



SYLLABUS FOR

B. Sc. Clinical Research

(Three Year Course- Semester System)

OR

B. Sc. (Hons./Hons. with Research) Clinical Research

(Four Year Course-Semester System)

(Effective from Academic Session 2026-2027 Onward)

**School of Applied Sciences
Suresh Gyan Vihar University
Jaipur – 302017 Rajasthan**

OUTCOME BASED EDUCATION

Programme outcomes (POs)

Students will be able to

PO 1	Foundational Knowledge in Clinical Research: Students will possess a strong understanding of clinical research, human biology, pharmacology, biostatistics, and healthcare systems, applying this knowledge in practical settings.
PO2	Problem Identification and Analysis: Students will be able to identify, analyze, and interpret clinical and research-related problems using scientific reasoning.
PO3	Research Design and Development: Students will design and develop clinical studies and research protocols to address healthcare challenges.
PO4	Use of Modern Tools: Students will utilize contemporary tools, software, and technologies such as bioinformatics, data management systems, and statistical tools in clinical research.
PO5	Ethics and Regulatory Compliance: Students will understand ethical principles, regulatory guidelines (GCP, ICMR, FDA), and apply them in clinical trials.
PO6	Project Management and Communication Skills: Students will develop skills in project planning, documentation, teamwork, and scientific communication.
PO7	Career Readiness and Collaboration: Students will explore career opportunities in clinical trials, pharmaceuticals, CROs, and healthcare sectors, working effectively in multidisciplinary teams,
PO8	Lifelong Learning: Students will recognize the importance of continuous learning to keep pace with advancements in clinical research and healthcare technologies.
PO9	Scientific Writing Skills: Students will develop skills in report writing, research documentation, and publication in clinical research.
PO10	Effective Communication: Students will demonstrate clear verbal and written communication skills for interaction with patients, healthcare professionals, and research teams.
PO11	Ethical and Social Responsibility: Students will understand societal needs, patient safety, and ethical responsibilities in clinical research.
PO12	Practical and Interdisciplinary Learning: Students will integrate knowledge from medicine, biology, statistics, and technology to conduct clinical research effectively.

Program Specific Outcomes (PSOs)

PSO 1	Students will gain comprehensive knowledge of clinical research processes, including drug development, clinical trial phases, and regulatory frameworks.
PSO2	Students will develop proficiency in clinical trial management, data analysis, pharmacovigilance, and the use of analytical tools and software.
PSO3	Students will acquire practical skills by conducting clinical studies, handling biological samples, and performing data collection and analysis.
PSO4	Students will be equipped to pursue higher education or careers in clinical research organizations (CROs), pharmaceutical industries, hospitals, and regulatory bodies.
PSO5	Students will demonstrate the ability to critically evaluate clinical data, solve complex research problems, and contribute to advancements in healthcare and medicine.

B.Sc. Clinical Research OR B. Sc (Hons. / Hons. with Research) Clinical Research (3 year OR 4 Year course)

Certification and Duration of Study with Multiple Entry Multiple Exit (MEME)

The undergraduate degree will have a flexible duration of either three or four years, with multiple exit options during this period. The table below outlines the various certifications a student can earn at different stages of their undergraduate study (Table 1).

Table 1. Certification (and Duration) on MEME

Duration of Study	Semesters Completed	Certification Earned
4 years	Eight Semester	Bachelor's Degree (Honours)
		Bachelor's Degree (Honours with Research)
3 years	Six semesters	Bachelor's Degree
2 years	Four semesters	Undergraduate Diploma
1 year	Two Semester	Undergraduate Certificate

In consonance with the National Education Policy (NEP) 2020 and the guidelines of the University Grants Commission (UGC), Multiple Entry and Multiple Exit (MEME) scheme in undergraduate programme of Clinical Research has been implemented. This structure provides students with the flexibility to enter, exit, and re-enter the programme at various stages, each with its corresponding certification as demonstrated in Table 2.

Programme Exit	Credits Required	Additional Requirement	Awarded Qualification	Re-entry to Degree Programme
After Year 1	46	Completion of one 4-credit vocational course / internship/ apprenticeship (in addition to 4 credits from Skill based course) during summer vacation of Year 1	UG Certificate	Within three years of exit
After Year 2	91	Completion of one 4- credit vocational course during summer vacation of Year 2	UG Diploma	Within three years of exit
After Year 3	146	Compliance with minimum credit requirements specified in regulations	3-year UG Degree	Within three years of exit
After Year 4 (Honours)	187	Compliance with credit requirements as specified in regulations	4-year UG Honours Degree	NA

After Year 4 (Honours with Research)	187	75% marks and above in the first six semesters, completion of a research project/dissertation under faculty guidance in the major discipline	4-year UG Honours Degree with Research	NA
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The maximum time in which a student will be allowed to complete the Degree is Seven Years

The undergraduate curriculum will include credit-based courses and projects centred around community engagement, environmental education, and value-based education. Additionally, students will have opportunities for internships with local industries, businesses, artists, craftspeople, as well as research internships with faculty and researchers at their own or other Higher Education Institutions (HEIs)/research institutions. These practical experiences are integral to enhancing students' learning and employability.

Total Notional Learning hours in a year and Assignment for Credits (NCrF, 2023)

For the purpose of calculation under National credit Framework (NCrF), in general, 30 notional learning hours will be counted as one credit. The total notional Learning hours for assignment of credits across higher education and vocational education & training/Skilling have been agreed to be 1200 hrs per year (Table 3).

Thirty notional learning hours will generally be counted as one credit under the National credit Framework. Accordingly, every semester will comprise of minimum 20 credits. Within the parameters of curriculum design, students are also free to take programs, courses, and projects in excess of 40 credits in order to learn more credits. The current UG program have 21-25 credits/semesters.

Table 3: NCrF levels and Credit Assignment in Higher Education

S. o	Examples of higher education Qualifications located within each Level (including science/ arts. Commerce and vocational)	Total learning hours per year	Total credits per year	National Credit Framework (ncrf) Credit Levels	Credits Points
C-1	C-2	C-3	C-4	C-5	C-6(C-4 X C-5)
1.	Undergraduate Certificate Programme duration: first year (first two semesters) of any undergraduate programme	1200	40	4.5	180
2.	Undergraduate Diploma Programme duration: first two years (first four semesters) of any undergraduate programme.	1200	40	5	200
3.	Bachelor's Degree Programme duration: three years (Six semesters) of any undergraduate programme.	1200	40	5.5	220
4.	Bachelor's Degree (Honours/ research/ Engineering). Programme duration: four years (eight semesters) of any undergraduate programme.	1200	40	6	240



School of Applied Science
Teaching and Examination Scheme for
B. Sc Clinical Research
SESSION 2026-27

Year: I

Semester: I (AUTUMN/PAVAS)

S. No.	Course Code	Course Name	Course type	Credits	Contact Hrs/Wk.			Exam Hrs.	Weightage (in%)	
					L	T/S	P		CIE	ESE
A	University Core									
1	SODECA-I	Social Outreach, Discipline & Extra Curriculum Activities -I	AECC	2	0	0	0	0	100	-
2	UC1002	Human Values and Professional Ethics	SEC	Non-Credit	1	0	0	3	100	-
3	UC1003	English Language	AECC	2	2	0	0	3	40	60
4	UC1004	Yoga Education & Practices	SEC	2	0	0	2	-	100	-
5	UC1005	Elementary Computers	SEC	2	2	0	0	3	40	60
B	Program Core									
1	CR1001	Human Anatomy	DCC	3	3	0	0	3	40	60
2	CR1002	Fundamental of Clinical Research	DCC	3	3	0	0	3	40	60
3	CR1003	Community Health and Disease	DCC	3	3	0	0	3	40	60
4	CR1101	Human Anatomy Lab	DCC	2	0	0	3	3	60	40
5	CR1102	Fundamental of Clinical Research Lab	DCC	2	0	0	3	3	60	40
6	CR1103	Community Health and Disease Lab	DCC	2	0	0	3	3	60	40
		TOTAL		23						

NOTE: Non-credit courses (e.g., IKS, Human Values & Professional Ethics, Group Discussion, Aptitude & Reasoning etc.) require minimum 40% passing marks to qualify.

The University Electives are apart from minimum credits required for award of degree.

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**School of Applied Science
Teaching and Examination Scheme for
B. Sc Clinical Research
SESSION 2026 - 27**

Year: I

Semester: II (SPRING/BASANT)

S. No.	Course Code	Course Name	Course type	Credits	Contact Hrs/Wk.			Exam Hrs	Weightage (in%)	
					L	T/S	P		CIE	ESE
A	University Core									
1	SODECA-II	Social Outreach, Discipline & Extra Curriculum Activities-II	AECC	2	0	0	0	0	100	-
2	UC2001	Indian Knowledge System	AECC	Non-credit	2	0	0	-	100	-
3	UC2002	English Communication	AECC	2	2	0	0	3	40	60
4	UC2004	Environmental Studies	AECC	2	2	0	0	3	40	60
5	UCFV	Field Visit-I	SEC	2	0	0	2	-	100	-
B	Program Core									
1	CR2001	Principle of Biochemistry	DCC	3	3	0	0	3	40	60
3	CR2002	Human Physiology	DCC	3	3	0	0	3	40	60
4	CR2003	Fundamental of Biostatistics	GE	3	3	0	0	3	40	60
5	CR2101	Principle of Biochemistry Lab	DCC	2	3	0	0	3	60	40
7	CR2103	Human Physiology Lab	DCC	2	0	0	3	3	60	40
C	Program Electives (Any one)									
1	CR2004	Computer Application and Bioinformatics	DSE	2	0	0	3	3	40	60
2	CR2005	Public Health and Hygiene	DSE	2	0	0	3	3	40	60
D	University Elective									
		Opt from the list of University Electives								
		TOTAL		23						

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Teaching and Examination Scheme for
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SESSION 2026 - 27**

Year: II

Semester: III (AUTUMN/PAVAS)

S. No.	Course Code	Course Name	Course type	Credits	Contact Hrs/Wk.			Exam Hrs.	Weightage (in%)	
					L	T/S	P		CIE	ESE
A	University Core									
1	SODECA-III	Social Outreach, Discipline & Extra Curriculum Activities-III	AECC	2	0	0	0	0	100	-
2	UCEEPI	Election and Electoral Processes in India	SEC	Non-Credit	1	0	0	0	100	-
3	UCFV	Field Visit-II	SEC	2	0	0	2	-	100	-
B	Program Core									
1	CR3001	Pharmacology and Toxicology	DCC	3	3	0	0	3	40	60
2	CR3002	Design and Management of Clinical Trials	DCC	3	3	0	0	3	40	60
3	CR3003	Clinical Sampling and Analytical Techniques	DCC	3	3	0	0	3	40	60
4	CR3004	Critical Thinking and Writing	GE	3	3	0	0	3	40	60
5	CR3101	Pharmacology and Toxicology Lab	DCC	2	3	0	0	3	60	40
6	CR3102	Design and Management of Clinical Trials Lab	DCC	2	0	0	3	3	60	40
7	CR3103	Clinical Sampling and Analytical Techniques Lab	DCC	2	0	0	3	3	60	40
C	Program Electives (Any one)									
1	CR3005	Biosafety Guidelines	DSE	3	3			3	40	60
2	CR3006	Regulatory Aspects in Clinical Research	DSE	3	3			3	40	60
3	CR3007	MOOC (through SWAYAM/NPTEL etc) Under Credit Transfer Scheme	DSE/GE	3	3			3	40	60
D	University Elective									
		Opt from the list of University Electives								
		TOTAL		25						

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SESSION 2026-27

Year: II

Semester: IV (SPRING/BASANT)

S. No.	Course Code	Course Name	Course Type	Credits	Contact Hrs/Wk.			Exam Hrs.	Weightage (in%)	
					L	T/S	P		CIE	ESE
A	University Core									
1	SODECA-IV	Social Outreach, Discipline & Extra Curriculum Activities-IV	AECC	2	0	0	0	0	100	-
B	Program Core									
1	CR4001	Pharmacovigilance	DCC	3	3	0	0	3	40	60
2	CR4002	Clinical Pharmacokinetics	DCC	3	3	0	0	3	40	60
3	CR4003	Bioethics and Drug Safety	DCC	3	3	0	0	3	40	60
4	CR4101	Pharmacovigilance Lab	DCC	2	3	0	0	3	60	40
5	CR4102	Clinical Pharmacokinetics Lab	DCC	2	0	0	3	3	60	40
6	CR4103	Bioethics and Drug Safety Lab	DCC	2	0	0	3	3	60	40
C	Program Electives (Any one)									
1	CR4004	Clinical Pharmacokinetics	DSE	3	3	0	0	3	40	60
2	CR4005	Molecular Diagnostics	DSE	3	3	0	0	3	40	60
3	CR4006	MOOC (through SWAYAM/NPTEL etc) Under Credit Transfer Scheme	DSE/GE	3	3	0	0	3	40	60
D	University Elective									
		Opt from the list of University Electives								
		TOTAL		20						

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Year: III

Semester: V (AUTUMN/PAVAS)

S. No.	Course Code	Course Name	Course type	Credits	Contact Hrs/Wk.			Exam Hrs	Weightage (in%)	
					L	T/S	P		CIE	ESE
A	University Core									
1	SODECA-V	Social Outreach, Discipline & Extra Curriculum Activities-V	AECC	2	0	0	0	0	100	-
2	UCFV	Field Visit-III	SEC	2	0	0	2	-	100	-
3	UC5001	Group Discussion, Aptitude & Reasoning-I	SEC	Non-Credit	0	2	0	3	100	-
B	Program Core									
2	CR5001	Epidemiology and Global Health	DCC	3	3	0	0	3	40	60
3	CR5002	Immunology	DCC	3	3	0	0	3	40	60
4	CR5003	Bioinstrumentation	DCC	3	0	0	3	3	40	60
5	CR5101	Epidemiology and Global Health Lab	DCC	2	0	0	3	3	60	40
6	CR5102	Immunology Lab		2	0	0	3	3	60	40
7	CR5103	Bioinstrumentation Lab	DCC	2	0	0	3	3	60	40
C	Program Electives (Any one)									
1	CR5004	Ayush and Lifestyle	DSE	3	3	0	0	3	40	60
2	CR5005	Site Management Operations	DSE/GE	3	3	0	0	3	40	60
3	CR5006	MOOC (through SWAYAM/NPTEL etc) Under Credit Transfer Scheme	DSE/GE	3	3	0	0	3	40	60
D	University Elective									
		Opt from the list of University Electives								
		TOTAL		22						

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Year: III

Semester: VI (SPRING/BASANT)

S. No.	Course Code	Course Name	Course Type	Credits	Contact Hrs/Wk.			Exam Hrs.	Weightage (in%)	
					L	T/S	P		CIE	ESE
A University Core										
1	SODECA-VI	Social Outreach, Discipline & Extra Curriculum Activities-VI <i>(For B.Sc Hons/Hons. With research)</i>	AECC	2	0	0	0	0	100	-
B Program Core										
1	CR6001	Pharmacotherapeutics	DCC	3	3	0	0	3	40	60
2	CR6002	Biopharmaceutics	DCC	3	3	0	0	3	40	60
3	CR6003	Data Management Technologies	DCC	2	0	0	3	3	40	60
4	CR6101	Pharmacotherapeutics Lab	DCC	2	0	0	3	3	60	40
5	CR6102	Biopharmaceutics Lab	GE	2	0	0	3	3	60	40
6	CR6103	Internship/Minor Project	SEC	6	0	0	3	3	100	-
C Program Electives (Any one)										
1	CR6004	IPR, Bio-entrepreneurship and Bio-business Management	GE	3	3	0	0	3	40	60
2	CR6005	Molecular Modeling and Drug Designing	DSE	3	3	0	0	3	40	60
D University Elective										
		Opt from the list of University Electives								
		TOTAL		23						

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School of Applied Science
Teaching and Examination Scheme for
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SESSION 2026-27

Year: IV

Semester: VII (Autumn/Pavas)

S. No.	Course Code	Course Name	Course type	Credits	Contact Hrs/Wk.			Exam Hrs.	Weightage (in%)	
					L	T/S	P		CIE	ESE
A University Core										
1	SODECA-VII	Social Outreach, Discipline & Extra Curriculum Activities-VII	AECC	2					100	-
2	UC7001	Group Discussion, Aptitude & Reasoning-II	SEC	Non-Credit	0	2	0	3	100	-
B Program Core										
1	CR7001	Good laboratory and Manufacturing Practice	DCC	3	3	-	-	3	40	60
2	CR7002	Emerging Technologies in Clinical Trials	DCC	3	3	-	-	3	40	60
3	CR7003	Research Methodology and Scientific Communication skills	DCC	3	3	-	-	3	40	60
5	CR7101	Emerging Technologies in Clinical Trials Lab	DCC	2	-	-	3	3	60	40
6	CR7102	Good laboratory and Manufacturing Practices Lab	DCC	2	-	-	3	3	60	40
7	CR7103	Project Proposal Preparation and Presentation	GE	3	-	-	3	3	100	—
C Program Electives (any one)										
1	CR7004	Health Economics and Outcome Research	GE/DSE	3	3	-	-	3	40	60
2	CR7005	Epidemiology	GE/DSE	3	3	-	-	3	40	60
D University Elective										
		Opt from the list of University Electives								
		TOTAL		21						

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School of Applied Science
Teaching and Examination Scheme for
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Year: IV

Semester: VIII (Hons.) (Autumn/Pavas)

S. No.	Course Code	Course Name	Course type	Credits	Contact Hrs/Wk.			Exam Hrs	Weightage (in%)	
					L	T/S	P		CIE	ESE
A	University Core									
B	Program Core									
1	CR8001	Computer aided Drug Design (3)	DPR	3	3	-	-	3	40	60
2	CR8002	Entrepreneurship Development (3)	GE	3	3	-	-	3	40	60
3	CR8003	Seminar and Review Paper Writing	SEC	6	-	-	-	-	100	-
4	CR8004	Research Project//Internship (6 Credits)	PRJ	6	-	-	-	-	100	-
C	Program Electives (any one)									
1	CR8005	Global Regulations in Clinical Trials	GE/DSE	3	3	-	-	3	40	60
2	CR8006	Good Clinical Laboratory Practice	GE/DSE	3	3	-	-	3	40	60
D	University Elective									
		Opt from the list of University Electives								
		TOTAL		21						

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Year: IV

Semester: VIII (Autumn/Pavas)

S. No.	Course Code	Course Name	Course type	Credits	Contact Hrs/Wk.			Exam Hrs.	Weightage (in%)	
					L	T/S	P		CIE	ESE
A	University Core									
B	Program Core									
1	CR8001	Seminar and Review Paper Writing	DPR	6	-	-	-	-	100	-
2	CR8002	Research Project (For BSc Honours Students with Research)	PRJ	15	-	-	-	-	100	-
C	Program Electives (any one)									
D	University Elective									
		Opt from the list of University Electives								
		TOTAL		21						

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Programme Structure for B. Sc Clinical Research or B. Sc (Hons./Hons. with Research) Clinical Research

Semester	Discipline Core Courses (Credits) (T+P=3+2; T=3)	Generic Course/Discipline specific Elective (3)	University Core courses	Ability Enhancement compulsory Courses	Skill Enhancement Courses		Total Credits
					Skill based	Value added (Credits) L+T+P	
I	1.CR1001- Human Anatomy (3) 2. CR1002- Fundamental of Clinical Research (3) 3.CR1003- Community Health and Disease (3) 4.CR1101- Human Anatomy Lab (2) 5. CR1102- Fundamental of Clinical Research Lab (2) 6.CR1103- Community Health and Disease Lab (2)		SODECA-I Social Outreach, Discipline & Extra Curriculum Activities -I (2)	1. Human Values and Professional Ethics (Non-credit) 2. English Language (2)	1. Yoga Education & Practices (2) 2. Elementary Computers (2)	Sports (1)	24
II	1. CR2001- Principle of Biochemistry (3) 2. CR2002- Human Physiology (3) 3. CR2003- Fundamental of Biostatistics (3) 4. CR2101- Principle of Biochemistry Lab (2) 5. CR2103- Human Physiology Lab (2)	DSE Course (anyone)- 3 credits: 1. CR2004- Computer Application and Bioinformatics 2. CR2005- Public Health and Hygiene (3)	SODECA-II Social Outreach, Discipline & Extra Curriculum Activities - II (2)	1.UC2001- Indian Knowledge System (Non-credit) 2.UC2002-English Communication (2) 3.UC2004- Environmental Studies (2)	1. UCFV- Field Visit-I (2)	Health and Wellness (1)	25
Exit option with Certificate in Clinical Research (with completion of courses equal to a minimum of 48 credits)							

III	<p>1. CR3001- Pharmacology and Toxicology (3)</p> <p>2. CR3002- Design and Management of Clinical Trials (3)</p> <p>3. CR3003- Clinical Sampling and Analytical Techniques (3)</p> <p>4. CR3004- Critical Thinking and Writing (3)</p> <p>5. CR3101- Pharmacology and Toxicology Lab (2)</p> <p>6. CR3102- Design and Management of Clinical Trials Lab (2)</p> <p>7. CR3103- Clinical Sampling and Analytical Techniques Lab (2)</p>	<p>DSE Course (anyone)- 3 credits:</p> <ul style="list-style-type: none"> • CR3005- Biosafety Guidelines (3) • CR3006- Regulatory Aspects in Clinical Research (3) • CR3007- MOOC (through SWAYAM/ NPTEL etc) Under Credit Transfer Scheme 	<p>SODECA-III Social Outreach, Discipline & Extra Curriculum Activities-III (2)</p>		<p>1. UCEEPI- Election and Electoral Processes in India (Non-credit)</p> <p>2. UCFV- Field Visit-II (2)</p>	-	25
IV	<p>1.CR4001- Pharmacovigilance (3)</p> <p>2. CR4002- Clinical Pharmacokinetics (3)</p> <p>3. CR4003- Bioethics and Drug Safety (3)</p> <p>4. CR4101- Pharmacovigilance Lab (2)</p> <p>5. CR4102- Clinical Pharmacokinetics Lab (2)</p> <p>6. CR4103- Bioethics and Drug Safety Lab (2)</p>	<p>DSE Course (any one)- 3 credits:</p> <ul style="list-style-type: none"> • CR4004-Clinical Pharmacokinetics • CR4005-Molecular Diagnostic • CR4006-MOOC (through SWAYAM/ NPTEL etc) Under Credit Transfer Scheme 	<p>SODECA-IV Social Outreach, Discipline & Extra Curriculum Activities-IV (2)</p>			Sports (1)	21
Exit option with Diploma in Clinical Research (with completion of courses equal to a minimum of 96 credits OR continue with degree)							
V	<p>1. CR5001- Epidemiology and Global Health (3)</p>	<p>DSE Course (any one)- 3 credits:</p> <ul style="list-style-type: none"> • CR5004-Ayush and 	<p>SODECA-V Social</p>	-	<p>1. UCFV- Field Visit-III (2)</p>	-	22

	<p>2. CR5002- Immunology (3)</p> <p>3. CR5003- Bioinstrumentation (3)</p> <p>4. CR5101- Epidemiology and Global Health Lab (2)</p> <p>5. CR5103- Immunology Lab (2)</p> <p>6. CR5104- Bioinstrumentation Lab (2)</p>	<p>Lifestyle</p> <ul style="list-style-type: none"> • CR5005-Site Management and Operation • CR5006-MOOC (through SWAYAM/ NPTEL etc) under Credit Transfer Scheme 	<p>Outreach, Discipline & Extra Curriculum Activities-V (2)</p>		<p>2. UC5001- Group Discussion, Aptitude & Reasoning-I (Non-credit)</p>		
VI	<p>1. CR6001- Pharmacotherapeutics (3)</p> <p>2. CR6002- Biopharmaceutics (3)</p> <p>3. CR6003- Data Management Technologies (2)</p> <p>4. CR6101- Pharmacotherapeutics Lab (2)</p> <p>5. CR6102- Biopharmaceutics Lab (2)</p> <p>6. CR6103- Summer Internship/Minor Project (6)</p>	<p>DSE Course (any one)- 3 credits:</p> <ol style="list-style-type: none"> 1. CR6004- IPR, Bio-entrepreneurship and Bio-business Management 2. CR6005-Molecular Modeling and Drug Designing 	<p>SODECA-VI Social Outreach, Discipline & Extra Curriculum Activities-VI (for B.Sc Clinical Research (Hons./Hons. With research) only) (2)</p>	-		-	23
Exit option with BSc in Clinical Research (with completion of courses equal to a minimum of 140 credits OR continue for Hons/Research)							
VII	<p>1. CR7001- Good laboratory and Manufacturing Practice (3)</p> <p>2. CR7002- Emerging Technologies in Clinical Trials (3)</p> <p>3. CR7003- Research Methodology and Scientific Communication</p>	<p>Open Elective (3 credits):</p> <ol style="list-style-type: none"> 1. CR7004- Health Economics and Outcome Research 2. CR7005- Epidemiology 	<p>SODECA-VII-Social Outreach, Discipline & Extra Curriculum Activities-</p>	-	<p>UC7001-Group Discussion, Aptitude & Reasoning-I (Non-Credit)</p>	-	21

	skills (3) 4. CR7101- Good laboratory and Manufacturing Practice Lab (2) 5. CR7102- Emerging Technologies in Clinical Trials Lab (2) 6. CR7103- Project Proposal Preparation and Presentation (3)		VII (2)				
VIII (for Hons.)	1. CR8001-Computer aided Drug Design (3) 2. CR8002- Entrepreneurship Development (3) 3. CR8004- Seminar and Review Paper Writing (6) 4. CR8004- Research Project//Internship (6 Credits)	DSE Course (any one)- 3 credits: 1. CR8005- Global Regulations in Clinical Trials 2. CR8006- Good Clinical Laboratory Practice				-	21
VIII (for Hons. with Research)	1. CR8001- Seminar and Review Paper Writing (6) 2. CR8002- Research Project (15 Credits)					-	21
Award of B.Sc (Hons./ Hons. with Research) Degree in Clinical Research (with completion of courses equal to a minimum of 180 credits)							

SEMESTER-I

CR1001	Human Anatomy	
Version	1.0	
Prerequisite	All students are expected to have a general knowledge of Basic biology.	
Learning objective	At the end of the course, the student will be able to 1. Describe the anatomical terms, organization of human body and structure of cell, tissue, membranes and glands. 2. Describe the structure and functions of bones and joints. 3. Describe the structure and functions of systems in body. Have knowledge about Applied Anatomy	
Course outcome	CO1: Explains the Gross and Microscopic structure of human body. CO2: Explains the normal structure and integration of the functions of the organs and systems on basis of the structure of Human body. CO3: Explains the clinical correlation of the organs and structures involved and interprets the anatomical basis of the disease presentations. CO4: Knows about the General development of human body. CO5: Outlines the knowing of the hard & soft structures of the body.	
Unit-I	Introduction to Human Body	8 hours
	Terms of location, positions and planes, Cell and its organelles, Epithelium – Definition, classification, description with examples and functions, Glands–Classification, description of Serous and Mucous gland with examples, Basic tissues – Classification with examples. Locomotion and Support- Cartilage – Different types with examples and Histology, Bone – Classification, Names of bone cells, parts of Long bone Microscopy of Compact bone, Names of all bones, Vertebral column, Intervertebral disc, Fontanelles of Fetal Skull, Joints–Classification of Joints with examples, Synovial Joints (in detail for Medical Imaging Technology students, Muscular system: Classification of Muscular tissue and histology, Names of the muscles of the body.	
Unit-II	Circulatory and Respiratory System	7 hours
	Heart Size, Location, Chambers – Exterior & Interior-conducting System and Valves, Blood supply of heart, Systemic & Pulmonary circulation, Branches of Aorta, Common Carotid artery, Subclavian artery, Axillary artery, Brachial artery, Superficial Palmar arch, Femoral artery and Internal Iliac artery, Peripheral pulse, Inferior Venacava, Portal vein and Porto systemic anastomosis, Great Saphenous vein, Dural Venous Sinuses, Lymphatic System – Cisterna Chyli and Thoracic duct, Names of regionally Lmphatics, axillary and inguinal mph nodes in brief. Respiratory System: Parts of Respiratory System, Nose, Nasal Cavity, Larynx, Trachea, Lungs, Broncho pulmonary segments, Histology of Trachea, Lung and Pleura, Names of Para nasal air sinuses.	
Unit-III	Gastro-Intestinal, Urinary and Nervous System	7 hours
	GASTRO- INTESTINAL SYSTEM – Parts of GIT, Oral cavity (Tongue, Tonsil, Dentition, Pharynx, Salivary glands, Waldeyer’s ring), Oesophagus, Stomach, Small & Large Intestine, Liver, Gall Bladder, Pancreas URINARY SYSTEM - Kidney, Ureter, Urinary bladder, Male & Female Urethra Nervous System- Cerebrum, Cerebellum, Mid brain, Pons, Medulla Oblongata, Spinal cord with spinal nerve, Meninges, Ventricles and Cerebrospinal fluid, Names of Basal nuclei, Blood Supply of Brain, Cranial Nerves	
Unit-IV	Reproduction and Endocrine System	
	REPRODUCTIVE SYSTEM- Parts of Male Reproductive system, Testis, Vas deferens, Epididymis, Prostate, Parts of Female Reproductive System, Uterus, Fallopian, tubes, Ovary, Mammary gland ENDOCRINE GLANDS - Names of all Endocrine glands in detail on Pituitary, Gland, Thyroid Gland, Parathyroid gland and Suprarenal, Gland.	
Unit-V	Embryology and Course Specific Topics	7 hours
	EMBRYOLOGY- Spermatogenesis and Oogenesis, Ovulation, Fertilization, Fetal Circulation, Placenta COURSE SPECIFIC TOPICS- Skin, Eye, Arterial System and Venous Drainage System in detail	
Reference books	1. Principles of Anatomy and Physiology by Tortora Grabowski. Palmetto, GA, U.S.A. Wiley Publisher 16th edition, 2020. 2. Ross and Wilson: Anatomy and physiology in Health and Illness, 11th Edition, Church Hill Livingstone, 2011. 3. West, J.B.: Best and Taylor's Physiological Basis of Medical Practice, 11th Edition, 2007 4. Physiological basis of Medical Practice-Best and Tailor. Williams & Wilkins Co, Riverview,	

	<p>MI USA Wolters Kluwer India Pvt. Ltd.; Thirteenth edition (1 January 2011); Wolters Kluwer India Pvt. Ltd.</p> <p>5. Textbook of Medical Physiology- Arthur C, Guyton, and John. E. Hall. Miamisburg, OH,</p> <p>6. U.S.A. 11th Edition, Elsevier Saunders, 2006.</p> <p>7. Keel and Neil: Samson and Wright's Applied Physiology (12th edition), Oxford University Press. London.2004</p> <p>8. Essentials of Medical Physiology by K. Sembulingam and P. Sembulingam. Jaypee brothers' medical publishers, New Delhi.</p>
Mode of Examination	Assignment/Quiz/Viva-Voce/student seminar/written examination/PPT
Recommended By BOS on:	
Approved by academic council on:	

Mapping of COs with POs & PSOs

Course Outcomes	Program Outcomes (POs)												Program Specific Outcomes (PSOs)				
	PO 1	PO 2	PO 3	PO 4	PO5	PO6	PO 7	PO8	PO 9	PO 10	PO 11	PO 12	PSO 1	PSO 2	PSO 3	PS O4	PS O5
CO1	3	3	2	1	1	1	1	1	3	1	1	2	3	2	2	2	3
CO2	3	3	2	1	1	1	2	2	3	1	1	2	3	2	1	2	2
CO3	3	3	3	3	3	3	2	2	3	2	2	2	3	2	2	2	3
CO4	3	2	3	3	3	3	1	1	3	1	1	2	3	3	3	2	2
CO5	3	2	3	2	1	1	2	2	3	3	2	1	3	2	2	2	2

3: High, 2: Medium, 1: Low

CR1002	Fundamentals of Clinical Research	
Version	1.0	
Prerequisite	All students are expected to have a basic knowledge of clinical biology.	
Learning objective	This module covers the basics of clinical research, clinical trial definition, the drug development process and ethical regulations governing clinical research. Learners would also be exposed to scope of clinical research, career prospects, and overview of documentations.	
Course outcome	CO1. Explain the process of drug discovery and drug development and extrapolate data from animals to humans. CO2. Define the terms in clinical trials and understand the phases of clinical trials, their importance in clinical research and trial related issues. CO3. Describe the study design and methodologies in clinical trials, requirements, and regulations. CO4. Understand the roles of regulatory agencies EMA, US FDA, industry sponsors, in clinical research. CO5. Apply practical knowledge base for various approaches to clinical research.	
Unit-I	Introduction to Clinical Research	8 hours
	Glossary, Overview of clinical research and its importance, Historical perspectives and ethical considerations; Types of clinical research studies (observational, experimental, etc.) Drug Discovery and Development Process: Drug discovery and target identification; Preclinical testing and animal models; Investigational new drug (IND) application process	
Unit-II	Clinical Trial Fundamentals	7 hours
	Good Clinical Practices: Phases of clinical trials (Micro dosing, Phase I to Phase IV), Randomization and blinding, Outcome measures and endpoints, Tertiary endpoints.	
Unit-III	Clinical Trials Designs	7 hours
	ICH-E6 Regulations, Clinical trial design (observational and interventional) protocol consent in clinical trials, placebo, bias, and methods to prevent bias, monitoring, problems, and solutions of controlled clinical trials	
Unit-IV	Research Design and Methodology	7 hours
	Study designs (observational, experimental, cross-sectional, cohort, case-control, etc.); Sampling techniques and sample size determination; Data collection methods (questionnaires, interviews, medical records, etc.)	
Unit-V	Regulation in Clinical Research	7 hours
	Introduction of Clinical Trial Regulation; European Medicine Agency; Food and Drug Administration (US FDA); NDA and ANDA filing, Drug and cosmetic act; Schedule Y; ICMR Guidelines; Good Clinical Practice (GCP) guidelines; Protection of human subjects and privacy	
Reference books	1. Principles of Anatomy and Physiology by Tortora Grabowski. Palmetto, GA, U.S.A. Wiley Publisher 16th edition, 2020. 2. Ross and Wilson: Anatomy and physiology in Health and Illness, 11th Edition, Church Hill Livingstone, 2011. 3. West, J.B.: Best and Taylor's Physiological Basis of Medical Practice, 11th Edition, 2007 4. Physiological basis of Medical Practice-Best and Tailor. Williams & Wilkins Co, Riverview, MI USA Wolters Kluwer India Pvt. Ltd.; Thirteenth edition (1 January 2011); Wolters Kluwer India Pvt. Ltd. 5. Textbook of Medical Physiology- Arthur C, Guyton, and John. E. Hall. Miamisburg, OH, U.S.A. 11th Edition, Elsevier Saunders, 2006. 6. Keel and Neil: Samson and Wright's Applied Physiology (12th edition), Oxford University Press. London.2004 7. Essentials of Medical Physiology by K. Sembulingam and P. Sembulingam. Jaypee brothers' medical publishers, New Delhi.	
Mode of Examination	Assignment/Quiz/Viva-Voce/student seminar/written examination/PPT	
Recommended By BOS on:		

Approved by academic council on:	
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Mapping of COs with POs & PSOs

Course Outcomes	Program Outcomes (POs)												Program Specific Outcomes (PSOs)				
	PO 1	PO 2	PO 3	PO 4	PO5	PO6	PO 7	PO8	PO 9	PO 10	PO 11	PO 12	PSO 1	PSO 2	PSO 3	PS O4	PS O5
CO1	3	3	2	1	2	1	2	1	3	1	1	2	3	2	2	2	3
CO2	3	2	2	2	1	1	2	2	3	1	1	2	3	2	1	2	2
CO3	3	3	3	3	3	3	2	2	3	2	2	2	3	2	2	2	3
CO4	3	2	3	3	3	3	1	2	3	1	1	2	3	3	3	2	2
CO5	3	2	3	2	1	1	2	2	3	3	2	1	3	2	2	2	2

3: High, 2: Medium, 1: Low

CR1003	Community Health and Disease	
Version	1.0	
Prerequisite	All students are expected to have a basic knowledge of microbiology.	
Learning objective	This course focuses on the principles and practices of community health and disease prevention. It examines the social, environmental, and behavioral factors that influence health at the community level.	
Course outcome	CO1: Explain and understand the concept of community health, its significance, and epidemiological studies. CO2: Identify and distinguish the social, environmental, and behavioral determinants of health in community. CO3: Describe the principles and strategies for preventing diseases at community level. CO4: Describe the ethical considerations in community health and disease prevention. CO5: Analyze and evaluate the public health intervention programs like health promotion campaigns and disease surveillance in community health and disease prevention.	
Unit-I	Introduction to Community Health	8 hours
	Definition and scope of community health, social determinants of health, Health disparities in communities, Epidemiology of Common Diseases, Measures of disease frequency and association	
Unit-II	Community Health Assessment and Study designs	7 hours
	Community Health Assessment, Methods of assessing community health needs, Collection, and analysis of health data, Study designs in epidemiology risk factors and causation of diseases, Disease surveillance and outbreak investigation	
Unit-III	Health Centres and Disease Prevention	7 hours
	Identifying health priorities in communities, Health Promotion and Disease Prevention, Health Promotion and Disease Prevention, Health behavior theories and models Health Centres: Community Health Centres, Primary Health Centres, Hospitals, and their organization. Role of Health Centres in Disease Surveillance and Disease Prevention	
Unit-IV	Disease Surveillance Programs	7 hours
	Role of Health Centres in Disease Surveillance and Disease Prevention. Strategies for health promotion and behavior change, Primary, secondary, and tertiary prevention approaches, Community-Based Interventions, Community organizing and mobilization, Designing and implementing community health programs, Evaluation of community interventions.	
Unit-V	Environment Health Safety	7 hours
	Introduction to Environmental Health and Safety, Environmental risk factors and health effects, Water and air quality management, Occupational health, and safety	
Reference books	<ol style="list-style-type: none"> Harkness, G.A. and DeMarco, R.F., 2016. Community and public health nursing: Evidence for practice. Wolters Kluwer. Dicker, R.C., Coronado, F., Koo, D. and Parrish, R.G., 2006. Principles of epidemiology in public health practice; an introduction to applied epidemiology and biostatistics. Third edition Hunt, R., 2009. Introduction to community-based nursing. Lippincott Williams & Wilkins. Grim, M.L. and Fertman, C.I. eds., 2010. Health promotion programs: from theory to practice. John Wiley & Sons. Brown, A.E.C., Hobart, T.R. and Morrow, C.B. eds., 2019. Bioethics, Public Health, and the Social Sciences for the Medical Professions: An Integrated, Case-Based Approach. Springer. Szklo, M. and Nieto, F.J., 2014. Epidemiology: beyond the basics. Jones & Bartlett Publishers. Schneider, M.J., 2020. Introduction to public health. Jones & Bartlett Learning. 	
Mode of Examination	Assignment/Quiz/Viva-Voce/student seminar/written examination/PPT	
Recommended By BOS on:		

Approved by academic council on:	
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Mapping of COs with POs & PSOs

Course Outcomes	Program Outcomes (POs)												Program Specific Outcomes (PSOs)				
	PO 1	PO 2	PO 3	PO 4	PO5	PO6	PO 7	PO8	PO 9	PO 10	PO 11	PO 12	PSO 1	PSO 2	PSO 3	PS O4	PS O5
CO1	3	2	3	3	2	1	2	1	3	1	2	2	3	2	2	2	3
CO2	3	2	2	2	1	1	2	2	3	2	1	2	3	2	1	2	2
CO3	3	3	3	3	3	3	2	2	3	2	2	2	3	2	2	2	3
CO4	3	2	3	3	3	3	1	2	3	1	1	2	3	3	3	2	2
CO5	3	2	3	2	2	1	2	2	3	3	2	1	3	2	2	2	2

3: High, 2: Medium, 1: Low

SEMESTER-II

CR2001	Principles of Biochemistry	
Version	1.0	
Prerequisite	All students are expected to have a basic knowledge of microbiology.	
Learning objective	The main objective of the course will be to expose students to thermodynamics basis, bioenergetics of reaction, the basic role of biomolecules and their chemical interactions inside the cell. It provides deeper insight into structures, properties and functions of major biomolecules and metabolic pathways in the living systems	
Course outcome	<p>CO1: Understand thermodynamics basis of life, bioenergetics of a reaction and pathway and different intermolecular interactions in structural organization of proteins.</p> <p>CO2: Describe the structure and functions of different chemical building blocks (carbohydrates, proteins, and lipids) of life.</p> <p>CO3: Identify and draw structures of various types of biomolecules (carbohydrate, lipids, and proteins).</p> <p>CO4: Classify enzymes in different categories and explain what enzyme does, how enzyme works and primary biochemical pathways leading to synthesis and catabolism of major biomolecules.</p> <p>CO5: Demonstrate skills to prepare the solutions, buffers and identify and analyze any biological molecules in the given sample.</p>	
Unit-I	Introduction to biophysics	8 hours
	Introduction and history of biophysics, main features of quantum theory, elementary particles, and their interactions. Bioenergetics, endergonic and exergonic reactions, Laws of thermodynamics, entropy, enthalpy, Gibb's free energy, standard Gibb's free energy, ATP, and different high energy compounds. Properties and role of water. Buffers - action, capacity, relationship between pH & pKa (Henderson -Hasselbalch equation) and its importance	
Unit-II	Proteins	7 hours
	Amino acids and peptides- classification, chemical and physical properties, Introduction to protein structure and function, secondary, tertiary, and quaternary structure of proteins, fibrous and globular proteins, protein folding and Anfinsen's experiment. Amino acid metabolism-Amino acid deamination and transamination, urea cycle.	
Unit-III	Carbohydrates	7 hours
	Monosaccharides-structure of aldoses and ketoses, open and ring structure of sugars, conformations of sugars, mutarotation, anomers, epimers and enantiomers. Disaccharides- maltose, lactose, and sucrose. Polysaccharides-homo and heteropolysaccharides, structural and storage polysaccharides. Anabolism and catabolism, glycolysis citric acid cycle and gluconeogenesis.	
Unit-IV	Lipids	7 hours
	Definition, biological functions, general formulae, nomenclature and properties of fatty acids, essential and non-essential fatty acids, classification of lipids, building blocks of lipids - fatty acids, glycerol, ceramide, saponification number and iodine number, suitability of triglycerides as storage lipids, saponification number and iodine number. Introduction to lipid micelles, monolayer and bilayer, transport of fatty acids.	
Unit-V	Enzymes	7 hours
	Introduction to enzymes, classification of enzymes, mechanism of action, Michaelis-Menten equation and significance of Km, Vmax and Kcat.	

Reference books	<ol style="list-style-type: none"> 1. Lehninger: Principles of Biochemistry (2017) 7th ed., Nelson, D.L. and Cox, M.M., W.H. Freeman, and Company (New York), ISBN 13: 978-1464126116. 2. Textbook of Biochemistry with Clinical Correlations an Indian Adaptation (2022) 7th ed., Devlin, T.M., John Wiley & Sons, Inc., ISBN: 978-9354641558. 3. Biochemistry (2019) 9th ed., Berg, J.M., Tymoczko, J.L. and Stryer, L., W.H Freeman and Company (New York), ISBN 13:978-1319114671. 4. Principles and Techniques of Biochemistry and Molecular Biology (2018) 8th ed., Wilson, K. and Walker, J. Cambridge University Press, ISBN 13: 978-1316614761. 5. Introduction to Practical Biochemistry, Sawhney, S.K. and Singh R. so Narosa Publishing House (New Delhi), ISBN-13: 978-8173193026.
Mode of Examination	Assignment/Quiz/Viva-Voce/student seminar/written examination/PPT
Recommended By BOS on:	
Approved by academic council on:	

Mapping of COs with POs & PSOs

Course Outcomes	Program Outcomes (POs)												Program Specific Outcomes (PSOs)				
	PO 1	PO 2	PO 3	PO 4	PO5	PO6	PO 7	PO8	PO 9	PO 10	PO 11	PO 12	PSO 1	PSO 2	PSO 3	PS O4	PS O5
CO1	3	3	3	3	2	2	2	1	3	1	2	2	3	3	2	2	3
CO2	3	3	2	3	1	2	2	2	3	2	1	2	3	2	2	2	2
CO3	3	3	3	3	3	3	2	2	3	2	2	2	3	2	2	2	3
CO4	3	2	3	3	3	3	1	2	3	1	1	2	3	3	3	2	2
CO5	3	2	3	2	2	1	2	2	3	3	2	1	3	3	2	2	2

3: High, 2: Medium, 1: Low

CR2002	Human Physiology	
Version	1.0	
Prerequisite	All students are expected to have a basic knowledge of Human Anatomy and basic biology.	
Learning objective	<p>At the end of the course, the student will be able to</p> <ul style="list-style-type: none"> • Describe the physiology of cell, tissues, membranes and glands. • Describe the physiology of blood and functions of heart. • Demonstrate blood cell count, coagulation, grouping, Hb; BP and Pulse monitoring • Describe the physiology and mechanism of respiration. • Demonstrate Spirometry • Describe the physiology of Excretory system 	
Course outcome	<p>CO1: Understand normal structure and functioning of the organs and organ systems of the body CO2: Understand the regulatory mechanisms in normal and physiological variations. CO3: Understand age-related physiological changes in the organ functions that reflect normal growth and development. CO4: Understand the physiological basis of diseases. CO5: Interpret laboratory data pertaining to normal function of organ and organ system.</p>	
Unit-I	Introduction to Physiology and Hematology	8 hours
	<p>General physiology - Structure and functions of cell and cell organelles, Transport across cell membrane, Homeostasis: definition and feedback mechanisms Hematology - Composition and function of blood and body fluids, Plasma proteins and their functions, RBC: morphology, production, functions and fate, Anemia: etiological & morphological classification, Immunity : Types, mechanism of immune response, Hemostasis and anticoagulants, Blood groups: Types, cross matching and clinical importance</p>	
Unit-II	Cardiovascular Physiology	7 hours
	<p>Functional anatomy, Conductive system of heart: origin, spread of cardiac impuls, Properties of cardiac muscle, ECG: leads, principles of normal recording. Normal waves and interpretations, Cardiac cycle, Heart sounds, Physiological basis of murmur, Cardiac output: definition, factors affecting, factors regulating and its measurement, Blood pressure: total pressure, lateral pressure, importance of different pressure, measurements, factors controlling BP, Shock: definition &types.</p>	
Unit-III	Respiratory and Renal Physiology	7 hours
	<p>Functional anatomy- Mechanism of respiration, Lung volumes and capacities: definition, normal-values, measurements and clinical importance, Transport of gases: oxygen and carbon dioxide, Control of respiration: neural and chemical regulation, Dyspnoea, Asphyxia, cyanosis, periodic breathing, Hypoxia : definition and types Renal physiology- Nephrons: structure, types and functions, Juxta glomerular apparatus, RBF: definition, normal values, factor affecting, GFR: definition, normal values factor affecting and factors regulating, measurement, Renal handlings of solutes : Na⁺ , Cl⁻ ,Glucose, water (diuretics, diuresis), H⁺, ammonia, Renin-angiotensin- aldosterone mechanism, Concentration of urine – countercurrent multiplier and countercurrent exchanger, Micturition, Renal dialysis</p>	
Unit-IV	Endocrine and Reproductive System	7 hours
	<p>Endocrine physiology- Pituitary gland: hormones secreted and their functions, applied: dwarfism, gigantism, Diabetes Insipitus. Thyroid gland: hormones secreted and their functions, applied: hypothyroidism, hyperthyroidism, Parathyroid gland: hormones secreted and their functions, Adrenal gland: hormones secreted and their functions, Pancreas: hormones secreted and their functions, applied: Diabetes Mellitus Reproductive physiology- Male reproductive system: spermatogenesis, endocrine functions of testis, Female reproductive system: oogenesis, ovulation, functions of estrogen and progesterone. Menstrual cycle: ovarian cycle, uterine cycle, hormonal changes, abnormalities of menstruation. Contraception</p>	
Unit-V	Nerve-Muscle, Central nervous and Special Sense	7 hours
	<p>Nerve-Muscle physiology- Neurons: structure, types, properties, degeneration and regeneration. Neuromuscular junction: transmission of impulse and its clinical applications. Skeletal muscle: structure, muscle proteins, contraction& relaxation, types of contraction Central nervous system- Organization of nervous system. Synapse: types, functions. CSF: functions. Cerebral cortex: Broca's area and their functions. Cerebellum: lobes &function. Basal ganglia:</p>	

	nucleus & functions, Parkinsonism Special Sense- Vision: Errors of refraction, visual pathway and effects of lesion. Hearing: functions of middle ear, Conductive deafness and nerve deafness. Smell and taste: receptors and pathways
Reference books	<ol style="list-style-type: none"> 1. Principles of Anatomy and Physiology by Tortora Grabowski. Palmetto, GA, U.S.A. Wiley Publisher 16th edition, 2020. 3. Ross and Wilson: Anatomy and physiology in Health and Illness, 11th Edition, Church Hill Livingstone, 2011. 4. West, J.B.: Best and Taylor's Physiological Basis of Medical Practice, 11th Edition, 2007 5. Physiological basis of Medical Practice-Best and Tailor. Williams & Wilkins Co, Riverview, MI USA Wolters Kluwer India Pvt. Ltd.; Thirteenth edition (1 January 2011); Wolters Kluwer India Pvt. Ltd. 6. Textbook of Medical Physiology- Arthur C, Guyton, and John. E. Hall. Miamisburg, OH, U.S.A. 11th Edition, Elsevier Saunders, 2006. 7. U.S.A. 11th Edition, Elsevier Saunders, 2006. 8. Keel and Neil: Samson and Wright's Applied Physiology (12th edition), Oxford University Press. London.2004 Essentials of Medical Physiology by K. Sembulingam and P. Sembulingam. Jaypee brothers' medical publishers, New Delhi.
Mode of Examination	Assignment/Quiz/Viva-Voce/student seminar/written examination/PPT
Recommended By BOS on:	
Approved by academic council on:	

Mapping of COs with POs & PSOs

Course Outcomes	Program Outcomes (POs)												Program Specific Outcomes (PSOs)				
	PO 1	PO 2	PO 3	PO 4	PO5	PO6	PO 7	PO8	PO 9	PO 10	PO 11	PO 12	PSO 1	PSO 2	PSO 3	PSO 4	PSO 5
CO1	3	2	3	2	1	2	2	2	2	3	2	3	3	3	3	3	3
CO2	3	2	3	2	1	3	2	2	3	3	1	3	3	3	3	3	2
CO3	3	3	2	2	1	3	2	2	2	3	2	2	3	3	3	2	3
CO4	3	2	3	3	0	3	3	2	2	2	3	3	3	3	3	3	2
CO5	3	3	3	3	0	3	3	2	2	2	2	3	3	3	3	3	3

3: High, 2: Medium, 1: Low

CR2003	Fundamentals of Biostatistics	
Version	1.0	
Prerequisite	All students are expected to have a basic knowledge of biology and maths.	
Learning objective	This course introduces the fundamental principles and techniques of Biostatistics. It emphasizes the application of statistical methods in Health Sciences & Technology. Students will learn to analyze and interpret data, conduct hypothesis testing, and apply statistical techniques to make evidence-based decisions in various healthcare and research settings	
Course outcome	<p>CO1. Understand the basic concepts and principles of biostatistics and its relevance to healthcare and clinical research.</p> <p>CO2. Apply appropriate statistical techniques to analyze and investigate scientific questions in healthcare and research settings.</p> <p>CO3. Design and conduct basic experiments or studies to investigate scientific questions in the relevant disciplines.</p> <p>CO4. Apply statistical software tools to perform data analysis, interpret the output, and effectively communicate the findings of statistical analyses in healthcare and clinical research.</p>	
Unit-I	Introduction to Biostatistics and Data Types	8 hours
	Understand the importance of biostatistics in healthcare and clinical research. Define different types of data. Variables: continuous, nominal, ordinal. Scales of measurement	
Unit-II	Descriptive Statistics and Probability Distributions	7 hours
	Measures of central tendency: mean, median and mode. Measures of variability: range, variance, and standard deviation. Frequency distributions and graphical representations of data: histograms, box plots, and scatter plots. Basic principles of Probability. Discuss probability distributions: discrete and continuous, normal distribution.	
Unit-III	Sampling Techniques and Sampling Distributions	7 hours
	Understand different sampling techniques and their applications. Discuss sampling distributions and the Central Limit Theorem. Calculate confidence intervals and understand their interpretation.	
Unit-IV	Hypothesis Testing – Parametric and Non-parametric methods	7 hours
	One-Sample Tests: formulate null and alternative hypotheses, conduct hypothesis tests for one-sample mean and proportion, Interpret test results and inferencing. Two-Sample Tests: hypothesis testing for two independent samples, Compare means and proportions between groups. Paired T-tests. Analysis of Variance (ANOVA), Understand the principles of analysis of variance, one-way ANOVA, and result interpretation. Apply post hoc tests for multiple comparisons. Nonparametric tests for situations with violated assumptions and their interpretations: Chi square tests, Wilcoxon-Signed rank test, Kruskal-Wallis, Fischer's Exact Test. Compare parametric and nonparametric tests.	
Unit-V	Correlation and Regression Analysis	7 hours
	Understand the concepts of correlation and regression. Correlation coefficients. Perform simple linear regression and assess the model's goodness of fit. Multiple regression for multiple variables	
Reference books	<ol style="list-style-type: none"> 1. Dawson, B. and Trapp, R.G. 2019. Basic and Clinical Biostatistics. 5th ed. Lange medical books/McGraw-Hill Inc. 2. Zar, Jerrold H. 2014. Biostatistical Analysis. 5th ed. Pearson Education. 3. Selvin, S. 2011. Biostatistics: Statistical Tools for Epidemiological Research. Oxford University Press. 4. Lepš, J. and Šmilauer, P. 2020. Biostatistics with R: An introductory guide for Field Biologists. 1st ed. Cambridge University Press. 	
Mode of Examination	Assignment/Quiz/Viva-Voce/student seminar/written examination/PPT	
Recommended By BOS on:		

Approved by academic council on:	
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Mapping of COs with POs & PSOs

Course Outcomes	Program Outcomes (POs)												Program Specific Outcomes (PSOs)				
	PO 1	PO 2	PO 3	PO 4	PO5	PO6	PO 7	PO8	PO 9	PO 10	PO 11	PO 12	PSO 1	PSO 2	PSO 3	PSO 4	PSO 5
CO1	3	3	3	2	1	1	2	2	1	1	1	2	3	2	2	2	2
CO2	3	2	3	2	1	1	1	2	2	1	1	1	3	2	2	2	2
CO3	2	2	2	1	2	2	2	2	2	1	1	2	3	2	2	2	3
CO4	3	2	3	2	1	0	3	1	2	1	0	2	3	3	2	1	2
CO5	3	2	2	2	1	1	2	2	3	1	0	2	3	2	3	3	3

3: High, 2: Medium, 1: Low

Elective Course

CR2004	Computer Applications and Bioinformatics	
Version	1.0	
Prerequisite	All students are expected to have a basic knowledge of microbiology.	
Learning objective	The basic objective is to give students an introduction to the basic practical techniques of Computer Application and Bioinformatics. Emphasis will be given to the application of Computer Application and Bioinformatics and biological databases to problem solving in real research problems	
Course outcome	<p>CO1: Understand the basics of computer application and bioinformatics.</p> <p>CO2: Identify and define the basic concepts of bioinformatics and its significance in biological data analysis.</p> <p>CO3: Demonstrate the ability to choose the methods to symbolize and manage the different types of biological database, sequence alignment and phylogenetic tree analysis.</p> <p>CO4: Overview about biological macromolecular structures and structure prediction methods, molecular docking, and drug designing.</p> <p>CO5: Develop competency in bioinformatics for solving different biological problems, data handling process and data retrieval process from different, biological databases, usage of different software for analyzing biological data, sequence alignment, molecular docking, and drug designing.</p>	
Unit-I	Introduction to Computer Application	8 hours
	Basics of computer hardware, software, and networking. Operating Systems software and Application Systems software. Windows features, Microsoft office, data format for biological samples.	
Unit-II	Biological Databases	7 hours
	Definition and History and Applications of Computational Biology and Bioinformatics, Internet resources, various databases and bioinformatics tools, organization of databases. Sequencing database, 3D Structure Database, Chemical Structure database, Gene Expression database, Derived Databases, Structure classification database, Protein-Protein interaction database and Pathway database.	
Unit-III	Sequence Alignment and Phylogenetic Tree	7 hours
	File formats, Basic concepts of sequence analysis, Scoring matrices, Pair wise sequence alignments, Multiple sequence alignment, Database Searches: Keyword-based searches and Sequence-based searches. Phylogenetic Trees: phylogenetic tree representation, building phylogenetic trees,	
Unit-IV	Structure Prediction	7 hours
	General approach to discovery of new drugs, lead discovery, lead modification physiochemical, principles of drug action, 3D database search, computer aided drug design, AI based drug screening, docking, molecular modelling in drug design, structure-based drug design	
Unit-V	Molecular Docking and Drug Designing	7 hours
	General approach to discovery of new drugs, lead discovery, lead modification physiochemical, principles of drug action, 3D database search, computer aided drug design, AI based drug screening, docking, molecular modelling in drug design, structure-based drug design	

Reference books	<ol style="list-style-type: none"> 1. Bioinformatics and Computational Biology-A Primer for Biologists by Basant K. Tiwary. 2022, ISBN: 978-981-16-4240-1 2. Lopes H, editor. Computational Biology and Applied Bioinformatics. InTech; 2011. Available from: http://dx.doi.org/10.5772/772 3. Encyclopedia of Bioinformatics and Computational Biology-ABC of Bioinformatics. Shoba Ranganathan, Kenta Nakai, Christian Schonbach. August 21, 2018, ISBN: 9780128114148 4. Introduction to Bioinformatics, Teresa Attwood, David Parry-Smith, Pearson Education. ISBN: 978-8178085074 5. Bioinformatics: A Practical Guide to the Analysis of Genes and Proteins, Second Edition, Andreas D. Baxevanis, B. F. Francis Ouellette. A John Wiley & Sons, Inc., Publication. ISBN: 978-0471478782
Mode of Examination	Assignment/Quiz/Viva-Voce/student seminar/written examination/PPT
Recommended By BOS on:	
Approved by academic council on:	

Mapping of COs with POs & PSOs

Course Outcomes	Program Outcomes (POs)												Program Specific Outcomes (PSOs)				
	PO 1	PO 2	PO 3	PO 4	PO5	PO6	PO 7	PO8	PO 9	PO 10	PO 11	PO 12	PSO 1	PSO 2	PSO 3	PS O4	PS O5
CO1	3	3	3	3	2	2	2	2	3	1	2	2	3	3	3	2	3
CO2	3	2	2	2	1	1	2	2	3	2	1	2	3	2	2	2	2
CO3	3	3	3	3	3	3	2	2	3	2	2	2	3	2	2	2	2
CO4	3	2	3	3	3	3	1	3	3	1	1	2	3	3	3	2	2
CO5	3	2	3	2	2	1	2	3	3	3	2	2	3	2	2	2	2

3: High, 2: Medium, 1: Low

CR2005	Public Health and Hygiene	
Version	1.0	
Prerequisite	All students are expected to have a basic knowledge of clinical research.	
Learning objective	To understand the concepts, significance and relevance of public health and Hygiene. To understand the health hazards as associated with public health and hygiene	
Course outcome	CO1: Explain the concepts and importance of public health and hygiene in disease prevention. CO2: Describe environmental, personal, and community hygiene practices for health promotion. CO3: Identify causes, transmission, and control measures of communicable and non-communicable diseases. CO4: Apply principles of sanitation, waste management, and safe water supply in community health. CO5: Interpret national health programs and strategies for improving public health outcomes.	
Unit-I	Introduction	8 hours
	Definition and Concept of Public Health, historical aspects, public health system in India and in the rest of world	
Unit-II	Aspects of Health	7 hours
	Indicators of health, Determinants of Health, (Social, Economic, Cultural, Environmental, Education, Genetics, Food and Nutrition).Burden and prevention of disease. Environmental health-sanitation, air, water pollution, waste management. Mental health.	
Unit-III	Epidemiology	7 hours
	Introduction, principles and concepts, study design, analysis methods, presentation and interpretation of epidemiological data	
Unit-IV	Hygiene Concepts	7 hours
	Definition, importance, personal hygiene, medical hygiene, food hygiene, industrial Hygiene.	
Unit-V	Public Health Programs and Community Health	
	National and international public health programs, primary health care services, and community health awareness. Occupational health, biomedical waste management, and sanitation practices for disease prevention. Role of WHO and other health organizations in improving public health outcomes.	
Reference books	1. Introduction to Public Health, Raymond L. Goldsteen, Karen Goldsteen, David G. Graham, 2011, Springer publishing company 2. Introduction To Community Health Nursing, KasturiSundarRao, 4th edition, Bi Publications Pvt Ltd 3. Concepts of Epidemiology, Raj S Bhopal, 2002, Oxford University press.	
Mode of Examination	Assignment/Quiz/Viva-Voce/student seminar/written examination/PPT	
Recommended By BOS on:		
Approved by academic council on:		

Mapping of COs with POs & PSOs

Course Outcomes	Program Outcomes (POs)												Program Specific Outcomes (PSOs)				
	PO 1	PO 2	PO 3	PO 4	PO5	PO6	PO 7	PO8	PO 9	PO 10	PO 11	PO 12	PSO 1	PSO 2	PSO 3	PSO 4	PSO 5
CO1	3	3	3	2	1	1	2	2	1	1	1	2	3	2	2	2	2
CO2	3	2	3	2	1	1	1	2	2	1	1	1	3	2	2	2	2
CO3	2	2	2	1	2	2	2	2	2	1	1	2	3	2	2	2	3
CO4	3	2	3	2	1	0	3	1	2	1	0	2	3	3	2	1	2
CO5	3	2	2	2	1	1	2	2	3	1	0	2	3	2	3	3	3

3: High, 2: Mediu, 1: Low

SEMESTER-III

CR3001	Pharmacology and Toxicology
Version	1.0
Prerequisite	Basic understanding of biology and laboratory procedures.
Learning objective	The main purpose of the subject is to understand what drugs do to the living organisms and how their effects can be applied to therapeutics. The subject covers the information about the drugs like, mechanism of action, physiological and biochemical effects (pharmacodynamics) as well as absorption, distribution, metabolism, and excretion (pharmacokinetics) along with the adverse effects, clinical uses, interactions, doses, contraindications, and routes of administration of different classes of drugs.
Course outcome	CO1: Explain targets and pharmacology of underlying diseases. CO2: Understand the pharmacological actions of different categories of drugs. CO3. Apply the basic pharmacological knowledge in the prevention and treatment of various diseases. CO4: Analyse the effect of drugs on animals by simulated experiments. CO5: Report the clinical applications, adverse effects and toxicities of drugs used as medicines.
Unit-I	General Pharmacology
	Introduction to Pharmacology- nature and source of drugs, essential drugs concept and routes of drug administration, Basic terminologies in pharmacology, types of agonists and antagonists. Overview of Pharmacodynamics: Principles and mechanisms of drug action, receptors pharmacology, drug receptors interactions signal transduction mechanisms, dose response relationship, therapeutic index, combined effects of drugs and factors modifying drug action. Pharmacokinetics- Membrane transport, absorption, distribution, metabolism, and excretion of drugs. Enzyme induction, enzyme inhibition. Adverse drug reactions. Overview of phases of clinical trials and pharmacovigilance
Unit-II	Pharmacology of drugs acting on Nervous system
	Neurohumoral transmission, co-transmission, and classification of neurotransmitters. Classification, mechanism, use and adverse effect of drugs in: Parasympathomimetic, Parasympatholytic, Sympathomimetics, sympatholytic. Neuromuscular blocking agents, skeletal muscle relaxants (peripheral), Local anesthetic agents, and glaucoma General anesthetics and pre-anesthetics, Sedatives, hypnotics and centrally acting muscle relaxants, Anti-epileptics, Antipsychotics, antidepressants, anti-anxiety agents, anti-manics, Anti-parkinsonian Anti-Alzheimer's, and Opioid analgesics.
Unit-III	Pharmacology of drugs acting on cardiovascular system and blood
	Classification, mechanism, use and adverse effect of: Drugs used in congestive heart failure, Anti-hypertensive drugs, Anti-anginal drugs, Anti-arrhythmic drugs, Anti-hyperlipidemic drug, Hematinic, coagulants and anticoagulants. Fibrinolytics and anti-platelet drugs.
Unit-IV	Drugs acting on Gastrointestinal tracts and Renal system:
	Drugs for Peptic ulcer, diarrhea, and constipation, Antiemetics and Prokinetics. Physiology of Urine formation, Pharmacology of diuretics and antidiuretics. Drugs acting on respiratory and NSAIDs: Expectorants, Antitussives, Drugs for Asthma, Pharmacology of Prostaglandins and NSAIDs. Chemotherapeutic agents and Immunopharmacology: General consideration of antimicrobial agents. Pharmacology of antifungal, antibacterial, antiviral, antimalarial and anticancer drugs. Pharmacology of Immunomodulators.
Unit-V	Toxicology
	Principles of Toxicology, Introduction to toxicology and toxicokinetic- Routes of exposure and factors influencing toxicity, Mechanisms of toxicity and types of toxicological hazards, Evaluation of Chemical Hazards, Risk assessment and risk management Carcinogenicity, mutagenicity, and teratogenicity, Environmental toxicology, and ecotoxicology
Reference books	<ol style="list-style-type: none"> 1. Rang, H.P., Dale, M.M., Ritter, J.M. and Moore, P.K., 2003. Pharmacology, Churchill Livingstone. New York, pp.3-4. 2. Katzung, B.G., 2012. Basic and clinical pharmacology. 3. Goodman, L.S., 1996. Goodman and Gilman's the pharmacological basis of therapeutics (Vol. 1549, pp. 1361-1373). New York: McGraw-Hill. 4. Goodman, L.S. and Gilman, A., 1955. The pharmacological basis of therapeutics. The Macmillan. 5. Howland, R.D., and Mycek, M.J., 2006. Lippincotts Illustrated reviews, Pharmacology. Teaching Learning, 5, p.5. 6. Tripathi, K.D., 2003. Essentials of medical pharmacology, Jaypee Brothers. Med Pub Ltd New Delhi Edn, 5, pp.93-94. 7. Kulkarni SK. Handbook of experimental pharmacology. VallabhPrakashan, Dawson, B. and Trapp,

	R.G. 2019.
Mode of Examination	Assignment/Quiz/Viva-Voce/student seminar/written examination/PPT
Recommended By BOS on:	
Approved by academic council on:	

Mapping of COs with POs & PSOs

Course Outcomes	Program Outcomes (POs)												Program Specific Outcomes (PSOs)				
	PO 1	PO 2	PO 3	PO 4	PO5	PO6	PO 7	PO8	PO 9	PO 10	PO 11	PO 12	PSO 1	PSO 2	PSO 3	PSO 4	PSO 5
CO1	3	3	3	3	1	2	2	2	2	2	2	3	3	3	3	3	3
CO2	3	3	3	2	1	3	2	2	2	3	1	3	3	3	3	3	2
CO3	3	3	2	2	2	3	2	2	2	3	2	2	2	3	2	2	2
CO4	3	3	3	3	2	3	3	2	1	2	3	3	3	3	3	3	2
CO5	3	2	3	2	1	3	3	2	2	2	2	3	3	3	3	3	3

3: High, 2: Medium, 1: Low

CR3002	AI-Driven Design and Management of Clinical Trials	
Version	1.0	
Prerequisite	All students are expected to have a general knowledge of Basic biology.	
Learning objective	This course provides an overview of design, conduct, and management of clinical trials. This course describes the fundamental principles of clinical trial design, ethical considerations, data collection and analysis, regulatory requirements, and trial management strategies.	
Course outcome	<p>CO1. Explain the purpose, phases, and significance of clinical trials in evaluating the safety and efficacy of healthcare interventions.</p> <p>CO2. Describe the principles of clinical trial design including study objectives, endpoints, randomization, blinding, adaptive designs, and sample size estimation.</p> <p>CO3. Identify ethical considerations, regulatory guidelines, informed consent procedures, data privacy, and Good Clinical Practice (GCP) requirements in clinical trials.</p> <p>CO4. Develop skills in clinical data collection, AI-assisted data management, electronic data capture (EDC), case report form (CRF) development, and statistical analysis.</p> <p>CO5. Explain the applications of artificial intelligence, big data analytics, machine learning, pharmacovigilance systems, and real-world evidence in modern clinical trial management and decision-making.</p>	
Unit-I	Fundamentals of Clinical Trial Design	8 hours
	Introduction to clinical trials and phases of clinical research, Study objectives and formulation of research questions, Selection of study population and eligibility criteria, Randomization, blinding, and allocation concealment, Primary and secondary endpoints, Sample size and power calculation, Non-inferiority and equivalence trials, Introduction to adaptive clinical trial designs	
Unit-II	Clinical Data Collection and AI-Based Data Management	7 hours
	Case Report Form (CRF) development, Clinical data collection tools and databases, Electronic Data Capture (EDC) systems, Data validation and quality assurance, Introduction to AI and machine learning in clinical data management, AI-assisted patient data processing and anomaly detection, Data privacy, cybersecurity, and data integrity, Statistical concepts and hypothesis testing in clinical trials, Basics of predictive analytics in clinical research.	
Unit-III	Participant Recruitment, Retention, and Adherence	7 hours
	Strategies for participant recruitment and informed consent, Retention and follow-up of study participants, Adherence monitoring and strategies. Clinical Trial Monitoring and Safety, Role of clinical research monitors, Data safety monitoring boards (DSMBs) and interim analysis, Pharmacovigilance, and adverse event reporting, AI applications in safety signal detection and risk assessment.	
Unit-IV	Good Clinical Practice (GCP) and Trial Management	7 hours
	Principles of Good Clinical Practice (GCP), Regulatory compliance in clinical research, Responsibilities of sponsors, investigators, and study coordinators, Institutional Ethics Committee (IEC) and IRB approvals, Trial documentation and audit preparation, Study site management and coordination, AI-enabled workflow automation in trial management, Clinical Trial Management Systems (CTMS).	
Unit-V	Virtual and decentralized trials	7 hours
	Virtual and decentralized clinical trials, Wearable devices and digital health technologies, Precision medicine and biomarker-driven trials, Big data analytics and real-world evidence (RWE), AI and machine learning applications in clinical research, Blockchain applications in clinical data security, Future trends in smart clinical trials and digital therapeutics.	
Reference books	<ol style="list-style-type: none"> 1. Spriet, A., Dupin-Spriet, T. and Simon, P., 1994. Methodology of clinical drug trials. Karger Publishers. 2. Chow, S.C. and Liu, J.P., 2008. Design and analysis of clinical trials: concepts and methodologies (Vol. 507). John Wiley & Sons. 3. EDITION, T., 1988. Principles and Practice of Pharmaceutical Medicine. 	

	<p>4. Rees, J., 2004. The fundamentals of clinical discovery. Perspectives in Biology and Medicine, 47(4), pp.597-607.</p> <p>5. Spriet, A., Dupin-Spriet, T. and Simon, P., 1994. Methodology of clinical drug trials. Karger Publishers.</p> <p>6. Chow, S.C. and Liu, J.P., 2008. Design and analysis of clinical trials: concepts and methodologies (Vol. 507). John Wiley & Sons.</p> <p>7. Karlberg, J.P.E. and Speers, M.A., 2010. Reviewing clinical trials: a guide for the ethics committee. Hong Kong.</p>
Mode of Examination	Assignment/Quiz/Viva-Voce/student seminar/written examination/PPT
Recommended By BOS on:	
Approved by academic council on:	

Mapping of COs with POs & PSOs

Course Outcomes	Program Outcomes (POs)												Program Specific Outcomes (PSOs)				
	PO 1	PO 2	PO 3	PO 4	PO5	PO6	PO 7	PO8	PO 9	PO 10	PO 11	PO 12	PSO 1	PSO 2	PSO 3	PSO 4	PSO 5
CO1	3	2	2	3	3	2	2	2	2	3	2	3	3	3	3	2	3
CO2	3	3	3	3	3	3	2	2	2	3	2	3	2	3	3	3	2
CO3	3	3	2	2	3	3	2	2	2	3	2	2	2	3	2	2	2
CO4	3	3	3	3	3	3	3	2	1	2	3	3	3	3	3	3	2
CO5	3	2	3	2	3	3	3	2	2	2	2	3	3	3	3	3	3

3: High, 2: Medium, 1: Low

CR3003	Clinical Sampling and Analytical Techniques	
Version	1.0	
Prerequisite	All students are expected to have a general knowledge of Basic biology.	
Learning objective	This course provides an overview of clinical sampling and analytical techniques used in healthcare and biomedical research. It covers the principles and procedures for sample collection, handling, and storage, as well as the analytical techniques used for measuring various clinical parameters	
Course outcome	CO1: Explain the principles and importance of clinical sampling in healthcare and biomedical research. CO2: Describe different types of clinical samples and their collection techniques. CO3: Demonstrate skills in performing common clinical tests, analytical techniques used for clinical sample analysis. CO4: Explain quality control and quality assurance measures in clinical sample analysis. CO5: Discuss the emerging technologies and advancements in clinical sample analysis.	
Unit-I	Introduction to Clinical Sampling and Analysis	8 hours
	Importance of clinical sampling in healthcare and research, Ethical considerations and informed consent in sample collection, Overview of analytical methods used in clinical sample analysis. Types of Clinical Samples and Collection Techniques, blood, and serum samples: venipuncture, fingerstick, and arterial sampling, Urine, saliva, and other bodily fluid samples: collection methods and considerations, Tissue, and biopsy samples: collection techniques and processing.	
Unit-II	Clinical Sample Handling	7 hours
	Clinical sample handling, storage, and transport, pre-analytical factors: sample collection tubes, anticoagulants, and additives, Sample handling procedures: centrifugation, aliquoting, and labeling, Storage conditions and sample stability, transport considerations and chain of custody. Analytical techniques in clinical sample analysis.	
Unit-III	Quality Control and Assurance	7 hours
	Quality control and assurance in clinical sample analysis, calibration and standardization of analytical instruments used in clinical sample handling. Internal and external quality control measures, Validation and verification of analytical methods, Accreditation, and proficiency testing.	
Unit-IV	Common Clinical Tests and Interpretation of Results	7 hours
	Complete blood count (CBC) and differential analysis, Basic metabolic panel (BMP) and liver function tests, Lipid profile, hormone assays, and therapeutic drug monitoring, Microbiological and molecular diagnostic tests.	
Unit-V	Point-of-Care Testing (POCT) and Rapid Diagnostics	7 hours
	Overview of POCT devices and their applications, Selection and use of POCT devices in different clinical settings, Quality assurance and regulatory considerations for POCT. Emerging Technologies in Clinical Sample Analysis, Advances in molecular diagnostics: PCR, next-generation sequencing (NGS), Point-of-care molecular testing and biosensors, Omics technologies: genomics, proteomics, and metabolomics	
Reference books	1. Harr, R.R., 2012. Medical laboratory science review. FA Davis. 2. Bishop, M.L., 2020. Clinical Chemistry: Principles, Techniques, and Correlations, Enhanced Edition: Principles, Techniques, and Correlations. Jones & Bartlett Learning. 3. B McKenzie, S., 2015. Clinical laboratory hematology. Lynne Williams. 4. Grody, W.W., Nakamura, R.M., Kiechle, F.L. and Strom, C. eds., 2009. Molecular diagnostics: techniques and applications for the clinical laboratory. Academic Press.	

	5. Rifai, N., 2017. Tietz textbook of clinical chemistry and molecular diagnostics-e-book. Elsevier Health Sciences
Mode of Examination	Assignment/Quiz/Viva-Voce/student seminar/written examination/PPT
Recommended By BOS on:	
Approved by academic council on:	

Mapping of COs with POs & PSOs

Course Outcomes	Program Outcomes (POs)												Program Specific Outcomes (PSOs)				
	PO 1	PO 2	PO 3	PO 4	PO5	PO6	PO 7	PO8	PO 9	PO 10	PO 11	PO 12	PSO 1	PSO 2	PSO 3	PSO 4	PSO 5
CO1	3	3	3	2	2	2	2	2	2	3	2	3	2	2	3	3	3
CO2	3	2	3	2	2	3	2	2	2	3	2	3	2	3	3	3	2
CO3	2	3	2	2	2	3	2	2	2	3	2	2	2	3	2	2	2
CO4	2	2	3	3	2	3	3	2	1	2	3	3	2	2	3	3	2
CO5	3	3	3	2	2	3	3	2	2	2	2	3	3	3	3	3	3

3: High, 2: Medium, 1: Low

Elective Course

CR3004	Biosafety Guidelines	
Version	1.0	
Prerequisite	All students are expected to have a general knowledge of Basic biology.	
Learning objective	This course provides details of biosafety principles and guidelines for working with biological agents in laboratory and healthcare settings. This course will cover the important concepts of containment measures, risk assessment, personal protective equipment (PPE), regulatory frameworks and waste management.	
Course outcome	<p>CO1: Explain the importance of biosafety and its role in preventing occupational hazards and the spread of infectious diseases.</p> <p>CO2: Familiarize students with national and international biosafety guidelines, regulations, and standards.</p> <p>CO3: Develop knowledge and skills to assess risks associated with biological agents and implement appropriate containment measures.</p> <p>CO4: Identify different types of personal protective equipment (PPE) and their proper use in biosafety practices.</p> <p>CO5: Explain the techniques for safe handling, storage, and transport of biological materials.</p>	
Unit-I	Introduction to Biosafety	8 hours
	Definition and importance of biosafety, Historical overview and major biosafety incidents, Regulatory frameworks and guidelines (e.g., WHO, CDC, OSHA) Risk Assessment and Management, Principles of risk assessment Identification and characterization of biological hazards, Biosafety levels and facility design considerations, Containment and Engineering Controls, Primary, secondary, and tertiary containment measures, Laboratory design and engineering controls, biological safety cabinets and other containment equipment, Digital monitoring systems and smart technologies for real-time biosafety monitoring	
Unit-II	Personal Protective Equipment (PPE) and Transport of Biological Materials	7 hours
	Personal Protective Equipment (PPE), Selection and use of PPE based on risk assessment Proper donning and doffing of PPE, Maintenance and disposal of PPE, Innovative PPE technologies (e.g., smart textiles, antimicrobial coatings) and their application in biosafety. Safe Handling and Transport of Biological Materials, Packaging, labeling, and documentation requirements, Shipping regulations and transport considerations, Security measures for handling select agents and toxins, Implementation of blockchain and traceability systems for secure tracking and monitoring of biological materials.	
Unit-III	Waste Management and Decontamination	7 hours
	Introduction to waste management and decontamination, proper disposal of biohazardous waste, Decontamination techniques and disinfectants, Spill response and emergency procedures, Biosafety in Specific Settings, Healthcare-associated infections (HAIs), Biosafety in clinical laboratories and diagnostic facilities, Biosafety in animal research facilities, Novel decontamination methods (e.g., advanced oxidation processes, plasma sterilization).	
Unit-IV	Emerging Trends in Biosafety	7 hours
	Advanced containment systems and technologies, Genome editing and biosafety implications, Biosafety challenges in the era of globalization and bioterrorism threats,	
Unit-V	Emerging Technologies in Biosafety	7 hours
	Biosafety in Specific Settings, including the application of automation, robotics, and	

	artificial intelligence in biosafety practices, Gene drive technology, viral vectors, and their biosafety considerations.
Reference books	<ol style="list-style-type: none"> 1. Chosewood, L.C., and Wilson, D.E., 2009. Biosafety in microbiological and biomedical laboratories. US Department of Health and Human Services, Public Health Service, Centers for Disease Control and Prevention, National Institutes of Health. 2. Richmond, J.Y. and McKinney, R.W., 2009. Biosafety in microbiological and biomedical laboratories. US Government Printing Office. 3. National Academies of Sciences, Engineering, and Medicine, 2016. Soliciting Stakeholder Input for a Revision of Biosafety in Microbiological and Biomedical Laboratories (BMBL): Proceedings of a Workshop. National Academies Press. 4. Fleming, D.O. and Hunt, D.L., 2006. Biological safety: principles and practices (No. Ed. 4). ASM Press. 5. Burnett, L.C., Lunn, G. and Coico, R., 2009. Biosafety: guidelines for working with pathogenic and infectious microorganisms. Current protocols in microbiology, 13(1), pp.1A-1.
Mode of Examination	Assignment/Quiz/Viva-Voce/student seminar/written examination/PPT
Recommended By BOS on:	
Approved by academic council on:	

Mapping of COs with POs & PSOs

Course Outcomes	Program Outcomes (POs)												Program Specific Outcomes (PSOs)				
	PO 1	PO 2	PO 3	PO 4	PO5	PO6	PO 7	PO8	PO 9	PO 10	PO 11	PO 12	PSO 1	PSO 2	PSO 3	PSO 4	PSO 5
CO1	3	3	3	2	2	2	2	2	2	3	2	3	2	2	3	3	3
CO2	3	2	3	2	2	3	2	2	2	3	2	3	2	3	3	3	2
CO3	2	3	2	2	2	3	2	2	2	3	2	2	2	3	2	2	2
CO4	2	2	3	3	2	3	3	2	1	2	3	3	2	2	3	3	2
CO5	3	3	3	2	2	3	3	2	2	2	2	3	3	3	3	3	3

3: High, 2: Medium, 1: Low

CR3005	Regulatory Aspects in Clinical Research	
Version	1.0	
Prerequisite	All students are expected to have a general knowledge of Basic biology.	
Learning objective	This course will cover on understanding the importance of Good Clinical Practices (GLP) aspects, regulations governing the conduct of Clinical Trials and the Intellectual Property Rights	
Course outcome	<p>CO1. Explain about the conduct of Clinical Trials and understanding of ethical principles underlined research involving human subjects.</p> <p>CO2. Improves ideas and updating information on the current trend in Good Clinical Practices</p> <p>CO3. Explain the role of global as well as Indian regulatory authorities, guidelines while conducting clinical trials</p> <p>CO4. Apply the Information of IPR and GCP guidelines for conducting clinical trials</p>	
Unit-I	Ethical Aspects	8 hours
	Ethical principles underlined research involving human subjects, legal authorities for Institutional Review Board (IRB), Health and Human Services regulations (HHS), FDA regulations, regulatory requirements, duties of IRBs, IRB membership, role of IRB in reviewing Clinical Drug Trials, Assessment of scientific design, competence of investigator, selection of subjects, balancing benefits, and risks. Compensation for research related injuries, special issues like role of Lay member of IRB, review of multi-institutional trials, duty to monitor, financial risks of clinical trial subject, compliance with new regulations.	
Unit-II	Applicable GCP Guidelines	7 hours
	International Conference on Harmonization of technical requirements for registration of Pharmaceuticals for human use guidelines (ICH-GCP). Indian Council of Medical Research-Ethical Guidelines for Biomedical Research on Human participants (ICMR), Indian Good Clinical Practices. Regulatory guidelines for Biomaterials and Medical Devices	
Unit-III	Council for International Organizations of Medical Science (CIOMS) guidelines	7 hours
	CIOMS International Ethical guidelines for biomedical research involving human subjects. Principles Of Medical Ethics Relevant to the Protection of Prisoners Against Torture (1983), Intellectual Property Rights: Terminology, Patent Laws, TRIPS (Trade Related Intellectual Property Rights) Agreement, Trademarks, copyrights, Clinical Trial Application Requirements:	
Unit-IV	Investigational New drug (IND)	7 hours
	Classifications, IND application submission, check list, FDA IND review check list, IND application process, Information for sponsors-investigator submitting IND, IND forms and instructions	
Unit-V	New Drug Application (NDA)	7 hours
	Pre NDA meeting, NDA submission Check list, FDA NDA review check list, Abbreviated New drug Application (ANDA): ANDA content, ANDA, Submission check list, FDA ANDA review check list, ANDA process for generic drugs, guidance documents for ANDAs, ANDA forms and electronic submissions, Orphan Drugs Application: Submission check list, FDA orphan drug review check list, FDA documents	
Reference books	<ol style="list-style-type: none"> 1. The Fundamentals of Clinical Research: A Universal Guide for Implementing Good Clinical Practice, by P. Michael Dubinsky, Karen A. Henry Wiley; 1st edition (1 February 2022). 2. Clinical Trials Audit Preparation - A Guide for Good Clinical Practice (GCP) Inspections – Illustrated, 18 June 2010, John Wiley & Sons Inc; 1st edition (18 June 2010). 3. Good Clinical Practice - Standard Operating Procedures for Clinical Researchers Paperback – 27 March 1998, John Wiley & Sons Inc; 1st edition (27 March 1998); 01149344934 	

	4. Principles of Good Clinical Practice (Pharmacy Business Administration) Paperback – Pharmaceutical Press; 1st edition (3 August 2010) 5. Guide for Clinical Trial Staff: Implementing Good Clinical Practice Spiral-bound – Import, S Karger AG (14 October 2003)
Mode of Examination	Assignment/Quiz/Viva-Voce/student seminar/written examination/PPT
Recommended By BOS on:	
Approved by academic council on:	

Mapping of COs with POs & PSOs

Course Outcomes	Program Outcomes (POs)												Program Specific Outcomes (PSOs)				
	PO 1	PO 2	PO 3	PO 4	PO5	PO6	PO 7	PO8	PO 9	PO 10	PO 11	PO 12	PSO 1	PSO 2	PSO 3	PSO 4	PSO 5
CO1	3	3	3	2	1	1	2	2	1	1	1	2	3	2	2	2	2
CO2	3	2	3	2	1	1	1	2	2	1	1	1	3	2	2	2	2
CO3	2	2	2	1	2	2	2	2	2	1	1	2	3	2	2	2	3
CO4	3	2	3	2	1	0	3	1	2	1	0	2	3	3	2	1	2
CO5	3	2	2	2	1	1	2	2	3	1	0	2	3	2	3	3	3

3: High, 2: Medium, 1: Low

SEMESTER-IV

CR4001	Pharmacovigilance	
Version	1.0	
Prerequisite	All students are expected to have a general knowledge of Basic biology.	
Learning objective	This course provides an overview of pharmacovigilance, the science and activities related to the detection, assessment, understanding, and prevention of adverse effects or any other drug-related problems	
Course outcome	CO1. Explain the basic principle and importance of pharmacovigilance in drug safety monitoring. CO2. Describe the global regulatory framework and guidelines for pharmacovigilance. CO3. Explain the methods and tools used in collection, analysis, and reporting of ADR CO4. Discuss the role of pharmacovigilance in signal detection and risk management. CO5. Describe the challenges and future trends in pharmacovigilance and gain insights into pharmacovigilance in special populations	
Unit-I	Introduction to Pharmacovigilance	8 hours
	Definition, scope, and objectives of pharmacovigilance, Historical background and milestones in pharmacovigilance, Roles, and responsibilities of stakeholders in pharmacovigilance, Pharmacovigilance databases and information systems, Global Regulatory Framework and Guidelines. International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use (ICH) guidelines, World Health Organization (WHO) guidelines and programs, National regulatory authorities, and their roles in pharmacovigilance.	
Unit-II	Adverse Drug Reaction (ADR) Reporting and Data Collection	7 hours
	ADR reporting methods, data collection and sources of ADR reporting: spontaneous reporting, clinical trials, literature, and electronic health records, Signal detection and data mining techniques, Adverse Event Assessment and Causality Assessment. Causality assessment methods: WHO-Uppsala Monitoring Centre (UMC) criteria, Naranjo algorithm, Severity assessment and seriousness criteria, Quality assessment of ICSR	
Unit-III	Pharmacovigilance in Special Populations	7 hours
	Pediatric pharmacovigilance: challenges and considerations, Geriatric pharmacovigilance: age-related changes and medication safety, Pharmacovigilance in pregnancy and lactation, Pharmacovigilance in Drug Development and Clinical Trials, Pre-marketing safety assessment and clinical trial safety monitoring, Role of the clinical research team in pharmacovigilance, Reporting of serious adverse events (SAEs) in clinical trials.	
Unit-IV	Pharmacovigilance in the Real-World Setting	7 hours
	Post-marketing surveillance and real-world evidence, Pharmacoepidemiology and observational studies in pharmacovigilance, Role of healthcare professionals and patients in pharmacovigilance, Pharmacovigilance Challenges and Future Trends, Challenges in signal detection and benefit-risk assessment. Pharmacovigilance in the era of big data and artificial intelligence, Emerging trends, and future directions in pharmacovigilance	
Unit-V	Vaccine safety surveillance and Materiovigilance	7 hours
	Vaccine pharmacovigilance, vaccination failure, adverse events following immunization, Pharmacovigilance methods passive surveillance – spontaneous reports and case series, stimulated reporting, active surveillance – sentinel sites, drug event monitoring and registries, comparative observational studies – cross sectional study, case control study and cohort study, targeted clinical investigations. Materiovigilance, Hemovigilance, Identification and reporting of medication errors, Communication in Pharmacovigilance	
Reference books	<ol style="list-style-type: none"> 1. Mann, R.D., and Andrews, E.B. eds., 2007. Pharmacovigilance. John Wiley & Sons. 2. Waller, P. and Harrison-Woolrych, M., 2017. An introduction to pharmacovigilance. John Wiley & Sons. 3. Andrews, E.B. and Moore, N. eds., 2014. Mann's pharmacovigilance. John Wiley & Sons. 	

	<p>4. Nour, S. and Plourde, G., 2018. Pharmacoepidemiology and pharmacovigilance: Synergistic tools to better investigate drug safety. Academic Press.</p> <p>5. Plotkin, S.A., Orenstein, W. and Offit, P.A., 2012. Vaccines E-book. Elsevier Health Sciences.</p> <p>6. Mal, D.K., Ehsan, I. and Mukherjee, B., MATERIOVIGILANCE and HAEMOVIGILANCE.</p>
Mode of Examination	Assignment/Quiz/Viva-Voce/student seminar/written examination/PPT
Recommended By BOS on:	
Approved by academic council on:	

Mapping of COs with POs & PSOs

Course Outcomes	Program Outcomes (POs)												Program Specific Outcomes (PSOs)				
	PO 1	PO 2	PO 3	PO 4	PO5	PO6	PO 7	PO8	PO 9	PO 10	PO 11	PO 12	PSO 1	PSO 2	PSO 3	PSO 4	PSO 5
CO1	3	2	2	2	1	2	2	3	2	3	3	3	3	3	3	3	3
CO2	3	3	3	2	1	3	2	2	2	3	2	3	3	3	3	3	2
CO3	3	3	3	2	2	3	2	2	2	3	2	2	3	3	3	2	2
CO4	3	3	3	3	2	3	3	3	1	2	3	3	3	3	3	3	2
CO5	3	2	3	2	3	3	3	2	2	2	2	3	3	3	3	3	3

3: High, 2: Medium, 1: Low

CR4002	Clinical Pharmacokinetics	
Version	1.0	
Prerequisite	All students are expected to have a general knowledge of Basic biology.	
Learning objective	This course is intended to teach students the fundamental principles and applications of pharmacokinetics in designing the individualized dosage regimen, to interpret the plasma drug concentration profile in altered pharmacokinetics, drug interactions and in therapeutic drug monitoring processes to optimize the drug dosage regimen.	
Course outcome	CO1: Define pharmacokinetic drug interactions CO2: Discuss pharmacokinetic parameters in clinical settings CO3: Recommend dosage adjustment for pediatric and geriatric populations CO4: Design the drug dosage regimen for individual patients; recommend dosage adjustment for patients with renal/hepatic impairment	
Unit-I	Introduction to clinical pharmacokinetics	8 hours
	Compartmental and non-compartmental models, renal and non-renal clearance, models of hepatic clearance, estimation of bioavailability, multiple dosing, calculation of loading and maintenance doses. Designing of dosage regimens - determination of dose and dosing intervals, conversion from intravenous to oral dosing, nomograms, and tabulations in designing dosage regimen.	
Unit-II	Pharmacokinetics of Drug Interaction	7 hours
	Pharmacokinetic drug interactions, inhibition and induction of drug metabolism, inhibition of biliary excretion.	
Unit-III	Non-Linear Mixed Effects Modelling	7 hours
	Structural or base model, modeling random effects, modeling covariate relationships, mixture model, estimation methods, model building techniques, covariate screening methods, testing the model assumptions, precision of the parameter estimates and confidence intervals, model misspecification and violation of the model assumptions, model validation, simulation of dosing regimens and dosing recommendations.	
Unit-IV	Altered Pharmacokinetics	7 hours
	Drug dosing in the elderly, pediatrics, obese patients, and during pregnancy and lactation, drug dosing in renal failure and extracorporeal removal of drugs, drug dosing in hepatic failure	
Unit-V	Therapeutic Drug Monitoring	7 hours
	Introduction, individualization of drug dosage regimen (variability – genetic, age, weight, disease and interacting drugs). TDM protocol, pharmacokinetic/pharmacodynamic correlation in drug therapy. TDM in Cardiovascular disease - lidocaine, digoxin, and amiodarone; Antibiotics - gentamicin, vancomycin, and meropenem; Seizure disorders - carbamazepine, phenytoin, and sodium valproate; Psychiatric conditions - fluoxetine, lithium, and amitriptyline; Organ transplantation - cyclosporine; Cytotoxic agents - 5-fluorouracil, methotrexate, and cisplatin.	
Reference books	1. Gibaldi, M., 1991. Biopharmaceutics and clinical pharmacokinetics. 2. Shargel, L., Andrew, B.C. and Wu-Pong, S., 1999. Applied biopharmaceutics & pharmacokinetics (Vol. 264). Stamford: Appleton & Lange. 3. Huang, X.H. and Li, J., 2007. PETER L. BONATE. Pharmacokinetic-Pharmacodynamic Modeling and Simulation. New York: Springer, 2005. 387 ISBN: 038727197X. 4. Burton, M.E. ed., 2006. Applied pharmacokinetics & pharmacodynamics: principles of therapeutic drug monitoring. Lippincott Williams & Wilkins. 5. Wong, S.H. and Sunshine, I., 1996. Handbook of analytical therapeutic drug monitoring and toxicology. CRC Press. 6. Dhillon, S. and Kostrzewski, A. eds., 2006. Clinical pharmacokinetics. Pharmaceutical Press.	

	7. Notari, Robert E. Biopharmaceutics and clinical pharmacokinetics: an introduction. Routledge, 2017. 8. Doogue, M.P. and Polasek, T.M., 2013. The ABCD of clinical pharmacokinetics. Therapeutic advances in drug safety, 4(1), pp.5-7.
Mode of Examination	Assignment/Quiz/Viva-Voce/student seminar/written examination/PPT
Recommended By BOS on:	
Approved by academic council on:	

Mapping of COs with POs & PSOs

Course Outcomes	Program Outcomes (POs)												Program Specific Outcomes (PSOs)				
	PO 1	PO 2	PO 3	PO 4	PO5	PO6	PO 7	PO8	PO 9	PO 10	PO 11	PO 12	PSO 1	PSO 2	PSO 3	PSO 4	PSO 5
CO1	3	3	3	2	2	2	2	2	2	3	2	3	3	3	3	2	3
CO2	3	3	3	2	2	3	2	2	2	3	1	3	3	3	2	3	2
CO3	3	3	2	2	3	3	2	2	2	3	2	2	2	3	2	2	2
CO4	3	3	3	3	3	3	3	2	1	2	3	3	3	3	2	3	2
CO5	3	2	3	2	2	3	3	2	2	2	2	3	3	3	2	3	3

3: High, 2: Medium, 1: Low

CR4003	Bioethics and Drug Safety	
Version	1.0	
Prerequisite	All students are expected to have a general knowledge of Basic biology.	
Learning objective	This course describes the ethical considerations and principles about the development, regulation, and use of pharmaceutical drugs. Students will understand the fundamentals of bioethics and drug safety, addressing ethical issues related to clinical trials, informed consent, access to medications, off-label use, adverse events, and post-marketing surveillance.	
Course outcome	CO1: Explain the principles of bioethics and their application to drug safety. CO2: Describe the ethical considerations in the design, conduct, and reporting of clinical trials. CO3: Discuss the concept of informed consent and its importance in drug research and use. CO4. Analyze the ethical dimensions of access to medications, including affordability and availability.	
Unit-I	Introduction to Bioethics and Drug Safety	8 hours
	Overview of bioethics and its relevance to drug safety, Ethical frameworks and principles in healthcare, Historical perspective on drug safety and regulation, Ethical Considerations in Clinical Trials, Ethical guidelines, and regulations for clinical trials.	
Unit-II	Informed consent and participant autonomy	7 hours
	Elements of informed consent, consent process and documentation, special considerations for vulnerable populations, Balancing risks and benefits in trial design and recruitment, Informed Consent in Drug Research and Use, Elements and challenges of informed consent, Ethics of placebo-controlled trials and equipoise. Participant Recruitment and Retention in clinical trials.	
Unit-III	Access to Medications: Ethics and Equity	7 hours
	Ethical issues in medication affordability and accessibility, Global health disparities and access to essential medicines, pharmaceutical industry practices and drug pricing. Off-label prescribing: benefits and risks, Compassionate use programs and expanded access, Informed decision-making and patient autonomy, Ethics of Adverse Event Reporting and Patient Safety	
Unit-IV	Ethical Issues in Drug Safety	7 hours
	Ethical considerations in monitoring drug safety post-approval, ethical case studies in drug safety, analysis of real-life case studies involving ethical issues in drug safety, Ethical reasoning, and decision-making in complex scenarios. Discussion and debate on different perspectives and ethical frameworks	
Unit-V	Ethical Issues in Emerging Technologies and Innovative Therapies	7 hours
	Ethical considerations in clinical trials for modern technologies, New Drugs in Clinical Trials 2019, Emerging Ethical Issues in Drug Safety, Exploration of emerging ethical challenges in drug safety, Ethical considerations in personalized medicine and gene therapy, Ethical implications of emerging technologies in drug development	
Reference books	<ol style="list-style-type: none"> 1. Rozovsky, F.A. and Adams, R.K., 2003. Clinical trials and human research: A practical guide to regulatory compliance. 2. Evans, B.J. and Meslin, E.M., 2006. Encouraging translational research through harmonization of FDA and common rule informed consent requirements for research with banked specimens. The Journal of Legal Medicine, 27(2), pp.119-166. 3. Gallin, J.I. and Ognibene, F.P. eds., 2012. Principles and practice of clinical research. Academic Press. 4. Karlberg, J.P.E. and Speers, M.A., 2010. Reviewing clinical trials: a guide for the ethics committee. Hong Kong. 5. Cartwright, A.C. and Matthews, B.R. eds., 2016. International pharmaceutical product 	

	registration (Vol. 200). CRC Press. 6. Beecher, H.K., 2001. Ethics and clinical research. Bulletin of the World Health Organization, 79, pp.367-372. 7. Angell, M., 1997. The ethics of clinical research in the Third World. New England journal of medicine, 337(12), pp.847-849.
Mode of Examination	Assignment/Quiz/Viva-Voce/student seminar/written examination/PPT
Recommended By BOS on:	
Approved by academic council on:	

Mapping of COs with POs & PSOs

Course Outcomes	Program Outcomes (POs)												Program Specific Outcomes (PSOs)				
	PO 1	PO 2	PO 3	PO 4	PO5	PO6	PO 7	PO8	PO 9	PO 10	PO 11	PO 12	PSO 1	PSO 2	PSO 3	PSO 4	PSO 5
CO1	2	2	3	2	1	2	2	2	1	3	2	3	3	3	3	2	3
CO2	2	3	3	2	1	3	2	2	2	3	1	3	2	3	3	3	2
CO3	2	3	2	2	2	3	2	2	2	3	2	2	2	3	2	2	2
CO4	2	3	3	3	2	3	3	2	1	2	3	3	3	3	3	3	2
CO5	2	2	3	2	1	3	3	2	2	2	2	3	3	3	3	3	3

3: High, 2: Medium, 1: Low

Elective Course

CR4004	Clinical Pharmacokinetics	
Version	1.0	
Prerequisite	All students are expected to have a general knowledge of Basic biology.	
Learning objective	This course is intended to teach students the fundamental principles and applications of pharmacokinetics in designing the individualized dosage regimen, to interpret the plasma drug concentration profile in altered pharmacokinetics, drug interactions and in therapeutic drug monitoring processes to optimize the drug dosage regimen.	
Course outcome	CO1: Define pharmacokinetic drug interactions CO2: Discuss pharmacokinetic parameters in clinical settings CO3: Recommend dosage adjustment for pediatric and geriatric populations CO4: Design the drug dosage regimen for individual patients; recommend dosage adjustment for patients with renal/hepatic impairment	
Unit-I	Introduction to clinical pharmacokinetics	8 hours
	Compartmental and non-compartmental models, renal and non-renal clearance, models of hepatic clearance, estimation of bioavailability, multiple dosing, calculation of loading and maintenance doses. Designing of dosage regimens - determination of dose and dosing intervals, conversion from intravenous to oral dosing, nomograms, and tabulations in designing dosage regimen.	
Unit-II	Pharmacokinetics of Drug Interaction	7 hours
	Pharmacokinetic drug interactions, inhibition and induction of drug metabolism, inhibition of biliary excretion.	
Unit-III	Non-Linear Mixed Effects Modelling	7 hours
	Structural or base model, modeling random effects, modeling covariate relationships, mixture model, estimation methods, model building techniques, covariate screening methods, testing the model assumptions, precision of the parameter estimates and confidence intervals, model misspecification and violation of the model assumptions, model validation, simulation of dosing regimens and dosing recommendations.	
Unit-IV	Altered Pharmacokinetics	7 hours
	Drug dosing in the elderly, pediatrics, obese patients, and during pregnancy and lactation, drug dosing in renal failure and extracorporeal removal of drugs, drug dosing in hepatic failure.	
Unit-V	Therapeutic Drug Monitoring	7 hours
	Introduction, individualization of drug dosage regimen (variability – genetic, age, weight, disease and interacting drugs). TDM protocol, pharmacokinetic/pharmacodynamic correlation in drug therapy. TDM in Cardiovascular disease - lidocaine, digoxin, and amiodarone; Antibiotics - gentamicin, vancomycin, and meropenem; Seizure disorders - carbamazepine, phenytoin, and sodium valproate; Psychiatric conditions - fluoxetine, lithium, and amitriptyline; Organ transplantation - cyclosporine; Cytotoxic agents - 5-fluorouracil, methotrexate, and cisplatin.	
Reference books	<ol style="list-style-type: none"> Gibaldi, M., 1991. Biopharmaceutics and clinical pharmacokinetics. Shargel, L., Andrew, B.C. and Wu-Pong, S., 1999. Applied biopharmaceutics & pharmacokinetics (Vol. 264). Stamford: Appleton & Lange. Huang, X.H. and Li, J., 2007. PETER L. BONATE. Pharmacokinetic-Pharma-codynamic Modeling and Simulation. New York: Springer, 2005. 387 ISBN: 038727197X. Burton, M.E. ed., 2006. Applied pharmacokinetics & pharmacodynamics: principles of therapeutic drug monitoring. Lippincott Williams & Wilkins. Wong, S.H. and Sunshine, I., 1996. Handbook of analytical therapeutic drug monitoring and toxicology. CRC Press. Dhillon, S. and Kostrzewski, A. eds., 2006. Clinical pharmacokinetics. Pharmaceutical Press. Notari, Robert E. Biopharmaceutics and clinical pharmacokinetics: an introduction. Routledge, 2017. Doogue, M.P. and Polasek, T.M., 2013. The ABCD of clinical pharmacokinetics. Therapeutic advances in drug safety, 4(1), pp.5-7. 	
Mode of Examination	Assignment/Quiz/Viva-Voce/student seminar/written examination/PPT	
Recommended By BOS on:		

Approved by academic council on:	
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Mapping of COs with POs & PSOs

Course Outcomes	Program Outcomes (POs)												Program Specific Outcomes (PSOs)				
	PO 1	PO 2	PO 3	PO 4	PO5	PO6	PO 7	PO8	PO 9	PO 10	PO 11	PO 12	PSO 1	PSO 2	PSO 3	PSO 4	PSO 5
CO1	2	2	3	2	1	2	2	2	1	3	2	3	3	3	3	2	3
CO2	2	3	3	2	1	3	2	2	2	3	1	3	2	3	3	3	2
CO3	2	3	2	2	2	3	2	2	2	3	2	2	2	3	2	2	2
CO4	2	3	3	3	2	3	3	2	1	2	3	3	3	3	3	3	2
CO5	2	2	3	2	1	3	3	2	2	2	2	3	3	3	3	3	3

3: High, 2: Medium, 1: Low

CR4005	Molecular Diagnostics	
Version	1.0	
Prerequisite	All students are expected to have a basic knowledge of Microbiology and Immunology	
Learning objective	<p>The course is designed to give an overview and applications of different molecular biology techniques used in disease diagnosis. The specific objectives of the course are:</p> <ol style="list-style-type: none"> 1. To teach students different molecular techniques used for disease diagnosis. 2. To make students understand the utilization of these techniques in disease diagnosis. 3. To teach the use of different enzyme immunoassay based diagnostic methods. 4. To impart the knowledge about the molecular diagnostic of different human diseases. 	
Course outcome	<p>CO1: Understand enzyme immunoassays, including enzyme comparison, conjugation, and solid phases. Analyze their applications in diagnostic microbiology.</p> <p>CO2: Evaluate molecular methods such as PCR, RFLP, and nuclear hybridization in clinical microbiology.</p> <p>CO3: Analyze laboratory tests for chemotherapy, including susceptibility tests and automated procedures for antimicrobial susceptibility.</p> <p>CO4: Understand automation in microbial diagnosis and rapid diagnostic approaches, including antigen and antibody standardization.</p> <p>CO5: Evaluate concepts and methods in idiotyping, including epitope design and applications in immunodiagnostic tests.</p>	
Unit-I	Enzyme Immunoassays	8 hours
	Comparison of enzymes available for enzyme immunoassays, conjugation of enzymes. Solid phases used in enzyme immunoassays. Homogeneous and heterogeneous enzyme immunoassays. Enzyme immunoassays after immunoblotting. Enzyme immuno-histochemical techniques. Use of polyclonal or monoclonal antibodies in enzyme immunoassays. Applications of enzyme immunoassays in diagnostic microbiology	
Unit-II	Molecular methods in clinical microbiology	7 hours
	Applications of PCR, RFLP, Nuclear hybridization methods, Single nucleotide polymorphism and plasmid fingerprinting in clinical microbiology	
Unit-III	Laboratory tests in chemotherapy	7 hours
	Susceptibility tests: Micro-dilution and macro-dilution broth procedures. Susceptibility tests: Diffusion test procedures. Susceptibility tests: Tests for bactericidal activity. Automated procedures for antimicrobial susceptibility tests.	
Unit-IV	Automation in diagnostics	7 hours
	Automation in microbial diagnosis, rapid diagnostic approach including technical purification and standardization of antigen and specific antibodies.	
Unit-V	Idiotyping	7 hours
	Concepts and methods in idiotypes. Anti-idiotypes and molecular mimicry and receptors. Epitope design and applications. Immunodiagnostic tests. Immunofluorescence. Radioimmunoassay.	
Reference books	<ol style="list-style-type: none"> 1. Practical Biochemistry, Principles and Techniques, Keith Wilson and John Walker 2. Bioinstrumentation, Webster 3. Advanced Instrumentation, Data Interpretation, and Control of Biotechnological Processes, J.F. Van Impe, Kluwer Academic 4. Ananthanarayan R and Paniker CKJ. (2005). Textbook of Microbiology. 7th edition (edited by Paniker CKJ). University Press Publication. 5. Brooks GF, Carroll KC, Butel JS and Morse SA. (2007). Jawetz, Melnick and Adelberg's Medical Microbiology. 24th edition. McGraw Hill Publication. 	

	<p>6. Goering R, Dockrell H, Zuckerman M and Wakelin D. (2007). Mims' Medical Microbiology. 4th edition. Elsevier.</p> <p>7. Joklik WK, Willett HP and Amos DB (1995). Zinsser Microbiology. 19th edition. Appleton-Century-Crofts publication.</p> <p>8. Willey JM, Sherwood LM, and Woolverton CJ. (2008). Prescott, Harley and Klein's Microbiology. 7th edition. McGraw Hill Higher Education.</p> <p>1. 9. Microscopic Techniques in Biotechnology, Michael Hoppert</p>
Mode of Examination	Assignment/Quiz/Viva-Voce/student seminar/written examination/PPT
Recommended By BOS on:	
Approved by academic council on:	

Mapping of COs with POs & PSOs

Course Outcomes	Program Outcomes (POs)												Program Specific Outcomes (PSOs)				
	PO 1	PO 2	PO 3	PO 4	PO5	PO6	PO 7	PO8	PO 9	PO 10	PO 11	PO 12	PSO 1	PSO 2	PSO 3	PSO 4	PSO 5
CO1	3	3	3	2	1	1	2	2	1	1	1	2	3	2	2	2	2
CO2	3	2	3	2	1	1	1	2	2	1	1	1	3	2	2	2	2
CO3	2	2	2	1	2	2	2	2	2	1	1	2	3	2	2	2	3
CO4	3	2	3	2	1	0	3	1	2	1	0	2	3	3	2	1	2
CO5	3	2	2	2	1	1	2	2	3	1	0	2	3	2	3	3	3

3: High, 2: Medium, 1: Low

SEMESTER-V

CR5001	Epidemiology and Global Health	
Version	1.0	
Prerequisite	All students are expected to have a general knowledge of Basic biology.	
Learning objective	The course objective of this course helps student to describe the science of epidemiology and the etiology of specific diseases, interpret epidemiological information contained in scientific literature and design interventions for treating and preventing ill health.	
Course outcome	CO1 Describe the evolution of epidemiology. CO2 Discuss various types of epidemiological studies and ethical considerations involving human subjects. CO3 Evaluate the process of investigation of an outbreak and causation in Epidemiology. CO4 Plan research project and critical reading of published reports. CO5 Develop analytical approaches to monitoring and evaluation.	
Unit-I	Epidemiology: Laying the Foundations	8 hours
	Definitions: Epidemiology, Public Health, and Health. Uses of Epidemiology, evolving patterns of morbidity and mortality-Demographics and disease patterns, mortality, and life expectancy trends. Roots of Epidemiology-John Graunt, Germ theory, The London Epidemiological Society, John Snow and William Farr. Global Health and Sustainable Development Goals	
Unit-II	Epidemiological Study Designs	7 hours
	Etiologic research- Hypothesis statement, Epidemiological variables-Person, place, time, and data. Descriptive versus Analytical, Longitudinal versus cross-sectional. Epidemiological studies. Experimental versus observational, cohort versus case-control. Ethical conduct of studies involving human subjects.	
Unit-III	Outbreak Investigation and Causation	7 hours
	Background-Initial detection of Outbreaks, goals, and methods. CDC prescribed investigatory steps. Case study on the outbreak investigation of Covid 19 and Foodborne outbreak. Causation in Epidemiology-Natural history of the disease, Variability in the expression of disease, causal models, Concept of cause, Establishing the cause of a disease.	
Unit-IV	Health Services and Health Policy	7 hours
	Healthcare planning and evaluation, Measuring the quality of healthcare, the planning cycle, health public policy in practice, Planning a research project, and critical reading of published reports.	
Unit-V	Monitoring and Evaluation	7 hours
	Monitoring Health Care Systems, Organizations, and Programs Surveillance, Health services information and Evaluation. Dimensions of Evaluation, The Evaluation Process, Conceptual Framework for Specifying Evaluation Criteria, and Analytical Approaches to Evaluation.	
Reference books	<ol style="list-style-type: none"> 1. Beaglehole, R. et al. (1993): <i>Basic Epidemiology</i>. Geneva, WHO. 2. Lilienfeld's Foundations of Epidemiology (Fourth Edition) Dona Schneider, David E. Lilienfeld 3. B. Burt Gerstman, Epidemiology Kept Simple: An Introduction to Traditional and Modern Epidemiology (3rd Edition) 4. Applied Epidemiology: Theory to Practice edited by Ross C. Brownson, Diana B. Petitti 5. Lilienfeld, Abraham M. (1994): <i>Foundations of Epidemiology</i>. New York, Oxford University Press, (Chapter 2) 	

	6. Denise M. Oleske: Epidemiology and the Delivery of Health Care Services (Third edition): Methods and Applications, Springer
Mode of Examination	Assignment/Quiz/Viva-Voce/student seminar/written examination/PPT
Recommended By BOS on:	
Approved by academic council on:	

Mapping of COs with POs & PSOs

Course Outcomes	Program Outcomes (POs)												Program Specific Outcomes (PSOs)				
	PO 1	PO 2	PO 3	PO 4	PO5	PO6	PO 7	PO8	PO 9	PO 10	PO 11	PO 12	PSO 1	PSO 2	PSO 3	PSO 4	PSO 5
CO1	3	3	3	3	1	2	2	2	1	1	1	3	3	3	3	2	3
CO2	3	3	3	2	1	2	2	2	2	1	1	3	3	3	3	3	2
CO3	3	3	3	3	1	3	2	2	2	1	2	2	3	3	2	2	2
CO4	3	2	3	3	0	3	3	2	1	1	1	3	3	3	3	3	3
CO5	3	2	3	2	1	3	3	2	1	1	2	3	3	3	3	3	3

3: High, 2: Medium, 1: Low

CR5002	Immunology	
Version	1.0	
Prerequisite	All students are expected to have a general knowledge of Basic biology.	
Learning objective	This course's main objective is to introduce the basic concepts of immunology and its application in disease diagnosis. This course addresses immunological disorders and discusses the techniques to be employed in diagnostic laboratories. This will also enable the students to know about the different cells which are associated with the body's defense mechanism against pathogens and cancer.	
Course outcome	CO1: Outline the history of scientists who contributed to immunology. CO2: Explain types of cells and organs that participate in defense mechanisms against pathogens and other foreign particles. CO3: Discuss the defense mechanism through Antibodies, Major histocompatibility complex and Complement systems. CO4: Apply advanced technologies in immunology to diagnose different diseases. CO5: Demonstrate basic skills of total Leukocyte Count and differential Leukocyte Count of the given blood sample	
Unit-I	History of immunology	8 hours
	Introduction to Innate and Adaptive immunity; Contributions of scientists to the development of the field of immunology - Edward Jenner, Karl Landsteiner, Robert Koch, Paul Ehrlich, Elie Metchnikoff, Peter Medawar, MacFarlane Burnet, Neils K Jerne, Rodney Porter, and Susumu Tonegawa.	
Unit-II	Immunity: Cells, organs, and Antigen-Antibody Interaction	7 hours
	Structure, and Functions of: Immune Cells – Stem cell, T cell, B cell, NK cell, Macrophage, Neutrophil, Eosinophil, Basophil, Mast cell, Dendritic cell; and Immune Organs – Bone Marrow, Thymus, Lymph Node, Spleen, GALT, MALT, CALT. Characteristics of antigens (Foreignness, Molecular size, and Heterogeneity); Haptens; Epitopes (T & B cell epitopes); T-dependent and T-independent antigens; Adjuvants; Structure, Types, Functions and Properties of antibodies; Antigenic determinants on antibodies (Isotypic, allotypic, idiotypic); VDJ rearrangements; Monoclonal and Chimeric antibodies.	
Unit-III	Immune responses	7 hours
	Primary and Secondary Immune Response; Generation of Humoral Immune Response (Plasma and Memory cells); Generation of Cell Mediated Immune Response (Self MHC restriction, T cell activation, Co- stimulatory signals).	
Unit-IV	Major Histocompatibility Complex and Complement System	7 hours
	Organization of MHC locus (Mice & Human); Structure and Functions of MHC I & II molecules; Antigen processing and presentation (Cytosolic and Endocytic pathways); Components of the Complement system; Activation pathways (Classical, Alternative and Lectin pathways).	
Unit-V	Immunological dysregulation and immunity in tumour	7 hours
	Types of Autoimmunity and Hypersensitivity with examples; Immunodeficiencies - SCID, DiGeorge syndrome, Chediak- Higashi syndrome, Leukocyte adhesion deficiency; Types of tumors, tumor Antigens, causes and therapy for cancers. Immune technology. Principles of Precipitation, Agglutination, Immunodiffusion, Immuno-electrophoretic, ELISA, Western blotting, Immunofluorescence, Flow cytometry, Immunoelectron microscopy.	
Reference books	<ol style="list-style-type: none"> 1. Abbas AK, Lichtman AH, Pillai S. (2007). Cellular and Molecular Immunology. 6th edition Saunders Publication, Philadelphia. 2. Delves P, Martin S, Burton D, Roitt IM. (2006). Roitt's Essential Immunology. 11th edition Wiley Blackwell Scientific Publication, Oxford. 3. Goldsby RA, Kindt TJ, Osborne BA. (2007). Kuby's Immunology. 6th edition W.H. Freeman and Company, New York. 4. Murphy K, Travers P, Walport M. (2008). Janeway's Immunobiology. 7th edition Garland Science Publishers, New York. 	

	5. Peakman M, and Vergani D. (2009). Basic and Clinical Immunology. 2nd edition Churchill Livingstone Publishers, Edinberg. 6. Richard C and Geiffrey S. (2009). Immunology. 6th edition. Wiley Blackwell Publication.
Mode of Examination	Assignment/Quiz/Viva-Voce/student seminar/written examination/PPT
Recommended By BOS on:	
Approved by academic council on:	

Mapping of COs with POs & PSOs

Course Outcomes	Program Outcomes (POs)												Program Specific Outcomes (PSOs)				
	PO 1	PO 2	PO 3	PO 4	PO5	PO6	PO 7	PO8	PO 9	PO 10	PO 11	PO 12	PSO 1	PSO 2	PSO 3	PSO 4	PSO 5
CO1	3	2	2	3	1	2	2	2	1	1	1	3	3	3	3	2	3
CO2	3	3	3	2	1	2	2	2	1	0	1	3	3	3	3	3	3
CO3	3	3	3	3	2	3	2	2	2	0	2	2	3	2	3	2	2
CO4	3	2	3	3	2	3	3	2	1	1	1	3	3	3	3	3	3
CO5	3	2	3	2	3	2	3	2	2	1	2	3	3	3	3	3	3

3: High, 2: Medium, 1: Low

CR5003	Bioinstrumentation	
Version	1.0	
Prerequisite	All students are expected to have a general knowledge of Basic biology.	
Learning objective	This course is introduced with an idea to fill the gap between academia and research. This course introduces analytical techniques along with working principles, common instrumentation, and their applications. This course engenders students with the fundamental knowledge of analytical techniques required for research careers in allied health fields.	
Course outcome	CO1: Outline different analytical techniques and their instrumentation, and operation. CO2: Demonstrate skill in carrying out research projects by employing centrifugation, and chromatographic and electrophoresis-based separation techniques. CO3: Describe the terms, principle, instrumentation, operation, and applications of molecular spectroscopic and microscopic techniques. CO4: Apply appropriate bioanalytical techniques for identification, separation, isolation, and purification of biomolecules. CO5: Apply principles of various analytical devices used in research and enhance problem solving techniques.	
Unit-I	Centrifugation	8 hours
	Basic principles of centrifugation, standard sedimentation coefficient, types of centrifuges based on speed, different types of rotors, principles and applications of differential, rate zonal and density gradient centrifuge.	
Unit-II	Chromatography	7 hours
	Introduction to chromatography, principle and applications of paper chromatography, thin layer chromatography, column chromatography (adsorption, gel filtration, ion exchange, and affinity) and high-performance liquid chromatography (HPLC).	
Unit-III	Electrophoresis	7 hours
	Introduction to electrophoresis, polyacrylamide, and agarose gel electrophoresis SDS and Native-PAGE, isoelectric focusing (IEF) and 2-D gel electrophoresis.	
Unit-IV	Spectroscopy	7 hours
	Introduction to spectroscopy, electromagnetic spectrum, Jablonski's diagram, Lambert-Beer law, principle, instrumentation, and applications of UV-visible, fluorescence, Fourier-transform infrared (FT-IR) and nuclear magnetic resonance (NMR). Introduction, principle and applications of mass spectrometry, types of ionization methods (Electron impact, chemical ionization, ESI, MALDI).	
Unit-V	Microscopy	7 hours
	Principle of microscopy, resolving powers of different microscopes, magnification, principle, and applications of: Compound microscopy, dark field microscopy, fluorescent microscopy, phase contrast microscopy, confocal and electron microscopy (SEM & TEM), Fixation and staining.	
Reference books	1. Principles and Techniques of Biochemistry and Molecular Biology (2018) 8 th ed., Wilson, K. and Walker, J. Cambridge University Press, ISBN 13: 978-1316614761. 2. Introduction to Practical Biochemistry (2009) Sawhney, S.K. and Singh R. Narosa Publishing House (New Delhi), ISBN-13: 978-8173193026. 3. Biophysical Chemistry: Principles and Techniques (2016) Upadhyay A., Upadhyay K. and Nath N. Himalaya Publishing House, ISBN 13: 978-8183188654. 4. Principles of Fluorescence Spectroscopy (2010) 5 th ed. Lakowicz J.R. Springer, ISBN 13: 978-0387312781.	
Mode of Examination	Assignment/Quiz/Viva-Voce/student seminar/written examination/PPT	
Recommended By BOS on:		
Approved by		

academic council on:	
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Mapping of COs with POs & PSOs

Course Outcomes	Program Outcomes (POs)												Program Specific Outcomes (PSOs)				
	PO 1	PO 2	PO 3	PO 4	PO5	PO6	PO 7	PO8	PO 9	PO 10	PO 11	PO 12	PSO 1	PSO 2	PSO 3	PSO 4	PSO 5
CO1	3	3	2	2	1	2	2	3	1	1	1	3	3	3	2	2	3
CO2	3	3	3	2	2	3	3	3	2	0	1	3	3	2	3	3	3
CO3	3	3	2	3	2	3	2	3	2	1	2	2	3	3	3	3	3
CO4	3	2	3	3	2	3	3	3	1	1	1	3	3	3	3	3	3
CO5	3	2	3	2	3	3	3	3	1	1	2	3	3	3	3	3	3

3: High, 2: Medium, 1: Low

Elective Course

CR5004	Ayush and Lifestyle	
Version	1.0	
Prerequisite	All students are expected to have a general knowledge of Basic biology.	
Learning objective	The objective of the course on Ayush and Lifestyle is to provide students with a comprehensive understanding of the principles, practices, and applications of Ayurveda, Yoga & Naturopathy, Unani, Siddha, and Homeopathy, along with the significance of lifestyle factors in promoting health and well-being.	
Course outcome	CO1. Explain the fundamental principles, philosophies, and concepts of Ayurveda, Yoga & Naturopathy, Unani, Siddha, and Homeopathy. CO2. Analyze and apply diagnostic methods and assessment tools used in Ayush systems to evaluate individual constitution and health conditions. CO3. Demonstrate the use of Ayush therapies, treatments, and lifestyle interventions to promote health, prevent diseases, and manage common health conditions. CO4. Evaluate and apply principles of nutrition, dietetics, and herbal medicine in the context of Ayush and lifestyle practices. CO5. Apply the principles of lifestyle medicine in addressing chronic diseases and health promotion.	
Unit-I	Introduction to Ayush and Lifestyle	8 hours
	Overview and principles of Ayush systems including Ayurveda, Yoga & Naturopathy, Unani, Siddha, and Homeopathy. Fundamental concepts of Ayurveda such as Doshas, Dinacharya, and Ritucharya. Basics of Yoga practices, meditation, and naturopathy for health promotion and stress management. Role of lifestyle in maintaining physical and mental well-being.	
Unit-II	Unani Medicine, Siddha and Homeopathy Medicine	7 hours
	Introduction to principles and concepts of Unani, Siddha, and Homeopathy systems of medicine. Diagnostic methods, treatment approaches, and use of herbal and natural remedies. Importance of individualized treatment and lifestyle modifications in disease prevention and management.	
Unit-III	Lifestyle Medicine	7 hours
	Importance of nutrition, physical activity, sleep, and stress management in maintaining health. Lifestyle interventions for prevention and management of chronic diseases such as diabetes, obesity, and cardiovascular disorders. Integration of Ayush principles into modern lifestyle practices and public health.	
Unit-IV	Introduction to research methodologies in Ayush and lifestyle medicine	7 hours
	Basics of research methodology, evidence-based practices, and ethical considerations in Ayush and lifestyle medicine research. Critical appraisal of scientific studies and public health perspectives related to lifestyle interventions. Applications of research in health promotion and disease prevention.	
Unit-V	Innovations and advancements in Ayush practices	7 hours
	Recent innovations and global perspectives in Ayush and lifestyle medicine. Integration of traditional medicine with modern healthcare systems. Emerging opportunities, challenges, and future prospects in Ayush-based healthcare practices.	
Reference books	<ol style="list-style-type: none"> "Ayurveda: The Science of Self-Healing" by Dr. Vasant Lad Lotus Press; 2nd edition (28 July 1993). "The Complete Book of Ayurvedic Home Remedies" by Dr. Vasant Lad, Little, Brown Book Group (2 November 2006). "The Yoga Bible" by Christina Brown, Krause Publications; 39820th edition (29 May 2003) Naturopathic Medicine: Treating the Whole Person, Health Advisory Lectures & Literature; 3rd Revised edition (1 November 2000) 	

	5. "Unani Medicine: Towards a Global Approach" by Hakeem Syed Zillur Rahman Betascript Publishing, 2011 6. Rasayana: Ayurvedic Herbs for Longevity and Rejuvenation, H.S. Puri · 2002 7. Tridosha Made Easy: The Basic Ayurvedic Principle, Janardhana V Hebbar, Raghuram YS, Manasa S · 2019 8. "Lifestyle Medicine: Lifestyle, the Environment, and Preventive Medicine in Health and Disease" edited by James M. Rippe.
Mode of Examination	Assignment/Quiz/Viva-Voce/student seminar/written examination/PPT
Recommended By BOS on:	
Approved by academic council on:	

Mapping of COs with POs & PSOs

Course Outcomes	Program Outcomes (POs)												Program Specific Outcomes (PSOs)				
	PO 1	PO 2	PO 3	PO 4	PO5	PO6	PO 7	PO8	PO 9	PO 10	PO 11	PO 12	PSO 1	PSO 2	PSO 3	PSO 4	PSO 5
CO1	3	3	2	2	1	2	2	3	1	1	1	3	3	3	2	2	3
CO2	3	3	3	2	2	3	3	3	2	0	1	3	3	2	3	3	3
CO3	3	3	2	3	2	3	2	3	2	1	2	2	3	3	3	3	3
CO4	3	2	3	3	2	3	3	3	1	1	1	3	3	3	3	3	3
CO5	3	2	3	2	3	3	3	3	1	1	2	3	3	3	3	3	3

3: High, 2: Medium, 1: Low

CR5005	Site Management Operations	
Version	1.0	
Prerequisite	All students are expected to have a general knowledge of Basic biology.	
Learning objective	This course will provide information on clinical research services, clinical research organization, clinical investigator, and pharmaceutical or Biotechnology Company, hospitals, or medical device company. An SMO specializes in managing clinical research sites.	
Course outcome	CO1: Explain about the functions of monitor, investigator, sponsor in Clinical Research Organization CO2: Demonstrate knowledge of good clinical practice (GCP) guidelines and regulatory requirements for conducting clinical research. CO3. Apply site selection criteria and conduct feasibility assessments for clinical trial participation. CO4. Demonstrate Effective management of site documentation and ensure compliance with regulatory standards. CO5. Describe study start-up activities, including site initiation visits and investigator meetings.	
Unit-I	Introduction to Site Management Operations	8 hours
	Overview of site management operations in clinical research, Roles and responsibilities of site managers and clinical research coordinators, Importance of good clinical practice (GCP) and regulatory compliance, Contract Research Organizations (CRO), their functions and importance in clinical trials, Difference between Site Management Organization (SMOs) and CROs, General comments on the site's status and GCP compliance, using company- or trial-specific checklists. Visit details – who was seen by whom, what was discussed, the date of the next planned visit.	
Unit-II	Site Documentation and Regulatory Compliance	7 hours
	Essential documents in clinical research and their management, Regulatory requirements and submissions for site approval, Compliance with local, national, and international regulations and guidelines	
Unit-III	Study Start-up and Site Initiation	7 hours
	Study start-up activities and timelines, Site initiation visits and investigator meetings, Study-specific training and site staff qualification, Subject Recruitment and Enrollment, Strategies for subject recruitment and retention, Informed consent process and documentation, Screening, eligibility criteria, and subject enrollment procedures	
Unit-IV	Site Monitoring and Quality Assurance	7 hours
	Role of site monitors and clinical research associates (CRAs), Monitoring visits, source data verification, and compliance checks, Quality assurance processes and corrective actions, Investigational Product Management, Handling and accountability of investigational products, Drug storage, dispensing, and reconciliation, Adherence to Good Manufacturing Practice (GMP) guidelines	
Unit-V	Study Close-out and Archiving, Study close-out activities and timelines	7 hours
	Documentation completion and final reporting, archiving and retention of study records Emerging Trends and Future Directions in Site Management Operations, Advances in technology and their impact on site operations, Risk-based monitoring and remote monitoring approaches, Innovations, and challenges in site management operations.	
Reference books	1. Swink, M., Melnyk, S.A., Cooper, M. and Hartley, J., 2014. Managing operations (Vol. 1260547639). New York: McGraw-Hill/Irwin. 2. The CRA's Guide to Monitoring Clinical Research, Fourth Edition Perfect Paperback – 1 June 2016. 3. "Site Management Handbook: An Operational Guide for Investigators, Sponsors, and Site Personnel" by Gregory K. Mislick and Laura C. Bonifacio 4. "Good Clinical Practice Guide" by Medicines and Healthcare products Regulatory	

	Agency (MHRA) 5. "Clinical Trials Handbook: Design and Conduct" by Curtis L. Meinert 6. "Managing the Investigational Product Supply Chain: Ensuring Effective Distribution in Clinical Trials" by Nigel Rulewski 7. "Risk-Based Monitoring and Fraud Detection in Clinical Trials Using JMP and SAS" by Richard C. Zink and Christi Lalanne.
Mode of Examination	Assignment/Quiz/Viva-Voce/student seminar/written examination/PPT
Recommended By BOS on:	
Approved by academic council on:	

Mapping of COs with POs & PSOs

Course Outcomes	Program Outcomes (POs)												Program Specific Outcomes (PSOs)				
	PO 1	PO 2	PO 3	PO 4	PO5	PO6	PO 7	PO8	PO 9	PO 10	PO 11	PO 12	PSO 1	PSO 2	PSO 3	PSO 4	PSO 5
CO1	3	3	3	2	1	1	2	2	1	1	1	2	3	2	2	2	2
CO2	3	2	3	2	1	1	1	2	2	1	1	1	3	2	2	2	2
CO3	2	2	2	1	2	2	2	2	2	1	1	2	3	2	2	2	3
CO4	3	2	3	2	1	0	3	1	2	1	0	2	3	3	2	1	2
CO5	3	2	2	2	1	1	2	2	3	1	0	2	3	2	3	3	3

3: High, 2: Medium, 1: Low

SEMESTER-VI

CR6001	Pharmacotherapeutics	
Version	1.0	
Prerequisite	All students are expected to have a general knowledge of Basic biology.	
Learning objective	This course is designed to impart a thorough knowledge of the relevant aspects of pharmacotherapy of various conditions with reference to its pharmacological approaches and understanding of basic pathophysiological mechanisms. Hence, it will help study the syllabus of pharmacotherapeutic approaches and get baseline knowledge required to practice medicine safely, confidently, rationally, and effectively	
Course outcome	CO1: Understand the etiology and pathogenesis of the disease states and basic mechanism of the disease. CO2: Explain the functions of different drugs used in the mitigation of the diseased condition. CO3: Identify the signs and symptoms of the diseases. CO4: Describe various therapeutic approaches and the importance of individualized therapeutic plans based on diagnosis. CO5: Create a plan of rational medicine therapy for common diseases and design and deliver discharge counselling for patients.	
Unit-I	Introduction to Pharmacotherapeutics	8 hours
	Pharmacotherapeutics – Introduction, scope, and objectives. Rational use of Medicines, Evidence Based Medicine, Essential Medicines List, Standard Treatment Guidelines (STGs). Basic principles of Cell injury and Adaptation: Introduction, definitions, Homeostasis, Components and Types of Feedback systems, Causes of cellular injury, Pathogenesis (Cell membrane damage, Mitochondrial damage, Ribosome damage, Nuclear damage), Morphology of cell injury – Adaptive changes (Atrophy, Hypertrophy, hyperplasia, Metaplasia, Dysplasia), Cell swelling, Intra cellular accumulation, Calcification, Enzyme leakage and Cell Death Acidosis & Alkalosis, Electrolyte imbalance	
Unit-II	Basic mechanism involved in the process of inflammation	7 hours
	Basic mechanism involved in the process of inflammation and repair: Introduction, Clinical signs of inflammation, Different types of Inflammation, Mechanism of Inflammation – Alteration in vascular permeability and blood flow, migration of WBC's, Mediators of inflammation, Basic principles of wound healing in the skin, Pathophysiology of Atherosclerosis	
Unit-III	Etiopathogenesis and treatment of cardiovascular disorders	7 hours
	Definition, etiopathogenesis, clinical manifestations, nonpharmacological and pharmacological management of the diseases associated with Cardiovascular System: Hypertension, congestive heart failure, ischemic heart disease (angina, myocardial infarction, atherosclerosis, and arteriosclerosis)	
Unit-IV	Etiopathogenesis and treatment of respiratory, kidney and blood related disorders	7 hours
	Definition, etiopathogenesis, clinical manifestations, nonpharmacological and pharmacological management of the diseases associated with Respiratory system: Asthma, Chronic obstructive airways diseases. Renal system: Acute and chronic renal failure. Hematological Diseases: Iron deficiency, megaloblastic anemia (Vit B12 and folic acid), sickle cell anemia, thalassemia, hereditary acquired anemia, hemophilia.	
Unit-V	Etiopathogenesis and treatment of nervous, endocrine, and gastrointestinal disorders	7 hours
	Definition, etiopathogenesis, clinical manifestations, nonpharmacological and	

	pharmacological management of the diseases associated with Endocrine system: Diabetes, thyroid diseases, disorders of sex hormones. Nervous system: Epilepsy, Parkinson's disease, stroke. Psychiatric disorders: depression, schizophrenia, and Alzheimer's disease. Gastrointestinal system: Peptic Ulcer
Reference books	<ol style="list-style-type: none"> 1. Rang, H.P., Dale, M.M., Ritter, J.M. and Moore, P.K., 2003. Pharmacology, Churchill Livingstone. New York, pp.3-4. 2. Katzung, B.G., 2012. Basic and clinical pharmacology. 3. Goodman, L.S., 1996. Goodman and Gilman's the pharmacological basis of therapeutics (Vol. 1549, pp. 1361-1373). New York: McGraw-Hill. 4. Goodman, L.S. and Gilman, A., 1955. The pharmacological basis of therapeutics. The Macmillan. 5. Howland, R.D., and Mycek, M.J., 2006. Lippincotts Illustrated reviews, Pharmacology. Teaching Learning, 5, p.5. 6. Tripathi, K.D., 2003. Essentials of medical pharmacology, Jaypee Brothers. Med Pub Ltd New Delhi Edn, 5, pp.93-94. 7. Kulkarni SK. Handbook of experimental pharmacology. Vallabh Prakashan, Dawson, B. and Trapp, R.G. 2019.
Mode of Examination	Assignment/Quiz/Viva-Voce/student seminar/written examination/PPT
Recommended By BOS on:	
Approved by academic council on:	

Mapping of COs with POs & PSOs

Course Outcomes	Program Outcomes (POs)												Program Specific Outcomes (PSOs)				
	PO 1	PO 2	PO 3	PO 4	PO5	PO6	PO 7	PO8	PO 9	PO 10	PO 11	PO 12	PSO 1	PSO 2	PSO 3	PSO 4	PSO 5
CO1	3	3	2	2	1	2	2	2	1	1	1	3	3	3	3	2	3
CO2	3	3	3	2	1	2	2	2	2	1	1	3	3	3	3	3	2
CO3	3	3	2	3	2	3	2	2	1	1	2	2	3	3	2	2	2
CO4	3	2	3	3	2	3	3	2	1	1	3	3	3	3	3	3	3
CO5	3	2	3	2	1	2	3	2	1	1	2	3	3	3	3	3	3

3: High, 2: Medium, 1: Low

CR6002	Biopharmaceutics	
Version	1.0	
Prerequisite	All students are expected to have a general knowledge of Basic biology.	
Learning objective	This course provides an in-depth understanding of the principles and applications of biopharmaceutics, which is the study of the relationship between the physicochemical properties of drugs, their formulation, and their pharmacological and therapeutic effects. The course covers topics such as drug absorption, distribution, metabolism, and excretion, as well as drug delivery systems and bioavailability.	
Course outcome	<p>CO1 Understand biopharmaceutical, physiological, biochemical and cell biology-related aspects on the transport and metabolism of drugs in the gastrointestinal tract and in the liver.</p> <p>CO2 Explain mechanisms behind the transport of drug and metabolism and how drugs can interact with other drugs and food and methods to study these interactions.</p> <p>CO3 Describe the role of biopharmaceutics in clinical research within the pharmaceutical industry.</p> <p>CO4 Apply regulatory requirements within the biopharmaceutical area. CO5 Compile the findings of biopharmaceutical studies in clinical research.</p>	
Unit-I	Introduction to Biopharmaceutics	8 hours
	Overview of biopharmaceutics and its significance in drug development and delivery. Basic concepts of drug absorption, distribution, metabolism, and elimination (ADME). Physiological, biochemical and cell biology-related background to the physiology of the gastrointestinal tract and the liver and different pathophysiological conditions associated with gastrointestinal tract and the liver.	
Unit-II	Drug Delivery Systems	7 hours
	Routes of administration: oral, parenteral (intravenous, intramuscular, subcutaneous), topical, transdermal, inhalation, etc. Formulation considerations for different drug delivery systems. Drug release kinetics and mechanisms	
Unit-III	Drug Absorption and Distribution	7 hours
	Absorption: Mechanisms of drug absorption through GIT, factors influencing drug absorption through GIT, absorption of drug from Non per oral extra-vascular routes. Tissue permeability of drugs, binding of drugs, apparent, volume of drug distribution, plasma and tissue protein binding of drugs, factors affecting protein-drug binding. Kinetics of protein binding, Clinical significance of protein binding of drugs.	
Unit-IV	Drug metabolism and elimination	7 hours
	Drug metabolism and basic understanding metabolic pathways Microsomal oxidation. Phases of biotransformation of Drugs and endogenous toxic compounds. Microsomal oxidation reactions. II phase of biotransformation of medicines. Conjugation reactions in the liver. Renal excretion of drugs, factors affecting renal excretion of drugs, renal clearance, non-renal routes of drug excretion of drugs	
Unit-V	Biopharmaceutics and Pharmacokinetics	7 hours
	Mathematical models for drug absorption, distribution, and elimination. PK/PD (pharmacokinetic/pharmacodynamic) modeling and simulation, Application of modeling in drug development and dosage regimen optimization.	
Reference books	<ol style="list-style-type: none"> Shargel, L., Andrew, B.C. and Wu-Pong, S., 1999. Applied biopharmaceutics & pharmacokinetics (Vol. 264). Stamford: Appleton & Lange. Notari, R.E., 1975. Biopharmaceutics and pharmacokinetics: an introduction. (No Title). Gibaldi, M., 1971. Introduction to biopharmaceutics. Wagne, J.G., 1970. Biopharmaceutics and relevant pharmacokinetics. Drug Information Bulletin, 4(2), pp.226-226. Niazi, S., 1979. Textbook of biopharmaceutics and clinical pharmacokinetics. 	

	6. Handbook of Bioequivalence Testing, by Niazi, S. K. 7. Macheras, P. and Iliadis, A., 2016. Modeling in biopharmaceutics, pharmacokinetics, and pharmacodynamics: homogeneous and heterogeneous approaches (Vol. 30). Springer. 8. Riviere, J.E. ed., 2011. Comparative pharmacokinetics: principles, techniques, and applications. John Wiley & Sons.
Mode of Examination	Assignment/Quiz/Viva-Voce/student seminar/written examination/PPT
Recommended By BOS on:	
Approved by academic council on:	

Mapping of COs with POs & PSOs

Course Outcomes	Program Outcomes (POs)												Program Specific Outcomes (PSOs)				
	PO 1	PO 2	PO 3	PO 4	PO5	PO6	PO 7	PO8	PO 9	PO 10	PO 11	PO 12	PSO 1	PSO 2	PSO 3	PSO 4	PSO 5
CO1	3	3	2	2	1	2	2	2	2	1	1	2	3	3	3	3	3
CO2	3	3	3	2	1	2	2	2	2	1	1	2	3	3	3	3	2
CO3	3	3	2	3	1	3	2	2	1	1	2	2	3	2	2	2	2
CO4	3	2	3	3	1	3	1	2	0	1	0	3	3	3	2	3	3
CO5	3	2	3	2	1	2	2	2	1	1	0	2	3	3	3	3	3

3: High, 2: Medium, 1: Low

CR6003	Data Management Technologies	
Version	1.0	
Prerequisite	All students are expected to have a general knowledge of Basic biology.	
Learning objective	This course introduces data management technology focused on its applications in clinical research. Students will learn about the principles and techniques involved in managing clinical research data effectively and ensuring data quality and integrity. The course covers both theoretical concepts and practical skills necessary for data management in clinical research settings.	
Course outcome	<p>CO1: Explain and understand the importance of data management, regulatory requirements, and guidelines for data management in clinical research.</p> <p>CO2: Develop skills in designing and implementing databases for clinical research studies</p> <p>CO3: Explain data entry, validation, and cleaning techniques specific to clinical research.</p> <p>CO4: Apply knowledge and hands-on on electronic data capture (EDC) systems and understand the principles of data security and privacy in clinical research.</p> <p>CO5: Explore emerging trends and technologies in data management for clinical research.</p>	
Unit-I	Introduction to Data Management in Clinical Research	8 hours
	Overview of data management in the clinical research process, Role of data management in ensuring data integrity and regulatory compliance, Types of Clinical data including image data, tabular data, EM waves data, Bio signal data.	
Unit-II	Designing Databases for Clinical Research Studies	7 hours
	Study database architecture and design considerations, Electronic Case Report Forms (eCRFs) and data collection instruments, Data entry best practices and techniques, Data validation checks and edit checks, Double data entry and reconciliation. Identification and resolution of data discrepancies, Query management and resolution process, Data quality assessment and monitoring.	
Unit-III	Electronic Data Capture (EDC) Systems	7 hours
	Introduction to EDC systems and their features, EDC system implementation and user training, Data extraction and reporting from EDC systems, Data Security and Privacy, Protection of personal health information (PHI), Data encryption and anonymization techniques, Compliance with Health Insurance Portability and Accountability Act (HIPAA)	
Unit-IV	Data Integration and Interoperability	7 hours
	Data standards in clinical research (e.g., CDISC standards), Data integration techniques for multi-site studies, Electronic Health Records (EHR) integration Risk Based Monitoring, statistical monitoring, central monitoring, involvement of real time data monitor, data visualization and monitoring.	
Unit-V	Emerging Trends in Data Management for Clinical Research	7 hours
	Use of artificial intelligence and machine learning in data management, Mobile health (mHealth) technologies and their impact on data collection, AI based Healthcare applications, Challenges and Benefits of using AI in healthcare applications.	
Reference books	<ol style="list-style-type: none"> 1. Rondel, R.K., Varley, S.A. and Webb, C.F. eds., 2000. Clinical data management. New York: Wiley. 2. Prokscha, S., 2011. Practical guide to clinical data management. CRC Press. 3. Ngari, M.M., Waithira, N., Chilengi, R., Njuguna, P., Lang, T. and Fegan, G., 2014. Experience of using an open-source clinical trials data management software system in Kenya. BMC research notes, 7(1), pp.1-8. 4. Huberman, A.M., and Miles, M.B., 1994. Data management and analysis methods. 5. "Schadt, E.E., Linderman, M.D., Sorenson, J., Lee, L. and Nolan, G.P., 2010. Computational solutions to large-scale data management and analysis. Nature reviews genetics, 11(9), pp.647-657. 6. Callahan, S.P., Freire, J., Santos, E., Scheidegger, C.E., Silva, C.T. and Vo, H.T., 2006, June. VisTrails: visualization meets data management. In Proceedings of the 2006 ACM SIGMOD international conference on Management of data (pp. 745-747). 	

Mode of Examination	Assignment/Quiz/Viva-Voce/student seminar/written examination/PPT
Recommended By BOS on:	
Approved by academic council on:	

Mapping of COs with POs & PSOs

Course Outcomes	Program Outcomes (POs)												Program Specific Outcomes (PSOs)				
	PO 1	PO 2	PO 3	PO 4	PO5	PO6	PO 7	PO8	PO 9	PO 10	PO 11	PO 12	PSO 1	PSO 2	PSO 3	PSO 4	PSO 5
CO1	3	3	2	2	1	2	2	2	2	1	1	2	3	3	3	3	3
CO2	3	3	3	2	1	2	2	2	2	1	1	2	3	3	3	3	2
CO3	3	3	2	3	1	3	2	2	1	1	2	2	3	2	2	2	2
CO4	3	2	3	3	1	3	1	2	0	1	0	3	3	3	2	3	3
CO5	3	2	3	2	1	2	2	2	1	1	0	2	3	3	3	3	3

3: High, 2: Medium, 1: Low

Elective Course

CR6004	IPR, Bio-entrepreneurship and Bio-business Management	
Version	1.0	
Prerequisite	Basic understanding of business concepts and intellectual property rights.	
Learning objective	<ol style="list-style-type: none"> 1. Classify different types of intellectual property and analyze their significance in research and development. 2. Evaluate the impact of international agreements and treaties on intellectual property rights in biotechnology. 3. Assess the role of entrepreneurship in fostering innovation and economic development in the biotechnology sector. 4. Analyze the process of establishing and managing a biotechnology enterprise, including project identification and feasibility assessment. 	
Course outcome	<p>CO1: Classify different types of intellectual property and assess their relevance to the biotechnology industry.</p> <p>CO2: Analyze the legal frameworks and international agreements governing intellectual property rights in biotechnology.</p> <p>CO3: Evaluate the role of entrepreneurship in driving innovation and commercialization in the biotechnology sector.</p> <p>CO4: Assess the process of establishing and managing a biotechnology enterprise, including project feasibility and business planning.</p> <p>CO5: Analyze the global market landscape of biotechnology-based businesses and develop strategies for effective bio-business management.</p>	
Unit-I	Intellectual Property	8 hours
	Introduction to Intellectual Property: Types of IP: Patents, Trademarks, Copyright & Related Rights, Industrial Design, Traditional Knowledge, Geographical Indications, Protection of GMOs IP as a factor in R&D;	
Unit-II	Agreement and Treaties	7 hours
	IPs of relevance to Biotechnology and few. Introduction to Indian Patent Law. World Trade Organization and its related intellectual property provisions. History of GATT & TRIPS Agreement; Madrid Agreement; Hague Agreement; WIPO Treaties; Budapest Treaty; PCT; Indian Patent Act 1970 & recent Amendments.	
Unit-III	Entrepreneurship	7 hours
	Meaning, Needs and Importance of Entrepreneurship, Entrepreneurs and Innovators, Promotion of entrepreneurship, Factors influencing entrepreneurship, Features of a successful Entrepreneurship. Selection of a product, line, design and development processes, economics on material and energy requirement, stock the product and release the same for making etc.	
Unit-IV	Establishing and enterprise	7 hours
	Forms of Business Organization, Project Identification, Selection of the product, Project formulation, Assessment of project feasibility. Demand for a given product, feasibility of its production under given constraints of raw material, energy input, financial situations export potential etc.	
Unit-V	Bio-business Management	7 hours

	Worldwide market scenario of biotechnology based business, Bio-business prospective in India. Management Process & organization, General analysis of Indian Bio-business, Project formulation Business Plan, technological assessment, Cost estimation, feasibility and commercial viability of project.
Reference books	<ol style="list-style-type: none"> Holt DH. Entrepreneurship: New Venture Creation. Kaplan JM Patterns of Entrepreneurship. Gupta CB, Khanka SS. Entrepreneurship and Small Business Management, Sultan Chand & Sons. P. Narayan: Patent Law. S. L Rao: Economic reforms and Indian markets.
Mode of Examination	Assignment/Quiz/Viva-Voce/student seminar/written examination/PPT
Recommended By BOS on:	
Approved by academic council on:	

Mapping of COs with POs & PSOs

Course Outcomes	Program Outcomes (POs)												Program Specific Outcomes (PSOs)				
	PO 1	PO 2	PO 3	PO 4	PO5	PO6	PO 7	PO8	PO 9	PO 10	PO 11	PO 12	PSO 1	PSO 2	PSO 3	PSO 4	PSO 5
CO1	3	3	3	2	1	1	2	2	1	1	1	2	3	2	2	2	2
CO2	3	2	3	2	1	1	1	2	2	1	1	1	3	2	2	2	2
CO3	2	2	2	1	2	2	2	2	2	1	1	2	3	2	2	2	3
CO4	3	2	3	2	1	0	3	1	2	1	0	2	3	3	2	1	2
CO5	3	2	2	2	1	1	2	2	3	1	0	2	3	2	3	3	3

3: High, 2: Medium, 1: Low

CR6006	Molecular Modeling and Drug Designing	
Version	1.0	
Prerequisite	All students are expected to have a basic knowledge of Bioinformatics and drugs	
Learning objective	<p>The course is designed to give an overview of the process of drug design and development. The specific objectives of the course are as follows:</p> <ol style="list-style-type: none"> 1. To teach the criteria used for drug development as a process involving target selection and lead discovery. 2. To impart the knowledge about computer aided drug design. 3. To give students an overview of drug delivery system, pre-clinical and clinical testing. 	
Course Outcomes	<p>CO1: Understand the stability profile and barriers to protein and peptide delivery. Analyze methods for delivery of protein and peptide drugs, including lymphatic transportation and site-specific protein modification.</p> <p>CO2: Evaluate drug targeting and delivery systems, including ligands, carrier systems, and vesicular systems for targeting. Analyze cellular-level events in targeting and blood cell receptors.</p> <p>CO3: Analyze various types of vaccines, including multivalent subunit vaccines, synthetic peptide vaccines, and vector vaccines. Evaluate new generation vaccines and novel vaccine delivery systems.</p> <p>CO4: Understand the drug design cycle and principles of structure-activity relationship (SAR). Analyze rational drug design methods, pharmacophoric patterns, and quantitative structure-activity relationship (QSAR).</p> <p>CO5: Evaluate molecular modeling techniques, including quantum mechanical methods and molecular orbital methods. Analyze docking and modeling of substrate-receptor interactions using software tools for computer-aided drug design (CADD).</p>	
Unit-I	Biotechnological products	8 hours
	Introduction, Stability profile, Barriers to proteins and peptide delivery, Delivery of protein & peptide drugs, Lymphatic transportation of proteins, Site specific protein modification (protein engineering), Toxicology profile characterization.	
Unit-II	Basic principles of molecular dynamics	7 hours
	Drug targeting and drug delivery systems: Introduction, Historical perspectives, Drug targeting, Cellular levels events in targeting. Ligands as means of targeting, Blood cell receptors for endogenous compounds, Carrier system for targeting, Vesicular systems for ligand mediated drug targeting, Specialized liposomes for cellular drug targeting.	
Unit-III	Vaccines	7 hours
	Introduction, Multivalent subunit vaccines, Purified macromolecules, Synthetic peptide vaccines, Immuno-adhesions, Recombinant antigen vaccines, Vector vaccines, Anti-idiotypic vaccines, Targeted immune stimulants, Miscellaneous approaches, New generation vaccines, Novel vaccine delivery systems.	
Unit-IV	Drug Design	7 hours
	Introduction to drug design cycle: Structure Activity Relationship (SAR), Rational Drug Design, Pharmacophoric patterns, Quantitative Structure-Activity Relationship. (Q SAR) & Hans equation	
Unit-V	Molecular Modelling	7 hours
	Introduction to molecular modeling: Quantum mechanical and molecular orbital methods,	

	Introduction to semiempirical, molecular mechanics and ab initio techniques. Potential energy surface, Docking and modeling substrate – receptor interactions. Introduction to s/w tools for CADD.
Reference books	<ol style="list-style-type: none"> 1. Andrew Leach, Molecular Modelling: Principles and Applications (2nd Edition), Addison Wesley Longman, Essex, England, 1996. 2. Alan Hinchliffe, Modelling Molecular Structures, 2nd Edition, John-Wiley, 2000. 3. Alan Hinchliffe, Molecular Modelling for Beginners, John-Wiley, 2003. 4. N. Cohen (Ed.), Guide Book on Molecular Modeling in Drug Design, Academic Press, San Diego, 1996. 5. D. Frenkel and B. Smith, Understanding Molecular Simulations. From Algorithms to Applications, Academic Press, San Diego, California, 1996. 6. C. Rauter and K. Horn, X-ray crystallography and drug design, Elsevier, 1984. 7. M. Kalos and P. A. Whitlock, Monte Carlo Methods. John Wiley & Sons, New York, 1986. 8. J.A. McCammon and S.C. Harvey. Dynamics of Proteins and Nucleic Acids. Cambridge University Press, Cambridge, 1987. 9. D.C. Rapaport. The Art of Molecular Dynamics Simulation. Cambridge University Press, Cambridge, England., 1995
Mode of Examination	Assignment/Quiz/Viva-Voce/student seminar/written examination/PPT
Recommended By BOS on:	
Approved by academic council on:	

Mapping of COs with POs & PSOs

Course Outcomes	Program Outcomes (POs)												Program Specific Outcomes (PSOs)				
	PO 1	PO 2	PO 3	PO 4	PO 5	PO 6	PO 7	PO 8	PO 9	PO 10	PO 11	PO 12	PSO 1	PSO 2	PSO 3	PSO 4	PSO 5
CO1	3	3	3	2	1	1	2	2	1	1	1	2	3	2	2	2	2
CO2	3	2	3	2	1	1	1	2	2	1	1	1	3	2	2	2	2
CO3	2	2	2	1	2	2	2	2	2	1	1	2	3	2	2	2	3
CO4	3	2	3	2	1	0	3	1	2	1	0	2	3	3	2	1	2
CO5	3	2	2	2	1	1	2	2	3	1	0	2	3	2	3	3	3

3: High, 2: Medium, 1: Low

SEMESTER-VII (For B.Sc (Hons./Hons. with Research))

CR7001	Good Laboratory and Manufacturing Practices	
Version	1.0	
Prerequisite	All students are expected to have a general knowledge of Basic biology.	
Learning objective	The main objective of this course is to introduce the basic concepts of Quality assurances in Good Laboratory Practices. This course addresses Federal Food and Drug Law and discusses the Trade and Company Standards Control by National, International. This will also enable the students to know about the Scope and importance of GLP and GMP.	
Course outcome	CO1: To know about the detailed guidelines on GLP and GMP. CO2: To study the trade standards of quality Federal Food and Drug Law FDA. CO3: Understand the concept of Regulatory requirements and approval procedures for New Drugs and technologies. CO4: Identify and understand the GLP and GMP CO5: Describe the procedures and importance of GLP and GMP.	
Unit-I	Good Laboratory Practices	8 hours
	Introduction to GLP, WHO guidelines on GLP and GMP, Quality assurances in Good Laboratory Practices and Quality Standards. Advantages and Disadvantages, Concept of Quality Control. Government and trade standards of quality Federal Food and Drug Law FDA Action BSTI Laws, BSTI action and activities other food laws (Legalization).	
Unit-II	Validation of Analytical Procedures	7 hours
	Implications of cGMP and Food plant sanitation. The regulations of cGMPs Planning of Plant Sanitation Programs and Construction factors Hygienic design of food plants and equipment Sanitation in warehousing, storage, shipping, receiving, containers and packaging materials Control of rats, rodents, birds, insects, and microbes. Cleaning and Disinfection: Physical and Microbiological Approach. Food Quality and Quality control including the HACCP system Critical quality control points in different stages of production including raw materials and processing materials)	
Unit-III	Good Manufacturing Practice	7 hours
	Definitions, requirements, and historical background. Quality assurance, quality management, design of quality systems. Principles for documentation in GMP, Site Master File, SMF, Monographs, Protocols (production protocols, standard operating procedures, SOP).	
Unit-IV	Risk Analysis and Precautions	7 hours
	Risk analysis and risk assessment, Clinical trials, Qualification and validation, Microbiological test and quality control, Aseptic production, localities, clothing, Audit, monitoring, internal and external inspections	
Unit-V	Sampling	7 hours
	Sampling: Introduction, WHO guidelines, sampling plans and techniques, operating characteristics curves, maintenance of sampling records of finished product and packaging material. Ethics in manufacturing and control, Principles of quality by design (QBD). Introduction to the concept of Design of Experiment (DOE) Application of QBD principles in Biotech product development.	
Reference books	<ol style="list-style-type: none"> cGMP starter guide: Principles in Good Manufacturing Practices for Beginners, Emmet P. Tobin, Createspace Independent Publishing Platform, April 2016. Good Manufacturing Practices for Pharmaceuticals: GMP in Practice, B Cooper, Createspace Independent Publishing Platform, July 2017. Sarwar Beg and Md Saquib Hasnain, Pharmaceutical Quality by design: Principles and application, Academic press, March 2019. Ron S. Kenett, Shelemyahu Zacks, Daniele Amberti, Modern Industrial Statistics: with applications in R, MINITAB and JMP, 2nd Edition, Wiley, January 2014. N Politis S, Colombo P, Colombo G, M RekkasD.Design of experiments (DoE) in pharmaceutical development, Drug Dev Ind Pharm. 2017 Jun;43(6):889-901. doi: 	

	10.1080/03639045.2017.1291672. 6. Andrew Teasdale, David Elder, Raymond W. Nims, ICH quality guidelines- An implementation guide, Dec 2017. 7. Singh, G., Agarwal, G. and Gupta, V. Drug regulatory affairs, CBS publication, 2005. 8. Marc P. Mathieu, New Drug Development: A regulatory overview, Nov 2000.
Mode of Examination	Assignment/Quiz/Viva-Voce/student seminar/written examination/PPT
Recommended By BOS on:	
Approved by academic council on:	

Mapping of COs with POs & PSOs

Course Outcomes	Program Outcomes (POs)												Program Specific Outcomes (PSOs)				
	PO 1	PO 2	PO 3	PO 4	PO5	PO6	PO 7	PO8	PO 9	PO 10	PO 11	PO 12	PSO 1	PSO 2	PSO 3	PSO 4	PSO 5
CO1	3	3	2	2	1	2	2	2	2	1	1	2	3	3	3	3	3
CO2	3	3	3	2	1	2	2	2	2	1	1	2	3	3	3	3	2
CO3	3	3	2	3	1	3	2	2	1	1	2	2	3	2	2	2	2
CO4	3	2	3	3	1	3	1	2	0	1	0	3	3	3	2	3	3
CO5	3	2	3	2	1	2	2	2	1	1	0	2	3	3	3	3	3

3: High, 2: Medium, 1: Low

CR7002	Emerging Technologies in Clinical Trials	
Version	1.0	
Prerequisite	All students are expected to have a general knowledge of Basic biology.	
Learning objective	The objective of the course on Emerging Technologies in Clinical Research is to provide students with an in-depth understanding of the latest technological advancements and their applications in the field of clinical research. The course aims to familiarize students with the potential benefits, challenges, and regulatory considerations associated with adopting emerging technologies in clinical trials	
Course outcome	<p>CO1. Evaluate the impact of wearable devices, sensors, and other data collection technologies on clinical trial design and data quality.</p> <p>CO2. Analyze the potential applications and benefits of electronic health records (EHR) and real-world data (RWD) in clinical research.</p> <p>CO3. Assess the role of mobile health (mHealth) technologies in patient recruitment, remote monitoring, and data collection in clinical trials.</p> <p>CO4. Examine the use of artificial intelligence (AI) and machine learning (ML) in clinical trial design, patient stratification, and adverse event detection.</p> <p>CO5. Explain the principles and challenges of virtual and decentralized clinical trials and their impact on trial design and patient engagement.</p>	
Unit-I	Introduction to Emerging Technologies in Clinical Trials	8 hours
	Overview of clinical trials and their importance in medical research, Introduction to emerging technologies and their impact on clinical trials, Ethical and regulatory considerations for adopting emerging technologies, Wearable Devices and Sensors in Clinical Trials, Introduction to wearable devices and sensors, Applications of wearables and sensors in data collection, Data integration and analysis from wearables and sensors, Challenges and considerations in using wearable devices in clinical trials	
Unit-II	Electronic Health Records (EHR) and Real-World Data (RWD) in Clinical Trials	7 hours
	Utilizing electronic health records in clinical trial design and recruitment; Leveraging real-world data for trial feasibility, patient selection, and outcomes assessment; Ensuring data quality and privacy in the use of EHR and RWD; Regulatory considerations and guidelines for utilizing EHR and RWD in clinical trials; Mobile Health (mHealth) Technologies in Clinical Trials	
Unit-III	Introduction to mobile health technologies and applications	7 hours
	Mobile apps for patient recruitment, informed consent, and study participation, Remote monitoring and telemedicine in clinical trials, Data security and privacy considerations in mHealth technologies,	
Unit-IV	Artificial Intelligence (AI) and Machine Learning (ML) in Clinical Trials	7 hours
	Overview of AI and ML techniques in clinical trial design and analysis, Predictive modeling and patient stratification using AI and ML, Adverse event detection and signal identification using AI and ML, Ethical considerations and challenges in adopting AI and ML in clinical trials	
Unit-V	Data Analytics and Big Data in Clinical Trials	7 hours
	Introduction to big data and its applications in clinical trials, Predictive analytics for patient recruitment and trial outcomes, Real-time monitoring and adaptive trial design using big data. Digital Biomarkers and Endpoint Assessment	
Reference books	<ol style="list-style-type: none"> 1. Cortez, N., 2018. Digital Health: Scaling Healthcare to the World. Cham, Switzerland: Springer, Cham, pp.249-269. 2. Rosa, C., Campbell, A.N., Miele, G.M., Brunner, M. and Winstanley, E.L., 2015. Using e-technologies in clinical trials. Contemporary clinical trials, 45, pp.41-54. 3. Gresham, G., Schrack, J., Gresham, L.M., Shinde, A.M., Hendifar, A.E., Tuli, R., Rimel, B.J., Figlin, R., Meinert, C.L. and Piantadosi, S., 2018. Wearable activity monitors in oncology trials: current use of an emerging technology. Contemporary 	

	<p>clinical trials, 64, pp.13-21.</p> <ol style="list-style-type: none"> 4. "mHealth: Multidisciplinary Verticals" edited by SasanAdibi 5. "Real-World Evidence Generation and Evaluation of Therapeutics: Proceedings of a Workshop" by the National Academies of Sciences, Engineering, and Medicine 6. "Blockchain in Healthcare: Innovations that Empower Patients, Connect Professionals and Improve Care" by Corey Todaro and John D. Halamka 7. "Artificial Intelligence in Healthcare: A Comprehensive Guide" edited by Shailendra Singh and Rajendra Akerkar 8. "Chang, H., 2015. Book review: Data-driven healthcare & analytics in a big data world. Healthcare informatics research, 21(1), pp.61-62. 9. Manogaran, G., Lopez, D., Thota, C., Abbas, K.M., Pyne, S. and Sundarasekar, R., 2017. Big data analytics in healthcare Internet of Things. Innovative healthcare systems for the 21st century, pp.263-284.
Mode of Examination	Assignment/Quiz/Viva-Voce/student seminar/written examination/PPT
Recommended By BOS on:	
Approved by academic council on:	

Mapping of COs with POs & PSOs

Course Outcomes	Program Outcomes (POs)												Program Specific Outcomes (PSOs)				
	PO 1	PO 2	PO 3	PO 4	PO5	PO6	PO 7	PO8	PO 9	PO 10	PO 11	PO 12	PSO 1	PSO 2	PSO 3	PSO 4	PSO 5
CO1	3	3	2	2	1	2	2	2	2	1	1	2	3	3	3	3	3
CO2	3	3	3	2	1	2	2	2	2	1	1	2	3	3	3	3	2
CO3	3	3	2	3	1	3	2	2	1	1	2	2	3	2	2	2	2
CO4	3	2	3	3	1	3	1	2	0	1	0	3	3	3	2	3	3
CO5	3	2	3	2	1	2	2	2	1	1	0	2	3	3	3	3	3

3: High, 2: Medium, 1: Low

CR7003	RESEARCH METHODOLOGY AND SCIENTIFIC COMMUNICATION SKILLS	
Version	I	
Prerequisite	All students are expected to have a basic knowledge of life sciences and their applications in research.	
Learning objective	The objectives of this course are to give background on history of science, emphasizing methodologies used to do research, use framework of these methodologies for understanding effective lab practices and scientific communication and appreciate scientific ethics.	
Course Outcome	<p>CO1: Understand research methodologies, literature search techniques, and bibliometric analysis in life sciences.</p> <p>CO2: Develop research hypotheses, distinguish between hypothesis-driven and hypothesis-generating research, and apply them effectively in scientific projects.</p> <p>CO3: Design experiments, analyze data using statistical software, and present findings with clarity and precision.</p> <p>CO4: Enhance formal presentation skills, defend research findings, and participate in group discussions effectively.</p> <p>CO5: Master technical writing skills, navigate the scientific publication process, and adhere to ethical standards in scientific communication.</p>	
Unit-I	Introduction to Research Methodology	7 hours
	Fundamentals of Research Methodology, Applications in life sciences, Literature Search: Use of databases, framing query with examples, Bibliometric: Citation, Impact factor, Eigen factor.	
Unit- II	Formulating Research Hypothesis and Experimental Design	7 hours
	Hypothesis Testing: Hypothesis as a framework for scientific projects, Alternatives of hypothesis driven research and hypothesis generating research.	
Unit-III	Experimental Design and Data Analysis	8 hours
	Different types of experimental designs, Controls, Taking measurements, Data Analysis: Between-individual variation, replication and sampling. Data collection, presentation and analysis by using Excel and other statistical software's.	
Unit-IV	Presentation skills	7 hours
	Presentation skills - formal presentation skills, preparing and presenting using over-head projector, PowerPoint; defending interrogation; scientific poster preparation & presentation; participating in group discussions; Computing skills for scientific research - web browsing for information search; search engines and their mechanism of searching; hidden Web and its importance in scientific research; internet as a medium of interaction between scientists; effective email strategy using the right tone and conciseness.	
Unit-V	Scientific communication	7 hours

	Technical writing skills - types of reports; layout of a formal report; scientific writing skills - importance of communicating science; problems while writing a scientific document; plagiarism, software for plagiarism; scientific publication writing: elements of a scientific paper including abstract, introduction, materials & methods, results, discussion, references; drafting titles and framing abstracts; publishing scientific papers - peer review process and problems, recent developments such as open access and non-blind review; plagiarism; characteristics of effective technical communication; scientific presentations; ethical issues; scientific misconduct.
Reference Books	<ol style="list-style-type: none"> 1. Experimental Design for Biologists. David J. Glass. Cold Spring Harbor Laboratory. 2. On Being a Scientist: a Guide to Responsible Conduct in Research. (2009). Washington, D.C.: National Academies Press. 3. Gopen, G. D., & Smith, J. A. The Science of Scientific Writing. American Scientist, 78 (Nov-Dec 1990), 550-558. 4. Research Methods for the Biosciences. Holmes, Moody & Dine. Oxford University Press. 5. C.R. Kotari, Research Methodology Methods and Techniques, Second Revised Edition, New Age International (P) Limited, Publishers.
Mode of Examination	Assignment/Quiz/Viva-Voce/student seminar/written examination/PPT
Recommended By BOS on:	
Approved by academic council on:	

Mapping of COs with POs & PSOs

Course Outcomes	Program Outcomes (POs)												Program Specific Outcomes (PSOs)				
	PO 1	PO 2	PO 3	PO 4	PO5	PO6	PO 7	PO8	PO 9	PO 10	PO 11	PO 12	PSO 1	PSO 2	PSO 3	PSO 4	PSO 5
CO1	3	2	2	2	1	1	1	2	3	2	1	2	3	3	2	2	3
CO2	2	2	2	1	1	2	1	2	3	3	1	1	3	2	2	2	3
CO3	2	2	3	2	1	2	2	2	2	2	0	1	2	2	2	2	3
CO4	2	1	2	1	1	3	1	1	3	3	1	1	2	2	1	1	2
CO5	2	2	2	2	2	3	2	2	3	3	1	1	2	2	2	1	2

3: High, 2: Medium, 1: Low

CR7004	Health Economics and Outcome Research	
Version	I	
Prerequisite	All students are expected to have a basic knowledge of life sciences and their applications in research.	
Learning objective	This course provides an overview of the structure of health care markets and its economy. Students will understand the impact of the health care system on the competing goals of broad access, high quality, and affordability. Identify how consumers and providers respond to changes in incentives and develop an appreciation for opposing views on health care reform.	
Course Outcome	CO1. Explain the use of central ethical principles that are considered when government makes decisions and influence public health. CO2. Summarize which health indices can be used to combine different aspects of health and explain how to derive the cost of illnesses. CO3. Describe how government insurance programs affect participants, medical providers, and private insurance markets. CO4. Distinguish the different types of medical care data and how those measurements are driven by reimbursement and quality measurement needs. CO5. Evaluate the impact of health care reform from both the free-market and government-interventionist perspectives.	
Unit-I	Introduction to Health Economics.	7 hours
	Introduction to Health Economics, Demand; Supply; Market Equilibrium; Elasticity; Market Efficiency; Ethical principles in health economic analysis; Measuring status of health and cost of illness. Introduction to outcome research and its role in evaluating healthcare interventions.	
Unit- II	Economic Evaluation Methods.	7 hours
	Cost-effectiveness analysis (CEA): principles, measures of effectiveness, and cost-effectiveness ratios. Cost-utility analysis (CUA): quality-adjusted life years (QALYs) and utility measures. Cost-benefit analysis (CBA): monetizing health outcomes and interpreting benefit-cost ratios. Budget impact analysis (BIA): assessing the financial implications of healthcare interventions.	
Unit-III	Health Technology Assessment (HTA) and Health Outcomes Measurement	8 hours
	Overview of HTA and its role in evaluating the value of healthcare technologies. HTA agencies, guidelines, and processes in different countries. Conducting economic evaluations for HTA purposes. Health Outcomes Measurement: Patient-reported outcomes (PROs) and quality of life assessments. Health-related quality of life instruments and utility measurement. Preference-based valuation methods (e.g., time trade-off, standard gamble).	
Unit-IV	Economic Evaluation in Pharmaceutical Industry.	7 hours
	Economic Evaluation in Pharmaceutical Industry: Economic considerations in pharmaceutical product development. Pricing and reimbursement strategies. Real-world evidence (RWE) and its role in economic evaluations.	
Unit-V	Health Policy and Health Economics.	7 hours
	Health policy analysis and its relationship with health economics. Economic evaluation in healthcare policy decision-making. The role of economic evaluations in healthcare resource allocation. Ethical and Methodological Issues: Ethical considerations in health economic research. Methodological challenges and limitations in conducting economic evaluations. Interpretation and reporting of health economic analyses.	

Reference Books	Health Economics, Jay Battacharya, Timothy Hyde, and Peter Tu, 1st Edition, Palgrave Macmillan, 2014. 2. Health Care Reform: What It Is, Why It is Necessary, How It Works, Jonathan Gruber, 2012. An Introduction to Health Economics (Pharmacoeconomics & outcomes research). Brookwood Medical Publications Ltd (1 January 1995). M.F. Drummond. 4. https://www.econ.berkeley.edu/undergrad/home/learning-goals
Mode of Examination	Assignment/Quiz/Viva-Voce/student seminar/written examination/PPT
Recommended By BOS on:	
Approved by academic council on:	

Mapping of COs with POs & PSOs

Course Outcomes	Program Outcomes (POs)												Program Specific Outcomes (PSOs)				
	PO 1	PO 2	PO 3	PO 4	PO5	PO6	PO 7	PO8	PO 9	PO 10	PO 11	PO 12	PSO 1	PSO 2	PSO 3	PSO 4	PSO 5
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CO2	3	2	3	2	1	1	1	2	2	1	1	1	3	2	2	2	2
CO3	2	2	2	1	2	2	2	2	2	1	1	2	3	2	2	2	3
CO4	3	2	3	2	1	0	3	1	2	1	0	2	3	3	2	1	2
CO5	3	2	2	2	1	1	2	2	3	1	0	2	3	2	3	3	3

3: High, 2: Medium, 1: Low

CR7005	Epidemiology
Version	I
Prerequisite	Basic understanding of public health concepts and familiarity with statistical analysis methods.
Learning objective	Understand epidemiological concepts and methods, and apply them to analyze disease patterns and outbreaks. Evaluate the effectiveness of public health interventions in preventing and controlling diseases, and address global health challenges.
Course Outcome	<p>CO1: Understand the fundamentals of epidemiology in public health, including its definition, historical development, and the principles and methods of disease surveillance.</p> <p>CO2: Identify and differentiate between various epidemiological study designs, including observational and experimental studies, and evaluate their strengths and limitations in establishing causality.</p> <p>CO3: Analyse epidemiological data using measures of disease frequency and association, interpret findings using statistical tools, and recognize and address biases, confounding factors, and effect modification in study design.</p> <p>CO4: Explore the role of epidemiologists in detecting, monitoring, and controlling outbreaks of infectious and non-communicable diseases, and analyse case studies to understand real-life epidemiological outbreaks.</p> <p>CO5: Evaluate strategies for disease prevention and control, including primary, secondary, and tertiary prevention measures, and understand the significance of public health interventions in addressing global health challenges, including emerging infectious diseases and global health disparities.</p>
Unit-I	Introduction to Epidemiology and Disease surveillance 7 hours
	Epidemiology in public health- Definition and importance; Historical development in epidemiological research. Principles and methods of disease surveillance. Steps in outbreak investigation: Identification, confirmation, descriptive epidemiology, hypothesis generation, analytical studies, and control measures.
Unit- II	Epidemiological Study Designs 7 hours
	Observational studies: Cross-sectional, case-control, and cohort studies; Experimental studies: Randomized controlled trials and community trials. Strengths and limitations of different study designs in establishing causality and informing public health interventions.
Unit-III	Analyzing Epidemiological Data 8 hours
	Measures of disease frequency and association: Incidence, prevalence, Odds ratio, relative risk, and attributable risk. Interpretation of epidemiological data using tables, graphs, and statistical software. Bias, confounding, and effect modification: Identification and control in epidemiological studies.
Unit-IV	Disease prevention and control 7 hours
	Role of epidemiologists in detecting, monitoring, and controlling outbreaks of infectious and non-communicable diseases. Case studies of real-life epidemiological outbreaks
Unit-V	Public Health Interventions and Global Health 7 hours
	Strategies for disease prevention and control: Primary, secondary, and tertiary prevention. Public health interventions: Vaccination programs, health promotion campaigns, and environmental interventions. Epidemiology in global health: Emerging infectious diseases, pandemic preparedness, and global health disparities.

Reference Books	<ol style="list-style-type: none"> "Epidemiology: Beyond the Basics" by Moyses Szklo and Javier Nieto (2014) "Epidemiology: An Introduction" by Kenneth J. Rothman (2021) "Modern Epidemiology" by Kenneth J. Rothman, Sander Greenland, and Timothy L. Lash (2008) "Principles of Epidemiology in Public Health Practice" by Richard Dicker, Daniel E. Smith, and William R. Teutsch (2020) "Introduction to Epidemiology" by Ray M. Merrill (2010)
Mode of Examination	Assignment/Quiz/Viva-Voce/student seminar/written examination/PPT
Recommended By BOS on:	
Approved by academic council on:	

Mapping of COs with POs & PSOs

Course Outcomes	Program Outcomes (POs)												Program Specific Outcomes (PSOs)				
	PO 1	PO 2	PO 3	PO 4	PO5	PO6	PO 7	PO8	PO 9	PO 10	PO 11	PO 12	PSO 1	PSO 2	PSO 3	PSO 4	PSO 5
CO1	3	3	3	2	1	1	2	2	1	1	1	2	3	2	2	2	2
CO2	3	2	3	2	1	1	1	2	2	1	1	1	3	2	2	2	2
CO3	2	2	2	1	2	2	2	2	2	1	1	2	3	2	2	2	3
CO4	3	2	3	2	1	0	3	1	2	1	0	2	3	3	2	1	2
CO5	3	2	2	2	1	1	2	2	3	1	0	2	3	2	3	3	3

3: High, 2: Medium, 1: Low

SEMESTER-VIII [For B.Sc (Hons.) Clinical Research]

CR8001	Computer Aided Drug Designing (CADD)	
Version	1.0	
Prerequisite	All students are expected to have a basic knowledge of Computer Sciences, and Clinical Research.	
Course objective	This subject is designed to provide detailed knowledge of rational drug design process and various techniques used in rational drug design process.	
Course outcome	<p>Upon completion of the course, the student shall be able to understand</p> <p>CO1: Understand various rational approaches to lead discovery in drug design, including traditional medicine-based, random screening, and serendipitous discovery methods.</p> <p>CO2: Familiarize with bioinformatics and chemoinformatics tools, including ADME databases, and comprehend their role in drug design and discovery.</p> <p>CO3: Identify and analyze different types of drug targets, including proteins/enzymes, receptor proteins, and nucleic acids, along with understanding the intermolecular binding forces between drugs and targets.</p> <p>CO4: Gain proficiency in molecular modeling and virtual screening techniques, such as pharmacophore mapping, molecular docking, and de novo drug design, for lead optimization and compound screening.</p> <p>CO5: Understand the principles and applications of Quantitative Structure-Activity Relationship (QSAR) in drug design, including the history, types of physicochemical parameters, and experimental/theoretical approaches for parameter determination.</p>	
Unit-I	Lead discovery and Analog Based Drug Design	7 hours
	Rational approaches to lead discovery based on traditional medicine, Random screening, Non-random screening, serendipitous drug discovery, lead discovery based on drug metabolism, lead discovery based on clinical observation	
Unit-II	Informatics & Methods in drug design	7 hours
	Introduction to Bioinformatics, chemoinformatics. ADME databases, chemical, biochemical and pharmaceutical databases.	
Unit-III	Drug Targets	7 hours
	Molecular Concept of Disease, Disease Pathway (example of inflammation pathway), Drug-Targets; Types of Drug targets: Proteins/Enzymes, Receptor Proteins, Nucleic Acids & other drug targets, Active sites and pharmacophores, allosteric sites, Intermolecular binding force of drugs with targets: electrostatic or ionic bonds, Hydrogen bonds, Vander Waals forces, Dipole-dipole and ion dipole interaction, Repulsive interaction and Pi-Pi interaction	
Unit-IV	Molecular Modeling and virtual screening techniques	8 hours
	Virtual Screening techniques: Drug likeness screening, Concept of pharmacophore mapping and pharmacophore-based Screening, Molecular docking: Rigid docking, flexible docking, manual docking, Docking based screening. De novo drug design.	
Unit-V	Quantitative Structure Activity Relationship (QSAR)	7 hours
	History and development of QSAR, Types of physicochemical parameters, experimental and theoretical approaches for the determination of physicochemical parameters such as Partition	

	coefficient, Hammett's substituent constant and Taft's steric constant.
Reference books	<ol style="list-style-type: none"> 1. Textbook: Molecular Modelling: Principles and Applications (Paperback), by Andrew R. Leach, Pearson Higher Education, USA, 2001 (ISBN 0582382106). b) Handouts and notes for the computer labs 2. Bioinformatics for Beginners: Genes, Genomes, Molecular Evolution, Databases, and Analytical Tools by Supratim Choudhuri (2019) 3. Principles of Drug Design by Hansch, C., et al. (2010)
Mode of Examination	Assignment/Quiz/Viva-Voce/student seminar/written examination/PPT
Recommended By BOS on:	
Approved by academic council on:	

Mapping of COs with POs & PSOs

Course Outcomes	Program Outcomes (POs)												Program Specific Outcomes (PSOs)				
	PO 1	PO 2	PO 3	PO 4	PO 5	PO 6	PO 7	PO 8	PO 9	PO 10	PO 11	PO 12	PSO 1	PSO 2	PSO 3	PSO 4	PSO 5
CO1	3	3	3	2	1	1	2	2	1	1	1	2	3	2	2	2	2
CO2	3	2	3	2	1	1	1	2	2	1	1	1	3	2	2	2	2
CO3	2	2	2	1	2	2	2	2	2	1	1	2	3	2	2	2	3
CO4	3	2	3	2	1	0	3	1	2	1	0	2	3	3	2	1	2
CO5	3	2	2	2	1	1	2	2	3	1	0	2	3	2	3	3	3

3: High, 2: Medium, 1: Low

CR8002	Entrepreneurship Development	
Version	1.0	
Prerequisite	Basic understanding of business concepts and principles, including organizational structures and financial management.	
Course objective	<ol style="list-style-type: none"> 1. To understand the meaning and importance of Entrepreneurship. 2. To understand the various forms of business organization. 3. To analyze the importance of finance in an enterprise. 4. To analyze the importance of marketing management in an enterprise. 5. To understand the meaning of international business. 	
Course outcome	<p>CO1: Remember and define the terms and basic concepts of entrepreneurship development and their different roles to influencing entrepreneurship, features of a successful Entrepreneurship</p> <p>CO2: Understand and remember the introduction and principle, mechanism of entrepreneurship, features, financing the enterprise, marketing management and entrepreneurship and international business.</p> <p>CO3: Applying, understanding and remembering the detailed processes of mechanism of entrepreneurship, features, financing the enterprise, marketing management and entrepreneurship and international business.</p> <p>CO4: Analyzing, Applying, remembering, understanding the detailed and complete study related to Biotechnological entrepreneurship features for the growth or individual person and society</p> <p>CO5: Evaluating, analyzing, applying, remembering, and understanding the properties of mechanism of entrepreneurship, features, financing the enterprise, marketing management and entrepreneurship and international business.</p> <p>CO6: Constructing (Creating), Evaluating, Analyzing, demonstrating, remembering, and understanding the entrepreneurship and the awareness, appreciation and applicability in environment, and their diverse functions.</p>	
Unit-I	INTRODUCTION TO ENTREPRENEURSHIP	7 hours
	Meaning, Needs and Importance of Entrepreneurship, Promotion of entrepreneurship, Factors influencing entrepreneurship, Features of a successful Entrepreneurship.	
Unit-II	ESTABLISHING AN ENTERPRISE	7 hours
	Forms of Business Organization, Project Identification, Selection of the product, Project formulation, Assessment of project feasibility.	
Unit-III	FINANCING THE ENTERPRISE	7 hours
	Importance of finance / loans and repayments, Characteristics of Business finance, Fixed capital management: Sources of fixed capital, working capital its sources and how to move for loans, Inventory direct and indirect raw materials and its management.	
Unit-IV	MARKETING MANAGEMENT	8 hours
	Meaning and Importance, Marketing-mix, product management – Product line, Product mix, stages of product like cycle, marketing Research and Importance of survey, Physical Distribution and Stock Management.	
Unit-V	ENTREPRENEURSHIP AND INTERNATIONAL BUSINESS	7 hours
	Meaning of International business, Selection of a product, Selection of a market for	

	international business, Export financing, Institutional support for exports
Reference books	1. Holt DH. Entrepreneurship: New Venture Creation. (2019) 2. Kaplan JM Patterns of Entrepreneurship. (2017) 3. Gupta CB, Khanka SS. Entrepreneurship and Small Business Management, Sultan Chand & Sons. (2018)
Mode of Examination	Assignment/Quiz/Viva-Voce/student seminar/written examination/PPT
Recommended By BOS on:	
Approved by academic council on:	

Mapping of COs with POs & PSOs

Course Outcomes	Program Outcomes (POs)												Program Specific Outcomes (PSOs)				
	PO 1	PO 2	PO 3	PO 4	PO5	PO6	PO 7	PO8	PO 9	PO 10	PO 11	PO 12	PSO 1	PSO 2	PSO 3	PSO 4	PSO5
CO1	2	3	2	2	2	2	2	1	2	2	2	1	3	2	1	3	2
CO2	1	2	1	2	2	2	3	3	2	2	2	1	1	2	2	3	3
CO3	1	2	2	2	2	1	2	2	1	2	3	0	3	3	2	2	2
CO4	2	1	2	2	2	3	2	1	2	2	3	2	2	3	3	2	2
CO5	1	2	2	2	2	2	3	2	1	2	2	1	3	2	1	2	2
CO6	2	1	2	2	3	2	2	1	2	2	2	1	2	1	2	2	2

3: High, 2: Medium, 1: Low

Elective Courses

CR8005	Global Regulations of Clinical Trials	
Version	1.0	
Prerequisite	All students are expected to have a general knowledge of Basic biology.	
Learning objective	This course is designed to impart the fundamental knowledge on the clinical development process of drugs, pharmaceuticals and medical devices, regulations and guidance governing the conduct of clinical research in India, USA, and EU.	
Course outcome	<p>CO1: Discuss global regulations in clinical research, medical device development process and different types and phases of Clinical trials.</p> <p>CO2: Describe different regulations governing clinical trials in India as well as USA and EU.</p> <p>CO3: Explore the ethical considerations and principles underlying clinical trial regulations.</p> <p>CO4: Examine the processes involved in clinical trial approval, monitoring, and reporting.</p> <p>CO5. Analyze the challenges and harmonization efforts in global clinical trial regulations.</p>	
Unit-I	Regulatory Authorities and Roles	8 hours
	International regulatory bodies: ICH, WHO, and their guidelines, Regional regulatory authorities: FDA, EMA, PMDA, and others, Roles, and responsibilities of regulatory agencies in clinical trial oversight.	
Unit-II	Clinical Research Regulations	7 hours
	Clinical research regulations in India – Schedule Y, New Drugs in Clinical Trials 2019 & Medical device guidelines-ISO14155. Guidance USA: Regulations to conduct drug studies in USA (FDA) NDA 505(b) (1) of the FD&C Act (Application for approval of a new drug) NDA 505(b) (2) of the FD&C Act (Application for approval of a new drug that relies, at least in part, on data not developed by the applicant) ANDA 505(j) of the FD&C Act (Application for approval of a generic drug products Biosimilar Guidelines)	
Unit-III	Clinical Research Related Guidelines:	7 hours
	<p>E4 – Dose Response Information to support Drug Registration</p> <p>E7 – Studies in support of General Population: Geriatrics</p> <p>E8 – General Considerations of Clinical Trials</p> <p>E10 – Choice of Control Groups and Related Issues in Clinical Trials,</p> <p>E11 – Clinical Investigation of Medicinal Products in the Pediatric Population</p>	
Unit-IV	Code of federal regulations related to clinical trials	7 hours
	<p>CFR 21Part 50: Protection of Human Subjects</p> <p>CFR 21Part 54: Financial Disclosure by Clinical Investigators</p> <p>CFR 21Part 312: IND Application</p> <p>CFR 21Part 314: Application for FDA Approval to Market a New Drug</p> <p>CFR 21Part 320: Bioavailability and bioequivalence requirements</p> <p>CFR 21Part 812: Investigational Device Exemptions</p> <p>CFR 21Part 822: post-market surveillance</p>	
Unit-V	Harmonization Efforts and Future Trends	7 hours
	Global harmonization initiatives in clinical trial regulations, international collaboration and mutual recognition agreements, Emerging trends, and future directions in global clinical trial regulations	
Reference books	<ol style="list-style-type: none"> Chin, R. and Bairu, M. eds., 2011. Global clinical trials: effective implementation and management. Academic Press. Gallin, J.I. and Ognibene, F.P. eds., 2012. Principles and practice of clinical research. Academic Press. Gad, S.C. ed., 2009. Clinical trials handbook. John Wiley & Sons. Plomer, A., 2013. The law and ethics of medical research: international bioethics and human rights. Routledge. 	

	5. Chow, S.C. and Liu, J.P., 2008. Design and analysis of clinical trials: concepts and methodologies (Vol. 507). John Wiley & Sons. 6. Lang, T. and Siribaddana, S., 2012. Clinical trials have gone global: is this a good thing? PLoS medicine, 9(6), p.e1001228.
Mode of Examination	Assignment/Quiz/Viva-Voce/student seminar/written examination/PPT
Recommended By BOS on:	
Approved by academic council on:	

Mapping of COs with POs & PSOs

Course Outcomes	Program Outcomes (POs)												Program Specific Outcomes (PSOs)				
	PO 1	PO 2	PO 3	PO 4	PO5	PO6	PO 7	PO8	PO 9	PO 10	PO 11	PO 12	PSO 1	PSO 2	PSO 3	PSO 4	PSO5
CO1	2	3	2	2	2	2	2	1	2	2	2	1	3	2	1	3	2
CO2	1	2	1	2	2	2	3	3	2	2	2	1	1	2	2	3	3
CO3	1	2	2	2	2	1	2	2	1	2	3	0	3	3	2	2	2
CO4	2	1	2	2	2	3	2	1	2	2	3	2	2	3	3	2	2
CO5	1	2	2	2	2	2	3	2	1	2	2	1	3	2	1	2	2
CO6	2	1	2	2	3	2	2	1	2	2	2	1	2	1	2	2	2

3: High, 2: Medium, 1: Low

CR8006	Good Clinical Laboratory Practice	
Version	1.0	
Prerequisite	All students are expected to have a basic knowledge of clinical research.	
Learning objective	To understand the relevance, importance and basic concepts of good laboratory practices To apply the knowledge to become familiar with the basic laboratory skills	
Course outcome	CO1: Explain the principles and importance of Good Clinical Laboratory Practice (GCLP). CO2: Describe laboratory organization, personnel roles, and safety guidelines. CO3: Apply proper procedures for sample collection, handling, and documentation. CO4: Implement quality control and quality assurance practices in laboratories. CO5: Interpret regulatory guidelines and manage laboratory data in compliance with standards.	
Unit-I	Introduction	8 hours
	Introduction to Bioethics and Biosafety. Biosafety Guidelines and Regulations. Legal and Socio-economic Impacts of Biotechnology. Use of Genetically Modified Organisms and their Release in the Environment. Hazardous Materials used in Biotechnology their Handling and Disposal.	
Unit-II	Good Laboratory Practice Principle	7 hours
	Test Facility Organization and Personnel: Management responsibility, Study directors responsibility, safety measures and personal responsibility. Quality assurance program. Facilities: Test System Facilities, Facilities for Handling test and Reference Substances. Archive Facilities. Waste Disposal, Animal Care Facilities, Animal Supply Facilities.	
Unit-III	Standardized Operating Procedures	7 hours
	Definition, Initiation of SOP, Preparation of SOP, Administration, Distribution and Implementation. Maintenance of laboratory records. Formatting SOP, Reagent/materials certification, Certification of analysts, Certification of laboratory facilities, Documentation and maintenance of record.	
Unit-IV	Date Reporting and Storage	7 hours
	Performance of study, Study plan, Conduct of study, Reporting of results. Archival storage of records and reports.	
Reference books	Dawson, B. and Trapp, R.G. 2019. Basic and Clinical Biostatistics. 5 th ed. Lange medical books/McGraw-Hill Inc. Zar, Jerrold H. 2014. Biostatistical Analysis. 5 th ed. Pearson Education. Selvin, S. 2011. Biostatistics: Statistical Tools for Epidemiological Research. Oxford University Press. Lepš, J. and Šmilauer, P. 2020. Biostatistics with R: An introductory guide for Field Biologists. 1 st ed. Cambridge University Press.	
Mode of Examination	Assignment/Quiz/Viva-Voce/student seminar/written examination/PPT	
Recommended By BOS on:		
Approved by academic council on:		

Mapping of COs with POs & PSOs

Course	Program Outcomes (POs)	Program Specific Outcomes (PSOs)
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Outcomes	PO 1	PO 2	PO 3	PO 4	PO5	PO6	PO 7	PO8	PO 9	PO 10	PO 11	PO 12	PSO 1	PSO 2	PSO 3	PSO 4	PSO5
CO1	2	3	2	2	2	2	2	1	2	2	2	1	3	2	1	3	2
CO2	1	2	1	2	2	2	3	3	2	2	2	1	1	2	2	3	3
CO3	1	2	2	2	2	1	2	2	1	2	3	0	3	3	2	2	2
CO4	2	1	2	2	2	3	2	1	2	2	3	2	2	3	3	2	2
CO5	1	2	2	2	2	2	3	2	1	2	2	1	3	2	1	2	2
CO6	2	1	2	2	3	2	2	1	2	2	2	1	2	1	2	2	2

3: High, 2: Medium, 1: Low