SPECIALISATION: CLINICAL PHARMACY
SEMESTER-II
SCHEME OF TEACHING

SUB CODE	NAME OF SUBJECT	CONTACT HOURS PER WEEK		CREDITS	
		T	P	T	P
721	Pharmacotherapeutics - I	3	---	4	---
722	Pharmacotherapeutics - II	3	---	4	---
723	Clinical Pharmacy - II	3	---	4	---
724	Bio-pharmaceutics and Pharmacokinetics - I	3	---	3	---
725	Clinical Pharmacy Practical - II	---	18	---	6
726	Subject Seminar	6	---	---	3
	TOTAL	18	18	15	9

SCHEME OF EXAMINATION

SUB CODE	NAME OF SUBJECT	DURATION OF EXAM (HRS)	MARKS			
			THEORY		PRACTICAL	
			University level evaluation	Institute level evaluation	University level evaluation	Institute level evaluation
721	Pharmacotherapeutics - I	3	80	20	--	--
722	Pharmacotherapeutics - II	3	80	20	--	--
723	Clinical Pharmacy - II	3	80	20	--	--
724	Bio-pharmaceutics and Pharmacokinetics - I	3	80	20	--	--
725	Clinical Pharmacy Practical - II	12	--	--	80	20
726	Subject Seminar		--	--	--	100
	TOTAL		320	80	80	120

SUBJECT : Pharmacotherapeutics - I
SUBJECT CODE : 721
RATIONALE : This unit acquaints students with therapeutic strategies of different ailments.

COURSE OBJECTIVES : To train students on drug therapy and management of disease;

- To train and teach students medicine safety
- To develop skill and core knowledge in students to identify and solve any medicine related problems;
- To train students preliminary administration, policy and working of health care, system in hospital and community setting.
- To improve and appreciate quality and rational use of medicine;

LEARNING OUTCOMES: Upon the completion of semester, it is expected that students will be able to:

- Appreciate and implement rational use of medicines';
- Summarize therapeutic approach for management of disease;
- Explain and discuss controversies in therapy management and evidence based medicine;
- Able to set a goal based on diagnosis;
- Able to identify and correlate problems of therapy in patient

PREREQUISITES: Basic Pharmacology

TEACHING AND EVALUATION SCHEME:

SUB CODE	TITLE OF SUBJECT	TEACHING SCHEME			CREDITS	EVALUATION SCHEME				TOTAL MARKS
						INTERNAL		EXTERNAL		
		T	P	TOTAL HRS		Theory	Practical	Theory	Practical	
721	Pharmacotherapeutics - I	3	--	3	4	20	--	80	--	100

721. Pharmacotherapeutics - I

	Pathophysiology & Pharmacotherapeutics of disease associated with following System/Disease.- including basic concept of Pharmacotherapeutics	
1	Cardiovascular System: Hypertension b) Congestive Cardiac Failure c) Myocardial Infarction. d) Arrhythmias e) hyperlipidemias	18
2	Neuron System : Epilepsy b) Parkinson's c) Stroke d) headache e) TID f) Migraine	12
3	Psychiatric Disorders : Schizophrenia b) Depression & Mania c) Anxiety & sleep Disorders d) Drug induced psychosis. e) Drug induced psychosis	10
4	Renal System: a) Acute Renal Failure. b) Chronic Renal Failure. c) Renal dialysis & Transplantation d) Drug induced Renal Disease.	18
5	Respiratory System : Concept of Restrictive disease and Obstructive airway Diseases, Asthma and COPD Drug induced pulmonary Disease	12
6	Gastrointestinal System: a) Peptic ulcer disease. b) GERD c) IBD d) Hepatitis e) Jaundice f) Cirrhosis g) Diarrhea & Constipation e) Drug induced GIT diseases	12
7	Pain Management : Pain Pathways , Analgesics and NSAIDS, Neurologic including Trigeminal glossophalangeal pain	10
8	Immunology – Concept, Classification of immunity, Immunoglobulins and various vaccines and sera against different disease. Role of pharmacist in Immunization.	8

SUBJECT : **Pharmacotherapeutics – II**
SUBJECT CODE : **722**
RATIONALE **:** This unit acquaints students with therapeutic strategies of different ailments.

COURSE OBJECTIVES **:** To train students on drug therapy and management of disease;

- To train and teach students medicine safety
- To develop skill and core knowledge in students to identify and solve any medicine related problems;
- To train students preliminary administration, policy and working of health care, system in hospital and community setting.
- To improve and appreciate quality and rational use of medicine;

LEARNING OUTCOMES: Upon the completion of semester, it is expected that students will be able to:

- Appreciate and implement rational use of medicines';
- Summarize therapeutic approach for management of disease;
- Explain and discuss controversies in therapy management and evidence based medicine;
- Able to set a goal based on diagnosis;
- Able to identify and correlate problems of therapy in patient

PREREQUISITES: Basic Pharmacology

TEACHING AND EVALUATION SCHEME:

SUB CODE	TITLE OF SUBJECT	TEACHING SCHEME			CREDITS	EVALUATION SCHEME				TOTAL MARKS
						INTERNAL		EXTERNAL		
		T	P	TOTAL HRS		Theory	Practical	Theory	Practical	
722	Pharmacotherapeutics – II	3	---	3	4	20	--	80	--	100

722. Pharmacotherapeutics – II

1	Hematological Diseases:- Anemias. b) Sickling Diseases c) Drug induced hematological disorders.	15
2	Skin and Sexually Transmitted Disease:- Psoriasis b) Eczema and Scabies c) Syphilis and Gonorrhea. Drug related /induced skin reaction disorders.	10
3	Endocrine System :- Diabetes Mellitus & Diabetes insipidus, c) thyroid disease Osteoporosis Oral hormonal contraceptives	15
4	Oncology / Neoplastic Disorders:- • General principles of Chemotherapy, Commonly used cytotoxic drugs • Chemotherapy of lung cancer, hematological malignancies, carcinoma of breast, Hodge- king Diseases, Management of nausea and vomiting.	15
5	Optic System /Ophthalmology :- Glaucoma, Eye Infection,	7
6	Infectious Diseases. General guideline for rational use of Antibiotic, Meningitis, RTI, Gastroenteritis, Bacterial Endocarditic, TB, HIV and opportunities infection in HIV, Septicemia , Warm infection/Helmenthiasis, Fungal Infection, UTI, Antibiotic pharmacist	15
7	Nucleus (r) medicine therapy	7
8	Enteral and parenteral nutrition	10
9	Concept of other medicine with special emphasis on herbal drugs, Ayurvedic drugs, Unani, Homeopathic and role of pharmacist.	6

BOOKS RECOMMENDED

1	British National Formulary (Current Edition) – BMA/RPSGB
2	Avery's Drug Treatment, Adis International Limited.
3	Clinical Pharmacy and Therapeutics. Roger Walker and Clive Edwards, Churchill Livingstone Edinburg/London.
4	Pathology & Therapeutics for Pharmacists. Russel. J. Greene and Normal F. Harris. Chapman & Hall, London/Glasgow/Madras.
5	Text Book of Therapeutics: Drug and Disease Management. 7th Edition, Editors: Eric T. Herfindal and Dick R. Gourley, Williams and Wilkins, 2000.
6	Davidson's Principles and Practice of Medicine, Eds. Christopher R. W. Edwards and Lan A. D. Bouchier ELBS with Churchill Livingstone, Edinburgh, Latest Edition.
7	Applied Therapeutics: The Clinical Use or Drugs Eds. Brain S. Katcher, Lioyd Yee Young. Marry Anne Koda-kimble, Applied Therapeutics Inc. Spokane. Latest Edition.
8	Melmon and Morrelli's Clinical Pharmacology, 4th Edition, Author : S. George Carrathers, Brian B. Hoftman, Kenneth L. Melmon and David W. Nierenberg, McGrow Hill, 2000.
9	Pathology & Therapeutics for Pharmacists, Greene, R. J.& Harris, N. D. (1993). The Pharmaceutical Press.
10	De Gruchi's Clinical Haemotology in Medical Practice. Frank Firkin, Bryan Rush, David Penington, Colin Chesterman, Blactwell Scientific, Publication. 5th edition.
11	Robbins Pathologic Basis of Disease, Cartan, Kumar, Collins, W. B. Godkar, Saunders. 6th edition.
12	Text book of Medical laboratory Technology. Praful B. Godkar, Bhalani Publication House, Mumbai, 2nd edition.
13	Manual of basis techniques for a health laboratory, 2nd edition, World Health Organization, Geneva.
14	Principles of Pharmacology, the Path physiologic Basis of Drug Therapy, Lippincott, Williams & Wilkins.
15	Drug Interaction Facts, 2003. David S. Tatro.
16	Emergency Toxicology, 2nd edition. Peter Viccellio.
17	Toxicology – The basic science of poisons, international edition, Curtis D. Klaassen, 6th edition.
18	Toxicology – Principles and Applications, Raymond j. M. Niesink, John dr. Vries, Mannfred A. Hollinger.
19	Textbook of Nuclear and Radio pharmacy
20	Textbook of infectious disease by graham
21	Relevant review articles from recent medical and pharmaceutical literature/journals likes:
	clinical therapeutics
	Annals of Internal Medicine
	Oxford journal
	British Medical Journal
	Annals of Pharmacotherapy
	New England Journal of Medicine
	Lancet

SUBJECT : **Clinical Pharmacy – II**
SUBJECT CODE : **723**
RATIONALE **:** This unit acquaints students with Concept of drug therapy monitoring and therapeutic drug monitoring concept, need and significance, theory, TDM of common drugs.

COURSE OBJECTIVES: To train students on drug therapy and management of disease;

- To train and teach students medicine safety
- To develop skill and core knowledge in students to identify and solve any medicine related problems;
- To train students preliminary administration, policy and working of health care, system in hospital and community setting.
- To improve and appreciate quality and rational use of medicine;

LEARNING OUTCOMES: Upon the completion of semester, it is expected that students will be able to:

- Appreciate and implement rational use of medicines';
- Summarize therapeutic approach for management of disease;
- Explain and discuss controversies in therapy management and evidence based medicine;
- Able to set a goal based on diagnosis;
- Able to identify and correlate problems of therapy in patient

PREREQUISITES: Basic pharmacology
TEACHING AND EVALUATION SCHEME:

SUB CODE	TITLE OF SUBJECT	TEACHING SCHEME			CREDITS	EVALUATION SCHEME				TOTAL MARKS
						INTERNAL		EXTERNAL		
		T	P	TOTAL HRS		Theory	Practical	Theory	Practical	
723	Clinical Pharmacy – II	3	---	3	4	20	--	80	--	100

723. Clinical Pharmacy – II

1	**Concept of drug therapy monitoring and therapeutic drug monitoring concept, need and significance, theory, TDM of common drugs,**
2	***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
3	***Evidence Based Medicine*** Definition, concept of evidence based medicine Approach and practice of evidence based medicine in clinical settings
4	***Essential Drug*** Definition, need, concept of essential drug and role of WHO, National essential drug policy and list
5	***Rational Drug Use*** Definition, concept and need for rational drug use , Rational drug prescribing, rational formulation, Role of pharmacist in rational drug use, rational use of drug domestic and international perspective
6	General principles of clinical toxicology
7	Pharmacoeconomics. Definition, concept of cost and cost modules, different methods, theory of economics

BOOKS RECOMMENDED

	How to Read a Paper: The Basics of Evidence-Based Medicine By Trisha Greenhalgh weley books
1	Evidence-Based Medicine: A Framework for Clinical Practice, Daniel J. Friedland Appleton & Lange, 1998
2	Evidence-Based Medicine: How to Practice and Teach It Sharon E. Straus, Paul Glasziou, W. Scott Richardson
3	**Evidence-Based Medicine Guidelines By Ilkka Kunnamo**
4	Rational use of drug by Dr. Ranjeet Roy chaudhry
5	**Pharmacoeconomics By Tom Walley, Alan Haycox, Angela Boland**
6	Pharmacoeconomics: From Theory to Practice by Renee J. G. Arnold
7	Quality of life and pharmacoeconomics: an introduction Joyce A. Cramer, Bert Spilker
8	Practical pharmacoeconomics: how to design, perform and analyze outcomes research by Lorne E. Basskin
9	**Essentials of Pharmacoeconomics by** Karen Rascati
10	**The role of Pharmacoeconomics in outcomes management** Nelda E. Johnson, David B. Nash by American Hospital Pub
11	Essential drug list and publication by WHO and Govt of india.
12	Pharmacoepidemiology: principles and practice Brenda Waning, Michael Montagne, William W. McCloskey
13	Pharmacoepidemiology Stanley A. Edlavitch
14	Pharmacoepidemiology: an introduction by Abraham G. Hartzema, Miquel S. Porta, Hugh Hanna Tilson
15	Textbook of Pharmacoepidemiology: Brian L. Strom, Stephen E. Kimmel
16	Understanding Pharmacoepidemiology by Yi Yang, Donna West-Strum
17	Relevant review articles from recent medical and pharmaceutical literature/journals likes:
	Journal of pharmacoeconomics
	Journal of Pharmacoepidemiology
	Bulletins from national and international body working on RUD

SUBJECT : Bio-pharmaceutics and Pharmacokinetics - I
SUBJECT CODE : 724
RATIONALE : This unit acquaints students with course of drug after administration and to quantify drug at different sites at given time.
COURSE OBJECTIVES: To train students on drug therapy and management of disease;

- To train and teach students medicine safety
- To develop skill and core knowledge in students to identify and solve any medicine related problems;
- To train students preliminary administration, policy and working of health care, system in hospital and community setting.
- To improve and appreciate quality and rational use of medicine;

LEARNING OUTCOMES: Upon the completion of semester, it is expected that students will be able to:

- Appreciate and implement rational use of medicines';
- Summarize therapeutic approach for management of disease;
- Explain and discuss controversies in therapy management and evidence based medicine;
- Able to set a goal based on diagnosis;
- Able to identify and correlate problems of therapy in patient

PREREQUISITES: Human Physiology
TEACHING AND EVALUATION SCHEME:

SUB CODE	TITLE OF SUBJECT	TEACHING SCHEME			CREDITS	EVALUATION SCHEME				TOTAL MARKS
						INTERNAL		EXTERNAL		
		T	P	TOTAL HRS		Theory	Practical	Theory	Practical	
724	Bio-pharmaceutics and Pharmacokinetics – I	3	--	3	3	20	--	80	--	100

724. Bio-pharmaceutics and Pharmacokinetics – I

1	**Drug Absorption** Relevant anatomy & Physiology of organs involved in drug absorptions: factors affecting drug absorption following oral, parenteral, topical, Buccal, rectal, vaginal, urethral and nasal administration of drugs; methods of studying drug absorption following different routes of administration; kinetics of drug absorption.	20
2	**Drug Distribution** Distribution in the blood, beyond the blood compartment tissue localization; volumes of distribution	20
3	**Drug Biotransformation** Sties of drug biotransformation; kinetics of drug biotransformation, Phase-I and Phase-II biotransformation reactions; mechanisms of microsomal oxidation; mechanisms of glucuronide formation; factors affecting biotransformation; methods of studying biotransformation of drugs; usefulness of biotransformation study in drug design and dosage forms.	20
4	**Drug Excretion** Excretion in urine, bleary, excretion, excretion in expired air, excretion in the stomach; excretion in the intestine, saliva, breast-milk, genital secretions, sweat.	20
5	**Bioavailability and Bioequivalence Testing** Absolute and relative bioavailability, Types of Bioequivalence study	20

SUBJECT : Clinical Pharmacy Practical – II
SUBJECT CODE : 725
TEACHING AND EVALUATION SCHEME:

SUB CODE	TITLE OF SUBJECT	TEACHING SCHEME			CREDITS	EVALUATION SCHEME				TOTAL MARKS
						INTERNAL		EXTERNAL		
		T	P	TOTAL HRS		Theory	Practical	Theory	Practical	
725	Clinical Pharmacy Practical – II	--	18	18	6	--	20	--	80	100

725. Clinical Pharmacy Practical - II

1.	Hospital based ward rounds and clinical case studies
2.	Acute care medicine Managing ICUs, T.P.N. and Emergencies.
3.	Interaction with patients in community.
4.	Common practice of drug treatment schedule and Guidelines.
5.	Clinical Trials Phases
6.	Sampling and randomization techniques.
7.	Protocol, Investigator Brochure, CRF, Inform Consent Form preparations and Ethics Committee permission.
8.	Essential documents and study file.
9.	Data interpretation and final report preparations.
10.	Regulatory Guidelines and comparison
11.	Hospital data management and budget preparation.
12.	Pharmacoeconomics
13.	Adverse drug reactions
14.	Pharmacovigilance
15.	Drug interactions
16.	Therapeutic drug monitoring
17.	Essential drugs and Rational Drug use

SUBJECT **: Subject Seminar**
SUBJECT CODE **: 726**
RATIONALE : This unit is complementary to compensate the boundryless content of theory syllabus. It includes all aspects of core subject specialization which tangentially touch the content of syllabus. (It does not include routine syllabus topics) All research and reviewed articles along with reference books are taken as basis for preparing a seminar. Innovative topics are ensured in each session.

COURSE OBJECTIVES : At the end of the course the student should be able to:

1. Develop knowledge to refer literature for given topic. Literature search include key words, Library use and internet use.
2. Develop presentation skills.
3. Get peripheral knowledge of the subject with current perspective.

LEARNING OUTCOMES: At the end of the course the student will be able to:

1. Find any reference related to the theme.
2. Have presentation skills in terms of precise and contented, relevant presentation.
3. Identify current perspectives related to the subject.

PREREQUISITES: None
TEACHING AND EVALUATION SCHEME:

SUB CODE	TITLE OF SUBJECT	TEACHING SCHEME			CREDITS	EVALUATION SCHEME				TOTAL MARKS
						INTERNAL		EXTERNAL		
		T	P	TOTAL HRS		Theory	Practical	Theory	Practical	
726	Subject Seminar	6	-	6	3	-----	100	-----	-----	100

SPECIALISATION: CLINICAL PHARMACY
SEMESTER-III
SCHEME OF TEACHING

SUB CODE	NAME OF SUBJECT	CONTACT HOURS PER WEEK		CREDITS	
		T	P	T	P
731	Bio-pharmaceutics and Pharmacokinetics – II	3	---	3	---
732	Clinical Pharmacy - III	3	---	3	---
733	Hospital and Community Pharmacy	3	---	3	---
734	Regulatory Affairs in Clinical Research	3	---	3	---
735	Clinical Pharmacy Practical - III	---	18	---	6
736	Synopsis / ITD	---	---	---	3
737	Subject Seminar	6	---	---	3
	TOTAL	18	18	12	12

SCHEME OF EXAMINATION

SUB CODE	NAME OF SUBJECT	DURATION OF EXAM (HRS)	MARKS			
			THEORY		PRACTICAL	
			University level evaluation	Institute level evaluation	University level evaluation	Institute level evaluation
731	Bio-pharmaceutics and Pharmacokinetics – II	3	80	20	---	---
732	Clinical Pharmacy - III	3	80	20	---	---
733	Hospital and Community Pharmacy	3	80	20	---	---
734	Regulatory Affairs in Clinical Research	3	80	20	---	---
735	Clinical Pharmacy Practical - III	12	---	---	80	20
736	Synopsis / ITD	---	80	20	---	----
737	Subject Seminar	---	---	---	----	100
	TOTAL		400	100	80	120

SUBJECT : Bio-pharmaceutics and Pharmacokinetics – II
SUBJECT CODE : 731
RATIONALE : This unit discusses application of biopharmaceutics and Clinical pharmacokinetics in clinical practice.

COURSE OBJECTIVES:

- To train and teach students on pharmacokinetics and movement of drug in body.
- To teach student on safety of medicine and reporting of mishaps
- To provide an opportunity to learn drug development process especially the phases of clinical trials;
- To prepare students about requirement for conducting clinical trials specially on designing, conducting, managing and reporting in clinical trials;
- To train student on elements and components of clinical research including different guidelines
- to train students on organization, component, activity in hospital pharmacy
- To train students on requirement, legal issues and running of pharmacy in India and overseas.

LEARNING OUTCOMES: Upon the completion of this semester it is expected that students will be able to:

- Able to understand pharmacokinetics of the medicines
- Able to report mishaps
- Understand safety of medicine
- Materialized on regulatory requirement for conducting clinical trials, types of trials, initiation and issues of QA of trials.
- Draft protocol of clinical research;
- Able to discuss policy and procedures of IEC;
- Describe and explain the therapy for diseases;
- Quality use of medicines
- Pharmacokinetic aspects of medicines
- able to handle and work in hospital and community pharmacy

PREREQUISITES: Human Physiology

TEACHING AND EVALUATION SCHEME:

SUB CODE	TITLE OF SUBJECT	TEACHING SCHEME			CREDITS	EVALUATION SCHEME				TOTAL MARKS
						INTERNAL		EXTERNAL		
		T	P	TOTAL HRS		Theory	Practical	Theory	Practical	
731	Bio-pharmaceutics and Pharmacokinetics – II	3	--	3	3	20	---	80	---	100

731. Bio-pharmaceutics and Pharmacokinetics – II

1	Pharmacokinetic Models instantaneous distribution models; delay distribution equilibrium model; nonlinear pharmacokinetic models; pharmacological pharmacokinetic model.	30
2	Clinical Applications of Pharmacokinetic Parameters Blood level curves; continuous blood and tissue levels in therapy; dosage regimens accumulation during repetitive dosing; adjustment of dosage regimen in renal failure; distribution dependent dosage adjustment; pharmacokinetic drug interaction.	20
3	Applications in TDM and patient care specific drugs and disease states, effects of age and concomitant drug administration.	10
4	Pharmacokinetic Basis of Controlled Drug Delivery.	10
5	Statistical treatment of data, test for significance, t-test, analysis of variance repression analysis, standard deviation, standard error, fiducial limits, hypothesis testing, randomization etc.	20
6	Application of computer in clinical research.	10

BOOKS RECOMMENDED

1	Modern Pharmaceutics by Banker and Rhodes.
2	Pharmacokinetics, Milo Gibaldi and Donald Perrier.

SUBJECT : Clinical Pharmacy – III
SUBJECT CODE : 732
RATIONALE : This unit discusses Principles of Pharmacovigilance, Pharmacoepidemiology and General prescribing guideline for pediatric, geriatric and pregnant and lactating women.

COURSE OBJECTIVES :

- To train and teach students on pharmacokinetics and movement of drug in body.
- To teach student on safety of medicine and reporting of mishaps
- To provide an opportunity to learn drug development process especially the phases of clinical trials;
- To prepare students about requirement for conducting clinical trials specially on designing, conducting, managing and reporting in clinical trials;
- To train student on elements and components of clinical research including different guidelines
- to train students on organization, component, activity in hospital pharmacy
- To train students on requirement, legal issues and running of pharmacy in India and overseas.

LEARNING OUTCOMES: Upon the completion of this semester it is expected that students will be able to

- Able to understand pharmacokinetics of the medicines
- Able to report mishaps
- Understand safety of medicine
- Materialized on regulatory requirement for conducting clinical trials, types of trials, initiation and issues of QA of trials.
- Draft protocol of clinical research;
- Able to discuss policy and procedures of IEC;
- Describe and explain the therapy for diseases;
- Quality use of medicines
- Pharmacokinetic aspects of medicines
- able to handle and work in hospital and community pharmacy

PREREQUISITES: Clinical pharmacokinetics

TEACHING AND EVALUATION SCHEME:

SUB CODE	TITLE OF SUBJECT	TEACHING SCHEME			CREDITS	EVALUATION SCHEME				TOTAL MARKS
						INTERNAL		EXTERNAL		
		T	P	TOTAL HRS		Theory	Practical	Theory	Practical	
732	Clinical Pharmacy – III	3	--	3	3	20	---	80	---	100

732. Clinical Pharmacy – III

1	Basic Concepts of Pharmacotherapeutics.	05
2	Principles of 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 pharmacists in Pharmacovigilance • Theory of Pharmacovigilance • Drugs induced diseases, adverse drug reactions	25
3	Drug interactions, Prescription monitoring, documentation and other methods for minimizing clinically relevant drug interactions.	12
4	Pharmacoepidemiology • Definition, scope and theory • Methods • Sources of data • Meta-analysis • Social, cultural and economical factors influencing drug use System for monitoring drug use	18
5	General prescribing guideline for pediatric, geriatric and pregnant and lactating women including dysmenorrheal, fertility control and hormone replacement therapy.	15
6	Drug dose adjustment in renal failure and hepatic failure and Calculation of loading dose and maintenance dose	15
7	Self-care, and use of OTC	10

SUBJECT : **Hospital and Community Pharmacy**
SUBJECT CODE : **733**
RATIONALE : This unit acquaints students of Hospital pharmacy organization and management.

COURSE OBJECTIVES :

- To train and teach students on pharmacokinetics and movement of drug in body.
- To teach student on safety of medicine and reporting of mishaps
- To provide an opportunity to learn drug development process especially the phases of clinical trials;
- To prepare students about requirement for conducting clinical trials specially on designing, conducting, managing and reporting in clinical trials;
- To train student on elements and components of clinical research including different guidelines
- to train students on organization, component, activity in hospital pharmacy
- To train students on requirement, legal issues and running of pharmacy in India and overseas.

LEARNING OUTCOMES: Upon the completion of this semester it is expected that students will be able to:

- Able to understand pharmacokinetics of the medicines
- Able to report mishaps
- Understand safety of medicine
- Materialized on regulatory requirement for conducting clinical trials, types of trials, initiation and issues of QA of trials.
- Draft protocol of clinical research;
- Able to discuss policy and procedures of IEC;
- Describe and explain the therapy for diseases;
- Quality use of medicines
- Pharmacokinetic aspects of medicines
- able to handle and work in hospital and community pharmacy

PREREQUISITES: Pharmaceutical practice, Basic clinical pharmacy

TEACHING AND EVALUATION SCHEME:

SUB CODE	TITLE OF SUBJECT	TEACHING SCHEME			CREDITS	EVALUATION SCHEME				TOTAL MARKS
						INTERNAL		EXTERNAL		
		T	P	TOTAL HRS		Theory	Practical	Theory	Practical	
733	Hospital and Community Pharmacy	3	--	3	3	20	---	80	---	100

733. Hospital and Community Pharmacy

	Concept of health	
1	Hospital – as an organization -- Introduction, the hospitals, its need, organization-departments/services and, role of administrator/governing body,	5
2	Hospital pharmacy as a department -- Organization, staffing, legal requirement, promotion of HP and staff, role and responsibility, set up, work load, remuneration, grievance- conflict Redressal, teaching and training.	8
3	Hospital/ hospital pharmacy policy--- PTC – concept, constitution, working and its different role, Drug and therapeutic News Letter/bulletin,	6
	Hospital formulary – concept, preparation, legal issues,	
	Hospital pharmacy committees - antibiotic committee, IEC, Infection control committee	
4	Finance and budget; Concept of cost and billing, income-expense and budget, revenue generation, finance in HP, capital and running budget,	6
5	Drug distribution and dispensing: concept, different drug dispensing system/methods, modern concept in drug dispensing viz: robotic and automation in Dispensing	8
6	Material management in HP Purchase and inventory, methods of inventory, stocking, record keeping- including special emphasis on ancillary and surgical items and narcotic and psychotropic drugs, repackaging and pre-packaging, Intravenous programme- iv admixtures,	7
7	Record keeping : importance/need, methods of record keeping – conventional and modern	5
8	Nuclear and radio pharmacy: concept, uses and handling, legal issues, role and responsibility of permission holder, pharmacist, central and state government in N/R pharmacy.	5
9	National and state health policy,	3

Community Pharmacy

1	Concept of community pharmacy in India and overseas, development, seven star role of pharmacist, extended role of community pharmacist,	8
2	Community pharmacy management Concept, layout and site selection, material management, legal requirement to run community pharmacy, computer application	5
3	Over the counter medicines; concept, sale and role of pharmacist, rational use of OTC	7
4	Role of Clinical pharmacist and its relationship to other local health care providers and services to nursing home and Clinics, home care pharmacist, concept of social pharmacy/pharmacist	10
5	Prescribed medication order /Rx – interpretation, recordkeeping and legal requirements.	7
6	Primary care in community Pharmacy. a) Family Planning b) First Aid c) Smoking cessation d) Women welfare e) Disease prevention	7
7	Education and training Training & Education to Staff, CE, CPD, for pharmacist work- shops and Reference Course	6

SUBJECT : Regulatory Affairs in Clinical Research
SUBJECT CODE : 734

RATIONALE : This unit discusses Evaluating efficacy and safety of drugs Preclinical toxicological requirements for biological, biotechnological products, herbal drugs, Preclinical Testing strategy & Basic concepts and introduction to Clinical Drug Development.

COURSE OBJECTIVES :

- To train and teach students on pharmacokinetics and movement of drug in body.
- To teach student on safety of medicine and reporting of mishaps
- To provide an opportunity to learn drug development process especially the phases of clinical trials;
- To prepare students about requirement for conducting clinical trials specially on designing, conducting, managing and reporting in clinical trials;
- To train student on elements and components of clinical research including different guidelines
- to train students on organization, component, activity in hospital pharmacy
- To train students on requirement, legal issues and running of pharmacy in India and overseas.

LEARNING OUTCOMES: Upon the completion of this semester it is expected that students will be able to:

- Able to understand pharmacokinetics of the medicines
- Able to report mishaps
- Understand safety of medicine
- Materialized on regulatory requirement for conducting clinical trials, types of trials, initiation and issues of QA of trials.
- Draft protocol of clinical research;
- Able to discuss policy and procedures of IEC;
- Describe and explain the therapy for diseases;
- Quality use of medicines
- Pharmacokinetic aspects of medicines
- able to handle and work in hospital and community pharmacy

PREREQUISITES: Drug laws

TEACHING AND EVALUATION SCHEME:

SUB CODE	TITLE OF SUBJECT	TEACHING SCHEME			CREDITS	EVALUATION SCHEME				TOTAL MARKS
						INTERNAL		EXTERNAL		
		T	P	TOTAL HRS		Theory	Practical	Theory	Practical	
734	Regulatory Affairs in Clinical Research	3	-	3	3	20	---	80	---	100

734. Regulatory Affairs in Clinical Research

1	Evaluating efficacy and safety of drugs as per regulatory requirements ICH, CDSCO, OECD, WHO guidelines	10
2	Single dose, Repeat dose, Reproductive, Mutagenicity, Carcinogenicity, Toxicokinetic methods	10
3	Preclinical toxicological requirements for biological, biotechnological products, herbal drugs	10
4	Preclinical Testing strategy. Experimental clarification of human risks, Flowchart for development of preclinical testing	10
5	Basic concepts and introduction to Clinical Drug Development	10
6	Design and organization of Phase-I to Phase-IV clinical trials including Pharmacovigilance	15
7	Introduction to the fundamentals of the design and analysis of clinical trials. Ethical considerations -- intention-to-treat versus efficacy trials, principles of sampling and exclusion, methods of allocation and techniques of randomization, parallel versus cross over designs, monitoring treatment outcomes, adverse effects, stopping rules, data interpretation and logistical issues in the management of clinical trials. FDA guidelines for clinical trials, reviews and approval of a clinical study	25
8	Application for NDA/ANDA with essential documents as per current regulatory requirements i.e. CTD, DMF, Protocol design for preclinical, clinical research study, Investigator's Brochure etc	10

BOOKS RECOMMENDED:

1	New Drug Approval Process, Third Edition by Richard A. Guarino, Volume 100, Marcel Decker Inc.
2	IND and NDA Guidelines of Various Regulatory Authorities.
3	ICH Guidelines
4	GCP Guidelines
5	OECD Guidelines
6	WHO Guidelines

SUBJECT : Clinical Pharmacy Practical - III
SUBJECT CODE : 735

TEACHING AND EVALUATION SCHEME:

SUB CODE	TITLE OF SUBJECT	TEACHING SCHEME			CREDITS	EVALUATION SCHEME				TOTAL MARKS
						INTERNAL		EXTERNAL		
		T	P	TOTAL HRS		Theory	Practical	Theory	Practical	
735	Clinical Pharmacy Practical - III	-	18	18	6	---	20	---	80	100

735. Clinical Pharmacy Practical - III

	PRACTICALS - based on theory in Hospital visits, ward rounds, medication history and prescription analysis, etc with main emphasis on
1	Hospital visits and record keeping.
2	Prescription Behavior and analysis.
3	Pharmacoeconomics
4	Patient compliance
5	Patient Counseling
6	ADR – adverse drug reactions and Pharmacovigilance
7	Drug Interactions
8	TDM – Therapeutic Drug Monitoring
9	Essential Drugs and rational drug use
10	OTC Drugs.
11	Filling and interpretation of Medical history and Case Record Form of Patients.
12	Case studies related to path physiology and clinical symptoms.
13	Emergency medicines
14	Drug treatment during diseases conditions (renal and hepatic failure)
15	Statistics tools
	Assignments for Hospital Pharmacy
1	You have been asked to establish a drug information centre in a 50, 100-500 and 1200 -1500 bed hospital. Prepare a written Report for the hospital's administration summarizing the resources. You will need to do this including financial aspects.
2	Compare, Describe & evaluate the lay out and work flow pattern in the dispensary/departments of a local hospital. Include in your report any improvements within you would recommend to achieve more efficient work practices.
3	Examine and Report on the drug distribution pattern and methods used in local hospital.
4	Prepare formulary
5	Prepare hospital Bulletin.
6	Study the constitution of different committees in nearby hospital.
7	You have been asked to prepare a budget for present fiscal year
8	You have been asked to establish a drug information centre in a 50, 100-500 and 1200 -1500 bed hospital. Prepare a written Report for the hospital's administration summarizing the resources. You will

	need to do this including financial aspects.
9	Compare, Describe & evaluate the lay out and work flow pattern in the dispensary/departments of a local hospital. Include in your report any improvements within you would recommend to achieve more efficient work practices.
10	Examine and Report on the drug distribution pattern and methods used in local hospital.
11	Prepare formulary
12	Prepare hospital Bulletin.
13	Study the constitution of different committees in nearby hospital.
14	You have been asked to prepare a budget for present fiscal year
	Assignment for Community Pharmacy
1	Critical study of two community pharmacies in the neighborhood for Schedule M & N Compliance.
2	Comparison of Prescription handling in two community pharmacies.
3	Audit of Sales over the 24 hr Period in a local clinical pharmacy.
4	Study Financial & material management of Clinical pharmacy;
5	Code of Ethics for Pharmacist
6	Compile the summary of the advices and recommendation which should be provided to the Following Consumers at a pharmacy.
	a) Parents asking a medication for their 1-5 yr old child.
	b) A Student of 2 to 25 yrs of age who wishes to purchase medicines for temporary relief of headache & fevers
	c) A 60 yrs old woman /man who requests a cough mixtures, she/he was no other associated symptoms and in being Trained for DM & HT.
	d) A patient of anemia who have been advised or their doctor to take Iron Formulation & vitamin Formulation.
7	Preparation & Distribution of patient information leaflets.
8	Patient education on specific topics.

BOOKS RECOMMENDED

1	Text book of hospital pharmacy by William Hassan
2	Text book of Hospital Pharmacy by Alwood
3	Text book of Hospital Pharmacy by Marchant and Quadry
4	Text book of Hospital Pharmacy – Pharmaceutical press
5	Textbook practical standards for hospital Pharmacist – ASHP, American health system of Pharmacist,
6	Text book of Hospital Management – CRC Press
7	Text book of HOSPITAL Accounting –
8	Textbook of Institutional Pharmacy Practice – ASHP
9	Community Pharmacy: Strategic Change Management by Alison
	Journals
1	Indian journal of hospital pharmacy
2	Indian journal of pharmacy practice
3	Journal of pharmacy practice
4	Clinical pharmacist
5	Am j hosp pharm
6	J am Pharm Assoc
7	Ann Pharmacother
8	Australian prescriber
	GR and Policy

1	Consultative group and committee reports from WHO
2	General resolution and policy from Central Govt and State government with respect to subject and area applicable at suitable level and setting

1	Goodman and Gilman's The Pharmacological Basis of Therapeutics 11th edi, 2005, McGraw Hill Publication.
2	H. P. Rand, M. M. Dale, Pharmacology, 5th, 2003, Churchill Livingstone Publications.
3	Bertram G. Katzung Basic and Clinical Pharmacology (Lange Medical Books), 8th edi, 2001, McGraw Hill Publications.
4	Coleman, Michael D, Human Drug Metabolism; An introduction, 2001, John Wiley Pub.
5	Rothstein, Mark A Pharmacogenomics: Social, Ethical and Clinical Dimensions. 2003, Wiley-Liss
6	Chorghade, Mukund S, Drug Discovery and Development: Volume 1: Drug Discovery, 2006, Marcel Dekker Publications.
7	Winter Michael E, Basic Clinical Pharmacokinetics 4th edi, 2004, Lippincott Williams and Wilkins.
8	Tozer, Thomas N introduction to Pharmacokinetics and Pharmacodinamics: The Quantitative Basis of Drug Therapy. 2006, Lippincott Williams and Wilkins.
9	Kenakin, Terry A Pharmacology Primer: Theory, Applications, and Methods. 2003, Academic Press.
10	Hernandez, Maria Basic Pharmacology: Understanding Drug Actions and Reactions. 2006, Taylor & Francis Pub.
11	Ritschel, W. A., Handbook of Basic Pharmacokinetics, 5th edi., 1999, American Pharmaceutical Association.
12	Cooper, Jack R. The Biochemical Basis of Neuropharmacology. 8th edi, 2002, Oxford Uni. Press
13	Mantovani, Alberto, Pharmacology of Cytokines. Oxford Uni. Press.
14	Leon, Darryl, In Silco Technologies in Drug Target Identification and Validation. 2006, Taylor and Francis Pub.
15	Halbach, Oliver Von Bohlen Und, Neurotransmitters and Neuromodulators: Handbook of Receptors and Biological Effects. 2nd edi, 2006, Wiley-VCh veriag Pub.
16	Nestler, Eric J. Molecular Basis of Neuropharmacology: A Foundation for Clinical Neuroscience. 2001, McGraw Hill Medical Pub.
17	Carvey Paul M, Drug Action in the Central Neuropharmacology: A Foundation for Clinical Neuroscience. 2001, McGraw Hill Medical Pub.
18	Andriole Vincent T, The Quinolones. 3rd edition, 1988, Oxford Uni. Press.
19	Hall, Ian P. Dukes, Pharmacogenetics. 2006, Taylor & Francis.
20	Demuth, James Basic Statistics and Pharmaceutical Statistical Applications, 2nd edi. 1999, Marcel Dekkar.
21	Broadley Kenneth, Autonomic Pharmacology, 1996, Tayloe & Francis.

22	Rowland Malcoim, Clinical Pharmacokinetics. 3rd edi,1996, B. I. Waverly Publication.
23	Herfindahi, Clinical Pharmacy and Therapeutics: 2nd edi, 1978, William Morrow & Comp Pub.
24	Rang H. P., Drug Receptors. 1986, Uni. Press.
25	Dereianko Michael, CRC Hand Book of Toxicology, 1995, CRC Press Pub.
26	Shayne Cox Gad, Drug Discovery Handbook
27	Vogel H. Gerhald, Drug Bioscreening : Drug Evaluation Methods.
28	Gillstrap Larry, Drugs and Pregnancy. 1992, Elsevier Pub.
29	Abdel-Magid, Fundamentals of Early Clinical Drug Development: From Synthesis Design to Formulation, 2006, John Wiley & Sons.
30	Abood, Pharmacy Practice and the Law, 4th edi, 2007, Johns Wiley & Sons.
31	Arcangeio, Pharmacotherapeutics for Advanced Practice, : A Practical Approach, 2nd edi, 2006, Lppincott Williams & Wilkins Pub.
32	Aronson Mayler's Side Effects of Drugs: The International Encyclopedia of Adverse Drug Reactions & Interactions, 15th edi, 2006, 6 Vol. Set. J. K. Aronson Eisevier Pub.
33	Atkinson, Principles of Clinical Pharmacology, 2nd edi, 2003, 2003, Churchill Livingstone Pub.
34	Bennett, Clinical Pharmacology, 9th edi, 2003, Churchill Livingstone Publication.
35	Berry, The Pharmaceutical Regulatory Process (HB), 2004, Marcel Dekker Pub.
36	Bolton, Pharmaceutical Statistics: Practical and Clinical Applications, 4edi., 2004, Marcel Dekker Publication.
37	Bonate Pharmacokinetic – Pharmacodynamic Modeling & Simulation. 2005, Birkhanuser.
38	Coleman, Human Drug Metabolism: An introduction. 2005, John Wiley Pub.
39	Cupp, Toxicology & Clinical Pharmacology of Herbal Products, 2003, Marcel Dekkar Pub.
40	Dipiro, Encyclopedia of Clinical Pharmacy, Single Volume, 2003, Marcel Dekkar Pub.
41	Ebadi, Pharmacodynamic Basis of Herbal Medicine, 2nd edi, 2006, CRC Press.
42	Ette, Pharmacometrics: The Science of Quantitative Pharmacology. 2007, John Wiley & Sons.
43	Evans, A Handbook of Bioanalysis and Drug Metabolism, 2004, CRC Press.
44	Feinendegen, Molecular Medicine: The Challenge of Genomics & Proteomics & Proteomics to Clinical Practice, 2003, Birkhauser, Springer.
45	Fu, Protein-Protein Interactions:Methods and Applications, 2004, Human Press.
46	Gad, Drug Discvery Handbook, 2005, Wiley Interscience Pub.
47	Gaginella, Drug Development: Molecular Targets for GI Diseases, 1999, Humana Press.
48	Hall, Pharmacogenetics, 2006, Taylor & Francis.
49	Hauschke Bioequivalence Studies in Drug Development: Methods & Applications, 2007, Wiley Pub.
50	Ho, Biotechnology and Biopharmaceuticals: Transforming Proteins and Genes into Drugs, 2003, Wiley Pub.
51	John Wiley, Wiley Encyclopedia of Molecular Medicine, 5 Vol. Set, 2001, John Wiley & Sons.
52	Kucers, The use of Antibiotics: A Clinical Review of Antibacterial, antifungal and Antiviral Drugs,

	5th edi, 1997. Butterworth-heinemann Pub.
53	Kulkarni, Biopharmaceutics, 2003, CBS Pub.
54	Larson, Bioinformatics and Drug Discovery. 2006, Humanaa Press.
55	Lee, Clinical Trials of Drugs & Biopharmaceuticals, 2005, Taylor & Francis Pub/CRC Press.
56	Macheras, Modeling in Biopharmaceutics, Pharmacokinetics & Pharmacodynamics: Homogeneous & Heterogeneous Approaches, 2006, Springer.
57	Minor, Handbook of Assay Development in Drug Discovery, 2006, Taylor & Francis Pub.
58	Mozayani, Handbook of Drug interactions: A Clinical and Forensic Guide, 2003, Humana Press.
59	Murphy, Clinical Pharmaceutics, 3rd edi.
60	Notari, Biopharmaceutics and Clinical Pharmacokinetics, 4th edi, Marcel Dekkar Pub.
61	Offermanns, Encyclopedic Reference of Molecular Pharmacology, 2006, Springer Pub.
62	Page, integrated pharmacology, 2nd edi, 2002, Mosby College Pub.
63	Patterson, Bioequivalence & Statistics in Clinical Pharmacology, 2005, CRC Press.
64	PDR Physicians' Desk Reference, 61st edi, 2007, Medical Economics Comp Pub.
65	Rang, Drug Discovery & Development Technology in Transition, 2006, Churchill Living stone Pub.
66	Ritschel, Handbook of Basic Pharmacokinetics including Clinical Applications, 6th edi, American Pharmaceutical Association.
67	Sahajwall, Now Drug Development: Regulatory Paradigms for Clinical Pharmacology & Biopharmaceutics, 2004, Informa Health Cara.
68	Schieef, DNA Pharmaceuticals: Formulation & delivery in Gene Therapy, DNA Vaccination & immunotherapy, 2005, Wiley Pub.
69	Shargel, Comprehensive Pharmacy Review, 4th edi, 2001, Lippincott Williams.
70	Smith, Enzymes & Their inhibition Drug Development, 2005, CRC Press Pub.
71	Smith, Pharmacokinetics & Metabolism in Drug Design, 2nd dei, Vol.31(HB).
72	Smith, The Process of New Drug Discovery & Development, 2nd edi, 1992, CRC Press.
73	Sneader, Drug Discovery : A History (PB)
74	Strom, Pharmacoepidemiology, 4th edi.
75	Strom, Textbook of Pharmacoepidemiology, 2006, john Wiley Pub.
76	Tozer, Introduction to Pharmacokinetics & Pharmacodynamics : The Quantitative Basis of Drug Therapy, 2006,
77	Roger Walker, Clinical Pharmacy & Therapeutics, 4th edi, 2007, Churchill Livingstone Pub.
78	Ruth Levine's Pharmacology Drug Actions & Reactions, 5th edi, 1996, The Parthenon Pub.
79	Washington, Physiological Pharmaceutics: Barriers to Drug Absorption, 2nd edi, 2001, Taylor & Francis Pub.
80	Welling, Pharmaceutical Bioequivalence, 1991, Informa Health Care
81	Welling Pharmacokinetics: Regulatory-Industrial-Academic Perspective, Informa Health Care.

SUBJECT **: Subject Seminar**
SUBJECT CODE **: 737**
RATIONALE : This unit is complementary to compensate the boundryless content of theory syllabus. It includes all aspects of core subject specialization which tangentially touch the content of syllabus. (It does not include routine syllabus topics) All research and reviewed articles along with reference books are taken as basis for preparing a seminar. Innovative topics are ensured in each session.

COURSE OBJECTIVES : At the end of the course the student should be able to:

1. Develop knowledge to refer literature for given topic. Literature search include key words, Library use and internet use.
2. Develop presentation skills.
3. Get peripheral knowledge of the subject with current perspective.

LEARNING OUTCOMES: At the end of the course the student will be able to:

1. Find any reference related to the theme.
2. Have presentation skills in terms of precise and contented, relevant presentation.
3. Identify current perspectives related to the subject.

PREREQUISITES: None
TEACHING AND EVALUATION SCHEME:

SUB CODE	TITLE OF SUBJECT	TEACHING SCHEME			CREDITS	EVALUATION SCHEME				TOTAL MARKS
						INTERNAL		EXTERNAL		
		T	P	TOTAL HRS		Theory	Practical	Theory	Practical	
737	Subject Seminar	6	----	6	3	-----	100	-----	-----	100

SPECIALISATION: CLINICAL PHARMACY
SEMESTER-IV

SCHEME OF TEACHING

SUB CODE	NAME OF SUBJECT	CONTACT HOURS PER WEEK	CREDITS
741	Dissertation (Project Work)	36	12
742	Viva- Voce	----	12

SCHEME OF EXAMINATION

SUB CODE	NAME OF SUBJECT	UNIVERSITY LEVEL EVALUATION
741	Dissertation	100
742	Viva- Voce	100
	TOTAL	200