system through concurrent meticulous education.
PSO6	To plan the modern tools to integrate health care systems. Design an effective product with commercial advantage and societal welfare, execute risk and become an entrepreneur.

PSO's of M. Pharmacy (PHARMACY PRACTICE)	
PSO1	Knowledge and skills in optimizing drug therapy of patient through evidence-based medicines.
PSO2	Ameliorate the skills that are required to practice pharmacy, to both health care professionals and patients in clinical settings.
PSO3	Apprentice in the field of handling first aid.
PSO4	Insight regarding the regulatory aspects in pharmaceutical industry.

PROGRAM EDUCATIONAL OUTCOMES (PEO'S)

PEO'S OF M.PHARMACY COURSE	
PEO1	To provide extensive and advanced proficiency in pharmaceutical education leading to M. Pharm.
PEO2	To expertise the apprentice in the field of pharmacy to contribute in the social health care system.
PEO3	To doctrine the ground work for handling the infrastructure which is included in research aptitude in pharmaceutical sciences
PEO4	To imprint leadership and entrepreneurship capabilities in future pharmacy professionals

PEO'S OF M. PHARMACY (PHARMACY PRACTICE)	
PEO1	To impart the knowledge and skills in optimizing drug therapy of patient through evidence based medicines.
PEO2	To ameliorate the skills that are required to practice pharmacy, to both health care professionals and patients in clinical settings.
PEO3	To expertise the apprentice in the field of handling first aid.
PEO4	To increase the insight regarding the regulatory aspects in pharmaceutical industry.

COURSE OUTCOMES OF M.PHARM (PHARMACY PRACTICE) R25 REGULATIONS

M.PHARMACY (PHARMACY PRACTICE) I YEAR I SEMESTER	
COURSE CODE: PC I	**PHARMACOTHERAPEUTICS I**
CO1	Summarise the therapeutic approach for management of various diseases conditions including reference to the latest available evidence.
CO2	Discuss the clinical controversies in drug therapy and evidence based medicine
CO3	Prepare individualised therapeutic plans based on diagnosis
CO4	Describe and explain the rationale for drug therapy.
CO5	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). Etiopathogenesis and pharmacotherapy of diseases associated with following systems
COURSE CODE: PC II	**CLINICAL PHARMACY PRACTICE**
CO1	Provide integrated, critically analysed medicine and poison information to enable healthcare professionals in the efficient patient management
CO2	Interpret the laboratory results to aid the clinical diagnosis of various disorders.
CO3	Understand the elements of pharmaceutical care and to provide comprehensive patient care services.
CO4	Provide systematic approach in answering medicine information queries.
COURSE CODE: PE I	**CLINICAL TOXICOLOGY**
CO1	Discuss clinical symptoms and management of acute poisoning for given compounds.
CO2	handling the first aid, elimination enhancement and treatment of poisoning and supportive care in poisoning due to • Pesticides • Drug over usage • Heavy metals • Radiation • Snakes and arthropod bites • Food poisoning
CO3	Detect signs and symptoms of drug abuse and suggest suitable

	remedial methods.
CO4	Thorough knowledge on principles involved in management of poisoning, antidotes and clinical applications.
COURSE CODE: PE I	**HOSPITAL AND COMMUNITY PHARMACY**
CO1	Command on organisation structure of hospital pharmacy.
CO2	To know about procurement and drug distribution practices.
CO3	Know the admixtures of radiopharmaceuticals
CO4	Understand the community pharmacymanagement
CO5	Be aware of drug policy and drug committees.
CO6	To be acquainted with the value-added services in community pharmacies.
COURSE CODE: PE I	**CLINICAL RESEARCH AND PHARMACOVIGILANCE**
CO1	Demonstrate the types of clinical trial designs
CO2	Execute safety monitoring, reporting, and close out activities
CO3	Explain the regulatory requirements for conducting clinical trial
CO4	Explain the responsibilities of key players involved in clinical trials
CO5	Explain the principles of Pharmacovigilance
CO6	Detect new adverse drug reactions and their assessment
CO7	Perform the adverse drug reaction reporting system and communication in pharmacovigilance.
COURSE CODE: PE II	**MOLECULAR BIOLOGY**
CO1	Recall, introduction to molecular biology regarding the structure and functions of DNA and RNA and different experiments pertaining to it.
CO2	Thorough knowledge on DNA topology and organization of DNA into chromosomes
CO3	Well acquittance with transport of RNA with in eukaryotic cell and regulatory elements of genes promoters.
CO4	Provide integrated knowledge on translation, synthesis and processing of proteome, regulation of gene expression in prokaryotes and eukaryotes.
COURSE CODE: PE II	**ADVANCES IN PRECLINICAL EVALUATION**
CO1	Appreciate the care and handling experimental animals
CO2	Conversant about preclinical and clinical studies of different ANS drugs and their models.
CO3	Aware of drug rules and regulations for conducting animal studies
CO4	Well versed with principles of toxicological evaluations and strategies used in drug discovery
COURSE CODE: PE II	**DRUG REGULATORY AFFAIRS**

CO1	Mind full of technical aspects pertaining to the marketing authorization application.
CO2	The regulatory guidelines and directions framed by the regulatory authorities will be helpful to place the drug products in market for marketing approvals
CO3	Detail study of regulatory aspects that effect drug product design and pharmaceutical and bulk drug manufacture
CO4	Appraised of different competent regulatory authorities globally.
CO5	Well versed with quality, safety and legislation for cosmetic products and herbal products.
COURSE CODE: MC	**RESEARCH METHODOLOGY AND IPR**
CO1	To analyse the research related information.
CO2	To understand that when IPR would take such important place in growth of individuals & nation To emphasise the need of information about intellectual property rights among students.
CO3	To Follow research ethics
CO4	To understand that today's world is controlled by Computer, Information Technology, but tomorrow world will be ruled by ideas, concept, and creativity.
CO5	To Understand that IPR protection provides an incentive to inventors for further research work and investment in R & D, which leads to creation of new and better products, and in turn brings about, economic growth and social benefits.
CO6	To Figure out research problems and formulations
CO7	To investigate solutions to research problems, data collection, analysis and interpretation of data.
COURSE CODE: LAB 1	**PHARAMCOTHERAPEUTICS I LAB**
CO1	Student are required to be posted to various clinical wards for their exposure with therapeutic managements and other clinical aspects.
CO2	Expected to have experience and do a tutorial as well as case presentation in certain clinical conditions.
CO3	Interpretation of therapeutic drug monitoring reports of a given patient.
CO4	Calculation of various pharmacoeconomic outcome analysis for the given data from the mentioned assignments
COURSE CODE: LAB 2	**CLINICAL PHARMACY PRACTICE LAB**
CO1	Presentation of clinical cases of various disease conditions adapting pharmaceutical care plan model
CO2	Preparation of content of a medicine with proper justification, for the inclusion in the hospital formulary.

CO2	Preparation of patient information leaflet, study protocol and informed consent form
CO3	Formulation and dispensing of IV admixtures
COURSE CODE: AUDIT COURSE I	**ENGLISH FOR RESEARCH PAPER WRITING**
CO1	To know how to improve writing skills and level of readability.
CO2	Knowing the skills needed when writing Title Ensure the good quality of paper at very first submission.
CO3	Ascertain about what to write in each section.
CO4	Flourish with skills needed when writing methods, results, conclusions etc.
COURSE CODE: AUDIT COURSE I	**DISASTER MANAGEMENT**
CO1	Learn to demonstrate and critical understanding of key concepts in disaster risk reduction and humanitarian response.
CO2	Critically evaluate disaster risk reduction and humanitarian response policy and practice from multiple perspectives.
CO3	Develop an understanding of standards of humanitarian response and practical relevance in specific types of disasters and conflict situations.
CO4	Planning and programming in different countries, particularly their home country or the countries they work in.
CO5	Critically understand the strengths and weakness of disaster management approaches.
COURSE CODE: AUDIT COURSE I	**SANSKRIT FOR TECHNICAL KNOWLEDGE**
CO1	To obtain working knowledge in illustrious Sanskrit, the scientific language in the world.
CO2	Learning of Sanskrit to improve brain functioning.
CO3	The engineering scholars equipped with Sanskrit will be able to explore the huge knowledge from ancient literature.
CO4	Learning of Sanskrit to develop the logic in mathematics, science, and other subjects enhancing the memory power.
COURSE CODE: AUDIT COURSE I	**VALUE EDUCATION**
CO1	Sympathise value of education and self-development.
CO2	Imbibe good values in students.
CO3	Developing the overall personality.
CO4	learn the importance of character and competence.
M.PHARMACY (PHARMACY PRACTICE) I YEAR II SEMESTER	
COURSE CODE: PC II	**PHARMACOTHERAPEUTICS II**

CO1	Discuss the clinical controversies in drug therapy and evidence-based medicine
CO2	Able to explain rationale for drug therapy
CO3	Summarize the therapeutic approach for management of various diseases conditions including reference to the latest available evidence
CO4	Prepare individualized therapeutic plans based on diagnosis
CO5	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)
COURSE CODE: PC II	**CLINICAL PHARMACOKINETICS AND DRUG MONITORING**
CO1	Design the drug dosage regimen for individual patients
CO2	Manage pharmacokinetic drug interactions
CO3	Interpret and correlate the plasma drug concentrations with patients' therapeutic outcomes; Recommend dosage adjustment for patients with renal/ hepatic impairment; Recommend dosage adjustment for pediatrics and geriatrics
CO4	Apply pharmacokinetic parameters in clinical settings
CO5	Interpret the impact of genetic polymorphisms of individuals on pharmacokinetics and or pharmacodynamics of drugs
CO6	Do pharmacokinetic modelling for the given data using the principles of pharmacometrics
COURSE CODE: PE III	**BIOPHARMACEUTICS AND PHARMACOKINETICS**
CO1	Critically evaluate biopharmaceutic studies involving drug product equivalency
CO2	Use plasma data and derive the pharmacokinetic parameters to describe the process of drug absorption, distribution, metabolism and elimination.
CO3	Impart basic knowledge about biopharmaceutics
CO4	Discuss bioavailability and bioequivalence and methods to improve bioavailability
COURSE CODE: PE III	**CLINICAL RESEARCH**
CO1	Discuss the pharmacological and toxicological consideration in process of drug development
CO2	know approaches for drug discovery, Explain the regulatory requirements for conducting clinical trial
CO3	Discuss the principles and phases in clinical trials of drug
CO4	Explain the responsibilities of key players involved in clinical trials
CO5	Explain the guidelines GCP and methods of post marketing surveillance

COURSE CODE: PE III	QUALITY USE OF MEDICINES
CO1	Understand the principles of quality use of medicines
CO2	Identify and resolve medication related problems
CO3	Understand regulatory aspects of quality use of medicines
CO4	Know the benefits and risks associated with use of medicines
CO5	Promote quality use of medicines
CO6	Practice evidence-based medicine
COURSE CODE: PE IV	**PRINCIPLES OF DRUG DISCOVERY**
CO1	Explain the various stages of drug discovery
CO2	Appreciate the importance of the role of computer aided drug design in drug discovery
CO3	Explain various targets for drug discovery.
CO4	Explain various lead seeking method and lead optimization
CO5	Know the importance of role of genomics, proteomics and bioinformatics
COURSE CODE: PE IV	**CELLULAR AND MOLECULAR PHARMACOLOGY**
CO1	Be able to explain the receptor signal transduction processes
CO2	Explain the molecular pathways affected by drugs
CO3	Appreciate the applicability of molecular pharmacology and biomarkers in drug discovery process
CO4	Demonstrate molecular biology techniques as applicable for pharmacology
COURSE CODE: PE IV	**NUTRACEUTICALS**
CO1	Understand the importance of nutraceuticals in various common problems
CO2	Well acquainted with the concept of free radicals and measurement of free radicals
CO3	Expose to various food laws and regulations, health claims and dietary supplement claims
CO4	Know the occurrence and characteristic features of various phytochemicals
COURSE CODE: LAB III	**PHARMACOTHERAPEUTICS II LAB**
CO1	Required to be posted to various clinical wards for their exposure with therapeutic management and other clinical aspects
CO2	Expected to have experience and do a tutorial as well as case presentation in certain clinical conditions
CO3	Interpret therapeutic drug monitoring reports of a patient
CO4	Calculate various pharmacoeconomic outcome analysis for the given

	data
COURSE CODE: LAB IV	**CLINICAL PHARMACOKINETICS AND DRUG MONITORING LAB**
CO1	Causality assessment of various adverse drug reactions
CO2	Detection and management of medication errors
CO3	Development of hospital formulary for a teaching hospital
CO4	Study of design and management of hospital pharmacy department of a hospital
	MINI PROJECT WITH SEMINAR
CO1	Allows the students to study, do research and act by themselves using their abilities.
CO2	Improves communication skills and networking with others.
CO3	Helps in gaining expert knowledge and renewing motivational confidence.
CO4	Provides latest information in the field of science and technology.
COURSE CODE: AUDIT COURSE II	**CONSTITUTION OF INDIA**
CO1	Understanding the growth of the demand for civil rights in India for the bulk of Indians before the arrival of Gandhi in Indian politics.
CO2	Confer the intellectual origins of the frame work of argument that informed the conceptualization of social reforms leading to revolution in India.
CO3	Dissertate the circumstances surrounding the foundation of the congress socialist party under the leadership of Jawaharlal Nehru and eventual failure of the proposal of direct elections through adult suffrage in the Indian constitution.
CO4	Discuss the passage of the Hindu Code Bill of 1956.
AUDIT COURSE II	**PEDAGOGY STUDIES**
CO1	Figure out what pedagogical practices are being used by teachers in formal and informal class rooms in developing countries.
CO2	The evidence on the effectiveness of these pedagogical practices, in what conditions and with what population of learners.
CO3	How can teacher education, school curriculum and guidance materials best support effective pedagogy?
CO4	Identify critical evidence gaps to guide the development.
AUDIT COURSE II	**STRESS MANAGEMENT BY YOGA**
CO1	Develop healthy mind in a healthy body thus improving social health.
CO2	Improve efficiency
CO3	To overcome stress.

CO4	To get well acquainted with types of pranayama.
AUDIT COURSE II	**PERSONALITY DEVELOPMENT THROUGH LIFE ENLIGHTENMENT SKILLS**
CO1	Study of Shrimad-Bhagwad-Geeta help the student in developing his personality and achieve the highest goal in life.
CO2	Study of neethishatakam will help in developing versatile personality of students.
CO3	To awaken wisdom in students.
CO4	To became a person with stable mind, pleasing personality and determination.
M.PHARMACY (PHARMACY PRACTICE) II YEAR I SEMESTER	
COURSE CODE: PE V	**BIOSTATISTICS**
CO1	Discuss the basic concept and importance of statistical analysis.
CO2	To Know the Biostatistics arrangement, presentation and formation of tables and charts.
CO3	To know the correlation and regression & application of different methods, analysis of data
CO4	Explain various methods of testing hypothesis.
CO5	Dissert the methods of collection of data, analysis and interpretation.
CO6	To understand the basic aspects of statistics such as central tendency, dispersion and correlation.
COURSE CODE: PE V	**PHARMACOEPIDEMIOLOGY AND PHARMACOECONOMICS**
CO1	Perceive various epidemiological methods and their applications.
CO2	Be able to understand fundamental principles of Pharmacoeconomics.
CO3	Should perform the key Pharmacoeconomics analysis methods.
CO4	Understand Pharmacoeconomics decision analysis methods and their applications.
CO5	To Identify and determine relevant cost and consequences associated with pharmacy products and services.
CO6	Describe current Pharmacoeconomic methods and issues.
CO7	Understand the applications of Pharmacoeconomics to various pharmacy settings
PE V	**PHYTOPHARMACEUTICALS**
CO1	Should be able to explain the sources of phytoconstituents
CO2	Capable of isolating and study the characterization of various chemical constituents
CO3	Detect chemical entity by different spectra's
CO4	Isolation and characterization of phytoconstituents
COURSE CODE: DISSERTATION	**DISSERTATION WORK REVIEW II**

CO1	Search and evaluate the available literature in your given subject or chosen topic area
CO2	Read the selected articles thoroughly and evaluate them
CO3	Organise the selected papers by looking for patterns and by developing subtopics
CO4	Analyse critically a segment of published body of knowledge through summary
M.PHARMACY (PHARMACY PRACTICE) II YEAR II SEMESTER	
COURSE CODE: DISSERTATION	**DISSERTATION WORK REVIEW III**
CO1	Apply knowledge and understanding in relation to the agreed area of study
CO2	Communicate in written form by integrating, analysing and applying key texts and practices
CO3	Demonstrate advanced critical research skills in relation to career development
CO4	Integrate the theory and practice in evaluation
COURSE CODE: DISSERTATION	**DISSERTATION VIVA VOCE**
CO1	Demonstrate knowledge in the program domain
CO2	Presenting views cogently and precisely
CO3	Exhibit professional etiquette suitable for career progression
CO4	Exhibit sustained curiosity and have an attitude of attention in detailing of the project

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R-25 REGULATIONS AS PER JNTUH, Hyderabad.

ACADEMIC REGULATIONS, COURSE STRUCTURE AND DETAILED SYLLABUS FOR M.PHARMACY I & II Years – I TO IV SEMESTERS

UNDER AUTONOMOUS STATUS FOR THE BATCHES ADMITTED FROM THE ACADEMIC YEAR 2025-2026

PRELIMINARY DEFINITIONS AND NOMENCLATURE

- "Autonomous Institute / College" means an institute / college designated as autonomous institute / college by the UGC, New Delhi and JNTUH Statutes, 2023.
- "Academic Autonomy" means freedom to a College in all aspects of conducting its academic programs granted by the University for promoting excellence.
- "Commission" means University Grants Commission (UGC), New Delhi.
- "University" means the Jawaharlal Nehru Technological University, Hyderabad.
- "Institute/College" means SRI INDU INSTITUTE OF PHARMACY, Hyderabad unless indicated otherwise by the context.
- "Programme" means: Master of Pharmacy (M.Pharmacy) degree programme with its specialization.
- "Course" or "Subject" means a Theory or Practical subject, identified by its course–number and course-title.
- T – Tutorial, P – Practical, D – Drawing, L - Theory, C – Credits.

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ACADEMIC REGULATIONS OF M.PHARMACY COURSE (REGULAR/FULL TIME) STUDENTSWITH EFFECT FROM THE ACADEMIC YEAR 2025-26 (R-25)

AT PAR WITH

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD

(Established by Act No. 30 of 2008)

Kukatpally, Hyderabad, Telangana (India).

Academic Regulations of M.Pharm. (Regular/Full Time) Programmes, 2025-26 (R25)(CBCS)
(Effective for the students admitted into I year from the Academic Year 2025-26 and onwards)

1.0 Jawaharlal Nehru Technological University Hyderabad (JNTUH) offers **Two** Years (**Four** Semesters) full-time Master of Pharmacy (M. Pharm.) Degree programmes, under Choice Based Credit System (CBCS) at its non-autonomous constituent and affiliated colleges in different specializations.

2.0 Eligibility for Admissions

2.1 Admission to the M. Pharm. programme shall be made subject to eligibility, qualification and specializations prescribed by the University from time to time, for each specialization under each M. Pharm. programme.

2.2 Admission to the post graduate programme shall be made on the basis of either the merit rank or Percentile obtained by the qualified student in the relevant GPAT Examination/ the merit rank obtained by the qualified student in PGECET, entrance test conducted by Telangana Government for M. Pharm. programmes / an entrance test conducted by JNTUH/ on the basis of any other exams approved by the University, subject to reservations as laid down by the Govt. from time to time.

2.3 The medium of instruction for all PG programmes will be English only.

3.0 M. Pharm. Programme Structure

3.1 The M. Pharm. Programmes of JNTUH are of Semester pattern, consisting of **Two** academic years, each academic year having **Two** Semesters (Odd and Even Semesters). The student shall not take more than **four** academic years to fulfill all the academic requirements for the award of M. Pharm. degree from the date of commencement of first year first semester, failing which the student shall forfeit the seat in M. Pharm. programme.

3.2 **UGC/PCI** specified definitions/descriptions are adopted appropriately for various terms and abbreviations used in these PG academic regulations, as listed below:

3.3 Semester Scheme

There shall be a minimum of 15 weeks of instruction, excluding the mid-term and semester-end exams. Around 15 instruction hours, 30 instruction hours and 45 hours of learning need to be followed per one credit of theory course, practical course and project/field-based learning respectively. Each Semester shall have 'Continuous Internal Evaluation (CIE)' and 'Semester End Examination (SEE)'. Choice Based Credit System (CBCS) and Credit Based Semester System (CBSS) are taken as 'references' for the present set of Regulations.

3.3.1 Credit Courses

All courses are to be registered by the student in a semester to earn credits which shall be assigned to each course in an L: T: P: C (Lecture Periods: Tutorial Periods: Practical Periods: Credits) structure based on the following general pattern:

- One credit for one hour/week/semester for theory/lecture (L) courses
- One credit for two hours/ week/semester for laboratory/ practical (P) courses or tutorials (T)
- One credit is allocated for three hours per week in a semester for Project/Mini-Project session.

3.3.2 Course Classification

All courses offered for the Post-Graduate Programme in Pharmacy (M. Pharm. Degree Programme) are broadly classified as follows. The University follows in general the guidelines issued by PCI/UGC.

S.No.	Broad Course Classification	Course Group/ Category	Course Description
1	Core Courses (CoC)	PC - Professional Core	Includes courses related to the Specialization in Pharmacy
		Dissertation	Major Project
		Mini Project/ Seminar	Mini Project/Seminar based on core contents related to the Specialization in Pharmacy
2	Elective Courses (EıE)	PE - Professional Electives	Includes elective courses related to the Specialization in Pharmacy
		OE - Open Electives	Elective courses which include inter-disciplinary courses or courses in an area outside the Specialization in Pharmacy
3	Audit Courses	--	Non-Credit Audit Courses

4.0 Course Registration

4.1 A faculty advisor/ mentor shall be assigned to a specified numbers of students belong each specialization, who will advise on M. Pharm. Course Structure, Curriculum, Choices/Options for Courses, based on their individual competencies, progress, fulfilment of pre-requisites and interest.

4.2 The academic section of the college invites registration forms from students before the beginning of the semester through on-line registration, ensuring date and time stamping. The online registration requests for semester courses shall be completed two weeks before the commencement of SEEs (Semester End Examinations) of the preceding semester.

4.3 A Student can apply for on-line Registration, only after obtaining the written approval from his Faculty Advisor, which should be submitted to the College Academic Section through the Head of Department (a copy of it being retained with Head of Department, Faculty Advisor and the Student).

4.4 If the Student submits ambiguous choices or multiple options or erroneous entries during on-line Registration for the Course(s) / Course(s) under a given/ specified Course Group/ Category as listed in the Course Structure, only the first mentioned Course in that Category will be taken into consideration.

4.5 Course Options exercised through on-line Registration are final and cannot be changed, nor can they be inter-changed; further, alternate choices also will not be considered. However, if the Course that has already been listed for Registration by the University in a Semester could not be offered due to unforeseen or unexpected reasons, then the Student will be allowed to have alternate choice either for a new Course, if it is offered, or for another existing Course (subject to availability of seats). Such alternate arrangements will be made by the Head of Department, with due notification

and time-framed schedule, within the first week from the commencement of Class-work for that Semester.

5.0 Attendance Requirements

Attendance is calculated for each course separately. Promotion/ detention rules are applied course- wise.

5.1 Attendance in all classes (Lectures/Laboratories) is compulsory. The minimum required attendance in each theory course including the audit courses should be 80%. The attendance of mid-term examination / Laboratory etc. at the rate of two periods of attendance for each theory course shall be considered, if the student appears for the mid-term examination of that course. This attendance should also be included in the fortnightly upload of attendance to the University. The attendance of mandatory audit courses should be uploaded separately to the University. A student shall not be permitted to appear for the Semester End Examinations (SEE), if his attendance is less than 80%.

5.2 A student's Seminar report and presentation on Mini Project shall be eligible for evaluation, only if the student obtain a minimum of **80%** of attendance in Seminar presentation classes on Mini Project during that Semester.

5.3 Condoning of shortage of attendance up to a maximum of 10% (considering the days of attendance in sports, games, NCC, NSS activities and Medical grounds) in each course (Theory/Lab/Mini Project/ Seminar) of a semester shall be granted by the College Academic Committee on genuine reasons.

5.4 A prescribed fee per course shall be payable for condoning shortage of attendance after getting the approval of College Academic Committee for the same. The condonation fee particulars need to be displayed in website/portal of the college. The College Academic Committee shall maintain relevant documents along with the requests from the students.

5.5 Shortage of Attendance below 70% in any course shall in **no case be condoned.**

5.6 A Student, whose shortage of attendance is not condoned in any Course(s) (Theory/Lab/Mini Project /Seminar) in any Semester or having the attendance less than 70 percentage, shall be detained in that course and is not eligible to write Semester End Examination/Evaluation of that Course. Such students have to seek re-registration for those Course(s) in subsequent Semesters, and attend the same as and when offered.

5.7 A student fulfills the attendance requirement in the present semester, shall not be eligible for readmission into the same semester.

5.8 A student shall put in a minimum required attendance in at least **three theory courses (excluding *audit* course)** in first Year I semester for promotion to first Year

II Semester. Same criteria shall be followed for promotion from first Year II semester to second Year I Semester.

6.0 Academic Requirements

The performance of the candidate in each semester shall be evaluated course-wise, with a maximum of 100 marks per course (theory / practical), based on Internal Evaluation and Semester End Examination. The following academic requirements must be satisfied, in addition to the attendance requirements mentioned in clause no. 5.

6.1 A student shall be deemed to have satisfied the academic requirements and earned the credits allotted to each course, if he secures not less than **40%** of marks (**28** out of **70** marks) in the Semester End Examination, and a minimum of **50%** of marks in the sum total of CIE (Continuous Internal Evaluation) and SEE (Semester End Examination) taken together. In terms of Letter Grades and this implies securing **'D'** Grade or above in a course.

6.2 A student shall be deemed to have satisfied the academic requirements and earned the credits allotted to **Mini Project**, if student secures not less than **50%** marks (i.e. 50 out of 100 allotted marks). The student would be treated as failed, if student (i) does not submit a report on Mini Project or does not make a presentation of the same before the evaluation committee as per schedule or (ii) secures less than 50% marks in Mini Project evaluation. The failed student may reappear once for the above evaluation, as and when they are scheduled again; if the student fails in such „one reappearance" evaluation also, the student has to reappear for the same in the next subsequent semester, as and when it is scheduled.

6.3 A student shall be deemed to have satisfied the academic requirements and earned the credits allotted to **seminar**, if student secures not less than 50% marks i.e. 50 out of 100 allotted marks. The student would be treated as failed, if student (i) does not submit a report on seminar as prescribed or does not make a seminar presentation before the evaluation committee as per schedule or (ii) secures less than 50% (i.e. < **50** marks out of **100**) marks in the seminar evaluation. The student failed in seminar evaluation may reappear once for it, as and when it is scheduled again. If the student fails in such one reappearance evaluation also, the student has to reappear for the same in the next subsequent semester, as and when it is scheduled.

6.4 A student shall register for all courses for total of **98** credits as specified and listed in the course structure for the chosen specialization, put in the required attendance and fulfill the academic requirements for securing **98** credits obtaining a minimum of **'D'** Grade or above in each course, and shall **pass all the audit courses** to complete the M. Pharm. program successfully.

Note: (1) The SGPA will be computed and printed on the grades memo only if the candidate passes in all the courses offered and gets minimum 'D' grade in all the courses.

(2) CGPA is calculated only when the candidate passes in all the courses offered in all the semesters

6.5 Marks and Letter Grades obtained in all those courses covering the above specified **98** credits alone shall be considered for the calculation of final CGPA, which will be indicated in the Grade Card of second year second semester.

6.6 When a student is detained due to shortage of attendance in any course(s) in any semester, no Grade allotment will be made for such course(s). However, he is eligible for re-registration of such course(s) in the subsequent semester(s), with the academic regulations of the batch into which he is re- registered, by paying the prescribed fees per course and earn credits.

6.7 A student eligible to appear for the Semester End Examination in any course, but absent from it or treated as failed (failing to secure **'D'** Grade or above), may reappear for that course at the supplementary examination as and when conducted. In such cases, his Internal Marks assessed earlier for that course will be carried over, and added to the marks secured in the supplementary examination, for the purpose of evaluating his performance in that course.

6.8 A Student who fails to earn **98** credits as per the specified course structure, and as indicated above, within **four** academic years from the date of commencement of his first year first semester, shall forfeit his seat in M. Pharm. programme and his admission **shall stand cancelled.**

7.0 Evaluation - Distribution and Weightage of Marks:

The performance of a student in each semester shall be evaluated course- wise (irrespective of credits assigned) for a maximum of 100 marks. The performance of a student in every theory course will be evaluated for 100 marks**.**

7.1 For theory courses, 30 marks shall be awarded for Continuous Internal Evaluation (CIE) and 70 marks shall be awarded for the performance in the Semester End Examination (SEE).

7.1.1 The Continuous Internal Evaluation for each course shall be carriedout based on the average of the marks secured in the two Mid-Term Examinations conducted and assignments. The first Mid-Term examinations shall be conducted in middle of the Semester and second Mid-Term examinations during the last week of instruction. Each Mid-Term Examination shall be conducted for a total duration of 120 minutes with Part-A as compulsory section consisting of 5 questions carrying 2 marks each (10 marks), and Part-B with 3 questions to be answered out of 5 questions, each question carrying 5 marks (15 marks). Five marks in each course are allotted for the assignments.

7.1.2 The details of the Question Paper pattern for Semester End Examination (SEE) are given below:

The Semester End Examination will be conducted for 70 marks. It consists of two parts: i) Part A for 20 marks and ii) Part B for 50 marks

- Part A is compulsory and consists of five questions, one from each unit and carrying four marks each.
- Part B consists of five questions carrying 10 marks each. There will be two questions from each unit and only one should be answered.

7.2 For practical courses there shall be a Continuous Internal Evaluation (CIE) during the semester for 30 marks and 70 marks for semester end examination (SEE).

7.2.1 **The rubrics for the** 30 marks internal evaluation is as follows:

1. A write-up on day-to-day experiment in the laboratory (in terms of aim, components/procedure, expected outcome) which shall be evaluated for 10 marks
2. 10 marks for viva-voce in the course concerned.
3. Internal practical examination conducted by the laboratory teacher concerned shall be evaluated for 10 marks.

7.2.2 The Semester End Examination shall be conducted with an external examiner and the laboratory teacher. The external examiner shall be appointed from the cluster/other colleges which will be decided by the examination branch of the University.

In the Semester End Examination held for 3 hours, the rubrics for a total of 70 marks are as shown below:

1. 15 marks for Synopsis
2. 40 marks for experiment
3. 15 marks for viva-voce on concerned laboratory course

A student has to secure 50 marks out of 100 (i.e. 50% marks) allotted for CIE and SEE taken together.

7.3 There shall be Mini Project during I year II semester. There shall be only i**nternal evaluation in** Mini Project for 100 marks. Student shall carryout the mini project in consultation with the mini project supervisor which may include critically reviewing the literature, project implementation and submit it to the department in the form of a report and shall make an oral presentation before the Departmental Academic Committee (DAC) consisting of Head of the Department, Mini Project supervisor and two other senior faculty members of the department. DAC will review the progress of the mini project during the presentations and evaluate the same for 50 marks. Mini Project Viva Voce will be evaluated by the DAC for another 50 marks before the semester-end examinations. The student has to secure a minimum of 50% of marks in this internal evaluation, to be declared passed. If he fails to obtain the minimum marks, he has to reappear for the same as and when scheduled.

7.4 There shall be one seminar each during I Year I Semester & I Year II Semester. **100** marks are allotted for each of the Seminars. There shall be only i**nternal evaluation in Seminar.**

7.4.1 For **Seminar course**, the student in consultation with the seminar supervisor shall collect the information on a specialized topic, prepare a report, and submit it to the department. The Departmental Academic Committee (DAC) consisting of Head of the Department, seminar supervisor and two other senior faculty members of the department will evaluate the seminar report for 100 marks before the semester end examinations. The student has to secure a minimum of 50 marks (i.e. 50% marks) to be declared as passed. If he fails to obtain the minimum marks, he has to reappear for the same as and when scheduled.

7.5 There shall be comprehensive viva-voce during II year I semester. It is an **external evaluation course** of 100 marks. It shall be evaluated by the committee consisting of an external examiner, Head of the Department, and two other senior faculty members of the department before the semester-end examinations. The external examiner shall be appointed from the cluster/other colleges which will be decided by the examination branch of the University. The student has to secure a minimum of 50 marks (i.e. 50% of the marks) to be declared as passed. If he fails to obtain the minimum marks, he has to reappear for the same as and when scheduled.

7.6 Every candidate shall be required to submit a dissertation on a topic approved by the Dissertation Review Committee.

7.7 A Dissertation Review Committee (DRC) shall be constituted with the Head of the Department as Chairperson, Dissertation Supervisor and one senior faculty member of the Department offering the M. Pharm. programme.

7.8 Registration of Dissertation Work: A candidate is permitted to register for the Dissertation Work after satisfying the attendance requirement in all the courses, both theory and laboratory.

7.9 After satisfying the above clause, the candidate in consultation with his Dissertation Supervisor, the title, objective and plan of action of his Dissertation work must be finalized and present before the Dissertation Review Committee (DRC), which is termed as in Dissertation Work Review–I, for approval within four weeks from the commencement of Second year First Semester. Only after obtaining the approval of the DRC, the student can initiate the Dissertation work. Dissertation Work Review–I does not carry any credits.

7.10 If a candidate wishes to change his supervisor or topic of the Dissertation, he can do so with the approval of the DRC. However, the DRC shall examine whether or not the change of topic/supervisor leads to a major change of his initial plans of Dissertation proposal. If yes, his date of registration for the project work starts from the date of change of Supervisor or topic as the case may be.

7.11 A candidate shall submit his Dissertation progress report in two stages at least with a gap of **three** months between them.

7.12 The work on the Dissertation shall be initiated at the beginning of the II year and the duration of the Dissertation is two semesters. A candidate is permitted to submit Dissertation only after successful completion of all theory and practical courses with the approval of DRC not earlier than 40 weeks from the date of approval of the Dissertation work. For the approval of DRC the candidate shall submit the draft copy of thesis to the Head of the Department and make an oral presentation before the DRC.

7.13 The Dissertation Work Review - II in II Year I Sem. carries internal marks of 100. Evaluation should be done by the DRC for 50 marks and the Supervisor will evaluate the work for the other 50 marks. The Supervisor and DRC will examine the Problem Definition, Objectives, Scope of Work, Methodology Adopted, Literature Survey in the same domain and progress of the Dissertation Work.

7.14 The Dissertation Work Review - III in II Year II Sem. carries 100 internal marks. Evaluation should be done by the DRC for 50 marks and the Supervisor will evaluate it for the other 50 marks. The DRC will examine the overall progress of the Dissertation Work and decide whether or not the Dissertation is eligible for final submission.

7.15 The evaluation of each of Dissertation Work Review – II and Dissertation Work Review - III by the DRC shall be carried out as per the criteria given below:

Objective(s) of the work done	- 5 Marks
Methodology adopted	- 15 Marks
Results and Discussions	- 25 Marks
Conclusions and Outcomes	- 5 Marks
Total	**- 50 Marks**

7.16 A candidate has to secure a minimum of 50% of marks to be declared successful in each of Dissertation Work Review — II and Dissertation Work Review - III. If he fails to obtain the required minimum marks, he has to reappear for the same Dissertation Work Review as and when conducted.

7.15 Dissertation Evaluation (Viva Voce) shall be done in II Year II Sem. There shall be external marks of 100 and it is evaluated by the external examiner. The evaluation shall be done as per the criteria given below:

Presentation of work	- 40 Marks
Communication skills	- 20 Marks
Viva-Voce	- 40 Marks
Total	**- 100 Marks**

The candidate has to secure a minimum of 50% marks in Dissertation Evaluation (Viva-Voce) examination. If he fails to obtain the required minimum marks, he has to reappear for the same as and when conducted.

7.16 Dissertation Work Reviews - II and III shall be conducted in phase I (Regular) and Phase II (Supplementary). Phase II will be conducted only for unsuccessful students in Phase I. The unsuccessful students in Dissertation Work Review - II (Phase II) shall reappear for it at the time of Dissertation Work Review - III (Phase I). These students shall reappear for Dissertation Work Review - III in the next academic year at the time of Dissertation Work Review - II only after completion of Dissertation Work Review - II, and then Dissertation Work Review - III follows. The unsuccessful students in Dissertation Work Review - III (Phase II) shall reappear for Dissertation Work Review - III in the next academic year only at the time of Dissertation Work Review - II (Phase I).

7.17 After approval from the DRC, a soft copy of the thesis should be submitted for Anti-Plagiarism check and the plagiarism report should be submitted to the University and be included in the final thesis. The Thesis will be accepted for submission, if the similarity index is less than **30%**. If the similarity index is more than the required percentage, the student is advised to modify accordingly and re-submit the soft copy of the thesis after one month. The maximum number of re-submissions of thesis after plagiarism check is limited to two. The candidate has to register for the dissertation work and work for two semesters. After three attempts, the admission is liable to be cancelled. The college authorities are advised to make plagiarism check of every soft copy of dissertation before submissions.

7.18 Three copies of the Dissertation certified by the supervisor shall be submitted to the College/School/Institute for the evaluation.

7.19 The dissertation shall be adjudicated by an external examiner selected by the University. For this, the Principal of the College/School/Institute shall submit a panel of **three** examiners from among the list of experts in the relevant specialization as submitted by the supervisor concerned and Head of the Department.

7.20 If the report of the external examiner is unsatisfactory, the candidate shall revise and resubmit the dissertation. If the report of the examiner is unsatisfactory again, the dissertation shall be summarily rejected. Subsequent actions for such dissertations may be considered, only on the specific recommendations of the external examiner and /or Dissertation Review Committee. No further correspondence in this matter will be entertained, if there is no specific recommendation for resubmission.

7.21 If the report of the examiner is satisfactory, the Head of the Department shall coordinate and make arrangements for the conduct of Dissertation Viva-Voce examination. The Dissertation Viva-Voce examination shall be conducted by a board consisting of the Supervisor, Head of the Department and the external examiner who adjudicated the Thesis. The student has to secure a minimum of 50% of marks in Dissertation Evaluation (Viva-Voce) examination.

7.22 If the student fails to fulfill the requirements as specified earlier, he will reappear for the Dissertation Viva-Voce examination only after three months. In the reappeared examination also, if he fails to fulfill the requirements, he will not be eligible for the award of the degree, unless he is asked to revise and resubmit his Dissertation Work by the board within a specified time period (within **four** years from the date of commencement of his first year first semester).

7.23 The Dissertation Viva-Voce External examination marks must be submitted to the University on the day of the examination.

7.24 For audit courses, a student has to secure 50 marks out of 100 marks (i.e. 50% of the marks) in the continuous internal evaluation for passing the course. These marks should also be uploaded along with the internal marks of other courses.

7.25 No marks or letter grades shall be allotted for audit courses. Only Pass/Fail shall be indicated in Grade Card.

8.0 Re-Admission/Re-Registration

8.1 Re-Admission for Discontinued Student

A student, who has discontinued the M. Pharm. degree programme due to any reason whatsoever, may be considered for '**readmission'** into the same degree programme (with the same specialization) with the academic regulations of the batch into which he gets readmitted, with prior permission from the authorities concerned.

8.2 If a student is detained in a course (s) due to shortage of attendance in any semester, he may be permitted to **re-register** for the same course(s) in the same category (core or elective group) or equivalent course, if the same course is not available, as suggested by the Board of Studies of that department, as and when offered in the subsequent semester(s), with the academic regulations of the batch into which he seeks re-registration, with prior permission from the authorities concerned.

8.3 A candidate must re-register for failed courses within four weeks of commencement of the class work and secure the required minimum attendance. In the event of the student taking this chance, his Continuous Internal Evaluation marks obtained in the previous attempt stands cancelled.

9.0 Examinations and Assessment - The Grading System

9.1 Grades will be awarded to indicate the performance of each student in each Theory Course, Lab/ Practical, or Mini Project, Seminar, Dissertation, etc., based on the percentage of marks obtained in Continuous Internal Evaluation (CIE) and Semester End Examination (SEE), both taken together, as specified in clause 7 above, and the corresponding Letter Grade shall be given.

9.2 As a measure of the student‟s performance, a 10-point Absolute Grading System using

the following percentage of marks and the corresponding letter grades are followed:

% of Marks Secured in a Course (Class Intervals)	Letter Grade	Grade Points
Greater than or equal to 90%	O (Outstanding)	10
80 and less than 90%	A (Excellent)	9
70 and less than 80%	B (Good)	8
60 and less than 70%	C (Fair)	7
50 and less than 60%	D (Average)	6
Below 50%	F (FAIL)	0
Absent	Ab	0

9.3 A student obtaining **'F'** Grade in any Course is deemed to have „failed" and is required to reappear as „Supplementary Candidate" for the Semester End Examination (SEE), as and when conducted. In such cases, his Continuous Internal Marks (CIE Marks) in those courses will remain as obtained earlier.

9.4 If a student has not appeared for the examinations, **'Ab'** Grade will be allocated to him for any course and shall be considered „failed" and will be required to reappear as „Supplementary Candidate" for the Semester End Examination (SEE), as and when conducted.

9.5 A Letter Grade does not imply any specific marks percentage; it is only the range of percentage of marks.

9.6 In general, a student shall not be permitted to repeat any Course (s) only for the sake of „Grade Improvement" or „SGPA/ CGPA Improvement".

9.7 A student earns Grade Point (GP) in each Course, on the basis of the Letter Grade obtained by him in that Course. The corresponding „Credit Points" (CP) are computed by multiplying the Grade Point with Credits for that particular Course.

Credit Points (CP) = Grade Point (GP) x Credits …. For a Course

9.8 The Semester Grade Point Average (SGPA) is calculated by dividing the Sum of Credit Points secured from all Courses registered in a Semester, by the Total Number of Credits registered during that Semester. SGPA is rounded off to two Decimal Places. SGPA is thus computed as

$$\textbf{SGPA} = \{ \sum_{i=1}^{N} C_i G_i \} \; / \; \{ \sum_{i=1}^{N} C_i \} \textbf{ …. For each Semester,}$$

where „i" is the Course indicator index (taking into account all Courses in a Semester), „N" is the no. of Courses registered for the Semester (as specifically required and listed under the Course Structure of the parent Department), C_i is the no. of Credits allotted to the i^{th} Course, and G_i represents the Grade Points corresponding to the Letter Grade awarded for that i^{th} Course.

9.9 The Cumulative Grade Point Average (CGPA) is a measure of the overall cumulative performance of a student over all semesters considered for registration. The CGPA is the ratio of the total credit points secured by a student in all registered Courses in all Semesters, and the Total Number of credits registered in all the Semesters. CGPA is rounded off to two decimal places. CGPA is thus computed from the I Year Second Semester onwards, at the end of each Semester, as per the formula.

$$\textbf{CGPA} = \{ \sum_{j=1}^{M} C_j G_j \} / \{ \sum_{j=1}^{M} C_j \}$$

where „M" is the total no. of Courses (as specifically required and listed under the Course Structure of the parent Department) the Student has registered. C_j is the no. of Credits allotted to the j^{th} Course, and G_j represents the Grade Points corresponding to the Letter Grade awarded for that j^{th} Course. After registration and completion of I Year I Semester however, the SGPA of that Semester itself may be taken as the CGPA, as there are no cumulative effects.

Illustration of calculation of SGPA

Course	Credits	Letter Grade	Grade Points	Credit Points
Course 1	4	A	9	4 x 9 = 36
Course 2	4	O	10	4 x 10 = 40
Course 3	4	C	7	4 x 7 = 28
Course 4	3	B	8	3 x 8 = 24
Course 5	3	A	10	3 x 10 = 30
Course 6	3	C	7	3 x 7 = 21
	Total Credits = 21			Total Credit Points = 179

SGPA = 179/21 = 8.52

Illustration of calculation of CGPA

Course	Credits	Letter Grade	Grade Points	Credit Points
I Year I Semester				
Course 1	4	A	9	4 x 9 = 36
Course 2	4	A	9	4 x 9 = 36
Course 3	4	B	8	4 x 8 = 32
Course 4	3	O	10	3 x 10 = 30
Course 5	3	B	8	3 x 8 = 24
Course 6	3	D	6	3 x 6 = 18
I Year II Semester				
Course 7	4	B	8	4 x 8 = 32
Course 8	4	O	10	4 x 10 = 40
Course 9	4	A	9	4 x 9 = 36
Course 10	3	D	6	3 x 6 = 18
Course 11	3	C	7	3 x 7 = 21
Course 12	3	A	9	3 x 9 = 27
	Total Credits = 42			Total Credit Points = 350

CGPA upto II Year II Semester = 350/42 = 8.33

10.0 Award of Degree and Class

10.1 If a student who registers for all the specified Courses as listed in the Course Structure, satisfies all the Course Requirements, and passes the examinations prescribed in the entire M. Pharm. Programme, and secures the required number of **98** Credits (with CGPA □ 6.0), shall be declared to have qualified for the award of the M. Pharm. Degree in the chosen specialization of Pharmacy that he was admitted into.

10.2 **Award of Class**

After a student has earned the requirements prescribed for the completion of the programme and is eligible for the award of M. Pharm. Degree, he shall be placed in one of the following three classes based on the CGPA:

Class Awarded	CGPA
First Class with Distinction	≥ 7.50
First Class	$6.50 \leq$ CGPA < 7.50
Second Class	$6.00 \leq$ CGPA < 6.5

11.0 Withholding of Results

If the student has not paid the dues, if any, to the University or if any case of indiscipline is pending against him, the result and degree of the student will be withheld and he will not be allowed into the next semester.

12.0 General

12.1 **Credit**: A unit by which the course work is measured. It determines the number of hours of instructions required per week. One credit is equivalent to one hour of teaching (lecture or tutorial) or two hours of practical work/field work per week.

12.2 **Credit Point:** It is the product of grade point and number of credits for a course.

12.3 Wherever the words “he”, “him”, “his”, occur in the regulations, they shall include “she”, “her”.

12.4 The academic regulation should be read as a whole for the purpose of any interpretation.

12.5 In case of any doubt or ambiguity in the interpretation of the above rules, the decision of the University is final.

The University may change or amend the academic regulations or syllabi at any time and the changes or amendments made shall be applicable to all the students with effect from the dates notified by the University

MALPRACTICES RULES

DISCIPLINARY ACTION FOR IMPROPER CONDUCT IN EXAMINATIONS

S.No	Nature of Malpractices/Improper conduct	Punishment
	If the candidate:	
1.(a)	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 to 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 the subject of the examination).	Expulsion from the examination hall and cancellation of the performance in that subject only.
(b)	Gives assistance or guidance or receives it from any other candidate orally or by any other body language methods or communicates through cell phones with any candidate or persons in or outside the exam hall in respect of any matter.	Expulsion from the examination hall and cancellation of the performance in that subject only of all the candidates involved. Incase of anoutsider, 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 to the examination (theory or practical) in which the candidate is appearing.	Expulsion from the examination hall and cancellation of the performance in that subject and all other subjects the candidate has alreadyappeared including practical examinations and project work and shall not be permitted to appearfor 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.	Impersonates any other candidate inconnection 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 imposter is an outsider, he will be handed over to the police and a case is registered against him.
4.	Smuggles in the Answer book or additional sheet or takes out or arranges to send out the question paper during the examination or answer book or additional sheet, during or after the examination.	Expulsion from the examination hall and cancellation of performance in that subject and all the other subjects the candidate has alreadyappeared 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.	Uses objectionable, abusive or offensive language in the answer paper or in letters to the examiners or writes to the examiner Requesting him to award pass marks.	Cancellation of the performance in that subject.

6.	Refuses to obey the orders of the Chief Superintendent/Assistant – Superintendent/ any officer on duty or misbehaves or creates disturbance of any kind in and around the examination hall or organizes a walk out or instigates others to walk out, or threatens the officer-in charge or any person on duty in oroutside the examination hall of any injury to his person or to any of his relations whetherby words, either spoken or written or by signs or by visible representation, assaults the officer-in- charge, or any person on duty in or outside the examination hall or any of his relations, or indulges in any other act of misconduct or mischief which result in damage to or destruction of property in the examination hall or any part of the College campus or engages in any other act which in the opinion of the officer on duty amounts touse of unfair means or misconduct or has the tendency to disrupt the orderly conduct of the Examination.	Incase 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 examinations of the subjects of that 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.
7.	Leaves the exam hall taking away answer script or intentionally tears of the script or any par there of inside or outside the examination hall.	Expulsion from the examination hall and cancellation of performance in that subject and all the other subjects the candidate has alreadyappeared 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.
8.	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.
9.	If student of the college, who is not a candidate for the particular examination or any person not connected with the college indulges in any malpractice or improper conduct mentioned in clause 6 to 8.	Student of the colleges 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 debarredand 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.
10.	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.
11.	Copying detected on the basis of internal evidence, such as, during valuation or during special scrutiny.	Cancellation of the performance in that subject and all other subjects the candidate has appeared including practical examinations and project work of that semester/year 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 periodof not less than one year.

M.PHARMACY (PHARMACY PRACTICE)
R25 COURSE STRUCTURE AND SYLLABUS
Effective from Academic Year 2025-26 Admitted Batch

I YEAR I Semester

Course Code	Course Title	L	T	P	Credits
Professional Core-I	Pharmacotherapeutics – I	3	1	0	4
Professional Core-II	Clinical Pharmacy Practice	3	1	0	4
Professional Elective-I	1. Clinical Toxicology 2. Hospital and Community Pharmacy 3. Clinical Research and Pharmacovigilance	3	1	0	4
Professional Elective-II	1. Molecular Biology 2. Advances in Preclinical Evaluation 3. Drug Regulatory Affairs	3	1	0	4
	Research Methodology and IPR	2	0	0	2
Laboratory-I	Pharmacotherapeutics – I Lab	0	0	6	3
Laboratory-II	Clinical Pharmacy Practice Lab	0	0	6	3
Audit - I	Audit Course - I	2	0	0	0
	Seminar & Assignment	0	0	4	2
	Total	**16**	**4**	**16**	**26**

I YEAR II Semester

Course Code	Course Title	L	T	P	Credits
Professional Core-III	Pharmacotherapeutics – II	3	1	0	4
Professional Core-IV	Clinical Pharmacokinetics and Drug monitoring	3	1	0	4
Professional Elective-III	1. Biopharmaceutics and Pharmacokinetics 2. Clinical Research 3. Quality use of Medicines	3	1	0	4
Professional Elective-IV	1. Principles of Drug Discovery 2. Cellular and Molecular Pharmacology 3. Nutraceuticals	3	1	0	4
Laboratory- III	Pharmacotherapeutics – II Lab	0	0	6	3
Laboratory- IV	Clinical Pharmacokinetics and Drug Monitoring Lab	0	0	6	3
	Mini Project	2	0	0	2
Audit - II	Audit Course- II	2	0	0	0
	Seminar & Assignment	0	0	4	2
	Total	**16**	**4**	**16**	**26**

II YEAR I Semester

Course Code	Course Title	L	T	P	Credits
Professional Elective-V	1. Biostatistics 2. Pharmacoepidemiology and Pharmacoeconomics 3. Phytopharmaceuticals	3	1	0	4
Open Elective	Open Elective	3	1	0	4
	Comprehensive Viva voce	0	0	8	4
	Dissertation Work Review - II	0	0	24	12
	Total	**6**	**2**	**32**	**24**

II YEAR II Semester

Course Code	Course Title	L	T	P	Credits
Dissertation	Dissertation Work Review - III	0	0	24	12
Dissertation	Dissertation Viva-Voce	0	0	20	10
	Total	**0**	**0**	**44**	**22**

***For Dissertation Work Review - I, Please refer R22 Academic Regulations.Audit**

Courses I & II:

1. English for Research Paper Writing
2. Disaster Management
3. Sanskrit for Technological Learning
4. Value Education
5. Constitution of India
6. Pedagogy Studies
7. Stress Management by Yoga
8. Personality Development through Life Enlightenment Skills

M.Pharm I Year I Sem (PHARMACY PRACTICE)
PHARMACOTHERAPEUTICS- I (Professional Core - I)

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

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

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

UNIT- I

Cardiovascular System: Hypertension, Congestive cardiac failure, Acute coronary syndrome, Arrhythmias, Hyperlipidemias. Hematological diseases: Anemia, Deep vein thrombosis, Drug induced hematological disorders

UNIT- II

Respiratory System: Asthma, Chronic obstructive airways disease, Drug induced pulmonary diseases Endocrine system: Diabetes, Thyroid diseases

UNIT- III

Gastrointestinal System: Peptic ulcer diseases, Reflux esophagitis, inflammatory bowel diseases, Jaundice, & hepatitis, Cirrhosis, Diarrhea and Constipation, Drug-induced liver disease

UNIT-IV

Bone And Joint Disorders: Rheumatoid arthritis, Osteoarthritis, Gout, Osteoporosis

UNIT-V

Dermatological Diseases: Psoriasis, Eczema and scabies, impetigo, drug induced skin disorders
Ophthalmology: Conjunctivitis, Glaucoma

REFERENCE BOOKS:

1. Roger and Walker. Clinical Pharmacy and Therapeutics – Churchill Livingstone publication
2. Joseph T. Dipiro et al. Pharmacotherapy: A Pathophysiologic Approach-Appleton & Lange
3. Robins SL. Pathologic basis of disease -W.B. Saunders publication
4. Eric T. Herfindal. Clinical Pharmacy and Therapeutics- Williams and Wilkins Publication
5. Lloyd Young and Koda-Kimble MA Applied Therapeutics: The clinical Use of Drugs-LWW
6. Chisholm- Burns Wells Schwinghammer Malone and Joseph P Dipiro. Pharmacotherapy Principles and practice-– McGraw Hill Publication
7. Carol Mattson Porth. Principles of Pathophysiology- Lippincott Williams and Wilkins
8. Harrison's. Principles of Internal Medicine - McGraw Hill
9. Clinical Pharmacy and Pharmacotherapeutics by Ravi Shankar, Pharma med Press
10. Pharmacotherapeutics by laxmi, Pharmamed Press.

M.Pharm I Year I Sem (PHARMACY PRACTICE)
CLINICAL PHARMACY PRACTICE (Professional Core - II)

Course Objective: 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.

Course Outcome: 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

UNIT- I

Introduction to Clinical Pharmacy: Definition, evolution and scope of clinical pharmacy, International and national scenario of clinical MPP, Pharmaceutical care Clinical Pharmacy Services: Ward round participation, Drug therapy review (Drug therapy monitoring including medication order review, chart endorsement, clinical review and pharmacist interventions)

UNIT - II

Clinical Pharmacy Services: Patient medication history interview, Basic concept of medicine and poison information services, Basic concept of pharmacovigilance, Hemovigilance, Materiovigilance and AEFI, Patient medication counseling, Drug utilization evaluation, Documentation of clinical pharmacy services, Quality assurance of clinical pharmacy services.

UNIT - III

Patient Data Analysis: Patient Data & Practice Skills: Patient's case history – its structure and significances in drug therapy management, Common medical abbreviations, and terminologies used in clinical practice, Communication skills: verbal and non-verbal communications, its applications in patient care services. Lab Data Interpretation: Hematological tests, Renal function tests, Liver functiontests

UNIT - IV

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

UNIT - V

Medicines & Poisons Information Services:

Medicine Information Service: Definition and need for medicine information service, Medicine information resources, Systematic approach in answering medicine information queries, Preparation of verbal and written response, establishing a drug information centre.

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

REFERENCE BOOKS:

1. A Textbook of Clinical MPP – Essential concepts and skills –Parthasarathi G, Karin Nyfort-Hansen and Milap Nahata
2. Practice Standards and Definitions - The Society of Hospital Pharmacists of Australia

3. Basic skills in interpreting laboratory data - Scott LT, American Society of Health SystemPharmacists Inc
4. Thomas J Johnson, Critical Care Pharmacotherapeutics
5. Collen D L, Sneha B S, Fundamental Skills for Patient Care in MPP
6. Patient Assessment in Pharmacy, by Yolanda M H
7. Patient Communication for Pharmacy : A Case-Study Approach on Theory and Practice, MinLiu, Lakesha M. Butler
8. 11. Fundamental Skills for Patient Care in Pharmacy Practice by Colleen Doherty Lauster, Sneha Baxi Srivastava
9. Relevant review articles from recent medical and pharmaceutical literature
10. Fundamentals of Clinical Pharmacy Practice by D. Sudheer Kumar, Dr. J. Krishnaveni

M. Pharm I Year I Sem (PHARMACY PRACTICE)
CLINICAL TOXICOLOGY (Professional Elective – I)

Course Objective: In the current scenario of accidental, homicidal and suicidal excessive consumption of drugs, pesticides, heavy metals and other poisonings, this elective helps the students to acquire the required knowledge and skills in the management of poisoning.

Course Outcome: At the end of the course the student is equipped with handling the first aid, elimination enhancement and treatment of poisoning and supportive care in poisoning due to

- Pesticides
- Drug over usage
- Heavy metals
- Radiation
- Snakes and anthropod bites
- Food poisoning

The student also gains knowledge in substance abuse and treatment of drug dependence.

UNIT - I

General principles involved in the management of poisoning, antidotes and the clinical applications.

UNIT - II

Supportive care in clinical toxicology. Gut decontamination, elimination enhancement and toxicokinetics.

UNIT - III

Clinical symptoms and management of acute poisoning with the following agents –

a) Pesticide poisoning: organophosphorus compounds, carbamates, organochlorines, pyrethroids. b) Opiates overdose. c) Antidepressants d) Barbiturates and benzodiazepines. e) Alcohol: ethanol, methanol. f) Paracetamol and salicylates. g) Non-steroidal anti-inflammatory drugs. h) Hydrocarbons: Petroleum products and PEG. i) Caustics: inorganic acids and alkalis. j) Radiation poisoning

UNIT - IV

Clinical symptoms and management of chronic poisoning with the following agents –

a) Heavy metals: Arsenic, lead, mercury, iron, copper b) Venomous snake bites: Families of venomous snakes, clinical effects of venoms, general management as first aid, early manifestations, complications and snake bite injuries. c) Plants poisoning. Mushrooms, Mycotoxins. d) Food poisonings e) Envenomations – Arthropod bites and stings.

UNIT - V

Substance Abuse:

Signs and symptoms of substance abuse and treatment of dependence

a) CNS stimulants: amphetamine
b) Opioids
c) CNS depressants
d) Hallucinogens: LSD
e) Cannabis group
f) Tobacco

REFERENCE BOOKS:

1. Matthew j ellenhorn. Ellenhorns medical toxicology – diagnosis and treatment of poisoning.Second edition. Williams and willkins publication, london b.
2. 2. V V Pillay. Handbook of forensic medicine and toxicology. Thirteenth edition 2003 paraspublication, Hyderabad

M. Pharm I Year I Sem (PHARMACY PRACTICE) HOSPITAL &

COMMUNITY PHARMACY (Professional Elective - I)

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

Course Outcome: 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

UNIT- I

Introduction to Hospitals: Definition, classification, organizational structure Hospital Pharmacy: Definition, Relationship of hospital pharmacy department with other departments, Organizational structure, legal requirements, work load statistics, Infrastructural requirements, Hospital Pharmacy Budget and Hospital Pharmacy management Hospital Drug Policy: Pharmacy & Therapeutics Committee, Infection Control committee, Research & Ethics Committee, Management of Medicines asper NABH

UNIT- II

Hospital Formulary Guidelines: And its development, Developing Therapeutic guidelines, Drug procurement process, and methods of Inventory control, Methods of Drug distribution, Intravenous admixtures, Hospital Waste Management

UNIT- III

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 MPP: Definition, roles & responsibilities of community pharmacists, and their relationship with other health care providers. Community Pharmacy management: Legal requirements to start community pharmacy, site selection, lay out & design, drug display, super drug store model, accounts and audits, Good dispensing practices, Different softwares & databases used in community pharmacies. Entrepreneurship in community pharmacy.

UNIT- IV

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

UNIT- V

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 andoutcomes Research in community MPP

REFERENCE BOOKS:

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)

CLINICAL RESEARCH AND PHARMACOVIGILANCE (Professional Elective - I)

Course Objectives: This subject will provide a value addition and current requirement for the students in clinical research and pharmacovigilance. It will teach the students on conceptualizing, designing, conducting, managing and reporting of clinical trials. This subject also focuses on global scenario of pharmacovigilance in different methods that can be used to generate safety data. It will teach the students in developing drug safety data in pre-clinical, clinical phases of drug development and post market surveillance.

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

- explain the regulatory requirements for conducting clinical trial
- Demonstrate the types of clinical trial designs
- Explain the responsibilities of key players involved in clinical trials
- Execute safety monitoring, reporting and close-out activities
- Explain the principles of Pharmacovigilance
- Detect new adverse drug reactions and their assessment
- Perform the adverse drug reaction reporting systems and communication inpharmacovigilance

UNIT - I

Regulatory Perspectives of Clinical Trials:

Origin and Principles of International Conference on Harmonization - Good Clinical Practice (ICH-GCP) guidelines Ethical Committee: Institutional Review Board, Ethical Guidelines for Biomedical Research and Human Participant-Schedule Y, ICMR, Informed Consent Process: Structure and content of an Informed Consent Process Ethical principles governing informed consent process

UNIT - II

Clinical Trials: Types and Design:

Experimental Study- RCT and Non RCT, Observation Study: Cohort, Case Control, Cross sectional Clinical Trial Study Team Roles and responsibilities of Clinical Trial Personnel: Investigator, Study Coordinator, Sponsor, Contract Research Organization and its management.

UNIT - III

Clinical Trial Documentation:

Guidelines to the preparation of documents, Preparation of protocol, Investigator Brochure, Case Report Forms, Clinical Study Report Clinical Trial Monitoring-Safety Monitoring in CT Adverse Drug Reactions: Definition and types. Detection and reporting methods. Severity and seriousness assessment. predictability and preventability assessment. Management of adverse drug reactions; Terminologies of ADR.

UNIT - IV

Basic aspects, terminologies and establishment of pharmacovigilance:

History and progress of pharmacovigilance, Significance of safety monitoring, Pharmacovigilance in India and international aspects, WHO international drug monitoring Program, WHO and Regulatory terminologies of ADR, evaluation of medication safety, establishing pharmacovigilance centres in Hospitals, Industry and National Programs related to pharmacovigilance. Roles and responsibilities in Pharmacovigilance.

UNIT - V

Methods, ADR reporting and tools used in pharmacovigilance:

International classification of diseases, International Nonproprietary names for drugs, Passive and Active surveillance, Comparative observational studies, Targeted clinical investigations and Vaccine safety surveillance. Spontaneous reporting system and Reporting to regulatory authorities, Guidelines for ADRs reporting. Argus, Aris G Pharmacovigilance, VigiFlow, Statistical methods for evaluating medication safety
data.

REFERENCE BOOKS:

1. Central Drugs Standard Control Organization- Good Clinical Practices, Guidelines for Clinical Trials on Pharmaceutical Products in India. New Delhi: Ministry of Health; 2001.
2. International Conference on Harmonization of Technical requirements for registration of Pharmaceuticals for human use. ICH Harmonized Tripartite Guideline. Guideline for Good Clinical Practice. E6; May 1996.230
3. Ethical Guidelines for Biomedical Research on Human Subjects 2000. Indian Council of Medical Research, New Delhi.
4. Textbook of Clinical Trials edited by David Machin, Simon Day and Sylvan Green, March 2005, John Wiley and Sons.
5. Clinical Data Management edited by R K Rondels, S A Varley, C F Webbs. Second Edition, Jan 2000, Wiley Publications.
6. Handbook of clinical Research. Julia Lloyd and Ann Raven Ed. Churchill Livingstone.
7. Principles of Clinical Research edited by Giovanna di Ignazio, Di Giovanna and Haynes.
8. Textbook of Pharmacovigilance: Concept and Practice. G.P. Mohanta and P. K. Manna. 2016, Pharma Med Press.
9. A textbook of Clinical Pharmacy Practice: Essential Concepts and Skills. Second Edition,2012, University Press
10. A Textbook of Clinical Research and Pharmacovigilance by KPR Chowdary, PharmamedPress

M. Pharm I Year I Sem (PHARMACY PRACTICE)
MOLECULAR BIOLOGY (Professional Elective - II)

Course Objective: This subject will provide the knowledge about nucleic acid-DNA and RNA structures, DNA Topology, organization of DNA into chromosomes, mutation problems. This subject also provides knowledge about transcription and translation processes occur in molecular biology.

Course Outcome: Upon completion of the course, the student shall be able to, know about total molecular biology with structures, chromosomes arrangement, the processes occur in cell, synthesis and processing of prokaryotic and eukaryotic transcripts. Transport of RNA within eukaryotic cell. Regulatory elements of genes-promoters.

UNIT - I

Introduction to Molecular biology

Nucleic acids - DNA and RNA structure and functions, DNA as genetic material. Griffth, Avery-McCarty-MCLeod, Hershy- Chase, Franklin Conrat Experiments

DNA Structure: Chemistry of DNA, Forces stabilizing DNA structure, Helix parameters, Forms of DNA (A,B,C,D,T and Z), Watson – Crick and Hoogsteen base pairing , Physical Properties of ds DNA (UV absorption spectra Denaturation and renaturation), Chemical that react with DNA.

UNIT - II

DNA topology: DNA supercoiling, Supercoiled form of DNA, Super helical density, Energetic of supercoiled DNA, Biology of supercoiled DNA (Topological domain of DNA, DNA topoisomerases, Mechanisms of supercoiling in cells, mechanisms of action of topoisomerase I and II, effect of supercoiling on structure of DNA and role of supercoiling in gene expression and DNA replication).

Organization of DNA into chromosomes: Packaging of DNA and organization of chromosome in bacteria and eukaryotic cells; packaging of DNA in eukaryotic nucleosome and chromatin condensation assembly of nucleosomes upon replication. Chromatin modification and genome expression.

UNIT - III

Mutations- molecular mechanism - types of DNA mutations and its significance. DNA repair - repair mechanisms - need of DNA repairs, DNA recombination – molecular mechanism of recombination-relationship between repair and recombination, SOS mechanism. Proteins and enzymes involved DNA repair and recombination.

DNA – Protein Interactions: General features interaction of Helix- turn Helix motif, B sheet, Zn-DNAbinding domain etc with DNA.

UNIT - IV

DNA Replication: Mechanism of DNA polymerase catalyzed synthesis of DNA, types of DNA polymerases in bacteria and their role. Initiation of chromosomal DNA replication and its regulation in prokaryotes assembly of replisome and progress of replication fork, termination of replication. Types and function of eukaryotic DNA polymerases initiation of replication in eukaryotes, role of telomerases in replication of eukaryotic chromosomes. Inhibitor of DNA replication (Blocking precursor synthesis nucleotide polymerization, altering DNA structure).

Transcription: RNA polymerases, features of prokaryotic and eukaryotic promoters. Strong and weakpromoters. Assembly of transcription initiation complex in prokaryotes and eukaryotes and its regulation; synthesis and processing of prokaryotic and eukaryotic transcripts. Transport of RNA within eukaryotic cell. Regulatory elements of genes-promoters. Fate of mRNA.

UNIT - V

Translation- Synthesis and Processing of Proteome: Structure and role of tRNA in protein synthesis, ribosome structure, basic feature of genetic code and its deciphering, translation (initiation, elongation and termination in detail in prokaryotes as well as eukaryotes), Post translational processing of protein (protein folding, processing by proteolytic cleavage, processing by chemical modification, inteins). Protein degradation.

Regulation of Gene expression in prokaryotes and eukaryotes: Positive and negative regulation. lac-, ara-, his- and trp- operon regulation; antitermination, global regulatory responses; Regulation of gene expression in eukaryotes: Transcriptional, translational and processing level control mechanisms.

DNA- transposable elements- types of transposable elements, its importance in variation and evolution. Possible origin of virus, Oncogenes.

REFERENCE BOOKS:

1. Cell & Molecular Biology: Cell and Molecular Biology: Concepts and Experiments, GeraldKarp, John Wiley, NY
2. Molecular Cell Biology, H.S. Bramrah, Anmol Publications Pvt. Ltd., New Delhi
3. Advanced Molecular Biology, H.S. Bhamrah Viva Books, Pvt. Ltd., New Delhi
4. Plant Biochemistry and Molecular Biology, Hans Walter Held, Oxford, NY
5. Molecular Biology of the Gene, Watson, Baker, Bell, Gann Levine, Losick, Pearson EducationPvt. Ltd., New Delhi
6. Essential Molecular Biology: A Practical Approach, TA Brown, oxford.

M. Pharm I Year I Sem (PHARMACY PRACTICE)

ADVANCES IN PRECLINICAL EVALUATION – I (Professional Elective-II)

Course Objective: This course is designed to impart basic knowledge and skills that are required animals and their regulatory requirements. The students will know about screening programmes, preclinical and clinical models to perform activities.

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

- Understand the care and handling experimental animals
- Understand drug rules and regulations for conducting animal studies
- Know about preclinical & clinical studies of different ANS drugs and their models.

UNIT - I

Care, handling and breeding techniques of laboratory animals. Regulations for laboratory animal care and ethical requirement. Knowledge of the CPCSEA proforma for performing experiments on animals.

UNIT - II

Organization of preclinical screening programme (Blind screening)

UNIT - III

Drug Discovery Process: Principles, techniques and strategies used in drug discovery. High throughput screening, human genomics.

UNIT - IV

Preclinical and clinical models employed in the screening of new drugs belonging to following categories.

1. Drugs acting on Autonomic nervous system: Sympathomimetics, Parasympathomimetics, Anticholinesterages, anticholinergics, adrenolytics. Muscle relaxants (peripheral)
2. Cardiovascular Pharmacology: Cardiac glycosides, antiarrhythmics, antihypertensives, antiatherosclerotics.
3. Screening of free radical scavenging activity
4. Immunopharmacology: Specific (Cell and humoral mediated) and non-specific methods.
5. Drugs for metabolic disorders: Anti-diabetic agents, Hepatoprotective agents, Anti-hyperlipidemic agents

UNIT - V

Principles of Toxicological evaluations, ED50, LD50 and TD values, acute, sub-acute and chronic toxicity studies.

REFERENCE BOOKS:

1. Biological standardization by J. H. Burn D.J. Finney and I.G. Goodwin
2. Screening methods in Pharmacology by Robert Turner. A
3. Evaluation of drugs activities by Laurence and Bachrach
4. Methods in Pharmacology by Arnold Schwartz.
5. Fundamentals of experimental Pharmacology by M. N. Ghosh
6. Pharmacological experiment on intact preparations by Churchill Livingstone
7. Drug discovery and Evaluation by Vogel H.G.
8. Experimental Pharmacology by R. K. Goyal.

9. Preclinical evaluation of new drugs by S. K. Gupta
10. Pharmacological screening methods and Toxicology by A. Srinivasa Rao

11. Handbook of Experimental Pharmacology, S K. Kulkarni
12. Practical Pharmacology and Clinical Pharmacy, S K. Kulkarni, 3rd Edition.
13. David R. Gross. Animal Models in Cardiovascular Research, 2nd Edition, Kluwer AcademicPublishers, London, UK.
14. Screening Methods in Pharmacology, Robert A. Turner.
15. Rodents for Pharmacological Experiments, Dr. Tapan Kumar chatterjee.
16. Practical Manual of Experimental and Clinical Pharmacology by Bikash Medhi (Author), AjayPrakash (Author)

M. Pharm I Year I Sem (PHARMACY PRACTICE)

DRUG REGULATORY AFFAIRS (Professional Elective - II)

Course Objective: The topics which are present in the Drug regulatory affairs are very much useful which increases the knowledge regarding the regulatory aspects in the pharmaceutical industries.

Course Outcome:

- Students will come to know the different competent regulatory authorities globally.
- Students be aware of technical aspects pertaining to the marketing authorization application (MAA)
- The regulatory guidelines and directions framed by the regulatory authorities will be helpful toplace the drug products in market for marketing approvals.

UNIT - I

Drug Regulatory Aspects (India)

1. Indian drug regulatory authorities, Central and State regulatory bodies (FDA)
2. Drugs and Cosmmetics Act and Rules with latest Amendments (Selective)
3. Special emphasis – Schedule M and Y
4. New drugs – Importation, Registration, development, Clinical Trials, BE NOC & BE studies
5. Various Licences – Test Lic., Import lic., for testing of drugs and API‟s, Manufacturing Contractand Loan licence manufacturing.

UNIT - II

Good Manufacturing Practices (GMP)

1. Indian GMP certification, WHO GMP certification.
2. ICH guidelines for stability testing and other relevant ones (Q1-Q10)
3. Export permissions and manufacturing for semi-regulated countries
4. Understanding of the plant layouts with special emphasis on the environment & safety (HVAC, Water Systems, Stores Management, Effluent etc.)
5. Quality Assurance and Qulaity Control – Basic understanding for in-built quality.

UNIT - III

A detailed study of regulatory aspects that affect drug product design, manufacture and distribution in a developed country such as USA and in a developing country such as Brazil, Hatch Waxmann Act; Bolar Provisions and other FDA Regulations. Regulatory aspects of pharmaceutical and bulk drug manufacture, regulatory drug analysis.

UNIT - IV

Documentation related to manufacturing, cleaning methods, retention samples and records, quality control, batch release documents, distribution records, complaints and recalls.
Quality, safety and legislation for cosmetic products and herbal products.

UNIT - V

Governing Regulatory Bodies across the globe.

Country Authority Submission

a. U.S Food & Drug Administration USDMF
b. Canada Therapeutic Product Directorate DMF
c. Europe

1) European Medicines Agency (EMEA/ National Authorities) EDMF
2) European Directorate for Quality of Medicines CEP/COS & Health Care Products.
3) MHRA – Medicines and Health Care Products Regulatory Agency

d. Product Filing
e. Responding Regulatory Deficiencies
f. Final Approval Procedure

Preparation, review and submission of Drug Master Files to Regulatory Authorities as per their specific requirements.

TEXT AND REFERENCE BOOKS:

1. Original laws published by Govt. of India.
2. Text Book of Forensic Pharmacy by Mithal B. M.; Vallabh Prakashan, New Delhi.
3. Laws of Drugs in India by Hussain.
4. Text Book of Forensic Pharmacy by Jain N. K.; Vallabh Prakashan, New Delhi.
5. Text Book of Forensic Pharmacy by CK Kokate
6. Pharmaceutical Regulatory Affairs - Selected Topics, CVS Subramanyam and J Thimmasetty, Vallabh Prakashan Delhi - 2013

M. Pharm I Year I Sem (PHARMACY PRACTICE)

RESEARCH METHODOLOGY AND IPR

Course Objectives:

- To understand the research problem
- To know the literature studies, plagiarism and ethics
- To get the knowledge about technical writing
- To analyze the nature of intellectual property rights and new developments
- To know the patent rights

Course Outcomes: At the end of this course, students will be able to

- Understand research problem formulation.
- Analyze research related information
- Follow research ethics
- Understand that today"s world is controlled by Computer, Information Technology, but tomorrow world will be ruled by ideas, concept, and creativity.
- Understanding that when IPR would take such important place in growth of individuals & nation, it is needless to emphasis the need of information about Intellectual Property Right to be promoted among students in general & engineering in particular.
- Understand that IPR protection provides an incentive to inventors for further research work and investment in R & D, which leads to creation of new and better products, and in turn brings about, economic growth and social benefits.

UNIT - I

Meaning of research problem, Sources of research problem, Criteria Characteristics of a good research problem, Errors in selecting a research problem, Scope and objectives of research problem. Approaches of investigation of solutions for research problem, data collection, analysis, interpretation,Necessary instrumentations

UNIT - II

Effective literature studies approaches, analysis, Plagiarism, Research ethics

UNIT - III

Effective technical writing, how to write report, Paper Developing a Research Proposal, Format of research proposal, a presentation and assessment by a review committee

UNIT - IV

Nature of Intellectual Property: Patents, Designs, Trade and Copyright. Process of Patenting and Development: technological research, innovation, patenting, development. International Scenario: International cooperation on Intellectual Property. Procedure for grants of patents, Patenting under PCT.

UNIT - V

Patent Rights: Scope of Patent Rights. Licensing and transfer of technology. Patent information and databases. Geographical Indications. New Developments in IPR: Administration of Patent System. New developments in IPR; IPR of Biological Systems, Computer Software etc. Traditional knowledge Case Studies, IPR and IITs.

TEXT BOOKS:

1. Stuart Melville and Wayne Goddard, "Research methodology: an introduction for science &engineering students""
2. Wayne Goddard and Stuart Melville, "Research Methodology: An Introduction"
3. Pharmaceutical Research Methodology and BioStatistics, B Subba Rao, Pharmamed Press
4. Intellectual Property Rights in Pharmaceutical Industry, B Subba Rao, Pharmamed Press

REFERENCES:

1. Ranjit Kumar, 2nd Edition, "Research Methodology: A Step by Step Guide for beginners"
2. Halbert, "Resisting Intellectual Property", Taylor & Francis Ltd ,2007.
3. Mayall, "Industrial Design", McGraw Hill, 1992.
4. Niebel, "Product Design", McGraw Hill, 1974.
5. Asimov, "Introduction to Design", Prentice Hall, 1962.
6. Robert P. Merges, Peter S. Menell, Mark A. Lemley, "Intellectual Property in New
7. Technological Age", 2016.
8. T. Ramappa, "Intellectual Property Rights Under WTO", S. Chand, 2008

M. Pharm I Year I Sem (PHARMACY PRACTICE)

PHARMACOTHERAPEUTICS LAB - I (Laboratory - I)

The students are required to be posted to various clinical wards for their exposure with therapeutic management and other clinical aspects. They are expected to have experience and do a tutorial as well as case presentation in the following clinical conditions. The students have to make at least 10 case presentations covering most common diseases found in the hospital to which the college is attached. The student should also submit a record of the cases presented. The list of clinical cases presented should include follow-up of the clinical cases mentioned below from the day of admission till discharge and presented in the SOAP (Subjective, Objective, Assessment and Plan) format.

a) The cases may be selected from the following Wards:
   - Gastroenterology
   - Cardiology
   - Pulmonology
   - Orthopedics
   - Endocrinology
   - Dermatology

b) Rational use of medicines in special population admitted in above wards (three)

c) Calculation of Bioavailability and Bioequivalence from the given data (two)

d) Interpretation of Therapeutic Drug Monitoring reports of a given patient of any of the above wards (three)

e) Calculation of various Pharmacoeconomic outcome analysis for the given data from the above (two) Assignments The students are required to submit a minimum of three written assignments (1500 to 2000 words) selected from the topics on different disease conditions given to them. The students are required to discuss both the clinical and therapeutic aspects in the same.

REFERENCE BOOKS:

1. Roger and Walker. Clinical Pharmacy and Therapeutics – Churchill Livingstone publication
2. Joseph T. Dipiro et al. Pharmacotherapy: A Pathophysiologic Approach-Appleton & Lange
3. Robins SL. Pathologic basis of disease -W.B. Saunders publication
4. Eric T. Herfindal. Clinical Pharmacy and Therapeutics- Williams and Wilkins Publication
5. Lloyd Young and Koda-Kimble MA Applied Therapeutics: The clinical Use of Drugs-LippincottWilliams and Wilkins
6. Chisholm- Burns Wells Schwinghammer Malone and Joseph P Dipiro. Pharmacotherapy Principles and practice-– McGraw Hill Publication

M. Pharm I Year I Sem (PHARMACY PRACTICE)

CLINICAL PHARMACY PRACTICE LAB (Laboratory - II)

List of Experiments:

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

REFERENCE BOOKS

1. Practice Standards and Definitions - The Society of Hospital Pharmacists of Australia
2. Thomas J Johnson, Critical Care Pharmacotherapeutics
3. Collen D L, Sneha B S, Fundamental Skills for Patient Care in MPP
4. Patient Assessment in Pharmacy, by Yolanda M H
5. Relevant review articles from recent medical and pharmaceutical literature

M. Pharm I Year II Sem (PHARMACY PRACTICE)
PHARMACOTHERAPEUTICS - II (Professional Core - III)

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

Course Outcome: Upon completion of this course it is expected that students shall be able to: - Describe and explain the rationale for drug therapy - Summarize the therapeutic approach for management of various disease conditions including reference to the latest available evidence - Discuss the clinical controversies in drug therapy and evidence based medicine - Prepare individualized therapeutic plans based on diagnosis - Identify the patient specific parameters relevant in initiating drug therapy, and monitoring therapy (including alternatives, time- course of clinical and laboratory indices of therapeutic response and adverse effect/s)

UNIT - I

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

UNIT - II

Psychiatric Disorders: Schizophrenia, Depression, Anxiety disorders, Sleep disorders, Drug induced psychiatric disorders

Renal system: Acute renal failure, Chronic renal failure, Renal dialysis, Drug induced renal disease

UNIT - III

Infectious Diseases I: General guidelines for the rational use of antibiotics and surgical prophylaxis, Urinary tract infections, Respiratory tract infections, Gastroenteritis, Tuberculosis, Malaria, Bacterial endocarditis, Septicemia.

UNIT - IV

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

UNIT - V

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

REFERENCE BOOKS:

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

M. Pharm I Year II Sem (PHARMACY PRACTICE)

CLINICAL PHARMACOKINETICS AND DRUG MONITORING (Professional Core - IV)

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

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

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

UNIT - I

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

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

UNIT - II

Pharmacokinetics of Drug Interactions: Pharmacokinetic drug interactions, Inhibition and Induction of Drug metabolism, Inhibition of Biliary Excretion.

Pharmacogenetics: Genetic polymorphism in Drug metabolism: Cytochrome P-450 Isoenzymes, Genetic Polymorphism in Drug Transport and Drug Targets, Pharmacogenetics and Pharmacokinetic/ Pharmacodynamic considerations.

Introduction to Pharmacometrics: Introduction to Bayesian Theory, Adaptive method or Dosing with feedback, Analysis of Population pharmacokinetic Data.

UNIT - III

Non-Linear Mixed Effects Modelling: The Structural or Base Model, Modeling Random Effects, Modeling Covariate Relationships, Mixture Model, Estimation Methods, Model Building Techniques, Covariate Screening Methods, Testing the model assumptions, Precision of the parameter estimates and confidence intervals, Model misspecification and violation of the model assumptions, Model Validation, Simulation of dosing regimens and dosing recommendations, Pharmacometrics software.

UNIT - IV

Altered Pharmacokinetics: Drug dosing in the elderly, Drug dosing in the pediatrics, Drug dosing in

the obese patients, Drug dosing in the pregnancy and lactation, Drug dosing in the renal failure and extracorporeal removal of drugs, Drug dosing in the in hepatic failure

UNIT - V

Therapeutic Drug Monitoring: Introduction, Individualization of drug dosage regimen (Variability –Genetic, age, weight, disease and Interacting drugs), Indications for TDM, Protocol for TDM, Pharmacokinetic/Pharmacodynamic Correlation in drug therapy.

TDM of drugs used in the following conditions:

Cardiovascular disease: Digoxin, Lidocaine, Amiodarone;
Seizure disorders: Phenytoin, Carbamazepine, Sodium Valproate;
Psychiatric conditions: Lithium, Fluoxetine, Amitriptyline;
Organ transplantations: Cyclosporine;
Cytotoxic Agents: Methotrexate, 5-FU, Cisplatin;
Antibiotics: Vancomycin, Gentamicin,
Meropenem.

REFERENCE BOOKS:

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

M. Pharm I Year II Sem (PHARMACY PRACTICE)
BIOPHARMACEUTICS AND PHARMACOKINETICS (Professional Elective - III)

Course Objective: This course is designed to impart basic knowledge about biopharmaceutics, drug ADME process, kinetic modeling and distribution of drug. T

Course Outcome: 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

UNIT - I

Introduction to Biopharmaceutics

I. Absorption of drugs from gastrointestinal tract.
II. Drug Distribution. III. Drug Elimination.

UNIT - II

Introduction to Pharmacokinetics.

a. Mathematical model b.Drug levels in blood.
c. Pharmacokinetic model d.Compartment models
e. Pharmacokinetic study.

UNIT-III

One compartment and Multicompartment models.

a. Intravenous Injection (Bolus)
b. Intravenous infusion.
c. Two compartment open model.
d. IV bolus, IV infusion and oral administration

UNIT-IV

Nonlinear Pharmacokinetics.

a. Introduction
b. Factors causing Non-linearity.
c. Michaelis-menton method of estimating parameters.

UNIT-V

Bioavailability and Bioequivalence.

a. Introduction.
b. Bioavailability study protocol.
c. Methods of Assessment of Bioavailability

TEXT BOOKS:

1. Biopharmaceutics and Clinical Pharmacokinetics by Milo Gibaldi.
2. Learn Shargel and ABC yu, Applied Biopharmacokinetics and
3. Biopharmaceutics and Pharmacokinetics by C.V.S. Subrahmanyam, Vallabh Prakashan.2010.
4. Basic biopharmaceutics, Sulnil S. Jambhekar and Philip J Brean.
5. Text book of Biopharmaceutics and Clinical Pharmacokinetics by Niazi Sarfaraz
6. Bio-Pharmaceutics and Pharmacokinetics by V. Venkateshwarlu.

M. Pharm I Year II Sem (PHARMACY PRACTICE)CLINICAL RESEARCH (Professional Elective - III)

Course Objective: This subject will provide different approaches to drug discovery, pharmacological, toxicological and new drug applications. It will also impart knowledge about clinical trials, ICH guidelines and their implementation, rules and regulations of GCP, CDSCO and different protocols.

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

- know approaches for drug discovery, Explain the regulatory requirements for conducting clinicaltrial
- Demonstrate the types of clinical trial designs
- Explain the responsibilities of key players involved in clinical trials
- □know the regulations of GCP, ICH and different protocols.

UNIT - I

Drug development process: Introduction, Various Approaches to drug discovery, Pharmacological,Toxicological, IND Application, Drug characterization & Dosage form

UNIT - II

Clinical development of drug: a. Introduction to Clinical trials b. Various phases of clinical trial. c. Methods of post marketing surveillance d. Abbreviated New Drug Application submission.

UNIT - III

Good Clinical Practice – ICH, GCP, Central drug standard control organisation (CDSCO) guidelines, Challenges in the implementation of guidelines

UNIT - IV

Ethical guidelines in Clinical Research, Composition, responsibilities, procedures of IRB / IEC

UNIT - V

Role and responsibilities of clinical trial personnel as per ICH GCP a. Sponsor b. Investigators c. Clinical research associate d. Auditors e. Contract research coordinators f. Regulatory authority

a. Designing of clinical study documents (protocol, CRF, ICF, PIC with assignment)
b. Informed consent Process
c. Safety monitoring in clinical trials.

REFERENCE BOOKS:

1. Central Drugs Standard Control Organization. Good Clinical Practices-Guidelines for ClinicalTrials on Pharmaceutical Products in India. New Delhi: Ministry of Health; 2001.
2. International Conference on Harmonisation of Technical requirements for registration of Pharmaceuticals for human use. ICH Harmonised Tripartite Guideline. Guideline for GoodClinical Practice.E6; May 1996.
3. Ethical Guidelines for Biomedical Research on Human Subjects 2000. Indian Council ofMedical Research, New Delhi.
4. Textbook of Clinical Trials edited by David Machin, Simon Day and Sylvan Green, March2005, John Wiley and Sons.

5. Principles of Clinical Research edited by Giovanna di Ignazio, Di Giovanna and Haynes.
6. Clinical Data Management edited by R K Rondels, S A Varley, C F Webbs. Second Edition,Jan 2000, Wiley Publications.
7. Goodman & Gilman: JG Hardman, LE Limbard, 10th Edn. McGraw Hill Publications, 2001.
8. Clinical Research: Principles, Practices, Perspectives, Bikash Medhi, Pharmamed Press

M. Pharm I Year II Sem (PHARMACY PRACTICE)
QUALITY USE OF MEDICINES (Professional Elective - III)

Course objectives: 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.

Course Outcomes: Upon completion of this course itis 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

UNIT - I

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

UNIT - II

Concepts in QUM Evidence based medicine: Definition, concept of evidence-based medicine, Approach and practice of evidence-based medicine inclinical settings Essential drugs: Definition, need, concept of essential drug, National essential drug policy and list Rational drug use: Definition, concept and need for rational drug use, Rational drug prescribing, Role of pharmacist in rational drug use.

UNIT - III

QUM in various settings: 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 compromisedand organ failure patients.

UNIT - IV

Regulatory aspects of QUM in India: Regulation including scheduling, Regulation of complementary medicines, Regulation of OTC medicines, Professional responsibility of pharmacist, Role of industry inQUM in medicine development.

UNIT - V

Medication errors: Definition, categorization and causes of medication errors, Detection and prevention of medication errors, Role of pharmacist in monitoring and management of medication errors Pharmacovigilance: Definition, aims and need for pharmacovigilance, Types, predisposing factors and mechanism of adverse drug reactions (ADRs), Detection, reporting and monitoring of ADRs, Causality assessment of ADRs, Management of ADRs, Role of pharmacist in pharmacovigilance.

REFERENCE BOOKS:

1. A Textbook of Clinical Pharmacy Practice– Essential concepts and skills– Parthasarathi G, Karin Nyfort-Hansen and Milap Nahata
2. Andrews E B, Moore N. Mann‟s Pharmacovigilance
3. Dipiro JT, Talbert RL, Yee GC. Pharmacotherapy: A Pathophysiologic Approach
4. Straus SE, Richardson WS, Glasziou P, Haynes RB. Evidence-Based Medicine: How to practice and teach it
5. Cohen M R. Medication Errors

M. Pharm I Year II Sem (PHARMACY PRACTICE)
PRINCIPLES OF DRUG DISCOVERY (Professional Elective- IV)

Course Objective: The subject imparts basic knowledge of drug discovery process. This information will make the student competent in drug discovery process

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

- Explain the various stages of drug discovery.
- Appreciate the importance of the role of genomics, proteomics and bioinformatics in drugdiscovery
- Explain various targets for drug discovery.
- Explain various lead seeking method and lead optimization
- Appreciate the importance of the role of computer aided drug design in drug discovery

UNIT - I

An overview of modern drug discovery process: Target identification, target validation, lead identification and lead Optimization. Economics of drug discovery.

Target Discovery and validation-Role of Genomics, Proteomics and Bioinformatics. Role of Nucleic acid microarrays, Protein microarrays, Antisense technologies, siRNAs, antisense oligonucleotides, Zinc finger proteins. Role of transgenic animals in target validation.

UNIT - II

Lead Identification- combinatorial chemistry & high throughput screening, in silico lead discovery techniques, Assay development for hit identification.

Protein structure Levels of protein structure, Domains, motifs, and folds in protein structure. Computational prediction of protein structure: Threading and homology modeling methods. Application of NMR and X-ray crystallography in protein structure prediction

UNIT - III

Rational Drug Design Traditional vs rational drug design, Methods followed in traditional drug design, High throughput screening, Concepts of Rational Drug Design,

Rational Drug Design Methods: Structure and Pharmacophore based approaches

Virtual Screening techniques: Drug likeness screening, Concept of pharmacophore mapping and pharmacophore-based Screening

UNIT - IV

Molecular docking: Rigid docking, flexible docking, manual docking; Docking based screening. De novo drug design.

Quantitative analysis of Structure Activity Relationship History and development of QSAR, SAR versus QSAR, Physicochemical parameters, Hansch analysis, Fee Wilson analysis and relationship between them.

UNIT - V

QSAR Statistical methods – regression analysis, partial least square analysis (PLS) and other multivariate statistical methods.

3D-QSAR approaches like COMFA and COMSIA

Prodrug design-Basic concept, Prodrugs to improve patient acceptability, Drug solubility, Drug absorption and distribution, site specific drug delivery and sustained drug action. Rationale of prodrug design and practical consideration of prodrug design

REFERENCE BOOKS:

1. Mouldy Sioud. Target Discovery and Validation Reviews and Protocols: Volume 2 EmergingMolecular Targets and Treatment Options. 2007 Humana Press Inc.
2. Darryl León. Scott MarkelIn. Silico Technologies in Drug Target Identification and Validation.2006 by Taylor and Francis Group, LLC.
3. Johanna K. DiStefano. Disease Gene Identification. Methods and Protocols. Springer New YorkDordrecht Heidelberg London.
4. Hugo Kubiny. QSAR: Hansch Analysis and Related Approaches. Methods and Principles inMedicinal Chemistry. Publisher Wiley-VCH
5. Klaus Gubernator, Hans-Joachim Böhm. Structure-Based Ligand Design. Methods and Principles in Medicinal Chemistry. Publisher Wiley-VCH
6. Abby L. Parrill. M. Rami Reddy. Rational Drug Design. Novel Methodology and Practical Applications. ACS Symposium Series; American Chemical Society: Washington, DC, 1999.
7. J. Rick Turner. New drug development design, methodology and, analysis. John Wiley & Sons,Inc., New Jersey.
8. Current Concepts in Drug Design, T Durai Ananda Kumar, Pharma Med Press

M. Pharm I Year II Sem (PHARMACY PRACTICE)

CELLULAR AND MOLECULAR PHARMACOLOGY (Professional Elective - IV)

Course Objectives: The subject imparts a fundamental knowledge on the structure and functions of cellular components and help to understand the interaction of these components with drugs. This information will further help the student to apply the knowledge in drug discovery process.
Course Outcomes: Upon completion of the course, the student shall be able to, Explain the receptor signal transduction processes. Explain the molecular pathways affected by drugs. Appreciate the applicability of molecular pharmacology and biomarkers in drug discovery process. Demonstrate molecular biology techniques as applicable for pharmacology

UNIT - I
Cell biology Structure and functions of cell and its organelles Genome organization. Gene expression and its regulation, importance of siRNA and micro RNA, gene mapping and gene sequencing Cell cycles and its regulation. Cell death– events, regulators, intrinsic and extrinsic pathways of apoptosis. Necrosis and autophagy.

UNIT- II
Cell signaling Intercellular and intracellular signaling pathways. Classification of receptor family and molecular structure ligand gated ion channels; G-protein coupled receptors, tyrosine kinase receptors and nuclear receptors. Secondary messengers: cyclic AMP, cyclic GMP, calcium ion, inositol 1,4,5-trisphosphate, (IP3), NO, and diacylglycerol. Detailed study of following intracellular signaling pathways: cyclic AMP signaling pathway, mitogen-activated protein kinase (MAPK) signaling, Janus kinase (JAK)/signal transducer and activator of transcription (STAT) signaling pathway.

UNIT- III
Principles and applications of genomic and proteomic tools DNA electrophoresis, PCR (reverse transcription and real time), Gene sequencing, micro array technique, SDS page, ELISA and western blotting, Recombinant DNA technology and gene therapy Basic principles of recombinant DNA technology-Restriction enzymes, various types of vectors. Applications of recombinant DNA technology. Gene therapy- Various types of gene transfer techniques, clinical applications and recent advances in gene therapy.

UNIT- IV
Pharmacogenomics Gene mapping and cloning of disease gene. Genetic variation and its role in health/ pharmacology Polymorphisms affecting drug metabolism Genetic variation in drug transporters Genetic variation in G protein coupled receptors Applications of proteomics science: Genomics, proteomics, metabolomics, functionomics, nutrigenomics Immunotherapeutics Types of immunotherapeutics, humanisation antibody therapy, Immunotherapeutics in clinical practice

UNIT- V
Cell culture techniques Basic equipment used in cell culture lab. Cell culture media, various types of cell culture, general procedure for cell cultures; isolation of cells, subculture, cryopreservation, characterization of cells and their application. Principles and applications of cell viability assays, glucose uptake assay, Calcium influx assays Principles and applications of flow cytometry b. Biosimilars

REFERENCE BOOKS:

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

M.Pharm I Year II Sem (PHARMACY PRACTICE)

NUTRACEUTICALS (Professional Elective - IV)

Course Objectives: The students will expose to characteristic features of various phytochemicals as nutraceuticals in various diseased conditions and also know the role of antioxidant in free radical induced disease conditions and will expose to various food laws and regulations.

Course Outcomes: Helps the student to understand the importance of Nutraceuticals in variouscommon problems with the concept of free radicals

UNIT - I

a. Definitions of Functional foods, Nutraceuticals and Dietary supplements. Classification of Nutraceuticals, Health problems and diseases that can be prevented or cured by Nutraceuticals i.e. weight control, diabetes, cancer etc.

b. Source, Name of marker compounds and their chemical nature, Medicinal uses and health benefits of following used as nutraceuticals/functional foods:

Spirulina, Soyabean, Ginseng, Garlic, Broccoli, Gingko, Flaxseeds

UNIT - II

Phytochemicals as nutraceuticals: Occurrence and characteristic features (chemical nature medicinal benefits) of following

a) Carotenoids- α and β-Carotene, Lycopene, Xanthophylls, lutein
b) Sulfides: Diallylsulfides, Allyltrisulfide.
c) Polyphenolics: Reservetrol
d) Flavonoids- Rutin , Naringin, Quercitin, Anthocyanidins, catechins, Flavones
e) Prebiotates / Probiotics.: Fructo oligosaccharides, Lactobacillum
f) Phytoestrogens: Isoflavones, daidzein, Geebustin, lignans
g) Tocopherols

UNIT - III

a. Introduction to free radicals: Free radicals, reactive oxygen species, production of free radicals in cells, damaging reactions of free radicals on lipids, proteins, Carbohydrates, nucleic acids.

b. Measurement of free radicals: Lipid peroxidation products, lipid hydroperoxide, malondialdehyde.

UNIT - IV

a. Free radicals in Diabetes mellitus, Inflammation, Ischemic reperfusion injury, Cancer, Atherosclerosis, Free radicals in brain metabolism and pathology, kidney damage, muscle damage. Free radicals involvement in other disorders. Free radicals theory of ageing.

b. Antioxidants: Endogenous antioxidants – enzymatic and nonenzymatic antioxidant defence, Superoxide dismutase, catalase, Glutathione peroxidase, Glutathione Vitamin C, Vitamin E, α-Lipoic acid, melatonin

Synthetic antioxidants: Butylatedhydroxy Toluene, Butylatedhydroxy Anisole.

UNIT - V

Food Laws and Regulations; FDA, FPO, MPO, AGMARK. HACCP and GMPs on Food Safety. Adulteration of foods.

Regulations and Claims – Current Products: Label Claims, Nutrient Content Claims, Health Claims, Dietary Supplements Claims

REFERENCE BOOKS:

1. Dietetics by Sri Lakshmi
2. Role of dietary fibres and nutraceuticals in preventing diseases by K. T. Agusti and P. Faizal: BS Publication.
3. Advanced Nutritional Therapies by Cooper. K.A., (1996).
4. The Food Pharmacy by Jean Carper, Simon & Schuster, UK Ltd., (1988).
5. Prescription for Nutritional Healing by James F.Balch and Phyllis A. Balch 2nd Edn., AveryPublishing Group, NY (1997).
6. G. Gibson and C. Williams Editors *2000 Functional foods* Woodhead Publ. Co. London.
7. Goldberg, I. *Functional Foods*. 1994. Chapman and Hall, New York.
8. Labuza, T.P. 2000 Functional Foods and Dietary Supplements: Safety, Good Manufacturing Practice (GMPs) and Shelf Life Testing in *Essentials of Functional Foods* M. K. Sachmidl and T.P. Labuza eds. Aspen Press.
9. Handbook of Nutraceuticals and Functional Foods, Third Edition (Modern Nutrition)
10. Shils, ME, Olson, JA, Shike, M. 1994 *Modern Nutrition in Health and Disease*. Eighth edition. Lea and Febiger

M.Pharm I Year II Sem (PHARMACY PRACTICE)

PHARMACOTHERAPEUTICS - II LAB (Laboratory - III)

The students are required to be posted to various clinical wards for their exposure with therapeutic management and other clinical aspects. They are expected to have experience and do a tutorial as well as case presentation in the following clinical conditions. The students have to make at least 10 case presentations covering most common diseases found in the hospital to which the college is attached. The student should also submit a record of the cases presented. The list of clinical cases presented should include follow-up of the clinical cases mentioned below from the day of admission till discharge and presented in the SOAP (Subjective, Objective, Assessment and Plan) format.

I. The cases may be selected from the following diseases: 7. Neurology & Psychiatry 8. Oncology 9. Infectious Diseases & Immunology 10. Dermatology
II. Rational use of medicines in special population admitted in above wards (three)
III. Calculation of Bioavailability and Bioequivalence from the given data (two)
IV. Interpretation of Therapeutic Drug Monitoring reports of a given patient of any of the abovewards (three)
V. Calculation of various Pharmacoeconomic outcome analysis for the given data from the above (two)

ASSIGNMENTS: The students are required to submit a minimum of three written assignments (1500 to 2000 words) selected from the topics on different disease conditions given to them. The students are required to discuss both the clinical and therapeutic aspects in the same.

REFERENCE BOOKS:

1. Roger and Walker. Clinical Pharmacy and Therapeutics – Churchill Livingstone publication.
2. Joseph T. Dipiro et al. Pharmacotherapy: A Pathophysiologic Approach-Appleton & Lange
3. Robins SL. Pathologic basis of disease -W. B. Saunders publication
4. Eric T. Herfindal. Clinical Pharmacy and Therapeutics- Williams and Wilkins Publication
5. Lloyd Young and Koda-Kimble MA Applied Therapeutics: The clinical Use of Drugs-LippincottWilliams and Wilkins
6. Clinical Pharmacy and Pharmacotherapeutics by Ravi Shankar, Pharma med Press
7. Chisholm - Burns Wells Schwinghammer Malone and Joseph P Dipiro. Pharmacotherapy Principles and practice-– McGraw Hill Publication

M.Pharm I Year II Sem (PHARMACY PRACTICE)

CLINICAL PHARMACOKINETICS AND THERAPEUTIC DRUG MONITORING LAB
(Laboratory - IV)

List of Experiments:

1. Causality assessment of adverse drug reactions (three)
2. Detection and management of medication errors (three)
3. Manufacture of parenteral formulations, powders.
4. Drug information queries.
5. Inventory control
6. Study of Design and Management of Hospital pharmacy department of a hospital.
7. Composition of Pharmacy and Therapeutics committee – Organization, functions, and limitations.
8. Development of a hospital formulary for a teaching hospital
9. Various sources of drug information and systematic approach to provide unbiased drug information.
10. Evaluation of prescriptions generated in hospital for drug interactions and find out the suitablemanagement

REFERENCE BOOKS:

1. Leon Shargel, Susanna Wu-Pong, Andrew Yu. Applied Biopharmaceutics & Pharmacokinetics. New York: McGraw Hill.
2. Peter L. Bonate. Pharmacokinetic - Pharmacodynamic Modeling and Simulation. Springer Publications.
3. Michael E. Burton, Leslie M. Shaw, Jerome J. Schentag, William E. Evans. Applied Pharmacokinetics & Pharmacodynamics: Principles of Therapeutic Drug Monitoring. IippincottWilliams & Wilkins.
4. Steven How-Yan Wong, Irving Sunshine. Handbook of AnalyticalTherapeutic Drug Monitoringand Toxicology. CRC Press, USA.
5. Soraya Dhillon, Andrzej Kostrzewski. Clinical pharmacokinetics. 1st edition. London: Pharmaceutical Press.
6. Joseph T. Dipiro, William J. Spruill, William E. Wade, Robert A.Blouin and Jane M. Pruemer Concepts in Clinical Pharmacokinetics. AmericanSociety of Health-System Pharmacists, USA.
7. Malcolm Rowland, Thomas N. Tozer. Clinical Pharmacokinetics and pharmacodynamics: concepts and applications. Iippincott Williams & Wilkins, USA.

M.Pharm II Year I Sem (PHARMACY PRACTICE)

BIOSTATISTICS (Professional Elective - V)

Course Objectives: The student shall know the introduction, scope of biostatistics and Research work, calculation and present of the data.

Course Outcomes: The student will be known the Biostatistics arrangement, presentation and formation of tables and charts. They also know the correlation and regression & application of different methods, analysis of data.

UNIT - I

Introduction and scope of biostatistics: Use of statistics in Pharmacy. Population and Sample collection. Stages of research, types of data and methods of data collections. Data arrangement and presentation, formation of table and charts.

UNIT - II

Measures of central tendency: computation of means, median and mode from grouped and ungrouped data.

Measure of dispersion: computation of variance, standard deviation, standard error and their coefficients.

UNIT - III

Measures of Correlation and Regression

Probability rules: Binomial, Poison and Normal distribution.

UNIT - IV

Experimental designing, planning of an experiment, replication and randomization.

Analysis of Variance (ANOVA): 1-way, 2- Way

UNIT - V

Hypothesis testing: Student „t" test, Chi square test,

Non- Parametric Tests: Sign Test, Sign Rank Test, Wilcoxon Sign Rank Test

REFERENCE BOOKS:

1. Statistics for business and economics 3rd edition by Vikas books publications
2. Biostatistics & Computer applications by GN Rao and NK Tiwari
3. A Textbook of Research Methodologies and Biostatistics for Pharmacy Students,KPRChowdary, Pharmamed Press
4. Sokal, R.R. and Rohlf, F.J. 1987. An Introduction to Biostatistics. W.H. Freeman and Company.
5. Bailey, N.T.J. 1981. Statistical Methods in Biology. English University Press.
6. Mitchell, K. and Glover, T. 2001. Introduction to Biostatistics. McGraw Hill, Publishing Co.

M.Pharm II Year I Sem (PHARMACY PRACTICE)

PHARMACOEPIDEMIOLOGY & PHARMACOECONOMICS (Professional Elective - V)

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

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

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

UNIT - I

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

UNIT - II

Pharmacoepidemiological Methods: Qualitative models: Drug Utilization Review; Quantitative models: case reports, case series, Cross sectional studies, Cohort and case control studies, Calculation of Odds‟ ratio, Meta-analysis models, Drug effects study in populations: Spontaneous reporting, Prescription event monitoring, Post marketing surveillance, Record linkage systems, Applications of Pharmacoepidemiology

UNIT - III

Introduction to Pharmacoeconomics: Definition, history of Pharmacoeconomics, Need of Pharmacoeconomic studies in Indian healthcare system. Cost categorization and resources for cost estimation: Direct costs. Indirect costs. Intangible costs. Outcomes and Measurements of Pharmacoeconomics: Types of outcomes: Clinical outcome, Economic outcomes, Humanistic outcomes; Quality Adjusted Life Years, Disability Adjusted Life Years Incremental Cost-Effective Ratio, Average Cost-Effective Ratio. Person Time, Willingness to Pay, Time Trade Off and Discounting.

UNIT - IV

Pharmacoeconomic evaluations: Definition, Steps involved, Applications, Advantages and disadvantages of the following Pharmacoeconomic models: Cost Minimization Analysis (CMA),Cost Benefit Analysis (CBA), Cost Effective Analysis (CEA), Cost Utility Analysis (CUA), Cost of Illness (COI), Cost Consequences Analysis (COA).

UNIT - V

Definition, Steps involved, Applications, Advantages and disadvantages of the following: Health related quality of life (HRQOL): Definition, Need for measurement of HRQOL, CommonHRQOL 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.

REFERENCE BOOKS:

1. Rascati K L. Essentials of Pharmacoeconomics, Woulters Kluwe rLippincott 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 Modeling for Health Economic Evaluation, Oxford University Press, London.
4. K G Revikumar, Pharmacoepidemiology and Pharmacoeconomics Concepts and Practices.
5. Michael Drummond, Mark Sculpher, George Torrence, Bernie O'Brien and Greg Stoddart. Methods for the Economic Evaluation of Health Care Programs Oxford University Press, London.
6. George E Mackinnon III. Understanding health outcomes and Pharmacoeconomics.
7. Graker, Dennis. Pharmacoeconomics and outcomes.
8. Walley, Pharmacoeconomics.
9. Pharmacoeconomic – ed. by Nowakowska – University of Medical Sciences, Poznan.
10. Relevant review articles from recent medical and pharmaceutical literature
11. Guru Prasad Mohanta and P K Manna, Textbook of Pharmacovigilance Concepts and Practice

M.Pharm II Year I Sem (PHARMACY PRACTICE)

PHYTOPHARMACEUTICALS (Professional Elective - V)

Course Objective: This subject will provide the knowledge about the sourse, phytochemistry, physiological activities of anticancer, CVS &Nervous systems and anti-inflammatory drugs from natural sources. This also gives information about isolation and characterization of phytoconstituents.

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

- Explain the sourses of phytoconstituents
- able to know activities of different kind
- able to isolate and characterization constituents.
- Detect chemical nature by different spectra"s.

Source, phytochemistry (isolation, identification, chemical nature), and physiological activities of following phytopharmaceuticals.

UNIT - I

1) Anticancer: Taxol, other taxanes, Camptothecin, vinblastine, Genistein, Etoposide

UNIT - II

2) Nervous system activities: Hypericin, Valepotriates, Gingkolides

3) CVS activities: Colenol, Streptokinase

UNIT - III

4) Anti-inflammatory: Curcuminoids, Guggulipids, Boswellic acid, Serratiopeptidase.

UNIT - IV

5) Miscellaneous: Silymarin, Artemisinin, Omega-3 fatty acids. Charantin and momordicosides, Resveretrol, Protamine sulphate, prostaglandins.

UNIT - V

Occurrence, isolation and characteristic features (Chemical nature, uses in pharmacy, medicinal and health benefits) of following.

a) Carotenoids – i) α and β - Carotene ii) Xanthophyll (Lutein)

b) Limonoids – i) d-Limonene ii) α – Terpineol

c) Saponins – i) Shatavarins

d) Flavonoids – i) Resveratrol ii) Rutin iii) Hesperidin iv) Naringin v) Quercetin

e) Phenolic acids- Ellagic acid

f) Tocotrienols and Tocopherols

TEXT BOOKS:

1. Pharmacognosy: Trease and Evans, Bailliere & Tindall, 14th edth.
2. Pharmacognosy: Kokate, Purohit, Gokhale, Nirali Prakashan, Pune, 15th edtn.
3. Biochemistry: Delvin
4. Alkaloids Edited by J.R.F. Manske
5. Various Research Journals on Natural products and therapeutics.

M.Pharm (PHARMACY PRACTICE)

ENGLISH FOR RESEARCH PAPER WRITING (Audit Course - I & II)

Prerequisite: None

Course objectives: Students will be able to:

- Understand that how to improve your writing skills and level of readability
- Learn about what to write in each section
- Understand the skills needed when writing a Title Ensure the good quality of paper at very first-time submission

UNIT-I:
Planning and Preparation, Word Order, Breaking up long sentences, Structuring Paragraphs and Sentences, Being Concise and Removing Redundancy, Avoiding Ambiguity and Vagueness

UNIT-II:
Clarifying Who Did What, Highlighting Your Findings, Hedging and Criticizing, Paraphrasing and Plagiarism, Sections of a Paper, Abstracts. Introduction

UNIT-III:
Review of the Literature, Methods, Results, Discussion, Conclusions, The Final Check.

UNIT-IV:
key skills are needed when writing a Title, key skills are needed when writing an Abstract, key skills are needed when writing an Introduction, skills needed when writing a Review of the Literature,

UNIT-V:
skills are needed when writing the Methods, skills needed when writing the Results, skills are needed when writing the Discussion, skills are needed when writing the Conclusions. useful phrases, how to ensure paper is as good as it could possibly be the first- time submission

TEXT BOOKS/ REFERENCES:

1. Goldbort R (2006) Writing for Science, Yale University Press (available on Google Books)
2. Day R (2006) How to Write and Publish a Scientific Paper, Cambridge University Press
3. Highman N (1998), Handbook of Writing for the Mathematical Sciences, SIAM. Highman‟sbook.
4. Adrian Wallwork, English for Writing Research Papers, Springer New York Dordrecht Heidelberg London, 2011
5. Academic Writing,Ajay Semalty, Pharmamed Press

M.Pharm (PHARMACY PRACTICE)

DISASTER MANAGEMENT (Audit Course - I & II)

Prerequisite: None

Course Objectives: Students will be able to

- learn to demonstrate a critical understanding of key concepts in disaster risk reduction and humanitarian response.
- critically evaluate disaster risk reduction and humanitarian response policy and practice from multiple perspectives.
- develop an understanding of standards of humanitarian response and practical relevance in specific types of disasters and conflict situations.
- critically understand the strengths and weaknesses of disaster management approaches,
- planning and programming in different countries, particularly their home country or the countriesthey work in

UNIT-I:

Introduction:

Disaster: Definition, Factors and Significance; Difference Between Hazard and Disaster; Natural and Manmade Disasters: Difference, Nature, Types and Magnitude.

Disaster Prone Areas in India:

Study of Seismic Zones; Areas Prone to Floods and Droughts, Landslides and Avalanches; Areas Prone to Cyclonic and Coastal Hazards with Special Reference to Tsunami; Post-Disaster Diseases and Epidemics

UNIT-II:

Repercussions of Disasters and Hazards:

Economic Damage, Loss of Human and Animal Life, Destruction of Ecosystem. Natural Disasters: Earthquakes, Volcanisms, Cyclones, Tsunamis, Floods, Droughts and Famines, Landslides and Avalanches, Man-made disaster: Nuclear Reactor Meltdown, Industrial Accidents, Oil Slicks and Spills, Outbreaks of Disease and Epidemics, War and Conflicts.

UNIT-III:

Disaster Preparedness and Management:

Preparedness: Monitoring of Phenomena Triggering A Disaster or Hazard; Evaluation of Risk: Application of Remote Sensing, Data from Meteorological and Other Agencies, Media Reports: Governmental and Community Preparedness.

UNIT-IV:

Risk Assessment Disaster Risk:

Concept and Elements, Disaster Risk Reduction, Global and National Disaster Risk Situation. Techniques of Risk Assessment, Global Co-Operation in Risk Assessment and Warning, People‟s Participation in Risk Assessment. Strategies for Survival.

UNIT-V:

Disaster Mitigation:

Meaning, Concept and Strategies of Disaster Mitigation, Emerging Trends In Mitigation. Structural Mitigation and Non-Structural Mitigation, Programs of Disaster Mitigation in India.

TEXT BOOKS/ REFERENCES:

1. Disaster Management: Hazard and Risk Awareness – A Comprehensive Approach, N. V. S. Raju,BS Publications
2. Sahni, Pardeep Et. Al. (Eds.)," Disaster Mitigation Experiences and Reflections", Prentice Hall ofIndia, New Delhi.
3. Goel S. L., Disaster Administration and Management Text and Case Studies", Deep &Deep Publication Pvt. Ltd., New Delhi.

M.Pharm (PHARMACY PRACTICE)

SANSKRIT FOR TECHNICAL KNOWLEDGE (Audit Course - I & II)

Prerequisite: None

Course Objectives:

- To get a working knowledge in illustrious Sanskrit, the scientific language in the world
- Learning of Sanskrit to improve brain functioning
- Learning of Sanskrit to develop the logic in mathematics, science & other subjects enhancing the memory power
- The engineering scholars equipped with Sanskrit will be able to explore the huge knowledge from ancient literature

Course Outcomes: Students will be able to

- Understanding basic Sanskrit language
- Ancient Sanskrit literature about science & technology can be understood
- Being a logical language will help to develop logic in students

UNIT-I:
Alphabets in Sanskrit,

UNIT-II:
Past/Present/Future Tense, Simple Sentences

UNIT-III:
Order, Introduction of roots,

UNIT-IV:
Technical information about Sanskrit Literature

UNIT-V:
Technical concepts of Engineering-Electrical, Mechanical, Architecture, Mathematics

TEXT BOOKS/ REFERENCES:

1. "Abhyaspustakam" – Dr. Vishwas, Samskrita-Bharti Publication, New Delhi
2. "Teach Yourself Sanskrit" Prathama Deeksha-Vempati Kutumbshastri, Rashtriya Sanskrit Sansthanam, New Delhi Publication
3. "India‟s Glorious Scientific Tradition" Suresh Soni, Ocean books (P) Ltd., New Delhi.

M.Pharm (PHARMACY PRACTICE)

VALUE EDUCATION (Audit Course - I & II)

Prerequisite: None

Course Objectives: Students will be able to

- Understand value of education and self- development
- Imbibe good values in students
- Let the should know about the importance of character

Course outcomes: Students will be able to

- Knowledge of self-development
- Learn the importance of Human values
- Developing the overall personality

UNIT-I:

Values and self-development –Social values and individual attitudes. Work ethics, Indian vision of humanism. Moral and non- moral valuation. Standards and principles. Value judgements

UNIT-II:

Importance of cultivation of values. Sense of duty. Devotion, Self-reliance. Confidence, Concentration. Truthfulness, Cleanliness. Honesty, Humanity. Power of faith, National Unity. Patriotism. Love for nature, Discipline

UNIT-III:

Personality and Behavior Development - Soul and Scientific attitude. Positive Thinking. Integrity and discipline, Punctuality, Love and Kindness.

UNIT-IV:

Avoid fault Thinking. Free from anger, Dignity of labour. Universal brotherhood and religious tolerance. True friendship. Happiness Vs suffering, love for truth. Aware of self-destructive habits. Association and Cooperation. Doing best for saving nature

UNIT-V:

Character and Competence –Holy books vs Blind faith. Self-management and Good health. Science of reincarnation, Equality, Nonviolence, Humility, Role of Women. All religions and same message. Mind your Mind, Self-control. Honesty, Studying effectively

TEXT BOOKS/ REFERENCES:

1. Chakroborty, S.K. “Values and Ethics for organizations Theory and practice”, Oxford UniversityPress, New Delhi
2. Indian Culture Values and Professional Ethics, P. S. R. Murty,BS Publications

M.Pharm (PHARMACY PRACTICE)

CONSTITUTION OF INDIA (Audit Course - I & II)

Prerequisite: None

Course Objectives: Students will be able to:

- Understand the premises informing the twin themes of liberty and freedom from a civil rights perspective.
- To address the growth of Indian opinion regarding modern Indian intellectuals‟ constitutional role and entitlement to civil and economic rights as well as the emergence of nationhood in the early years of Indian nationalism.
- To address the role of socialism in India after the commencement of the Bolshevik Revolution in 1917 and its impact on the initial drafting of the Indian Constitution.

Course Outcomes: Students will be able to:

- Discuss the growth of the demand for civil rights in India for the bulk of Indians before the arrival of Gandhi in Indian politics.
- Discuss the intellectual origins of the framework of argument that informed the conceptualization of social reforms leading to revolution in India.
- Discuss the circumstances surrounding the foundation of the Congress Socialist Party [CSP] under the leadership of Jawaharlal Nehru and the eventual failure of the proposal of direct elections through adult suffrage in the Indian Constitution.
- Discuss the passage of the Hindu Code Bill of 1956.

UNIT-I:

History of Making of the Indian Constitution: History Drafting Committee, (Composition & Working), **Philosophy of the Indian Constitution:** Preamble**,** Salient Features.

UNIT-II:

Contours of Constitutional Rights & Duties: Fundamental Rights Right to Equality**,** Right to Freedom**,** Right against Exploitation**,** Right to Freedom of Religion**,** Cultural and Educational Rights**,** Right to Constitutional Remedies, Directive Principles of State Policy**,** Fundamental Duties.

UNIT-III:

Organs of Governance: Parliament**,** Composition**,** Qualifications and Disqualifications**,** Powers and Functions**,** Executive**,** President**,** Governor**,** Council of Ministers, Judiciary, Appointment and Transfer of Judges, Qualification, Powers and Functions.

UNIT-IV:

Local Administration: District‟s Administration head: Role and Importance, Municipalities: Introduction, Mayor and role of Elected Representative, CEO of Municipal Corporation. Pachayati raj: Introduction, PRI: Zila Pachayat. Elected officials and their roles, CEO Zila Pachayat: Position and role. Block level: Organizational Hierarchy (Different departments), Village level: Role of Elected and Appointed officials, Importance of grass root democracy.

UNIT-V:

Election Commission: Election Commission: Role and Functioning. Chief Election Commissioner and Election Commissioners. State Election Commission: Role and Functioning. Institute and Bodies for the welfare of SC/ST/OBC and women.

TEXT BOOKS/ REFERENCES:

1. The Constitution of India, 1950 (Bare Act), Government Publication.
2. Dr. S. N. Busi, Dr. B. R. Ambedkar framing of Indian Constitution, 1st Edition, 2015.
3. M. P. Jain, Indian Constitution Law, 7th Edn., Lexis Nexis, 2014.
4. D.D. Basu, Introduction to the Constitution of India, Lexis Nexis, 2015.

M.Pharm (PHARMACY PRACTICE)

PEDAGOGY STUDIES (Audit Course - I & II)

Prerequisite: None

Course Objectives: Students will be able to:

- Review existing evidence on the review topic to inform programme design and policy makingundertaken by the DfID, other agencies and researchers.
- Identify critical evidence gaps to guide the development.

Course Outcomes: Students will be able to understand:

- What pedagogical practices are being used by teachers in formal and informal classrooms in developing countries?
- What is the evidence on the effectiveness of these pedagogical practices, in what conditions, and with what population of learners?
- How can teacher education (curriculum and practicum) and the school curriculum and guidance materials best support effective pedagogy?

UNIT-I:

Introduction and Methodology: Aims and rationale, Policy background, Conceptual framework and terminology Theories of learning, Curriculum, Teacher education. Conceptual framework, Research questions**.** Overview of methodology and Searching.

UNIT-II:

Thematic overview: Pedagogical practices are being used by teachers in formal and informal classrooms in developing countries. Curriculum, Teacher education.

UNIT-III:

Evidence on the effectiveness of pedagogical practices, Methodology for the indepth stage: quality assessment of included studies. How can teacher education (curriculum and practicum) and the scho curriculum and guidance materials best support effective pedagogy? Theory of change. Strength and nature of the body of evidence for effective pedagogical practices. Pedagogic theory and pedagogical approaches. Teachers‟ attitudes and beliefs and Pedagogic strategies.

UNIT-IV:

Professional development: alignment with classroom practices and follow-up support, Peer support, Support from the head teacher and the community. Curriculum and assessment, Barriers to learning: limited resources and large class sizes

UNIT-V:

Research gaps and future directions: Research design**,** Contexts**,** Pedagogy**,** Teacher education**,** Curriculum and assessment**,** Dissemination and research impact.

TEXT BOOKS/ REFERENCES:

1. Ackers J, Hardman F (2001) Classroom interaction in Kenyan primary schools, Compare, 31 (2): 245-261.
2. Agrawal M (2004) Curricular reform in schools: The importance of evaluation, Journal

ofCurriculum Studies, 36 (3): 361-379.
3. Akyeampong K (2003) Teacher training in Ghana - does it count? Multi-site teacher educationresearch project (MUSTER) country report 1. London: DFID.
4. Akyeampong K, Lussier K, Pryor J, Westbrook J (2013) Improving teaching and learning of basic maths and reading in Africa: Does teacher preparation count? International Journal Educational Development, 33 (3): 272–282.
5. Alexander RJ (2001) Culture and pedagogy: International comparisons in primary education. Oxford and Boston: Blackwell.
6. Chavan M (2003) Read India: A mass scale, rapid, „learning to read" campaign.
7. www.pratham.org/images/resource%20working%20paper%202.pdf.

M.Pharm (PHARMACY PRACTICE)

STRESS MANAGEMENT BY YOGA (Audit Course - I & II)

Prerequisite: None

Course Objectives:

- To achieve overall health of body and mind
- To overcome stress

Course Outcomes: Students will be able to:

- Develop healthy mind in a healthy body thus improving social health also
- Improve efficiency

UNIT-I:
Definitions of Eight parts of yog. (Ashtanga)

UNIT-II:
Yam and Niyam.

UNIT-III:
Do`s and Don‟t‟s in life.
i) Ahinsa, satya, astheya, bramhacharya and aparigraha
ii) Shaucha, santosh, tapa, swadhyay, ishwarpranidhan

UNIT-IV:
Asan and Pranayam

UNIT-V:
i) Various yog poses and their benefits for mind & body
ii) Regularization of breathing techniques and its effects-Types of pranayam

TEXT BOOKS/ REFERENCES:

1. „Yogic Asanas for Group Tarining-Part-I”: Janardan Swami Yogabhyasi Mandal, Nagpur
2. “Rajayoga or conquering the Internal Nature” by Swami Vivekananda, Advaita Ashrama (Publication Department), Kolkata

M.Pharm (PHARMACY PRACTICE)
PERSONALITY DEVELOPMENT THROUGH LIFE ENLIGHTENMENT SKILLS
(Audit Course - I & II)

Prerequisite: None

Course Objectives:

- To learn to achieve the highest goal happily
- To become a person with stable mind, pleasing personality and determination
- To awaken wisdom in students

Course Outcomes: Students will be able to

- Study of Shrimad-Bhagwad-Geeta will help the student in developing his personality andachieve the highest goal in life
- The person who has studied Geeta will lead the nation and mankind to peace and prosperity
- Study of Neetishatakam will help in developing versatile personality of students

UNIT-I:

Neetisatakam-Holistic development of personality

- Verses- 19,20,21,22 (wisdom)
- Verses- 29,31,32 (pride & heroism)
- Verses- 26,28,63,65 (virtue)

UNIT-II:

Neetisatakam-Holistic development of personality

- Verses- 52,53,59 (dont‟s)
- Verses- 71,73,75,78 (do‟s)

UNIT-III:

Approach to day to day work and duties.

- Shrimad Bhagwad Geeta: Chapter 2-Verses 41, 47,48,
- Chapter 3-Verses 13, 21, 27, 35, Chapter 6-Verses 5,13,17, 23, 35,
- Chapter 18-Verses 45, 46, 48.

UNIT-IV:

Statements of basic knowledge.

- Shrimad Bhagwad Geeta: Chapter2-Verses 56, 62, 68
- Chapter 12 -Verses 13, 14, 15, 16,17, 18
- Personality of Role model. Shrimad Bhagwad Geeta:

UNIT-V:

- Chapter2-Verses 17, Chapter 3-Verses 36,37,42,
- Chapter 4-Verses 18, 38,39
- Chapter18 – Verses 37,38,63

TEXT BOOKS/ REFERENCES:

1. “Srimad Bhagavad Gita” by Swami Swarupananda Advaita Ashram (Publication Department),Kolkata.
2. Bhartrihari‟s Three Satakam (Niti-sringar-vairagya) by P.Gopinath, Rashtriya Sanskrit Sansthanam, New Delhi.