MGM INSTITUTE OF HEALTH SCIENCES

(Deemed to be University u/s 3 of UGC Act, 1956)
Grade 'A' Accredited by NAAC
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CHOICE BASED CREDIT SYSTEM

(CBCS)

(with effect from 2025-26 Batches)

Curriculum for

M.Sc. Clinical Research

Amended as per AC-52/2025, Dated 28/11/2025

Amended History

1. Amended as per AC-51/2025, [Resolution No.3.1(Annexure-3.15)], [Resolution No.3.5, (Annexure-7)]; Dated 29/04/2025.

2. Amended as per AC-52/2025, [Resolution No.5.1(Annexure- 17P)], [Resolution No.5.8, (Annexure- 24N)]; Dated 28/11/2025.

Resolution No. 3.1 of Academic Council (AC-51/2025):

Resolved to approve the CBCS syllabus, including Program Outcomes (POs), Course Outcomes (COs), and PO-CO Mapping for 15 two-year postgraduate programs under MGMSBS for Semesters I and II. These include : M.Sc. Medical Biotechnology, M.Sc. Medical Genetics, M.Sc. Clinical Embryology, M.Sc. Clinical Nutrition, M. Sc. Medical Dialysis Technology, M.Sc. Molecular Biology, M.Sc. Medical Radiology & Imaging Technology, M. Sc. Cardiac Care Technology, M.Sc. Operation Theatre and Anaesthesia Technology, M.Sc. Emergency and Trauma Care, M. Optometry , Master in Hospital Administration , Master of Public Health , M.Sc. Health Informatics & **M.Sc. Clinical Research** to be effective from batch admitted in Academic Year 2025-26 onwards [ANNEXURE-3.1 to 3.30].

Annexure-3.15 of AC-51/2025

MGM SCHOOL OF BIOMEDICAL SCIENCES, NAVI MUMBAI
(A constituent unit of MGM INSTITUTE OF HEALTH SCIENCES)
(Deemed to be University u/s 3 of UGC Act 1956)
Grade "A^{++}" Accredited by NAAC
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CHOICE BASED CREDIT SYSTEM (CBCS)

(Academic Year 2025 - 26)

Curriculum for

M.Sc. Allied Health Sciences

M.Sc. Clinical Research

Semester I & II

DIRECTOR'S MESSAGE

Welcome Message from the Director

Dear Postgraduate Students,

Welcome to **MGM School of Biomedical Sciences (MGMSBS), MGMIHS**, a premier institution dedicated to advancing allied and health sciences education. As you embark on this transformative academic journey, you are joining a community that fosters excellence in research, clinical expertise, and innovation**.**

MGMIHS, accredited with **NAAC 'A^{++}' Grade (CGPA 3.55, 2022)** and recognized as a **Category I Institution by UGC**, offers an ecosystem that nurtures both academic and professional growth. With **NIRF (151-200 rank band) recognition, NABH-accredited hospitals, NABL-accredited diagnostic labs, and JCI accreditation for MGM New Bombay Hospital**, we uphold global benchmarks in education and healthcare.

At MGMSBS, our **15 postgraduate programs** are meticulously designed to align with the National Commission for Allied and Healthcare Professionals **(NCAHP)** standards**,** National Education Policy **(NEP)** 2020**,** and the National Credit Framework **(NCrF).** We have implemented the **Choice-Based Credit System (CBCS)** to provide academic flexibility while ensuring rigorous training in clinical and technical skills**.** Our state-of-the-art research laboratories, digital classrooms, and the Central Research Laboratory (CRL) foster an environment that encourages innovation and evidence-based learning**.**

Postgraduate education at MGMSBS goes beyond theoretical learning—our curriculum integrates **hands-on clinical training, interdisciplinary collaboration, and exposure to real-world healthcare challenges**. We emphasize **research-driven education**, encouraging students to actively participate in **scientific discoveries, publications, and international collaborations**.

Beyond academics, we believe in **holistic development**, with initiatives such as the **AARAMBH Science and Wellness Club**, which promotes **mental well-being, leadership, and professional networking**.

As you step into this **next phase of academic and professional growth**, we encourage you to explore new ideas, engage in impactful research, and contribute meaningfully to the **healthcare ecosystem**. We are confident that your journey at MGMSBS will shape you into **skilled, compassionate, and visionary professionals**, ready to lead in the ever-evolving healthcare landscape.

We look forward to witnessing your achievements and contributions!

Dr. Mansee Thakur
Director, MGM School of Biomedical Sciences
MGM Institute of Health Sciences, Navi Mumbai

ABOUT MGM SCHOOL OF BIOMEDICAL SCIENCES

Mission

To improve the quality of life, both at individual and community levels by imparting quality medical education to tomorrow's doctors and medical scientists and by advancing knowledge in all fields of health sciences though meaningful and ethical research.

Vision

By the year 2022, MGM Institute of Health Sciences aims to be top-ranking Centre of Excellence in Medical Education and Research. Students graduating from the Institute will have the required skills to deliver quality health care to all sections of the society with compassion andbenevolence, without prejudice or discrimination, at an affordable cost. As a research Centre, it shall focus on finding better, safer and affordable ways of diagnosing, treating and preventing diseases. In doing so, it will maintain the highest ethical standards.

About – School of Biomedical Sciences

MGM School of Biomedical Sciences is formed under the aegis of MGM IHS with the vision of offering basic Allied Science and Medical courses for students who aspire to pursue their career in the Allied Health Sciences, teaching as well as research.

School of Biomedical Sciences is dedicated to the providing the highest quality education in basic medical sciences by offering a dynamic study environment with well-equipped labs. The school encompasses 23 courses each with its own distinct, specialized body of knowledge and skill. This includes 8 UG courses and 15 PG courses. The college at its growing years started with mere 100 students has recorded exponential growth and is now a full-fledged educational and research institution with the student strength reaching approximately **800** at present.

Our consistent theme throughout is to encourage students to become engaged, be active learners and to promote medical research so that ultimately they acquire knowledge, skills, and understanding so as to provide well qualified and trained professionals in Allied Health Sciences to improve the quality of life.

As there is increased need to deliver high quality, timely and easily accessible patient care system the collaborative efforts among physicians, nurses and allied health providers become ever more essential for an effective patient care. Thus the role of allied health professionals in ever-evolving medical system is very important in providing high-quality patient care.

Last but by no means least, School of Biomedical Sciences envisions to continuously grow and reform. Reformations are essential to any growing institution as it fulfills our bold aspirations of providing the best for the students, for us to serve long into the future and to get ourselves updated to changing and evolving trends in the health care systems.

Name of the Degree: M.Sc. Clinical Research

Duration of Study:

2 Years Full-Time/4 Semesters/Mandatory dissertation project in last semester

Eligibility Criteria:

Bachelor's degree in a related field like medicine, dentistry, pharmacy, Nursing, AHS, or life sciences, with a minimum of 55% marks.

Medium of Instruction:

English shall be the Medium of Instruction for all the Subjects of study and for examinations.

For any query visit the website: www.mgmsbsa.edu.in

M.Sc. Clinical Research

Program Outcome

Code	Program Outcome (PO)	Description	Domain
PO1	**Advanced Knowledge in Clinical Research**	Demonstrate comprehensive knowledge of clinical research methodologies, study design, biostatistics, and ethical principles to conduct high-quality research.	Knowledge
PO2	**Regulatory Compliance & Ethical Conduct**	Apply national and international regulatory guidelines, ethical considerations, and Good Clinical Practice (GCP) standards in clinical trials and patient safety.	Knowledge & skill, decision making
PO3	**Research Design & Data Analysis**	Develop, implement, and analyze clinical research studies using appropriate methodologies, statistical tools, and data interpretation techniques.	Methodology & Analytical Skills
PO4	**Leadership & Communication in Research**	Exhibit leadership, teamwork, and effective communication skills in interdisciplinary clinical research settings for successful project management and collaboration.	Professional & Interpersonal Skills
PO5	**Innovation & Evidence-Based Decision Making**	Utilize critical thinking, innovation, and evidence-based approaches to address challenges in drug development, clinical trials, and healthcare advancements.	Critical Thinking & Problem-Solving

Course Outcomes
Semester I

MCR 101 T Practical Lab I (MCR 101)	History & Fundamentals of Clinical Research	Mapped PO	Teaching-Learning Methodology	Assessment Tools
CO1	Explain the Evolution of Clinical Research	**PO1-PO5**	Lecture, Practical, Journal, Assignment, E-Learning and Poster / Videos	Internal Assessment and University Exam, Theory exam, Practical Exam, MCQ, Viva-voce, Station Exercise, Seminar, Assignment
CO2	Demonstrate Understanding of Ethical and Regulatory Frameworks, Define the Scope and Importance of Clinical Research, Describe the Phases of Clinical Trials	**PO1**	Lecture, Journal, Assignment, E-Learning and Poster / Videos	Internal Assessment and University Exam, Theory exam, Practical Exam, MCQ, Viva-voce, Station Exercise, Seminar, Assignment
CO3	Evaluate the Impact of Landmark Clinical Trials, Integrate Lessons from History into Modern Clinical Research	**PO1,PO4**	Lecture, Journal, Assignment, E-Learning and Poster / Videos	Internal Assessment and University Exam, Theory exam, Practical Exam, MCQ, Viva-voce, Station Exercise, Seminar, Assignment
CO4	Apply Principles of Good Clinical Practice (GCP)	**PO2**	Lecture, Journal, Assignment, E-Learning and Poster / Videos	Internal Assessment and University Exam, Theory exam, Practical Exam, MCQ, Viva-voce, Station Exercise, Seminar, Assignment
CO5	Identify Key Figures in Clinical Research, Analyze Regulatory and Ethical Considerations, Develop Skills in Protocol Design and Study Methodology	**PO1-PO5**	Lecture, Journal, Assignment, E-Learning and Poster / Videos	Internal Assessment and University Exam, Theory exam, Practical Exam, MCQ, Viva-voce, Station Exercise, Seminar, Assignment
CO 6	Assess Societal and Ethical Challenges in Clinical Research	**PO5**	Lecture, Journal, Assignment, E-Learning and Poster / Videos	Internal Assessment and University Exam, Theory exam, Practical Exam, MCQ, Viva-voce, Station Exercise, Seminar, Assignment

CO7	Understand Pharmacovigilance and Safety Monitoring	**PO1, PO3,PO5**	Lecture, Journal, Assignment, E-Learning and Poster / Videos	Internal Assessment and University Exam, Theory exam, Practical Exam, MCQ, Viva-voce, Station Exercise, Seminar, Assignment

MCR 102 T Practical Lab I (MCR 102)	**Clinical Research Methodologies**	**Mapped PO**	**Teaching- Learning Methodology**	**Assessment Tools**
CO1	Explain the fundamental concepts, definitions, and applications of research.	**PO1,PO4**	Lecture, Seminar, Problem Based Learning, Guest Lecture, Assignment	Internal Assessment, University Exam, Theory exam, Seminar, MCQ, Assignment
CO2	Classify research types based on applications, objectives, and paradigms.	**PO1-PO5**	Lecture, Seminar, Problem Based Learning, Guest Lecture, Assignment	Internal Assessment, University Exam, Theory exam, Seminar, MCQ, Assignment
CO3	Describe and explain the eight-step research process.	**PO1,PO4**	Lecture, Seminar, Problem Based Learning, Guest Lecture, Assignment	Internal Assessment, University Exam, Theory exam, Seminar, MCQ, Assignment
CO4	Formulate a research problem, design, and proposal.	**PO3**	Lecture, Seminar, Problem Based Learning, Guest Lecture, Assignment	Internal Assessment, University Exam, Theory exam, Seminar, MCQ, Assignment
CO 5	Demonstrate data collection methods, sampling techniques, and instrument construction.	**PO1-PO5**	Lecture, Seminar, Problem Based Learning, Guest Lecture, Assignment	Internal Assessment, University Exam, Theory exam, Seminar, MCQ, Assignment
CO6	Analyze literature to identify research gaps and synthesize findings.	**PO1,PO2,PO4**	Lecture, Seminar, Problem Based Learning, Guest Lecture, Assignment	Internal Assessment, University Exam, Theory exam, Seminar, MCQ, Assignment

CO7	Develop skills for structuring and writing research reports effectively.	**PO3, PO5**	Lecture, Seminar, Problem Based Learning, Guest Lecture, Assignment	Internal Assessment, University Exam, Theory exam, Seminar, MCQ, Assignment

MCR 103 T Practical Lab I (MCR 103)	**Pharmacology- I**	**Mapped PO**	**Teaching-Learning Methodology**	**Assessment Tools**
CO1	Explain the history, sources, drug development process, and principles of pharmacology.	**PO1,PO4**	Lecture, Practical, Assignment, Journal	Internal Assessment and University Exam, Theory exam, Practical Exam, Seminar, Viva-Voce, Station exercise, MCQ,
CO2	Describe different routes of drug administration and the pharmacokinetics of drugs.	**PO1,PO4**	Lecture, Practical, Assignment, Journal	Internal Assessment and University Exam, Theory exam, Practical Exam, Seminar, Viva-Voce, Station exercise, MCQ,
CO3	Explain drug interactions, mechanisms of action, and adverse drug reactions (ADRs).	**PO1,PO4**	Lecture, Practical, Assignment, Journal	Internal Assessment and University Exam, Theory exam, Practical Exam, Seminar, Viva-Voce, Station exercise, MCQ,
CO4	Classify and explain the pharmacology of cholinergic, anticholinergic, adrenergic, and antiadrenergic drugs.	**PO1,PO4**	Lecture, Practical, Assignment, Journal	Internal Assessment and University Exam, Theory exam, Practical Exam, Seminar, Viva-Voce, Station exercise, MCQ,
CO 5	Explain the action and uses of skeletal muscle relaxants and local anesthetics.	**PO1,PO4**	Lecture, Practical, Assignment, Journal	Internal Assessment and University Exam, Theory exam, Practical Exam, Seminar, Viva-Voce, Station exercise, MCQ,
CO6	Apply pharmacological concepts in clinical settings and drug therapy decision-making.	**PO1,PO4, PO5**	Lecture, Practical, Assignment,	Internal Assessment and University Exam, Theory exam,

			Journal	Practical Exam, Seminar, Viva-Voce, Station exercise, MCQ,

CC 001 T & CC 001 P	Research Methodology & Biostatistics	Mapped PO	Teaching-Learning Methodology	Assessment Tools
CO1	Students will demonstrate the ability to design a research study, including the formulation of research questions, hypothesis generation, and selection of appropriate study design (e.g., experimental, observational).	**PO3, PO4, PO5**	Lecture, Practical, Assignment, Journal	Internal Assessment and University Exam, Theory exam, Practical Exam, Seminar, Viva-Voce, Station exercise, MCQ,

MCR 105 CP	MCR Directed Clinical Education-I	Mapped PO	Teaching- Learning Methodology	Assessment Tools
CO1	Build a robust theoretical foundation, enabling students to understand healthare practices, disease management, and patient care, thereby empowering them to make informed decisions and adapt to evolving medical technologies.	**PO1, PO2, PO3, PO4, PO5, PO6,**	Practical, Clinical Posting, Demonstration, Case-study, Clinical Simulation	Practical Exam, Station Exercise, Viva-voce, Case-Study
CO 2	Emphasize hands-on training, ensuring proficiency in clinical procedures, diagnostic techniques, and the use of advanced medical equipment. This practical exposure will bridge the gap between theory and practice, enhancing students' confidence and competence in delivering quality patient care.	**PO1, PO2, PO3, PO4, PO5, PO6,**	Practical, Clinical Posting, Demonstration, Case-study, Clinical Simulation	Practical Exam, Station Exercise, Viva-voce, Case-Study
CO 3	Focus on developing professionalism, empathy, ethical conduct, teamwork, and communication skills—key traits for holistic patient care and effective collaboration in interdisciplinary healthcare teams.	**PO1, PO2, PO3, PO4, PO5, PO6,**	Practical, Clinical Posting, Demonstration, Case-study, Clinical Simulation	Practical Exam, Station Exercise, Viva-voce, Case-Study

DSE 001 T	Ethics in Clinical Research	Mapped PO	Teaching- Learning Methodology	Assessment Tools
CO1	Explain the historical development of clinical research ethics, including key ethical guidelines (Nuremberg Code, Declaration of Helsinki, Belmont Report, etc.).	**PO1,PO2, PO4**	Lecture, Demonstration, Group Discussion, Quiz, Assignment, Seminar	Internal Exam, University Exam (Theory Exam), Seminar, Assignment
CO 2	Identify and analyze legal liabilities, investigator responsibilities, and compensation-related obligations in clinical research.	**PO1-PO4**	Lecture, Demonstration, Group Discussion, Quiz, Assignment, Seminar	Internal Exam, University Exam (Theory Exam), Seminar, Assignment
CO 3	Describe the role of CIOMS, NIH, and ICMR guidelines in ethical clinical research.	**PO2**	Lecture, Demonstration, Group Discussion, Quiz, Assignment, Seminar	Internal Exam, University Exam (Theory Exam), Seminar, Assignment
CO4	Explain the function and significance of IRB/IEC/ERB in clinical trials.	**PO2**	Lecture, Demonstration, Group Discussion, Quiz, Assignment, Seminar	Internal Exam, University Exam (Theory Exam), Seminar, Assignment
CO 5	Analyze the ethics review process and the importance of informed consent in clinical trials.	**PO2-PO5**	Lecture, Demonstration, Group Discussion, Quiz, Assignment, Seminar	Internal Exam, University Exam (Theory Exam), Seminar, Assignment
CO6	Evaluate the ethical and legal aspects of informed consent and patient information documentation.	**PO2, PO5**	Lecture, Demonstration, Group Discussion, Quiz, Assignment, Seminar	Internal Exam, University Exam (Theory Exam), Seminar, Assignment

DSE 002 T	Different Systems of Medicine	Mapped PO	Teaching-Learning Methodology	Assessment Tools
CO1	Explain the origins, evolution, and significance of Ayurveda, Siddha, Unani, Yoga, Naturopathy, and Homeopathy.	**PO1,PO4**	Lecture, Demonstration, Group Discussion, Quiz, Assignment, Seminar	Internal Exam, University Exam (Theory Exam), Seminar, Assignment
CO 2	Describe the fundamental principles of disease prevention and treatment in different systems of medicine.	**PO1,PO2, PO4**	Lecture, Demonstration, Group Discussion, Quiz, Assignment, Seminar	Internal Exam, University Exam (Theory Exam), Seminar, Assignment

CO 3	Examine how traditional practices align with or differ from modern medical approaches.	**PO1,PO4**	Lecture, Demonstration, Group Discussion, Quiz, Assignment, Seminar	Internal Exam, University Exam (Theory Exam), Seminar, Assignment
CO4	Identify key medicinal plants used in different systems and their therapeutic applications.	**PO1,PO4**	Lecture, Demonstration, Group Discussion, Quiz, Assignment, Seminar	Internal Exam, University Exam (Theory Exam), Seminar, Assignment
CO 5	Discuss recent advances in validating traditional medicine and US botanical drug development.	**PO1,PO4**	Lecture, Demonstration, Group Discussion, Quiz, Assignment, Seminar	Internal Exam, University Exam (Theory Exam), Seminar, Assignment
CO6	Assess how globalization has influenced Ayurveda and other traditional systems.	**PO1,PO4, PO5**	Lecture, Demonstration, Group Discussion, Quiz, Assignment, Seminar	Internal Exam, University Exam (Theory Exam), Seminar, Assignment

Semester II

MCR 106 T Practical Lab II (MCR 106)	**Drug Analysis**	**Mapped PO**	**Teaching-Learning Methodology**	**Assessment Tools**
CO1	Explain the principles and types of analytical methods used in drug analysis.	**PO1,PO4**	Lecture, Demonstration, Group Discussion, Quiz, Assignment, Seminar	Internal Exam, University Exam (Theory Exam), Seminar, Assignment
CO2	Identify and describe various laboratory apparatus used in drug analysis.	**PO1,PO4**	Lecture, Demonstration, Group Discussion, Quiz, Assignment, Seminar	Internal Exam, University Exam (Theory Exam), Seminar, Assignment
CO3	Explain the theory, mathematical concepts, and principles behind IR absorption spectroscopy.	**PO1,PO4**	Lecture, Demonstration, Group Discussion, Quiz, Assignment, Seminar	Internal Exam, University Exam (Theory Exam), Seminar, Assignment
CO4	Analyze and interpret IR spectra for organic and inorganic compounds.	**PO1,PO4, PO5**	Lecture, Demonstration, Group Discussion, Quiz, Assignment, Seminar	Internal Exam, University Exam (Theory Exam), Seminar, Assignment
CO5	Explain the working of Single Beam and Double Beam spectrometers and their applications.	**PO1,PO4**	Lecture, Demonstration, Group Discussion, Quiz, Assignment, Seminar	Internal Exam, University Exam (Theory Exam), Seminar, Assignment
CO6	Evaluate the applications of IR spectroscopy in the qualitative and quantitative analysis of drugs.	**PO1,PO4**	Lecture, Demonstration, Group Discussion, Quiz, Assignment, Seminar	Internal Exam, University Exam (Theory Exam), Seminar, Assignment
CO7	Discuss advanced techniques such as ATR, Non-dispersive IR, and Polythermal Beam Deflection Spectroscopy.	**PO1,PO4**	Lecture, Demonstration, Group Discussion, Quiz, Assignment, Seminar	Internal Exam, University Exam (Theory Exam), Seminar, Assignment

MCR 107 T Practical Lab II (MCR 107)	Clinical Research Guidelines I	Mapped PO	Teaching-Learning Methodology	Assessment Tools
CO1	Explain the CDSCO guidelines for bioavailability & bioequivalence studies and their significance in clinical research.	**PO1,PO2, PO4**	Lecture, Demonstration, Group Discussion, Quiz, Assignment, Seminar	Internal Exam, University Exam (Theory Exam), Seminar, Assignment
CO2	Analyze the ethical principles from the World Medical Association's Declaration of Helsinki.	**PO1,PO2, PO4**	Lecture, Demonstration, Group Discussion, Quiz, Assignment, Seminar	Internal Exam, University Exam (Theory Exam), Seminar, Assignment
CO3	Interpret regulatory requirements for clinical trials in India as per Schedule Y.	**PO1,PO2, PO4**	Lecture, Demonstration, Group Discussion, Quiz, Assignment, Seminar	Internal Exam, University Exam (Theory Exam), Seminar, Assignment
CO4	Describe the principles of GCP and their role in ensuring ethical and high-quality clinical trials.	**PO1,PO2, PO4**	Lecture, Demonstration, Group Discussion, Quiz, Assignment, Seminar	Internal Exam, University Exam (Theory Exam), Seminar, Assignment
CO5	Compare international regulatory guidelines for BA/BE studies in veterinary and human medicine.	**PO1,PO2, PO4**	Lecture, Demonstration, Group Discussion, Quiz, Assignment, Seminar	Internal Exam, University Exam (Theory Exam), Seminar, Assignment
CO6	Examine the importance of clinical safety data management and periodic safety update reports.	**PO1,PO2, PO4, PO5**	Lecture, Demonstration, Group Discussion, Quiz, Assignment, Seminar	Internal Exam, University Exam (Theory Exam), Seminar, Assignment

MCR 108 T Practical Lab II (MCR 108)	Pharmacology II	Mapped PO	Teaching-Learning Methodology	Assessment Tools
CO1	Explain the mechanism of action, uses, and side effects of diuretics and antidiuretics.	**PO1, PO4**	Lecture, Demonstration, Group Discussion, Quiz,	Internal Exam, University Exam (Theory Exam), Seminar, Assignment

			Assignment, Seminar	
CO2	Describe the pharmacology of drugs used for peptic ulcers, emetics, antiemetics, constipation, and diarrhea.	**PO1, PO4**	Lecture, Demonstration, Group Discussion, Quiz, Assignment, Seminar	Internal Exam, University Exam (Theory Exam), Seminar, Assignment
CO3	Classify and explain the mechanisms of action of beta-lactam antibiotics, tetracyclines, aminoglycosides, and chloramphenicol.	**PO1, PO4**	Lecture, Demonstration, Group Discussion, Quiz, Assignment, Seminar	Internal Exam, University Exam (Theory Exam), Seminar, Assignment
CO4	Understand the pharmacokinetics, pharmacodynamics, and clinical applications of anti-TB and antileprotic drugs.	**PO1, PO4**	Lecture, Demonstration, Group Discussion, Quiz, Assignment, Seminar	Internal Exam, University Exam (Theory Exam), Seminar, Assignment
CO5	Identify different antifungal and antiviral drugs and their applications in treating infections.	**PO1, PO4**	Lecture, Demonstration, Group Discussion, Quiz, Assignment, Seminar	Internal Exam, University Exam (Theory Exam), Seminar, Assignment
CO6	Explain the mode of action, resistance mechanisms, and therapeutic uses of drugs for malaria and urinary tract infections.	**PO1, PO4**	Lecture, Demonstration, Group Discussion, Quiz, Assignment, Seminar	Internal Exam, University Exam (Theory Exam), Seminar, Assignment

MCR 110 CP	**MCR Directed Clinical Education-II**	**Mapped PO**	**Teaching-Learning Methodology**	**Assessment Tools**
CO1	Build a robust theoretical foundation, enabling students to understand healthcare practices, disease management, and patient care, thereby empowering them to make informed decisions and adapt to evolving medical technologies.	**PO1, PO2, PO3, PO4,**	Practical, Clinical Posting, Demonstration, Internship, Case-study, Clinical Simulation	Practical Exam, Station Exercise, Viva-voce
CO 2	Emphasize hands-on training, ensuring proficiency in clinical procedures, diagnostic techniques, and the use of advanced medical equipment.	**PO2, PO3, PO4, PO5,**	Practical, Clinical Posting, Demonstration, Internship, Case-study, Clinical	Practical Exam, Station Exercise, Viva-voce

	This practical exposure will bridge the gap between theory and practice, enhancing students' confidence and competence in delivering quality patient care.		Simulation	
CO 3	Focus on developing professionalism, empathy, ethical conduct, teamwork, and communication skills—key traits for holistic patient care and effective collaboration in interdisciplinary healthcare teams.	**PO2, PO3, PO4,**	Practical, Clinical Posting, Demonstration, Internship, Case-study, Clinical Simulation	Practical Exam, Station Exercise, Viva-voce

DSE 003 T	**Epidemiological Principles Relevant to Clinical Research**	**Mapped PO**	**Teaching-Learning Methodology**	**Assessment Tools**
CO1	Explain mortality and morbidity indicators, and their relevance in epidemiological studies.	**PO1, PO3, PO4**	Lecture, Demonstration, Group Discussion, Quiz, Assignment, Seminar	Internal Exam, University Exam (Theory Exam), Seminar, Assignment
CO 2	Analyze different types of bias (study, response, information, interviewer, site selection, measurement, and confounding) in research.	**PO1, PO4, PO5**	Lecture, Demonstration, Group Discussion, Quiz, Assignment, Seminar	Internal Exam, University Exam (Theory Exam), Seminar, Assignment
CO 3	Interpret diagnostic tests, screening tests, and prognostic tests using an evidence-based approach.	**PO1, PO3, PO4, PO5**	Lecture, Demonstration, Group Discussion, Quiz, Assignment, Seminar	Internal Exam, University Exam (Theory Exam), Seminar, Assignment
CO4	Understand the principles and applications of pharmaco epidemiological studies in clinical settings.	**PO1, PO3, PO4**	Lecture, Demonstration, Group Discussion, Quiz, Assignment, Seminar	Internal Exam, University Exam (Theory Exam), Seminar, Assignment
CO5	Explain how molecular and genetic epidemiology contribute to clinical research.	**PO1, PO3, PO4**	Lecture, Demonstration, Group Discussion, Quiz, Assignment, Seminar	Internal Exam, University Exam (Theory Exam), Seminar, Assignment

CO6	Discuss the impact of race, ethnicity, social class, and culture on clinical research methodologies.	**PO1, PO3, PO4**	Lecture, Demonstration, Group Discussion, Quiz, Assignment, Seminar	Internal Exam, University Exam (Theory Exam), Seminar, Assignment

DSE 004 T	**Clinical trial Operations**	**Mapped PO**	**Teaching- Learning Methodology**	**Assessment Tools**
CO1	Explain the process of selecting trial sites, investigators, and vendors.	**PO1,PO2,PO4**	Lecture, Demonstration, Group Discussion, Quiz, Assignment, Seminar	Internal Exam, University Exam (Theory Exam), Seminar, Assignment
CO 2	Describe the responsibilities of sponsors, institutions, coordinators, and investigators.	**PO1,PO2,PO4**	Lecture, Demonstration, Group Discussion, Quiz, Assignment, Seminar	Internal Exam, University Exam (Theory Exam), Seminar, Assignment
CO 3	Identify essential trial documents (protocol, CRF, ICD, investigator brochure, agreements).	**PO1,PO2,PO4**	Lecture, Demonstration, Group Discussion, Quiz, Assignment, Seminar	Internal Exam, University Exam (Theory Exam), Seminar, Assignment
CO4	Manage recruitment, site master file, SOPs, and regulatory compliance.	**PO1,PO2,PO4**	Lecture, Demonstration, Group Discussion, Quiz, Assignment, Seminar	Internal Exam, University Exam (Theory Exam), Seminar, Assignment
CO5	Understand the role of monitors, auditors, and data monitoring committees.	**PO1,PO2,PO4**	Lecture, Demonstration, Group Discussion, Quiz, Assignment, Seminar	Internal Exam, University Exam (Theory Exam), Seminar, Assignment
CO6	Develop strategies to handle unexpected challenges during clinical trials.	**PO1,PO2,PO4**	Lecture, Demonstration, Group Discussion, Quiz, Assignment, Seminar	Internal Exam, University Exam (Theory Exam), Seminar, Assignment

SEC 001 T	**Alternative in Toxicity Testing**	**Mapped PO**	**Teaching- Learning Methodology**	**Assessment Tools**
CO1	Explain CPCSEA guidelines and ethical considerations in animal testing.	**PO1,PO2,PO4**	Lecture, Demonstration, Group Discussion, Quiz, Assignment, Seminar	Internal Exam, University Exam (Theory Exam), Seminar, Assignment

CO2	Describe the principles of Reduce, Refine, Replace, and Rehabilitate in animal research.	**PO1,PO2,PO4**	Lecture, Demonstration, Group Discussion, Quiz, Assignment, Seminar	Internal Exam, University Exam (Theory Exam), Seminar, Assignment
CO3	Analyze non-mammalian and non-animal models used for toxicity testing.	**PO1,PO2,PO4**	Lecture, Demonstration, Group Discussion, Quiz, Assignment, Seminar	Internal Exam, University Exam (Theory Exam), Seminar, Assignment
CO4	Explain the standard procedures for reporting animal trial data.	**PO1,PO2,PO4**	Lecture, Demonstration, Group Discussion, Quiz, Assignment, Seminar	Internal Exam, University Exam (Theory Exam), Seminar, Assignment
CO5	Assess the effectiveness of alternative testing methods such as the Draize test.	**PO1,PO2,PO4**	Lecture, Demonstration, Group Discussion, Quiz, Assignment, Seminar	Internal Exam, University Exam (Theory Exam), Seminar, Assignment
CO6	Describe the use of zebrafish, drosophilae, and C. elegans in toxicity studies.	**PO1,PO2,PO4**	Lecture, Demonstration, Group Discussion, Quiz, Assignment, Seminar	Internal Exam, University Exam (Theory Exam), Seminar, Assignment

OUTLINE OF COURSE CURRICULUM

M. Sc. Clinical Research

Semester I

Code No.	Core Course	Credits/Week					Hrs/Semester					Marks		
		Lecture (L)	Tutorial (T)	Practical (P)	Clinical Posing/ Rotation (CP)	Total Credits (C)	Lecture (L)	Tutorial (T)	Practical (P)	Clinical Posing/ Rotation (CP)	Total (hrs.)	Internal Assement (IA)	Semester End Exam (SEE)	Total
Discipiline Specific Core Theory														
MCR 101 T	History & Fundamentals of Clinical Research	3	-	-	-	**3**	45	-	-	-	**45**	**20**	**80**	**100**
MCR 102 T	Clinical Research Methodologies	3	-	-	-	**3**	45	-	-	-	**45**	**20**	**80**	**100**
MCR 103 T	Pharmacology- I	3	-	-	-	**3**	45	-	-	-	**45**	**20**	**80**	**100**
CC 001 T	Research Methodology & Biostatistics (Core Course)	3	-	-	-	**3**	45	-	-	-	**45**	-	**50**	**50**
Discipiline Specific Core Practical														
MCR 104 P	Practical Lab I (MCR 101 to MCR 103)	-	-	4	-	**2**	-	-	60	-	**60**	**10**	**40**	**50**
MCR 105 CP	MCR Directed Clinical Education-I	-	-	-	12	**4**	-	-	-	180	**180**	-	**50**	**50**
CC 001 P	Research Methodology & Biostatistics (Core Course)	-	-	4	-	**2**	-	-	60	-	**60**	-	**50**	**50**
Discipiline Specific Elective Theory														
DSE 001 T	Ethics in Clinical Research	2	-	-	-	**2**	30	-	-	-	**30**	20	80	100
DSE 002 T	Different Systems of Medicine													
Total		**14**	**0**	**8**	**12**	**22**	**210**	**0**	**120**	**180**	**510**	**90**	**510**	**600**

Resolution No. 5.8 of Academic Council (AC-52/2025):

The Academic Council resolved to approve the continuation of SWAYAM /NPTEL elective courses for postgraduate students, wherever applicable to their respective programmes. Accordingly, students admitted from the Academic Year 2025-26 onwards shall be permitted to choose any one approved elective course. The Council further approved the inclusion of 2 and 3 credit courses in the index. This approach is in alignment with the current NCAHP curriculum guidelines, which recommend flexibility for open electives through recognized national platforms.

Accordingly, the names of individual elective courses shall be removed from the existing syllabi. The links of SWAYAM/ NPTEL courses (https://swayam.gov.in/nc_details/NPTEL) shall be incorporated in the syllabus index under the existing course code SEC-002 T, titled: "NPTEL/SWAYAM (Name of the Course Chosen by the Student)"

In alignment with Resolution No. 3.1 of the Academic Council (AC-51/2025), the detailed syllabi of individual courses shall be removed and replaced with the approved links of SWAYAM /NPTEL or common reference pool courses. The complete course content shall remain accessible on the official SWAYAM/NPTEL portals. Students may select any one course from the provided links, in alignment with the credit requirements mentioned in their respective syllabi, as per Annexures 24A, 24B, 24C, 24D, 24E, 24F, 24G, 24H, 24I, 24J, 24K, 24L, 24M, 24N, and 24O.

OUTLINE OF COURSE CURRICULUM

M. Sc. Clinical Research

Semester II

Code No.	Core Course	Credits/Week					Hrs/Semester					Marks		
		Lecture (L)	Tutorial (T)	Practical (P)	Clinical Posing/ Rotation (CP)	Total Credits (C)	Lecture (L)	Tutorial (T)	Practical (P)	Clinical Posing/ Rotation (CP)	Total (hrs.)	Internal Assement (IA)	Semester End Exam (SEE)	Total
Discipiline Specific Core Theory														
MCR 106 T	Drug Analysis	3	-	-	-	**3**	45	-	-	-	**45**	**20**	**80**	**100**
MCR 107 T	Clinical Research Guidelines I	3	-	-	-	**3**	45	-	-	-	**45**	**20**	**80**	**100**
MCR 108 T	Pharmacology II	3	-	-	-	**3**	45	-	-	-	**45**	**20**	**80**	**100**
Discipiline Specific Core Practical														
MCR 109 P	Practical Lab II (MCR 106 to MCR 108)	-	-	8	-	**4**	-	-	120	-	**120**	**10**	**40**	**50**
MCR 110 CP	MCR Directed Clinical Education-II	-	-	-	12	**4**	-	-	-	180	**180**	-	**50**	**50**
Discipiline Specific Elective Theory														
DSE 003 T	Epidemiological Principles Relevant to Clinical Research	2	-	-	-	**2**	30	-	-	-	**30**	20	80	100
DSE 004 T	Clinical Trial Operations													
Skill Ehancement Course														
SEC 001 T	Alternatives in Toxicity Testing	3	-	-	-	**3**	45	-	-	-	**45**	-	**100**	**100**
SEC 002 T	NPTEL Swayam (Course Selected as per Below List)													
Total		**14**	**0**	**8**	**12**	**22**	**210**	**0**	**120**	**180**	**510**	**90**	**510**	**600**

Common Pool of Swayam/NPTEL Coureses offered as elective option (SEC 002)

Course ID	Discipline	Course Name	Institute	Duration	Start date	End date	Exam date	Enrollment End date	Exam Registration End date	UG/PG	Click here to Join the course	NPTEL URL	NPTEL ID
noc25-bt06	Biotechnology and Bioengineering	BioInformatics: Algorithms and Applications	IIT Madras	12 Weeks	20-01-2025	11-04-2025	26-04-2025	27-01-2025	28-02-2025	UG/PG	https://onlinecourses.nptel.ac.in/noc25_bt06/preview	https://nptel.ac.in/courses/102106065	https://nptel.ac.in/courses/102106065
noc25-bt13	Biotechnology and Bioengineering	Computational Genomics	IISER Bhopal	12 Weeks	20-01-2025	11-04-2025	27-04-2025	27-01-2025	28-02-2025	PG	https://onlinecourses.nptel.ac.in/noc25_bt13/preview	https://nptel.ac.in/courses/102106339	https://nptel.ac.in/courses/102106339
noc25-bt29	Biotechnology and Bioengineering	Maternal Infant Young Child Nutrition	IIT Bombay	12 Weeks	20-01-2025	11-04-2025	26-04-2025	27-01-2025	28-02-2025	UG/PG	https://onlinecourses.nptel.ac.in/noc25_bt29/preview	https://nptel.ac.in/courses/102101091	https://nptel.ac.in/courses/102101091
noc25-ge05	Multidisciplinary	Biophotonics	IIT Kharagpur	12 Weeks	20-01-2025	11-04-2025	03-05-2025	27-01-2025	28-02-2025	PG	https://onlinecourses.nptel.ac.in/noc25_ge05/preview	https://nptel.ac.in/courses/127105225	https://nptel.ac.in/courses/127105225
noc25-ge07	Multidisciplinary	Comprehensive Molecular Diagnostics and Advanced Gene Expression Analysis	IIT Kharagpur	12 Weeks	20-01-2025	11-04-2025	03-05-2025	27-01-2025	28-02-2025	UG/PG	https://onlinecourses.nptel.ac.in/noc25_ge07/preview	https://nptel.ac.in/courses/127105391	https://nptel.ac.in/courses/127105391
noc25-ge25	Multidisciplinary	One Health	ICMR - Regional Medical Research Centre, Bhubaneswar	12 Weeks	20-01-2025	11-04-2025	03-05-2025	27-01-2025	28-02-2025	PG	https://onlinecourses.nptel.ac.in/noc25_ge25/preview	https://nptel.ac.in/courses/127106233	https://nptel.ac.in/courses/127106233
noc25-ge27	Multidisciplinary	Qualitative Research Methods and Research Writing	IIT Kharagpur	12 Weeks	20-01-2025	11-04-2025	27-04-2025	27-01-2025	28-02-2025	PG	https://onlinecourses.nptel.ac.in/noc25_ge27/preview	https://nptel.ac.in/courses/109105115	https://nptel.ac.in/courses/109105115
noc25-bt21	Biotechnology and Bioengineering	Host-Pathogen Interaction (Immunology)	IISER Bhopal	12 Weeks	20-01-2025	11-04-2025	04-05-2025	27-01-2025	28-02-2025	PG	https://onlinecourses.nptel.ac.in/noc25_bt21/preview	https://onlinecourses.nptel.ac.in/noc24_bt24/preview	https://onlinecourses.nptel.ac.in/noc24_bt24/preview
noc25-bt22	Biotechnology and Bioengineering	Human Physiology	IISER Pune	12 Weeks	20-01-2025	11-04-2025	26-04-2025	27-01-2025	28-02-2025	PG	https://onlinecourses.nptel.ac.in/noc25_bt22/preview	https://onlinecourses.nptel.ac.in/noc24_bt05/preview	https://onlinecourses.nptel.ac.in/noc24_bt05/preview
noc25-hs61	Humanities and Social Sciences	Patent Law for Engineers and Scientists	IIT Madras	12 Weeks	20-01-2025	11-04-2025	03-05-2025	27-01-2025	28-02-2025	UG/PG	https://onlinecourses.nptel.ac.in/noc25_hs61/preview	https://onlinecourses.nptel.ac.in/noc24_hs155/preview	https://onlinecourses.nptel.ac.in/noc24_hs155/preview
noc25-mg05	Management	AI in Human Resource Management	IIT Guwahati	12 Weeks	20-01-2025	11-04-2025	04-05-2025	27-01-2025	28-02-2025	PG	https://onlinecourses.nptel.ac.in/noc25_mg05/preview	https://nptel.ac.in/courses/110103626	https://nptel.ac.in/courses/110103626
noc25-hs70	Humanities and Social Sciences	Science Communication: Research Productivity and Data Analytics using Open Source Software	IIT Delhi	12 Weeks	20-01-2025	11-04-2025	03-05-2025	27-01-2025	28-02-2025	PG	https://onlinecourses.nptel.ac.in/noc25_hs70/preview	https://nptel.ac.in/courses/109102392	https://nptel.ac.in/courses/109102392
noc25-ag04	Agricultural and Food Engineering	Food Science and Technology	IIT Kharagpur	12 Weeks	20-01-2025	11-04-2025	26-04-2025	27-01-2025	28-02-2025	UG/PG	https://onlinecourses.nptel.ac.in/noc25_ag04/preview		

FIRST YEAR

M.Sc. CLINICAL RESEARCH

SEMESTER-I

Code No.	Core Subjects
Discipline Specific Core Theory	
MCR 101 T	History & Fundamentals of Clinical Research
MCR 102 T	Clinical Research Methodologies
MCR 103 T	Pharmacology- I
CC 001 T	Research Methodology & Biostatistics (Core Course)
Discipline Specific Core Practical	
MCR 104 P	Practical Lab I (MCR 101 to MCR 103)
MCR 105 CP	MCR Directed Clinical Education – I
CC 001 P	Research Methodology & Biostatistics (Core Course)
Discipline Specific Elective Theory	
DSE 001 T	Ethics in Clinical Research
DSE 002 T	Different Systems of Medicine

Name of the Program	**M.Sc. Clinical Research**
Semester	**Semester I**
Name of the Subject	**History & Fundamentals of Clinical Research**
Subject Code	**MCR 101 T**

Course Outcome	• Explain the Evolution of Clinical Research • Demonstrate Understanding of Ethical and Regulatory Frameworks, Define the Scope and Importance of Clinical Research, Describe the Phases of Clinical Trials • Evaluate the Impact of Landmark Clinical Trials, Integrate Lessons from History into Modern Clinical Research • Apply Principles of Good Clinical Practice (GCP) • Identify Key Figures in Clinical Research, Analyze Regulatory and Ethical Considerations, Develop Skills in Protocol Design and Study Methodology • Assess Societal and Ethical Challenges in Clinical Research • Understand Pharmacovigilance and Safety Monitoring

Sr. No.	Topics	No. of Hrs.
	History of Clinical Research	
1	**Understand the Evolution of Clinical Research:** Trace the historical development of clinical research from ancient times to modern-day clinical trials, Analyse the key milestones in drug discovery and development.	**3**
	Explore Ethical and Regulatory Frameworks: Examine historical cases that led to ethical guidelines such as the Nuremberg Code, Declaration of Helsinki, and Belmont Report, Understand the role of regulatory agencies (FDA, EMA, ICH) in clinical research evolution.	**4**
3	**Analyse Landmark Clinical Trials:** Study pivotal clinical trials that shaped modern medical practices, Assess the impact of these trials on drug approval and patient safety.	**4**
4	**Understand the Development of Good Clinical Practice (GCP):** Explore the origins and implementation of GCP principles,Examine how clinical research standards have improved over time.	**3**
5	**Recognize the Role of Key Figures in Clinical Research:** Learn about influential scientists, researchers, and physicians who contributed to clinical research advancements.	**3**
6	**Evaluate the Societal and Ethical Challenges in Clinical Research:** Discuss the ethical dilemmas faced in historical and contemporary clinical research, Assess how past research failures have influenced current clinical trial methodologies.	**4**
	Apply Lessons from History to Modern Clinical Research: Understand how historical events shape contemporary clinical research practices, Develop critical thinking on ethical considerations in drug development.	**5**
	Fundamentals of Clinical Research	
8	**Understand the Basics of Clinical Research:** Define clinical research and its significance in drug development, Differentiate between various types of clinical research, including observational and interventional studies.	**2**
9	**Learn the Phases of Clinical Trials:** Describe the objectives, design, and regulatory	**3**

	requirements of Phase I–IV clinical trials, Understand the role of pharmacokinetics, pharmacodynamics, and dose-escalation studies in early-phase trials.	
10	**Explore Good Clinical Practice (GCP) Guidelines:** Learn the principles of GCP and its importance in conducting ethical and high-quality research, Understand the responsibilities of key stakeholders, including investigators, sponsors, and ethics committees.	**3**
11	**Examine Regulatory and Ethical Aspects:** Study international regulatory agencies (FDA, EMA, CDSCO, ICH) and their role in clinical research, Understand ethical considerations, including informed consent, patient rights, and risk-benefit assessment.	**3**
12	**Develop Protocol Design and Study Methodology Skills:** Learn how to design clinical trial protocols, including inclusion/exclusion criteria, endpoints, and study designs, Understand randomization, blinding, and statistical considerations in clinical trials.	**3**
13	**Analyze Data Management and Biostatistics:** Explore methods of data collection, monitoring, and reporting in clinical trials, Understand key statistical concepts used in clinical research, such as hypothesis testing, p-values, and confidence intervals.	**2**
14	**Understand Pharmacovigilance and Safety Monitoring:** Learn about adverse drug reactions (ADR), safety reporting, and risk management in clinical trials, Explore the role of Data Safety Monitoring Boards (DSMBs) in ensuring patient safety.	**3**
Total		**45 hrs**

Name of the Program	**M.Sc. Clinical Research**
Semester	**Semester I**
Name of the Subject	**Clinical Research Methodologies**
Subject Code	**MCR 102 T**

Course Outcome	• Explain the fundamental concepts, definitions, and applications of research. • Classify research types based on applications, objectives, and paradigms. • Describe and explain the eight-step research process. • Formulate a research problem, design, and proposal. • Demonstrate data collection methods, sampling techniques, and instrument construction. • Analyze literature to identify research gaps and synthesize findings. • Develop skills for structuring and writing research reports effectively.

Sr. No.	Topics	No. of Hrs.
1	**Research: A way of Thinking:** Research: A way of Thinking, Applications of Research, Definitions of Research, Characteristics of Research, paradigms of Research **Types of research:** Applications, Objectives, Type of Information sought	**2**
2	**Research process: A quick Glance** The Research process an eight-step model: Step I: Formulating a research problem Step II: Conceptualizinga Research Design, Step III: constructing a instrument for data collection Step V: Selecting a sample, Step V: Writing a research proposal Step VI: Collecting Data, Step VII: processing Data, Step VIII: Writing A research Report	**2**
3	**Reviewing the Literature:** Reasons for Reviewing Literature, Procedure for Reviewing the Literature, Writing up the literature-reviewed	**2**
4	**Formulating a Research problem:** The research problem, The importance of formulating a research problem, Sources of Research problem, Considerations in selecting a research problem, Steps in the formulation of a research problem, The formulation of a objectives, Establishing operational definitions	**2**
5	**Identifying Variables:** The definition of a variable, The difference between a concept and a variable, Concepts, Indicators and variables Types of Variables: From the viewpoint of causation, From the viewpoint of study design, From the view point of the unit of measurement Types of measurement scale: The normal or classificatory scale, The ordinal or ranking scale, The Interval scale, The ration scale	**2**
6	**Constructing Hypothesis:** The definition of a Hypothesis, The function of a Hypothesis, The characteristics of a hypothesis, Types of Hypothesis, Errors in testing a hypothesis	**2**
7	**The research design:** The definition of a research design, The function of a research design	**2**
8	**Selecting a method of data collection:** collecting data using primary sources, Observation, The interview, The questionaire Collecting data using secondary sources: Problems with using data from secondary sources	**3**

9	**Collecting data using attitudinal scales:** Functions of attitudinal scales, Difficulties in developing an attitudinal scale, The relationship between attitudinal and measurement scales Types of attitudinal scale: The summated rating or Likert scale, The equal-appearing-interval or Thurstone scale, The cumulative or Guttman scale	**3**
10	**Establishing the validity and reliability of a research Instrument:** The concept of Validity- Types of Validity The concept of Reliability: Factors affecting the reliability of a research instrument, Methods of determining the reliability of an instrument	**2**
11	**Sampling:** The concept of sampling, Sampling Technology, Principles of sampling, Factors affecting the inference drawn from the a sample, Aims in selecting a sample, Types of sampling, The calculation of sample size	**3**
12	**Writing a research proposal:** The research proposal, The preamble introduction, The problem, The objectives of the study, The hypothesis to be tested, The study design, The setting, Measurement procedures, Sampling, Analysis of Data, Structure of Report, Problems and limitations, Work Schedule, Appendix	**3**
13	**Considering ethical issues in data collection:** Ethics, Stakeholders in research Ethical considerations concerning research participants - Collecting information, Seeking consent, Providing incentives, Seeking sensitive information, The possibility of causing harm to participants, Maintaining confidentiality Ethical issues relating to the researcher - Avoiding bias - Types of Bias, Provision of deprivation of a treatment, Using appropriate research methodology, Correct reporting, Using information Ethical considerations regarding the sponsoring organization - Restrictions imposed by the sponsoring organization, The use of information	**4**
14	**Processing data:** Editing data, Coding data, Developing a frame of analysis, Analyzing data, The role of computers in Research, The role of statistics in Research	**3**
15	**Displaying data** Tables – Structure, Types of Tables, Types of percentages Graphs - The histogram, The bar chart, The stacked bar chart, The 100 percent bar chart, The frequency polygon, The cumulative frequency polygon, The stem and leaf display, The line diagram or trend curve, The area chart, The scattergram.	**2**
16	**Writing a research Report:** Research writing in general, Referencing, Writing bibliography, Developing an outline, Writing about a variable	**2**
17	**Types of clinical trials:** Treatment trials, Prevention trials, Diagnostic trials, Screening trials, Quality of life trials, Descriptive trial Experimental trial - Randomized controlled trial, Double-blind trial, Single blind trial, Non-blind trial, Non-randomized controlled trial, Randomized database study, Placebo controlled trial Non-Experimental trial - Cross-sectional study, Longitudinal study, Cohort study- Prospective cohort, Retrospective cohort, Time trend study, Case cohort study- Case-control study, Nested case-control study	**2**
18	**Clinical Trial Designs:** Parallel Study Design, Crossover Study Design, Parallel-Crossover Study Design, Sequential Study Design	**2**
19	**Standard Operating Procedures (SOP's), Quality policy:** What are SOP's? , Why SOP's are needed? , How to write a SOP? , Implementation of SOP's	**2**
Total		**45 hrs**

Suggested Reading:

1. Guide to Clinical Trials. Author: Bert Spilker; Raven press, New york, 1991. 11gl pages.
2. Becoming a Successful Clinical Research Investigator. Authors: Dr. David Ginsberg and Karen E. Woodin. Thomson Centerwatch publication.
3. A Guide to Patient Recruitment and Retention. Author: Diana L. Anderson. Thomson Centerwatch Publication.
4. Protecting Study Volunteers in Research. Authors: Cynthia McGuire Dunn & Gary Chadwick. Thomson Centerwatch publication.
5. The CRC's Guide to Coordinating Clinical Research Author: Karen E. Woodin. Thomson Centerwatch Publication.
6. The CRA's Guide to Monitoring Clinical Research. Author: Karen E. Woodin and John C. Schneider. Thomson Centerwatch publication.

Name of the Program	**M.Sc. Clinical Research**
Semester	**Semester I**
Name of the Subject	**Pharmacology**
Subject Code	**MCR 103 T**

Course Outcome	• Explain the history, sources, drug development process, and principles of pharmacology. • Describe different routes of drug administration and the pharmacokinetics of drugs. • Explain drug interactions, mechanisms of action, and adverse drug reactions (ADRs). • Classify and explain the pharmacology of cholinergic, anticholinergic, adrenergic, and antiadrenergic drugs. • Explain the action and uses of skeletal muscle relaxants and local anesthetics. • Apply pharmacological concepts in clinical settings and drug therapy decision-making.

Sr. No.	Topics	No. of Hrs.
1.	**General Pharmacology:** History of Pharmacology, Pharmacokinetics, Pharmacodynamics, ADRs Drug Sources- Drug and Active Principle, Drug Development Drug Administration- Various routes of drug administration	**5**
2.	**Drug Acting on the Autonomic Nervous System:** General Considerations, Cholinergic system and cholinergic drugs, Anticholinergic drugs and Drugs acting on Autonomic Ganglia, Adrenergic system and drugs, Antiadrenergic drugs	**7**
3.	**Drugs Acting on the Peripheral (somatic) Nervous System:** Skeletal Muscle relaxants, Local anesthetics	**5**
4.	**Drugs Acting on the Central Nervous System:** General Anaesthetics, Sedatives and Hypnotics, Antiepileptic drugs, Antiparkinsonian drugs, Opioid Analgesics and antagonists, Nonopioids and NSAIDS, CNS stimulants	**10**
5.	**Autacoids:** Histamines, 5-HT and their Antagonists, Plasma kinins, Angiotensin and ACE inhibitors, PGs, Leukotrienes and Platelet activating factors.	**7**
6.	**Drugs Acting on Respiratory System:** Drugs for cough and Bronchial Asthma	**4**
7.	**Cardiovascular Drugs:** Cardiac Glycosides and drugs for CCF, Antiarrhythmic Drugs, Antianginal drugs, Antihypertensive drugs	**7**
Total		**45 hrs**

Suggested Readings:

1. Satoskar and Bhandarkar
2. KD Tripathi

Name of the Program	**M.Sc. Clinical Research**
Semester	**Semester - I**
Name of the Course	**Research Methodology & Biostatistics (Core Course)**
Course Code	**CC 001 T**

Teaching Objective	• The course is intended to give an overview of research and statistical models commonly used in medical and bio-medical sciences. The goal is to impart an intuitive, understanding and working knowledge of research designs and statistical analysis. The strategy would be to simplify, analyse the treatment of statistical inference and to focus primarily on how to specify and interpret the outcome of research.
Learning Outcomes	• Student will be able to understand develop statistical models, research designs with the understating of background theory of various commonly used statistical techniques as well as analysis, interpretation & reporting of results and use of statistical software.

Sr. No.	Topic	No. of Hrs.
A	**Research Methodology:**	**23**
1	**Scientific Methods of Research**: Definition of Research, Assumptions, Operations and Aims of Scientific Research. Research Process, Significance and Criteria of Good Research, Research Methods versus Methodology	4
2	**Research Designs**: Observational Studies: Descriptive, explanatory, and exploratory, Experimental Studies: Pre-test design, post-test design, Follow-up or longitudinal design, Cohort Studies, Case – Control Studies, Cross-sectional studies, Intervention studies.	5
3	**Sampling Designs**: Census and Sample Survey, Need and importance for Sampling, Implications of a Sample Design, Different Types of Sample Designs (Probability sampling and non-probability sampling), Systematic sampling, Stratified sampling, Cluster sampling, Multi-stage sampling, Sampling with probability proportional to size, Sequential sampling.	5
4	**Measurement in research**: Measurement Scales, Sources of Error in Measurement,	3
5	**Methods of Data Collection**: Types of data, Collection of Primary Data, Observation Method, Interview Method	4
6	Research Ethics and plagiarism	2
B	**Biostatistics**	**22**
7	**Data Presentation**: Types of numerical data: Nominal, Ordinal, Ranked, Discrete and continuous. Tables: Frequency distributions, Relative frequency, Graph: Bar charts, Histograms, Frequency polygons, scatter plots, line graphs	3
8	**Measures of Central Tendency and Dispersion**: Mean, Median, Mode, Range, Inter quartile range, variance and Standard Deviation, Coefficient of variation, grouped mean and grouped standard deviation (including merits and demerits).	3
9	**Testing of Hypotheses**: Definition, Basic Concepts, Procedure for Hypothesis Testing, power of test, Normal distribution, Parametric Tests including Z-test, t-test,	4

	and ANOVA	
10	**Chi-square Test**: Chi-square as a Non-parametric Test, Applications.	2
11	**Measures of Relationship**: Correlation and Simple Regression Analysis	3
12	**Non-parametric test**: Sign test, Wilcoxon signed-Rank Test, Wilcoxon Rank Sum Test: Mann-Whitney U test, Kruskal Walli's test, Friedman's test, and Spearman Rank correlation test.	3
13	**Vital Health Statistics**: rate, crude rate, age specific rate, Measurement of fertility, Rate, Measures of mortality.	4
Total		**45 hrs**

CC 001 P–Research Methodology & Biostatistics

Sr. No.	Topics	No. of Hrs.
A	**Research Methodology**	
1	Research Article Presentation (Seminar)	**5**
B	**Biostatistics**	
2	Data Presentation	**4**
3	Measures of Central Tendency and Dispersion	**6**
4	Testing of Hypotheses	**16**
5	Chi-square Test	**4**
6	Measures of Relationship	**6**
7	Analysis of Variance	**5**
8	Non parametricor Distribution-free Tests	**8**
9	Computer Application Using Statistical Software including SPSS	**6**
Total		**60 hrs**

Reference Books:

1. Daniel WW. Biostatistics: A foundation for analysis in the health sciences. 10th ed. Wiley; 2013.

2. Gupta SC, Kapoor VK. Fundamentals of mathematical statistics. Sultan Chand & Sons; 2020 Sep.

3. Kothari CR, Garg G. Research methodology: Methods and techniques.2019.

4. Mahajan BK. Methods in biostatistics for medical students and research workers. 7th ed. Jaypee Brothers Medical Publishers; 2010.

5. Murthy MN. Sampling theory and methods. Statistical Publishing Society; 1967.

6. Singh YK. Fundamental of research methodology and statistics. New Age International; 2006.

Resolution No. 3.5 of Academic Council (AC-51/2025):

Resolved to approve the submitted list of recommended books for M.Sc. Clinical Nutrition and the course on **Biostatistics and Research Methodology** [ANNEXURE-7].

Annexure-7 of AC-51/2025

Biostatistics & Research Methodology Books List

Subject	Book Name	Author
Biostatistics & Research Methodology	Biostatistics: A Foundation for Analysis in the Health Sciences (10th ed.)	Daniel WW.
	Biostatistical Analysis (5th ed.)	Zar JH.
	Research Methodology: Methods and Techniques	Kothari CR, Garg G.
	Methods in Biostatistics for Medical Students and Research Workers (7th ed.)	Mahajan BK.
	Sampling Theory and Methods	Murthy MN.
	Fundamentals of Research Methodology and Statistics	Singh YK.
	Fundamentals of Biostatistics (8th ed.)	Rosner B.
	An Introduction to Medical Statistics (4th ed.)	Bland M.

MCR 104 P: - Practical Lab I (MCR 101 to MCR 103)

Sr. No.	Topics	No. of Hrs.
1	Visits to hospital: Patient's history and demographics, Medical record keeping, Bioethics- do's and don'ts, confidentiality, cultural/social ethics	**12**
2	Basic learning of operation of common laboratory equipment	**12**
3	Demonstration of routes of exposure/administration of drugs, Demonstration of some non – invasive techniques in preclinical screening of drug	**15**
4	Visit to research institute/CRO/SMO	**21**
Total		**60 hrs**

Course code- MCR 105 CP: MCR Directed Clinical Education – I

Course Outcome	• Build a robust theoretical foundation, enabling students to understand healthcare practices, disease management, and patient care, thereby empowering them to make informed decisions and adapt to evolving medical technologies. • Emphasize hands-on training, ensuring proficiency in clinical procedures, diagnostic techniques, and the use of advanced medical equipment. This practical exposure will bridge the gap between theory and practice, enhancing students; confidence and competence in delivering quality patient care. • Focus on developing professionalism, empathy, ethical conduct, teamwork, and communication skills—key traits for holistic patient care and effective collaboration in interdisciplinary healthcare teams.

Students will gain additional skills in clinical research and recent advancements. Students apply knowledge from previous clinical learning experience under the supervision of a senior researcher. Student will peruse training in clinical trial unit **(Total-180 hrs.)**

Discipline Specific Elective Theory

Name of the Program	**M.Sc. Clinical Research**
Semester	**Semester I**
Name of the Subject	**Ethics in Clinical Research**
Subject Code	**DSE 001 T**

Course Outcome	• Explain the historical development of clinical research ethics, including key ethical guidelines (Nuremberg Code, Declaration of Helsinki, Belmont Report, etc.). • Identify and analyze legal liabilities, investigator responsibilities, and compensation-related obligations in clinical research. • Describe the role of CIOMS, NIH, and ICMR guidelines in ethical clinical research. • Explain the function and significance of IRB/IEC/ERB in clinical trials. • Analyze the ethics review process and the importance of informed consent in clinical trials. • Evaluate the ethical and legal aspects of informed consent and patient information documentation.

Sr. No.	Topics	No. of Hrs.
1.	Evolution of ethics in clinical research, Tuskegee experiment, Nuremberg Code, Declaration of Helsinki, Belmont report, Establishment of CIOMS, NIH and ICMR guidelines, Legal Liability in Clinical research, negligence, strict liability, criminal liability, Legal obligations of the investigator, Compensation to subjects/patients for clinical trial related injuries	**15**
2.	Independent Ethics Committees, Ethics review procedure, Importance of Inform Consent Document; Patient Information Sheet & Inform Consent Form, Fraud and misconduct, detection of fraud in clinical research, Ethics in academia, Violations of ethics in research	**15**
Total		**30 hrs**

Suggested Readings:

1. Basic Principles of Clinical Research and Methodology by S.K Gupta;Jaypee Brothers and Medical Publishers; First Edition
2. Oxford Text Book of Clinical Research Ethics by Ezekiel J. Emanuel, Christine C. Grady, Robert A. Crouch; OUP USA; 2008 Edition

Name of the Program	**M.Sc. Clinical Research**
Semester	**Semester I**
Name of the Subject	**Different systems of Medicine**
Subject Code	**DSE 002 T**

Course Outcome	• Explain the origins, evolution, and significance of Ayurveda, Siddha, Unani, Yoga, Naturopathy, and Homeopathy. • Describe the fundamental principles of disease prevention and treatment in different systems of medicine. • Examine how traditional practices align with or differ from modern medical approaches. • Identify key medicinal plants used in different systems and their therapeutic applications. • Discuss recent advances in validating traditional medicine and US botanical drug development. • Assess how globalization has influenced Ayurveda and other traditional systems.

Sr. No.	Topics	No. of Hrs.
1.	Historical background of the different systems of medicines, Different traditional practices, Principles of prevention and treatment of diseases in alternative systems of medicine	**15**
2.	Recent developments in the validation of different systems of medicine, Uses of medicinal plants and the utilization of different herbs, Medicinal plants and their different system of medicine, Recent advances: US botanical drug development	**15**
Total		**30 hrs**

Suggested Readings

1. Ayurvedic perspectives of certain communicable diseases by K.V Dilip Kumar
2. Indian systems of Medicine by B Ravishankar & V J Shukla- Pub med Central
3. Ancient Indian Medicine by P.Kutumbiah

FIRST YEAR

M.Sc. Clinical Research

SEMESTER-II

Code No.	Core Subjects
Discipline Specific Core Theory	
MCR 106 T	Drug Analysis
MCR 107 T	Clinical Research Guidelines I
MCR 108 T	Pharmacology II
Discipline Specific Core Practical	
MCR 109 P	Practical Lab II (MCR 106 to MCR 108)
MCR 110 CP	MCR Directed Clinical Education-II
Discipline Specific Elective Theory	
DSE 003 T	Epidemiological Principles Relevant to Clinical Research
DSE 004 T	Clinical trial Operations
Skill Enhancement Course	
SEC 001 T	Alternative in toxicity testing
SEC 002 T	NPTEL Swayam

Name of the Program	**M.Sc. Clinical Research**
Semester	**Semester II**
Name of the Subject	**Drug Analysis**
Subject Code	**MCR 106 T**

Course Outcome	• Explain the principles and types of analytical methods used in drug analysis. • Identify and describe various laboratory apparatus used in drug analysis. • Explain the theory, mathematical concepts, and principles behind IR absorption spectroscopy. • Analyze and interpret IR spectra for organic and inorganic compounds. • Explain the working of Single Beam and Double Beam spectrometers and their applications. • Evaluate the applications of IR spectroscopy in the qualitative and quantitative analysis of drugs. • Discuss advanced techniques such as ATR, Non-dispersive IR, and Polythermal Beam Deflection Spectroscopy.

Sr. No.	Topics	No. of Hrs.
1	Analytical Methods, Apparatus used, Spectro-Analytical Methods	**3**
2	**IR Absorption Spectroscopy:** Introduction, The Range of Infrared Radiation, Nomenclature of Infra spectra, Theory of Infrared Absorption Spectroscopy or Requirement for Infrared Radiation Absorption, Mathematical Theory of IR Absorption Spectroscopy, Linear Molecules, Symmetric Top Molecules, Asymmetric Top Molecules, Instrumentation, Single Beam and Double Beam Spectrometers, Mode of Vibrations of Atoms in Polyatomic Molecules, Factors Influencing Vibrational Frequencies, Selection Rules, Position and Intensity of Bands Intensity of Absorption Bands, Units of Measurements, Application of IR Spectroscopy to Organic Compounds, Application of IR Spectroscopy to In-organic Complexes, Miscellaneous Examples, Attenuated Total Reflectance, Non-dispersive IR, Polythermal Beam Deflection Spectroscopy, Application of IR Spectroscopy to Quantitative Analysis, Limitations of IR Spectroscopy	**3**
3	**Visible Spectroscopy Colorimetry:** Introduction, Theory of spectrophotometer and Colorimetry Deviations from Beer's law, Instrumentation, Obtaining and Interpreting Data, Applications of Colorimetry and Spectrophotometry, Molar Compositions of Complexes, Spectrophotometry Titrations	**3**
4	**UV Spectroscopy:** Introduction, Origin and Theory of UV Spectra, Types of Transitions of In-organic Molecules, Types of Transitions of Organic Molecules, The Shape of UV Absorption Curves, Transition Probability, Chromospheres and Related Terms, Effect of Conjugation, Solvent Effects, Woodward-Feiser Rules for Calculating Absorption Maximum, Instrumentation, Application of Spectroscopy to Organic Compounds, General Application of UV Absorption Spectroscopy	**3**
5	**NMR Spectroscopy:** Introduction, Quantum Description of NMR, Rules Predicting Spin Numbers of Nuclei and Calculation of Spin Numbers of Elements Responding to NMR, Width of Absorption Lines in NMR, Number of Signals: Equivalent and Non-equivalent Protons, Chemical Shift, Chemical Shift of Different Types of Protons & Positions of PMR Signals,	**3**

	Spin-Spin Coupling: Splitting of Signals, Coupling Constants, Instrumentations, Relationship between Area of Peaks & Molecular Formula, Solvents Used in NMR, Interpretations of NMR Spectra, Application of NMR Spectroscopy, Limitations of NMR Spectroscopy, F1uorine-9 NMR, Phosphorus-31 NMR, Carbon-13 NMR	
6	**Mass Spectroscopy:** Introduction Theory, Components of Mass Spectrometer, Recordings of Mass Spectrogram, Resolution of Mass Spectrometer, Types of the Ions Produced in Mass Spectrometer, General Rule for the Interpretations of Mass Spectra, Typical Example of Interpretation of Molecular Mass Spectra, Some Examples of Mass Spectra, Quantitative Analysis, Applications of Mass Spectroscopy	**3**
Chromatography		
7	**Introduction:** Definition, Types of Chromatography, Theoretical Principles Underlying Chromatographic Techniques, Theories of Chromatography, Development of Chromatogram, Qualitative and Quantitative Analysis by Chromatography	**3**
8	**Paper Chromatography:** Introduction, Principle, Migration Parameter, Types of Paper chromatography, Experimental Details for Qualitative Analysis, Experimental Details for Quantitative Analysis, Application	**3**
9	**Thin Layer Chromatography:** Introduction, Superiority of TLC Over other Chromatographic Techniques, Experimental Techniques, Applications of TLC, Applications of Some Other Forms of TLC, Limitations Scope, High Performance Thin Layer Chromatography	**3**
10	**Liquid-Liquid Partition Chromatography:** Introduction, Theory, Solid Supports, Selection of Mobile and Stationary Phases, Solvent Systems, Reversed Phase Chromatography, Choice of Adsorption or Partition, Applications of Partition Chromatography	**3**
11	**HPLC:** Introduction, Principle, Instrumentation, Apparatus & Materials, Column Efficiency and Selectivity, Comparison of HPLC & GLC, Applications, HPLC Adsorption Chromatography, HPLC Partition Chromatography	**3**
12	**Column Chromatography:** Introduction, Principle, Experimental Details, Theory of Development, Column Efficiency, Applications of Column Chromatography	**3**
13	**Gel Chromatography:** Introduction, Principle, Materials, Gel Preparation, Column Packing and Detectors, Applications, Advantage of Gel Chromatography	**3**
14	**Ion Exchange Chromatography:** Introduction, Definition, Principle, Cation Exchangers, Anion Exchangers, Regeneration, Ion Exchange Column Used in Chromatographic Separations Selection of Suitable Systems, Ion Exchange Capacity, Ion Exchange Techniques, Applications of Ion Exchangers	**3**
15	**Gas Chromatography:** Introduction, Principle of Gas Chromatographic Separations, Gas-Liquid Chromatography, Instrumentation, Evaluation, Retention volume, Resolution, Branches of Gas Chromatography, Applications, Gas-Solid Chromatography, Gas Chromatography-Mass Spectrometry (GC-MS)	**3**
Total		**45 hrs**

Suggested Reading:

1. “Pharmaceutical Analysis”, Kasture AV, Wadodkar SG, Volume II, NiraliPrakashan.

Name of the Program	**M.Sc. Clinical Research**
Semester	**Semester II**
Name of the Subject	**Clinical Research Guidelines I**
Subject Code	**MCR 107 T**

Course Outcome	• Explain the CDSCO guidelines for bioavailability & bioequivalence studies and their significance in clinical research. • Analyze the ethical principles from the World Medical Association's Declaration of Helsinki. • Interpret regulatory requirements for clinical trials in India as per Schedule Y. • Describe the principles of GCP and their role in ensuring ethical and high-quality clinical trials. • Compare international regulatory guidelines for BA/BE studies in veterinary and human medicine. • Examine the importance of clinical safety data management and periodic safety update reports.

Sr. No.	Topics	No. of Hrs.
1	CDSCO Guideline Published by Ministry of Health and Family Welfare, Guideline for Bioavailability & Bioequivalence Studies.	**5**
2	World Medical Association Declaration of Helsinki: Ethical principles for Medical Research Involving Human Subjects.	**3**
3	Drugs and Cosmetics Act, Schedule Y.	**2**
4	Guidelines for Good Clinical practice E6 (R1).	**5**
5	EMEA Guideline: BA BE studies for veterinary Medicines.	**2**
6	ASEAN Guidelines for The Conduct of Bioavailability and Bioequivalence Studies	**3**
7	E2A: Clinical Safety Data Management: Definitions and Standards for Expedited Reporting	**2**
8	E2B (M): Maintenance of The ICH Guideline on Clinical Safety Data Management, Data Elements for Transmission of individual Case Safety Reports.	**2**
9	E2B (R3): Revision of The ICH Guideline on Clinical Safety Data Management Data Elements for Transmission of Individual Case safety Reports.	**2**
10	E2C (R1): Clinical Safety Data Management, Periodic Safety Update Reports for Marketed Drugs.	**2**
11	E7: studies In Support of special Populations, Geriatrics.	**2**
12`	E9: Statistical principles For Clinical Trials.	**4**
13	FDA Comment for highly variable drugs	**3**
14	FDA Guideline for, Waiver of In Vivo Bioavailability and Bioequivalence Studies for Immediate-Release Solid oral Dosage Forms Based on a Biopharmaceutics Classification System.	**4**
15	EU Guidelines For, Evaluation of Bioequivalence of Highty variable Drugs And Drug Products.	**2**
16	FDA Guideline for The Monitoring of Clinical Investigations.	**2**
Total		**45 hrs**

Name of the Program	**M.Sc. Clinical Research**
Semester	**Semester II**
Name of the Subject	**Pharmacology-II**
Subject Code	**MCR 108 T**

Course Outcome	• Explain the mechanism of action, uses, and side effects of diuretics and antidiuretics. • Describe the pharmacology of drugs used for peptic ulcers, emetics, antiemetics, constipation, and diarrhea. • Classify and explain the mechanisms of action of beta-lactam antibiotics, tetracyclines, aminoglycosides, and chloramphenicol. • Understand the pharmacokinetics, pharmacodynamics, and clinical applications of anti-TB and antileprotic drugs. • Identify different antifungal and antiviral drugs and their applications in treating infections. • Explain the mode of action, resistance mechanisms, and therapeutic uses of drugs for malaria and urinary tract infections.

Sr. No.	Topics	No. of Hrs.
1	**Drugs acting on Kidneys:** Diuretics, Antidiuretics	**12**
2	**Drugs acting on GIT:** Drugs used for Peptic ulcers, Emetics, Antiemetics, Drugs for constipation and diarrhoea	**10**
3	**Antimicrobial drugs:** Beta lactum antibiotics, Tetracyclines and Chloramphenicol, Aminoglycosides, Anti TB, Drugs used for UTI, Antileprotic drugs, Antifungal drugs, Antiviral drugs, Antimalerial drugs, Antiamoebic and antiprotozoal drugs, Anthelmintics	**15**
4	**Hormones and related drugs:** Anterior Pituitary Hormones, Thyroid hormones and thyroid inhibitors, Insulin, oral hypoglycaemics and glucagon, Corticosteroids, Oxytocin and drugs acting on Uterus	**8**
Total		**45 hrs**

Suggested Readings:

1. Satoskar and Bhandarkar
2. KD Tripathi

MCR 109 P- Practical Lab II (MCR 106 to MCR 108)

Sr. No.	Topics	No. of Hrs.
1	Measurement of Pulse rate, BP, Temperature, Assessment of Height, weight, demography, waist, ECG recoding, Application of Simple statistical test to the results obtained in above tests	**40**
2	Exposure to various components of planning, co-ordination and conduct of clinical trials viz., screening and enrolment of subjects, obtaining informed consent, monitoring of drug administration, adverse events, vital functions, collection and processing of blood samples, SOPs, protocol design, adverse event reporting. Some practical exercise will comprise use of statistical packages in clinical research, Basic orientation to common analytical instruments used in clinical research: LC- MS and related instruments, Validation and calibration of biomedical instruments Students will be exposed to ongoing clinical research activities viz., Different Phases of CTs, Bioavailability (BA) and bioequivalence (BE) studies, Pharmacokinetics & pharmacodynamics, Monitoring and auditing of CTs, data management, Statistical software used in clinical research, Drug regulatory activities.	**80**
Total		**120 hrs**

Course Code- MCR 110 CP: MCR Directed Clinical Education – II

Course Outcome	• Build a robust theoretical foundation, enabling students to understand healthcare practices, disease management, and patient care, thereby empowering them to make informed decisions and adapt to evolving medical technologies. • Emphasize hands-on training, ensuring proficiency in clinical procedures, diagnostic techniques, and the use of advanced medical equipment. This practical exposure will bridge the gap between theory and practice, enhancing students; confidence and competence in delivering quality patient care. • Focus on developing professionalism, empathy, ethical conduct, teamwork, and communication skills—key traits for holistic patient care and effective collaboration in interdisciplinary healthcare teams.

Trainees acquire the knowledge and procedural skills necessary to deliver a high standard of research with clinical research. **(Total- 180 hrs.)**

Discipline Specific Elective Theory

Name of the Program	**M.Sc. Clinical Research**
Semester	**Semester II**
Name of the Subject	**Epidemiological Principles Relevant to Clinical Research**
Subject Code	**DSE 003 T**

Course Outcome	• Explain mortality and morbidity indicators, and their relevance in epidemiological studies. • Analyze different types of bias (study, response, information, interviewer, site selection, measurement, and confounding) in research. • Interpret diagnostic tests, screening tests, and prognostic tests using an evidence-based approach. • Understand the principles and applications of pharmaco epidemiological studies in clinical settings. • Explain how molecular and genetic epidemiology contribute to clinical research. • Discuss the impact of race, ethnicity, social class, and culture on clinical research methodologies.

Sr. No.	Topics	No. of Hrs.
1	Measures of disease occurrence and disease association, Mortality indicators, Morbidity indicators, The different mechanisms of bias in clinical research (study, response, information, interviewer, site selection, measurement, and confounding); and a conceptual approach to multivariable analysis, Instruction in the research implications of evidence-based clinical medicine, including the specifications of diagnostic tests, screening tests, and prognostic tests, Pharmacoepidemiological studies	**15**
2	Introduction to the concepts, principles, and use of molecular and genetic methods in epidemiology and clinical research, Human Genome Project, Framework for interpreting, assessing, and incorporating molecular and genetic measures in research, Meaning of race, ethnicity, social class, and culture, their effects on the conduct and interpretation of clinical research, Pharmacogenomics and its application in clinical research, GWAS	**15**
Total		**30 hrs**

Suggested Reading

1. Epidemiology: Basis for Disease Prevention and Health Promotion by David Duncan Collier Macmillan publishers 5th edition
2. Clinical Epidemiology: The Essentials by Robert H. Fletcher and Suzanne W. Fletcher; WHO Press;5 TH Edition

Name of the Program	**M.Sc. Clinical Research**
Semester	**Semester II**
Name of the Subject	**Clinical Trial Operations**
Subject Code	**DSE 004 T**

Course Outcome	• Explain the process of selecting trial sites, investigators, and vendors. • Describe the responsibilities of sponsors, institutions, coordinators, and investigators. • Identify essential trial documents (protocol, CRF, ICD, investigator brochure, agreements). • Manage recruitment, site master file, SOPs, and regulatory compliance. • Understand the role of monitors, auditors, and data monitoring committees. • Develop strategies to handle unexpected challenges during clinical trials.

Sr. No.	Topics	No. of Hrs.
1	**Site initiation:** Selection of Clinical trial sites, Clinical Investigators and making budget and vendor selection, The roles and responsibilities of the following in CT: Sponsor, institution, Clinical Trial Coordinator: Clinical Investigator, Documents required at site, Site initiation and conduct activities: Protocol, CRF,ICD, Investigator brochure, Clinical trial agreement, ethics Committee and regulatory approval, site-initiation visits	**10**
2	**Site conduct:** Recruitment, IP/IMP/Pharmacy file receipt and storage, CT site master file, Databases, SOPs, Roles and responsibilities of Monitors and Auditors/Inspectors, Monitoring visits, audits and inspections, independent data monitoring activities, Contingency planning to prepare for unexpected situations.	**10**
3	**Site close-out activities:** Suspending and premature termination of a trial, Handling missing data, query and resolution Database lock, Site close-out report, Clinical study report, submission to ethics committee and regulatory agency, publication of results	**10**
Total		**30 hrs**

Suggested Reading

1. Principles and practice of Clinical Research by John. I Gallin.;Academic Press;3rd Edition
2. Principles and practice of clinical trial medicine by Richard Cin and Bruce Y. Lee; Academic Press; Ist Edition
3. Guidelines like GCP, USFDA, EMEA, Indian GCP etc.

SKILL ENHANCEMENT COURSES

Name of the Program	**M.Sc. Clinical Research**
Semester	**Semester I**
Name of the Subject	**Alternatives in Toxicity Testing**
Subject Code	**SEC 001 T**

Course Outcome	• Explain CPCSEA guidelines and ethical considerations in animal testing. • Describe the principles of Reduce, Refine, Replace, and Rehabilitate in animal research. • Analyze non-mammalian and non-animal models used for toxicity testing. • Explain the standard procedures for reporting animal trial data. • Assess the effectiveness of alternative testing methods such as the Draize test. • Describe the use of zebrafish, drosophilae, and C. elegans in toxicity studies.

Sr. No.	Topics	No. of Hrs.
1	Animal ethics and regulatory requirements, CPCSEA guidelines, Concept of 4Rs (reduce, refine, replacement and rehabilitation), Alternative models in toxicity testing (non-mammalian and non-animal models), APPROVE: reporting of animal trials	**25**
2	Examples of successful replacement: Draize test, Zebra fish, Drosophilae, C.elegans	**20**
Total		**45 hrs**

Suggested Readings

1. Principles of toxicological testing by Franke A Barley; CRC press; Second edition
2. Animals and Alternatives in Toxicity Testing: Present Status and Future Prospects by Pal Grave McMillan; Second Edition
3. Principles of toxicological testing by Franke A Barley; CRC press; Second edition

Name of the Program	**M.Sc. Clinical Research**
Semester	**Semester II**
Name of the Course	**NPTEL Swayam**
Course Code	**SEC 002 T**

Note: The links of SWAYAM/NPTEL courses (https://swayam.gov.in/nc_details/NPTEL)

Scheme of University Examination Theory for PG Program:

General structure / patterns for setting up question papers for Theory / Practical courses, their evaluation weightages for PG programs of MGMSBS are given in the following tables

Marks scheme for the University exam:

Final theory marks will be 100 marks (80 marks University Theory exam + 20 Marks Internal assessment).

Question		Marks distribution	Marks allotted per section	Marks
Sec: A	MCQ	10 x 1 M = 10	10	**10**
Sec: B	SAQ	3/4x 5 M = 15	15	**35**
Sec: B	LAQ	2/3 x 10 M = 10	20	
Sec: C	SAQ	3/4x 5 M = 15	15	**35**
Sec: C	LAQ	2/3x 10 M = 10	20	
Total				**80 Marks**

Marks Scheme for the University Examination (50 Marks)

Final theory marks will be 50 marks University Theory exam pattern Research Methodology & Biostatistics (Core course)

Question	Question No.	Question Type	Marks Distribution	Marks
Sec: A	1.	LAQ (2 out of 3)	2 X 10 Marks = 20	20
Sec: B	2.	SAQ (6 out of 8)	6 X 05 Marks = 30	30
Total				**50 Marks**

Marks Scheme for the University Examination (100 Marks)

Final theory marks will be 100 marks University Theory exam pattern Elective Course

Question	Question No.	Question Type	Marks Distribution	Marks
Sec: A	1.	LAQ (10 out of 12)	10 X 10 Marks = 100	100
Total				**100 Marks**

Practical exam pattern: Total 40 marks with following breakup:

Exercise	Description	Marks
Q No 1	Practical exercise - 1	1 x15=15 M
Q No 2	Station exercise	2x5M=10 M
Q No 3	VIVA	10 M
Q No 4	Journal	5M
Total		**40 Marks**

Practical exam pattern Research Methodology & Biostatistics (Core course)

Total 50-mark distribution:

Exercise	Description	Marks
Q No 1	**Practical/Problem-Solving:** These questions can assess statistical analysis, research design, hypothesis testing, or interpretation of data etc.	2 × 10 marks each) = **20 marks**
Q No 2	Identification of study designs, Critical appraisal of research papers, Application of biostatistical tools, Sampling techniques etc.	(4 × 5 marks each) = **20 marks**
Q No 3	**Viva Voce (Oral Examination)** Assessing conceptual clarity, application of research methodology, and statistical reasoning.	**10 marks**
Total		**50 Marks**

Practical to be conducted at respective departments and marks submitted jointly by the parent department to the university.

Breakup of theory IA calculation for 20 marks

Description	Marks
Internal exam (at department)	15 marks
Seminar	5 marks
Total	**20 Marks**

Breakup of practical IA calculation:

Description	Marks
Internal exam (at department)	10 marks
Viva	5 marks
Journal	5 marks
Total	**20 Marks**

Note –20 marks to be converted to 10 marks weightage for submission to the university.

Model Checklist for Evaluation of the Clinical Directed Posting (PG)

Name of the student: _____Date:_____
Program:_____
Semester: _____ Name of the Internal faculty/Observer:_____
Name of the External Faculty/Observer:_____

Core Competencies	Marks allotted	Marks obtained
Students will begin to develop critical thinking abilities utilizing the allied health personnel roles of communicator and caregiver. Students will learn principles of professional allied health personnel practice and provide direct care to individuals within a medical surgical setting while recognizing the diverse uniqueness of individuals with health alterations.		
Clinical Teaching		
a. Demonstrate beginning competency in technical skills.	10	
Independent Work by Student guided by faculty		
a. Develop effective communication skills (verbally and through charting) with patients, team members, and family	2.5	
b. Identify intra and inter-professional team member roles and scopes of practice. Establish appropriate relationships with team members.	2.5	
Hands on practical work by students		
a. Protect confidentiality of electronic/manual health records data, information, and knowledge of technology in an ethical manner	05	
Independent work by student		
a. Demonstrate expected behaviors and complete tasks in a timely manner. Arrive to clinical experiences at assigned times. Maintain professional behavior and appearance.	05	
Log book	10	
Viva	10	
Attendance	05	
Total	**50 Marks**	

Sign of Internal Examiner:_____
_____
Sign of External Examiner: _____

Resolution No. 5.1 of Academic Council (AC-52/2025):
Resolved to approve the CBCS syllabus, including Program Outcomes (POs) and Course Outcomes (COs), for Postgraduate (PG) 2-year programs under MGMSBS (semester III & IV) for M.Sc. Medical Biotechnology, M.Sc. Medical Genetics, M.Sc. Clinical Embryology, M.Sc. Clinical Nutrition, M.Sc. Medical Dialysis Technology, M.Sc. Molecular Biology, M.Sc. Medical Radiology & Imaging Technology, M.Sc. Cardiac Care Technology, M.Sc. Operation Theatre and Anaesthesia Technology, M.Sc. Emergency and Trauma Care, M. Optometry, Masters in Hospital Administration, Masters of Public Health, M.Sc. Health Informatics, M.Sc. Medical Laboratory Technology, M.Sc. Clinical Research, to be effective from batch admitted in the Academic Year 2025-26 onwards. Guidelines for selected programmes as per National Commission for Allied & Healthcare Professions will be adopted for the given programmes from academic year 2026-27 onwards [ANNEXURE-17A, 17B, 17C, 17D, 17E, 17F, 17G, 17H, 17I, 17J, 17K, 17L, 17M, 17N, 17O & 17P and ANNEXURE-18A, 18B, 18C, 18D, 18E, 18F, 18G, 18H, 18I, 18J, 18K, 18L, 18M, 18N, 18O & 18P].

Annexure-17P of AC-52/2025

MGM SCHOOL OF BIOMEDICAL SCIENCES, NAVI MUMBAI
(A constituent unit of MGM INSTITUTE OF HEALTH SCIENCES)
(Deemed to be University u/s 3 of UGC Act 1956)
Grade "A^{++}" Accredited by NAAC
Sector 1, Kamothe Navi Mumbai-410209, Tel.No.022-27437631, 27437632
Email. sbsnm@mgmuhs.com / Website: www.mgmsbsnm.edu.in

CHOICE BASED CREDIT SYSTEM (CBCS)

(Academic Year 2025 - 26)

Curriculum for

M.Sc. Allied Health Sciences

M.Sc. Clinical Research

Semester III & IV

Course Outcomes
Semester III

MCR 111 T	Clinical Research Guidelines – II	Mapped PO	Teaching- Learning Methodology	Assessment Tools
CO1	Explain the principles of international and national clinical research guidelines (ICH-GCP, Schedule Y, CDSCO, FDA, EMA, WHO).	PO1, PO2	Lectures, Guideline document analysis	Internal Assessment, University Exam, Theory exam, Seminar, MCQ, Assignment
CO2	Interpret ethical requirements, informed consent processes, and subject protection measures in line with guidelines.	PO2	Case studies, Ethics committee SOP review, Role play	Internal Assessment, University Exam, Theory exam, Seminar, MCQ, Assignment
CO3	Apply regulatory guidelines in protocol design, submission, and conduct of clinical trials.	PO2, PO3	Practical assignments, Mock protocol preparation, Workshops	Internal Assessment, University Exam, Theory exam, Seminar, MCQ, Assignment
CO4	Compare and contrast global regulatory requirements and their implications on multinational trials.	PO1, PO3, PO5	Comparative analysis, Seminar discussions	Internal Assessment, University Exam, Theory exam, Seminar, MCQ, Assignment
CO 5	Demonstrate professional communication and teamwork in preparing regulatory submissions and SOPs.	PO4	Group projects, Team-based workshops	Internal Assessment, University Exam, Theory exam, Seminar, MCQ, Assignment
CO6	Critically evaluate the impact of regulatory guidelines on drug development, patient safety, and clinical research quality.	PO3, PO5	Research paper review, Critical appraisal, Panel discussions	Internal Assessment, University Exam, Theory exam, Seminar, MCQ, Assignment

MCR 112 T	Pharmacovigilance Materiovigilance	Mapped PO	Teaching-Learning Methodology	Assessment Tools
CO1	Explain the principles, scope, and importance of pharmacovigilance and materiovigilance in ensuring patient safety.	PO1	Lectures, Interactive discussions	Internal Assessment and University Exam, Theory exam, Practical Exam, Seminar, Viva-Voce, Station exercise, MCQ,
CO2	Describe regulatory requirements and guidelines for pharmacovigilance and materiovigilance in India and globally (e.g., CDSCO, WHO, USFDA, EMA).	PO1, PO2	Lectures, Case studies	Internal Assessment and University Exam, Theory exam, Practical Exam, Seminar, Viva-Voce, Station exercise, MCQ,
CO3	Apply methods of adverse drug reaction (ADR) reporting, signal detection, and risk assessment in pharmacovigilance.	PO2, PO3	Practical sessions, Workshops, Hands-on exercises	Internal Assessment and University Exam, Theory exam, Practical Exam, Seminar, Viva-Voce, Station exercise, MCQ,

CO4	Analyze pharmacovigilance and materiovigilance databases, software, and tools used for data management and signal detection.	PO3	Demonstrations, Software training, Simulations	Internal Assessment and University Exam, Theory exam, Practical Exam, Seminar, Viva-Voce, Station exercise, MCQ,
CO5	Demonstrate teamwork and communication skills in preparing safety reports, regulatory submissions, and patient information documents.	PO4	Group projects, Role play, Team-based activities	Internal Assessment and University Exam, Theory exam, Practical Exam, Seminar, Viva-Voce, Station exercise, MCQ,
CO6	Critically evaluate real-world case studies of drug/device safety issues, regulatory actions, and global safety surveillance.	PO3, PO5	Case study analysis, Panel discussions	Internal Assessment and University Exam, Theory exam, Practical Exam, Seminar, Viva-Voce, Station exercise, MCQ,

MCR 113 T	**Introduction to Database & Various Software in Clinical Data Management**	**Mapped PO**	**Teaching- Learning Methodology**	**Assessment Tools**
CO1	Explain the fundamentals of clinical databases, data flow, and their role in clinical research.	PO1	Lectures, Interactive discussions, Concept mapping	Internal Exam, University Exam (Theory Exam), Seminar, Assignment
CO 2	Describe the features and applications of commonly used CDM software (Oracle Clinical, Medidata Rave, Open Clinica, Red Cap, SAS).	PO1, PO2	Lectures, Demonstrations, Software tutorials	Internal Exam, University Exam (Theory Exam), Seminar, Assignment
CO 3	Apply principles of data entry, query management, and validation using simulated databases or software tools.	PO2, PO3	Hands-on sessions, Workshops, Practical exercises	Internal Exam, University Exam (Theory Exam), Seminar, Assignment
CO4	Analyze data management processes including CRF design, edit checks, data cleaning, and audit trails in compliance with GCP.	PO2, PO3, PO5	Case studies, SOP review, Group discussions	Internal Exam, University Exam (Theory Exam), Seminar, Assignment
CO 5	Demonstrate teamwork and communication skills in preparing mock CDM workflows, project reports, and presentations.	PO4	Group projects, Team-based workshops, Collaborative tasks	Internal Exam, University Exam (Theory Exam), Seminar, Assignment
CO6	Critically evaluate the importance of data integrity, security, and regulatory compliance in clinical databases and software systems.	PO2, PO3, PO5	Panel discussions, Debates, Research paper review	Internal Exam, University Exam (Theory Exam), Seminar, Assignment

MCR 114 T	**Pharmacoeconomics and Health Technology Assessment**	**Mapped PO**	**Teaching-Learning Methodology**	**Assessment Tools**
CO1	Explain the basic concepts of pharmacoeconomics, cost types, and health technology assessment.	PO1	Lectures, Concept mapping,	Internal Exam, University Exam

			Interactive discussions	(Theory Exam), Seminar, Assignment
CO2	Describe national and international perspectives on HTA and its role in healthcare decision-making and policy.	PO1, PO2	Lectures, Policy document review, Guest lectures	Internal Exam, University Exam (Theory Exam), Seminar, Assignment
CO3	Apply pharmacoeconomic evaluation methods (CMA, CEA, CUA, CBA) to clinical and healthcare scenarios.	PO2, PO3	Case studies, Workshops, Hands-on exercises	Internal Exam, University Exam (Theory Exam), Seminar, Assignment
CO4	Analyze cost-effectiveness studies and HTA reports to assess the value of drugs, devices, and interventions.	PO3, PO5	Research paper review, Seminar discussions, Group analysis	Internal Exam, University Exam (Theory Exam), Seminar, Assignment
CO5	Demonstrate teamwork and communication skills in preparing and presenting pharmacoeconomic evaluations.	PO4	Group projects, Team-based workshops, Collaborative tasks	Internal Exam, University Exam (Theory Exam), Seminar, Assignment
CO6	Critically evaluate the ethical, social, and policy implications of pharmacoeconomics and HTA on healthcare systems and patient access.	PO3, PO5	Panel discussions, Debates, Critical appraisal	Internal Exam, University Exam (Theory Exam), Seminar, Assignment

MCR 115 T	**Medical Writing**	**Mapped PO**	**Teaching-Learning Methodology**	**Assessment Tools**
CO1	Explain the scope, principles, and ethical aspects of medical writing in clinical research and healthcare.	PO1, PO2	Lectures, Interactive discussions	Internal Exam, University Exam (Theory Exam), Seminar, Assignment
CO2	Describe the structure and content of key clinical research documents such as protocols, informed consent forms, study reports, and regulatory submissions.	PO1, PO2	Lectures, Document reviews, Case examples	Internal Exam, University Exam (Theory Exam), Seminar, Assignment
CO3	Apply scientific writing skills to prepare clear, concise, and well-structured research documents in compliance with regulatory standards (ICMJE, GCP, ICH).	PO2, PO3	Workshops, Practical writing exercises, Hands-on assignments	Internal Exam, University Exam (Theory Exam), Seminar, Assignment
CO4	Analyze published scientific articles, clinical trial reports, and regulatory documents for quality, accuracy, and compliance.	PO3, PO5	Journal clubs, Critical appraisal sessions, Group discussions	Internal Exam, University Exam (Theory Exam), Seminar, Assignment
CO5	Demonstrate professional communication and teamwork in preparing manuscripts, posters, and presentations for conferences and publications.	PO4	Group projects, Role play, Peer collaboration	Internal Exam, University Exam (Theory Exam), Seminar, Assignment

CO6	Critically evaluate real-world challenges in medical writing such as plagiarism, authorship disputes, data transparency, and publication ethics.	PO2, PO5	Panel discussions, Debates, Case study analysis	Internal Exam, University Exam (Theory Exam), Seminar, Assignment

MCR 116	**Research Project / Dissertation**	**Mapped PO**	**Teaching-Learning Methodology**	**Assessment Tools**
CO1	**Formulate a research problem** by reviewing scientific literature and identifying knowledge gaps in field of clinical research.	PO1, PO2	Lectures, Interactive discussions	Internal Exam, University Exam (Theory Exam), Seminar, Assignment
CO2	**Design and execute research projects** using appropriate methodologies, tools, and techniques relevant to biomedical research.	PO1, PO2	Lectures, Document reviews, Case examples Workshops	Internal Exam, University Exam (Theory Exam), Seminar, Assignment
CO3	**Demonstrate proficiency** in designing ,handling & conducting advanced research project including clinical trials	PO2, PO3	Workshops, Practical writing exercises, Hands-on assignments	Internal Exam, University Exam (Theory Exam), Seminar, Assignment
CO4	**Critically analyze and interpret experimental data** using appropriate statistical and computational tools.	PO3, PO5	Journal clubs, Critical appraisal sessions, Group discussions, Workshops	Internal Exam, University Exam (Theory Exam), Seminar, Assignment
CO5	**Adhere to ethical standards** in biomedical research, including biosafety, data integrity, and responsible reporting.	PO1 – PO5	Workshops , Group projects	Internal Exam, University Exam (Theory Exam), Seminar, Assignment
CO6	**Communicate research findings effectively** through well-structured dissertation writing, presentations, and potential publications.	PO1 – PO5	Workshops, Practical writing exercises, Hands-on assignments	Internal Exam, University Exam (Theory Exam), Seminar, Assignment
CO7	**Work independently and collaboratively** to solve research challenges and manage time efficiently during the project.	PO1 – PO5	Workshops, Practical writing exercises, Hands-on assignments	Internal Exam, University Exam (Theory Exam), Seminar, Assignment
CO8	**Develop a research-oriented mindset** that prepares them for higher studies, industrial R&D, or academic research careers	PO1 – PO5	Workshops, Practical writing exercises, Hands-on assignments	Internal Exam, University Exam (Theory Exam), Seminar, Assignment

MCR 117 P	Practical's/ Hands on training	Mapped PO	Teaching-Learning Methodology	Assessment Tools
CO1	Apply the principles of **clinical trial design, documentation, and ethical conduct** by preparing essential research documents such as study protocols, case report forms, and informed consent forms.	PO1 – PO5	Workshops, Practical writing exercises, Hands-on assignments	Internal Exam, University Exam (Practical Exam), Seminar, Assignment
CO2	Demonstrate the ability to **record, code, and manage clinical and safety data** using appropriate databases, coding systems (MedDRA/ICD), and electronic data capture tools following GCP and regulatory standards	PO1 – PO5	Workshops, Practical writing exercises, Hands-on assignments	Internal Exam, University Exam (Practical Exam), Seminar, Assignment
CO3	Develop competency in **medical and regulatory writing** by preparing clinical study reports, safety summaries, and scientific manuscripts suitable for regulatory submission or publication.	PO1 – PO5	Workshops, Practical writing exercises, Hands-on assignments	Internal Exam, University Exam (Practical Exam), Seminar, Assignment
CO4	Analyze and interpret **economic, legal, and intellectual property aspects** of pharmaceuticals and medical devices to support evidence-based decision-making and compliance with national and international regulations.	PO1 – PO5	Workshops, Practical writing exercises, Hands-on assignments	Internal Exam, University Exam (Practical Exam), Seminar, Assignment
CO5	Integrate multidisciplinary knowledge to perform **comprehensive clinical research management tasks**, including documentation, safety evaluation, ethical review, and communication of findings in a professional and compliant manner.	PO1 – PO5	Workshops, Practical writing exercises, Hands-on assignments	Internal Exam, University Exam (Practical Exam), Seminar, Assignment

MCR 118 P	Medical Writing	Mapped PO	Teaching- Learning Methodology	Assessment Tools
CO1	Explain the scope, principles, and ethical aspects of medical writing in clinical research and healthcare.	PO1, PO2	Lectures, Interactive discussions	Internal Exam, University Exam (Practical Exam), Seminar, Assignment
CO2	Describe the structure and content of key clinical research documents such as protocols, informed consent forms, study reports, and regulatory submissions.	PO1, PO2	Lectures, Document reviews, Case examples	Internal Exam, University Exam (Practical Exam), Seminar, Assignment
CO3	Apply scientific writing skills to prepare clear, concise, and well-structured	PO2, PO3	Workshops, Practical writing	Internal Exam, University Exam

	research documents in compliance with regulatory standards (ICMJE, GCP, ICH).		exercises, Hands-on assignments	(Practical Exam), Seminar, Assignment
CO4	Analyze published scientific articles, clinical trial reports, and regulatory documents for quality, accuracy, and compliance.	PO3, PO5	Journal clubs, Critical appraisal sessions, Group discussions	Internal Exam, University Exam (Practical Exam), Seminar, Assignment
CO5	Demonstrate professional communication and teamwork in preparing manuscripts, posters, and presentations for conferences and publications.	PO4	Group projects, Role play, Peer collaboration	Internal Exam, University Exam (Practical Exam), Seminar, Assignment
CO6	Critically evaluate real-world challenges in medical writing such as plagiarism, authorship disputes, data transparency, and publication ethics.	PO2, PO5	Panel discussions, Debates, Case study analysis	Internal Exam, University Exam (Practical Exam), Seminar, Assignment

Semester – IV

MCR 119 T	**Clinical Research Management**	**Mapped PO**	**Teaching-Learning Methodology**	**Assessment Tools**
CO1	Explain the principles, scope, and processes of clinical research management, including trial planning and execution.	PO1	Lectures, Concept mapping, Interactive discussions	Internal Exam, University Exam (Theory Exam), Seminar, Assignment
CO2	Describe the roles of sponsors, CROs, investigators, and ethics committees in trial management.	PO1, PO2	Lectures, Case studies, Guest lectures	Internal Exam, University Exam (Theory Exam), Seminar, Assignment
CO3	Apply project management tools and techniques in budgeting, resource allocation, site management, and monitoring	PO2, PO3	Workshops, Simulations, Practical assignments	Project reports, Practical assignment evaluation Internal Exam, University Exam (Theory Exam), Seminar, Assignment
CO4	Analyse challenges in clinical trial operations including recruitment, retention, risk management, and quality assurance	PO3, PO5	Case studies, Group discussions, Research paper reviews	Internal Exam, University Exam (Theory Exam), Seminar, Assignment
CO5	Demonstrate teamwork, leadership, and communication skills in coordinating trial teams and preparing project deliverables	PO4	Group projects, Team-based activities, Role play	Internal Exam, Group project evaluation, Peer assessment University Exam

				(Theory Exam), Seminar, Assignment
CO6	Critically evaluate the ethical, regulatory, and strategic dimensions of managing multinational and multicentric clinical trials.	PO2, PO3, PO5	Panel discussions, Debates, Critical appraisals	Internal Exam, University Exam (Theory Exam), Seminar, Assignment

MCR 120 T	**Pharmaceuticals Organisations & Pharmaceutical Jurisprudence in India**	**Mapped PO**	**Teaching- Learning Methodology**	**Assessment Tools**
CO1	Explain the structure and role of the Indian pharmaceutical industry and CROs in clinical research.	PO1, PO2	Lectures, Case discussions, Industry reports review	Internal Assessment and University Exam, Theory exam, Practical Exam, MCQ, Viva-voce, Station Exercise, Seminar, Assignment
CO2	Describe the regulatory framework governing pharmaceuticals and CRO operations in India.	PO2	Lectures, Regulatory guideline review, Guest lecture from industry experts	Internal Assessment and University Exam, Theory exam, Practical Exam, MCQ, Viva-voce, Station Exercise, Seminar, Assignment
CO3	Analyze the business models, organizational structure, and functional areas of CROs.	PO1, PO3	Case studies, Group discussions, Role play	Internal Assessment and University Exam, Theory exam, Practical Exam, MCQ, Viva-voce, Station Exercise, Seminar, Assignment
CO4	Compare Indian CROs with global CROs in terms of opportunities, challenges, and quality standards.	PO3, PO5	Comparative analysis, Seminars, Research paper review	Internal Assessment and University Exam, Theory exam, Practical Exam, MCQ, Viva-voce, Station Exercise, Seminar, Assignment
CO 5	Evaluate the contribution of CROs in innovation, drug development, and healthcare delivery in India in Comparison with global CROs in terms of opportunities, challenges, and quality standards.	PO3, PO5	Research assignments, Critical review of CRO impact	Internal Assessment and University Exam, Theory exam, Practical Exam, MCQ, Viva-voce, Station Exercise, Seminar, Assignment
CO 6	Explain the principles of pharmaceutical legislation in India, including the Drugs and Cosmetics Act, Pharmacy Act, and related rules.	PO1, PO2	Lectures, Law document review, Interactive discussions	Internal Assessment and University Exam, Theory exam, Practical Exam, Seminar, Viva-

				Voce, Station exercise, MCQ,
CO 7	Apply legal requirements in clinical trial conduct, drug approval, import–export, and manufacturing processes.	PO2, PO3	Case studies, Compliance check exercises, Workshops	Internal Assessment and University Exam, Theory exam, Practical Exam, Seminar, Viva-Voce, Station exercise, MCQ,
CO8	Critically evaluate ethical and legal challenges in drug regulation, pricing, marketing, and patient safety.	PO2, PO3, PO5	Debates, Panel discussions, Critical appraisal	Internal Assessment and University Exam, Theory exam, Practical Exam, Seminar, Viva-Voce, Station exercise, MCQ,

MCR 121 T	**Bioethics IPR and Biosafety**	**Mapped PO**	**Teaching-Learning Methodology**	**Assessment Tools**
CO1	**Evaluate** ethical concerns in biomedical and biotechnological practices.	PO1, PO4	Lectures, Demonstrations, Interactive discussions	Practical Exam, Station Exercise, Viva-voce
CO2	**Understand** different types of IPR and their applications.	PO1, PO4	Lectures, Demonstrations, Interactive discussions	Practical Exam, Station Exercise, Viva-voce
CO3	**Apply** various national and international guidelines in biomedical and health research**.**	PO1, PO4	Lectures, Demonstrations, Interactive discussions	Practical Exam, Station Exercise, Viva-voce

MCR 122 T	**Communication Skills**	**Mapped PO**	**Teaching-Learning Methodology**	**Assessment Tools**
CO1	Explain the principles of effective verbal, non-verbal, and written communication in professional and clinical research settings.	PO1, PO4	Lectures, Demonstrations, Interactive discussions	Practical Exam, Station Exercise, Viva-voce
CO 2	Demonstrate the ability to draft professional documents including emails, reports, SOPs, and regulatory submissions.	PO2, PO4	Workshops, Practical exercises, Writing assignments	Practical Exam, Station Exercise, Viva-voce
CO 3	Apply presentation skills using modern tools (PowerPoint, posters, infographics) for communicating research outcomes.	PO4	Hands-on sessions, Peer presentations, Tutorials	Practical Exam, Station Exercise, Viva-voce
CO4	Analyze communication barriers and develop strategies for effective cross-cultural and interdisciplinary communication.	PO3, PO4, PO5	Case studies, Role play, Group discussions	
CO5	Demonstrate teamwork, leadership, and negotiation skills in group activities, discussions, and project settings.	PO4	Group projects, Team-based tasks, Simulations	

CO6	Critically evaluate the role of communication in patient engagement, informed consent, conflict resolution, and stakeholder management.	PO2, PO3, PO5	Debates, Panel discussions, Critical reflections	

MCR 116	**Research Project / Dissertation**	**Mapped PO**	**Teaching-Learning Methodology**	**Assessment Tools**
CO1	**Formulate a research problem** by reviewing scientific literature and identifying knowledge gaps in field of clinical research.	PO1, PO2	Lectures, Interactive discussions	Internal Exam, University Exam (Theory Exam), Seminar, Assignment
CO2	**Design and execute research projects** using appropriate methodologies, tools, and techniques relevant to biomedical research.	PO1, PO2	Lectures, Document reviews, Case examples Workshops	Internal Exam, University Exam (Theory Exam), Seminar, Assignment
CO3	**Demonstrate proficiency** in designing ,handling & conducting advanced research project including clinical trials	PO2, PO3	Workshops, Practical writing exercises, Hands-on assignments	Internal Exam, University Exam (Theory Exam), Seminar, Assignment
CO4	**Critically analyze and interpret experimental data** using appropriate statistical and computational tools.	PO3, PO5	Journal clubs, Critical appraisal sessions, Group discussions, Workshops	Internal Exam, University Exam (Theory Exam), Seminar, Assignment
CO5	**Adhere to ethical standards** in biomedical research, including biosafety, data integrity, and responsible reporting.	PO1 – PO5	Workshops , Group projects	Internal Exam, University Exam (Theory Exam), Seminar, Assignment
CO6	**Communicate research findings effectively** through well-structured dissertation writing, presentations, and potential publications.	PO1 – PO5	Workshops, Practical writing exercises, Hands-on assignments	Internal Exam, University Exam (Theory Exam), Seminar, Assignment
CO7	**Work independently and collaboratively** to solve research challenges and manage time efficiently during the project.	PO1 – PO5	Workshops, Practical writing exercises, Hands-on assignments	Internal Exam, University Exam (Theory Exam), Seminar, Assignment
CO8	**Develop a research-oriented mindset** that prepares them for higher studies, industrial R&D, or academic research careers	PO1 – PO5	Workshops, Practical writing exercises, Hands-on assignments	Internal Exam, University Exam (Theory Exam), Seminar, Assignment

MCR 123 P	**Internship/Training (Clinical/ Industrial)**	**Mapped PO**	**Teaching-Learning Methodology**	**Assessment Tools**

CO1	Apply theoretical knowledge of **clinical research design, pharmacovigilance, and regulatory frameworks** to real-world clinical or industrial settings, demonstrating practical competency and ethical conduct.	PO1, PO2	Workshops, Practical writing exercises, Hands-on assignments, Interactive discussions	University Exam (Practical Exam), Assignment
CO2	Develop proficiency in **clinical documentation and data management**, including source data verification, CRF entry, query resolution, and adherence to GCP and SOPs during project execution.	PO1, PO2	Workshops, Practical writing exercises, Hands-on assignments, Interactive discussions	University Exam (Practical Exam), Assignment
CO3	Demonstrate effective **professional communication, teamwork, and coordination** with multidisciplinary teams including investigators, monitors, regulatory personnel, and data managers.	PO2, PO3	Workshops, Practical writing exercises, Hands-on assignments, Interactive discussions	University Exam (Practical Exam), Assignment
CO4	Analyze and interpret **clinical, safety, and operational data** to support evidence-based decision-making and contribute to ongoing or completed clinical studies, pharmacovigilance activities, or regulatory submissions.	PO3, PO5	Workshops, Practical writing exercises, Hands-on assignments, Interactive discussions	University Exam (Practical Exam), Assignment
CO5	Reflect critically on the **industrial/clinical work experience**, identifying areas for skill enhancement, understanding organizational workflows, and integrating ethical, regulatory, and quality perspectives into professional practice.	PO1 – PO5	Workshops, Practical writing exercises, Hands-on assignments, Interactive discussions	University Exam (Practical Exam), Assignment

OUTLINE OF COURSE CURRICULUM

M. Sc. CLINICAL RESEARCH

Semester III

Code No.	Core Course	Credits/Week					Hrs/Semester					Marks		
		Lecture (L)	Tutorial (T)	Practical (P)	Clinical Posing/ Rotation (CP)	Total Credits (C)	Lecture (L)	Tutorial (T)	Practical (P)	Clinical Posing/ Rotation (CP)	Total (hrs.)	Internal Assement (IA)	Semester End Exam (SEE)	Total
Discipline Specific Core Theory														
MCR 111 T	Clinical Research Guidelines-II	3	-	-	-	**3**	45	-	-	-	**45**	**20**	**80**	**100**
MCR 112 T	Pharmacovigilance Materiovigilance	3	-	-	-	**3**	45	-	-	-	**45**	-	**50**	**50**
MCR 113 T	Introduction to Database & Various Software in Clinical Data Management	3	-	-	-	**3**	45	-	-	-	**45**	-	**50**	**50**
MCR 114 T	Pharmacoeconomics and Health Technology Assessment	3	-	-	-	**3**	45	-	-	-	**45**	-	**50**	**50**
MCR 115 T	Medical Writing	3	-	-	-	**3**	45	-	-	-	**45**	-	**50**	**50**
MCR 116	Research Project / Dissertation	-	-	14	-	**7**	-	-	**210**	-	**210**	**50**	-	**50**
Discipline Specific Core Practical														
MCR 117 P	Practical's/Hands-on Training	-	-	4	-	**2**	**60**	-		-	**60**	**10**	**40**	**50**
MCR 118 P	Medical Writing	-	-	4	-	**2**	**60**	-		-	**60**	**10**	**40**	**50**
Total		**15**	**0**	**22**	**0**	**26**	**345**	**0**	**210**	**0**	**555**	**90**	**360**	**450**

OUTLINE OF COURSE CURRICULUM

M. Sc. CLINICAL RESEARCH

Semester IV

Code No.	Core Course	Credits/Week					Hrs/Semester					Marks		
		Lecture (L)	Tutorial (T)	Practical (P)	Clinical Posing/ Rotation (CP)	Total Credits (C)	Lecture (L)	Tutorial (T)	Practical (P)	Clinical Posing/ Rotation (CP)	Total (hrs.)	Internal Assement (IA)	Semester End Exam (SEE)	Total
Discipline Specific Core Theory														
MCR 119 T	Clinical Research Management	2	-	-	-	**2**	30	-	-	-	**30**	**20**	**80**	**100**
MCR 120 T	Pharmaceutical Organisations & Pharmaceutical Jurisprudence in India	2	-	-	-	**2**	30	-	-	-	**30**	-	**50**	**50**
MCR 121 T	Bioethics IPR and Biosafety	3	-	-	-	**3**	45	-	-	-	**45**	**20**	**80**	**100**
MCR 122 T	Communication Skills	2	-	-	-	**2**	30	-	-	-	**30**	-	**50**	**50**
Discipline Specific Core Practical														
MCR 123 P	Internship/Training (Clinical/ Industrial)	-	-	9	-	**3**	-	-	135	-	**135**	-	**50**	**50**
MCR 116	Research Project / Dissertation	-	-	18	-	**9**	-	-	270	-	**270**	-	**200**	**200**
Total		**9**	**0**	**27**	**0**	**21**	**135**	**0**	**405**	**0**	**540**	**40**	**510**	**550**

SECOND YEAR

M.Sc. CLINICAL RESEARCH

SEMESTER-III

Code No.	Core Subjects
Discipline Specific Core Theory	
MCR 111 T	Clinical Research Guidelines-II
MCR 112 T	Pharmacovigilance & Materiovigilance
MCR 113 T	Introduction to Database & Various Software in Clinical Data Management
MCR 114 T	Pharmacoeconomics and Health Technology Assessment
MCR 115 T	Medical Writing
MCR 116	Research Project / Dissertation
Discipline Specific Core Practical	
MCR 117 P	Practical's/Hands-on Training
MCR 118 P	Medical Writing

Name of the Program	**M.Sc. Clinical Research**
Semester	**Semester III**
Name of the Subject	**Clinical Research Guidelines – II**
Subject Code	**MCR 111 T**

Course Outcome	• Explain the principles of international and national clinical research guidelines (ICH-GCP, Schedule Y, CDSCO, FDA, EMA, WHO). • Interpret ethical requirements, informed consent processes, and subject protection measures in line with guidelines. • Apply regulatory guidelines in protocol design, submission, and conduct of clinical trials. • Compare and contrast global regulatory requirements and their implications on multinational trials. • Demonstrate professional communication and teamwork in preparing regulatory submissions and SOPs. • Critically evaluate the impact of regulatory guidelines on drug development, patient safety, and clinical research quality.

Sr. No.	Topics	No. of Hrs.
1	Overview of Schedule Y (revisited with emphasis on amendments)	**2**
2	New Drugs and Clinical Trials (NDCT) Rules, 2019 – key provisions	**3**
3	CDSCO & DCGI roles in clinical trial oversight	**4**
4	Indian Council of Medical Research (ICMR) – Ethical Guidelines (2023 update)	**3**
5	NABH & Indian GCP (comparison with ICH-GCP)	**3**
6	International Good Clinical Practice Guidelines	**2**
7	Belmont Report & Nuremberg Code – relevance today	**4**
8	Declaration of Helsinki (2013 version & updates)	**2**
9	CIOMS Guidelines (2016) – ethical guidance in LMICs	**3**
10	US FDA Code of Federal Regulations (21 CFR Part 50 & 56) – informed consent & ethics committees	**3**
11	EU Clinical Trials Regulation (CTR) – 2022 implementation	**2**
12	Guidelines for research in vulnerable populations (children, elderly, pregnant women, socio-economically disadvantaged)	**3**
13	Guidelines for genomic, genetic, and biobanking research	**2**
14	Stem cell & regenerative medicine research regulations in India	**2**
15	Medical device and diagnostic clinical trial guidelines (Indian & international)	**2**
16	AYUSH clinical trial guidelines in India	**2**
17	Safety & Post-Marketing Guidelines	**3**
Total		**45 hrs**

Name of the Program	**M.Sc. Clinical Research**
Semester	**Semester III**
Name of the Subject	**Pharmacovigilance & Materiovigilance**
Subject Code	**MCR 112 T**

Course Outcome	• Explain the principles, scope, and importance of pharmacovigilance and materiovigilance in ensuring patient safety. • Describe regulatory requirements and guidelines for pharmacovigilance and materiovigilance in India and globally (e.g., CDSCO, WHO, USFDA, EMA). • Apply methods of adverse drug reaction (ADR) reporting, signal detection, and risk assessment in pharmacovigilance. • Analyze pharmacovigilance and materiovigilance databases, software, and tools used for data management and signal detection. • Demonstrate teamwork and communication skills in preparing safety reports, regulatory submissions, and patient information documents. • Critically evaluate real-world case studies of drug/device safety issues, regulatory actions, and global safety surveillance.

Sr. No.	Topics	No. of Hrs.
1	Introduction & Basics	**4**
2	Classification of ADRs (Type A–F, others)	**8**
3	Mechanisms of ADRs (dose-related, immune-mediated, idiosyncratic, etc.)	**4**
4	Risk factors for ADRs (age, genetics, comorbidities, polypharmacy)	**2**
5	Case studies of major ADRs leading to drug withdrawals	**2**
6	Spontaneous reporting systems (e.g., Yellow Card, MedWatch, PvPI)	**2**
7	Active surveillance methods (registries, cohort event monitoring, EHR-based systems)	**2**
8	Signal detection, validation, and management	**2**
9	**Materiovigilance** Definition, scope, and need for Materiovigilance, Materiovigilance Programme of India (MvPI) – structure & operations, Global device safety regulations (US FDA MDR, EU Medical Device Regulation), Case studies of device failures/recalls (e.g., metal-on-metal hip implants, pacemakers)	**3**
10	Methods of causality assessment (WHO-UMC, Naranjo scale, CIOMS)	**4**
11	Regulatory & Global Perspective	**2**
12	Safety Reporting & Risk Management	**2**
13	PV in vaccines (VAERS, VigiBase, AEFI reporting in India)	**2**
14	PV for herbal, AYUSH & nutraceutical products	**2**
15	PV in medical devices & combination products	**2**
16	PV in biologics, biosimilars, and gene therapies	**2**
Total		**45 hrs**

Name of the Program	**M.Sc. Clinical Research**
Semester	**Semester III**
Name of the Subject	**Introduction to Database & Various Software in Clinical Data Management**
Subject Code	**MCR 113 T**

Course Outcome	• Explain the fundamentals of clinical databases, data flow, and their role in clinical research. • Describe the features and applications of commonly used CDM software (Oracle Clinical, Medidata Rave, Open Clinical, Red Cap, SAS). • Apply principles of data entry, query management, and validation using simulated databases or software tools. • Analyze data management processes including CRF design, edit checks, data cleaning, and audit trails in compliance with GCP. • Demonstrate teamwork and communication skills in preparing mock CDM workflows, project reports, and presentations. • Critically evaluate the importance of data integrity, security, and regulatory compliance in clinical databases and software systems.

Sr. No.	Topics	No. of Hrs.
1	**Fundamentals of Databases** Introduction to data, information, and databases Types of databases – relational, hierarchical, object-oriented Basics of Relational Database Management Systems (RDBMS) Database concepts: tables, fields, records, keys (primary, foreign), indexes Introduction to SQL (queries, joins, data retrieval)	**6**
2	**Clinical Data Management (CDM) Overview** Role of CDM in clinical trials – end-to-end process Data flow in clinical research (CRF → database → analysis → submission) Clinical Data Management Plan (CDMP) Data entry, query management, discrepancy management Audit trails, data validation, and quality assurance	**7**
3	**Data Standards in Clinical Research** CDISC standards: SDTM (Study Data Tabulation Model), ADaM (Analysis Data Model), ODM HL7 and FHIR in healthcare data exchange MedDRA (for adverse events) and WHO-DD (for drug coding) Importance of standardization for regulatory submissions (FDA, EMA)	**7**
4	**Clinical Data Management Systems (CDMS)** Introduction to CDMS: purpose, features, workflow Popular CDMS platforms: Oracle Clinical, Medidata Rave Inform EDC (Oracle/Phase Forward), Veeva Vault CDMS RED Cap (academic/research use) Paper CRF vs. Electronic Data Capture (EDC) systems eCRF design principles and best practices	**7**
5	**Specialized Software in CDM** SAS in CDM – data analysis & reporting R programming – role in CDM and statistical analysis Pharmacovigilance databases: Argus Safety, ARISg, VigiFlow	**6**

	Clinical Trial Management Systems (CTMS) – overview and examples Integration of CDMS with EHRs, ePRO, and wearable devices	
6	**Data Integrity, Security & Regulations** GCP and 21 CFR Part 11 compliance for electronic records/signatures GDPR, HIPAA, and Indian DPDP Act – data privacy in clinical research Data backup, archiving, and disaster recovery Role of IT, cloud computing, and cybersecurity in CDM	**8**
7	**Future Trends** Artificial Intelligence (AI) and Machine Learning (ML) in CDM Real-world data (RWD) & Real-world evidence (RWE) integration Blockchain in clinical data security and transparency Future of cloud-based and decentralized clinical trial databases	**4**
Total		**45 hrs.**

Name of the Program	**M.Sc. Clinical Research**
Semester	**Semester III**
Name of the Subject	**Pharmacoeconomics and Health Technology Assessment**
Subject Code	**MCR 114 T**

Course Outcome	• Explain the basic concepts of pharmacoeconomics, cost types, and health technology assessment. • Describe national and international perspectives on HTA and its role in healthcare decision-making and policy. • Apply pharmacoeconomic evaluation methods (CMA, CEA, CUA, CBA) to clinical and healthcare scenarios. • Analyze cost-effectiveness studies and HTA reports to assess the value of drugs, devices, and interventions. • Demonstrate teamwork and communication skills in preparing and presenting pharmacoeconomic evaluations. • Critically evaluate the ethical, social, and policy implications of pharmacoeconomics and HTA on healthcare systems and patient access.

Sr. No.	Topics	No. of Hrs.
1	**Introduction & Fundamentals** Definition, scope, and importance of pharmacoeconomics Role of pharmacoeconomics in clinical research, drug development & policy Overview of HTA – purpose, stakeholders, and process Relationship between evidence-based medicine, pharmacoeconomics, and HTA	**7**
2	**Pharmacoeconomic Evaluation Methods** Cost-Minimization Analysis (CMA) Cost-Effectiveness Analysis (CEA) Cost-Utility Analysis (CUA) – QALYs, DALYs, utilities Cost-Benefit Analysis (CBA) Budget Impact Analysis (BIA)	**8**
3	**Data Sources & Methodology** Types of costs: direct, indirect, intangible Outcome measures: clinical, humanistic, and economic Decision analytic models – decision trees, Markov models, simulation models Systematic reviews & meta-analyses in economic evaluation Sensitivity analysis & handling uncertainty	**8**
4	**Health Technology Assessment (HTA)** Principles and components of HTA (clinical, economic, ethical, social) HTA process flow: scoping, evidence collection, appraisal, reporting HTA in drug pricing, reimbursement, and policy-making HTA and priority setting in healthcare systems Role of HTA in India – HTAIn (Health Technology Assessment India)	**7**
5	**Global Perspectives in Pharmacoeconomics & HTA** NICE (UK), CADTH (Canada), ICER (USA), PBAC (Australia) WHO guidelines on cost-effectiveness thresholds Pharmacoeconomics in low- and middle-income countries (LMICs) Comparative global case studies in drug pricing & reimbursement International Society for Pharmacoeconomics and Outcomes Research (ISPOR) – role & guidelines	**8**

6	**Applications & Future Trends** Use of pharmacoeconomic data in clinical trial design & regulatory submissions Pricing and market access strategies based on pharmacoeconomics Value-based healthcare & outcome-based reimbursement models Digital health & real-world evidence (RWE) in HTA Future challenges: orphan drugs, gene therapies, personalized medicine	**7**
Total		**45 hrs.**

Name of the Program	**M.Sc. Clinical Research**
Semester	**Semester III**
Name of the Subject	**Medical Writing**
Subject Code	**MCR 115 T**

Course Outcome	• Explain the scope, principles, and ethical aspects of medical writing in clinical research and healthcare. • Describe the structure and content of key clinical research documents such as protocols, informed consent forms, study reports, and regulatory submissions. • Apply scientific writing skills to prepare clear, concise, and well-structured research documents in compliance with regulatory standards (ICMJE, GCP, ICH). • Analyze published scientific articles, clinical trial reports, and regulatory documents for quality, accuracy, and compliance. • Demonstrate professional communication and teamwork in preparing manuscripts, posters, and presentations for conferences and publications. • Critically evaluate real-world challenges in medical writing such as plagiarism, authorship disputes, data transparency, and publication ethics.

Sr. No.	Topics	No. of Hrs.
1.	Introduction to Medical Writing	**4**
2.	Protocol writing – key components and structure	**4**
3.	Investigator's Brochure (IB) preparation	**4**
4.	Informed Consent Forms (ICFs) – ethical and readability aspects	**4**
5.	Case narratives and SAE reports	**4**
6.	Writing abstracts, posters, and conference presentations	**4**
7.	Manuscript writing for peer-reviewed journals – IMRAD format	**4**
8.	Systematic reviews and meta-analyses	**4**
9.	Reference management tools (EndNote, Mendeley, Zotero)	**2**
10.	Authorship criteria, plagiarism, and publication ethics (ICMJE guidelines, COPE)	**3**
11.	Patient information leaflets (PILs) and lay summaries	**4**
12.	Style guides – AMA Manual of Style, ICMJE, CONSORT guidelines	**4**
Total		**45 hrs**

Name of the Program	M. Sc. Clinical Research
Semester	Semester III
Name of the Subject	Medical Writing
Subject Code	MCR 118 P

Course Objective	• Develop skills in **scientific and regulatory writing**, preparing structured clinical study reports (CSR), summary of product characteristics (SmPC), and case narratives in compliance with ICH-E3 and GCP guidelines.
Course Outcomes	• Explain the scope, principles, and ethical aspects of medical writing in clinical research and healthcare. • Describe the structure and content of key clinical research documents such as protocols, informed consent forms, study reports, and regulatory submissions. • Apply scientific writing skills to prepare clear, concise, and well-structured research documents in compliance with regulatory standards (ICMJE, GCP, ICH). • Analyze published scientific articles, clinical trial reports, and regulatory documents for quality, accuracy, and compliance. • Demonstrate professional communication and teamwork in preparing manuscripts, posters, and presentations for conferences and publications. • Critically evaluate real-world challenges in medical writing such as plagiarism, authorship disputes, data transparency, and publication ethics.

Sr. No.	Topics	No. of Hrs.
1.	Protocol Design	**6**
2.	CRF Preparation	**6**
3.	ICF preparation	**6**
4.	Investigator's Brochure (IB) & Safety Summary Preparation	**6**
5.	AI-assisted writing and data summarization in clinical research	**6**
6.	Manuscript writing	**6**
7.	Promotional literature writing	**6**
8.	Writing source documents	**6**
9.	Case narrative writing & SAE report	**6**
10	CSR writing	**6**
Total		**60 hrs.**

Name of the Program	M. Sc. Clinical Research
Semester	Semester III
Name of the Subject	Research Project / Dissertation
Subject Code	MCR 116

Course Objective	• The dissertation course is designed to provide postgraduate students with hands-on experience in scientific research, enabling them to apply theoretical knowledge and laboratory skills acquired during the M.Sc. Clinical Research program. • The objective is to cultivate independent thinking, critical analysis, problem-solving abilities, and technical expertise in experimental design, data collection, analysis, and interpretation. • It also aims to nurture scientific communication skills, ethical research practices, and the capacity to contribute meaningfully to biomedical and translational research.
Course Outcomes	After completing this course, students will be able to: • **Formulate a research problem** by reviewing scientific literature and identifying knowledge gaps in field of clinical research. • **Design and execute research projects** using appropriate methodologies, tools, and techniques relevant to biomedical research. • **Demonstrate proficiency** in designing, handling & conducting advanced research project including clinical trials • **Critically analyze and interpret experimental data** using appropriate statistical and computational tools. • **Adhere to ethical standards** in biomedical research, including biosafety, data integrity, and responsible reporting. • **Communicate research findings effectively** through well-structured dissertation writing, presentations, and potential publications. • **Work independently and collaboratively** to solve research challenges and manage time efficiently during the project. • **Develop a research-oriented mindset** that prepares them for higher studies, industrial R&D, or academic research careers.

Research Project / Dissertation:

The dissertation is a mandatory component of the M.Sc. Clinical Research program, designed to provide students with hands-on research experience and the opportunity to apply theoretical knowledge to practical problems. It involves independent project work under the guidance of a faculty supervisor, focusing on advanced areas of Clinical Research. The dissertation aims to develop critical thinking, problem-solving, data analysis, and scientific writing skills, preparing students for careers in research, industry, or higher studies**.** The dissertation process is stringent and span over two year, the student has to design a protocol and submit it to the institutional research advisory committee and get it approved form it, thereafter the student has to submit the proposal for ethical approval for animal and human ethics committees**,** post approval the student has to conduct a thorough project work to achieve the objectives mentioned in the approved proposal **(**210 Hrs.)

Name of the Program	**M. Sc. Clinical Research**
Semester	**Semester III**
Name of the Subject	**Practical's/Hands-on Training**
Subject Code	**MCR 117 P**

Course Objective	• To provide practical exposure to real-world clinical, regulatory, or industrial research environments and bridge the gap between theoretical knowledge and professional application. • To develop core competencies in clinical trial operations, pharmacovigilance, data management, and regulatory documentation through supervised experiential learning. • To cultivate professional skills in teamwork, communication, problem-solving, and adherence to ethical and regulatory standards (ICH-GCP, ICMR, Schedule Y). • To enhance analytical and decision-making abilities by engaging in ongoing research, monitoring, or quality assurance activities within clinical or industrial settings. • To encourage self-assessment and reflective learning for identifying career interests, strengths, and areas for improvement in the field of clinical research.
Course Outcomes	• Apply the principles of clinical trial design, documentation, and ethical conduct by preparing essential research documents such as study protocols, case report forms, and informed consent forms. • Demonstrate the ability to record, code, and manage clinical and safety data using appropriate databases, coding systems (MedDRA/ICD), and electronic data capture tools following GCP and regulatory standards • Develop competency in medical and regulatory writing by preparing clinical study reports, safety summaries, and scientific manuscripts suitable for regulatory submission or publication. • Analyze and interpret economic, legal, and intellectual property aspects of pharmaceuticals and medical devices to support evidence-based decision-making and compliance with national and international regulations. • Integrate multidisciplinary knowledge to perform comprehensive clinical research management tasks, including documentation, safety evaluation, ethical review, and communication of findings in a professional and compliant manner.

Sr. No.	**Topics**	**No. of Hrs.**
		5
1.	Informed Consent Form (ICF) Preparation & Role-Play	**5**
2.	Case Record Form (CRF) & Medical Record Review Exercise	**5**
3.	Adverse Event & SAE Reporting	**5**
4.	Intellectual Property & Patent Drafting Simulation	**5**
5.	Database Entry & Query Resolution in Clinical Data Management Software	**5**
6.	Pharmacoeconomic Evaluation Exercise	**4**
7.	Perform a cost-effectiveness or cost–utility analysis of two treatment options using Excel.	**4**

8.	Prepare a short HTA-style report including ICER calculation and recommendation.	**4**
9.	Legal & Regulatory Document Review (Jurisprudence & Ethics Practical)	**4**
10	Review sample clinical trial agreements, ethics committee approvals, and regulatory submissions.	**4**
11	Identify key legal clauses, responsibilities, and GCP compliance aspects.	**3**
12	Materiovigilance case review: analyze a medical device recall scenario	**4**
13	Pharmacovigilance database demo using Vigi Flow or Argus	**3**
Total		**60 hrs.**

SECOND Year

M.Sc. Clinical Research

SEMESTER-IV

Code No.	Core Subjects
Discipline Specific Core Theory	
MCR 119 T	Clinical Research Management
MCR 120 T	Pharmaceutical Organisations & Pharmaceutical Jurisprudence in India
MCR 121 T	Bioethics IPR and Biosafety
MCR 122 T	Communication skills
Discipline Specific Core Practical	
MCR 123 P	Internship/Training (Clinical/ Industrial)
MCR 116	Research Project / Dissertation

Name of the Program	**M.Sc. Clinical Research**
Semester	**Semester IV**
Name of the Subject	**Clinical Research Management**
Subject Code	**MCR 119 T**

Course Outcome	• Explain the principles, scope, and processes of clinical research management, including trial planning and execution. • Describe the roles of sponsors, CROs, investigators, and ethics committees in trial management. • Apply project management tools and techniques in budgeting, resource allocation, site management, and monitoring • Analyse challenges in clinical trial operations including recruitment, retention, risk management, and quality assurance • Demonstrate teamwork, leadership, and communication skills in coordinating trial teams and preparing project deliverables • Critically evaluate the ethical, regulatory, and strategic dimensions of managing multinational and multicentric clinical trials.

Sr. No.	Topics	No. of Hrs.
1	**Introduction to Clinical Research Management** Definition, scope, and importance of clinical research management Evolution of clinical research and global perspectives Roles of stakeholders – sponsor, CRO, investigator, ethics committees, regulators Organizational structure of a clinical research team	**6**
2	**Planning & Design of Clinical Trials** Clinical trial phases (I–IV) and study designs Protocol development: key components and considerations Feasibility assessment and site selection Budgeting and financial management in clinical trials	**6**
3	**Regulatory & Ethical Aspects** ICH-GCP guidelines and Indian GCP Regulatory requirements in India (Schedule Y, NDCT Rules 2019, ICMR Guidelines) Global regulatory perspectives – US FDA, EMA, MHRA, WHO Ethical issues: informed consent, compensation, protection of vulnerable populations	**4**
4	**Clinical Trial Operations** Clinical trial project management principles Recruitment and retention strategies for participants Trial supplies management (IP accountability, storage, randomization, blinding) Site initiation, monitoring visits, and close-out activities	**4**
5	**Data & Quality Management** Clinical data management (CRFs, EDC systems, query resolution) Pharmacovigilance and safety monitoring during trials Risk-based monitoring and quality management systems Audits, inspections, and compliance with regulatory authorities	**4**
6	**Role of CROs in Clinical Research Management** CRO business models – full-service vs. niche CROs Outsourcing strategies and sponsor–CRO relationships Quality oversight of CROs and vendors Emerging trends in CRO management	**4**

7	**Post-Trial & Advanced Concepts** Trial reporting, publication, and dissemination of results Post-marketing surveillance and pharmacovigilance integration Patient-centric and decentralized clinical trials (DCTs) Digital transformation in trial management – AI, e Consent, wearable devices, big data	**2**
Total		**30 hrs.**

Name of the Program	**M.Sc. Clinical Research**
Semester	**Semester IV**
Name of the Subject	**Pharmaceutical Organisations & Pharmaceutical Jurisprudence in India**
Subject Code	**MCR 120 T**

Course Outcome	• Explain the structure and role of the Indian pharmaceutical industry and CROs in clinical research. • Describe the regulatory framework governing pharmaceuticals and CRO operations in India. • Analyze the business models, organizational structure, and functional areas of CROs. • Compare Indian CROs with global CROs in terms of opportunities, challenges, and quality standards. • Evaluate the contribution of CROs in innovation, drug development, and healthcare delivery in India in Comparison with global CROs in terms of opportunities, challenges, and quality standards. • Explain the principles of pharmaceutical legislation in India, including the Drugs and Cosmetics Act, Pharmacy Act, and related rules. • Apply legal requirements in clinical trial conduct, drug approval, import–export, and manufacturing processes. • Critically evaluate ethical and legal challenges in drug regulation, pricing, marketing, and patient safety.

Sr. No.	Topics	No. of Hrs.
1	Introduction to Pharmaceutical Jurisprudence	**2**
2	The Drugs and Cosmetics Act, 1940 and Rules, 1945 – overview	**2**
3	Drug schedules (Schedule Y, H, H1, X, G, etc.) and their relevance	**2**
4	Pharmacy Act, 1948 – regulation of pharmacy education and profession	**2**
5	Drugs and Magic Remedies (Objectionable Advertisements) Act, 1954	**2**
6	Narcotic Drugs and Psychotropic Substances (NDPS) Act, 1985 – clinical implications	**2**
7	CDSCO, DCGI – powers and responsibilities	**2**
8	New Drugs and Clinical Trials Rules (NDCT), 2019	**2**
9	ICMR Ethical Guidelines (2023 update) – legal enforceability	**2**
10	Medical Device Rules, 2017	**2**
11	AYUSH regulations in drug development and trials	**2**
12	Informed consent: legal validity and case laws	**2**
13	Compensation for injury in clinical trials (Indian provisions)	**2**
14	Legal responsibilities of investigators, sponsors, CROs, and IECs	**2**
15	Jurisprudence in biologics, biosimilars, and gene therapies	**1**
16	Stem cell research – legal frameworks in India & abroad	**1**
Total		**30 hrs.**

Name of the Program	M. Sc. Clinical Research
Semester	Semester IV
Name of the Subject	Bioethics, IPR and Biosafety
Subject Code	MCR 121 T

Course Objective	• To familiarize students with ethical issues in biomedical research and healthcare. • To provide knowledge about intellectual property rights and their relevance in biotechnology. • To understand biosafety principles and regulatory frameworks related to research and product development.
Course Outcomes	After completing this course, students will be able to: • **Evaluate** ethical concerns in biomedical and biotechnological practices. • **Understand** different types of IPR and their applications. • **Apply** various national and international guidelines in biomedical and health research**.**

Sr. No.	Topics	No. of Hrs.
1	**Introduction to Bioethics:** Principles of biomedical ethics: autonomy, beneficence, non-maleficence, justice. Ethics in clinical research: Informed consent, confidentiality, human and animal experimentation. Ethical guidelines: ICMR, DHR, ANRF, Helsinki Declaration, Belmont Report. Case studies in biomedical ethics.	**12**
2	**Intellectual Property Rights (IPR):** Types of IPR: Patents, Copyrights, Trademarks, Trade secrets, Plant variety protection. Patent filing process (India and international). Patentability criteria and limitations in biotechnology. Importance of IPR in academia and industry.	**12**
3	**Biosafety and Biosecurity:** Definition and classification of biological hazards, Risk assessment and management in laboratory and field research, Containment facilities: Biosafety levels (BSL I–IV), Guidelines: Cartagena Protocol, NIH Guidelines, DBT & WHO norms, Dual-use research and bioterrorism concerns.	**12**
4	**Regulatory Frameworks and Institutional Oversight:** Institutional Biosafety Committee (IBSC), Review Boards, Ethical Committees. NABH, NABH Digital Health Standards for Hospitals, NABL, JCI, ISO. National and international regulatory bodies: RCGM, GEAC, CDSCO, WHO. Biosafety and ethics in genome editing (e.g., CRISPR), stem cell research, GMOs. Recent advancements and controversies. Cyber Security, HIPAA, GDPR, DPDP Act 2023 India.	**9**
Total		**45 hrs.**

Reference book:

1. **Bioethics & Biosafety** – R. C. Dubey
2. **Intellectual Property Rights in Biotechnology** – P. Narayanan
3. **Bioethics and Biosafety in Biotechnology** – V. Sree Krishna
4. **ICMR Ethical Guidelines for Biomedical Research** (latest version)
5. WIPO, DBT, ICMR, DHR, ANRF, NABH, NABL, HIPPA, GDPR, DPDP Act 2023, India and WHO online resources.

Name of the Program	**M.Sc. Clinical Research**
Semester	**Semester IV**
Name of the Subject	**Communication skill**
Subject Code	**MCR 122 T**

Course Outcome	• Explain the principles of effective verbal, non-verbal, and written communication in professional and clinical research settings. • Demonstrate the ability to draft professional documents including emails, reports, SOPs, and regulatory submissions. • Apply presentation skills using modern tools (PowerPoint, posters, infographics) for communicating research outcomes. • Analyze communication barriers and develop strategies for effective cross-cultural and interdisciplinary communication. • Demonstrate teamwork, leadership, and negotiation skills in group activities, discussions, and project settings. • Critically evaluate the role of communication in patient engagement, informed consent, conflict resolution, and stakeholder management.

Sr. No.	Topics	No. of Hrs.
1	**Basics of Communication** Fundamentals of communication – process, elements, types (verbal, non-verbal, written, visual) Barriers to communication in healthcare and clinical research Importance of communication in clinical trial management Cross-cultural communication and sensitivity in global trials	**6**
2	**Oral Communication Skills** Effective speaking and active listening techniques Patient–investigator communication (informed consent, explaining procedures, adverse events) Communicating with ethics committees, regulators, and sponsors Presentation skills – delivering scientific talks, trial updates, and team briefings	**6**
3	**Written Communication Skills** Scientific writing – abstracts, manuscripts, posters Writing clinical research documents (protocols, informed consent forms, case report forms, SOPs) Professional email and business correspondence in research settings Medical writing and regulatory submissions	**6**
4	**Interpersonal & Team Communication** Teamwork and collaboration in multi-disciplinary research teams Negotiation and conflict resolution in clinical research settings Leadership communication – motivating teams, giving and receiving feedback Networking and professional etiquette in research collaborations	**6**
5	**Digital & Modern Communication Tools** Use of telemedicine and e-consent platforms in trials Communicating via electronic data capture (EDC) systems and trial portals Social media and science communication – ethics and professionalism Crisis communication – handling trial-related adverse events and public/media queries	**6**
Total		**30 hrs**

Name of the Program	M. Sc. Clinical Research
Semester	Semester IV
Name of the Subject	Research Project / Dissertation
Subject Code	MCR 116

Course Objective	• The dissertation course is designed to provide postgraduate students with hands-on experience in scientific research, enabling them to apply theoretical knowledge and laboratory skills acquired during the M.Sc. Clinical research program. The objective is to cultivate independent thinking, critical analysis, problem-solving abilities, and technical expertise in experimental design, data collection, analysis, and interpretation. It also aims to nurture scientific communication skills, ethical research practices, and the capacity to contribute meaningfully to biomedical and translational research.
Course Outcomes	After completing this course, students will be able to: • Formulate a research problem by reviewing scientific literature and identifying knowledge gaps in field of clinical research. • Design and execute research projects using appropriate methodologies, tools, and techniques relevant to biomedical research. • Demonstrate proficiency in designing, handling & conducting advanced research project including clinical trials • Critically analyze and interpret experimental data using appropriate statistical and computational tools. • Adhere to ethical standards in biomedical research, including biosafety, data integrity, and responsible reporting. • Communicate research findings effectively through well-structured dissertation writing, presentations, and potential publications. • Work independently and collaboratively to solve research challenges and manage time efficiently during the project. • Develop a research-oriented mindset that prepares them for higher studies, industrial R&D, or academic research careers

Research Project / Dissertation:

The dissertation is a mandatory component of the M.Sc. Clinical Research program, designed to provide students with hands-on research experience and the opportunity to apply theoretical knowledge to practical problems. It involves independent project work under the guidance of a faculty supervisor, focusing on advanced areas of Clinical Research. The dissertation aims to develop critical thinking, problem-solving, data analysis, and scientific writing skills, preparing students for careers in research, industry, or higher studies**.** The dissertation process is stringent and span over two year, the student has to design a protocol and submit it to the institutional research advisory committee and get it approved form it, thereafter the student has to submit the proposal for ethical approval for animal and human ethics committees**,** post approval the student has to conduct a thorough project work to achieve the objectives mentioned in the approved proposal **(Total - 270 hrs.)**

Name of the Program	M. Sc. Clinical Research
Semester	Semester IV
Name of the Subject	Internship/Training (Clinical/ Industrial)
Subject Code	MCR 123 P

Course Outcomes	• Apply theoretical knowledge of clinical research design, pharmacovigilance, and regulatory frameworks to real-world clinical or industrial settings, demonstrating practical competency and ethical conduct. • Develop proficiency in clinical documentation and data management, including source data verification, CRF entry, query resolution, and adherence to GCP and SOPs during project execution. • Demonstrate effective professional communication, teamwork, and coordination with multidisciplinary teams including investigators, monitors, regulatory personnel, and data managers. • Analyze and interpret clinical, safety, and operational data to support evidence-based decision-making and contribute to ongoing or completed clinical studies, pharmacovigilance activities, or regulatory submissions. • Reflect critically on the industrial/clinical work experience, identifying areas for skill enhancement, understanding organizational workflows, and integrating ethical, regulatory, and quality perspectives into professional practice.

Internship/Training (Clinical/ Industrial):

The Industrial Visit / Internship is an integral part of the M.Sc. Clinical research program, designed to provide students with exposure to real-world applications of Clinical research in industry, research laboratories, hospitals, and healthcare settings. It enables students to bridge classroom learning with practical experience, understand professional work environments, and gain insights into industrial processes, regulatory practices, and advanced technologies. This component also enhances problem-solving, teamwork, and communication skills, preparing students for careers in Clinical research, clinical diagnostics, pharmaceuticals, and allied industries. The students has to search the Internship/Training (Clinical/ Industrial) opportunities on their own at least 2 to 3 months prior before starting of the actual course. The student has to prepare the detailed log book along with weekly summary report **(Total - 135 hrs.)**

MGM SCHOOL OF BIOMEDICAL SCIENCES, NAVI MUMBAI
(A constituent unit of MGM INSTITUTE OF HEALTH SCIENCES)
Department of Clinical Research
(Deemed to be University u/s 3 of UGC Act 1956)
Grade "A++" Accredited by NAAC
Sector 1, Kamothe Navi Mumbai-410209, Tel.No.:022-27437631,27432890
Email. sbsnm@mgmuhs.com / Website : www.mgmsbsnm.edu.in

Internship / Training Logbook

M. Sc. Clinical Research

STUDENT NAME: _____

PRN NUMBER: _____

BATCH: _____

SEMESTER:_____

PERIOD FROM:_____**TO**_____

COORDINATOR **HOD** **DIRECTOR**

MGM SCHOOL OF BIOMEDICAL SCIENCES, NAVI MUMBAI

(A constituent unit of MGM INSTITUTE OF HEALTH SCIENCES)

Department of Clinical Research

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Sector 1, Kamothe Navi Mumbai-410209, Tel.No.:022-27437631,27432890

Email. sbsnm@mgmuhs.com / Website : www.mgmsbsnm.edu.in

AIM:

To provide a structured learning experience that enhances students' technical, analytical, and professional skills while addressing the evolving needs of healthcare organizations. By integrating academic knowledge with hands-on practice, these internships prepare M. Sc. Clinical Pharmacology Students to become competent professionals capable of driving clinical research applications in healthcare.

Guidelines:

1. The internship shall commence after the student has completed and passed all subjects up to Semester III
2. The internship is compulsory
3. The duration of the internship shall be 210 Hours.
4. Activities carried out by the student during the internship must be clearly mentioned.

Evaluation of Internees:

Formative Evaluation: The continuous assessment of interns during their internship should be conducted by the Head of the Department, assigned faculty, or a designated individual from the organization (in the case of industry-based internships). The primary objective of this evaluation is to ensure that interns develop the necessary competencies to function effectively in real-world scenarios. This can be facilitated through the maintenance of records or a logbook by all interns. Such documentation serves as tangible evidence of the training process and, more importantly, reflects the intern's progression in acquiring the required competencies for professional performance.

Summative Evaluation: It will be based on the observations of the assigned person from the Department/Organization and record/logbook maintained by the intern.

Based on this two evaluations, the Head of the Department shall issue certificate of satisfactory completion of the training.

MGM SCHOOL OF BIOMEDICAL SCIENCES

(A constituent unit of MGM INSTITUTE OF HEALTH SCIENCES)

(Deemed to be University u/s 3 of UGC Act 1956)

Grade "A^{++}" Accredited by NAAC

Sector 1, Kamothe, Navi Mumbai-410209, Tel.No.: 022-2743763, 27437632, 27432890

Email. sbsnm@mgmuhs.com/ Website: www.mgmsbsnm.edu.in

DEPARTMENT OF PHARMACOLOGY / CLINICAL RESEARCH

Internship/ Training Completion Certificate

Class: _____ **Year:** _____

This is to certify that_____, bearing PRN_____, has successfully completed the internship at _____ **from** _____to_____. During this period, the student has completed a total of **210 hours** of internship, as per the university guidelines.

The student demonstrated a high level of professionalism, technical competence, and problem-solving skills. We wish him/her success in his/her future endeavours.

Head of the Department Dept. of Pharmacology MGMSBS, MGMIHS	Director MGMSBS Kamothe, Navi Mumbai

Weekly Summary Report

Week: _____

Total Hours Completed This Week: _____

Key Activities Performed:

Challenges Faced & How They Were Addressed:

New Skills Acquired:

Comments by Internship Supervisor:

STUDENT'S DAILY LOG RECORD

Date/Day	Task & Activities	Skill gained	Hours Completed	Supervisor Signature

MGM SCHOOL OF BIOMEDICAL SCIENCES

(A constituent unit of MGM INSTITUTE OF HEALTH SCIENCES)

(Deemed to be University u/s 3 of UGC Act 1956)

Grade "A^{++}" Accredited by NAAC

Sector 1, Kamothe, Navi Mumbai-410209, Tel.No.: 022-2743763, 27437632, 27432890

Email. sbsnm@mgmuhs.com/ Website: www.mgmsbsnm.edu.in

Final Evaluation (50 Marks)

1. Technical Knowledge & Application (10 marks): _____
2. Problem-Solving & Critical Thinking (5 marks): _____
3. Communication & Teamwork (5 marks): _____
4. Professionalism & Punctuality (5 marks): _____
5. Quality of Log Book Maintenance (5 marks): _____
6. Learning Outcome & Skill Development (5 marks): _____
7. Final Internship Report Quality (5 marks): _____
8. Student's Initiative & Engagement (5 marks): _____
9. Overall Performance (5 marks): _____
10. Total: _____
11. **Final Remark:**

    _____

    _____

Sign of Internal Examiner: _____

Sign of External Examiner: _____

Scheme of University Examination Theory for PG Program:

General structure / patterns for setting up question papers for Theory / Practical courses, their evaluation weightages for PG programs of MGMSBS are given in the following tables

Marks scheme for the University exam:

Final theory marks will be 100 marks (80 marks University Theory exam + 20 Marks Internal assessment).

Question		**Marks distribution**	**Marks allotted per section**	**Marks**
Sec: A	MCQ	10 x 1 M = 10	10	10
Sec: B	SAQ	3/4x 5 M = 15	15	35
Sec: B	LAQ	2/3 x 10 M = 10	20	
Sec: C	SAQ	3/4x 5 M = 15	15	35
Sec: C	LAQ	2/3x 10 M = 10	20	
Total				**80 Marks**

Marks Scheme for the University Examination (50 Marks)

Final theory marks will be 50 marks University Theory exam pattern

Question	**Question No.**	**Question Type**	**Marks Distribution**	**Marks**
Sec: A	1.	LAQ (2 out of 3)	2 X 10 Marks = 20	20
Sec: B	2.	SAQ (6 out of 8)	6 X 05 Marks = 30	30
Total				**50 Marks**

Practical exam pattern: Total 40 marks with following breakup:

Exercise	**Description**	**Marks**
Q No 1	Practical exercise - 1	1 x15=15 M
Q No 2	Station exercise	2x5M=10 M
Q No 3	VIVA	10 M
Q No 4	Journal	5M
Total		**40 Marks**

Practical to be conducted at respective departments and marks submitted jointly by the parent department to the university.

Breakup of theory IA calculation for 20 marks

Description	**Marks**
Internal exam (at department)	15 marks
Seminar	5 marks
Total	**20 Marks**

Breakup of practical IA calculation:

Description	**Marks**
Internal exam (at department)	10 marks
Viva	5 marks
Journal	5 marks
Total	**20 Marks**

Note –20 marks to be converted to 10 marks weightage for submission to the university.

Evaluation for Semester III – Dissertation (PG) (Internal Assessment)

Dissertation/Project Proposal: overall performance of the student	**Marks allotted**	**Marks Obtained**
Open mindedness/ Receptivity to feedback Integrates feedback	5 Marks	
Meets deadlines / Regularity in meeting / Consistency in communication	10 Marks	
Continuous Internal evaluation (CIE)		
Interest shown in selecting topic	5 marks	
Appropriate review	10 marks	
Discussion with guide and other faculty	10 marks	
Quality of protocol	5marks	
Preparation of proforma / log book / daily reports	5marks	
TOTAL	**Out of 50**	

Evaluation for Semester IV - Evaluation parameter (Research Project / Dissertation)

Evaluation parameter (Semester IV)	Continuous Internal Evaluation (CIE)	Semester End Evaluation (SEE)	
	Guide	Internal examiner	External examiner
Thesis preparation, Novelty, Overall Lab Work Culture	25	-	-
Dissertation/Project work book	25	25	25
Evaluation of thesis including Viva Voce	-	50	50
Total	50	75	75
Overall Total = 200			

Evaluation for Semester IV - Evaluation of the Internship/Training (Clinical/ Industrial) (PG)

Name of the student: _____Date:_____

Program: _____

Semester: _____ Name of the internal faculty/Observer: _____

Name of the External Faculty/Observer: _____

Final Evaluation (50 Marks)

1. Technical Knowledge & Application (10 marks): _____
2. Problem-Solving & Critical Thinking (5 marks): _____
3. Communication & Teamwork (5 marks): _____
4. Professionalism & Punctuality (5 marks): _____
5. Quality of Log Book Maintenance (5 marks): _____
6. Learning Outcome & Skill Development (5 marks): _____
7. Final Internship Report Quality (5 marks): _____
8. Student's Initiative & Engagement (5 marks): _____
9. Overall Performance (5 marks): _____
10. Total: _____
11. **Final Remark:**

    _____

    _____

Sign of Internal Examiner: _____

Sign of External Examiner: _____

MGM INSTITUTE OF HEALTH SCIENCES

(Deemed to be University u/s 3 of UGC Act, 1956)

Grade 'A' Accredited by NAAC

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