JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY ANANTAPUR
(Established by Govt. of A.P., ACT No.30 of 2008)
ANANTHAPURAMU – 515 002 (A.P) INDIA

M.PHARM. IN PHARMACY PRACTICE

COURSE STRUCTURE & SYLLABI

SEMESTER – I

S. No.	Course code	Course Name	Hours per week			Credits
			L	T	P	
1.	21S09101	Pharmacotherapeutics-I	4	-	-	4
2.	21S09102	Clinical Pharmacy Practice	4	-	-	4
3.	21S09103	Hospital & Community Pharmacy	4	-	-	4
4.	21S09104	Clinical Research	4	-	-	4
5.	21S09105	Pharmacotherapeutics-I Lab	-	-	6	3
6.	21S09106	Clinical Pharmacy Practice Lab	-	-	6	3
7.	21DAC101a 21DAC101b 21DAC101c	**Audit Course – I** English for Research paper writing Disaster Management Sanskrit for Technical Knowledge	2	-	-	0
8.	21S09107	Seminar/Assignment	-	1	6	4
		Total	18	1	18	26

SEMESTER – II

S.No.	Course code	Course Name	Hours per week			Credits
			L	T	P	
1.	21S09201	Pharmacotherapeutics- II	4	-	-	4
2.	21S09202	Clinical Pharmacokinetics and Therapeutic Drug Monitoring	4	-	-	4
3.	21S09203	Principles of Quality Use of Medicines	4	-	-	4
4.	21SOE301e	Pharmacoepidemiology & Pharmacoeconomics	4	-	-	4
5.	21S09204	Pharmacotherapeutics -II Lab	-	-	6	3
6.	21S09205	Clinical Pharmacokinetics and Therapeutic Drug Monitoring Lab	-	-	6	3
7.	21DAC201a 21DAC201b 21DAC201c	**Audit Course – II** Pedagogy Studies Stress Management from Yoga Personality Development through Life Enlightenment Skills	2	-	-	0
8.	21S09206	Seminar/Assignment	-	1	6	4
		Total	18	1	18	26

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COURSE STRUCTURE & SYLLABI

SEMSTER - III

S.No.	Course code	Course Name	Hours per			Credits
				T	P	
1.	21DRM101	Research Methodology and Intellectual Property Rights	4	-	-	4
2.	 21SOE301a 21SOE301b 21SOE301c	**Open Electives** Pharmaceutical Validation Biostatistics Entrepreneurship Management	3	-	-	3
3.	21S09301	Teaching Practice/Assignment	-	-	4	2
4.	21S09302	Comprehensive viva voce	-	-	-	2
5.	21S09303	Research Work – I	-		24	12
		Total	7	-	32	23

SEMESTER - IV

S.No.	Course code	Course Name	Hours per			Credits
			L	T	P	
1.	21S09401	Co-Curricular Activities	2	-	-	2
2.	21S09402	Research Work - II	3	-	30	18
		Total	5	-	30	20

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COURSE STRUCTURE & SYLLABI

Course Code	PHARMACOTHERAPEUTICS- I	L	T	P	C
21S09101		4	0	0	4
	Semester	I			

Course Objectives:

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 Outcomes (CO): Student will be able to

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.
Haematological diseases: Anaemia, 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, Diarrhoea 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- Lippincott Williams and Wilkins
6. Chisholm- Burns Wells Schwinghammer Malone and Joseph P Dipiro. Pharmacotherapy Principles and practice-– McGraw Hill Publication
7. Carol Mattson Porth. Principles of Pathophysiology- Lippincott Williams and Wilkins
8. Harrison's. Principles of Internal Medicine - McGraw Hill
9. Relevant review articles from recent medical and pharmaceutical literature

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COURSE STRUCTURE & SYLLABI

Course Code	CLINICAL PHARMACY PRACTICE	L	T	P	C
21S09102		4	0	0	4
	Semester	I			

Course Objectives:

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 Outcomes (CO): Student will 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 counselling, 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: Haematological tests, Renal function tests, Liver function tests

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

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 System Pharmacists Inc
4. Thomas J Johnson, Critical Care Pharmacotherapeutics

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COURSE STRUCTURE & SYLLABI

5. Collen D L, Sneha B S, Fundamental Skills for Patient Care in MPP
6. Patient Assessment in Pharmacy, by Yolanda M H
7. Relevant review articles from recent medical and pharmaceutical literature

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COURSE STRUCTURE & SYLLABI

Course Code	HOSPITAL & COMMUNITY PHARMACY	L	T	P	C
21S09103		4	0	0	4
	Semester	I			

Course Objectives:

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

Course Outcomes (CO): Student will be able to

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 as per 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 software's & 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 behaviour, 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 and outcomes 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 MPP – Ramesh Adepu, BSP Publishers, Hyderabad 5. Remington Pharmaceutical Sciences. 6. Relevant review articles from recent medical and pharmaceutical literature

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M.PHARM. IN PHARMACY PRACTICE

COURSE STRUCTURE & SYLLABI

Course Code	CLINICAL RESEARCH	L	T	P	C
21S09104		4	0	0	4
	Semester	**I**			

Course Objectives:

This course is designed to impart the basic knowledge and skills that are required in clinical research including drug development process especially the phases of clinical trials and also the ethical issues involved in the conduct of clinical research. Also, it aims to imparts knowledge and develop skills on conceptualizing, designing, conducting and managing clinical trials

Course Outcomes (CO): Student will be able to

- Upon completion of this course it is expected that students shall be able to:
- Know the new drug development process.
- Understand the regulatory and ethical requirements.
- Appreciate and conduct the clinical trials activities
- Know safety monitoring and reporting in clinical trials
- Manage the trial coordination process

UNIT - I

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

UNIT - II

Types and Designs used in Clinical Research: Planning and execution of clinical trials, Various Phases of clinical trials, Bioavailability and Bioequivalence studies, Randomization techniques (Simple randomization, restricted randomization, blocking method and stratification), Types of research designs based on Controlling Method (Experimental, Quasi experimental and Observational methods) Time Sequences (Prospective and Retrospective), Sampling methods (Cohort study, case Control study and cross sectional study), Health outcome measures(Clinical & Physiological, Humanistic and economic)Clinical Trial Study team: Roles and responsibilities of: Investigator, Study Coordinator, Sponsor, Monitor, Contract Research Organization.

UNIT - III

Clinical trial Documents: Guidelines to the preparation of following documents: Protocols, Investigator's Brochure, Informed Consent Form, Case report forms, Contracts and agreements, Dairy Cards Clinical Trial Start up activities: Site Feasibility Studies, Site/Investigator selection, Pre-study visit, Investigator meeting, Clinical trial agreement execution, Ethics committee document preparation and submission.

UNIT - IV

Investigational Product: Procurement and Storage of investigation product Filing procedures: Essential documents for clinical trial, Trial Master File preparation and maintenance, Investigator Site File, Pharmacy File, Site initiation visit, Conduct, Report and Follow up Clinical Trial Monitoring and Close out: Preparation and conduct of monitoring visit: Review of source documents, CRF, ICF, IP storage, accountability and reconciliation, Study Procedure, EC communications, Safety reporting, Monitoring visit reporting and follow-up Close-Out visit: Study related documents collection, Archival requirement, Investigational Product reconciliation and destruction, Close-Out visit report

UNIT - V

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COURSE STRUCTURE & SYLLABI

Quality Assurance and Quality Control in Clinical Trials: Types of audits, Audit criteria, Audit process, Responsibilities of stakeholders in audit process, Audit follow-up and documentation, Audit resolution and Preparing for FDA inspections, Fraud and misconduct management.
Data Management Infrastructure and System Requirement for Data Management: Electronic data capture systems, Selection and implementation of new systems, System validation and test procedures, Coding dictionaries, Data migration and archival.
Clinical Trial Data Management: Standard Operating Procedures, Data management plan, CRF & Data base design considerations, Study set-up, Data entry, CRF tracking and corrections, Data cleaning, Managing laboratory and ADR data, Data transfer and database lock, Quality Control and Quality Assurance in CDM, Data mining and warehousing

Reference Books:

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

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COURSE STRUCTURE & SYLLABI

Course Code	PHARMACOTHERAPEUTICS LAB - I	L	T	P	C
21S09105		0	0	6	3
	Semester	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.
1) The cases may be selected from the following Wards:
- ❖ Gastroenterology
- ❖ Cardiology
- ❖ Pulmonology
- ❖ Orthopedics
- ❖ Endocrinology
- ❖ Dermatology

2) Rational use of medicines in special population admitted in above wards (three)
3) Calculation of Bioavailability and Bioequivalence from the given data (two)
4) Interpretation of Therapeutic Drug Monitoring reports of a given patient of any of the above wards (three)
5) 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- Lippincott Williams and Wilkins.
6. Chisholm- Burns Wells Schwinghammer Malone and Joseph P Dipiro. Pharmacotherapy Principles and practice-– McGraw Hill Publication

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COURSE STRUCTURE & SYLLABI

Course Code	CLINICAL PHARMACY PRACTICE LAB	L	T	P	C
21S09106		4	0	0	4
	Semester	**I**			

List of Experiments:

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

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
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COURSE STRUCTURE & SYLLABI

Course Code	PHARMACOTHERAPEUTICS - II	L	T	P	C
21S09201		4	0	0	4
	Semester	II			

Course Objectives:

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 Outcomes (CO): Student will 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: 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: 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- Lippincott Williams and Wilkins.
6. Chisholm - Burns Wells Schwinghammer Malone and Joseph P Dipiro. Pharmacotherapy Principles and practice-– McGraw Hill Publication.
7. Carol Mattson Porth. Principles of Pathophysiology- Lippincott Williams and Wilkins.
8. Harrison's. Principles of Internal Medicine - McGraw Hill.
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COURSE STRUCTURE & SYLLABI

Course Code	CLINICAL PHARMACOKINETICS AND THERAPEUTIC DRUG MONITORING	L	T	P	C
21S09202		4	0	0	4
	Semester	**II**			

Course Objectives:

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 Outcomes (CO): Student will be able to

Design the drug dosage regimen for individual patients
Interpret and correlate the plasma drug concentrations with patients' therapeutic outcomes
Recommend dosage adjustment for patients with renal/ hepatic impairment Recommend dosage adjustment for paediatrics and geriatrics
Manage pharmacokinetic drug interactions
Apply pharmacokinetic parameters in clinical settings
Interpret the impact of genetic polymorphisms of individuals on pharmacokinetics and or Pharmacodynamic of drugs
Do pharmacokinetic modelling 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 Interaction: Pharmacokinetic drug interactions, Inhibition and Induction of Drug metabolism, Inhibition of Biliary Excretion.
Pharmacogenetics: Genetic polymorphism in Drug metabolism: Cytochrome P-450 Isoenzymes, Genetic Polymorphism in Drug Transport and Drug Targets, Pharmacogenetics and Pharmacokinetic/ Pharmacodynamic considerations.
Introduction to Pharmacometrics: Introduction to Bayesian Theory, Adaptive method or Dosing with feedback, Analysis of Population pharmacokinetic Data

UNIT - III

Non-Linear Mixed Effects Modelling: The Structural or Base Model, Modelling Random Effects, Modelling 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 paediatrics, Drug dosing in the obese patients, Drug dosing in the pregnancy and lactation, Drug dosing in the renal failure and extracorporeal removal of drugs, Drug dosing in the in hepatic failure.

UNIT - V

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COURSE STRUCTURE & SYLLABI

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. Iippincott Williams & Wilkins.
4. Steven How-Yan Wong, Irving Sunshine. Handbook of Analytical Therapeutic Drug Monitoring and Toxicology. CRC Press, USA.
5. Soraya Dhillon, Andrzej Kostrzewski. Clinical pharmacokinetics. 1st edition. London: Pharmaceutical Press.
6. Joseph T. Dipiro, William J. Spruill, William E. Wade, Robert A. Blouin and Jane M. Pruemer Concepts in Clinical Pharmacokinetics. American Society of Health-System Pharmacists,USA.
7. Malcolm Rowland, Thomas N. Tozer. Clinical Pharmacokinetics and pharmacodynamics: concepts and applications. Iippincott Williams &Wilkins, USA.
8. Evans, Schentag, Jusko. Applied pharmacokinetics. American Society of Health system Pharmacists, USA.
1. Michael E. Winter. Basic Clinical Pharmacokinetics. Iippincott Williams &Wilkins, USA.
2. 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

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M.PHARM. IN PHARMACY PRACTICE

COURSE STRUCTURE & SYLLABI

Course Code	PRINCIPLES OF QUALITY USE OF MEDICINES	L	T	P	C
21S09203		4	0	0	4
	Semester	II			

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 (CO): Student will 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 compromised and 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 in QUM 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

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COURSE STRUCTURE & SYLLABI

4. Straus SE, Richardson WS, Glasziou P, Haynes RB. Evidence-Based Medicine: How to practice and teach it
5. Cohen M R. Medication Errors
6. Online:
- http://medicinesaustralia.com.au/files/2012/05/MA_QUM_External_Reduced.pdf
- http://curriculum.racgp.org.au/statements/quality-use-of-medicines/
- http://www.rug.nl/research/portal/files/14051541/Chapter_2.pdf
- Relevant review articles from recent medical and pharmaceutical literature

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COURSE STRUCTURE & SYLLABI

Course Code	PHARMACOEPIDEMIOLOGY & PHARMACOECONOMICS	L	T	P	C
21SOE301e		4	0	0	4
	Semester	**II**			

Course Objectives:

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 Outcomes (CO): Student will 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, Common

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HRQOL measures. Definition, Steps involved, Applications of the following: Decision Analysis and Decision tree, Sensitivity analysis, Markov Modeling, Software used in Pharmacoeconomic analysis, Applications of Pharmacoeconomics
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

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COURSE STRUCTURE & SYLLABI

Course Code	PHARMACOTHERAPEUTICS - II LAB	L	T	P	C
21S09204		0	0	6	3
	Semester	II			

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 above wards (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- Lippincott Williams and Wilkins
6. Chisholm - Burns Wells Schwinghammer Malone and Joseph P Dipiro. Pharmacotherapy Principles and practice-– McGraw Hill Publication

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COURSE STRUCTURE & SYLLABI

Course Code	CLINICAL PHARMACOKINETICS AND	L	T	P	C
21S09205	THERAPEUTIC DRUG MONITORING LAB	0	0	6	3
	Semester	II			

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 suitable management

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. Iippincott Williams & Wilkins.
4. Steven How-Yan Wong, Irving Sunshine. Handbook of AnalyticalTherapeutic 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. AmericanSociety of Health-System Pharmacists, USA.
7. Malcolm Rowland, Thomas N. Tozer. Clinical Pharmacokinetics and pharmacodynamics: concepts and applications. Iippincott Williams & Wilkins, USA.

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COURSE STRUCTURE & SYLLABI

Course Code	RESEARCH METHODOLOGY AND INTELLECTUAL PROPERTY RIGHTS	L	T	P	C
21DRM101		4	0	0	4
	Semester	III			

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 (CO): Student 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.

Textbooks:

1. Stuart Melville and Wayne Goddard, "Research methodology: an introduction for science & engineering students'"

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COURSE STRUCTURE & SYLLABI

2. Wayne Goddard and Stuart Melville, "Research Methodology: An Introduction"
Reference Books:
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

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AUDIT COURSE-I

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COURSE STRUCTURE & SYLLABI

Course Code	ENGLISH FOR RESEARCH PAPER WRITING	L	T	P	C
21DAC101a		2	0	0	0
	Semester	I			

Course Objectives: This course will enable students:

- Understand the essentials of writing skills and their level of readability
- Learn about what to write in each section
- Ensure qualitative presentation with linguistic accuracy

Course Outcomes (CO): Student will be able to

- Understand the significance of writing skills and the level of readability
- Analyze and write title, abstract, different sections in research paper
- Develop the skills needed while writing a research paper

UNIT - I		Lecture Hrs:10

1Overview of a Research Paper- Planning and Preparation- Word Order- Useful Phrases - Breaking up Long Sentences-Structuring Paragraphs and Sentences-Being Concise and Removing Redundancy -Avoiding Ambiguity

UNIT - II		Lecture Hrs:10

Essential Components of a Research Paper- Abstracts- Building Hypothesis-Research Problem - Highlight Findings- Hedging and Criticizing, Paraphrasing and Plagiarism, Cauterization

UNIT - III		Lecture Hrs:10

Introducing Review of the Literature – Methodology - Analysis of the Data-Findings - Discussion-Conclusions-Recommendations.

UNIT - IV		Lecture Hrs:9

Key skills needed for writing a Title, Abstract, and Introduction

UNIT - V		Lecture Hrs:9

Appropriate language to formulate Methodology, incorporate Results, put forth Arguments and draw Conclusions

Suggested Reading

1. Goldbort R (2006) Writing for Science, Yale University Press (available on Google Books) Model Curriculum of Engineering & Technology PG Courses [Volume-I]
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

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COURSE STRUCTURE & SYLLABI

Course Code	DISASTER MANAGEMENT	L	T	P	C
21DAC101b		2	0	0	0
	Semester	I			

Course Objectives: This course will enable students:

- Learn to demonstrate critical understanding of key concepts in disaster risk reduction and humanitarian response.
- Critically evaluatedisasterriskreduction and humanitarian response policy and practice from Multiple perspectives.
- Developanunderstandingofstandardsofhumanitarianresponseandpracticalrelevanceinspecific types of disasters and conflict situations
- Criticallyunderstandthestrengthsandweaknessesofdisastermanagementapproaches,planningand programming in different countries, particularly their home country or the countries they work in

UNIT - I

Introduction:
Disaster:Definition,FactorsandSignificance;DifferenceBetweenHazardandDisaster;Naturaland 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,DroughtsandFamines,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 ADisasteror 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. TechniquesofRiskAssessment,GlobalCo-OperationinRiskAssessmentand Warning, People's Participation in Risk Assessment. Strategies for Survival.

UNIT - V

Disaster Mitigation:
Meaning,ConceptandStrategiesofDisasterMitigation,EmergingTrendsInMitigation.Structural Mitigationand Non-Structural Mitigation, Programs of Disaster Mitigation in India.

Suggested Reading

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COURSE STRUCTURE & SYLLABI

1. R.Nishith,SinghAK,"DisasterManagementinIndia:Perspectives,issuesandstrategies
2. "'New Royal book Company..Sahni,PardeepEt.Al.(Eds.),"DisasterMitigationExperiencesAndReflections",PrenticeHall OfIndia, New Delhi.
3. GoelS.L.,DisasterAdministrationAndManagementTextAndCaseStudies",Deep&Deep Publication Pvt. Ltd., New Delhi

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COURSE STRUCTURE & SYLLABI

Course Code	SANSKRITFOR TECHNICAL KNOWLEDGE	L	T	P	C
21DAC101c		2	0	0	0
	Semester	**I**			

Course Objectives: This course will enable students:

- To get a working knowledge in illustrious Sanskrit, the scientific language in the world
- Learning of Sanskrit to improve brain functioning
- LearningofSanskrittodevelopthelogicinmathematics,science&othersubjects enhancing the memory power
- The engineering scholars equipped with Sanskrit will be able to explore the huge
- Knowledge from ancientliterature

Course Outcomes (CO): Student 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		

Suggested Reading

1.“Abhyaspustakam” –Dr.Vishwas, Sanskrit-Bharti Publication, New Delhi
2.“Teach Yourself Sanskrit” Prathama Deeksha- VempatiKutumbshastri, RashtriyaSanskrit Sansthanam, New Delhi Publication
3.“India’s Glorious ScientificTradition” Suresh Soni, Ocean books (P) Ltd.,New Delhi

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AUDIT COURSE-II

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COURSE STRUCTURE & SYLLABI

Course Code	PEDAGOGY STUDIES	L	T	P	C
21DAC201a		2	0	0	0
	Semester	**II**			

Course Objectives: This course will enable students:

- Reviewexistingevidenceonthereviewtopictoinformprogrammedesignandpolicy making undertaken by the DfID, other agencies and researchers.
- Identify critical evidence gaps to guide the development.

Course Outcomes (CO): Student will be able to

Students will be able to understand:

- Whatpedagogicalpracticesarebeingusedbyteachersinformalandinformalclassrooms in developing countries?
- What is the evidence on the effectiveness of these pedagogical practices, in what conditions, and with what population of learners?
- Howcanteachereducation(curriculumandpracticum)andtheschoolcurriculumand guidance materials best support effective pedagogy?

UNIT - I

Introduction and Methodology: Aims and rationale, Policy back ground, Conceptual frame work and terminology Theories oflearning,Curriculum,Teachereducation.Conceptualframework,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 theeffectivenessofpedagogicalpractices,Methodologyfortheindepthstage:quality assessmen t of included studies. How can teacher education (curriculumandpracticum) andthescho curriculum and guidance materials best support effective pedagogy? Theory of change. Strength and nature of th 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 teacherandthecommunity.Curriculumandassessment,Barrierstolearning:limitedresourcesand large class sizes

UNIT - V

Researchgapsandfuturedirections: Researchdesign**,**Contexts**,**Pedagogy**,**Teachereducation**,** Curriculum and assessment**,** Dissemination and research impact.

Suggested Reading

1. AckersJ,HardmanF(2001)ClassroominteractioninKenyanprimaryschools,Compare, 31 (2): 245-261.
2. AgrawalM(2004)Curricularreforminschools:Theimportanceofevaluation,Journalof
3. Curriculum Studies, 36 (3): 361-379.
4. AkyeampongK(2003) Teacher training in Ghana - does it count? Multi-site teachereducation research project (MUSTER) country report 1. London: DFID.

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5. Akyeampong K, LussierK, PryorJ, Westbrook J (2013)Improving teaching and learning of basic maths and reading in Africa: Does teacherpreparation count?International Journal Educational Development, 33 (3): 272–282.
6. Alexander RJ(2001) Culture and pedagogy: International comparisons in primary education. Oxford and Boston: Blackwell.
   Chavan M (2003)ReadIndia: A mass scale, rapid, 'learning to read'campaign.
7. www.pratham.org/images/resource%20working%20paper%202.pdf.

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COURSE STRUCTURE & SYLLABI

Course Code	STRESSMANAGEMENT BY YOGA	L	T	P	C
21DAC201b		2	0	0	0
	Semester	**II**			

Course Objectives: This course will enable students:

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

Course Outcomes (CO): Student 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`sand Don't'sin life. i) Ahinsa,satya,astheya,bramhacharyaand aparigrahaii) Shaucha,santosh,tapa,swadhyay,ishwarpranidhan		
UNIT - IV		
Asan and Pranayam		
UNIT - V		
i)Variousyogposesand theirbenefitsformind &body ii)Regularizationofbreathingtechniques and its effects-Types ofpranayam		

Suggested Reading

1.'Yogic Asanas forGroupTarining-Part-I": Janardan SwamiYogabhyasiMandal, Nagpur
2."Rajayogaor conquering the Internal Nature" by Swami Vivekananda, Advaita Ashrama (Publication Department), Kolkata

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Course Code	PERSONALITY DEVELOPMENT THROUGHLIFE ENLIGHTENMENTSKILLS	L	T	P	C
21DAC201c		2	0	0	0
	Semester	**II**			

Course Objectives: This course will enable students:

- 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 (CO): Student will be able to

- StudyofShrimad-Bhagwad-Geetawillhelpthestudentindevelopinghispersonalityand achieve the highest goal in life
- The person who has studied Geetawilllead 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.
ShrimadBhagwadGeeta:Chapter2-Verses41,47,48,
Chapter3-Verses13,21,27,35,Chapter6-Verses5,13,17,23,35,
Chapter18-Verses45,46,48.

UNIT - IV

Statements of basic knowledge.
ShrimadBhagwadGeeta:Chapter2-Verses 56,62,68
Chapter12 -Verses13,14,15,16,17,18
Personality of Rolemodel. Shrimad Bhagwad Geeta:

UNIT - V

Chapter2-Verses 17,Chapter3-Verses36,37,42,
Chapter4-Verses18,38,39
Chapter18– Verses37,38,63

Suggested Reading

1."SrimadBhagavadGita"bySwamiSwarupanandaAdvaitaAshram(PublicationDepartment), Kolkata
2.Bhartrihari'sThree Satakam (Niti-sringar-vairagya) by P.Gopinath, RashtriyaSanskrit Sansthanam, New Delhi.

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ANANTHAPURAMU – 515 002 (A.P) INDIA

M.PHARM. IN PHARMACY PRACTICE

COURSE STRUCTURE & SYLLABI

OPEN ELECTIVE

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M.PHARM. IN PHARMACY PRACTICE

COURSE STRUCTURE & SYLLABI

Course Code	PHARMACEUTICAL VALIDATION (Elective)	L	T	P	C
21SOE301a		3	0	0	3
	Semester	III			

Course Objectives:

The main purpose of the subject is to understand about validation and how it can be applied to industry and thus to improve the quality of the products. The subject covers the complete information about validation, types, methodology and application

Course Outcomes (CO): Student will be able to

- Explain the aspect of validation
- Carryout validation of manufacturing processes
- Apply the knowledge of validation to instruments and equipments
- Validate the manufacturing facilities

UNIT - I

Introduction: Definition of Qualification and Validation, Advantage of Validation, Streamlining of Qualification & Validation process and Validation Master Plan. Qualification: User Requirement Specification, Design Qualification, Factory Acceptance Test (FAT)/ Site Acceptance Test (SAT), Installation Qualification, Operational Qualification, Performance Qualification, Re- Qualification (Maintaining status -Calibration Preventive Maintenance, Change management), Qualification of Manufacturing Equipment, Qualification of Analytical Instruments and Laboratory equipments

UNIT - II

Qualification of analytical instruments: Electronic balance, pH meter, UV-Visible spectrophotometer, FTIR, GC, HPLC, HPTLC
Qualification of Glassware: Volumetric flask, pipette, Measuring cylinder, beakers and burette.

UNIT - III

Qualification of laboratory equipments: Hardness tester, Friability test apparatus, tap density tester, Disintegration tester, Dissolution test apparatus.
Validation of Utility systems: Pharmaceutical water system & pure steam, HVAC system, Compressed air and nitrogen.

UNIT - IV

Cleaning Validation: Cleaning Validation - Cleaning Method development, Validation and validation of analytical method used in cleaning. Cleaning of Equipment. Cleaning of Facilities. Cleaning in place (CIP).

UNIT - V

Analytical method validation: General principles, Validation of analytical method as per ICH guidelines and USP

Textbooks:

1. T. Loftus & R. A. Nash, "Pharmaceutical Process Validation", Drugs and Pharm Sci. Series, Vol.129, 3rd Ed., Marcel Dekker Inc., N.Y.
2. The Theory & Practice of Industrial Pharmacy, 3rd edition, Leon Lachman, Herbert A. Lieberman,Joseph. L. Karig, Varghese Publishing House, Bombay.
3. Validation Master plan by Terveeks or Deeks, Davis Harwood International publishing.
4. Validation of Aseptic Pharmaceutical Processes, 2nd Edition, by Carleton & Agalloco, (Marcel Dekker).
5. Michael Levin, Pharmaceutical Process Scale-Up‖, Drugs and Pharm. Sci. Series, Vol. 157, 2nd Ed., Marcel Dekker Inc., N.Y.

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M.PHARM. IN PHARMACY PRACTICE

COURSE STRUCTURE & SYLLABI

Course Code	BIOSTATISTICS (Elective)	L	T	P	C
21SOE301b		3	0	0	3
	Semester	III			

Course Objectives:

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

Course Outcomes (CO): Student will be able to

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	12Hrs

An introduction to statistics and biostatistics-collection and organization of data, graphical, pictorial presentation of data, measures of central tendency and dispersion, sampling techniques, sample size, Coefficient of variation, mean error, relative error, precision and accuracy

UNIT - II	12Hrs

Tests of significance: Testing hypotheses – Principles and applications of Z, t, F–ratio and chi-square tests in pharmaceutical and medical research. Non-parametric tests: sign test, Wilcoxon signed rank test, Wilcoxon rank sum test, Kruskal Wallis test, run test and median tests

UNIT - III	12Hrs

Design of Experiments: Principles of randomization, replication and local control; CRD, RBD, LSD – their applications and analysis of data;

UNIT - IV	12Hrs

Factorial Experiments –
Principles and applications; Probit analysis: Dose – effect relationships, calculation of LD50, ED50.

UNIT - V	12Hrs

Statistical quality control: Meaning and uses, Construction of X, R, P, ηp and charts

Textbooks:

1. Remington"s Pharmaceutical Sciences
2. Theory & Practice of Industrial Pharmacy by Lachman
3. Statistics for business and economics 3rd edition by Vikas books publications
4. Biostatistics & Computer applications by GN Rao and NK Tiwari
5. Sokal, R.R. and Rohlf, F.J. 1987. An Introduction to Biostatistics. W.H. Freeman and Company.
6. Bailey, N.T.J. 1981. Statistical Methods in Biology. English University Press.
7. Mitchell, K. and Glover, T. 2001. Introduction to Biostatistics. McGraw Hill, Publishing Co.

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. Sokal, R.R. and Rohlf, F.J. 1987. An Introduction to Biostatistics. W.H. Freeman and Company.
4. Bailey, N.T.J. 1981. Statistical Methods in Biology. English University Press.
5. Mitchell, K. and Glover, T. 2001. Introduction to Biostatistics. McGraw Hill, Publishing Co.

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COURSE STRUCTURE & SYLLABI

Course Code	ENTREPRENEURSHIP MANAGEMENT	L	T	P	C
21SOE301c	(Elective)	3	0	0	3
	Semester	III			

Course Objectives:

This course is designed to impart knowledge and skills necessary to train the students on entrepreneurship management.

Course Outcomes (CO): Student will be able to

- The Role of enterprise in national and global economy
- Dynamics of motivation and concepts of entrepreneurship
- Demands and challenges of Growth Strategies and Networking

UNIT - I

Conceptual Frame Work: Concept need and process in entrepreneurship development. Role of enterprise in national and global economy. Types of enterprise – Merits and Demerits. Government policies and schemes for enterprise development. Institutional support in enterprise development and management.

UNIT - II

Entrepreneur: Entrepreneurial motivation – dynamics of motivation. Entrepreneurial competency – Concepts. Developing Entrepreneurial competencies - requirements and understanding the process of entrepreneurship development, self-awareness, interpersonal skills, creativity, assertiveness, achievement, factors affecting entrepreneur role.

UNIT - III

Launching and Organizing an Enterprise: Environment scanning – Information, sources, schemes of assistance, problems. Enterprise selection, market assessment, enterprise feasibility study, SWOT Analysis. Resource mobilization -finance, technology, raw material, site and manpower. Costing and marketing management and quality control. Feedback, monitoring and evaluation.

UNIT - IV

Growth Strategies and Networking: Performance appraisal and assessment. Profitability and control measures, demands and challenges. Need for diversification. Future Growth – Techniques of expansion and diversification, vision strategies. Concept and dynamics. Methods, Joint venture, coordination and feasibility study.

UNIT - V

Preparing Project Proposal to Start on New Enterprise Project work – Feasibility report; Planning, resource mobilization and implementation.

Reference Books:

1. Akhauri, M. M. P.(1990): Entrepreneurship for Women in India, NIESBUD, New Delhi.
2. Hisrich, R. D & Brush, C.G. (1996) The Women Entrepreneurs, D.C. Health& Co., Toranto.
3. Hisrich, R.D. and Peters, M.P. (1995): Entrepreneurship – Starting Developing and Managing a New Enterprise, Richard D., Inwin, INC, USA.
4. Meredith, G.G. etal (1982): Practice of Entrepreneurship, ILO, Geneva.
5. Patel, V.C. (1987): Women Entrepreneurship – Developing New Entrepreneurs, Ahmedabad EDII
6. Arya kumar.(2012): Entrepreneurship- Creating and Leading an Entrepreneurial Organization, Pearson