Sanjay Ghodawat University Kolhapur

School of Pharmaceutical Sciences

Department of Pharmacy

B. Sc. Clinical Research & Technology

Curriculum Structure and Syllabus (R25)

Semester: III-IV

Programme Structure for B.Sc.: Second Year Clinical Research & Technology (R25)

Semester III: Teaching Scheme

Course code	Course Name	Teaching scheme (Hrs/week)			Credits assigned			Total credits
		Theory	Practical	Tutorial	Theory	Practical	Tutorial	
UCRPC301	Fundamentals of Clinical Research	3	-	-	3	-	-	3
UCRPC302	General Pharmacology	3	-	-	3	-	-	3
UCRPC303	Microbiology	3	-	-	3	-	-	3
UCRPC304	Principles of Biochemistry	3	-	-	3	-	-	3
UCRPE3XX	Program Elective I	3	-	1	3	-	1	4
UXXMM0XX	Multidisciplinary Minor II	3	-	-	3	-	-	3
UCRPC305	General Pharmacology Lab	-	2	-	-	1	-	1
UCRPC306	Microbiology Lab	-	2	-	-	1	-	1
UCRPC307	Principles of Biochemistry Lab	-	2	-	-	1	-	1
UXXMM0XX	Multidisciplinary Minor II lab	-	2	-	-	1	-	1
UCRFP301	Field Project	-	4	-	-	2	-	2
	Total	**18**	**12**	**1**	**18**	**6**	**1**	**25**

Semester III: Evaluation Scheme

Course code	Course Name	Theory Marks					Practical Marks		Total
		Internal Assessment				SEE	Term work/ Tutorial	Practical Oral/POE	
		CA I	CA II	CA III	Total				
UCRPC301	Fundamentals of Clinical Research	10	10	5	25	50	-	-	75
UCRPC302	General Pharmacology	10	10	5	25	50	-	-	75
UCRPC303	Microbiology	10	10	5	25	50	-	-	75
UCRPC304	Principles of Biochemistry	10	10	5	25	50	-	-	75
UCRPE3XX	Program Elective I	10	10	5	25	50	25	-	100
UXXMM0XX	Multidisciplinary Minor II	10	10	5	25	50	-	-	75
UCRPC305	General Pharmacology Lab	-	-	-	-	-	25	-	25
UCRPC306	Microbiology Lab	-	-	-	-	-	25	-	25
UCRPC307	Principles of Biochemistry Lab	-	-	-	-	-	25	-	25
UXXMM0XX	Multidisciplinary Minor II lab	-	-	-	-	-	25	-	25
UCRFP301	Field Project	-	-	-	-	-	50	-	50
								Total	**625**

Semester IV: Teaching Scheme

Course code	Course Name	Teaching scheme (Hrs/week)			Credits assigned			Total credits
		Theory	Practical	Tutorial	Theory	Practical	Tutorial	
UCRPC401	Clinical Pharmacokinetics	3	-	-	3	-	-	3
UCRPC402	Systemic Pharmacology and autocoids	3	-	-	3	-	-	3
UCRPC403	Regulatory Aspects in Clinical Research	2	-	-	2	-	-	2
UCRPC404	Epidemiology and Global Health	2	-	-	2	-	-	2
UCRPE4XX	Program Elective II	3	-	1	3	-	1	4
UXXMM0XX	Multidisciplinary Minor III	2	-	-	2	-	-	2
UCRPC405	Systemic Pharmacology and autocoids Lab	-	2	-	-	1	-	1
UCRPC406	Clinical Sampling and Analytical Techniques Lab	-	2	-	-	1	-	1
UXXMM0XX	Multidisciplinary Minor III Lab	-	2	-	-	1	-	1
UCRSE401	Medical Writing	2	-	-	2	-	-	2
UCRVS401	Healthcare administration	2	-	-	2	-	-	2
	Total	**19**	**6**	1	**19**	**3**	1	**23**

Semester IV: Evaluation Scheme

Course code	Course Name	Theory Marks					Practical Marks		Total
		Internal Assessment				SEE	Term work/ Tutorial	Practical Oral /POE	
		CA I	CA II	CA III	Total				
UCRPC401	Clinical Pharmacokinetics	10	10	5	25	50	-	-	75
UCRPC402	Systemic Pharmacology and autocoids	10	10	5	25	50	-	-	75
UCRPC403	Regulatory Aspects in Clinical Research	-	10	5	15	35	-	-	50
UCRPC404	Epidemiology and Global Health	-	10	5	15	35	-	-	50
UCRPE4XX	Program Elective II	10	10	5	25	50	25	-	100
UXXMM0XX	Multidisciplinary Minor III	-	10	5	15	35	-	-	50
UCRPC405	Systemic Pharmacology and autocoids Lab	-	-	-	-	-	25	-	25
UCRPC406	Clinical Sampling and Analytical Techniques Lab	-	-	-	-	-	25	-	25
UXXMM0XX	Multidisciplinary Minor III Lab	-	-	-	-	-	25	-	25
UCRSE401	Medical Writing	-	10	5	15	35	-	-	50
UCRVS401	Healthcare administration	-	10	5	15	35	-	-	50
								Total	**575**

Exit Option:

- Students will have the flexibility to enter a programme in odd semesters and exit a programme after the successful completion of even semesters as per their future career needs.
- Students exiting the Second-Year program after securing Major with 80 credits and an additional 8 credits core NSQF course/Internship or continue with major & minor.

Course code	Course name	Teaching scheme (Hr/week)			Credits assigned		
UCRPC301	Fundamentals of Clinical Research	Theory	Practical	Tutorial	Theory	Practical	Tutorial
		3	-	-	3	-	-

Course code	Course name	Evaluation scheme (In semester)					Semester end exam (SEE)		Total (Marks)
UCRPC301	Fundamentals of Clinical Research	CAI	CAII	CAIII	Total	Min pass	Marks	Min pass	
		10	10	5	25	40%	50	40%	75

Course Description

This course covers the conduct and management of clinical trials, including trial design, patient recruitment, site visits, and data collection methods. It introduces data management, biostatistics, and safety reporting, along with post-marketing surveillance and emerging trends such as decentralized trials and digital health technologies.

Pre-requisites

Basic knowledge of Clinical Research, Pharmacology, and Biostatistics.

Course Objectives:

1. To introduce clinical trial conduct, design, and patient recruitment strategies.
2. To provide knowledge of clinical trial visits and data archival processes.
3. To develop understanding of data collection methods and safety reporting in clinical trials.
4. To train students in data management systems and basic biostatistical analysis.
5. To familiarize students with post-marketing surveillance and emerging trends in clinical research.

Course outcomes:

After successful completion of this course, students will able to

CO1 **Outline**[3] clinical trial designs and select appropriate patient recruitment and retention strategies.

CO2 **Organize**[3] clinical trial visits and manage site-related documentation and data archival processes.

CO3 **Apply4** data collection methods (CRFs, EDC systems) and analyze safety reporting requirements including adverse events, SAEs, and SUSARs.

CO4 **Utilize**[4] data management tools and interpret statistical outputs such as p-values, confidence intervals, and effect sizes.

CO5 **Analyze**[4] post-marketing surveillance data and evaluate emerging trends such as decentralized clinical trials, AI applications, and real-world data.

Module	Unit	Description	Hours
1.0		**Clinical Trial Conduct and Management**	**9**
	1.1	History of Clinical Research Clinical Trial Design: Paediatric and Geriatric clinical Trial	
	1.2	Patient recruitment and retention strategies	
2.0		**Clinical Trial Visits and Data Archival Process**	**9**
	2.1	Site Qualification Visit Site Initiation Visit Site Monitoring Visit	
	2.2	Site Close Out Visit Data Archival Process	
3.0		**Data Collection Method**	**9**
	3.1	Paper CRF Electronic CRF	
	3.2	Safety reporting Timelines (adverse events, SAEs, SUSARs)	
	3.3	Data base log	
4.0		**Data Management and Biostatistics**	**9**
	4.1	Data collection tools (EDC systems) Quality Management system and different SOPs in clinical Trial	
	4.2	Statistical analysis plans (SAP) Descriptive vs. inferential statistics Interpretation of p-values, confidence intervals, and effect sizes	
5.0		**Post-Market Surveillance & Emerging Trends in Clinical Research**	**9**
	5.1	Phase IV studies and pharmacoepidemiology Real-world data (RWD) vs. clinical trial data Post-marketing safety monitoring	
	5.2	Decentralized clinical trials (DCTs) Artificial Intelligence (AI) and machine learning in clinical trials Patient-centric approaches and digital health technologies (wearables, ePRO)	

Textbooks

1. Principles and Practice of Clinical Research, John I. Gallin, Frederick P. Ognibene, Laura Lee Johnson. Publisher: Academic Press (Elsevier).
2. Fundamentals of Clinical Trials, Lawrence M. Friedman, Curt D. Furberg, David L. DeMets. Publisher: Springer.
3. Textbook of Clinical Research, Vikas Dhikav, AITBS Publishers India
4. Textbook on Clinical Research A Guide for Aspiring Professionals and Professionals, Guru Prasad Mohanta, Prabal Kumar Manna, Pharmamed Press / OM Publications

Reference books

1. Clinical Trials Handbook, Shayne Cox Gad. Publisher: John Wiley & Sons.
2. Clinical Research Coordinator Handbook, Deborah Norris. Publisher: Plexus Publishing.

Internal Assessment (CAI, CAII and CAIII):

1. CAI should be based on first two modules and CAII should be based on next two modules, for 10 marks each.
2. CA III shall be assessed for 5 marks separately.

End Semester Examination:

1. Question paper will be of 50 marks comprise of 5 questions, each carrying 10 marks.
2. The duration of end semester examination shall be two hours.
3. The students need to solve all 5 questions.
4. Question No.1 will be compulsory and based on entire syllabus.
5. Remaining question (Q.2 to Q.5) will be selected from all the modules.

Course code	Course name	Teaching scheme (Hr/week)			Credits assigned		
UCRPC302	General Pharmacology	Theory	Practical	Tutorial	Theory	Practical	Tutorial
		03	-	-	03	-	-

Course code	Course name	Evaluation scheme (In semester)					Semester end exam (SEE)		Total (Marks)
UCRPC302	General Pharmacology	CAI	CAII	CAIII	Total	Min pass	Marks	Min pass	
		10	10	5	25	40%	50	40%	75

Course Description

This course introduces the fundamentals of pharmacology, including drug action, pharmacokinetics, and pharmacodynamics. It covers drug discovery and development, preclinical testing, toxicity evaluation, and regulatory aspects, and applies these principles to understand therapeutic drug classes.

Pre-requisite

Basic knowledge of Human Anatomy and Physiology studied in Semester I & II.

Course Objectives:

1. To understand fundamental concepts of pharmacology including drug nature, sources, routes of administration, and basic principles of pharmacokinetics and pharmacodynamics.
2. To explain drug disposition processes including absorption, distribution, metabolism, and excretion along with factors affecting drug action.
3. To interpret pharmacodynamic principles such as receptor mechanisms, dose–response relationships, signal transduction, drug interactions, and adverse drug reactions.
4. To describe drug discovery processes, preclinical evaluation methods, and emerging areas such as pharmacogenomics, precision therapy, antibody-based therapeutics, and modern screening approaches.
5. To understand basic toxicology principles including poisoning, antidotes, toxicity testing, and regulatory guidelines (OECD and ICH).

Course outcome(s):

After successful completion of this course, students will able to

CO1 **Outline**[2] fundamental concepts of pharmacology including drug sources, classification, routes of administration, and basic pharmacokinetics and pharmacodynamics.

CO2 **Classify**[2] pharmacokinetic processes including absorption, distribution, metabolism, and excretion of drugs with influencing factors.

CO3 **Apply**[3] pharmacodynamic principles to analyze drug-receptor interactions, dose–response relationships, drug interactions, and adverse drug reactions.

CO4 **Summarize**[2] drug discovery, preclinical evaluation, and emerging therapeutic approaches including pharmacogenomics and antibody-based therapies.

CO5 **Classify**[2] toxicology principles including poisoning, antidotes, toxicity testing, and regulatory guidelines in drug safety evaluation.

Module	Unit	Description	Hours
1.0		**Introduction to Pharmacology**	**9**
	1.1	Definition, historical perspectives, branches of pharmacology and their scope, drug, nature, sources of drugs and essential drugs.	
	1.2	Routes of drug administration along with their advantages and disadvantages.	
2.0		**Pharmacokinetics**	**9**
	2.1	Drug absorption, mechanisms of drug absorption, membrane transporters, bioavailability, bioequivalence, factors affecting drug absorption.	
	2.2	Drug distribution in different tissue/organ compartments, barriers to drug distribution, storage sites, plasma protein binding and its therapeutic importance, redistribution.	
	2.3	Drug biotransformation, phase I and II reactions, first-pass metabolism, entero-hepatic cycling, concept of prodrugs.	
	2.4	Drug elimination: Hepatic, renal, pulmonary, fecal, dermal, salivary, mammary etc.	
3.0		**Pharmacodynamics**	**9**
	3.1	Types drug action and mechanisms of drug action, dose response relationship.	
	3.2	Receptor theories, structure of receptors, classification and regulation of receptors, spare receptors. Concept of agonist, inverse agonist, partial agonist and antagonist.	
	3.3	Signal transduction mechanisms of receptors.	
	3.4	Factors modifying drug action including the concepts of tachyphylaxis, idiosyncrasy, drug tolerance etc.	
	3.5	Adverse drug reactions (ADR) and types of ADRs.	
	3.6	Drug interaction, types, pharmacokinetic and pharmacodynamic drug- drug interactions.	
4.0		**Overview of drug discovery and evaluation of new drug**	**9**
	4.1	Brief discussion on drug discovery and preclinical evaluation of new drugs.	
	4.2	Skin irritation tests in animals and human beings for new drugs.	
	4.3	Advantages and disadvantages of in vitro and in silico Pharmacological screening and evaluation Recent trends in pharmacology	
	4.4	Introduction, principles, applications and scope of Pharmacogenomics, Precision Therapy, Gene Therapy, Stem Cell Therapy and Biosimilar.	
	4.5	Introduction to Medical Genomics and antibody-based studies in therapeutics**:** Basics of medical genomics, Role of antibodies in diagnosis and therapy, Monoclonal and polyclonal antibodies.	
	4.6	Introduction to Antibody Drug Conjugates (ADC): Concept and components of ADC, Mechanism of action, Therapeutic applications in cancer and targeted therapy.	
5.0		**Toxicology**	**9**
	5.1	Introduction to toxicology and its branches. Classification of poisons based on actions and lethal doses, types of antidotes, drugs and their antidotes.	
	5.2	General principles of treatment of acute poisoning include heavy metal poisoning. Management of chronic poisoning.	
	5.3	Definition and basic knowledge of preclinical toxicity testing-acute toxicity, sub-acute toxicity, combined chronic and carcinogenicity testing as per OECD guidelines.	
	5.4	Basic understanding of principles of genotoxicity and teratogenicity as per OECD guidelines.	
	5.5	Definition and concepts of ICH safety guidelines. LOEL, NOEL, and MTD	

Textbooks

1. Rang & Dale's Pharmacology, H.P. Rang, M.M. Dale, J.M. Ritter, R.J. Flower, G. Henderson, Publisher: Elsevier
2. Essentials of Medical Pharmacology, K.D. Tripathi., Publishers: Jaypee Brothers Medical
3. Introduction to Pharmacology, S.K Kulkarni, Vallabh Prakashan.

Reference books

1. Goodman & Gilman's: The Pharmacological Basis of Therapeutics, Laurence L. Brunton, Randa Hilal-Dandan, Bjorn Knollmann. Publisher: McGraw-Hill Education, Edition: 13th Edition (2017)
2. Basic and Clinical Pharmacology, Bertram Katzung, Anthony Trevor. Publisher: McGraw- Hill Education.
3. Pharmacology and Pharmacotherapeutics, R.S. Satoskar, Nirmala N. Rege, S.D. Bhandarkar. Publisher: Elsevier India

Internal Assessment (CAI, CAII and CAIII):

1. CAI should be based on first two modules and CAII should be based on next two modules, for 10 marks each.
2. CA III shall be assessed for 5 marks separately.

End Semester Examination:

1. Question paper will be of 50 marks comprise of 5 questions, each carrying 10 marks.
2. The duration of end semester examination shall be two hours.
3. The students need to solve all 5 questions.
4. Question No.1 will be compulsory and based on entire syllabus.
5. Remaining question (Q.2 to Q.5) will be selected from all the modules.

Course code	Course name	Teaching scheme (Hr/week)			Credits assigned		
UCRPC303	Microbiology	Theory	Practical	Tutorial	Theory	Practical	Tutorial
		3	-	-	3	-	-

Course code	Course name	Evaluation scheme (In semester)					Semester end exam (SEE)		Total (Marks)
UCRPC303	Microbiology	CAI	CAII	CAIII	Total	Min pass	Marks	Min pass	
		10	10	5	25	40%	50	40%	75

Course Description

This course introduces fundamental microbiology concepts. It covers the industrial use of microorganisms, microbial contamination control under GMP, and essential evaluation techniques such as sterility and microbial limit testing. The course also includes sterilization methods, microbial spoilage control, and in vitro cell culture techniques relevant to pharmaceutical research and quality assurance.

Pre-requisite

Basic knowledge of Biology and introductory Biochemistry.

Course Objectives:

1. Introduce the fundamental concepts of microbiology.
2. Provide insights into the industrial application of microorganisms in the manufacture of pharmaceutical products.
3. Provide knowledge Good Manufacturing Practices (GMP) related to microbial contamination control.
4. Provide understanding in microbial evaluation techniques such as sterility testing, microbial limit tests, and microbial assay.
5. Familiarize students with sterilization technologies, microbial spoilage control, and in vitro cell culture techniques for pharmaceutical research and quality assurance.

Course outcomes:

After successful completion of this course, students will able to

CO1 **Classify**[2] microorganisms based on their structure, characteristics, and growth patterns.

CO2 **Apply**[3] microbial processes in the production of pharmaceutical products such as antibiotics, vaccines, and enzymes.

CO3 **Implement**[3] Good Manufacturing Practices (GMP) to control and prevent microbial Contamination in pharmaceutical industries.

CO4 **Perform and analyze**[4] microbial evaluation techniques including sterility testing, microbial limit tests, and microbial assays.

CO5 **Select**[5] appropriate sterilization methods, control microbial spoilage, and utilize in vitro cell culture techniques for pharmaceutical applications.

Module	Unit	Description	Hours
1.0		**Introduction and role of microorganisms**	**9**
	1.1	Fundamentals of microbiology: Microorganisms and medicines, Introduction to various microorganisms, Microbial cultivation, isolation and enumeration. Pharmaceutical importance of microorganisms.	
	1.2	Introduction to Microscope (Compound and Electron Microscope)	
	1.3	Identification of bacteria using staining techniques (simple, Gram's & Acid-fast staining) and biochemical tests (IMViC).	
	1.4	Antibiotics produced by microbiology (Production and uses streptomycin, cephalosporin)	
2.0		**Evaluation of microbiological contamination**	**9**
	2.1	Sources and types of microbial contaminant	
	2.2	Control of microbial contamination during manufacture of Nonsterile dosage forms and sterile dosage forms (including Aseptic area), control of Atmosphere, Water, Raw material, Facility, Packaging, Equipment	
	2.3	Microbiological spoilage of pharmaceuticals, Factors affecting microbial spoilage of pharmaceuticals.	
	2.4	Introduction to Fermentation, types and fermenters.	
3.0		**Microbial control and evaluation**	**9**
	3.1	Designing of aseptic area. Laminar flow equipment's, clean area classification, Biological Safety Level categories. Methods of prevention.	
	3.2	Disinfectants, antiseptics, and preservatives, and their evaluation, Factors affecting the antimicrobial activity of disinfectants	
4.0		**Sterilization procedures, assurance and evaluation**	**9**
	4.1	Physical, chemical, gaseous, radiation and mechanical methods of sterilization, Advances sterilization technologies, Evaluation of efficiency of sterilization; Validation of sterilization procedures and Sterility indicators.	
	4.2	Sterility assurance, Bioburden determination, modelling in predicting microbial growth and death, Test for bacteriostatic, bactericidal activity	
5.0		**Microbiological quality control**	**9**
	5.1	Microbial limit tests and Microbial assay (antibiotics, vitamins and amino acids)	
	5.2	Sterility testing of products according to IP, BP and USP	
	5.3	Methods for monitoring Water and Air Quality, In vitro cell cultures, general procedure for cell culture, Applications of cell cultures in pharmaceutical industry and research	

Textbooks

1. Pelczar, M. J., Chan, E. C. S. and Krieg, N. R. Microbiology: Concepts and Applications. McGraw-Hill.
2. Prescott, L. M., Harley, J. P. and Klein, D. A. Microbiology. McGraw-Hill.

Reference books

1. Denyer, S. P., Hodges, N. A. and Gorman, S. P. Hugo and Russell's Pharmaceutical Microbiology. Wiley-Blackwell.
2. Sandle, T. Pharmaceutical Microbiology: Essentials for Quality Assurance and Quality Control. Elsevier.

Internal Assessment (CAI, CAII and CAIII):

1. CAI should be based on first two modules and CAII should be based on next two modules, for 10 marks each.
2. CA III shall be assessed for 5 marks separately.

End Semester Examination:

1. Question paper will be of 50 marks comprise of 5 questions, each carrying 10 marks.
2. The duration of end semester examination shall be two hours.
3. The students need to solve all 5 questions.
4. Question No.1 will be compulsory and based on entire syllabus.
5. Remaining question (Q.2 to Q.5) will be selected from all the modules.

Course code	Course name	Teaching scheme (Hr/week)			Credits assigned		
UCRPC304	Principles of Biochemistry	Theory	Practical	Tutorial	Theory	Practical	Tutorial
		3	-	-	3	-	-

Course code	Course name	Evaluation scheme (In semester)					Semester end exam (SEE)		Total (Marks)
		CAI	CAII	CAIII	Total	Min pass	Marks	Min pass	
UCRPC304	Principles of Biochemistry	10	10	5	25	40%	50	40%	75

Course Description

This course covers the core concepts of biochemistry, focusing on metabolic pathways of carbohydrates, lipids, and proteins and their clinical relevance. It includes principles of energetics and biological oxidation, amino acid and protein metabolism, enzymology, and commonly used clinical chemistry tests. The course also introduces nucleic acid metabolism and the flow of genetic information.

Pre-requisite

Basic knowledge of Biology and introductory Biochemistry.

Course Objectives:

1. To understand biochemical pathways and interpret the clinical relevance of carbohydrate, lipid, and protein metabolism.
2. To analyze the principles of energetics and biological oxidation.
3. To explain amino acid and protein metabolism
4. To acquire knowledge of enzymology and various tests used in clinical chemistry.
5. To understand nucleic acid metabolism and interpret genetic information flow.

Course outcomes:

After successful completion of this course, students will able to

CO1 **Analyze**[4] biochemical pathways of carbohydrates, lipids, and proteins and **correlate** them with their clinical significance.

CO2 **Examine**[4] the processes of energetics and biological oxidation in living systems.

CO3 **Analyze**[4] amino acid and protein metabolism and **interpret** their physiological significance.

CO4 **Classify**[2] enzymes and **identify** various tests used in clinical chemistry.

CO5 **Interpret**[3] nucleic acid metabolism and **relate** it to the flow of genetic information.

Module	Unit	Description	Hours
1.0		**Biomolecules**	**9**
	1.1	**Introduction about biomolecules** Introduction, classification, chemical nature and biological role of carbohydrate, lipids, nucleic acids, amino acids and proteins.	
	1.2	**Bioenergetics** Concept of free energy; relationship between free energy, enthalpy, and entropy; energy-rich compounds (ATP, GTP, etc.) and their biological significance.	
	1.3	**Carbohydrate Metabolism** Overview and significance of major pathways: Glycolysis, Citric Acid Cycle (TCA), Gluconeogenesis, Hexose Monophosphate (HMP) shunt, and Glycogen metabolism; regulation of blood glucose levels; metabolic adaptations during fed state, fasting, and prolonged starvation; diabetes mellitus.	
	1.4	**Biological Oxidation** Electron Transport Chain (ETC), oxidative phosphorylation, and mechanisms of ATP synthesis; regulation and clinical implications of mitochondrial dysfunction and oxidative stress.	
2.0		**Lipid metabolism**	**9**
	2.1	Classification, functions, and properties of lipids.	
	2.2	β-oxidation and de-novo synthesis of fatty acids: Ketone bodies: synthesis, utilization, and clinical significance.	
	2.3	Biological significance of cholesterol, lipid profile, lipoproteins (HDL, LDL, VLDL, chylomicrons) and its clinical significance.	
	2.4	Disorders associated with lipid metabolism: Hyperlipidaemias and hypercholesterolemia, lipid storage diseases, atherosclerosis, fatty liver disease, and obesity.	
3.0		**Amino acids and protein metabolism**	**9**
	3.1	Classification and Biological Functions: Classification and physiological roles of amino acids. Structure and functions of proteins and plasma proteins.	
	3.2	General Metabolism of Amino Acids: Transamination, oxidative and non-oxidative deamination, decarboxylation. Urea cycle- nitrogen disposal and detoxification.	
4.0		**Enzymology**	**9**
	4.1	Introduction, properties, nomenclature, and IUB classification of enzymes and coenzymes. Factors affecting enzyme activity. Enzyme inhibitors with examples. Regulation of enzymes: enzyme induction and repression, allosteric enzyme regulation. Therapeutic and diagnostic application of enzymes and isoenzymes. Macro and Micronutrients, including Vitamins and Minerals.	
	4.2	pH and Buffer Systems: Concept of pH, Physiological buffer systems: Role in acid-base homeostasis	
	4.3	Clinical Chemistry: Liver function tests (routinely performed tests based on liver function and their significance). Renal function tests (routinely performed tests based on kidney function, ELISA test)	
5.0		**Nucleic acid metabolism and genetic information transfer**	**9**

	5.1	Nucleotide Metabolism: Biosynthesis of purine and pyrimidine nucleotides. Catabolism of purine nucleotides (uric acid formation).	
	5.2	Genome Structure and Central Dogma: Organization of the mammalian genome. DNA replication, Transcription, and Translation, Inhibitors of transcription and translation (antibiotics, toxins)	

Textbooks

1. A Textbook of Biochemistry, A.V.S.S.Rama Rao UBS Publishers' Distributors Pvt. Limited, 10th Edition, 2006,
2. Biochemistry by U.Satyanarayana, U.Chakrapani, Elsevier Health Sciences, 5th edition, 2020.
3. Fundamentals of Biochemistry by Deb, A. C. New Central Book Agency (P) Limited, Edition 7th, .2014.
4. Biochemistry. Ed. Donald Voet and Judith G. Voet. John Wiley & Sons, Inc.

Reference books

1. Lehninger's Principles of Biochemistry by David Nelson, Michael Cox, and Aaron Hoskins. Macmillan Publishing Company. Eight edition, 2021
2. Harper" s Biochemistry, Ed. R.K. Murray, D.K. Granner, P.A. Mayes and V.W. Rodwell. Appleton and Lange, Stamford, Connecticut.

Internal Assessment (CAI, CAII and CAIII):

1. CAI should be based on first two modules and CAII should be based on next two modules, for 10 marks each.
2. CA III shall be assessed for 5 marks separately.

End Semester Examination:

1. Question paper will be of 50 marks comprise of 5 questions, each carrying 10 marks.
2. The duration of end semester examination shall be two hours.
3. The students need to solve all 5 questions.
4. Question No.1 will be compulsory and based on entire syllabus.
5. Remaining question (Q.2 to Q.5) will be selected from all the modules.

Course code	Course name	Teaching scheme (Hr/week)			Credits assigned		
UCRPC305	General Pharmacology Lab	Theory	Practical	Tutorial	Theory	Practical	Tutorial
		-	2	-	-	1	-

Course code	Course name	Evaluation scheme (In semester)					Semester end exam (SEE)			Total (Marks)
UCRPC305	General Pharmacology Lab	CAI	CAII	CAIII	Total	Internal Assessment*	ESE*	Term work*/ Tutorial	Pract* Oral/ POE	
		-	-	-	-	-	-	25	-	25

Course Description

This course introduces the principles of experimental pharmacology, including its historical foundations and ethical conduct in laboratory animal use as per Committee for the Control and Supervision of Experiments on Animals guidelines. It focuses on pharmacological data acquisition and analysis, construction and interpretation of dose–response curves, and calculation of key pharmacological indices. The course also covers basic pharmacokinetic parameters and their role in drug effects and dosing schedules.

Pre-requisite

Basic knowledge of Pharmacology, Human Physiology, and Biostatistics.

Course Objectives:

1. To understand the historical and foundational aspects of experimental pharmacology.
2. To develop knowledge and practical awareness of ethical and regulatory standards in laboratory animal care and use, as outlined in CCSEA guidelines
3. To acquire skills in pharmacological data acquisition and analysis
4. To interpret and construct dose-response curves (DRCs) and calculate and interpret pharmacological indices such as ED50, threshold and ceiling dose, slope of DRC, and PD_2,
5. To calculate the pharmacokinetic parameters and analyse the roles of pharmacokinetic parameters in the drug effects, and dosing schedule.

Course outcomes:

After successful completion of this course, students will able to

CO1 **Summarize**[2] the historical and foundational principles of experimental pharmacology.

CO2 **Apply**[3] ethical and regulatory standards in laboratory animal care and use as per Committee for the Control and Supervision of Experiments on Animals guidelines.

CO3 **Perform**[4] pharmacological data acquisition and **analyze** experimental data using appropriate methods.

CO4 **Construct**[3] dose-response curves (DRCs) and **determine** pharmacological indices such as LD_{50}, threshold dose, ceiling dose, slope of DRC, and PD_2.

CO5 **Calculate**[5] pharmacokinetic parameters and **evaluate** their influence on drug effects and dosing schedules.

List of Experiments

Minimum 10 experiments must be performed

1	To describe the contributions of renowned pharmacologists and their discoveries based on pharmacological experiments
2	To study various laboratory safety precautions, hazards, personal hygiene, commonly used tools, devices and instruments in experimental pharmacology.
3	To study common experimental animals including transgenic animals along with their applications in the pharmacological experiments in current drug discovery paradigm. To study concept of 3Rs along with the maintenance and experimentation on laboratory animals as per the CCSEA guidelines.
4	To demonstrate collection/isolation of the following biological samples- blood, cerebrospinal fluid, DNA and RNA using computer simulations and audio-visual aids.
5	To study important anaesthetics and euthanasia procedures for experimental animals.
6	To demonstrate different routes drug administration using computer simulation and understand the significance of each route along with the maximum administrable dose.
7	To study preparation of different types of physiological salt solutions (PSS), cell culture media and to understand the role of each ingredient used in PSS preparation.
8	To study the instrumentation used for isolated tissue experiments (students organ bath assembly) and recent development in recording of the responses of isolated tissues.
9	To record the dose response curve of any two agonists on suitable isolated tissue preparation using computer simulation experiment.
10	To study the potentiating effect of physostigmine on DRC of acetyl choline through interactive computer simulation.
11	To study antagonizing effect of d-tubocurarine on the DRCs of acetylcholine through interactive computer simulation.
12	To determine of PD2 of given agonists using isolated tissue preparation using computer simulation experiment.
13	To study and determine various pharmacokinetic parameters (Cmax, tmax, KE, CAI/2, Vd, Clt, AUC, AUMC) from a given hypothetical data.
14	To estimate LD 50 by using the given of hypothetical data using computer simulation experimentation (as per OECD 425 guideline using opensource AOT software).

Textbooks

1. Fundamentals of Experimental Pharmacology. Ghosh MN. Publisher: Hilton & Company, Kolkata.
2. Handbook of experimental pharmacology. Kulkarni SK. Publisher: Vallabh Prakashan.
3. Practical Pharmacology, Goyal RK. Publisher: B. S. Shah Publisher805. OECD guidelines for toxicity and Safety Pharmacology

Guidelines

1. Organisation for Economic Co-operation and Development (OECD) Guidelines for Toxicity and Safety Pharmacology
2. ICH guideline 7A and 7B.

Software

1. Ex-Pharm software
2. CAL software package

Course code	Course name	Teaching scheme (Hr/week)			Credits assigned		
UCRPC306	Microbiology Lab	Theory	Practical	Tutorial	Theory	Practical	Tutorial
		-	2	-	-	1	-

Course code	Course name	Evaluation scheme (In semester)					Semester end exam (SEE)			Total (Marks)
UCRPC306	Microbiology Lab	CAI	CAII	CAIII	Total	Internal Assessment*	ESE*	Term work*/ Tutorial	Pract* Oral/ POE	
		-	-	-	-	-	-	25	-	25

Course Description

This practical course focuses on essential microbiological techniques. It includes handling laboratory equipment, sterilization methods, culture preparation, staining techniques, microbial isolation, and biochemical characterization. The course also covers microbiological assays, sterility testing, and bacteriological analysis relevant to pharmaceutical quality control and research.

Pre-requisite

Basic knowledge of Pharmacology, Human Physiology, and Biostatistics.

Course Objectives:

1. Develop skills in handling microbiological equipment and maintaining aseptic conditions.
2. Provide training in sterilization techniques and preparation of culture media.
3. Enable cultivation, subculturing, and isolation of microorganisms.
4. Build competency in staining methods and microbial identification techniques.
5. Introduce microbiological assays, sterility testing, and bacteriological analysis.

Course outcomes:

After successful completion of this course, students will able to

CO1 **Operate**[3] microbiological laboratory equipment and maintain aseptic conditions.

CO2 **Prepare**[3] and sterilize culture media and laboratory materials using standard procedures.

CO3 **Cultivate, isolate, and maintain**[3] microorganisms using appropriate techniques.

CO4 **Perform**[4] staining methods and analyze microbial characteristics for identification.

CO5 **Conduct**[4] microbiological assays, sterility testing, bacteriological analysis, and interpret biochemical test results.

List of Experiments

Minimum 10 experiments must be performed

1	Introduction and study of different equipment and processing, e.g., B.O.D. incubator, laminar flow, aseptic hood, autoclave, hot air sterilizer, deep freezer, refrigerator, microscopes used in experimental microbiology.
2	Sterilization of glassware, preparation and sterilization of media.
3	Sub culturing of bacteria and fungus. Nutrient stabs and slants preparations.
4	Staining methods- Simple, Grams staining and acid fast staining (Demonstration with practical).
5	Isolation of pure culture of micro-organisms by multiple streak plate technique and other techniques.
6	Microbiological assay of antibiotics by cup plate method and other methods
7	Motility determination by Hanging drop method.
8	Sterility testing of pharmaceuticals
9	Bacteriological analysis of water
10	Biochemical test

Textbooks

1. Prescott and Dunn's Industrial Microbiology. Delhi: CBS Publishers &Distributors
2. Bergey, D. H., Breed, R. S., Murray, E. G. D., Hitchens, A. P. *Bergey's Manual of Determinative Bacteriology*. Baltimore: The Williams & Wilkins Co.

Reference books

1. United States Pharmacopeia (USP).
2. Indian Pharmacopoeia. Ghaziabad: Indian Pharmacopoeia Commission, Ministry of Health & Family Welfare, Govt. of India.

Course code	Course name	Teaching scheme (Hr/week)			Credits assigned		
		Theory	Practical	Tutorial	Theory	Practical	Tutorial
UCRPC307	Principles of Biochemistry Lab	-	2	-	-	1	-

Course code	Course name	Evaluation scheme (In semester)					Semester end exam (SEE)			Total (Marks)
		CAI	CAII	CAIII	Total	Internal Assessment*	ESE*	Term work*/ Tutorial	Pract* Oral/ POE	
UCRPC307	Principles of Biochemistry Lab	-	-	-	-	-	-	25	-	25

Course Description

This practical course focuses on fundamental biochemical laboratory skills, including identification of carbohydrates and proteins through qualitative tests and estimation of clinically important biomolecules in biological fluids. It emphasizes the application of biochemical techniques for analyzing pathological samples, studying enzyme activity and influencing factors, and interpreting laboratory results in relation to clinical conditions.

Pre-requisite

Basic knowledge of Biochemistry and familiarity with laboratory techniques.

Course Objectives:

1. To develop skills to identify and differentiate carbohydrates and proteins through classical qualitative tests.
2. To apply biochemical techniques to analyze pathological conditions using urine and blood samples.
3. To perform estimations of clinically important biomolecules such as glucose, cholesterol, urea, creatinine, and proteins in biological fluids.
4. To demonstrate enzymatic activity and analyze factors affecting enzyme function, including substrate concentration and temperature.
5. To interpret biochemical results and relate them to clinical conditions, such as diabetes, renal dysfunction, or lipid disorders.

Course outcomes:

After successful completion of this course, students will able to

CO1 **Perform**[3] qualitative tests to identify and differentiate carbohydrates and proteins.

CO2 **Apply**[4] biochemical techniques to analyze pathological conditions using urine and blood samples.

CO3 **Perform**[3] quantitative estimations of clinically important biomolecules such as glucose, cholesterol, urea, creatinine, and proteins in biological fluids.

CO4 **Demonstrate**[4] enzymatic activity and analyze factors affecting enzyme function, including substrate concentration and temperature.

CO5 **Interpret**[4] biochemical test results and correlate them with clinical conditions such as diabetes, renal dysfunction, and lipid disorders.

List of Experiments

Minimum 10 experiments must be performed

1	Identification tests for Proteins (Albumin)
2	Identification tests for Proteins (Casein)
3	Qualitative analysis of carbohydrates (Glucose).
4	Qualitative analysis of carbohydrates (Fructose).
5	Qualitative analysis of carbohydrates (Lactose).
6	Qualitative analysis of carbohydrates (Sucrose).
7	Qualitative analysis of carbohydrates (starch).
8	Qualitative analysis of urine for normal/abnormal constituents.
9	Estimation of Blood Glucose.
10	Estimation of Total Cholesterol and HDL Cholesterol.
11	Estimation of Urea, Creatinine, and Uric Acid in Serum
12	Estimation of Serum Total Protein and Albumin
13	Study of the enzymatic hydrolysis of starch
14	Study the effect of Temperature on Salivary amylase activity.
15	Study the effect of substrate concentration on salivary amylase activity.

Textbooks

1. Gupta RC, Bhargava S, Practical Biochemistry. New Delhi: CBS Publishers & Distributors.
2. Plummer DT. Introduction of Practical Biochemistry. New York: McGraw-Hill Education.
3. Rajagopal G, Ramakrishnan S. Practical Biochemistry for Medical students. Hyderabad: Orient BlackSwan.

Reference books

1. Varley H. Practical Clinical Biochemistry. New Delhi: CBS Publishers & Distributors.
2. Nelson DL, Cox MM. Lehninger Principles of Biochemistry. New York: W. H. Freeman and Company, England: Macmillan Higher Education.

Course code	Course name	Teaching scheme (Hr/week)			Credits assigned		
UCRPE311	Clinical Data Management & standards	Theory	Practical	Tutorial	Theory	Practical	Tutorial
		03	-	01	03	-	01

Course code	Course name	Evaluation scheme (In semester)						Semester end exam (SEE)		Total (Marks)
		CAI	CAII	CAIII	Total	Min pass	Term Work/ Tutorial	Marks	Min pass	
UCRPE311	Clinical Data Management & Standards	10	10	5	25	40%	25	50	40%	100

Course Description

This course introduces students to the principles and practices of clinical data management (CDM) in clinical research. It covers the complete lifecycle of clinical data—from collection and validation to analysis and reporting—while emphasizing regulatory requirements and global data standards. Students will gain hands-on understanding of data handling, database design, data quality assurance, and industry standards such as CDISC. The course prepares learners for roles in clinical research organizations (CROs), pharmaceutical companies, and regulatory environments.

Pre-requisite

A basic understanding of clinical research concepts, biostatistics, and fundamental data handling or database principles.

Course Objectives:

1. To understand the role and importance of clinical data management in clinical trials.
2. To explain the clinical data lifecycle and associated processes.
3. To apply data validation, cleaning, and quality assurance techniques.
4. To analyze regulatory requirements and global data standards (e.g., CDISC).
5. To evaluate data management systems and tools used in clinical research.

Course outcomes:

After successful completion of this course, students will able to

CO1 **Recognise**[1] the fundamentals and significance of clinical data management

CO2 **Identify**[2] the stages of clinical data lifecycle and workflow processes

CO3 **Perform**[3] data validation and cleaning techniques on clinical datasets

CO4 **Examine**[4] regulatory guidelines and clinical data standards (CDISC, ICH-GCP)

CO5 **Assess**[5] different clinical data management systems and tools

Module	Unit	Description	Hours
1.0		**Introduction to Clinical Data Management**	**9**
	1.1	Overview of clinical research and role of CDM	
	1.2	CDM team structure and responsibilities	
	1.3	Types and sources of clinical trial data	
2.0		**Clinical Data Lifecycle**	**9**
	2.1	Data collection methods (CRFs, e CRFs)	
	2.2	Database design, development, and data entry	
	2.3	Data validation and discrepancy management	
3.0		**Data Quality and Validation**	**9**
	3.1	Data cleaning processes and query management	
	3.2	Quality assurance (QA) and quality control (QC)	
	3.3	Risk-based monitoring and data integrity	
4.0		**Regulatory Requirements and Standards**	**9**
	4.1	Good Clinical Practice (GCP) guidelines	
	4.2	Regulatory bodies and compliance (FDA, EMA)	
	4.3	CDISC standards (SDTM, ADaM) and data privacy basics	
5.0		**Clinical Data Management Systems & Tools**	**9**
	5.1	Electronic Data Capture (EDC) systems	
	5.2	Clinical Trial Management Systems (CTMS)	
	5.3	Emerging trends: AI, real-world data, and automation	

Tutorial Activities

1. CRF/eCRF Design Exercise
   Students design a simple Case Report Form for a mock clinical trial (e.g., diabetes study), focusing on relevant and structured data capture. CDISC Standards Mapping Activity
   Students map sample raw data to standard formats like SDTM domains (basic level).
2. EDC System Demo & Reflection
   Explore a demo of an Electronic Data Capture system and submit a short report on features, advantages, and challenges.

Textbooks

1. Susanne Prokscha – *Practical Guide to Clinical Data Management*
2. Richard K. Rondel, Sheila A. Varley, Colin F. Webb – *Clinical Data Management*

Reference books

1. Phillip I. Good – *A Manager's Guide to the Design and Conduct of Clinical Trials*
2. CDISC Standards Documentation (official publications and implementation guides)

Internal Assessment (CAI, CAII and CAIII):

1. CAI should be based on first two modules and CAII should be based on next two modules, for 10 marks each.
2. CA III shall be assessed for 5 marks separately.

End Semester Examination:

1. Question paper will be of 50 marks comprise of 5 questions, each carrying 10 marks.
2. The duration of end semester examination shall be two hours.
3. The students need to solve all 5 questions.
4. Question No.1 will be compulsory and based on entire syllabus.
5. Remaining question (Q.2 to Q.5) will be selected from all the modules.

Course code	Course name	Teaching scheme (Hr/week)			Credits assigned		
UCRPE321	Clinical Trials of Biotech Products	Theory	Practical	Tutorial	Theory	Practical	Tutorial
		03	-	01	03	-	01

Course code	Course name	Evaluation scheme (In semester)						Semester end exam (SEE)		Total (Marks)
UCRPE321	Clinical Trials of Biotech Products	CAI	CAII	CAIII	Total	Min pass	Term Work/ Tutorial	Marks	Min pass	
		10	10	5	25	40%	25	50	40%	100

Course Description

This course provides a comprehensive understanding of the design, conduct, and regulatory aspects of clinical trials for biotechnology products, including biologics, biosimilars, gene therapies, and vaccines. It emphasizes the unique scientific, ethical, and operational challenges associated with biotech products compared to conventional pharmaceuticals. Students will gain knowledge of clinical development pathways, regulatory frameworks, safety monitoring, immunogenicity, and data analysis specific to biotech trials.

Pre-requisite

Basic knowledge of clinical research methodology and fundamentals of biotechnology or pharmacology.

Course Objectives:

1. To understand the principles and phases of clinical trials for biotech products.
2. To analyze regulatory requirements governing biologics, biosimilars, and advanced therapies.
3. To evaluate trial design considerations including immunogenicity and safety assessment.
4. To apply ethical and quality standards in the conduct of biotech clinical trials.
5. To interpret clinical data and outcomes specific to biotechnology products.

Course outcomes:

After successful completion of this course, students will able to

CO1 **State**[2] the clinical development process of biotech products

CO2 **Interpret**[3] regulatory guidelines for biologics and biosimilars

CO3 **Analyze**[4] clinical trial designs and endpoints for biotech products

CO4 **Apply**[3] ethical, safety, and quality principles in biotech trials

CO5 **Evaluate**[5] clinical trial data and outcomes for decision-making

Module	Unit	Description	Hours
1.0		**Introduction to Biotech Products and Clinical Trials**	**9**
	1.1	Types of biotech products: biologics, biosimilars, vaccines, gene and cell therapies	
	1.2	Differences between small molecule drugs and biotech products	
	1.3	Phases of clinical trials and key challenges in biotech trials	
2.0		**Regulatory Framework and Guidelines**	**9**
	2.1	Global regulatory agencies: FDA, EMA, CDSCO	
	2.2	Regulatory pathways for biologics and biosimilars (IND, BLA, NDA)	
	2.3	ICH guidelines and compliance requirements for biotech trials	
3.0		**Clinical Trial Design for Biotech Products**	**9**
	3.1	Study design considerations and trial methodologies	
	3.2	Dose selection, escalation strategies, and biomarkers	
	3.3	Endpoints, efficacy evaluation, and immunogenicity assessment	
4.0		**Safety, Ethics, and Quality Assurance**	**9**
	4.1	Adverse events, pharmacovigilance, and risk management	
	4.2	Ethical considerations in biotech and advanced therapies	
	4.3	Good Clinical Practice (GCP) and quality assurance systems	
5.0		**Data Management, Analysis, and Emerging Trends**	**9**
	5.1	Data collection, management, and documentation in biotech trials	
	5.2	Statistical analysis and interpretation of clinical trial results	
	5.3	Emerging trends: personalized medicine, gene therapy, AI in clinical trials	

Tutorial Activities

1. Case study analysis of a biotech clinical trial (e.g., vaccine or monoclonal antibody)
2. Regulatory submission simulation (IND/BLA)
3. Critical review of published biotech trial data
4. Group discussion on ethical issues in gene therapy trials

Textbooks

1. Principles of Clinical Pharmacology – Arthur J. Atkinson Jr. et al.
2. Biopharmaceuticals: Biochemistry and Biotechnology – Gary Walsh

Reference books

1. Fundamentals of Clinical Trials – Lawrence M. Friedman et al.
2. Clinical Trials in Drug Development – Aleš Prokop & others

Internal Assessment (CAI, CAII and CAIII):

1. CAI should be based on first two modules and CAII should be based on next two modules, for 10 marks each.
2. CA III shall be assessed for 5 marks separately.

End Semester Examination:

1. Question paper will be of 50 marks comprise of 5 questions, each carrying 10 marks.
2. The duration of end semester examination shall be two hours.
3. The students need to solve all 5 questions.
4. Question No.1 will be compulsory and based on entire syllabus.
5. Remaining question (Q.2 to Q.5) will be selected from all the modules.

Course code	Course name	Teaching scheme (Hr/week)			Credits assigned		
UCRPE331	CRO Operations & Business Model	Theory	Practical	Tutorial	Theory	Practical	Tutorial
		03	-	01	03	-	01

Course code	Course name	Evaluation scheme (In semester)						Semester end exam (SEE)		Total (Marks)
		CAI	CAII	CAIII	Total	Min pass	Term Work/ Tutorial	Marks	Min pass	
UCRPE331	CRO Operations & Business Model	10	10	5	25	40%	25	50	40%	100

Course Description

This course provides an in-depth understanding of Contract Research Organizations (CROs), focusing on their operational frameworks and business models within the clinical research ecosystem. CROs play a vital role by offering outsourced services to pharmaceutical, biotechnology, and medical device companies to manage clinical trials efficiently and cost-effectively. The course explores CRO organizational structure, functional operations, project management, financial models, and regulatory compliance. It also highlights outsourcing strategies, client relationships, and emerging trends such as decentralized clinical trials and digital transformation. Students will gain practical insights into how CROs deliver value across the drug development lifecycle.

Pre-requisite

Fundamentals of Clinical Research, GCP & basics of drug development process.

Course Objectives:

1. To explain the concept, evolution, and role of CROs in clinical research.
2. To describe the organizational structure and functional units within CROs.
3. To analyze various CRO business models, costing mechanisms, and financial strategies.
4. To evaluate project management practices and quality systems in CRO operations.
5. To assess global trends, outsourcing strategies, and future opportunities in the CRO industry.

Course outcomes:

After successful completion of this course, students will able to

CO1 **Interpret**[2] the role, structure, and evolution of CROs in clinical research

CO2 **Classify**[2] functional units and operational workflows within CROs

CO3 **Analyze**[4] CRO business models and financial frameworks

CO4 **Evaluate**[5] project management practices and quality systems in CROs

CO5 **Formulate**[5] strategies based on emerging trends for CRO growth and sustainability

Module	Unit	Description	Hours
1.0		**Introduction to CRO Industry**	**9**
	1.1	Definition and role of CROs, Evolution of CRO industry.	
	1.2	Types of CROs (Full-service, Functional Service Provider, niche CROs)	
	1.3	CRO vs Sponsor roles and responsibilities, Global CRO market and outsourcing trends.	
2.0		**CRO Organizational Structure & Operations**	**9**
	2.1	Functional departments: Clinical operations, data management, biostatistics, regulatory affairs, pharmacovigilance.	
	2.2	Clinical trial lifecycle in CROs, Site selection, monitoring, and vendor management.	
	2.3	SOPs and operational workflows, Resource management and staffing models.	
3.0		**CRO Business Models & Financial Management**	**9**
	3.1	Business models: • Full-Service Outsourcing (FSO) • Functional Service Provider (FSP) • Hybrid models	
	3.2	Revenue streams: service vs pass-through costs, Budgeting, costing, and pricing strategies.	
	3.3	Proposal development and bid defense, Contracts and Service Level Agreements (SLAs)	
4.0		**Project Management & Quality Systems in CROs**	**9**
	4.1	Clinical project management lifecycle, Risk management in clinical trials	
	4.2	Quality assurance, audits, and inspections	
	4.3	Regulatory compliance: ICH-GCP, FDA, EMA	
5.0		**Global Trends & Future of CRO Industry**	**9**
	5.1	Outsourcing trends in pharma and biotech, Decentralized clinical trials (DCTs).	
	5.2	Digital transformation and AI in CROs, Strategic partnerships, mergers, and acquisitions	
	5.3	Challenges (regulatory, ethical, operational), Entrepreneurship and future opportunities	

Tutorial Activities

1. Case study analysis of CRO operations
2. Budget preparation and costing exercises
3. Proposal writing and bid defense simulation
4. Risk assessment exercises
5. Discussion on global CRO companies and trends

Textbooks

1. Gallin, J.I. and Ognibene, F.P., 2018. Principles and Practice of Clinical Research. Publisher: Academic Press (Elsevier).
2. Kremidas, J., 2006. Clinical Research Operations and Management. Publisher: ACRP (Association of Clinical Research Professionals).

Reference books

1. Ferrone, M., 2007. Handbook of Clinical Research. Publisher: Trafford Publishing.
2. International Council for Harmonisation (ICH), 2016. ICH Harmonised Guideline for Good Clinical Practice E6(R2). Publisher: ICH.

Internal Assessment (CAI, CAII and CAIII):

1. CAI should be based on first two modules and CAII should be based on next two modules, for 10 marks each.
2. CA III shall be assessed for 5 marks separately.

End Semester Examination:

1. Question paper will be of 50 marks comprise of 5 questions, each carrying 10 marks.
2. The duration of end semester examination shall be two hours.
3. The students need to solve all 5 questions.
4. Question No.1 will be compulsory and based on entire syllabus.
5. Remaining question (Q.2 to Q.5) will be selected from all the modules.

Programme Structure for B. Sc.: Second Year Clinical Research & Technology (R-25)

Semester IV: Teaching Scheme

Course code	Course Name	Teaching scheme (Hrs/week)			Credits assigned			Total credits
		Theory	Practical	Tutorial	Theory	Practical	Tutorial	
UCRPC401	Clinical Pharmacokinetics	3	-	-	3	-	-	3
UCRPC402	Systemic Pharmacology and autocoids	3	-	-	3	-	-	3
UCRPC403	Regulatory Aspects in Clinical Research	2	-	-	2	-	-	2
UCRPC404	Epidemiology and Global Health	2	-	-	2	-	-	2
UCRPE4XX	Program Elective II	3	-	1	3	-	1	4
UXXMM0XX	Multidisciplinary Minor III	2	-	-	2	-	-	2
UCRPC405	Systemic Pharmacology and autocoids Lab	-	2	-	-	1	-	1
UCRPC406	Clinical Sampling and Analytical Techniques Lab	-	2	-	-	1	-	1
UXXMM0XX	Multidisciplinary Minor III Lab	-	2	-	-	1	-	1
UCRSE401	Medical Writing	2	-	-	2	-	-	2
UCRVS401	Healthcare administration	2	-	-	2	-	-	2
	Total	**19**	**6**	1	**19**	**3**	1	**23**

Second Year B. Sc. Program Semester IV: Evaluation Scheme

Course code	Course Name	Theory Marks					Practical Marks		Total
		Internal Assessment				SEE	Term work/ Tutorial	Practical Oral /POE	
		CA I	CA II	CA III	Total				
UCRPC401	Clinical Pharmacokinetics	10	10	5	25	50	-	-	75
UCRPC402	Systemic Pharmacology and autocoids	10	10	5	25	50	-	-	75
UCRPC403	Regulatory Aspects in Clinical Research	-	10	5	15	35	-	-	50
UCRPC404	Epidemiology and Global Health	-	10	5	15	35	-	-	50
UCRPE4XX	Program Elective II	10	10	5	25	50	25	-	100
UXXMM0XX	Multidisciplinary Minor III	-	10	5	15	35	-	-	50
UCRPC405	Systemic Pharmacology and autocoids Lab	-	-	-	-	-	25	-	25
UCRPC406	Clinical Sampling and Analytical Techniques Lab	-	-	-	-	-	25	-	25
UXXMM0XX	Multidisciplinary Minor III Lab	-	-	-	-	-	25	-	25
UCRSE401	Medical Writing	-	10	5	15	35	-	-	50
UCRVS401	Healthcare administration	-	10	5	15	35	-	-	50
								Total	**575**

Exit Option: Students will have the flexibility to enter a programme in odd semesters and exit a programme after the successful completion of even semesters as per their future career needs. Students exiting the Second-Year program after securing Major with 88 credits and an additional 4 credits core NSQF course/Internship or continue with major & minor.

Course code	Course name	Teaching scheme (Hr/week)			Credits assigned		
UCRPC401	Clinical Pharmacokinetics	Theory	Practical	Tutorial	Theory	Practical	Tutorial
		03	-	-	03	-	-

Course code	Course name	Evaluation scheme (In semester)					Semester end exam (SEE)		Total (Marks)
UCRPC401	Clinical Pharmacokinetics	CAI	CAII	CAIII	Total	Min pass	Marks	Min pass	
		10	10	5	25	40%	50	40%	75

Course Description

This course provides a comprehensive understanding of the principles and clinical applications of Clinical Pharmacokinetics in optimizing drug therapy. It covers fundamental pharmacokinetic concepts, dosage regimen design, variability in drug response, and altered pharmacokinetics in special populations. The course also introduces advanced topics such as population pharmacokinetics, Bayesian approaches, and modeling techniques used in clinical decision-making. Emphasis is placed on applying pharmacokinetic principles to individualize therapy for improved efficacy and safety.

Pre-requisite

Prior knowledge of Pharmaceutics, general pharmacology, Mathematics and introductory Biostatstics

Course Objectives:

1. To explain the fundamental principles of Clinical Pharmacokinetics and key pharmacokinetic parameters.
2. To apply pharmacokinetic concepts in designing and optimizing dosage regimens.
3. To analyze pharmacokinetic variability and drug interactions affecting drug therapy.
4. To evaluate and adjust drug dosing in special populations with altered pharmacokinetics.
5. To introduce principles of Pharmacometrics and their role in clinical decision-making.

Course outcome(s):

After successful completion of this course, students will able to

CO1 **Illustrate**[2] the fundamental concepts of Clinical Pharmacokinetics, including compartment models and pharmacokinetic parameters.

CO2 **Calculate**[3] pharmacokinetic parameters and design appropriate dosage regimens based on clinical data.

CO3 **Differentiate**[4] sources of pharmacokinetic variability and assess drug interactions, including those involving the Cytochrome P450 enzyme system.

CO4 **Evaluate**[5] and modify drug dosing strategies in special populations such as renal/hepatic impairment, pediatrics, geriatrics, obesity, and pregnancy.

CO5 **Apply**[3] principles of Pharmacometrics, including population pharmacokinetics and Bayesian approaches, for therapeutic decision-making.

Module	Unit	Description	Hours
1.0		**Fundamentals of Clinical Pharmacokinetics**	**9**
	1.1	Introduction to clinical pharmacokinetics and its clinical relevance Compartmental and non-compartmental models Pharmacokinetic parameters: clearance, volume of distribution, half-life	
	1.2	Renal and non-renal clearance Hepatic clearance and extraction ratio models Bioavailability: estimation and determinants Multiple dosing and steady-state concentration Calculation of loading dose and maintenance dose	
2.0		**Dosage Regimen Design**	**9**
	2.1	Principles of dosage regimen design Determination of dose and dosing intervals Peak and trough concentration concepts	
	2.2	Conversion from intravenous to oral dosing Use of nomograms and tabulations in clinical practice	
3.0		**Pharmacokinetic Variability & Drug Interactions**	**9**
	3.1	Sources of variability in pharmacokinetics (age, disease, genetics) Pharmacokinetic drug interactions Enzyme induction and inhibition (CYP450 system)	
	3.2	Drug transporters and their role in drug disposition Introduction to pharmacogenetics and genetic polymorphism Clinical implications of pharmacogenetics in drug therapy	
4.0		**Altered Pharmacokinetics in Special Populations**	**9**
	4.1	Drug dosing in renal impairment and dialysis Drug dosing in hepatic impairment Pharmacokinetics in pediatrics and geriatrics	
	4.2	Drug dosing in obesity Pharmacokinetics during pregnancy and lactation Clinical considerations for dose adjustment	
5.0		**Introduction to Pharmacometrics & Clinical Applications**	**9**
	5.1	Introduction to pharmacometrics Advanced population of pharmacokinetics Introduction to Bayesian theory and adaptive dosing	
	5.2	Concepts of nonlinear mixed-effects modeling (basic overview) Simulation of dosing regimens Clinical application of pharmacokinetics in therapeutic decision-making	

Textbooks

1. Brahmankar, D.M., Jaiswal, S.B., 2021. *Biopharmaceutics and Pharmacokinetics: A Treatise*. Publisher: Vallabh Prakashan.
2. Shargel, L., Yu, A.B.C., 2022. *Applied Biopharmaceutics and Pharmacokinetics*. Publisher: McGraw Hill
3. Gowekar, N.M., Patel, M.J.J., Ali, S.J., 2023. *A Textbook of Biopharmaceutics and Pharmacokinetics* . Publisher: Notion Press.

Reference books

1. Notari, R.E., 1987. *Biopharmaceutics and Pharmacokinetics: An Introduction*. Publisher: Marcel Dekker.
2. Singh, M., Choudhary, R.K., Kumar, S., Waidya, K., Sivakumar, T., 2024. *Textbook of Biopharmaceutics and Pharmacokinetics*. Publisher: Shashwat Publication.

Internal Assessment (CAI, CAII and CAIII):

1. CAI should be based on first two modules and CAII should be based on next two modules, for 10 marks each.
2. CA III shall be assessed for 5 marks separately.

End Semester Examination:

1. Question paper will be of 50 marks comprise of 5 questions, each carrying 10 marks.
2. The duration of end semester examination shall be two hours.
3. The students need to solve all 5 questions.
4. Question No.1 will be compulsory and based on entire syllabus.
5. Remaining question (Q.2 to Q.5) will be selected from all the modules.

Course code	Course name	Teaching scheme (Hr/week)			Credits assigned		
UCRPC402	Systemic Pharmacology and autocoids	Theory	Practical	Tutorial	Theory	Practical	Tutorial
		03	-	-	03	-	-

Course code	Course name	Evaluation scheme (In semester)					Semester end exam (SEE)		Total (Marks)
UCRPC402	Systemic Pharmacology and autocoids	CAI	CAII	CAIII	Total	Min pass	Marks	Min pass	
		10	10	5	25	40%	50	40%	75

Course Description

This course provides a comprehensive understanding of drugs acting on major physiological systems, including the peripheral nervous system, cardiovascular system, blood, kidney, respiratory system, and autacoids. It integrates fundamental concepts of Pharmacology with therapeutic applications, emphasizing mechanism of action, pharmacological effects, adverse effects, and clinical uses. The course also introduces drugs used in immune modulation and highlights rational drug therapy in various pathological conditions.

Pre-requisite

Basic knowledge of Human Anatomy & Physiology and General Pharmacology.

Course Objectives:

1. To understand drug action on the peripheral nervous system including cholinergic, adrenergic, and neuromuscular systems.
2. To apply pharmacological principles to drugs used in cardiovascular disorders such as hypertension, arrhythmias, and heart failure.
3. To analyze pharmacology of drugs acting on blood and kidney including anticoagulants, diuretics, and lipid-lowering agents.
4. To interpret the role of autacoids and related drugs in inflammation, pain, and allergic disorders.
5. To evaluate pharmacological management of respiratory disorders and immune-related conditions.

Course outcomes:

After successful completion of this course, students will able to

CO1 **Classify**[2] drugs acting on the peripheral nervous system based on mechanism of action and therapeutic use.

CO2 **Classify**[2] and explain the mechanisms of action, pharmacological effects, and therapeutic uses of drugs used in cardiovascular disorders such as heart failure, arrhythmias, hypertension, angina, and lipid disorders.

CO3 **Differentiate**[4] drugs acting on blood and kidney systems, including anticoagulants, diuretics, and antihyperlipidemic agents, based on their mechanisms and uses.

CO4 **Evaluate**[5] the role of Autacoids and related drugs such as Non-steroidal anti-inflammatory drugs and antihistamines in disease management.

CO5 **Assess**[5] pharmacotherapy of respiratory and immune-related disorders, including asthma, COPD, and immunomodulation strategies.

Module	Unit	Description	Hours
1.0		**Pharmacology of drugs acting on the peripheral nervous system**	**9**
	1.1	Organization and functions of PNS.	
	1.2	Neurohumoral transmission, co-transmission. Neurotransmitters and their receptors, including non-adrenergic and non- cholinergic (NANC) neurotransmitters.	
	1.3	Parasympathomimetic and Parasympatholytic drugs.	
	1.4	Sympathomimetic and sympatholytic drugs.	
	1.5	Skeletal muscle relaxants (peripheral and central).	
	1.6	Drugs used in the treatment of myasthenia gravis and glaucoma.	
2.0		**Pharmacology of drugs acting on the cardiovascular system**	**9**
	2.1	Introduction to cardiovascular hemodynamic and cardiac electrophysiology.	
	2.2	Drugs used in congestive cardiac failure.	
	2.3	Anti-arrhythmic drugs.	
	2.4	Anti-anginal drugs.	
	2.5	Anti-hypertensive drugs.	
	2.6	Shock, types of shocks and drugs used in their management.	
	2.7	Stroke, types of strokes and drugs used in their management.	
3.0		**i) Pharmacology of drugs acting on blood**	**9**
	3.1.1	Anti-platelet agents	
	3.1.2	Coagulants and anticoagulants.	
	3.1.3	Fibrinolytics and Plasma expanders.	
	3.1.4	Haematinics.	
	3.1.5	Anti-hyperlipidaemic drugs.	
		ii) Pharmacology of drugs acting on kidney	
	3.2.1	Diuretics.	
	3.2.2	Anti-diuretics.	
4.0		**Pharmacology of autacoids and related drugs**	**99**
	4.1	Introduction to autacoids and their classification. Therapeutic significance of important agonists and antagonists of prostaglandins, thromboxane, leukotrienes, angiotensin, bradykinin and substance P.	
	4.2	Histamine and antihistamines.	
	4.3	5-HT, its agonists and antagonists, drugs used in migraine.	
	4.4	Non-steroidal anti-inflammatory drugs, antipyretics and analgesics.	
	4.5	Anti-gout and Antirheumatic drugs including Disease Modifying Antirheumatic Drugs (DMARDs).	
5.0		**i) Pharmacology of Drugs acting on respiratory system**	**9**
	5.1.1	Drugs used in the treatment of bronchial asthma and COPD.	
	5.1.2	Definitions, classification and therapeutic uses of nasal decongestants, mucolytics, expectorants and antitussives.	
	5.1.3	Respiratory stimulants.	
		ii) Introduction to immune stimulants and immunosuppressants.	

Textbooks

1. Rang & Dale's Pharmacology, H.P. Rang, M.M. Dale, J.M. Ritter, R.J. Flower, G. Henderson, Publisher: Elsevier
2. Essentials of Medical Pharmacology, K.D. Tripathi., Publishers: Jaypee Brothers Medical
3. Introduction to Pharmacology, S.K Kulkarni, Vallabh Prakashan.

Reference books

1. Goodman & Gilman's: The Pharmacological Basis of Therapeutics, Laurence L. Brunton, Randa Hilal-Dandan, Bjorn Knollmann. Publisher: McGraw-Hill Education, Edition: 13th Edition (2017)
2. Basic and Clinical Pharmacology, Bertram Katzung, Anthony Trevor. Publisher: McGraw- Hill Education.
3. Pharmacology and Pharmacotherapeutics, R.S. Satoskar, Nirmala N. Rege, S.D. Bhandarkar. Publisher: Elsevier India

Internal Assessment (CAI, CAII and CAIII):

1. CAI should be based on first two modules and CAII should be based on next two modules, for 10 marks each.
2. CA III shall be assessed for 5 marks separately.

End Semester Examination:

1. Question paper will be of 50 marks comprise of 5 questions, each carrying 10 marks.
2. The duration of end semester examination shall be two hours.
3. The students need to solve all 5 questions.
4. Question No.1 will be compulsory and based on entire syllabus.
5. Remaining question (Q.2 to Q.5) will be selected from all the modules.

Course code	Course name	Teaching scheme (Hr/week)			Credits assigned		
UCRPC403	Regulatory Aspects in Clinical Research	Theory	Practical	Tutorial	Theory	Practical	Tutorial
		02	-	-	02	-	-

Course code	Course name	Evaluation scheme (In semester)					Semester end exam (SEE)		Total (Marks)
		CAI	CAII	CAIII	Total	Min pass	Marks	Min pass	
UCRPC403	Regulatory Aspects in Clinical Research	-	10	5	15	40%	35	40%	50

Course Description

This course provides a comprehensive overview of global regulatory frameworks governing clinical research, with emphasis on ethical conduct, subject protection, and data integrity. It introduces major international regulatory authorities such as the U.S. Food and Drug Administration, European Medicines Agency, and Central Drugs Standard Control Organization, along with harmonized guidelines developed by the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use. The course covers Good Clinical Practice (GCP), regulatory submissions, ethical principles, and key provisions of 21 CFR. Students gain practical understanding of clinical trial approvals, documentation, and compliance requirements necessary for conducting ethically sound and legally compliant research.

Pre-requisite

Prior knowledge of Fundamentals of Clinical Research, Basic Pharmacology, Biostatistics, General understanding of healthcare systems and drug development.

Course Objectives:

1. To understand the need for regulatory frameworks and the role of global regulatory agencies in clinical research.
2. To apply principles of Good Clinical Practice to ensure ethical and quality conduct of clinical trials.
3. To interpret regulatory submission processes including IND and CTA and associated documentation.
4. To analyze ethical guidelines and the role of Institutional Review Boards (IRB/IEC) in protecting human subjects.
5. To evaluate key provisions of FDA regulations (21 CFR) and national guidelines for clinical trials.

Course outcome(s):

After successful completion of this course, students will able to

CO1 **Classify**[2] global clinical research regulations and regulatory authorities involved in drug development.

CO2 **Apply**[3] principles of Good Clinical Practice in clinical trial conduct, including roles of investigator, sponsor, and CRO.

CO3 **Interpret**[3] regulatory submission requirements such as IND and CTA, including essential documents and approval processes.

CO4 **Analyze**[4] ethical principles and the functioning of IRB/IEC in safeguarding participant rights, including informed consent procedures.

CO5 **Evaluate**[5] regulatory provisions under 21 CFR and national clinical trial rules for compliance in clinical research.

Module	Unit	Description	Hours
1.0		**Introduction to Clinical Research Regulations**	**6**
	1.1	Overview of clinical research regulations (Why regulations exist?) Key regulatory bodies: FDA (U.S.), EMA (EU), MHRA (UK), CDSCO (India), PMDA (Japan), NMPA (China)	
	1.2	ICH (International Council for Harmonization) and its role	
2.0		**ICH-GCP (Good Clinical Practice) Guidelines**	**6**
	2.1	ICH E6, E8, E9 Principles of GCP (Ethics, data integrity, subject protection)	
	2.2	Investigator, Sponsor, and CRO responsibilities	
3.0		**Regulatory Submissions & Approvals**	**6**
	3.1	IND (Investigational New Drug) Application (FDA Form 1571/1572) CTA (Clinical Trial Application) in EU/UK	
	3.2	Essential documents (Protocol, IB, ICF, Investigator's Brochure) Various meetings with regulators	
4.0		**Ethics & Institutional Review Boards (IRB/IEC)**	**6**
	4.1	Ethical principles (Declaration of Helsinki, Belmont Report) IRB/IEC composition & responsibilities	
	4.2	Informed Consent Process (ICF) and exceptions (emergency, pediatric)	
5.0		**FDA 21 CFR Regulations, NDCT**	**6**
	5.1	21 CFR Part 11 (Electronic Records/Signatures) 21 CFR Part 50 (Protection of Human Subjects)	
	5.2	21 CFR Part 54 (Financial Disclosures) 21 CFR Part 312 (IND Regulations)	

Textbooks

1. Clinical Research: Principles and Practice, John I. Gallin, Frederick P. Ognibene. Publisher: Academic Press (Elsevier).
2. Fundamentals of Clinical Trials, Lawrence M. Friedman, Curt D. Furberg, David L. DeMets. Publisher: Springer.
3. GCP and Clinical Research, S. K. Gupta. Publisher: CBS Publishers.

Reference books / Guidelines

1. ICH - GCP E6(R3) Comprehensive Resource Guide for Clinical Research Professionals, Alec Spinelli. Publisher: Amazon KDP.
2. ICH E6 (R3) Good Clinical Practice (GCP)
3. FDA Regulations (21 CFR)

Internal Assessment (CAI, CAII and CAIII):

1. CAII should be based on First to Fourth modules, for 10 marks each.
2. CA III shall be assessed for 5 marks separately.

End Semester Examination:

1. Question paper will be of 35 marks comprise of 5 questions, each carrying 07 marks.
2. The duration of end semester examination shall be two hours.
3. The students need to solve all 5 questions.
4. Question No.1 will be compulsory and based on entire syllabus.
5. Remaining question (Q.2 to Q.5) will be selected from all the modules.

Course code	Course name	Teaching scheme (Hr/week)			Credits assigned		
UCRPC404	Epidemiology and Global Health	Theory	Practical	Tutorial	Theory	Practical	Tutorial
		2	-	-	2	-	-

Course code	Course name	Evaluation scheme (In semester)					Semester end exam (SEE)		Total (Marks)
		CAI	CAII	CAIII	Total	Min pass	Marks	Min pass	
UCRPC404	Epidemiology and Global Health	-	10	5	15	40%	35	40%	50

Course Description

This course introduces the principles of epidemiology and their application to global health. It covers measures of disease frequency, study designs, outbreak investigation, and determinants of health and disease. The course also explores global health challenges, health systems, disease burden, and the role of international organizations in improving population health. Emphasis is placed on applying epidemiological tools to clinical research and public health decision-making.

Pre-requisite

Basic knowledge of biology, clinical research.

Course Objectives:

1. To introduce fundamental concepts and scope of epidemiology.
2. To develop understanding of disease distribution and determinants.
3. To familiarize with epidemiological study designs.
4. To provide knowledge of global health issues and disease burden.
5. To highlight the role of epidemiology in clinical research and public health

Course outcomes:

After successful completion of this course, students will able to

CO1 **Summarize**[2] key concepts and measures used in epidemiology

CO2 **Differentiate**[2] various epidemiological study designs and their applications

CO3 **Apply**[3] epidemiological methods to investigate disease patterns

CO4 **Analyze**[4] determinants of health and global disease burden

CO5 **Evaluate**[5] public health strategies and global health interventions.

Module	Unit	Description	Hours
1.0		**Introduction to Epidemiology**	**6**
	1.1	Definition, scope, and importance of epidemiology	
	1.2	Epidemiological triad (agent, host, environment)	
	1.3	Natural history of disease, Levels of prevention	
2.0		**Measures of Disease Frequency**	**6**
	2.1	Incidence and prevalence, Mortality and morbidity rates	
	2.2	Risk, odds ratio, relative risk, Standardization of rates	
3.0		**Epidemiological Study Designs**	**6**
	3.1	Observational studies: descriptive, case-control, cohort	
	3.2	Experimental studies: randomized controlled trials	
	3.3	Bias, confounding, and validity, Screening tests: sensitivity, specificity	
4.0		**Global Health Concepts**	**6**
	4.1	Definition and scope of global health, Global burden of disease	
	4.2	Communicable and non-communicable diseases	
	4.4	Role of World Health Organization and United Nations	
5.0		**Health Systems and Public Health Interventions**	**6**
	5.1	Health systems and policies	
	5.2	Disease surveillance and outbreak investigation	
	5.3	Vaccination programs and control strategies	
	5.4	Emerging and re-emerging diseases	

Textbooks

1. Park's Textbook of Preventive and Social Medicine; Banarsidas Bhanot Publishers
2. Epidemiology; Elsevier

Reference books

1. Epidemiology: An Introduction; Oxford University Press

Internal Assessment (CAI, CAII and CAIII):

1. CAII should be based on First to Fourth modules, for 10 marks each.
2. CA III shall be assessed for 5 marks separately.

End Semester Examination:

1. Question paper will be of 35 marks comprise of 5 questions, each carrying 07 marks.
2. The duration of end semester examination shall be two hours.
3. The students need to solve all 5 questions.
4. Question No.1 will be compulsory and based on entire syllabus.
5. Remaining question (Q.2 to Q.5) will be selected from all the modules.

Course code	Course name	Teaching scheme (Hr/week)			Credits assigned		
UCRPC405	Systemic Pharmacology and autocoids Lab	Theory	Practical	Tutorial	Theory	Practical	Tutorial
		-	2	-	-	1	-

Course code	Course name	Evaluation scheme (In semester)					Semester end exam (SEE)			Total (Marks)
UCRPC405	Systemic Pharmacology and autocoids Lab	CAI	CAII	CAIII	Total	Internal Assessment*	ESE*	Term work*/ Tutorial	Pract* Oral/ POE	
		-	-	-	-	-	-	25	-	25

Course Description

This laboratory course provides hands-on and simulation-based exposure to experimental pharmacology, focusing on drug effects on isolated tissues, whole-animal models, and biochemical assays. It integrates principles of Pharmacology with experimental techniques such as organ bath studies, bioassays, and in vitro screening methods. Students explore drug–receptor interactions, dose–response relationships, and pharmacological evaluation of drugs including anti-inflammatory, antiallergic, and diuretic agents. The course also introduces modern concepts such as cell-based assays, oxidative stress evaluation, and Biobanking, enhancing skills required for research and clinical pharmacology.

Pre-requisite

Knowledge of Human Anatomy & Physiology, General Pharmacology, Introductory Biochemistry

Course Objectives:

1. To demonstrate experimental techniques used to evaluate pharmacological effects on isolated tissues and organ systems.
2. To analyze drug responses using simulation-based and in vitro experimental models.
3. To apply bioassay principles to determine drug potency and receptor interactions (e.g., PA_2 using Schild plot).
4. To perform biochemical and cell-based assays for evaluation of drug activity and toxicity.
5. To interpret experimental and clinical data for rational drug use and research applications

Course outcome(s):

After successful completion of this course, students will able to

CO1 **Demonstrate**[3] experimental setups and techniques such as isolated organ preparations, bioassays, and pharmacological screening models.

CO2 **Analyze**[4] drug effects on physiological parameters (heart rate, blood pressure, bronchial tone, smooth muscle activity) using simulation-based experiments.

CO3 **Determine**[3] drug potency and receptor interactions using bioassay methods such as Schild plot for estimation of PA_2 values.

CO4 **Perform**[3] biochemical and cell-based assays including oxidative stress markers, protein estimation, and cell viability tests.

CO5 **Evaluate**[5] experimental data, drug interactions, and case studies to support rational pharmacotherapy and research conclusions.

List of Experiments

Minimum 10 experiments must be performed

1. To demonstrate Langendorff's heart assembly and its applications in pharmacology (only video demonstration/or charts and illustrations).
2. Recording of the effects of different electrolytes, agonists and antagonists on the isolated and perfused frog heart preparation using interactive computer simulation experiment.
3. To study the effect of various drugs on blood pressure and heart rate anaesthetized dog using interactive computer simulation experiment.
4. Demonstration of the estimation of intraocular pressure on rabbit eye and human eye by using conventional Schiotz tonometer and non-contact tonometer.
5. To evaluate the muscle relaxant activity of drugs on Rota-rod apparatus using interactive computer simulation experiment.
6. Demonstration of the effect of spasmogens and spasmolytic using rabbit jejunum using interactive computer simulation experiment.
7. Determination of PA2 value of Atropine using a suitable isolated tissue preparation by Schild plot method with the help of hypothetical data using interactive computer simulation experiment.
8. Determination of PA2 value of Prazosin using a suitable isolated tissue preparation by Schild plot method with the help of hypothetical data using interactive computer simulation experiment.
9. To study the antiallergic effects of drugs using mast cell degranulation assay using interactive computer simulated experiment.
10. Evaluation of diuretic activity of drugs in rats using metabolic cages (simulation) and estimation of electrolytes in the urine samples/serum using flame photometer/commercially available kits.
11. Evaluation of effects of antihistaminic drugs on the histamine-induced bronchospasm in guinea pigs using interactive simulated experiment.
12. To study and analyse drug-drug interaction/ rational drug management of asthma with the help of Case Study/ hypothetical data/ any clinical report.
13. To study clinical pharmacology of the plasma volume expanders and their importance (using charts/open sources videos).
14. Evaluation of anti-inflammatory activity in paw oedema model using plethysmometer.
15. Concept of Biobanking and its significance in drug screening
16. Determination of protein concentrations using Bradford reagent and plotting of standard curve of bovine serum albumin.

Textbooks

1. Fundamentals of Experimental Pharmacology. Ghosh MN. Publisher: Hilton & Company, Kolkata.
2. Handbook of experimental pharmacology. Kulkarni SK. Publisher: Vallabh Prakashan.
3. Practical Pharmacology, Goyal RK. Publisher: B. S. Shah Publisher805. OECD guidelines for toxicity and SaCAIIIy Pharmacology

Guidelines

1. Organisation for Economic Co-operation and Development (OECD) Guidelines for Toxicity and Safety Pharmacology
2. ICH guideline 7A and 7B.

Software

1. Ex-Pharm software
2. CAL software package

Course code	Course name	Teaching scheme (Hr/week)			Credits assigned		
UCRPC406	Clinical Sampling and Analytical Techniques Lab	Theory	Practical	Tutorial	Theory	Practical	Tutorial
		-	02	-	-	1	-

Course code	Course name	Evaluation scheme (In semester)					Semester end exam (SEE)			Total (Marks)
UCRPC406	Clinical Sampling and Analytical Techniques Lab	CAI	CAII	CAIII	Total	Internal Assessment*	ESE*	Term work*/ Tutorial	Pract* Oral/ POE	
		-	-	-	-	-	-	25	-	25

Course Description

This course covers clinical sampling workflows, biosafety, and laboratory practices across pre-analytical, analytical, and post-analytical phases. It includes sample handling, analytical techniques, quality systems, and data interpretation. The course also introduces molecular diagnostics, lab automation, and emerging trends such as AI and precision diagnostics.

Pre-requisite

Basic knowledge of Biology and Biochemistry.

Course Objectives:

1. To introduce clinical sampling workflows, biosafety practices, and ethical considerations in laboratory settings.
2. To develop understanding of pre-analytical variables, sample collection, processing, and management systems.
3. To provide knowledge of analytical techniques, instrumentation, and molecular diagnostic methods.
4. To train students in quality control, validation, and interpretation of laboratory data.
5. To familiarize students with advanced diagnostic technologies and emerging trends in clinical diagnostics.

Course outcome(s):

After successful completion of this course, students will able to

CO1 **Outline**[3] clinical laboratory workflow and **apply** biosafety and ethical practices in sample handling.

CO2 **Summarize**[2] pre-analytical variables and **classify** procedures for sample collection, processing, storage, and transport.

CO3 **Apply**[3] principles of analytical techniques and **operate** basic laboratory instruments and diagnostic methods.

CO4 **Utilize**[4] quality control tools and **interpret** laboratory data using validation and accreditation standards.

CO5 **Analyze**[4] advanced diagnostic methods and **evaluate** emerging technologies such as AI, omics, and precision medicine.

Module	Unit	Description	Hours
1.0		**Clinical Sampling Workflow & Biosafety**	**9**
	1.1	Overview of clinical laboratory workflow: pre-analytical, analytical, post-analytical phases Role of clinical sampling in diagnosis and research	
	1.2	Biosafety levels, infection control, and waste disposal Ethical considerations and informed consent	
	1.3	Types of samples: blood, urine, saliva, tissue, microbiological specimens Modern collection practices (vacutainers, micro-sampling, dried blood spots)	
2.0		**Pre-Analytical Variables & Sample Management**	**9**
	2.1	Pre-analytical errors and their impact on diagnosis Sample collection devices: anticoagulants, preservatives, additives	
	2.2	Sample processing: centrifugation, aliquoting, labeling Storage conditions (short-term vs long-term, biobanking concepts)	
	2.3	Transport logistics and cold chain management Introduction to Laboratory Information Systems (LIS)	
3.0		**Analytical Techniques & Instrumentation**	**9**
	3.1	Principles of clinical analytical techniques: Spectrophotometry, immunoassays, chromatography (basic concept) Hematology and biochemistry analyzers (automation in labs)	
	3.2	Molecular diagnostics: PCR, RT-PCR, basics of sequencing Immunological techniques (ELISA, rapid tests)	
	3.3	Point-of-care testing (POCT) devices Introduction to lab automation and robotics	
4.0		**Quality Systems, Validation & Data Interpretation**	**9**
	4.1	Quality control tools (Levey–Jennings charts, Westgard rules) Internal and external quality assurance programs	
	4.2	Method validation and verification Instrument calibration and maintenance	
	4.3	Accreditation standards (ISO/NABL concepts) Interpretation of laboratory data (reference ranges, sensitivity, specificity)	
5.0		**Advanced Diagnostics & Emerging Trends**	**9**
	5.1	Advanced molecular diagnostics: NGS overview Biosensors and wearable diagnostic devices	
	5.2	AI and machine learning in clinical diagnostics Digital health and tele-diagnostics	
	5.3	Omics technologies: genomics, proteomics, metabolomics Future trends: personalized medicine and precision diagnostics	

Textbooks

1. Textbook on Clinical Research A Guide for Aspiring Professionals and Professionals, Guru Prasad Mohanta, Prabal Kumar Manna, Pharmamed Press / OM Publications
2. Bishop, M.L., 2020. Clinical Chemistry: Principles, Techniques, and Correlations. Publisher: Jones & Bartlett Learning.
3. Kawthalkar, S.M., 2020. *Essentials of Clinical Pathology*. Publisher: Jaypee Brothers Medical Publishers.
4. Textbook of Clinical Research, Vikas Dhikav, AITBS Publishers India

Reference books

1. Krishnan, K. (Ed.), 2023. *PGI Textbook of Laboratory & Clinical Hematology*. Publisher: Bhalani Medical Book House.

Internal Assessment (CAI, CAII and CAIII):

1. CAI should be based on first two modules and CAII should be based on next two modules, for 10 marks each.
2. CA III shall be assessed for 5 marks separately.

End Semester Examination:

1. Question paper will be of 50 marks comprise of 5 questions, each carrying 10 marks.
2. The duration of end semester examination shall be two hours.
3. The students need to solve all 5 questions.
4. Question No.1 will be compulsory and based on entire syllabus.
5. Remaining question (Q.2 to Q.5) will be selected from all the modules.

Course code	Course name	Teaching scheme (Hr/week)			Credits assigned		
UCRSE401	Medical Writing	Theory	Practical	Tutorial	Theory	Practical	Tutorial
		2	-	-	2	-	-

Course code	Course name	Evaluation scheme (In semester)					Semester end exam (SEE)		Total (Marks)
UCRSE401	Medical Writing	CAI	CAII	CAIII	Total	Min pass	Marks	Min pass	
		-	10	5	15	40%	35	40%	50

Course Description

This course introduces medical writing and clinical research documentation, including clinical trial fundamentals, ICH-GCP guidelines, and Indian regulations. It covers protocol development, key clinical documents, and regulatory tools such as the Clinical Trials Registry of India (CTRI) and SUGAM portal under CDSCO.

Pre-requisite

Basic knowledge of Pharmacology, Clinical Research, and good written communication skills.

Course Objectives:

1. To introduce the fundamentals, scope, and types of medical writing and the role of medical writers in clinical research.
2. To develop understanding of clinical trial documentation and regulatory guidelines including ICH-GCP and NDCT Rules 2019.
3. To train students in clinical trial planning and preparation of protocol synopsis and related documents.
4. To enable students to design and develop clinical trial protocols and Investigator's Brochure.
5. To familiarize students with regulatory tools, clinical trial registries, and approval processes in India.

Course outcomes:

After successful completion of this course, students will able to

CO1 **Classify**[2] types of medical writing and **outline** the role of medical writers in clinical research.

CO2 **Interpret**[3] clinical trial documents and apply ICH-GCP and NDCT 2019 guidelines in documentation practices.

CO3 **Prepare**[3] clinical trial planning documents including schedule of assessments and protocol synopsis.

CO4 **Develop**[4] clinical trial protocols and construct Investigator's Brochure for drug trials.

CO5 **Utilize**[4] regulatory tools such as CTRI and SUGAM portal and analyze the drug approval process in India.

Module	Unit	Description	Hours
1.0		**Introduction to Medical Writing**	**6**
	1.1	Definition, scope, and importance of medical writing. Essential Skillsets for medical writing.	
	1.2	Types of medical writing (regulatory, scientific, clinical)	
	1.3	Role of medical writers & overview of clinical trials	
2.0		**Clinical Research Fundamentals**	**6**
	2.1	Structure and components of clinical trial documents	
	2.2	ICH-GCP guidelines & NDCT rule 2019	
3.0		**Clinical Trial Planning and Documentation**	**6**
	3.1	Schedule of Assessment preparation	
	3.2	Elements of protocol synopsis	
	3.3	Protocol synopsis for drug trials	
4.0		**Protocol Development**	**6**
	4.1	Structure of clinical trial protocols	
	4.2	Protocol writing for drug trials	
	4.4	Development of Investigators Brochure	
5.0		**Regulatory and Research Tools**	**6**
	5.1	Clinical Trials Registry India (CTRI)	
	5.2	Therapeutic indication-based trial identification	
	5.3	Regulatory framework in India	
	5.4	DCGI approval process, SUGAM portal registration	

Textbooks

1. Medical Writing: A Guide for Clinicians, Educators, and Researchers by Robert B. Taylor
2. Essentials of Clinical Research by Stephen P. Glasser

Reference books/Guidelines

1. ICH-GCP Guidelines (E6 R2) – Official guideline document
2. Clinical Trials: A Practical Guide to Design, Analysis, and Reporting by Duolao Wang and Ameet Bakhai
3. DCGI Guidelines and CDSCO Regulatory Documents (India)
4. ClinicalTrials.gov Glossary: https://clinicaltrials.gov/cCAII/about-studies/glossary
5. The full DHHS organizational chart: http://www.hhs.gov/about/orgchart/
6. UT Southwestern Human Research Protection Program (HRPP) Website: https://www.utsouthwestern.edu/research/hrpp/

Internal Assessment (CAI, CAII and CAIII):

1. CAII should be based on First to Fourth modules, for 10 marks each.
2. CA III shall be assessed for 5 marks separately.

End Semester Examination:

1. Question paper will be of 35 marks comprise of 5 questions, each carrying 07 marks.
2. The duration of end semester examination shall be two hours.
3. The students need to solve all 5 questions.
4. Question No.1 will be compulsory and based on entire syllabus.
5. Remaining question (Q.2 to Q.5) will be selected from all the modules.

Course code	Course name	Teaching scheme (Hr/week)			Credits assigned		
UCRVS401	Healthcare administration	Theory	Practical	Tutorial	Theory	Practical	Tutorial
		2	-	-	2	-	-

Course code	Course name	Evaluation scheme (In semester)					End semester exam (ESE)		Total (Marks)
UCRVS401	Healthcare administration	CAI	CAII	CAIII	Total	Min pass	Marks	Min pass	
		-	10	5	15	40%	35	40%	50

Course Description

This course provides an integrated understanding of healthcare systems, hospital administration, and their interface with the clinical research environment. It covers the structure and functioning of healthcare delivery in India and globally, including public, private, and trust sectors. The course emphasizes hospital operations, site management in clinical research, quality assurance, accreditation, and regulatory compliance. It also introduces healthcare finance, human resource management, and emerging digital health technologies such as Health Informatics and Artificial Intelligence in Healthcare. Students will gain practical insights into managing healthcare facilities and supporting clinical research activities efficiently.

Pre-requisite

Basics of Healthcare Management, Basic computer skills and understanding of digital systems.

Course Objectives:

1. To understand the structure and functioning of healthcare systems relevant to clinical research settings.
2. To develop knowledge of hospital administration and clinical research site management.
3. To familiarize students with healthcare regulations, quality standards, and accreditation systems applicable to research and hospitals.
4. To introduce concepts of healthcare operations, finance, and human resource management in clinical environments.
5. To create awareness about digital health technologies, data management, and their role in clinical research.

Course outcome(s):

After successful completion of this course, students will able to

CO1 **Classify**[2] the healthcare system and its role in clinical research and patient care.

CO2 **Apply**[3] principles of the management of hospitals and clinical research sites.

CO3 **Analyze**[4] quality standards, accreditation, and regulatory requirements in healthcare settings.

CO4 **Evaluate**[5] financial, operational, and human resource functions in healthcare organizations.

CO5 **Assess**[5] the role of health informatics, digital health, and emerging technologies in healthcare and clinical research.

Module	Unit	Description	Hours
1.0		**Healthcare Systems and Clinical Research Environment**	**6**
	1.1	Overview of healthcare systems (India and global) Structure of healthcare delivery: primary, secondary, tertiary care	
	1.2	Public vs private vs Trust healthcare sector	
	1.3	Introduction to clinical research environment in hospitals Role of healthcare administrators in clinical research	
2.0		**Hospital Administration and Site Management**	**6**
	2.1	Hospital organization and departmental structure, Functions of hospital administration	
	2.2	Clinical research site management (roles of CRC, CRA, PI)	
	2.3	Patient flow and hospital operations Inventory and logistics management	
3.0		**Quality Assurance, Accreditation and Regulations**	**6**
	3.1	Quality assurance and quality control in healthcare Patient saCAIIIy and risk management	
	3.2	Accreditation bodies: National Accreditation Board for Hospitals & Healthcare Providers, Hospital laboratory bodies (NABL, ISO etc.) and accreditation certification	
	3.3	Introduction to Good Clinical Practice (GCP) Clinical audit and regulatory compliance in research	
4.0		**Healthcare Finance and Human Resource Management**	**6**
	4.1	Basics of healthcare finance and budgeting	
	4.2	Hospital billing and insurance systems Cost management in healthcare	
	4.3	Human resource management in hospitals and research sites Training and performance evaluation	
5.0		**Regulatory Aspects and Health Applications**	**6**
	5.1	Health informatics and Hospital Information Systems (HIS)	
	5.2	Electronic Health Records (EHR) in clinical research Telemedicine and digital health in India	
	5.3	Role of AI and data analytics in healthcare Emerging trends: personalized medicine, wearable devices	

Textbooks

1. Sunder Lal, Adarsh, Pankaj, 2022. *Textbook of Community Medicine*. Publisher: CBS Publishers & Distributors.
2. Goel, S.L., Kumar, R., 2018. *Hospital Administration and Management*. Publisher: Deep & Deep Publications.
3. Gupta, S.K., 2017. *Fundamentals of Clinical Research*. Publisher: CBS Publishers & Distributors.

Reference Books

1. Francis, C.M., 2014. *Hospital Administration*. Publisher: Jaypee Brothers Medical Publishers.

Internal Assessment (CAI, CAII and CAIII):

1. CAII should be based on First to Fourth modules, for 10 marks each.
2. CA III shall be assessed for 5 marks separately.

End Semester Examination:

1. Question paper will be of 35 marks comprise of 5 questions, each carrying 07 marks.
2. The duration of end semester examination shall be two hours.
3. The students need to solve all 5 questions.
4. Question No.1 will be compulsory and based on entire syllabus.
5. Remaining question (Q.2 to Q.5) will be selected from all the modules.

Course code	Course name	Teaching scheme (Hr/week)			Credits assigned		
UCRPE411	Data Analytics for Clinical Research	Theory	Practical	Tutorial	Theory	Practical	Tutorial
		03	-	01	03	-	01

Course code	Course name	Evaluation scheme (In semester)						Semester end exam (SEE)		Total (Marks)
		CAI	CAII	CAIII	Total	Min pass	Term Work/ Tutorial	Marks	Min pass	
UCRPE411	Data Analytics for Clinical Research	10	10	5	25	40%	25	50	40%	100

Course Description

This course introduces students to the principles and applications of data analytics in clinical research. It covers data collection, cleaning, management, statistical analysis, and interpretation of clinical data using modern analytical tools. Emphasis is placed on real-world clinical datasets, regulatory standards, and evidence-based decision-making to support clinical trials and healthcare research.

Pre-requisite

Basic knowledge of statistics and fundamentals of clinical research methodology.

Course Objectives:

1. To understand the role of data analytics in clinical research and trial processes.
2. To develop skills in clinical data collection, cleaning, and management.
3. To apply statistical and analytical techniques to clinical datasets.
4. To interpret analytical results for clinical decision-making.
5. To familiarize students with regulatory standards and ethical considerations in clinical data handling.

Course outcome(s):

After successful completion of this course, students will able to

CO1 **State**[2] concepts of data analytics in clinical research

CO2 **Demonstrate**[3] data cleaning and management techniques

CO3 **Apply**[3] statistical tools to analyze clinical data

CO4 **Interpret**[4] and evaluate analytical results in clinical contexts

CO5 **Assess**[5] regulatory and ethical issues in clinical data analytics

Module	Unit	Description	Hours
1.0		**Introduction to Clinical Data Analytics**	**9**
	1.1	Overview of clinical research and data lifecycle	
	1.2	Role of data analytics in clinical trials	
	1.3	Types of clinical data (structured, unstructured, real-world data)	
2.0		**Data Collection and Management**	**9**
	2.1	Clinical data collection methods (CRFs, EDC systems)	
	2.2	Data cleaning, validation, and quality assurance	
	2.3	Database design and data standards (CDISC, SDTM)	
3.0		**Statistical Foundations for Clinical Data**	**9**
	3.1	Descriptive statistics and data visualization	
	3.2	Probability distributions and hypothesis testing	
	3.3	Regression and correlation analysis	
4.0		**Advanced Analytics and Tools**	**9**
	4.1	Introduction to tools (R, Python, SAS basics)	
	4.2	Predictive analytics and machine learning basics	
	4.3	Data visualization dashboards for clinical insights	
5.0		**Interpretation, Reporting, and Ethics**	**9**
	5.1	Interpretation of clinical results and outcomes	
	5.2	Clinical study reports and data presentation	
	5.3	Regulatory guidelines (ICH-GCP, FDA) and data ethics	

Tutorial Activities

1. Hands-on analysis of sample clinical datasets using Excel/R
2. Case study discussions on clinical trial data interpretation
3. Data cleaning and visualization exercises
4. Mini project: Analyze and present a mock clinical dataset
5. Group discussion on ethical issues in data handling

Textbooks

1. Clinical Data Management" by Susanne Prokscha
2. "Practical Guide to Clinical Data Management" by Susanne Prokscha

Reference books

1. "Statistical Methods for Rates and Proportions" by Joseph L. Fleiss
2. **"**Design and Analysis of Clinical Trials" by Shein-Chung Chow & Jen-Pei Liu

Internal Assessment (CAI, CAII and CAIII):

1. CAI should be based on first two modules and CAII should be based on next two modules, for 10 marks each.
2. CA III shall be assessed for 5 marks separately.

End Semester Examination:

1. Question paper will be of 50 marks comprise of 5 questions, each carrying 10 marks.
2. The duration of end semester examination shall be two hours.
3. The students need to solve all 5 questions.
4. Question No.1 will be compulsory and based on entire syllabus.
5. Remaining question (Q.2 to Q.5) will be selected from all the modules.

Course code	Course name	Teaching scheme (Hr/week)			Credits assigned		
		Theory	Practical	Tutorial	Theory	Practical	Tutorial
UCRPE421	Clinical Trials of Pharmaceuticals	03	-	01	03	-	01

Course code	Course name	Evaluation scheme (In semester)						Semester end exam (SEE)		Total (Marks)
		CAI	CAII	CAIII	Total	Min pass	Term Work/ Tutorial	Marks	Min pass	
UCRPE421	Clinical Trials of Pharmaceuticals	10	10	5	25	40%	25	50	40%	100

Course Description

This course provides a comprehensive understanding of the principles, design, conduct, and analysis of clinical trials for pharmaceutical products. It covers the full clinical development process from early-phase studies to post-marketing surveillance, along with regulatory, ethical, and quality considerations. The course emphasizes practical aspects of trial design, data interpretation, safety monitoring, and global regulatory requirements to prepare students for roles in clinical research and the pharmaceutical industry.

Pre-requisite

Basic knowledge of pharmacology and fundamentals of clinical research methodology.

Course Objectives:

1. To understand the fundamentals and phases of pharmaceutical clinical trials.
2. To examine regulatory and ethical requirements governing clinical research.
3. To analyze clinical trial designs, methodologies, and endpoints.
4. To apply principles of safety monitoring, data management, and quality assurance.
5. To interpret and evaluate clinical trial data for informed decision-making.

Course outcome(s):

After successful completion of this course, students will able to

CO1 **State**[2] the phases and processes of pharmaceutical clinical trials

CO2 **Recognize**[2] regulatory and ethical frameworks in clinical research

CO3 **Analyze**[4] different clinical trial designs and methodologies

CO4 **Apply**[3] safety, quality, and data management principles in trials

CO5 **Evaluate**[5] clinical trial data and outcomes for decision-making

Module	Unit	Description	Hours
1.0		**Introduction to Pharmaceutical Clinical Trials**	**9**
	1.1	Drug development process: preclinical to clinical phases	
	1.2	Phases of clinical trials (Phase I–IV) and objectives	
	1.3	Roles and responsibilities of stakeholders (sponsors, investigators, CROs)	
2.0		**Regulatory and Ethical Considerations**	**9**
	2.1	Regulatory authorities: FDA, EMA, CDSCO and approval processes	
	2.2	ICH-GCP guidelines and informed consent process	
	2.3	Ethics committees/IRB, patient rights, and safety oversight	
3.0		**Clinical Trial Design and Methodology**	**9**
	3.1	Types of study designs: randomized, controlled, blinded trials	
	3.2	Sampling methods, randomization, and bias control	
	3.3	Endpoints, outcome measures, and protocol development	
4.0		**Safety Monitoring and Quality Assurance**	**9**
	4.1	Adverse events (AE), serious adverse events (SAE), pharmacovigilance	
	4.2	Risk management and safety reporting	
	4.3	Quality assurance, audits, and inspections in clinical trials	
5.0		**Data Management, Analysis, and Reporting**	**9**
	5.1	Clinical data collection, management systems, and documentation	
	5.2	Statistical analysis and interpretation of trial results	
	5.3	Clinical study reports, publication, and post-marketing surveillance	

Tutorial Activities

1. Case study analysis of a Phase III clinical trial
2. Drafting informed consent forms
3. Protocol review and critique
4. Data interpretation exercises

Textbooks

1. Principles and Practice of Clinical Trial Medicine – Richard Chin & Bruce Y. Lee
2. Fundamentals of Clinical Trials – Lawrence M. Friedman, Curt D. Furberg, David L. DeMets

Reference books

1. Clinical Trials: A Practical Guide to Design, Analysis, and Reporting – Duolao Wang & Ameet Bakhai
2. Good Clinical Practice: A Question & Answer Reference Guide – Barnett International

Internal Assessment (CAI, CAII and CAIII):

1. CAI should be based on first two modules and CAII should be based on next two modules, for 10 marks each.
2. CA III shall be assessed for 5 marks separately.

End Semester Examination:

1. Question paper will be of 50 marks comprise of 5 questions, each carrying 10 marks.
2. The duration of end semester examination shall be two hours.
3. The students need to solve all 5 questions.
4. Question No.1 will be compulsory and based on entire syllabus.
5. Remaining question (Q.2 to Q.5) will be selected from all the modules.

Course code	Course name	Teaching scheme (Hr/week)			Credits assigned		
UCRPE431	Quality Assurance in Clinical Research	Theory	Practical	Tutorial	Theory	Practical	Tutorial
		03	-	01	03	-	01

Course code	Course name	Evaluation scheme (In semester)						Semester end exam (SEE)		Total (Marks)
		CAI	CAII	CAIII	Total	Min pass	Term Work/ Tutorial	Marks	Min pass	
UCRPE431	Quality Assurance in Clinical Research	10	10	5	25	40%	25	50	40%	100

Course Description

This course focuses on the principles and practices of quality assurance (QA) in clinical research. It provides a comprehensive understanding of regulatory requirements, Good Clinical Practice (GCP), auditing processes, risk management, documentation standards, and quality systems in clinical trials. The course emphasizes ensuring data integrity, subject safety, and compliance with national and international regulatory guidelines.

Pre-requisite

Fundamentals of Clinical Research, pharmacology and clinical trials.

Course Objectives:

1. To understand the principles and importance of quality assurance in clinical research.
2. To familiarize students with international regulatory guidelines and GCP standards.
3. To develop knowledge of auditing, monitoring, and inspection processes.
4. To understand risk management and quality management systems in clinical trials.
5. To enhance skills in documentation, reporting, and compliance in clinical research.

Course outcome(s):

After successful completion of this course, students will able to

CO1 **Summarize**[2] principles of quality assurance and Good Clinical Practice in clinical research

CO2 **Interpret**[2] regulatory requirements and ethical guidelines governing clinical trials

CO3 **Implement**[3] quality assurance procedures in monitoring, auditing, and inspection processes

CO4 **Examine**[4] deviations, risks, and quality management systems in clinical trials

CO5 **Assess**[5] compliance and construct quality assurance documentation and reports

Module	Unit	Description	Hours
1.0		**Introduction to Quality Assurance in Clinical Research**	**9**
	1.1	Concept of Quality Assurance (QA) and Quality Control (QC), Importance of QA in clinical trials.	
	1.2	Principles of Good Clinical Practice (GCP).	
	1.3	Overview of International Council for Harmonisation-GCP guidelines, Roles and responsibilities of sponsor, investigator, CRO.	
2.0		**Regulatory and Ethical Framework**	**9**
	2.1	Regulatory requirements: Central Drugs Standard Control Organization (CDSCO), Food and Drug Administration, European Medicines Agency	
	2.2	Schedule Y and Indian regulatory requirements, Ethics Committee (IEC/IRB): composition and functions	
	2.3	Informed Consent Process (ICP), Patient safety and rights	
3.0		**Quality Management Systems (QMS)**	**9**
	3.1	Elements of QMS in clinical research	
	3.2	Standard Operating Procedures (SOPs): development and implementation, Risk-based quality management	
	3.3	Corrective and Preventive Actions (CAPA), Training and documentation systems.	
4.0		**Monitoring, Auditing, and Inspection**	**9**
	4.1	Clinical trial monitoring: types and techniques, Role of Clinical Research Associate (CRA).	
	4.2	Audit process: internal and external audits	
	4.3	Regulatory inspections, Handling audit findings and compliance.	
5.0		**Documentation, Data Integrity, and Risk Management**	**9**
	5.1	Essential documents in clinical trials (Trial Master File), ALCOA principles (data integrity)	
	5.2	Handling protocol deviations and violations, Risk management in clinical trials	
	5.3	Quality metrics and continuous improvement	

Tutorial Activities

1. Case studies on audit findings
2. Preparation of SOPs
3. Mock audit and inspection exercises
4. Review of informed consent forms
5. Deviation and CAPA report preparation

Textbooks

1. S. K. Gupta – Fundamentals of Clinical Research 2007). Jaypee Brothers Medical Publishers Pvt. Ltd.
2. Mukesh S. Bhatt – Quality Assurance in Clinical Trials

Reference books

1. Gallin J.I., Ognibene F.P. – *Principles and Practice of Clinical Research*, Academic Press (Elsevier), 2007

Internal Assessment (CAI, CAII and CAIII):

1. CAI should be based on first two modules and CAII should be based on next two modules, for 10 marks each.
2. CA III shall be assessed for 5 marks separately.

End Semester Examination:

1. Question paper will be of 50 marks comprise of 5 questions, each carrying 10 marks.
2. The duration of end semester examination shall be two hours.
3. The students need to solve all 5 questions.
4. Question No.1 will be compulsory and based on entire syllabus.
5. Remaining question (Q.2 to Q.5) will be selected from all the modules.

Course code	Course name	Teaching scheme (Hr/week)			Credits assigned		
UCRPE321	Clinical Trials of Biotech Products	Theory	Practical	Tutorial	Theory	Practical	Tutorial
		03	-	01	03	-	01

Course code	Course name	Evaluation scheme (In semester)						Semester end exam (SEE)		Total (Marks)
		CAI	CAII	CAIII	Total	Min pass	Term Work/ Tutorial	Marks	Min pass	
UCRPE321	Clinical Trials of Biotech Products	10	10	5	25	40%	25	50	40%	100

Course Description

This course provides a comprehensive understanding of clinical development, regulation, and evaluation of biotechnology-derived products including biologics, biosimilars, and vaccines. It covers clinical trial phases, study design considerations, immunogenicity, biomarkers, and adaptive trial methodologies. The course also emphasizes regulatory requirements from agencies such as the Central Drugs Standard Control Organization and U.S. Food and Drug Administration, along with global guidelines for biologics and vaccines. Students will gain knowledge of post-marketing surveillance, real-world evidence generation, and pharmacovigilance practices essential for modern biotechnology clinical research.

Pre-requisite

Fundamentals of Clinical Research, Basic Pharmacology.

Course Objectives:

1. To understand the fundamentals of biotechnology products including biologics, biosimilars, and vaccines.
2. To analyze clinical trial phases and design considerations specific to biotech products.
3. To apply regulatory guidelines for clinical development and approval of biologics and vaccines.
4. To evaluate immunogenicity, biomarkers, and pharmacovigilance aspects in biotech clinical trials.
5. To interpret post-marketing surveillance data and real-world evidence in biotechnology research.

Course outcome(s):

After successful completion of this course, students will able to

CO1 **Classify**[2] biotechnology products and differentiate between biologics, biosimilars, vaccines, and small-molecule drugs..

CO2 **Analyze**[4] clinical trial designs for biotechnology products including dose escalation, adaptive designs, and pharmacokinetic considerations..

CO3 **Apply**[3] regulatory guidelines from agencies such as Central Drugs Standard Control Organization and U.S. Food and Drug Administration for biologics and vaccine development.

CO4 **Evaluate**[5] immunogenicity, biomarkers, and pharmacovigilance data for biotechnology-derived products.

CO5 **Assess**[5] post-marketing surveillance data and real-world evidence to support safety and effectiveness of biotech products.

Module	Unit	Description	Hours
1.0		**Introduction to Biotech Products and Clinical Trials**	**9**
	1.1	Introduction to biotechnology products (biologics, biosimilars, vaccines)	
	1.2	Differences between biologics and small-molecule drugs Overview of clinical trial phases (Phase I–IV)	
	1.3	Challenges in clinical trials of biotech products Role of biotechnology in modern therapeutics	
2.0		**Regulatory Framework and Guidelines**	**9**
	2.1	Regulatory authorities: Central Drugs Standard Control Organization, Food and Drug Administration	
	2.2	Guidelines for biologics, biosimilars & Vaccines (India and global) Good Clinical Practice (GCP) in biotech trials	
	2.3	Regulatory submission process for biologics Ethics and approval procedures	
3.0		**Biologics & Clinical Trial Design**	**9**
	3.1	Study design considerations for biologics	
	3.2	Dose escalation and pharmacokinetics of biologics Immunogenicity assessment and antibody response	
	3.3	Biomarkers and surrogate endpoints	
	3.4	Pharmacovigilance of biologics	
	3.5	Adaptive clinical trial designs	
4.0		**Post-Marketing Studies**	**9**
	4.1	Post-marketing surveillance (Phase IV studies)	
	4.2	Real-world evidence and saCAIIIy monitoring Future trends in biotech clinical research	
5.0		**Fundamental of Biosimilars, and Vaccines**	**9**
	5.1	Introduction to Biosimilars & Vaccines	
	5.2	Regulatory & quality aspect in Vaccine development	
	5.3	Applications & clinical importance	

Textbooks

1. Gupta, S.K., 2017. Fundamentals of Clinical Research. Publisher: CBS Publishers & Distributors.
2. Tripathi, K.D., 2023. Essentials of Medical Pharmacology. Publisher: Jaypee Brothers Medical Publishers.
3. Bansal, A.K., 2019. Pharmaceutical Biotechnology. Publisher: CBS Publishers & Distributors.
4. Dubey, R.C., 2018. A Textbook of Biotechnology. Publisher: S. Chand Publishing.

Reference books

1. Nair, S.C., 2020. Biotechnology and Clinical Research. Publisher: PharmaMed Press (India).

Internal Assessment (CAI, CAII and CAIII):

1. CAI should be based on first two modules and CAII should be based on next two modules, for 10 marks each.
2. CA III shall be assessed for 5 marks separately.

End Semester Examination:

1. Question paper will be of 50 marks comprise of 5 questions, each carrying 10 marks.
2. The duration of end semester examination shall be two hours.
3. The students need to solve all 5 questions.
4. Question No.1 will be compulsory and based on entire syllabus.
5. Remaining question (Q.2 to Q.5) will be selected from all the modules.

List of Co-curricular courses I & II	
Course Code	**Course Name**
UISCC011	National Service Scheme
UISCC012	Regular and Special NSS Camp Activity
UISCC021	Indian Music
UISCC022	Fine Arts
UISCC023	Indian Dance
UISCC031	Physical Fitness
UISCC032	Yoga & Meditation

Program Electives						
Program Elective	**Vertical I (Clinical Data Science and Analytics)**		**Vertical II (Clinical Trials of Biotech Products, Pharmaceuticals, & Medical Devices)**		**Vertical III (Clinical Research Operations & Entrepreneurship)**	
	Code	**Course**	**Code**	**Course**	**Code**	**Course Name**
I	UCRPE311	Clinical Data Management & Standards	UCRPE321	Clinical Trials of Biotech Products	UCRPE331	CRO Operations & Business Model
II	UCRPE411	Data Analytics for Clinical Research	UCRPE421	Clinical Trials of Pharmaceuticals	UCRPE431	Quality Assurance in Clinical Research
III	UCRPE511	Clinical SAS programming	UCRPE521	Clinical Trials of Medical Devices & Diagnostics	UCRPE531	Intellectual Property Right (IPR)
IV	UCRPE711	Artificial Intelligence in Clinical Research	UCRPE721	Cross-cutting Trial Management & Compliance	UCRPE731	Entrepreneurship in Healthcare

Open Elective I				
No.	**Course Code**	**Course**	**Faculty/School /Department**	**Credits**
1	UAEOE011	Basic Aeronautical Engineering	Department of Aerospace Engg.	2
2	UAIOE011	Software Models	Department of AIML	2
3	UCEOE011	Advanced Building Materials	Department of Civil Engg.	2
4	UCSOE011	Introduction to Latex	Department of Comp. Sc. & Engg.	2
5	UECOE011	Semiconductor Devices	Department of Elect. & Comm. Engg.	2
6	UCAOE012	Python Programming	School of Computer Applications	2
7	UPHOE011	World of Nano Science	School of Physical & Chemical Sciences	2
8	UFSOE012	Basics of Food Processing	Department of Food Science & Technology	2
9	UDCOE011	Selling Skills	Department of Commerce	2
10	UBAOE011	Basics of Marketing	Department of Management	2
11	UAROE011	Introduction To GIS	Department of Social Sciences	2
12	UAROE012	Applied Communicative English	Department of Social Sciences	2
13	UBTOE011	Introduction to Biotechnology	Department of Bio Technology	2
Open Elective II				
1	UAEOE021	Aircraft Systems and Instruments	Department of Aerospace Engg.	2
2	UAIOE021	Introduction to Python	Department of AIML	2
3	UCEOE021	Green Building	Department of Civil Engg.	2
4	UCSOE021	Advance Microsoft Office	Department of Comp. Sc. & Engg.	2
5	UECOE021	Fundamentals of Communication Engineering	Department of Elect. & Comm. Engg.	2
6	UCAOE022	Data Analytics Tools	School of Computer Applications	2
7	UPHOE021	Wonders in Nanotechnology	School of Physical & Chemical Sciences	2
8	UFSOE022	Bakery and Confectionary Skills	Department of Food Science & Technology	2
9	UDCOE021	Financial Literacy	Department of Commerce	2
10	UBAOE021	Export- Import Documentation and Procedures	Department of Management	2
11	UAROE021	Tourism & Travel Management	Department of Social Sciences	2
12	UAROE022	Language Analytics	Department of Social Sciences	2
13	UBTOE021	Basics in Bioinformatics	Department of Bio Technology	2
Open Elective III				
1	UAEOE031	Unmanned Aerial Vehicle	Department of Aerospace Engg.	2
2	UAIOE031	Introduction to Data Analytics	Department of AIML	2
3	UCEOE031	Disaster Management & Mitigation	Department of Civil Engg.	2
4	UCSOE031	Fundamental of C Programming	Department of Comp. Sc. & Engg.	2
5	UECOE031	Automotive Electronics	Department of Elect. & Comm. Engg.	2
6	UCAOE032	Data Visualization Techniques using Tableau	School of Computer Applications	2
7	UCHOE031	Green Chemistry & Sustainability	School of Physical & Chemical Sciences	2
8	UFSOE032	Basics of Food Adulteration	Department of Food Science & Technology	2
9	UDCOE031	Personal Financial Planning	Department of Commerce	2
10	UBAOE031	Event Management	Department of Management	2
11	UAROE031	English for Competitive Examinations	Department of Social Sciences	2
12	UAIOE032	Agentic AI	Department of AIML	2
13	UBTOE031	Microbial World and Its Applications	Department of Bio Technology	2

Note: For details of Syllabus, Teaching and Evaluation scheme, please refer to the structure and syllabus of respective departments.

For B. Sc. Programs

MDM Track: Biotechnology for Health Industry

Course code	Course name	Credits
UBTMM011	Basics in Biotechnology	2
UBTMM021	Biotechnology in Food and Nutritional Sciences	3
UBTMM022	Biotechnology in Food and Nutritional Sciences Lab	1
UBTMM033	Biotechnology in Healthcare	2
UBTMM032	Biotechnology in Healthcare Lab	1
UBTMM043	Industrial Biotechnology	2
UBTMM042	Industrial Biotechnology Lab	1
	Total	**12**

MDM Track: Translational Biotechnology

Course code	Course name	Credits
UBTMM012	Biomolecules & Cellular Systems	2
UBTMM013	Biomolecules & Cell Biology Lab	1
UBTMM023	Immunology, Diagnostics & Clinical Applications	2
UBTMM024	Immunology & Clinical Techniques Lab	1
UBTMM034	Microbial Science & Industrial Applications	2
UBTMM035	Microbiology & Fermentation Lab	1
UBTMM044	Bioanalytical Techniques & Bioinformatics	2
UBTMM045	Analytical & Bioinformatics Lab	1
	Total	**12**

MDM Track: Data Science and Analytics

Course code	Course name	Credits
UCAMM021	Statistical Computing	2
UCAMM027	Statistical Computing Lab	1
UCAMM031	Python for Data Science	2
UCAMM037	Python for Data Science Lab	1
UCAMM041	Foundation Skills of Machine Learning	2
UCAMM047	Foundation Skills of Machine Learning Lab	1
UCAMM051	Predictive Modelling and Analytics	2
UCAMM051	Predictive Modelling and Analytics Lab	1
	Total	**12**

MDM Track: Food Science and Technology

Course code	Course name	Credits
UFSMM012	Fundamentals of Food Science	2
UFSMM013	Fundamentals of Food Science Lab	1
UFSMM023	Processing of Fruits and Vegetables	2
UFSMM024	Processing of Fruits and Vegetables Lab	1
UFSMM033	Basics in Dairy Sciences	2
UFSMM034	Basics in Dairy Sciences Lab	1
UFSMM043	Fundamentals of Bakery Science	2
UFSMM044	Fundamentals of Bakery Science Lab	1
	Total	**12**