SPECIALISATION: PHARMACOLOGY
SEMESTER-II
SCHEME OF TEACHING

SUB CODE	NAME OF SUBJECT	CONTACT HOURS PER WEEK		CREDITS	
		T	P	T	P
321	General Pharmacology	3	---	3	---
322	Pharmacokinetics	3	---	4	---
323	Systemic Pharmacology - I	3	---	4	---
324	Systemic Pharmacology - II	3	---	4	---
325	Pharmacology Practical - II	---	18	---	6
326	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
321	General Pharmacology	3	80	20	--	--
322	Pharmacokinetics	3	80	20	--	--
323	Systemic Pharmacology - I	3	80	20	--	--
324	Systemic Pharmacology - II	3	80	20	--	--
325	Pharmacology Practical - II	12	--	--	80	20
326	Subject Seminar	--	--	--	--	100
	TOTAL		320	80	80	120

SUBJECT **: General Pharmacology**
SUBJECT CODE **: 321**
RATIONALE **:** This unit discusses the principles of general pharmacology which include receptor theories and function of receptors in drug action. It also details) Structure activity relationships, pharmacodynamics and pharmacokinetic aspects of chiral drugs and Transmembrane signal mechanisms.
COURSE OBJECTIVES **:** At the end of this course the student should be able to:

1. Understand the drug receptor interactions and its applications in disease treatment.
2. Know categorizing receptors, receptor regulations.
3. Understand structure activity relationships of drug and receptors.

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

1. Use knowledge of receptor theory in computing mechanism of action of drugs.
2. Predict therapeutic strategy for any treatment.

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	
321	General Pharmacology	3	--	3	3	20	--	80	--	100

Course content:

321 General Pharmacology

1) Drug Receptor Interaction Theories, Occupation Theory, Rate Theory etc.	10
2) Receptor occupation and Response relationship, spare receptors, silent receptors, orphan receptors, pre-synaptic and post synaptic receptors	10
3) Receptor characterization methods: Pharmacological characterization, radio ligand methods, Monoclonal antibodies, receptor subtypes, IUPHAR nomenclature, clinical significance of receptor sub classification.	15
4) Receptor down regulation and up regulation.	05
5) Dose response relationship and different types of antagonisms, Inverse agonism.	10
6) Mechanisms involved in Receptor Desensitization and Tachyphylaxis	10
7) Structure activity relationships, pharmacodynamics and pharmacokinetic aspects of chiral drugs, allosteric binding, thermodynamics of drug interactions with the receptors	20
8) Transmembrane signal mechanisms. Second Messenger viz. cAMP, cGMP, Ca++ etc. Receptor Classifications based on second messenger systems.	20

SUBJECT : Pharmacokinetics
SUBJECT CODE : 322
RATIONALE : This unit discusses pharmacokinetic parameters, their determination methods and understanding fate of drug inside the body.

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

1. Calculate all pharmacokinetic parameter for the drug.
2. Understand the pharmacokinetics of special category like maternal, fetal, Chrono, and renal failure.

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

1. Predict effective drug concentration at given time.
2. Design the required dose of drug.
3. Design multiple dosing for the therapy.

PREREQUISITES: Mathematical calculations.

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	
322	Pharmacokinetics	3	--	3	4	20	--	80	--	100

322 Pharmacokinetics

1. Basic concepts of Pharmacokinetics, Concentration time profile plotting the data, different fluid compartments and blood flow rates, compartment models, Effect of route of administration on pharmacokinetic profile. Saturation and First order kinetics.	10
2. Protein and Tissue binding, Factors affecting binding, kinetics of protein binding.	10
3. Determination of various rate constants (Drug absorption, Elimination, etc.).	05
4. Volume of Distribution,	05
5. Mechanisms of clearance. Factors affecting clearance rate, Integration kinetics	05
6. Microsomal, non-microsomal biotransformation of drugs, Factors affecting enzyme induction and inhibition, Drug metabolism in fetus and new born,	10
7. Case studies of metabolic drug interactions.	10
8. Mechanisms of renal, fecal, skin, biliary excretion of drugs.	10
9. Multiple dosing pharmacokinetics, Steady state concentration, Fluctuations in Plasma concentration and methods to limit them Dosage adjustment in elderly, Children, obese and diseased patients.	10
10. Nonlinear pharmacokinetics, direct linear and orbit graph methods of dosing. Non-linear pharmacokinetics due to drug protein binding	10
11. Chrono pharmacokinetics Kinetics of maternal fetal drug transfer	05
12. Dose and Time dependencies: Turnover concept	05
13. Dialysis and its effect on drug concentrations.	05

SUBJECT : **Systemic Pharmacology - I**
SUBJECT CODE : **323**
RATIONALE **:** This unit discusses physiological pharmacology that of ANS, Cardiovascular, GIT. It also details the pharmacology of hormones.

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

1. Discuss mechanism of drug action and therapeutic rationale of ANS, CVS and GIT drugs.
2. Discuss pharmacology of Antiulcer, antacids, antidiarrheal, purgative, emetics and antiemetics, cholagogues, antiflatulence drugs.
3. Understand pharmacology of different therapeutic hormones.

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

1. Make choice of drug from similar therapeutic class of ANS, CVS and GIT agents.
2. Decide theoretically about chronic therapy and combination therapy.
3. Know major side effects of therapeutic agents used like Antiulcer, antacids, antidiarrheal, purgative, emetics and antiemetics, cholagogues, antiflatulence drugs.
4. Know therapeutic rationale for hormonal therapy.

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	
323	Systemic Pharmacology - I	3	--	3	4	20	--	80	---	100

323 Systemic Pharmacology - I

1.	Autonomic Pharmacology: Chemical transmission of the ANS, Pharmacodynamics,	10
2.	pharmacokinetic and toxicological facets of agents acting on adrenergic and cholinergic receptors, neuromuscular junction blockers, Ganglion stimulants and blockers, MAO and COMT inhibitors, Adrenergic neuron blockers.	15
3.	CVS Pharmacology: Agents used in CCF, Dysrhythmias, angina, hypertension, hyperlipidemia, Diuretics. Special stress on ACE inhibitors, Angiotensin antagonists Organic Nitrates, Calcium channel blockers, K+ channel blockers, Natriuretic peptides	15
4.	Antiplatelet agents, Oral anticoagulants, Heparin and low molecular weight heparin, fibrinolytic and antifibrinolytic agents, hemostatic agents, Colony stimulating factors.	10
5.	Antiulcer, antacids, antidiarrheal, purgative, emetics and antiemetics, cholagogues, antiflatulence drugs.	10
6.	Histamine, bradykinin, eicosanoids and PAF – receptors agonists and antagonists	10
7.	Adenohypophyseal hormones and related substances, thyroid and antithyroid drugs, Insulin, oral hypoglycemic agents, anti-obesity agents, Adrenocortical hormones, synthesis inhibitors, natural and synthetic analogs Estrogen and Progesterone agonists and antagonists, Receptor modulators, oral contraceptives, androgens.	10
8.	Hormones for mineral homeostasis.	10
9.	Thyroid and Anthyroid drugs	10

SUBJECT : Systemic Pharmacology - II
SUBJECT CODE : 324
RATIONALE : This unit discusses the systemic pharmacology of CNS drugs, which include receptor based mechanism of action, side effects and pathophysiology of concerned disease.

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

1. Describe the adverse effects of ethanol on the central nervous system.
2. Describe the mechanisms involved in the development of drug tolerance and drug dependence, and be able to cite examples that are clinically relevant.
3. Describe the mechanisms of action, use, and adverse effects of drugs used to treat disorders of the nervous system.

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

1. Suggest drug of choice for particular disease.
2. Describe drug interactions.
3. Suggest proper dosage regimen depending on treatment required.

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	
324	Systemic Pharmacology - II	3	--	3	4	20	--	80	--	100

324 Systemic Pharmacology - II

1. Chemical neurotransmitters in CNS, Drugs used in Schizophrenia, Depression, Anxiety, Alzheimer's disease, Parkinson's Disease, Epilepsy, Pain management.	20
2. Local Anaesthetics, Analeptics, Anti migraine drugs	10
3. Bronchodilators and Anti-inflammatory drugs used in asthma, Cough suppressants, Expectorants, nasal decongestants.	10
4. Introduction to Immunopharmacology.	10
5. Pharmacology of immunomodulators, immunostimulants, and immunosuppresants.	05
6. General consideration of antimicrobial agents. Spectrum of activity, mechanism of action, ADME and therapeutic applications of Sulfonamides, Quinolones, B-lactams, aminoglycosides, chloramphenicol, Macrolides, Tetracyclines.	15
7. Pharmacology of Drugs used in tuberculosis, fungal, protozoal, helminth and viral infections.	10
8. Antineoplastic agents.	10
9. Concepts of pharmacogenomics, Gene Therapy	10

SUBJECT : Pharmacology Practical - II
SUBJECT CODE : 325

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	
325	Pharmacology Practical - II	--	18	18	6	--	20	--	80	100

325 Pharmacology Practical II

Following experiments need to be conducted by the students and duly recorded in journals.

1) Study of menstrual cycle in animals (Vaginal smear test).	2 Female Rats
2) Determination of PD2 using various isolated tissues.	01 Rat
3) Determination of PA2 using various isolated tissue of Rat.	01 Rat
4) Determination of PA2 using various isolated tissue of G. Pig.	01 G. Pig
5) Determination of PD'2 using various isolated tissues.	01 Rat
6) Determination of EC50 using various isolated tissues.	01 Rat
7) To study the effect to various drugs on Rat ileum.	01 Rat
8) To study the effect to various drugs on G. Pig ileum.	01 G. Pig
9) Tissue experiments involving role of second messengers in drug action.	02 Rats
10) Determination of nerve conduction velocity and its alteration by the drugs.	02 Rats
11) Simulation experiments for determination of various pharmacokinetic parameters.	--
12) Study of drug metabolism in-vitro using rat liver homogenate	01 Rat
13) Study of drug metabolism in-vitro using mice liver homogenate	01 Mouse
14) Study the effect of various drugs on rat blood pressure (invasive).	04 Rats
15) Study of various drugs on isolated rat heart.	02 Rats
16) Study the effect of various drugs on rat ECG (Identification of P wave, QRS complex, T wave, Determination of PR, QT intervals,)	02 Rats
17) Study the effect of Cyclophosphamide on differential WBC count	05 Rats
18) Demonstration of molecular Biology techniques, SDS PAGE, DNA GEL electrophoresis.	------
19-29) Study of Hematological & Biochemical Parameters Level in rat blood. Study of Hb, RBC count, WBC count, anticoagulants, Determination of Blood Sugar Level, Total protein, Alkaline phosphatase, SGOT, SGPT, Creatinine, Urea Nitrogen, Uric Acid, bilirubin etc	12 Rats
30-33) To study Normal and abnormal Urinary levels To quantify urinary constituents like Na+, K+ ,Ca++ , Glucose, albumin, creatinine.	12 Rats
34) To study the effect of various agents on bronchial musculature by in-vivo techniques.	03 Rats
35) To study the effect of various agents on bronchial musculature by in-vitro techniques.	01 Rat
36) Determine the antibacterial spectrum of antibiotics.	------
37-42) **Case Studies for pharmacokinetic data evaluation** (At least 6)	-------
43) Study of Drug Transport through biological membranes.	03 Rats
44) Study of changes in animal behavior by CNS drugs.	12 Rats, 12 Mice
45) To perform OGTT in rat.	03 Rats
46) To perform OGTT in mice.	03 Mice
47) To study the mydriatic and miotic effect on rabbit eyes.	02 Rabbits
48) To study the local anesthetics effect on rabbit eyes.	02 Rabbits

SUBJECT : Subject Seminar
SUBJECT CODE : 326
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	
326	Subject Seminar	--	6	6	3	---	100	---	---	100

M.PHARM: PHARMACOLOGY
SEMESTER-III

SCHEME OF TEACHING

SUB CODE	NAME OF SUBJECT	CONTACT HOURS PER WEEK		CREDITS	
		T	P	T	P
331	Pharmacological Screening - I	3	---	3	---
332	Pharmacological Screening - II	3	---	3	---
333	Clinical Pharmacology, Pathophysiology	3	---	3	---
334	Regulatory Affairs in Clinical Research (Common Subject With 734 M.Pharm Clinical Pharmacy)	3	---	3	---
335	Pharmacology Practical - III	---	18	---	6
336	Synopsis (Introduction To Dissertation) & Viva Voce	---	---	3	---
337	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
331	Pharmacological Screening - I	3	80	20	--	--
332	Pharmacological Screening - II	3	80	20	--	--
333	Clinical Pharmacology, Pathophysiology	3	80	20	--	--
334	Regulatory Affairs in Clinical Research (Common Subject With 734 M.Pharm Clinical Pharmacy)	3	80	20	--	--
335	Pharmacology Practical - III	12	--	--	80	20
336	Synopsis (Introduction To Dissertation) & Viva Voce	--	80	20	--	--
337	Subject Seminar	--	--	--	--	100
	TOTAL		400	100	80	120

SUBJECT **: Pharmacological Screening - I**
SUBJECT CODE **: 331**
RATIONALE **:** This unit discusses use of animal and human models for screening of drugs and its effective dose and also to establish the effectivity of new drug candidate in particular disease. It is also detailed for approving authorities and preparing protocols.

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

1. Understand types of models used for screening and why.
2. Know pros and cons of different animal models.
3. Maintaining and handling of animals, Basic laboratory animal data, Breeding of lab animals, Animal strains and their applications, CPCSEA guidelines for use of animals in teaching and research.

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

1. Decide the miniaturization of human dose in respective animal model.
2. Justify the model for either pharmacokinetic study or pharmacodynamics study.
3. Prepare animal study protocol with details about grouping of animals, parameters for estimating direct or indirect activity of drug, reference standards and controls.

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	
331	Pharmacological Screening - I	3	--	3	3	20	--	80	--	100

331 Pharmacological Screening I

1) General Principles of screening, Correlation between various animal models and human Situations.	15
2) Pharmacological screening models for	
a. Various CNS diseases	15
b. Allergic diseases	10
c. Asthma	15
d. Renal diseases	10
e. Hepatic diseases	10
f. Neoplastic diseases	10
3) Laboratory animals, Maintaining and handling of animals, Basic laboratory animal data, Breeding of lab animals, Animal strains and their applications, knock out and transgenic Animals. CPCSEA guidelines for use of animals in teaching and research.	15

SUBJECT **: Pharmacological Screening - II**
SUBJECT CODE **: 332**
RATIONALE **:** This unit discusses new screening methods for new drug candidate and establishing therapeutic efficacy for diseases like CVS diseases, Diabetes, hyperlipidemia, obesity. Atherosclerosis, Gastric and duodenal ulcers, pain, Inflammation including osteo and rheumatoid arthritis etc.

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

1. Discuss new technologies for high throughput drug screening.
2. Understand importance and methods of in-vitro screening models.
3. Describe models used for screening of drugs for diseases like CVS diseases, Diabetes, hyperlipidemia, obesity, etc.

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

1. Prepare protocols for screening drugs for above diseases.
2. Apply new techniques of high throughput screening.

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	
332	Pharmacological Screening - II	3	--	3	3	20	--	80	--	100

332 Pharmacological Screening - II

1. New approaches in drug discovery. Combinatorial chemistry, High throughput screening, ultra high throughput screening, and high content screening, Technologies for high throughput screening Pharmacogenomics, Proteomics, Array technology, in vitro pharmacokinetic analysis, Co-relation between in-vitro and in-vivo screens, Determination of Errors in screening procedures	15
2. Pharmacological screening models for	
a. Various CVS diseases	20
b. Diabetes, hyperlipidemia, obesity. Atherosclerosis	20
c. Gastric and duodenal ulcers	10
d. pain	05
e. Inflammation including osteo and rheumatoid arthritis	05
f. Inflammatory Bowel Disease	05
g Anemia	05
h Wounds and Burns	05
3. Concepts of Research management, planning and control, research ethics, time-cost analysis, domestic and international funding, project report preparation	10

SUBJECT **: Clinical Pharmacology, Pathophysiology**
SUBJECT CODE **: 333**
RATIONALE : This unit discusses Pathogenesis, symptoms, signs, laboratory findings, complications and management of various diseases. It also details the drug food interactions.

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

1. Understand pathophysiology of the diseases.
2. Derive symptomatic conclusions for particular diseases.
3. Know all possible drug food interactions and drug pollutant interactions.

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

1. Have clarity about pathogenesis of each diseases.
2. Compile data of symptoms/signs and laboratory findings.
3. Interpret the findings to conclude about the treatment.
4. Identify complications of diseases and manage the same.

PREREQUISITES: Pathophysiology.

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	
333	Clinical Pharmacology, Pathophysiology	3	--	3	3	20	--	80	--	100

333 Clinical Pharmacology, Pathophysiology

1. Pathogenesis, symptoms, signs, laboratory findings, complications and management of Respiratory, Urinary tract, GIT, venereal and meningeal infections, CCF, hypertension, cardiac arrhythmias, GI ulcers, pancreatitis, Diabetes mellitus, hepatitis, bronchial asthma, pleural effusion, emphysema, bronchial asthma, Schizophrenia, Depression, Epilepsy, Parkinson's and Alzheimer's Disease, Hypo and hyperthyroidism, Rheumatoid Arthritis, gout and anemia.	85
2. Drug-Drug and Drug-food and Drug-pollutant interactions.	15

SUBJECT **: Regulatory Affairs in Clinical Research**
SUBJECT CODE **: 334**
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	
334	Regulatory Affairs in Clinical Research	3	--	3	3	20	--	80	--	100

334 Regulatory Affairs in Clinical Research

1)	Evaluating efficacy and safety of drugs as per regulatory requirements ICH, CDSCO, OECD guidelines	10
2)	Single dose, Repeat dose, Reproductive, Mutagenicity, Carcinogenicity, Toxicokinetics 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 Design and organization of Phase-I to Phase-IV clinical trials including Pharmacovigilance	10
6)	Introduction to the fundamentals of the design and analysis of clinical trials.	15
7)	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

SUBJECT : Pharmacology Practical – III
SUBJECT CODE : 335

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	
335	Pharmacology Practical – III	--	18	18	6	--	20	--	80	100

335 Pharmacology Practical –III

Evaluation of drugs intended for following Therapeutic uses.	
Animal behavior by CNS drugs.	6 rats, 18 Mice
Antihypertensive, Hypotensive agents	10 Rats S
Cardiotonic	3 rats S
Angina	4 rats
Antihyperlipidemic	18 rats
Antiatherosclerotic	18 rats (9 rats S)
Antipsychotic	18 rats
Antidepressant	18 rats
Antianxiety	12 rats, 18 mice
Sedative and hypnotics,	6 rats, 9 mice
Memory enhancers	18 rats, 18 mice
Analgesics	18 rats, 9 mice
General Anaestherics	6 rats, 6 mice
Local Anaesthetics,	3 G pigs, 2 rabbits, 9 rats
AntiInflammatory	18 rats
Antidiabetics	12 rats
Antiobesity	18 rats
Antiulcer, GERD	9 G pigs, 18 Rats S
Inflammatory Bowel Disease	------
Antiasthmatic	9 G pigs, 6 rats S
Antiarthritic, Rheumatoid Arthritis	------
Hematinic	12 rats
Antineoplastics	-------
Antibacterial	--------
Hepatoprotective	18 rats, 18 mice
Wounds and Burns	-------
Antifertility	18 rats
Renal diseases	12 rats (6 Sacrifice)
Sub-acute toxicity studies for test drugs	48 rats, 48 mice (Project)
Mammalian Erythrocyte Micronucleus Test	-----
Bacterial Reverse Mutation Test	-----
Case Studies for Clinical Trials, Toxicity studies, Application of Biostatistics in Pharmacological Research (At least 6)	------
Protocol design, ICF and CRF for clinical research (At least 5)	---------

Protocol design for preclinical research (At least 5) ---------
CTD, e-CTD preparation
List of essential documents before, during, after clinical study
Investigator's brochure
Format of sample forms of CTRI
Sample of IEC's form for application for approval, Ethical sample case studies
Project report preparation and research fund application

BOOKS RECOMMENDED:

1. Goodman and Gilman's The Pharmacological Basis of Therapeutics 11th edi, 2005, McGraw Hill Publications.
2. H.P.Rang, 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 Pub.
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 Pub.
7. Winter Michael E, Basic Clinical Pharmacokinetics.4th edi, 2004, Lippincott Williams & Willkins.
8. Tozer, Thomas N Introduction to Pharmacokinetics and Pharmacodynamics: The Quantitative Basis of Drug Therapy.2006, , Lippincott Williams & Willkins
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 Silico 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 Verlag 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 Nervous System.1998, Oxford Uni Press.
18. Andriole Vincent T, the Quinolones. 3rd edi, 1988, Academic Press.
19. Hall, Ian P. Dukes, Pharmacogenetics. 2006, Taylor & Francis.
20. Demuth, James Basic Statistics and Pharmaceutical Statistical Applications, 2edi. 1999, Marcel Dekkar.
21. Broadley Kenneth, Autonomic Pharmacology, 1996, Taylor & Francis.
22. Rowland Malcolm, Clinical Pharmacokinetics. 3rd edi, 1996, B I Waverly Pub.
23. Herfindahl, Clinical Pharmacy and Therapeutics: 2nd edi, 1978, William Morrow & Comp Pub.
24. Rang H.P , Drug Receptors.1986, Uni. Press
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SUBJECT **: Subject Seminar**
SUBJECT CODE **: 337**
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	
337	Subject Seminar	6	--	6	3	-----	100	-----	-----	100

M.PHARM: PHARMACOLOGY
SEMESTER-IV

SCHEME OF TEACHING

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

SCHEME OF EXAMINATION

SUB CODE	NAME OF SUBJECT	UNIVERSITY LEVEL EVALUATION
341	Dissertation	100
342	Viva- Voce	100